



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Spodoptera exigua NPV

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**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT
THE VIEWS OF THE COMMISSION SERVICES**

Review 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.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance *Spodoptera exigua* nuclear polyhedrosis virus (hereafter "*Spodoptera exigua* NPV"), made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the Dutch authorities received on 12 July 1996 an application from Biosys (now: Certis USA), hereafter referred to as the applicant, for the inclusion of the active substance *Spodoptera exigua* NPV in Annex I to the Directive. The Dutch authorities indicated to the Commission on 2 April 1997 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on *Spodoptera exigua* NPV was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 29 May 1997, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 1997/865/EC¹ of 5 December 1997 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the work related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that the Netherlands, as rapporteur Member State would carry out the detailed examination of the dossier and report the conclusions of the examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

The Netherlands submitted to the Commission on 1 November 1999 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of *Spodoptera exigua* NPV in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Biosys (now: Certis USA) being the sole applicant on 28 January 2000.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and biological properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 28 April 2002.

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final

¹ OJ No L 351, 23.12.1997, p. 67.

examination took place from June 2002 to December 2006, and was finalised in the meeting of the Standing Committee on 15 May 2007.

The present review report contains the conclusions of this final examination; given the importance of the (revised) draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

The review of *Spodoptera exigua* NPV did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants or of the European Food Safety Authority which has taken over the role of that Committee.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2007/50/EC² concerning the inclusion of *Spodoptera exigua* NPV in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing *Spodoptera exigua* NPV they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

² OJ L 202, 3.8.2007, p. 15.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing *Spodoptera exigua* NPV will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VIB of Directive 91/414/EEC, for each *Spodoptera exigua* NPV containing plant protection product for which Member States will grant or review the authorisation.

In particular, these conclusions were reached taking into account the information compiled in the OECD Consensus Document on Information used in the Assessment of Environmental Applications involving Baculoviruses (ENV/JM/MONO(2002)1)³. This document underlines the exceptional properties of all currently known taxa of the virus family Baculoviridae resulting in a high host specificity and the fact that the Baculovirus itself is harmless regarding effects on human and animal health and the environment.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the sole data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VIB of Directive 91/414/EEC.

The review has concluded that, on the basis of current scientific knowledge, all known isolates of the species *Spodoptera exigua* NPV could be considered to be included in Annex I to Directive 91/414/EEC. In order to assist Member States in their evaluation whether a particular strain satisfies the aforementioned requirements, Appendix V contains a list of isolates for which such information is available at Member State level and for which has been taken note of in the Standing Committee.

Given the results of the evaluation of the information submitted, no particular conditions have been provided for, which would need short term attention from the Member States when granting new authorisations or varying existing provisional authorisations.

4. Identity and biological properties

The main properties of *Spodoptera exigua* NPV are given in Appendix I.

³ [http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono\(2002\)1](http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)1)

The review has established that for the active substance notified by the applicant (Biosys (now: Certis USA)), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VIB of that Directive, the most important end points as identified during the evaluation process are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing *Spodoptera exigua* NPV

On the basis of the proposed and supported uses, no particular issues have been identified as requiring short term attention from the Member States.

7. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of *Spodoptera exigua* NPV in Annex I.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the draft report. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

9. Updating of this review report

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such

adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for *Spodoptera exigua* NPV in Annex I of the Directive.

APPENDIX I

Identity, biological, physical and chemical properties

SPODOPTERA EXIGUA NPV Florida isolate

Active micro-organism	<i>Spodoptera exigua</i> nuclear polyhedrosis virus
Function (e.g. control of fungi)	Control of the beet armyworm <i>Spodoptera exigua</i> in vegetable and ornamental crops

Identity of the micro-organism

Name of the organism:	<i>Spodoptera exigua</i> nuclear polyhedrosis virus
Taxonomy:	<i>Spodoptera exigua</i> nuclear polyhedrosis virus belongs to the family of Baculoviridae.
Species, subspecies, strain:	<i>Spodoptera exigua</i> nuclear polyhedrosis virus, Florida isolate (SeNPV-F1)
Identification:	<i>Spodoptera exigua</i> nuclear polyhedrosis virus was isolated from beet armyworm in Florida, The Florida isolate can be distinguished from other SeNPVs by restriction endonuclease analysis
Culture collection:	The strain is deposited at American Type collection (ATCC), Manassas, Virginia 20108, USA and received SD-Number: SD-5339

