Commodity	Parts per million	Expiration/ Revocation Date
Corn, sweet stover	3.5	None
* * *	* *	*
Goat, meat by-products	1.0	None
* * *	* *	*
Hog, meat by-products	1.0	None
* * *	* *	*
Horse, meat by-products	1.0	None
* * *	* *	*
Juneberry	5.0	None
* * *	* *	*
Lingonberry	5.0	None
* * *	* *	*
Milk	0.5	None
* * *	* *	*
Pistachio	0.2	None
* * *	* *	*
Salal	5.0	None
Safflower	15.0	None
* * *	* *	*
Sheep, meat by-products	1.0	None
* * *	* *	*

(b) *Section 18 emergency exemptions.* [Reserved]

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[FR Doc. 03–24562 Filed 9–26–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0256; FRL–7328–8]

Indian Meal Moth Granulosis Virus; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the Indian Meal Moth Granulosis Virus (IMMGV) in or on all food commodities when applied/used in accordance with approved label rates and good agricultural practices. AgriVir, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of IMMGV.

DATES: This regulation is effective September 29, 2003. Objections and requests for hearings, identified by docket identification number OPP–2003–0256, must be received on or before November 28, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0256. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of July 30, 2003 (68 FR 447804) (FRL–7319–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 3F6736) by AgriVir, LLC, 1901 L Street, NW., Suite 250, Washington, DC 20036. This notice included a summary of the petition prepared by the petitioner AgriVir, LLC. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1218 be amended by establishing an exemption from the requirement of a tolerance for residues of IMMGV.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is

''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe '' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408 of the FFDCA (b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . '' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Based on the toxicology data cited and the limited exposure to humans and domestic animals, there is a reasonable certainty that no harm will result from aggregate exposure to IMMGV to the U.S. population including infants and children to residues of IMMGV when used as viral pest control agent to control the Indian Meal Moth on all food commodities. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the long history of research, use and safety of testing baculoviruses which is documented in the public scientific literature (Refs. 1–5). IMMGV is a naturally occurring organism to which some environmental and dietary exposure is likely to be common for most individuals. The conclusion of safety is further supported by the lack of toxic or pathogenic effects on test animals at high doses (data submitted by the registrant, MRID numbers 453070–01, 450662–07, and 450662–08). Baculoviruses have been described in the scientific literature for approximately 40 years. In addition to their natural occurrence, these viruses have a long history of safe use as bioinsecticides. Baculoviruses have been studied extensively in both laboratory and field experiments, which have shown that the virus host range is limited to arthropods. IMMGV has been shown to be very restricted in its insect host range. No toxicological or pathogenic effects produced by the baculovirus itself, have been observed in mammals, birds, fish or plants. The lack of mammalian toxicity at high levels of exposure to IMMGV demonstrates the safety of the product at levels well above maximum possible exposure levels anticipated in the crops. There has been a significant amount of research performed on baculoviruses and numerous scientific references are available which describe the biology of these viruses, their host range, and their mode of action. Toxicity studies submitted in support of this tolerance exemption include the following:

1. *Acute oral toxicity/pathogenicity (453070–01).* Thirteen male (254–321 grams (g)) and 13 female (160–208g) albino rats were divided into three groups and treated with 0.1 milliliter (mL) of the test substance. Treatment was administered by oral gavage with at least 1 x 10^8 viral particles per animal. No deaths occurred in any of the test animals. Other than diarrhea during the first few hours following dosing, there were no other apparent clinical symptoms. Based upon the data there were no significant adverse effects reported upon doses of at least 1 x 10^8 viral capsules. The toxicity category was deemed Toxicity Category IV.

2. *In vitro mammalian cell viral infectivity in mammalian cells (450662–08).* Human WI–38 and WS1 cell cultures and African green monkey CV–1 cell cultures were exposed to 1 x 10^6 units of the test substance. The cell cultures were observed daily for 21 days following inoculation for virus induced cytopathic effects. The test preparation was shown to be highly infectious and cytopathic to the target Plodia interpunctella larva. No differences were seen between the virus treated nor the solvent treated control cell cultures with respect to any cytopathic endpoint at any time post-inoculation. Based on the data, there was no evidence that the virus could infect any of the three mammalian cell lines.

3. *In vitro mammalian cell viral induced cytotoxicity (450662–07).* Human WI–38 and WS1 cell cultures and African green monkey CV-1 cell cultures were exposed to 1 x 10^6 units of IMMGV technical (IMMGV) for 1 hour. The cell cultures were then washed, refed with virus-free medium, incubated for 8 days, fixed, stained and the number of colonies counted. The test preparation was shown to be highly infectious and cytopathic to the target Plodia interpunctella larva although analysis determined that the actual number of viral capsules used was only 42% of the target value. No differences were seen between the virus treated and the solvent treated control cell cultures with respect to cloning efficiency in any of the three cell lines. Based on the data, there was no evidence that the test substance was cytotoxic to any of the three mammalian cell lines.

