pesticides would represent a negligible addition to those existing in drinking water.

2. *Non-dietary exposure.* Monsanto believes that non-dietary exposure to engineered coat proteins will be minimal to non-existent because the coat protein is expressed only within the plant tissues.

E. Cumulative Exposure

Exposure through other pesticides and substances with the common mode of toxicity as this pesticide. Monsanto believes that due to the lack of toxicity/pathogenicity associated with plant viruses or plant viral coat proteins, cumulative effects with other pesticides and substances will be non-existent.

F. Safety Determination

1. *U.S. population.* There is no known toxicity associated with coat proteins from plant viruses. Consequently, a safety assessment is not needed for these proteins. Given the long history of mammalian consumption of the entire plant virus particle in foods, without any adverse human health effects, Monsanto reasonable believes that consumption of a noninfectious component of the PVY plant virus is safe. There are no known data that indicate aggregate exposure to plant viral coat proteins under normal conditions will result in harm to any person.

2. *Infants and children.* Viral coat proteins are ubiquitous in foods, including those foods consumed by infants and children. Moreover, there is no reason to believe that plant viral coat proteins are likely to occur in different amounts in foods, consumed by children and infants. Further, there is no scientific evidence that viral coat proteins used as plant-pesticides would have a different effect on children than on adults. Viral coat proteins are not toxic and, therefore, Monsanto believes with reasonable certainty that no harm will result to infants and children from aggregate exposure to coat proteins from plant viruses.

G. Existing Tolerances

No tolerance or exemption from tolerance has been previously granted for PVY coat protein.

H. International Tolerance

No international tolerance or exemption from tolerance has been previously granted for PVY coat protein. Monsanto Company concludes that plant viruses, including PVY coat proteins, are not harmful to humans, and that there is a reasonable certainty that no harm will result from aggregate exposure to Coat Protein of Potato Virus Y and the genetic material necessary for its production, including all anticipated dietary exposures and all other non-occupational exposures. Accordingly, Monsanto believes that the PVY coat protein qualifies for an exemption from the requirement of a tolerance in or on all raw agricultural commodities.

[FR Doc. 97–16657 Filed 6–24–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–742; FRL–5723–2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

DATES: Comments, identified by the docket control number PF–742, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Divison (7505C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Product Manager (PM) 90, Biopesticides and Pollution Prevention Division, (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5th floor, CS1, 2800 Crystal Drive, Arlington, VA. 22202, (703) 308–8733; e-mail: hollis.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports grantinig of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–742 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (insert docket number) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 21 U.S.C. 346a.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 19, 1997.

Kathleen D. Knox,

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

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Monsanto Company

PP 7F4836

EPA has received a pesticide petition (PP 7F4836) from Monsanto Company of St. Louis, Missouri. The petition proposes to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the plant pesticide Replicase Protein of Potato Leaf Roll Virus and the Genetic Material necessary for its production in or on all raw agricultural commodities.

A. Proposed Use Practices

Recommended application method and rate(s), frequency of application, and timing of application. Monsanto states that the plant viral replicase is produced within tissues of the engineered plant and is not to be applied externally. Appropriate cultural practices for growing potatoes with genetically engineered virus resistance will be determined by individual growers, as such practices are for all other plant varieties. Accordingly, no special instructions for use will be necessary.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Monsanto has determined that the sequence of the engineered viral replicase gene transformed into potato plants is identical to a PLRV replicase gene found in nature.

2. *Magnitude of residue anticipated at the time of harvest and method used to determine the residue.* Monsanto states that the viral replicase protein is expressed in plant tissues, and therefore, is not a residue in the same manner as a pesticide applied externally to growing crop plants. Monsanto does not expect any measurable residue of the engineered viral replicase protein to remain on or in transformed raw agricultural commodities (RACs).

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* The PLRV replicase protein is produced at a level that is not detectable by either ELISA (Enzyme-Linked Immunoabsorbent Assay) or by Western analysis. There has been no reason to develop a commercial to detect PLRV replicase in naturally infected potatoes, thus, Monsanto believes that there is no reason to determine the PLRV replicase content in these PLRV-resistant potatoes.

