

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0313; FRL-8134-5]

Tobacco Mild Green Mosaic Tobamovirus (TMGMV); Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the tobacco mild green mosaic tobamovirus (TMGMV) on grass and grass hay when applied/used as a bioherbicide against the weed tropical soda apple. Interregional Research Project Number 4 (IR4), on behalf of BioProdex, Inc. 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 the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of TMGMV. The temporary tolerance exemption expires on June 30, 2009.

DATES: This regulation is effective June 27, 2007. Objections and requests for hearings must be received on or before August 27, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0313. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only

available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Rebecca Edelstein, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0513; e-mail address: edelstein.rebecca@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly

to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0313 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 August 27, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0313, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2006 (71 FR 38643) (FRL-8069-7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6E7029) by BioProdex, Inc., Gainesville Technology Enterprise Center (GTEC), Box 5, Suite 205, 2153 SE Hawthorne

Road, Gainesville, FL 32641. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of TMGMV. The docket for this action includes a summary of the petition prepared by the petitioner IR-4 on behalf of BioProdex, Inc. There were no comments received in response to the notice of filing.

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

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

III. Toxicological Profile

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

identifiable subgroups of consumers, including infants and children.

TMGMV is a tobamovirus, a type of plant virus, and tobamoviruses have no known toxicity or pathogenicity to any organisms other than plants. They are unable to infect animals because they lack cell surface binding site receptors common to animal viruses. Tobamoviruses enter plant cells only through open wounds (e.g., those produced by feeding insects or by mechanical methods) or by cell-to-cell transfer (Fraenkel-Conrat, *et. al.*, 1988). Almost all living things are routinely exposed to plant viruses, including tobamoviruses, through plants and plant products (e.g., foods). TMGMV is known to infect about 20 plants, including peppers (Plant Viruses Online, 2005; Wetter, C., 2005); therefore, humans are likely already exposed to TMGMV through food. Throughout the available literature, there are no reports of adverse effects in animals resulting from ingestion or exposure to TMGMV. TMGMV has not been reported to multiply in insects nor in any other known animal. One reference provided by the registrant may show replication of TMV (another tobamovirus) in cultured, immune-suppressed, monkey kidney cell lines (Atherton, J.G., 1968). However, this was an artificial system and does not indicate that plant viruses can normally replicate in animal cells. The specific mode of action of TMGMV is such that only some species within the plant family *Solanaceae* are susceptible to this virus. Laboratory animals such as rabbits, mice, chickens, and guinea pigs are routinely used for producing antibodies against tobamoviruses without causing adverse effects to the animals. In addition, there are no reports of humans that handle and administer the viruses or of these laboratory animals developing any nasal, eye, skin, or pulmonary allergies, or any other adverse reactions to the viruses.

In support of this tolerance exemption, mammalian toxicology requirements were satisfied by publicly available information submitted by BioProdex, summarized in the paragraph above. Specifically, the information provided supports the lack of toxicity to mammals and humans of tobamoviruses, the fact that only certain plants (and no animals) are susceptible to TMGMV, and that TMGMV poses little to no risk to humans.

1. *Acute oral toxicity/pathogenicity (OPPTS 885.3050)*. To satisfy this requirement, the registrant submitted supporting public literature rather than a study, which shows that plant viruses, including TMGMV, are found in food

ingested daily by humans and animals, and according to the published literature, no known adverse effects or deaths have occurred in any species as a result of such dietary exposures.

2. *Acute dermal toxicity/pathology (OPPTS 885.3100)*. The registrant submitted supporting public literature rather than a study to fulfill this requirement, showing that plant viruses, including TMGMV, are ubiquitous in plants, and they are not known to cause acute dermal toxicity or pathogenicity to mammals.

3. *Acute eye irritation (OPPTS 870.2400)*. The registrant submitted supporting public literature rather than a study to fulfill this requirement, showing that plant viruses, including TMGMV, are ubiquitous in plants, and they are not known to cause acute eye irritation or pathogenicity to mammals.

4. *Acute pulmonary toxicity/pathogenicity (OPPTS 885.3150)*. To fulfill this requirement, the registrant submitted supporting public literature rather than a study, which shows that plant viruses, including TMGMV, are ubiquitous in plants, and they are not known to cause acute pulmonary toxicity or pathogenicity to mammals.

