CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV)

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, Spain, for the pesticide active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses of *Spodoptera exigua* multicapsid nucleopolyhedrovirus as an insecticide on pepper and leafy vegetables (lettuce crops) (field, greenhouse and walk-in tunnel uses). The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: *Spodoptera exigua* multicapsid nucleopolyhedrovirus, peer review, risk assessment, pesticide, insecticide

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Summary

Spodoptera exigua multicapsid nucleopolyhedrovirus is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), Spain, received an application from Andermatt Biocontrol Suisse AG on 8 May 2018 for approval. Though the applicant did not submit an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005, the species was already included in Annex IV of Regulation (EC) No 396/2005 consequent to the presence in annex IV of *Spodoptera exigua* nuclear polyhedrosis virus. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 24 September 2018.

An initial evaluation of the dossier on *Spodoptera exigua* multicapsid nucleopolyhedrovirus was provided by the RMS in the draft assessment report (DAR), and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The uses of *Spodoptera exigua* multicapsid nucleopolyhedrovirus according to the representative uses as an insecticide on pepper and leafy vegetables (lettuce crops) (foliar spray application in the field, greenhouses and walk-in tunnels) as proposed at EU level, result in a sufficient insecticidal efficacy against the target *Spodoptera exigua* (LAPHEG).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity of the microorganism/biological properties/physical and technical properties of the representative formulation.

In the area of mammalian toxicology, there are no data gap and critical area of concern. No adverse effects on human health are reported in a broad range of tests performed with different baculoviruses, supported by a long history of safe use and the inclusion of the family of Baculoviridae in the EFSA Qualified Presumption of Safety (QPS) list since 2009.

In the area of residues, the consumer risk assessment was finalised and did not indicate health risks via consumer dietary exposure based on the current body of knowledge.

The information available on the fate and behaviour of *Spodoptera exigua* multicapsid nucleopolyhedrovirus in the environment was considered sufficient to assess the environmental exposure for the representative uses assessed.

Satisfactory information was not provided for the potential for infectivity and pathogenicity to bees, bee larvae, non-target arthropods other than bees for the representative uses in open field and walk-in tunnels (leading to issues not being finalised).

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, Spain (hereinafter referred to as the 'RMS'), received an application from Andermatt Biocontrol Suisse AG on 8 May 2018 for approval of the active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV). Though the applicant did not submit an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005, the species was already included in Annex IV of Regulation (EC) No 396/2005 consequent to the presence in annex IV of *Spodoptera exigua* nuclear polyhedrosis virus. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 24 September 2018.

The RMS provided its initial evaluation of the dossier on *Spodoptera exigua* multicapsid nucleopolyhedrovirus in the DAR, which was received by EFSA on 24 March 2020 (Spain, 2020). The peer review was initiated on 24 April 2020 by dispatching the DAR to the Member States and the applicant, Andermatt Biocontrol Suisse AG, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 28 September 2020. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the area mammalian toxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Spodoptera exigua* multicapsid nucleopolyhedrovirus can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in August–September 2021.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses of *Spodoptera exigua* multicapsid nucleopolyhedrovirus as an insecticide on pepper and leafy vegetables (lettuce crop) (field, greenhouse and walk-in tunnel uses) as proposed by the applicant. In

[1] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the DAR and considered during the peer review, if any, are presented in the conclusion.

Furthermore, this conclusion also addresses the requirement for an assessment by EFSA under Article 12 of Regulation (EC) No 396/2005, provided that the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV proposal from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required.

A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the DAR;
- the reporting table (28 September 2020);
- the evaluation table (14 September 2021);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (Spain, 2021), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

For the baculovirus species *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), a European Commission review report, that was consequent to the assessment in an RAR based on a reference isolate from Florida (isolate SeNPV-F1), resulted in the species being listed in Annex I of Directive 91/414/EEC in 2007, though at that time the listing used the name *Spodoptera exigua* nuclear polyhedrosis virus (SeNPV). This approval expired on 30/11/2017. This occurred because an application for renewal was not made by any applicant. Note that *Spodoptera exigua* nuclear polyhedrosis virus (SeNPV) has been included in Annex IV of Regulation (EC) No 396/2005.

The identity of the microorganism and the properties of the formulated product

This *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV*)* isolate is deposited in the German Collection of Microorganisms and Cell Cultures Leibniz-Institut (DSMZ) in Braunschweig, Germany, under the reference number BV-0004.

SeMNPV isolate BV-0004 originates from natural, indigenous wild-type viruses, isolated from *Spodoptera exigua* larval cadavers infected with nuclear polyhedrosis virus from a green pepper field in Huaian (China) in 2000 and is not genetically modified.

