Enforcement Fairness Act of 1996, the EPA submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 14, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 4, 1997.

Michael J. Sanderson,

Acting Regional Administrator.

[FR Doc. 97–21702 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300530; FRL–5738–3]

RIN 2070–AB78

Replicase Protein of Potato Leaf Roll Virus and the Genetic Material Necessary for Its production; Exemption from the requirement of a tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide Replicase Proteins of Potato Leaf Roll Virus and the genetic material necessary for its production in or on all raw agricultural commodities. Monsanto Company submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Replicase Proteins of Potato Leaf Roll Virus and the genetic material necessary for its production.

DATES: This regulation is effective August 15, 1997. Objections and requests for hearings must be received by EPA on or before October 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300530], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300530], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300530]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail: Rm. 5th fl., CS#1 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8733, e-mail: hollis.linda@epamail.epa.gov

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34283–34286)(FRL–5723–2), EPA issued a notice pursuant to section 408(d), of the Federal Food Drug & Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Monsanto Corporation, St. Louis, MO. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production in or on all raw agricultural commodities.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via data waivers from the open scientific literature.

I. Risk Assessment and Statutory Findings

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)(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(c)(2)(B) 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***.'' 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 us in residential settings.

II. 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.

Additionally, section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, 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.'' All available information indicates that viral coat proteins in food have no human toxicity and EPA is not aware of any other substances within or outside of the food supply that might have a common mechanism of human toxicity with residues of viral coat proteins produced in plants as part of a plant-pesticide.

Data waivers were requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity data. The data waivers were accepted based on the long history of mammalian consumption of the entire plant virus particle in foods, without causing any deleterious human health effects [See OPP–300367A; FRL–5716–6]. Virus-infected plants currently are and have always been a part of both the human and domestic animal food supply and there have been no findings which indicate that plant viruses are toxic to humans and other vertebrates. Further, plant viruses are unable to replicate in mammals or other vertebrates, thereby eliminating the possibility of human infection. More importantly, however, this tolerance exemption will apply to that portion of the viral genome coding for the whole replicase protein and any subcomponent of the replicase protein expressed in the plant. This component alone is incapable of forming infectious particles.

The genetic material necessary for the production of the plant-pesticides active and inert ingredients are the nucleic acids (DNA) which comprise (1) genetic material encoding these viral coat proteins and their regulatory regions. Regulatory regions are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant-pesticide's inert ingredient have been adequately characterized by the applicant and supports EPA's conclusion that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the replicase protein of Potato Leaf Roll Virus and inert plant pesticidal ingredients.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA 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 groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*—a. *Food*. The use of viral coat protein mediated resistance will not result in any new dietary exposure to plant viruses. Entire infectious particles of Potato Leaf Roll Virus, including the replicase protein component, are found in the fruit, leaves and stems of most plants. Viruses are ubiquitous in the agricultural environment at levels higher than will be present in transgenic plants. Virus infected food plants have historically been a part of the human and domestic animal food supply with no observed adverse effects to human health and infants and children upon consumption. Therefore, the lack of toxicity associated with plant viruses and the history of contamination of the food supply by replicase proteins provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants expressing replicase proteins and leads the Agency to conclude that the use of Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production will not pose a dietary risk of concern under normal conditions. Moreover, there is no evidence which indicates that adverse effects due to aggregate exposure of replicase proteins (with substances outside the food supply) through dietary, non-food oral, dermal and inhalation occurs. This conclusion is suppported by the EPA's Scientific Advisory Panel's discussion regarding the Agency's Regulatory approach for plant pesticides which concluded:

i. The levels of virus in the agricultural environment are much higher than those levels present in transgenic plants.

ii. The existing contamination of the current food supply provides a scientific rationale for exempting from the requirement of a tolerance transgenic plants which express replicase proteins.

b. *Drinking water exposure.* Potential non-occupational exposures in drinking water is negligible. Replicase proteins produced in plants as part of a plant-pesticide are an integral part of the living tissue of the plant. As such, these components are subject to degradation and decay, a process which occurs fairly rapidly. Replicase proteins produced in plants as part of a plant-pesticide do not persist in the environment or bioaccumulate. The rapid turnover of these substances in the environment limits their ability to present anything other than a very negligible exposure in drinking water drawn from either surface or groundwater sources.