Biological properties of the micro-organism

Origin and natural occurrence:	<i>Spodoptera exigua</i> nuclear polyhedrosis virus (SeNPV), was isolated from beet armyworm, <i>Spodoptera exigua</i> , in Florida by Dennis Warkinton, Crop Genetics International, Columbia, MD and is named Florida isolate (SeNPV-F1) <i>Spodoptera exigua</i> nuclear polyhedrosis virus occurs in nature where its host occurs. The beet armyworm, <i>Spodoptera exigua</i> , has a wide distribution in the tropical and subtropical areas of the world
Target organism(s):	The beet armyworm, <i>Spodoptera exigua</i>
Mode of action:	Larvae ingest the virus by feeding on leaf material. In the larval gut the occlusion bodies dissolve under the alkaline conditions. The liberated virions infect the midgut epithelial cells. In the nucleus of infected cells new virions are produced, which may leave the cell and infect cells of heamocoel and other tissues, such as the fat body. In these tissues

	<p>occlusion of the virions in polyhedra takes place. The process continues till all tissues are infected and cell-lysis occurs. The larvae usually dies after most tissues have been infected, 3 to 4 days after feeding on contaminated leaf material.</p>
Life cycle:	<p>See Mode of action</p>
Host specificity:	<p>The <i>Spodoptera exigua</i> nuclear polyhedrosis virus is only effective against all larval stages of the beet armyworm, <i>Spodoptera exigua</i>.</p>
Production of metabolites:	<p>Metabolites and toxins are not produced</p>
Resistance:	<p>Resistance development will probably not occur quickly and on a large scale</p>
Production:	<p>The virus is multiplied by infecting fourth instar larvae of <i>Spodoptera exigua</i>, which are reared on an artificial diet, with the virus. After incubation the diseased larvae are separated from the medium followed by purification of the virus.</p>
Production control:	<p>After the production of the formulation the number of occlusions is determined in an occlusion body count test, the presence of fecal coliforms in a coliform assay and mammal pathogens in a mouse safety test.</p>

Analytical methods for the micro-organism (Annex IIA, point 4.1)

Manufactured micro-organism (principle of method)

Restriction Endonuclease Analysis is used to identify SeMNPV
 The number of polyhedral occlusion bodies is assessed in heamocytometers with phase-contrast microscopy
 The concentration of polyhedra and the virus activity are assessed in bioassays with larvae of *Spodoptera exigua*

Impurities and contaminating micro-organisms in manufactured material (principle of method)

The bacterial contamination is determined with plate-count agar (PCA, Merck), API strips and gram-colouring; with plate count methods on oxy-agar the presence of fungi is determined.
 Contamination by mammalian pathogens or toxins is screened by an intraperitoneal injection of mice

Plant protection product (principle of method)

The number of polyhedral occlusion bodies is assessed in heamocytometers with phase-contrast microscopy

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms

(Annex IIA, point 4.2)

of the active micro-organism (principle of method)

not applicable

of relevant metabolites (principle of method)