The representative formulated product for the evaluation was 'SPEXIT', a suspension concentrate (SC) with a nominal content of 3.75×10^{12} viral occlusion bodies (OB) per L (minimum 3.0×10^{12} OB/L and maximum 7.5×10^{13} OB/L).

The representative uses evaluated comprise spray applications on field, greenhouse and walk-in tunnel grown pepper and leafy vegetables (lettuce) crops against *Spodoptera exigua* (LAPHEG). Full details of the good agricultural practice (GAP) can be found in the list of endpoints in Appendix A.

Data were submitted to conclude that the uses of SeMNPV isolate BV-0004 according to the representative uses proposed at EU level result in a sufficient insecticidal effect against the targeted organism, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

Conclusions of the evaluation

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion (European Commission, 2012, 2013).

Spodoptera exigua multicapsid nucleopolyhedrovirus belongs to the family *Baculoviridae*, genus *Alphabaculovirus*.

The technical grade microbial pest control agent (MPCA) is produced as an isolated technical material which is formulated to produce the microbial pest control product (MPCP) 'SPEXIT' and is also produced as a hypothetical stage in the continuous production process of the end-use product 'SPEXIT'. As a consequence, the specification is given for the technical grade active ingredient (TGAI) of minimum content of 2.0×10^{11} OB/g (max. content: 2.2×10^{11} OB/g), and for the formulated product 'SPEXIT' of minimum content of 3.0×10^{12} OB/L (max. content: 7.5×10^{13} OB/L).

Spodoptera exigua multicapsid nucleopolyhedrovirus isolate BV-0004 is not pathogenic to humans or animals other than insects. The analysis of contaminating microorganisms in commercially produced batches of 'SPEXIT', produced with both manufacturing processes, comply with the requirements of SANCO/12116/2012 rev.0 (European Commission, 2012).

Restriction endonucleases analysis of viral DNA method, counting under a light microscope and a bioassay are available for the qualitative and quantitative determination of *Spodoptera exigua* multicapsid nucleopolyhedrovirus isolate BV-0004 in the formulation. A data gap was identified regarding the quantification of the baculovirus OB in the MPCP in relation to using the bioassay (see Section 9). Appropriate methods are available to test for the presence of human pathogens in the MPCP.

The proposed shelf-life of the product is 2 years at 5°C in the original packaging (amber polyethylene and high-density polyethylene; HDPE); however, a data gap was identified for a storage stability study addressing physical and biological stability at the recommended storage temperature, including information on growth of contaminating microorganisms (see Section 9).

Residue definitions were not applicable for SeMNPV isolate BV-0004; therefore, post-registration monitoring methods are not required.

2. Mammalian toxicity

Viruses are obligate intracellular parasites and do not produce toxins, toxic metabolites or degradation products. Baculoviruses have a narrow host range and have been used for biological insect control for more than 100 years. There is no evidence in the literature review that these viruses have ever caused any disease in humans. Additionally, the Baculoviridae family is included in the QPS list (Qualified Presumption of Safety; EFSA BIOHAZ Panel, 2009, 2021), being considered as not pathogenic or virulent for humans.

No adverse effects were shown in people who were involved in research, development, manufacturing and formulation of pest control products containing SeMNPV isolate BV-0004. No cases of sensitisation have been reported in the current occupational health statement. Three sensitisation studies with different baculovirus isolates (*Spodoptera littoralis* NPV and *Cydia pomonella* GV) were considered only supplementary. In the absence of a reliable and validated test for respiratory sensitisation, as for other microorganisms, the following warning phrase is applicable, related to the potential to provoke allergic reactions by inhalation as well as by dermal exposure: 'Contains *Spodoptera exigua* multicapsid nucleopolyhedrovirus. Microorganisms may have the potential to provoke sensitising reactions'.

No specific studies were provided for the isolate BV-0004 of SeMNPV. However, considering the strict host specificity to certain arthropod species, and the high degree of similarity within the family *Baculoviridae*, the results of studies with other baculoviruses are considered applicable to SeMNPV isolate BV-0004.

All baculoviruses tested so far were non-toxic and non-pathogenic when administered to various mammalian species in acute toxicity studies using the oral, inhalation, intraperitoneal or intravenous route. Based on limited published information about short-term studies with different species such as mice, guinea pigs, rats and dogs, no adverse effects are to be expected upon repeated exposure neither by the oral nor by the inhalation route.

There is evidence that some baculoviruses under certain conditions may enter cells of human origin, nevertheless, they did not replicate and the only adverse effect was a cytokine response in vitro. Other results in cell culture studies demonstrated the lack of infectivity to vertebrate cells as well as the absence of interaction with mammalian cellular DNA.