C. Mammalian Toxicological Profile

Replicase proteins are substances that viruses produce during a plant infection to replicate their genetic material. When the genetic material encoding the replicase gene for a plant virus is introduced into a plant's genome, the plant is able to resist subsequent infections by that same virus as will as strains closely related to the donor virus. Virus-infected plants are currently, and have always been, a part of both the human and domestic animal food supply. Monsanto believes that plants containing replicase proteins are not harmful to humans or animal that consume these foods. All available data from the scientific literature indicates that plant viruses are not toxic to humans or other vertebrates. Additionally, plant viruses are unable to replicate in mammals or other vertebrates, eliminating the possibility of human infection. This has been shown by injections of purified whole virus into laboratory animals to develop antibodies for ELISA tests. More importantly, however, this tolerance exemption will apply to that portion of the viral genome coding for the whole replicase protein. This component alone is incapable of forming infectious particles. Because whole intact plant viruses are not known to cause deleterious human health effects, Monsanto believes that it is reasonable to assume that a subunit of these viruses likewise will not cause adverse human health effects.

D. Aggregate Exposure

1. *Dietary exposure: Food.* Monsanto believes that the use of replicase protein-mediated resistance will not result in any new dietary exposure to plant viruses. Entire infectious particles of Potato Leafroll Virus, including the replicase component, are found in the tubers, leaves and stems of potato plants. Virus-infected food plants are and have always been a part of the human and domestic animal food supply. Such food plants and food derived from them have been consumed with no detectable or observed adverse effects to human health, including children and infants. Given this information, Monsanto believes that exposure via the human diet provides a direct and better method of establishing the lack of toxicity versus animal models of toxicity.

2. *Drinking water.* No measurable residues of replicase from engineered plant viruses are expected to be in the drinking water. Plant viruses are a natural component of the environment and are present in soil and water. Consequently, Monsanto believes that the replicase protein produced as plant-pesticides would represent a negligible addition to those existing in drinking water.

3. *Non-dietary exposure.* Monsanto believes that non-dietary exposure to engineered replicase proteins will be minimal to non-existent because the replicase protein is expressed only within the plant tissues.

E. Cumulative Exposure

Exposure through other pesticides and substances with the common mode of toxicity as this pesticide. Monsanto believes that due to the lack of toxicity/pathogenicity associated with plant viruses or plant viral replicase proteins, cumulative effects with other pesticides and substances will be non-existent.

F. Safety Determination

1. *U.S. population.* There is no known toxicity associated with replicase proteins from plant viruses. Consequently, a safety assessment is not needed for these proteins. Given the long history of mammalian consumption of the entire plant virus particle in foods, without any adverse human health effects, Monsanto reasonable believes that consumption of a noninfectious component of the PLRV plant virus is safe. There are no known data that indicate aggregate exposure to plant viral replicase proteins under normal conditions will result in harm to any person.

2. *Infants and children.* Viral replicase proteins are present in any food which have replicating virus. Potatoes routinely are infected by virus and these potatoes are consumed by infants and children. Moreover, there is no reason to believe that plant viral replicase proteins are likely to occur in different amounts in foods that are consumed by children and infants. Further, there is no scientific evidence that viral replicase proteins used as plant-pesticides would have a different effect on children than on adults. Viral replicase proteins are not toxic and, therefore, Monsanto believes with

reasonable certainty that no harm will result to infants and children from aggregate exposure to replicase proteins from plant viruses.

G. Existing Tolerances

No tolerance or exemption from tolerance has been previously granted for PLRV replicase.

H. International Tolerance

No international tolerance or exemption from tolerance has been previously granted for PLRV replicase protein. Monsanto Company concludes that plant viruses, including PLRV replicase proteins, are not harmful to humans, and that there is a reasonable certainty that no harm will result from aggregate exposure to Replicase Protein of Potato Leafroll Virus and the genetic material necessary for its production, including all anticipated dietary exposures and all other non-occupational exposures. Accordingly, Monsanto believes that the PLRV protein qualifies for an exemption from the requirement of a tolerance in or on all raw agricultural commodities.

2. Mycogen Corporation

PP 7G4823

EPA has received a pesticide petition (PP) 7G4823 from Mycogen Corporation of San Diego, California. The petition proposes to amend 40 CFR part 180 by establishing a temporary exemption from the requirement of a tolerance for residues of the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens in or on all raw agricultural commodities.

