

responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

#### Collection of Information

This rule calls for no new collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501-3520).

#### Federalism

A rule has implication for federalism under Executive Order 13132. Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

#### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### Taking of Private Party

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b) (2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. It is not economically significant and creates no environmental risk to health or risk to safety disproportionately affecting children.

#### Environmental

The Coast Guard considered the environmental impact of this rule and concluded under Figure 2-1, paragraph 34(g) of Commandant Instruction M16475.1D, this rule is categorically

excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under ADDRESSES.

#### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationships between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or use. We have determined that it is not a "significant energy action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reports and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165, as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.04-1, 6.04-6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T07-115 is added to read as follows:

#### § 165.T07-115 Security Zones; Ports of Palm Beach, Port Everglades, Miami, and Key West, Florida.

(a) *Regulated area.* Temporary moving security zones are established 100 yards around all tank vessels with hazardous cargo onboard and all passenger vessels with passengers aboard during transits entering or departing the Ports of Palm Beach, Port Everglades, Miami or Key West, Florida. These moving security zones are activated when the subject

vessel passes: "LW" buoy, at approximate position 26° 46' 18N, 080° 00' 36W when entering the Port of Palm Beach, passes "PE" buoy, at approximate position 26° 05' 30N, 080° 04' 48W when entering Port Everglades; the "M" buoy, at approximate position 25° 46' 06N, 080° 05' when entering the Port of Miami; and "KW" buoy, at approximate position 24° 27' 42N, 081° 48' 06W when entering the Port of Key West. Temporary fixed security zones are established 100 yards around all tank vessels with hazardous cargo onboard and all passenger vessels with passengers aboard docked in the Ports of Palm Beach, Port Everglades, Miami or Key West, Florida.

(b) *Regulations.* In accordance with the general regulations of § 165.33 of this part, entry into these zones is prohibited except as authorized by the Captain of the Port, Miami or a Coast Guard commissioned, warrant, or petty officer designated by him. The Captain of the Port will notify the public via Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 22 (157.1 MHz) of all active security zones in port by identifying the names of the vessels around which they are centered.

(c) *Dates.* This regulation becomes effective at 11:59 p.m. on September 25, 2001 and will terminate at 11:59 p.m. on June 15, 2002 unless terminated earlier by the Captain of the Port, Miami, Florida.

Dated: September 25, 2001.

**J.A. Watson, IV,**

*Captain, U.S. Coast Guard, Captain of the Port Miami.*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-301193; FRL-6812-5]

RIN 2070-AB78

#### 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 on dried fruits and nuts when applied/used as a microbial pesticide to control the Indian Meal Moth (*Plodia interpunctella*). AriVir, 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 Indian Meal Moth Granulosis Virus (IMMGV).

**DATES:** This regulation is effective January 9, 2002. Objections and requests for hearings, identified by docket control number [OPP-301193], must be received by EPA, on or before March 11, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number [OPP-301193] in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8733; and e-mail address: hollis.linda@epa.gov.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this Action Apply to Me?*

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

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311  32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_180/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html), a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301193. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### **II. Background and Statutory Findings**

In the **Federal Register** of July 7, 2000 (65 FR 41984) (FRL-6556-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide tolerance petition by AgriVir, LLC., 1625 K St., NW., Washington, DC 20006. 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 part 180 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) 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(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) 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 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 stored nuts and dried fruits. 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 (Doller, G. 1985. The safety of insect virus as biological control agents. In "Viral Insecticides for Biological Control" (Eds. Maramorosch, K. and Sherman, H.G.), Academic Press, New York: 399, 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, 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). Consigili, R.A., D.L., Russell and M.E. Wilson. 1986. The biochemistry and molecular biology of the granulosis virus that infects *Plodia interpunctella*. Cur. Top. Microbiol. and Immunol. 131: 69-101. Hunter, D.K. 1970. Pathogenicity of a granulosis virus of the Indian meal moth. J. Invertebr. Pahtol. 16: 339-341.

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 #'s 453070-01, 450662-07 & 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 (254-321g) 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  $1 \times 10^8$  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  $1 \times 10^8$  viral capsules. 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  $\geq 1 \times 10^6$  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  $\geq 1 \times 10^6$  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 nor 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 ( $\sim 7.14 \times 10^9$  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. Toxicity Category IV.

Data waivers were requested for the following studies:

1. *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 & 450662-08). Cell culture infectivity and cytotoxicity 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, 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.

2. *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 viral pest control agent (450662-07 & 450662-08). Cell culture infectivity and cytotoxicity 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 inhalation toxicity study. In addition, the product labeling includes precautionary language for the pesticide handler to a dust mask as a further measure of safety.

3. *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 & 450662-08). Cell culture infectivity and cytotoxicity 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.

4. *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 to include 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, FFDC section 408 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 (Consigli, R.A., and Wilson, M.E., 1986. The Biochemical and Molecular Biology of the Granulosis Virus that Infects *Plodia interpunctella*. Current topics in Microbiology and Immunology 131:69-101. 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 likely there will not be an increase of IMMGV in drinking water. In addition, because the virus host range is limited to the Indian meal moth, even if the virus is found in drinking water, 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 (Consigli, R.A., and Wilson, M.E., 1986. The Biochemical and Molecular Biology of the Granulosis Virus that Infects *Plodia interpunctella*. Current topics in Microbiology and Immunology 131:69-101. 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

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.* FFDC section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) (MOE) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database 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 which 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 mammalian 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 FFDC, 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 FFDC by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDC sections 408 and 409. 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 control number OPP-301193 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 March 11, 2002.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260-4865.

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](mailto: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.

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.

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.2. Mail your copies, identified by docket number OPP-301193, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements**

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) 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 FFDCA section 408(d), such as the tolerance 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 FFDCA section 408(n)(4). 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.

#### **XI. Submission to Congress and the Comptroller General**

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: December 21, 2001.

**James Jones,**

*Acting Director, 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 added to subpart D 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 in or on dried fruits and nuts.

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