Some seroconversion (antibody formation) may occur in different species including man, but this is considered a rather unspecific immunological response (not at the usual antigen-binding site of the IgG) and not indicative of productive infection with virus replication.

Based on the available information, there is no evidence of genotoxicity, carcinogenicity, teratogenicity or reproductive toxicity of baculoviruses.

No toxicity study has been provided for the representative formulation SPEXIT containing SeMNPV. On the basis of data with several formulations containing other baculoviruses but comparable co-formulants and product components resulting from the technical material, the exposure to SPEXIT is not expected to trigger a concern for the health of humans or mammals.

Considering the lack of pathogenicity of the baculoviruses in mammals, it is considered not necessary to derive reference values for SeMNPV isolate BV-0004. Therefore, no operator, worker, resident and bystander exposure estimates are needed.

3. Residues

The assessment in the residue section is based on the following guidance document (European Commission, 2015).

Two representative uses on pepper and leafy vegetables (lettuce crops) are provided for *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV). Treatments are indicated to be started at infestation (preferably on early larva instar: L1 and L2; with a first treatment just before hatching). Indoor and outdoor foliar uses on pepper and leafy vegetables (lettuce crops) are all intended with a maximum of 18 applications at a maximum application rate of 7.5×10^{11} occlusion bodies (OB)/ha.

An extensive body of knowledge is generated for the family of Baculoviridae which includes *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) by the EFSA Panel on Biological Hazard in the context of the Qualified Presumption of Safety (QPS) assessments since 2009 where a comprehensive assessment was performed for the first time. At the time, the Panel concluded that 'on the basis of the available literature and other available sources of information it can be concluded that baculoviruses are safe for animals and human consumption. Baculoviruses in the form of OBs are specific for (certain) insects and do not productively infect (cells of) non-target insects or other organisms including humans and animals. It is therefore recommended to include plant protection viruses, more specifically baculoviruses (Baculoviridae) as the highest taxonomic unit, on the QPS list (EFSA BIOHAZ Panel, 2009)'.

Noting the long history of safe use as a biological pest control agent and related exposure of consumers with potentially remaining residues on agricultural commodities, there are no reports in the literature that indicate any adverse health effects following food consumption. In its most recent QPS update, the BIOHAZ Panel confirmed based on an updated search for papers potentially relevant for the QPS evaluation of *Baculoviridae* that no new safety concern was identified and that therefore, the current QPS status remains unchanged (EFSA, 2021). This conclusion is in line with the outcome of the literature search provided by the applicant and assessed by the RMS for *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) following the EFSA guidance (EFSA, 2011).

With regard to the five assessment criteria according to the Commission guidance (European Commission, 2015) for potential inclusion of *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) in Annex IV of Regulation (EC) No 396/2005, one of the three criteria relevant for viruses and microorganisms (namely, having no identified hazardous properties (criterion 3); natural exposure is higher than the one linked to the use as PPP (criterion 4) and/or consumer exposure is not expected linked to the supported uses (criterion 5)) is considered to be met for the following reasons:

Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) has a long-standing safe history of use based on an extensive body of knowledge and no hazardous properties via consumer dietary exposure are identified. Therefore, criterion 3 of the guidance is considered as fulfilled (see also Section 2).

However, it is not demonstrated that *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) residue levels resulting from the use of SeMNPV as a plant protection product according to the intended uses can be considered as negligible compared to the natural background levels and consumer exposure to these residues cannot also be excluded.

However, considering that SeMNPV was concluded not to have hazardous properties and is included on the QPS list without restrictions, risk managers might consider *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) as a candidate eligible for inclusion in Annex IV of Regulation (EC) No 396/2005[2]. Note the species was already included in Annex IV using a previous name (*Spodoptera exigua* nuclear polyhedrosis virus (SeNPV)).

4. Environmental fate and behaviour

Information regarding the potential interference of *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC[3] was addressed in the applicant's dossier. This is a specific decision-making criterion for the authorisation of plant protection products containing microorganisms (see uniform principles in Commission Regulation (EU) No 546/2011[4]). The virus SeMNPV is unlikely to interfere with the analytical systems used for the control of the quality of drinking water which have bacteria as their target.

Information on the potential transfer of genetic material from SeMNPV to other organisms was not included in the applicant's dossier. However, for SeMNPV infection and replication is known to be very specific to insects and has not been reported to occur in other organisms, including humans or animals (EFSA BIOHAZ Panel, 2009, 2021), so transfer of genetic material from SeMNPV to other organisms is unlikely to be a concern when using SeMNPV in plant protection.