A. Proposed Use Practices

Recommended application method and rate(s), frequency of application, and timing of application. Mycogen Corporation proposes to conduct testing under an Experimental Use Permit using 11,365 gallons of an end-use formulation containing the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens. The testing will occur during a two-year experimental program in Alabama, Arizona, California, Delaware, Florida, Georgia, Louisiana, Maryland, Mississippi, New Jersey, New York, North Carolina, South Carolina, Texas, Virginia and Puerto Rico. The total acreage for all sites over the two-year period will cover 2,740 acres.

The trials conducted will focus on control of armyworm, looper and cutworm pests in vegetable, field crop, legume, turf and ornamental, nut crop, stone and pome fruit, small fruit and berry, and herb commodities. Weekly and biweekly treatments with 7 and 3 to 4 day intervals will be evaluated starting shortly after plant emergence through whorl stage and, in selected cases, through harvest. Five rates at 0.5, 1, 2, 3, and 4 quarts per acre will be tested. Applications will be made using the conventional tractor-mounted spray booms operated by cooperating growers. Spray volumes of 25 to 100 GPA and pressures of 50 to 250 psi will be targeted.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The Cry1F delta endotoxin gene from *Bacillus thuringiensis* variety aizawai has been cloned and expressed in the gram negative bacterium Pseudomonas fluorescens. The Pseudomonas fluorescens host bacteria is then killed, thereby encapsulating the Cry1F delta endotoxin. The product is a light brown liquid with a slight earthy odor. The formulation is stable and non-corrosive with a pH of 4.86 and a density of 1.061 g/cm3. The viscosity was measured to be 1,379 cps.

2. *Magnitude of residue anticipated at the time of harvest and method used to determine the residue.* Mycogen expects the residue of the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens will be minimal at time of harvest due to the rapid degradation of the killed cells in the environment. In situations where treatments are made just prior to harvest, Mycogen believes residues on the commodity will not present any risk to human or animal health based on the established toxicology data and historical safe use of products containing delta endotoxins derived from *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens. Mycogen's petition for a temporary exemption from the requirement of a tolerance eliminates the need to determine the residue at time of harvest.

3. *A statement why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Mycogen states that residues of the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens at any level will not pose a threat to human health or to the environment. Mycogen is requesting a temporary exemption from the requirement of a tolerance for residues on all raw agricultural commodities; therefore, this action should prevent the need to quantify residues on food or feed commodities.

C. Mammalian Toxicological Profile

The aizawai strain of *Bacillus thuringiensis*, which produces the Cry1F delta endotoxin, is used commercially in several registered pesticide products based on the general tolerance exemption established under 40 CFR 180.1011. To confirm the human safety of the Cry1F derived delta endotoxin encapsulated in killed Pseudomonas fluorescens, Mycogen conducted an acute oral LD_{50} toxicity study using the technical material. The acute oral LD_{50} was determined to be greater than 5,000 mg/kg body weight.

Extensive toxicology tests have been performed by Mycogen with similar encapsulated delta endotoxins derived from *Bacillus thuringiensis*. Mycogen states that no toxic effects were observed for any of the organisms tested, including mammals, birds, fish and aquatic invertebrates.

D. Aggregate Exposure

1. *Dietary exposure: Food.* Mycogen states that any dietary exposure to the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens will not present a risk to human or animal health due to the nontoxic properties of the killed organism. Dietary exposure is suggested to be minimal as the killed cells breakdown in the environment into natural biochemical components.

2. *Drinking water.* Mycogen believes the immobility of the cells prevents transfer of the killed organism to aquatic habitats, groundwater or other drinking water sources.

3. *Non-dietary exposure.* The use of the encapsulated Cry1F derived delta endotoxin under a controlled Experimental Use Permit will mitigate the potential for non-occupational exposure. The product will be used only by participants in the experimental program, and applications will involve terrestrial food crops on commercial agricultural property. The product will not be used on sites involving schools, parks or recreation facilities, or any other site not listed on the experimental product label.

E. Cumulative Exposure

Like native strains of *Bacillus thuringiensis*, the encapsulated Cry1F derived delta endotoxin has a highly targeted mode of action on specific insect pests. This unique mode of action is a distinguishing factor of *Bacillus thuringiensis* delta endotoxins versus traditional chemistries. No cumulative exposure will occur with other pesticides and substances as a result of common mode of toxicity. Mycogen

believes normal use patterns and rapid degradation of the organism will not lead to accumulation of the killed cells in the environment.

