Governor Tommy G. Thompson of Wisconsin submitted two letters dated April 6, 1994 and August 2, 1994 requesting to opt-in the reformulated gasoline program. The DFRM published by EPA on January 11, 1995 (60 FR 2693) extended the reformulated gasoline program to three moderate ozone nonattainment areas in Wisconsin: Sheboygan, Manitowoc, and Kewaunee counties to be effective May 1, 1995 at the terminal and June 1, 1995 at the retail level. The Agency published a Direct Final Rule because it viewed the addition of the three ozone nonattainment areas in Wisconsin to the RFG program and the May 1/June 1 effective dates as non-controversial given the level of coordination between EPA, Wisconsin, and industry on the opt-in request and thus, anticipated no adverse or critical comments.

II. Withdrawal of the Wisconsin Opt-in DFRM

After publication of the DFRM in the **Federal Register**, Governor Tommy G. Thompson of Wisconsin submitted a letter dated March 31, 1995 requesting the termination of the federal reformulated gasoline program slated for extension to Wisconsin's three moderate ozone nonattainment counties of Sheboygan, Manitowoc, and Kewaunee.

After publication of the DFRM in the **Federal Register**, the Agency also received adverse comments expressing concern about the economic impact of the reformulated gasoline program on Kewaunee County citizens and small businesses, as well as border/supply issues. A copy of these comments can be found in Public Docket A–94–46.

Since receiving the Governor's letter and adverse comments which were submitted to EPA, as was stipulated in the DFRM, the final rule adding the three Wisconsin nonattainment areas to the RFG program is being withdrawn by today's action and is effective immediately. Today's withdrawal affects the amendment of § 80.70, paragraphs (l) and (l)(1) appearing at 60 FR 2693 (January 11, 1995), which were to become effective March 13, 1995.

EPA is withdrawing this provision to the reformulated and conventional gasoline regulations without providing prior notice and an opportunity to comment because it finds there is good cause within the meaning of 5 U.S.C. 553(b) to do so. For the same reasons, EPA finds it has good cause under 5 U.S.C. 533(d) to make this withdrawal immediately effective.

III. Statutory Authority

The statutory authority for the action finalized today is granted to EPA by Sections 114, 211(c) and (k) and 301 of the Clean Air Act, as amended; 42 U.S.C. 7414, 7545(c) and (k), and 7601.

IV. Administrative Requirements

A. Administrative Designation

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or,

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this withdrawal is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires Federal agencies to identify potentially adverse impacts of federal regulations upon small entities. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(B) et seq., the Administrator certifies that this regulation will not have a significant impact on a substantial number of small entities.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and implementing regulations, 5 CFR Part 1320, do not apply to this action as it does not involve the collection of information as defined therein.

D. Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate; or by the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the action promulgated today does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local or tribal governments in the aggregate, or to the private sector. This action has the net effect of reducing burden of the reformulated gasoline program on regulated entities. Therefore, the requirements of the Unfunded Mandates Act do not apply to this action.

List of Subjects in 40 CFR Part 80

Environmental protection, Air pollution control, Fuel additives, Gasoline, Motor vehicle pollution.

Dated: April 25, 1995.

Carol M. Browner,

Administrator.

40 CFR part 80 is amended as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

1. The authority citation for part 80 continues to read as follows:

Authority: Sections 114, 211 and 301(a) of the Clean Air Act as amended, (42 U.S.C. 7414, 7545 and 7601(a)).

§ 80.70 [Amended]

2. In § 80.70 paragraph (l) is removed.

[FR Doc. 95–10882 Filed 5–2–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[PP 3F4273/R2132; FRL–4953–2]

RIN 2070–AB78

Plant Pesticide Bacillus Thuringiensis CryIIIA Delta-Endotoxin and the Genetic Material Necessary for Its Production; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is establishing an exemption from the requirement of a tolerance for residues of the plant pesticide active ingredient *Bacillus thuringiensis* CryIIIA delta-endotoxin and the genetic material necessary for

its production in potatoes. The Monsanto Co. requested this exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this plant pesticide in potatoes.

EFFECTIVE DATE: Effective on May 3, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4273/R2132], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections 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 objections and requests for hearings filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and requests for hearings must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and requests for hearings will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and requests for hearings in electronic form must be identified by the docket number [PP 3F4273/R2132]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and requests for hearings on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Willie H. Nelson, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 51B6, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8128; e-mail: nelson.willie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of December 8, 1993 (58 FR 64583), which announced that the Monsanto Co., 700 Chesterfield Village Parkway, St. Louis, MO 63198, had submitted a pesticide petition, PP 3F4273, to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for the plant pesticide *Bacillus thuringiensis* subsp. *tenebrionis* (B.t.t) Colorado potato beetle (CPB) control protein (CryIIIA).

EPA has assigned the active ingredient of this product the name *Bacillus thuringiensis* CryIIIA delta-endotoxin and the genetic material necessary for its production. ''Genetic material necessary for production'' means the CryIIIA gene and its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the gene, such as promoters, terminators, and enhancers.