4.1. Fate and behaviour in the environment of the microorganism

Scientific papers showed that baculovirus remained in the soil following application and accumulated in soil following repeated applications. The structure of baculovirus occlusion bodies provides for their potential to persist in the environment in a variety of environmental conditions. Therefore, for the representative uses, it cannot be excluded that SeMNPV may persist and be present above natural background levels in soil, taking into account repeated applications over the years. However, multiplication of the virus outside the host organism will not occur. Consequently, EFSA concluded that the information is sufficient to address the uniform principles criterion associated with persistence and accumulation in the environment regarding soil. PECs in soil for SeMNPV were calculated and reported in the DAR and in Appendix A.

Scientific papers showed that intact occlusion bodies of baculovirus are stable in aqueous suspension. Once introduced into a water body, the viral particles are likely to deposit and absorb to sediments. Therefore, for the representative uses, it cannot be excluded that SeMNPV may persist and be present above natural background levels in surface water systems, taking into account repeated applications over the years. However, multiplication of the virus outside the host organism will not occur. Consequently, EFSA concluded that the information is sufficient to address the uniform principles criterion associated with persistence and accumulation in the environment regarding surface water. PECs in surface water for SeMNPV for the representative uses in open field were calculated and reported in the DAR and in Appendix A.

For the fate and behaviour in air, scientific papers support that viruses are inactivated by sunlight and multiplication of the virus outside the host organism will not occur.

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

Viruses do not produce metabolites, they can only modify host cell metabolism, as they self-replicate within host organisms. It is considered that no further information is required at EU level

[2] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[3] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 32–54.

[4] Commission 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. OJ L 155, 11.6.2011, p. 127–175.

since a qualified presumption of safety has been found to be applicable to the family *Baculoviridae* such as SeMNPV (EFSA BIOHAZ Panel, 2009, 2021).

5. Ecotoxicology

Spodoptera exigua multicapsid nucleopolyhedrovirus(SeMNPV) is a naturally occurring insect virus isolate belonging to the family *Baculoviridae*. Its host insects are mainly from the lepidopteran family. SeMNPV infection and replication are known to be very specific to insects and has not been reported to occur in other organisms (see Section 4).

No specific data on infectiveness or pathogenicity of SeMNPV were available for the assessments of **birds and mammals**. SeMNPV viruses or other members of the family *Baculoviridae* are not known to have effects on birds and mammals (see Section 2). Based on the available information and opinions of the EFSA BIOHAZ Panel (2009, 2021), a low risk is identified for all representative uses.

No specific data on infectiveness or pathogenicity of SeMNPV were available for the assessments of **aquatic organisms**. Acute toxicity studies on fish, freshwater invertebrates, algae and aquatic plants were available on other *Baculoviridae* viruses indicating a high Margin of Safety (MOS) for the representative uses. *Baculoviridae* viruses are generally considered to be pathogenic towards insect species only and not towards other organisms. Based on the available information mentioned above and opinions of the EFSA BIOHAZ Panel (2009, 2021) where Baculoviridae viruses are generally considered to be specific to insect species, a low risk to aquatic organisms was concluded for all representative uses.

Insufficient data were available to address infectivity and pathogenicity to **bees** from SeMNPV. The virus is targeted at the larval stage of the target organism and Baculoviridae viruses are generally considered to be pathogenic towards insect species and therefore infectivity and pathogenicity from SeMNPV to bees and bee larvae cannot be excluded. Consequently, a **data gap** leading to an assessment not finalised was identified for the infectivity and pathogenicity of SeMNPV to bees and bee larvae for the representative uses in open field and walk-in tunnels. For representative uses in permanent greenhouses, the risk is low as the exposure to populations of bees is expected to be marginal.

Insufficient data were available to address infectivity and pathogenicity to **non-target arthropods** from SeMNPV. It is noted that the relevance of the laboratory toxicity studies with SeMNPV on non-target arthropods is questionable, given that the duration of the studies could not be considered sufficient to address the risk from infectivity and pathogenicity. The virus is targeted at the larval stage of the target organism and Baculoviridae viruses are generally considered to be pathogenic towards insect species, and therefore, infectivity and pathogenicity from SeMNPV to **non-target arthropods** cannot be excluded. Consequently, a **data gap** leading to an assessment not finalised was identified for the infectivity and pathogenicity of SeMNPV to non-target arthropods for the representative uses in open field and walk-in tunnels. For representative uses in permanent greenhouses, the risk is low as the exposure to populations of non-target arthropods is expected to be marginal.