F. Safety Determination

1. *U.S. population.* Toxicology information regarding delta endotoxins derived from *Bacillus thuringiensis* is well established. During the widespread use of *Bacillus thuringiensis* over several decades for pest control purposes there has not been any confirmed reports indicating toxicity to humans or animals. In the Draft Registration Standard for *Bacillus thuringiensis*, EPA Case No. 0247 dated December 1986, EPA stated that the delta endotoxin in *Bacillus thuringiensis* ''has no known toxic pathogenic effect in humans or other mammals.''

2. Infants and Children. Mycogen states that the Cry1F derived delta endotoxin of *Bacillus thuringiensis* encapsulated in killed Pseudomonas fluorescens is practically non-toxic to humans and presents minimal risk to the environment. A determination of safety for infants and children can be made based on: (a) the established toxicology database demonstrating no mammalian toxicity; (b) the historical safe use of similar products using delta endotoxins from *Bacillus thuringiensis*; (c) the lack of persistence and mobility of the killed cells in the environment; and (d) the absence of use patterns under the Experimental Use Permit which may lead to exposure to infants and children.

G. Effects on the Immune and Endocrine Systems

Mycogen states that the toxicology database on delta endotoxins derived from *Bacillus thuringiensis* demonstrate no toxicity to mammalian immune or endocrine systems. Using the encapsulation process to effectively kill all cells ensures that no metabolic byproducts are produced which could potentially present an adverse effect to the immune or endocrine systems. The decomposition of the killed cells in the environment and in mammalian metabolic systems will not lead to adverse effects to the immune or endocrine systems.

H. Existing Tolerances

Strains of *Bacillus thuringiensis* are approved for use on raw agricultural commodities under the general tolerance exemption established by 40 CFR 180.1011. The gene encoding the Cry1F delta endotoxin is derived from *Bacillus thuringiensis* variety aizawai. Several products registered with EPA currently use the aizawai strain and are exempt from the requirement of a tolerance.

The use of other similar delta endotoxins derived from *Bacillus thuringiensis* and encapsulated in killed Pseudomonas fluorescens are approved under 40 CFR 180.1107, 180.1108, and 180.1154. The encapsulated Cry1F derived delta endotoxin was already previously approved on April 29, 1994 under a temporary tolerance exemption from Mycogens Petition Number 3G4224.

[FR Doc. 97–16658 Filed 6–24–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–59360; FRL–5727–5]

Certain Chemicals; Approval of a Test Marketing Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of an application for test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated this application as TME–97–6. The test marketing conditions are described below.

DATES: This notice becomes effective June 18, 1997. Written comments will be received until July 10, 1997.

ADDRESSES: Written comments, identified by the docket control number [OPPT–59360] and the specific TME number should be sent to: TSCA Nonconfidential Information Center (NCIC), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NEB–607 (7407), 401 M St., SW., Washington, DC, 20460, (202) 554–1404, TDD (202) 554–0551.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by [OPPT–59360]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: Shirley D. Howard, New Chemicals Notice Management Branch, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–611, 401 M St. SW., Washington, DC 20460, (202) 260–3780. e-mail: howard.sd@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to human health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

EPA hereby approves TME–97–6. EPA has determined that test marketing of the new chemical substance described below, under the conditions set out in the TME application, and for the time period and restrictions specified below, will not present an unreasonable risk of injury to human health or the environment. Production volume, use, and the number of customers must not exceed that specified in the application. All other conditions and restrictions described in the application and in this notice must be met.

A notice of receipt of this application was not published in advance of approval. Therefore, an opportunity to submit comments is being offered at this time. EPA may modify or revoke the test marketing exemption if comments are received which cast significant doubt on its finding that this test marketing activity will not present an unreasonable risk of injury.

The following additional restrictions apply to TME–97–6. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. In addition, the applicant shall maintain the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. Records of the quantity of the TME substance produced and the date of manufacture.

2. Records of dates of the shipments to each customer and the quantities supplied in each shipment.

3. Copies of the bill of lading that accompanies each shipment of the TME substance.