5. *Acute injection toxicity/pathogenicity (OPPTS 885.3200)*. To fulfill this requirement, the registrant submitted supporting public literature rather than a study, showing the following:

i. TMGMV, like all tobamoviruses, can evoke immune responses and produce antibodies if properly injected into laboratory animals such as rabbits, mice, chickens, and guinea pigs without causing adverse effects to the animals; and

ii. There are no reports of humans that handle and administer tobamoviruses or laboratory animals developing adverse reactions to the virus.

6. *Hypersensitivity incidents (OPPTS 885.3400)*. Workers handling TMGMV on a daily basis since 1999 have not had a single incidence of hypersensitivity. In addition, some workers have been handling tobamoviruses for nearly 40 years without encountering hypersensitivity to any of these viruses. There are no reports of hypersensitivity in humans or other animals to tobamoviruses in the literature.

7. *Cell culture (OPPTS 885.3500)*. To satisfy this requirement, the registrant submitted the following information, supported by public literature. Tobamoviruses are unable to infect animal cells since the cell surface plays an important role in infection of animal cells; during infection, animal viruses interact specifically with receptors on the animal cell surface. Tobamoviruses,

on the other hand, lack recognition for these receptors and only enter plant cells through open wounds or via cell-to-cell transfer through intercellular connections (Fraenkel-Conrat, *et al.*, 1988). There is one report in the literature of growing *Tobacco mosaic tobamovirus* (TMV; a different tobamovirus from the one that is the subject of this tolerance exemption) in cultured, immune-suppressed, monkey kidney cell lines (Atherton, J.G., 1968). However, this was an artificial system and does not indicate that tobamoviruses can normally replicate in or infect animal cells.

Based on the published literature, in accordance with Tier I toxicology data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III toxicology data requirements were not triggered in connection with this action.

IV. Aggregate Exposures

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

A. Dietary Exposure

1. *Food.* Virus-infected food plants have always been a part of the human and domestic animal food supply (Dewan and Pearson, 1995; McKinney, 1929; Provvidenti and Gonsalves, 1984; Palukaitis, 1991; Jones *et al.*, 1934; Beemster and de Bokx, 1987). Most plants may be infected by at least one virus, and components of plant viruses are often found in the produce of crop plants. Even plants that show no disease symptoms are often found to be infected with viruses (Jones *et al.*, 1934; Fulton, 1986). In addition, a common agricultural practice used since the 1920s for protection against viral disease involves intentionally inoculating healthy plants with a mild form of a virus in order to prevent infection by a more virulent form (Fulton, 1986). A great deal of information supports the ubiquitous appearance of plant viruses in foods, and to date there have been no reports of adverse human or animal health effects associated with consumption of plant viruses in food. Furthermore, the proposed experimental use permit (EUP) is not expected to result in increased exposures of TMGMV to the general population: The intended use of TMGMV is in rangelands, grass

pastures, sod-production fields, Conservation Reserve areas, and other natural areas in Florida, and the only residues anticipated on food with this EUP are on grass and grass hay. In addition, these residues on grass or grass hay would only be incidental to application to the target organism since grass is not a host for TMGMV; therefore, TMGMV cannot infect grass or replicate in grass. Accordingly, the Agency concludes that when TMGMV is used as intended, there is reasonable certainty that no harm will result to humans from all anticipated exposures through food to any residues resulting from such use.

2. *Drinking water exposure.* TMGMV is not intended for use in drinking water. However, in the event that TMGMV would reach water consumed by humans, for the reasons enumerated above, the Agency concludes that when TMGMV is used as intended, there is reasonable certainty that no harm will result to humans from all anticipated exposures through water to any residues resulting from such use.

B. Other Non-Occupational Exposure

EPA concludes that dermal or inhalation exposure to the general population as a result of this EUP is not likely to occur, based on the proposed uses and limited acreage. Moreover, the general population, including infants and children, are exposed to plant viruses daily in food with no known adverse effects ever being reported. Therefore, the Agency concludes that in the unlikely event that there is non-occupational, non-dietary exposure to TMGMV, such exposure would pose no risks to the general population, including infants and children.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that EPA consider available information on the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity when establishing, modifying, or revoking a tolerance. These considerations include the possible cumulative effects on infants and children of such residues and other substances with a common mode of toxicity. Because there is no indication of mammalian toxicity or pathogenicity from TMGMV, we conclude that there are no cumulative effects for this virus and any other substance.