No specific data on infectiveness or pathogenicity of SeMNPV were available for the assessments of **earthworms,** other soil macro-organisms and **soil micro-organisms**. Based on the available information and opinions of the EFSA BIOHAZ Panel (2009, 2021), a low risk to **earthworms,** other soil macro-organisms and **soil micro-organisms** was concluded for all representative uses.

6. Overview of the risk assessment of the organism or metabolite compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
Spodoptera exigua multicapsid nucleopolyhedrovirus(SeMNPV)	The risk for infectiveness and pathogenicity to earthworms and soil microorganisms was assessed as low for the representative uses

Table 2: Groundwater[(a)]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[(b)] Step 2	Biological (pesticidal) activity/relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
None	–	–	–	–	–

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV)	The risk for infectiveness and pathogenicity to aquatic organisms was assessed as low for the representative uses

Table 4: Air

Compound (name and/or code)	Toxicology
Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV)	No adverse effects after acute or repeated exposure to Baculoviruses by inhalation

7. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

- **None**

8. Concerns and related data gaps

8.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[5] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

[5] Commission 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. OJ L 155, 11.6.2011, p. 127–175.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

1) Satisfactory information was not available for the potential infectivity and pathogenicity to bees, bee larvae and non-target arthropods other than bees from *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) for the assessment of the representative uses in open field and walk-in tunnels leading to an assessment not finalised (see Section 5).

   a) Data and information for the assessment of the potential infectivity and pathogenicity to bees, bee larvae and non-target arthropods other than bees from *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) (relevant for the representative uses in open field and walk-in tunnels, see Section 5).

8.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

- **None**

8.3. Overview of the concerns identified for each representative use considered (Table 5)

Table 5: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

Representative use		**Pepper (open field and walk-in tunnels)**	**Pepper (permanent green house)**	**Leafy vegetables (lettuce, open field and walk-in tunnels)**	**Leafy vegetables (lettuce, permanent green house)**
		Foliar spray	**Foliar spray**	**Foliar spray**	**Foliar spray**
Operator risk	Risk identified				
	Assessment not finalised				
Worker risk	Risk identified				
	Assessment not finalised				
Resident/ bystander risk	Risk identified				
	Assessment not finalised				

Representative use		Pepper (open field and walk-in tunnels)	Pepper (permanent green house)	Leafy vegetables (lettuce, open field and walk-in tunnels)	Leafy vegetables (lettuce, permanent green house)
		Foliar spray	Foliar spray	Foliar spray	Foliar spray
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non-target terrestrial vertebrates	Risk identified				
	Assessment not finalised				
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised	X[1]		X[1]	
Risk to aquatic organisms	Risk identified				
	Assessment not finalised				
Groundwater exposure to active substance	Legal parametric value breached				
	Assessment not finalised				
Groundwater exposure to metabolites	Legal parametric value breached				
	Parametric value of 10 µg/L[(a)] breached				
	Assessment not finalised				

The superscript numbers relate to the numbered points indicated in Sections 8.1 and 8.2. Where there is no superscript number, see Sections 2–7 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

9. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- Details on the quantification of the baculovirus in the MPCP in relation to using the bioassay method (relevant for all representative uses evaluated; see Section 1).
- A storage stability study addressing physical and biological stability at the recommended storage temperature of the formulation, including information on growth of contaminating micro-organisms (relevant for all representative uses evaluated; see Section 1).

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Abbreviations

λ	wavelength
ε	decadic molar extinction coefficient
µg	microgram
µm	micrometer (micron)
ADE	actual dermal exposure
AF	assessment factor
AP	alkaline phosphatase
AV	avoidance factor
BUN	blood urea nitrogen
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary cells
CI	confidence interval
CL	confidence limits
cm	centimetre
d	day
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography – mass spectrometry
GPC	gel permeation chromatography
h	hour(s)
ha	hectare
HR	hazard rate
ISO	International Organization for Standardization

ITS	internal transcribed spacer
iv	intravenous
kg	kilogram
L	litre
LC	liquid chromatography
m	metre
M	mol
mg	milligram
M/L	mixing and loading
mm	millimetre (also used for mean measured concentrations)
MOA	mode of action
MPCA	active agent of the microbial pest control product
MPCP	microbial pest control product
MS	mass spectrometry
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PD	proportion of different food types
PDA	Potato Dextrose Agar
pH	pH-value
PHI	preharvest interval
PIE	potential inhalation exposure
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
SAR	systemic acquired resistance
SCAR	sequence characterized amplified region
SMILES	simplified molecular-input line-entry system
TGAI	technical grade active ingredient
TK	technical concentrate
TWA	time-weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WHO	World Health Organization

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2021.6848