not applicable

APPENDIX II

END POINTS AND RELATED INFORMATION

SPODOPTERA EXIGUA NPV Florida isolate

1 Impact on Human and Animal Health

<p>Medical data, surveillance and observations (Annex IIB, point 5.1)</p>	<p>Limited data: no adverse effects observed among researchers, production workers and field technicians.</p>
<p>Acute toxicity (Annex IIB, point 5.2.1 and 5.2.2) Pathogenicity:</p>	<p>no evidence of adverse effects from acute studies with SeNPV and other NPVs</p>
<p>Infectivity:</p>	<p>no evidence of adverse effects from acute studies with SeNPV and other NPVs</p>
<p>Toxicity:</p>	<p>no evidence of adverse effects from acute studies with SeNPV and other NPVs</p>
<p>Irritation, Sensitisation</p>	<p>rabbit: no skin irritation (24h) with other NPVs</p> <p>rabbit: some studies (other NPVs) indicate eye irritation, in other studies (other NPVs) no eye irritation was observed.</p> <p>SeNPV should be regarded as a sensitiser</p>
<p>Genotoxicity (Annex IIB, point 5.2.3, 5.4 and 5.5)</p>	<p>no genotoxic potential (other NPVs tested <i>in vitro</i> and <i>in vivo</i>)</p>
<p>Cell culture studies (Annex IIB, point 5.2.4)</p>	<p>no evidence for virus replication in mammalian cell cultures with SeNPV.</p>
<p>Short term toxicity (Annex IIB, point 5.2.5)</p>	<p>no evidence of adverse effects from short-term (28d, 90d) studies with other NPVs in rat, rabbit and dog</p>
<p>First aid measures, medical treatment (Annex IIB, point 5.2.6)</p>	<p>sufficient data submitted</p>
<p>Specific toxicity, pathogenicity and infectiveness studies (Annex IIB, point 5.5)</p>	<p>no evidence of adverse effects from (semi) chronic studies with other NPVs in rat and monkey</p>
<p>Summary (Annex IIB, point 5.6)</p>	<p>no evidence of adverse effects (toxicity, infectivity, pathogenicity) from (sub)acute and (semi)chronic studies.</p>
<p>Acceptable exposure scenarios (including method of calculation)</p>	
<p>Operator</p>	<p>Safe use anticipated with PPE en RPE</p>
<p>Workers</p>	<p>Safe use anticipated with PPE</p>
<p>Bystanders</p>	<p>Safe use anticipated</p>

Classification and proposed lab (Annex IIB, point 4)
with regard to toxicological data

considered to be a sensitiser

2 Fate and behaviour in the environment

Persistence and multiplication in soil, water and air:	5-10 days for NPV and GV virus in general (OECD, 2002)
Mobility:	Not mobile in soil. Transport and dispersal by wind or water of minor importance (OECD, 2002)

PEC soil

Colony Forming Units [CFU/g soil d.w.] (Annex IIIB, point 7.1.1; Annex IIIB, point 9)

Method of calculation

Equal distribution of the dose over top 5 cm soil, no degradation

Application rate

3E+11 Obs/ha. 6 applications interval 5-10 days

Colony Forming Units [CFU/g soil d.w.]

Days after last application	Single application actual	Maximum predicted CFUs considering 50% interception	Multiple application actual	Maximum predicted CFUs considering 50% interception
0	4E+5 OBs/kg	2E+5 OBs/kg	2.4E+6 OBs/kg	1.2E+6 OBs/kg
100 ¹⁾	-			

¹⁾degradation of conidia is not taken into calculation as the rate of degradation is not available. Calculations are performed with a worst-case scenario.

PEC Water

Colony Forming Units [CFU/L water]

Method of calculation

Assuming overspray, ditch 30 cm depth, no degradation.
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Application rate

3.0+11 OBs/ha, 6 applications interval 5-10 days.

Main routes of entry

overspray

Colony Forming Units [CFU/L water] (Annex IIIB, point 7.1.2; Annex IIIB, point 9)

Days after last application	Single application actual	Max. predicted CFUs	Multiple application actual	Max. predicted CFUs
0	1.0E+5 OBs/litre	1.0E+5 OBs/litre	6.0E+5 OBs/L	6.0E+5 OBs/L
100 ¹⁾	-			

¹⁾degradation of conidia is not taken into calculation as the rate of degradation is not available. Calculations are performed with a worst-case scenario.

Air

Colony Forming Units [CFU/m³ air] (Annex IIIB, point 7.1.3; Annex IIIB, point 9)

Colony Forming Units [CFU/m³ air] (Annex IIIB, point 7.1.3; Annex IIIB, point 9)

Method of calculation

-

Maximum concentration

-

Definition of the Residue (Annex IIIA, point 7.3)

Relevant to the environment/toxicologically relevant

Polyhedra (OBs)

3 Ecotoxicology

Effects on terrestrial vertebrates (Annex IIB, point 8.1, Annex IIIB, points 10.1)

Effects on birds

>1.0E+12 OBS/kg feed
Oral LD ₅₀ > 1*10 ⁹ SeNPV polyhedra/animal. No evidence of adverse effects from acute studies with SeNPV and other NPVs

Acute toxicity to mammals

Effect on other non-target organisms

Effects on aquatic organisms (Annex IIB 8.2; Annex IIIB 10.2)

<i>Lepomis macrochirus</i>	>3.4E+8 Obs/L, NOEC
<i>Daphnia magna</i>	>2.5E+5 Obs/L, NOEC
<i>Hesperocorixa interrupta</i>	>2.5E+5 Obs/L, NOEC
<i>Sigara gordita</i>	>2.5E+5 Obs/L, NOEC