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

1. *U.S. population.* For all of the reasons discussed above, there is

reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of TMGMV. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

2. *Infants and children.* Section 408(b)(2)(C) of the FFDCA provides that EPA shall apply an additional tenfold margin of exposure (MOE) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure, unless EPA determines that a different MOE will be safe for infants and children. MOEs, which are often referred to as uncertainty (safety) factors, are incorporated into EPA risk assessments either directly, or through the use of a MOE analysis or by using uncertainty factors in calculating a dose level that poses no appreciable risk. As previously mentioned in the toxicological profile, humans, including infants and children, have been exposed to plant viruses through food, where they are commonly found, with no known or reported adverse effects. As discussed above, the Agency has concluded that TMGMV is non-toxic to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when TMGMV is used as labeled, the Agency concludes that the additional MOE is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors

At this time, the Agency is not requiring information on the endocrine effects of this active ingredient, TMGMV. The Agency has considered, among other relevant factors, available information concerning whether the virus may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. Plant viruses cannot infect mammals, and there is no known metabolite that acts as an "endocrine disruptor" produced by this virus. Therefore, there is no impact via endocrine-related effects on the Agency's safety findings in this final rule.

B. Analytical Method

Through this action, the Agency is proposing to establish a temporary exemption from the requirement of a tolerance for residues of TMGMV on grass and grass hay for the purposes of an EUP. The Agency reached this decision based on the reasons discussed

above, including lack of toxicity to mammals, and therefore concludes that an analytical method for detecting TMGMV is not required for enforcement purposes.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the virus TMGMV.

D. References

1. Atherton, J.G. 1968. Formation of tobacco mosaic virus in an animal cell culture. *Archiv für die gesamte Virusforschung* 24:406–418.
2. Beemster ABR, de Bokx JA. Survey of properties and symptoms. In: de Bokx JA, van der Want JPH. Viruses of Potatoes and Seed Potato Production. Wageningen: Pudoc, 1987:84–93.
3. Dewan C, Pearson MN. Natural field infection of garlic by garlic yellow streak virus in the Pukekohe area of New Zealand and associated problems with the introduction of new garlic cultivars. *New Zealand Journal of Crop and Horticultural Science* 1995; 23:97–102.
4. Fraenkel-Conrat, H., Kimball, P.C., and Levy, J.A. 1988. Virology, 2nd edition. Prentice Hall, Englewood Cliffs, NJ (Virus cellular receptors and cell membrane changes, p. 299–300).
5. Fulton R. Practices and precautions in the use of cross protection for plant virus disease control. *Annual Review of Phytopathology* 1986; 24:67–81.
6. Jones L, Anderson E, Burnett G. The latent virus of potatoes. *Journal of Phytopathology* 1934; 7:93–115.
7. McKinney HH. Mosaic diseases in the Canary Islands, West Africa, and Gibraltar. *Journal of Agricultural Research* 1929; 39:557–78.
8. Palukaitis P. Virus-mediated genetic transfer in plants. In: Levin M, Strauss H. Risk Assessment in Genetic Engineering. New York: McGraw-Hill, 1991:140–62.
9. Provvidenti R, Gonsalves D. Occurrence of zucchini yellow mosaic virus in cucurbits from Connecticut, New York, Florida, and California. *Plant Disease* 1984; 68:443–6.
10. Palukaitis P. Virus-mediated genetic transfer in plants. In: Levin M, Strauss H. Risk Assessment in Genetic Engineering. New York: McGraw-Hill, 1991:140–62.
11. Plant Viruses Online, 2005. <http://image.fs.uidaho.edu/vide/descr801.htm>.
12. Wetter, C., 2005. Tobacco mild green mosaic virus. In: AAB Description of Plant Viruses No. 35. <http://www.dpvweb.net/dpv/showdpv.php?dpvno=351>.

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 15, 2007.

Debra Edwards,

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), 346a and 371.

■ 2. Section 180.1276 is added to subpart D to read as follows:

§ 180.1276 Tobacco mild green mosaic tobamovirus (TMGMV); temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of tobacco mild green mosaic tobamovirus in or on all grass and grass hay.

[FR Doc. E7–12338 Filed 6–26–07; 8:45 am]

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