Monsanto has genetically modified potato plants to produce the pesticidal protein derived from the common soil bacterium *Bacillus thuringiensis* subsp. *tenebrionis*. The protein produced by CPB-resistant potatoes is identical to that found in nature. Monsanto has genetically engineered potatoes by using plant-expressed vectors that transferred the CryIIIA and neomycin phosphotransferase II (nptII) marker gene into the genomic DNA of the potato plants. In the **Federal Register** of September 28, 1994 (59 FR 49353), EPA exempted nptII and the genetic material necessary for its production in or on all raw agricultural commodities when used as an inert. There were no adverse comments or requests for referral to an advisory committee received in response to the notice of filing of the petition, PP 3F4273 (58 FR 64582, Dec. 8, 1993).

Residue Chemistry Data

Residue chemistry data were not required because of the lack of toxicity to this active ingredient. This is similar to the Agency position regarding the submission of residue data for the microbial *Bacillus thuringiensis* products from which this plant pesticide was derived. (See 40 CFR 158.740(b).) For microbial products, residue data are required only when Tier II or III toxicology data are required. The kinds of studies submitted for this plant pesticide are like those in Tier I, not Tiers II or III. Submitted data indicated that the product is of low mammalian toxicity/pathogenicity and the kinds of studies required in Tier II or III were not appropriate. Therefore, no residue data are required in order to grant an exemption from the requirement of a tolerance for Monsanto's plant pesticide, *Bacillus thuringiensis* Cry IIIA delta-endotoxin protein, the CryIIIA gene and the genetic material necessary for its production in potato.

Product Analysis

Monsanto submitted information which adequately described the CryIIIA delta-endotoxin from B.t.t., as expressed in potato, along with the genetic material necessary for its production. Because it would be difficult, or impossible, to extract sufficient biologically active toxin from the plants to perform toxicology tests, Monsanto used delta-endotoxin produced in bacteria. Product analysis data were submitted to show that the microbially expressed and purified CryIIIA delta-endotoxin is sufficiently similar to that expressed in the plant to be used for mammalian toxicological purposes.

1. *Molecular characterization of CPB-resistant Russet Burbank Potatoes equivalence of microbially produced B.t.t. protein*. The relative size and number of copies of the DNA inserted into potatoes was demonstrated with endonuclease digested chromosomal DNA from field-grown potato plants southern blotted with the entire introduced plasmid PV-STBT02 as the probe. These southern blots provided information about the number of copies of introduced DNA, the lack of significant amount of DNA introduced outside the border regions, and integrity of the introduced DNA near the endonuclease cut site. These results indicate only that the DNA necessary to produce the CryIIIA delta endotoxin were introduced into the plant, thus indicating that exposure would only be to the CryIIIA delta-endotoxin and the nucleic acids found in the genetic material necessary for its production. Such nucleic acids have not, by themselves, been associated with toxic effects to animals or humans and are regular constituents of the human diet.

2. *Equivalence of microbially produced and plant-produced B.t.t. protein also called Colorado potato beetle active protein from Bacillus thuringiensis subsp. tenebrionis.* Microbially produced delta endotoxin from the CryIIIA gene as expressed in *Escherichia coli* and in potato tubers were compared. The data consists of SDS-PAGE comigration, Western blot analysis, staining for carbohydrate residues, *N*-terminal amino acid sequence analysis, and biological

equivalence against *Leptinotarsa decemlineata*. These data are adequate to support the equivalence of the microbially produced and plant-produced protein for use in the toxicology studies.

3. *Characterization of the major tryptic fragment from Colorado potato beetle active bacillus thuringiensis subsp. tenebrionis*. The purity and activity of a 55kD protein released with tryptic digestion of the B.t.t. delta endotoxin purified from *E. coli* was shown to have a similar size, immunoreactivity, and amino acid sequence to the 55kD fragment found in potato tubers. The 55kD protein had somewhat higher bioactivity than the 68kD full-length delta endotoxin from B.t.t. These data support the contention that both the 55kD and 68kD forms of the CryIIIA delta-endotoxin found in the plant were similar to those occurring in B.t.t.

4. *Characterization of Colorado potato beetle active bacillus thuringiensis subsp. tenebrionis protein produced in escherichia coli*. The method of preparing by fermentation the delta endotoxin from B.t.t. in *E. coli* was presented. The protein was characterized for purity and stability after purification. These data indicate that normal fermentation techniques were used to produce the plant equivalent, microbial CryIIIA delta-endotoxin.

5. *Compositional comparison of Colorado potato beetle (CPB) active bacillus thuringiensis subsp. tenebrionis proteins produced in CPB-resistant potato plants and commercial microbial products*. The CryIIIA delta-endotoxin as expressed in potato tissue or an *E. coli* alternative gives a similar immunoreactivity and electrophoretic mobility to registered microbial products producing the same delta-endotoxin.