4. *Acute eye irritation (450662–09).* The test substance was instilled in the eyes of four males and two female adult New Zealand albino rabbits at approximately 0.04 g/eye (~7.14 x 10^9 viral capsules). Animals were acclimated for 11 days and before treatment their eyes were checked for normalcy using ophthalmic fluorescein and an ultraviolet (UV) lamp. The right eye of each animal was treated and the other eye served as a control. No deaths occurred. Clinical signs noted included conjunctivitis, corneal opacity and iritis, all of which cleared within 4 days of treatment. The toxicity from this study was deemed Toxicity Category IV.

5. *Data waivers.* Data waivers were requested for the following studies:

i. *Acute dermal toxicity.* This study was waived based upon the lack of toxicity in animals dosed orally (453070–01) and more importantly cells inoculated with viral pest control agent (450662–07 and 450662–08). Cell culture infectivity and cytoxicity assays demonstrated that there were no toxic effects to mammalian cell lines (human lung, human endothelial and primate renal cell lines) when innoculated with doses of IMMGV. Cell culture assays provide valuable information on the ability of the viral pest control agent to infect, replicate in, transform or cause toxicity in mammalian cell lines. Thus, this assay is the most likely indicator of evaluating the toxicity of a viral pest control agent. Unlike the oral, dermal and inhalation routes of exposure, these barriers (exposure conditions) do not exist in cell culture assays as the host cell is completely exposed, thus,

providing a higher exposure scenario (for exposure of body tissues, organs and systems). Cell culture studies which demonstrate no toxicity to mammalian cell lines upon inoculation with the viral pest control agent can therefore be used as an indicator in determining the probability of toxicity to the viral pest control agent via other routes of exposure (oral, dermal, inhalation). Therefore, this evaluation criteria along with the data submitted (referenced above) and the long history of safe use of baculoviruses provided the Agency with a scientific rationale to waive the requirement for an acute dermal toxicity study. In addition, the IMMGV is a characteristically large molecular entity and is therefore unable to penetrate intact skin. However, in the unlikely event that viral penetration does occur through contact with broken skin, the studies submitted by the registrant have demonstrated a lack of toxicity/pathogenicity and infectivity associated with IMMGV.

ii. *Acute inhalation toxicity*. This study was waived based upon the lack of toxicity in animals dosed orally (453070–01) and, more importantly cells inoculated with the viral pest control agent (450662–07 and 450662–08). Cell culture infectivity and cytoxicity assays demonstrated that there were no toxic effects to mammalian cell lines (human lung, human endothelial and primate renal cell lines) when infected with doses of IMMGV. Cell culture assays provide valuable information on the ability of the viral pest control agent to infect, replicate in, transform or cause toxicity in mammalian cell lines. Thus, this assay is the most likely indicator of evaluating the toxicity of a viral pest control agent. Unlike the oral, dermal and inhalation routes of exposure, these barriers (exposure conditions) do not exist in cell culture assays as the host cell is completely exposed thus providing a higher exposure scenario (for exposure of body tissues, organs and systems). Cell culture studies which demonstrate no toxicity to mammalian cell lines upon infection with the viral pest control agent can therefore be used as an indicator in determining the probability of toxicity to the viral pest control agent via other routes of exposure (oral, dermal and inhalation). Therefore, this evaluation criteria along with the data submitted (referenced above) and the long history of safe use of baculoviruses provided the Agency with a scientific rationale to waive the requirement for an acute inhalation toxicity study. In addition, the product labeling includes precautionary language for the pesticide handler to use a dust mask as a further measure of safety.

iii. *Primary dermal irritation*. This study was waived based upon the lack of toxicity in animals dosed orally (453070–01) and, more importantly cells inoculated with viral pest control agent (450662–07 and 450662–08). Cell culture infectivity and cytoxicity assays demonstrated that there were no toxic effects to mammalian cell lines (human lung, human endothelial and primate renal cell lines) when infected with doses of IMMGV. Cell culture assays provide valuable information on the ability of the viral pest control agent to infect, replicate in, transform or cause toxicity in mammalian cell lines. Thus, this assay is the most likely indicator of evaluating the toxicity of a viral pest control agent. Unlike the oral, dermal and inhalation routes of exposure, these barriers (exposure conditions) do not exist in cell culture assays as the host cell is completely exposed thus providing a higher exposure potential (for exposure of body tissues, organs and systems). Cell culture studies which demonstrate no toxicity to mammalian cell lines upon infection with the viral pest control agent can therefore be used as an indicator in determining the probability of toxicity to the viral pest control agent via other routes of exposure (oral, dermal and inhalation). Therefore, this evaluation criteria along with the data submitted (referenced above) and the long history of safe use of baculoviruses provided the Agency with a scientific rationale to waive the requirement for an acute dermal toxicity study. In addition, the product labeling includes precautionary language for the pesticide handler to wear gloves as a further measure of safety.

iv. *Literature citations (450662–06)*. Information from the open scientific literature has been cited in support of the relative safety and lack of mammalian toxicity associated with baculoviruses, including the IMMGV. The IMMGV is very host-specific, it does not infect any host other than the Indian meal moth larvae and does not cross-infect any Lepidopteran or other insect. The range for the insect host is worldwide. Studies listed in the literature review provide information on the life cycle and mode of action of IMMGV such that it acts by pathogenicity, not a toxic mechanism. It presents no hazard potential to mammals and non-target species.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food*. Because baculoviruses are naturally occurring organisms, there is a great likelihood for previous exposure for most, if not all individuals. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions resulting from exposure to IMMGV. The amount of product used will result in a negligible increase, if any, of virus exposure. In addition, even if there is a significant increase in exposure to the virus, the toxicity studies submitted by the registrant along with the extensive reports in the scientific literature indicating the safety of the viruses, suggest that there should not be any additional risk of adverse effects due to exposure to IMMGV.