2. *Other non-occupational exposure.* Other non-occupational exposure of engineered coat proteins via residential and indoor uses, e.g., uses around homes, parks, recreation areas, athletic fields and golf courses, will be minimal to non-existent as the coat protein is expressed only within the plant tissues.

a. *Dermal exposure.* Due to the nature of replicase proteins produced in plants as part of a plant-pesticide, exposure through any route (i.e., dermal, respiratory) other than dietary is unlikely to occur. Physical contact with the plant or raw agricultural food from the plant may present some limited opportunity for dermal exposure. However, on a per person basis, the potential amounts involved in this exposure is negligible in comparison to exposure through the dietary route. Additionally, replicase proteins produced in plants as part of a plant-pesticide are unlikely to cross the barrier provided by the skin.

b. *Inhalation exposure*. The occurrence of respiratory exposure of replicase proteins produced in plants as part of a plant-pesticide is negligible in comparison to potential exposure through the dietary route. In some cases, replicase proteins may be present in pollen, thus affording exposure to those individuals in areas exposed to wind-blown pollen. However, it is unlikely

that exposure to the pollen is equivalent to exposure to replicase proteins produced in plants as part of a plant-pesticide. Replicase proteins, when present in pollen, will likely be integrated into the tissue of pollen grain and are unlikely to cross the barrier provided by the mucous membrane of the respiratory tract and thus are not additive to dietary exposure. Moreover, exposure through inhalation via wind-blown pollen occurs to the whole virus particle and there is no evidence which suggests that exposure to whole plant viruses by wind-blown pollen results in any adverse effects. Therefore, it is unlikely that exposure to pollen that may contain replicase proteins produced in plants as part of a plant-pesticide would result in adverse effects.

IV. Safety Factors

Rather than relying on available animal experimentation data to support a tolerance exemption for viral coat proteins, EPA relied on the long history of safe human consumption of food containing plant viruses as the appropriate information base for this tolerance exemption. Because the EPA did not rely on animal data, determination of appropriate safety factors to be used in a human risk assessment was not considered.

V. Infants and Children

Consistent with section 408(b)(2)(C) of the FFDCA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. Based on all available information, the Agency concludes that replicase proteins produced in plants as part of a plant-pesticide are ubiquitous in foods, including those foods consumed by infants and children. Moreover, there is no reason to believe that plant replicase proteins are likely to occur in different amounts in foods, consumed by children and infants. Children are exposed as part of a normal diet to replicase proteins and there is no evidence which indicates that replicase proteins would have a diferent effect on children than on adults. Further, there is no evidence which suggests that such exposure to either adults or infants and children leads to any harm.

VI. Other Considerations

1. *Endocrine disrupters.* The Agency has no informtion to suggest that Replicase Proteins of Potato Leaf Roll Virus and the genetic material necessary for its production will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biological pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

2. *Analytical method.* The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the agency has concluded that an analytical method is not required for enforcement purposes for Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production.

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

For the U.S. population, including infants and children, Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production has no known adverse effects. Extensive use and experience show the safety of foods containing viral coat proteins. There has been no evidence in the many years of human experience with the growing and consumption of food from plants containing viral coat proteins which indicates that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes occur. Therefore, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population from aggregate exposure to residues of replicase proteins produced in plants as part of a plant-pesticide including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for replicase protein of Potato Leaf Roll Virus and the genetic material necessary for its production. Thus, a tolerance for this Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

VIII. Objections and Hearing Requests

The new FFDCA 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 section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 14, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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). 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). 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.

IX. Public Docket

A record has been established for this rulemaking under docket control number [OPP–300530]. A public version of this record, 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 public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

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.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitiled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In additions, since tolerance exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business.

XI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This 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: August 7, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1183 is added to subpart D to read as follows:

§ 180.1183 Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production; Exemption from the requirement of a tolerance.

An exemption fron the requirement of a tolerance is established for residues of the biological plant pesticide Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for its production in or on all food commodities.

[FR Doc. 97–21691 Filed 8–14–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300531; FLR–5738–4]

RIN 2070–AB78

Coat Protein of Potato Virus Y and the Genetic Material Necessary for its Production; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide Coat Proteins of Potato Virus Y and the genetic material necessary for its production in or on all raw agricultural commodities. Monsanto Company submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Coat Proteins of Potato Virus Y and the genetic material necessary for its production.

DATES: This regulation is effective August 15, 1997. Objections and requests for hearings must be received by EPA on or before October 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300531], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300531], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of