Effects on bees and other arthropod species (Annex IIB 8.3; Annex IIIB 10.3 and Annex IIB 8.4; Annex IIIB 10.4)

No effects on (bumble-)bees from side effect trials.	
<i>Trichogramma cacoeciae</i> :	> 5.0E+13 Obs/ha oral > 5.0E+13 Obs/ha contact
<i>Chrysoperla carnea</i> :	> 5.0E+13 Obs/ha

Effects on earthworms (Annex IIB 8.5; Annex IIIB 10.5)

No data, non required

Effects on other soil micro-organisms (Annex IIB 8.6; Annex IIIB 10.6)

No data, non required

Additional studies (Annex IIB 8.7; Annex IIIB 10.7)

Effects on terrestrial plants

No data, non required

Effects on biological methods of sewage treatment

No data, non required

APPENDIX IIIA

SPODOPTERA EXIGUA NPV Florida isolate

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

B.1 Identity, B.2 Biological, physical, chemical and technical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ⁴ on previous use in granting national authorizations
IIB 1.4	Beach, R.M.	1994a	Spod-X LC-Product Chemistry: Complete composition including impurities Crop Genetics International (biosys), Subdivision M, guideline 151A-13 Not GLP, Unpublished	NL
IIB 1.4	Beach, R.M.	1994b	Spod-X LC Product Chemistry: Discussion of formation of unintended ingredients Crop Genetic International (biosys), Subdivision M, Guideline 151A-12 Not GLP, Unpublished	NL
IIB 1.4.3	Beach, R.M.	1994c	Spod-X LC-Product Chemistry: Description of Manufacturing process Crop Genetics International (biosys), Subdivision M, guideline 151A-11. Not GLP, Unpublished	NL
IIB 1.4.3	Beach, R.M.	1994d	Spod-X LC-Product Chemistry: Certification of ingredient limits Crop Genetics International (biosys), Subdivision M, guideline 151A-11. Not GLP, Unpublished	NL
IIB 2.1	Beek, N. van	1994	Genotypical variation among geographical isolates of <i>Spodoptera exigua</i> nuclear polyhedrosis virus. Crop Genetics International (biosys) Not GLP, Unpublished	NL
IIB 2.3	Vlak, J.M.	2005	Position paper on 'Biosafety of <i>Spodoptera exigua</i> NPV for vertebrates' Wageningen University, Laboratory of Virology Not GLP, Unpublished	

⁴ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ⁴ on previous use in granting national authorizations
IIB 2.7.4	Mourgues Loïs	2005	Wet sieving DEFITRACES, France Report No. 04-903041-001	
IIB 2.8	Dimock, M.B. & Erickson, M.A.	1993	Efficacy trials of Spod-X™ biological insecticide for control of <i>Spodoptera exigua</i> on chrysanthemums. Preliminary Report Crops Genetics International (biosys), CGI study 187ENT Not GLP, Unpublished	NL
IIB 2.8	Miller, D.P.	1995	Stability of liquid/glycerol formulation beet armyworm (<i>Spodoptera exigua</i>) nuclear polyhedrosis virus (Spod-X) at several temperatures. IVP Quality Assurance Group Crop Genetics International (biosys), 236IVP Not GLP, Unpublished	NL
IIB 4.3	Beach, R.M.	1994	Spod-X LC-Product Chemistry. Generated by: Crop Genetics International (biosys) Submitted by: Crop Genetics International (biosys) File no.: Subdivision M., Guideline 151A-12 Date: July 20, 1994 Not GLP, Unpublished	NL
IIB 4.3	Miller, D.P.	1994	Certificate of Analysis Generated by: Crop Genetics International (biosys) Submitted by: Crop Genetics International (biosys) Date: January 7, 1994 Not GLP, Unpublished	NL