2. *Drinking water exposure*. Because of the use site and amount of product that will be applied, potential non-occupational exposures in drinking water is negligible. Currently, there are no reports which show that IMMGV has been found in any drinking water. Baculoviruses occur naturally in soil and there is a low likelihood that they would survive passage through the soil to reach underground water (Ref. 1, MRID 450662–06). Even if the virus is able to reach ground water, it is highly unlikely that the viruses would survive municipal water treatment due to its inability to survive outside its host. Therefore, it is not likely there will be an increase of IMMGV in drinking water. In addition, because the virus host range is limited to the Indian meal moth, the results of the acute oral toxicity studies using a high dose of the virus, suggest that there will not be any adverse effects upon human consumption in the unlikely event any virus found its way into drinking water, therefore; the Agency has no drinking water exposure concerns.

B. Other Non-Occupational Exposure

Baculoviruses are naturally occurring viruses that have been described in the scientific literature for approximately 40 years. In addition to scientific research, there has been a long history of safe use of baculoviruses to control arthropods. Because the amount of virus which will be applied is small, it is not likely that there will be a significant increase in potential exposure. Any increase in virus titer is likely to be negligible at

most. Baculoviruses have been shown to have a host range limited to arthropods and the host range of this virus is even more restrictive than most baculoviruses (Ref. 1, MRID 450662–06). Therefore, even if there was an increase in exposure, there should not be any increase in potential human health effects.

VI. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to this or other baculovirus-containing products, the Agency is confident that there will not be cumulative effects from the registration of this product.

VII. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population from exposure to residues of IMMGV. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the long history of safe use of baculoviruses as bioinsecticides, the lack of mammalian toxicity associated with IMMGV, the limited host range of the virus and the inability of IMMGV to infect mammalian cell lines.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (MOE) (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different MOE will be safe for infants and children. MOEs are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that IMMGV is practically non-toxic to mammals, including infants and children and that they will consume only minimal, if any, residues of the microbial pesticide. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply.

As a result, EPA has not used a MOE approach to assess the safety of the IMMGV.

VIII. Other Considerations

A. Endocrine Disruptors

There are no reports or indications in the available scientific literature that suggests that Indian meal moth granulosis virus has caused or has the potential to cause adverse effects on the endocrine and/or immune systems of humans or animals. The virus host range is limited to the Indian meal moth, where it would be expected to affect the defense systems of the target insect pest. The target insect's response is not different from any animal's response to a disease agent. These suppositions are confirmed by the results of the mammailian toxicity tests cited above.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for the IMMGV.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues of the IMMGV.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object '' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0256 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 28, 2003.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0256, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. References

1. Consigili, R.A., D.L., Russell and M.E. Wilson. 1986. The biochemistry and molecular biology of the granulosis virus that infects plodia interpunctella. Current Topics in Microbiology and Immunology 131:69–101.

2. Doller, G. 1985. The safety of insect virus as biological control agents. In ''Viral Insecticides for Biolocial Control'' (Eds. Maramorosch, K. and Sherman, H.G.), Academic Press, New York: 399.

3. Groner, A. 1986. Specificity and safety of baculoviruses. In ''The Biology of Baculoviruses Vol. I: Biological Properties and Molecular Biology'' (Eds. Granados, R.D. and Federici, B.A.), CRC Press, Boca Raton, Florida: 177–202).

4. Heimpel, A.M. 1971. Safety of insect pathogens for man and vertebrates. In ''Microbial Control of Insects and Mites'' (Eds. Burges, H.D. and Hussey, N.W.), Academic Press, New York: 469–489.

5. Hunter, D.K. 1970. Pathogenicity of a granulosis virus of the Indian meal moth. J. Invertebr. Pathol. 16:339–341.

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2003.

Janet L. Andersen

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1218 is revised to read as follows:

§ 180.1218 Indian Meal Moth Granulosis Virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide Indian Meal Moth Granulosis Virus when used in or on all food commodities.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7563–8]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the Agency'') in determining which sites warrant further investigation. These further investigations will allow EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds 12 new sites to the NPL; all to the General Superfund Section of the NPL.

EFFECTIVE DATE: The effective date for this amendment to the NCP shall be October 29, 2003.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, ''Availability of Information to the Public'' in the **SUPPLEMENTARY INFORMATION** portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Yolanda Singer, phone (703) 603–8835, State, Tribal and Site Identification Center; Office of Emergency and Remedial Response (mail code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW., Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

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