B.6 Effects on human health

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIB 5.3	Becker, J. & Parke, G.St. E.	1976	The effects of insect virus L. dispar NPV bioserv lot 33 on the eye mucosa of New Zealand albino rabbits Generated by: Cannon Laboratories, Inc. Submitted by: USDA, Forest Service Date: July 20, 1976a Not GLP, Unpublished	NL
IIB 5.3	Becker, J. & Parke, G.St. E.	1976	The effects of insect virus L. dispar NPV bioserv lot 33 on the eye mucosa of New Zealand albino rabbits Generated by: Cannon Laboratories, Inc. Submitted by: USDA, Forest Service Date: August 19, 1976b Not GLP, Unpublished	NL
IIB 5.3	Fink, R.J.	1972	Primary skin irritation study in rabbits (project nr. 183-195). Generated by: Hazleton laboratories Submitted by: USDA Date: 1972a Not GLP, Unpublished	NL
IIB 5.3	Fink, R.J.	1973	Acute dermal toxicity-guinea pigs Generated by: Hazleton Laboratories Submitted by: USDA Date: March 21, 1973a Not GLP, Unpublished	NL
IIB 5.3	Fink, R.J.	1972	Authographa californica ME virus and freed virus in saline suspension. Final report. Eye irritation-rabbits. Generated by: Hazleton laboratories Submitted by: USDA Date: october 4, 1972b Not GLP, Unpublished	NL
IIB 5.3	Parke, G.St.E. & Charles, S.J.	1978	The effects of LDP 53 on the eye mucosa of New Zealand albino rabbits. Generated by: Cannon Laboratories, Inc. Submitted by: USDA, Forest Service Date: January 30, 1978 Not GLP, Unpublished	NL
IIB 5.3	Thornett, H.D. & Ross Hart, E.R.	1975	Primary skin irritation-rabbits. Nucleopolyhedrosis virus (NPV) of the gypsy moth. Final report. Generated by: Litton bionetics, Inc. Submitted by: USDA Forest Service Date: June 20, 1975a Not GLP, Unpublished	NL

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIB 5.3	Thornett, H.D. & Ross Hart, E.	1975	Inhalation toxicity study in rats. Nucleopolyhedrosis virus (NPV) of the <i>Orygia pseudotsugata</i> . Final report. Generated by: Litton Bionetics, Inc. Submitted by: USDA, Forest Service Date: March 25, 1975b Not GLP, Unpublished	NL
IIB 5.3	Thornett, H.D. & Ross Hart, E.	1975	Eye irritation-rabbits. Nucleopolyhedrosis virus (NPV) of the gypsy moth. Final report. Generated by: Litton Bionetics, Inc. Submitted by: USDA, Forest Service Date: June 20, 1975c Not GLP, Unpublished	NL
IIB 5.3	West, B.	1967	Acute dermal toxicity studies with <i>Spodoptera exigua</i> NPV and other NPVs Generated by: Rosner-Hixson Laboratories Submitted by: USDA Date: July 27, 1967 Not GLP, Unpublished	NL
IIB 5.3.1	Anonymous	1966	Acute oral toxicity/pathogenicity tests with <i>Spodoptera exigua</i> NPV and other NPVs Generated by: Rosner-Hixson Laboratories Submitted by: USDA Date: November 27, 1966 Not GLP, Unpublished	NL
IIB 5.3.1	Cunningham et al.	1977	Tests demonstrating the safety of a baculovirus of the spruce budworm to mammals, birds and fish: bioassay of selected vertebrate organs in larvae. Information report IP-X-17. Generated by: Insect Pathology Research institute, Canadian Forestry Service, Ontario, Canada Submitted by: Crop Genetics international (biosys) Date: April 1977 Not GLP, Unpublished	NL
IIB 5.3.3	Fink, R.J.	1973	Acute inhalation toxicity-rats. Project nr. 183-195. Generated by: Hazleton laboratories Submitted by: USDA Date: May 18, 1973b Not GLP, Unpublished	NL
IIB 5.3.3	Robbins, G.	1991	Acute intraperitoneal toxicity/pathogenicity in mice, study S3181. Generated by: Cosmopolitan Safety Evaluation Submitted by: Espro Date: June 1991	NL

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
			Not GLP, Unpublished	
IIB 5.3.5	Beek, N. van	1993	Human cell culture assay for insect virus replication. Generated by: Crop Genetics International (biosys) Submitted by: Crop Genetics International (biosys) Date: December 1, 1993a Not GLP, Unpublished	NL
IIB 5.3.5	Beek, N. van	1993	Assessment of infective potential of SeMNPV, used to inoculate cultured human cells. Generated by: Crop Genetics International (biosys) Submitted by: Crop Genetics International (biosys) Date: December 1, 1993b Not GLP, Unpublished	NL
IIB 5.3.5	Beek, N. van & Kolodny-Hirsch, D.	1993	Polyhedra occlusion body count in samples of human cell culture assay for insect virus replication. Generated by: Crop genetics International (biosys) Submitted by: Crop Genetics International (biosys) Date: December 1, 1993 Not GLP, Unpublished	NL
IIB 5.3.7	Ross Hart, E.	1975	Sub-acute toxicity study in dogs. Nucleopolyhedrosis virus (NPV) of the gypsy moth. Final report. Generated by: Litton Bionetics, Inc. Submitted by: USDA, Forest Service Date: January 15, 1975a Not GLP, Unpublished	NL
IIB 5.5	Ross Hart, E.	1975	2-year carcinogenicity study in rats. Nucleopolyhedrosis virus (NPV) of the gypsy moth. Final report. Generated by: Litton Bionetics, Inc. Submitted by: USDA, Forest Service Date: January 15, 1975b Not GLP, Unpublished	NL

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
None				

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
None				

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IB 8.1	Roberts S & Wineholt RL	1976	Report 8-day dietary study of gypsy moth virus in mallard ducks. Lab. No. 6E-3281. Generated by: Cannon Laboratories, Inc., USA. Not GLP, Unpublished	NL
IIB 8.2	Moore, R.B.	1976	Fish safety tests. From: Gypchek registration. Generated by: Essex Marine Laboratory, USA. Not GLP, Unpublished	NL
IIB 8.3	Streams FA	1976	Susceptibility of aquatic invertebrates to gypsy moth NPV. Final report. Gypchek registration. Generated by: Biology Ecology Section, Biological Sciences Group, University of Connecticut, USA. Not GLP, Unpublished	NL

APPENDIX IIIB

SPODOPTERA EXIGUA NPV Florida isolate

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

B.1 Identity, B.2 Biological, physical, chemical and technical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIB 1.3	OECD	2002	Series on Harmonization of Regulatory Oversight in Biotechnology, No.20 CONSENSUS DOCUMENT ON INFORMATION USED IN THE ASSESSMENT OF ENVIRONMENTAL APPLICATIONS INVOLVING BACULOVIRUSES, ENV/JM/MONO(2002)1, 08-Jan-2002
IIB 2.3	Vlak, J.M.	2005	Position paper on 'Biosafety of <i>Spodoptera exigua</i> NPV for vertebrates' Wageningen University, Laboratory of Virology Not GLP, Unpublished
IIB 2.7.4	Mourgues Lois	2005	Wet sieving DEFITRACES, France Report No. 04-903041-001

B.6 Effects on human health

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIB 5	OECD	2002	Series on Harmonization of Regulatory Oversight in Biotechnology, No.20 CONSENSUS DOCUMENT ON INFORMATION USED IN THE ASSESSMENT OF ENVIRONMENTAL APPLICATIONS INVOLVING BACULOVIRUSES, ENV/JM/MONO(2002)1, 08-Jan-2002

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
None.			

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
None.			

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIB 8	OECD	2002	Series on Harmonization of Regulatory Oversight in Biotechnology, No.20 CONSENSUS DOCUMENT ON INFORMATION USED IN THE ASSESSMENT OF ENVIRONMENTAL APPLICATIONS INVOLVING BACULOVIRUSES, ENV/JM/MONO(2002)1, 08-Jan-2002

APPENDIX IV

List of uses supported by available data

SPODOPTERA EXIGUA NPV Florida isolate

Crop and /or situation	Member state or Country	Product name	F G or	Pest or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
(a)			I (b)	(c)										(l)	(m)
glass-house vegetable crops (a.o. sweet pepper, tomato, cucumber, egg plant, and lettuce)	all Europe	Spod-X GH	G	larvae of the beet army worm <i>Spodoptera exigua</i>	SC	1 x 10 ¹² SeNPV /l	high volume spraying overall	when moths or caterpillars are present	3-6x	5-10 days	3 x 10 ¹⁰ SeNPV/ha	1000	3 x 10 ¹¹ SeNPV/ha	0	
glass-house ornamental crops (a.o. rose, chrysanthemum, gerbera, carnation and potted plants)	all Europe	Spod-X GH	G	larvae of the beet army worm <i>Spodoptera exigua</i>	SC	1 x 10 ¹² SeNPV /l	high volume spraying overall	when moths or caterpillars are present	3-6x	5-10 days	3 x 10 ¹⁰ SeNPV/ha	1000	3 x 10 ¹¹ SeNPV/ha	0	

- 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) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