Toxicology Assessment

Toxicity

The delta-endotoxin proteins of *B. thuringinesis* have been intensively studied, and no indications of mammalian toxicity have been reported. Furthermore, approximately 176 different *B. thuringiensis* products have been registered since 1961, and the Agency has not received any reports of dietary toxicity attributable to their use. This is especially significant because FIFRA section 6(a)(2) requires registrants to report any adverse effects to EPA. Therefore, EPA does not expect any mammalian toxicity from this protein in plants based on the use history of *B. thuringiensis* products.

The data submitted by Monsanto support the prediction that this protein would be nontoxic to humans. Adequate information was submitted to show that the test material derived from microbial cultures was essentially identical to the protein as produced by the potatoes. Production of a plant equivalent, microbial CryIIIA delta-endotoxin, was chosen to obtain sufficient material for mammalian testing. In addition, the *in vitro* digestibility studies indicate the protein would rapidly be degraded following ingestion.

The genetic material necessary for the production of the *Bacillus thuringiensis* CryIII(A) delta endotoxin are the nucleic acids (DNA and RNA) which comprise the CryIII(A) gene and its controlling sequences. DNA and RNA are common to all forms of life, including plants, and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to the consumption of food. These ubiquitous nucleic acids as they appear in the subject active ingredient have been adequately characterized by the applicant. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the *Bacillus thuringiensis* CryIII(A) delta endotoxin in potatoes.

Allergenicity

Despite decades of widespread use of *Bacillus thuringiensis* as a pesticide (it has been registered since 1961), there have been no confirmed reports of immediate or delayed allergic reactions from exposure. Such incidents, should they occur, are required to be reported under FIFRA section 6(a)(2) and as a data requirement for registration of microbial pesticides (40 CFR 158.740 and Subdivision M of the FIFRA testing guidelines, NTIS # PB89-211676).

Studies done in laboratory animals or as reported in the literature also have not indicated any potential for allergic reactions to *B. thuringiensis* or its components, including the delta-endotoxin in the crystal protein. Recent *in vitro* studies also confirm that the delta endotoxin would be readily digestible *in vivo*.

Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, are glycosylated, and are present at high concentrations in the food. The delta endotoxins are not present at high concentrations, are not resistant to degradation by heat, acid and proteases, and are apparently not glycosylated when produced in plants. The company has submitted data to indicate that the CryIIIA delta endotoxin is rapidly degraded by gastric fluid *in vitro*, is not present as a major component of food, and is apparently nonglycosylated when produced in plants.

Submitted Data

1. *Acute oral toxicity of B.t.t. protein*. The B.t.t. proteins were determined to be stable and the dosing concentrations were determined to be 74.9 mg/mL, 14.62 mg/mL, and 7.4 mg/mL. B.t.t. protein was not toxic by oral gavage when mice were dosed with up to 5220 mg/kg body weight. These results placed this protein in Tox Category IV.

2. *In-vitro digestibility of B.t.t. protein*. The 68 kD and 55kD B.t.t. proteins degraded within 30 seconds in simulated gastric fluid when analyzed by western blot and were not active against Colorado potato beetles after degradation. The 68kD B.t.t. protein degraded to 55kD within 2 hours of incubation in simulated intestinal fluid. The 55 kD form remained unchanged after 14 hours of incubation and retained its bioactivity and western blot results. These results indicate that, following ingestion by humans, the B.t.t. proteins will be degraded like other proteins to amino acids and peptides similar to those occurring in a normal human diet.

Scientific Advisory Panel Subpanel on Plant Pesticides

A Subpanel of the FIFRA Scientific Advisory Panel (SAP) met on March 1, 1995, to discuss the Agency's Preliminary Scientific Review for this use and concluded that ''The Monsanto B. t. potato presents little potential for human dietary toxicity. At a dose of one million-fold greater than that contained in a potato (a 150-gram potato contains about 300 micorgrams B.t. protein, 70 kg person = 4.5 micrograms/kg), no toxicity was observed. Moreover, several studies of B.t. potatoes are indistinguishable from strains of wild-type potatoes in nutritive content (total protein, total sugars, vitamin C, minerals, etc.). Furthermore, the B.t. toxin is rapidly digested by pepsin and is inactivated by heat encountered in cooking.''

Conclusions

In summary, based upon the submitted studies and other available information, the Agency does not foresee any human health hazards from the use of the *Bacillus thuringiensis* CryIII(A) delta-endotoxin and the genetic material necessary for its production.

Based upon submitted data and a review of its use, EPA has found that when used in accordance with good

agricultural practice, this ingredient is useful for the purpose for which the tolerance exemption is sought. Based on the information considered, EPA concludes that a tolerance is not necessary to protect the public health. Therefore, the exemption from the requirement of a tolerance is established as set forth below.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition because the data and information submitted demonstrate that this active ingredient is not toxic to mammalian species. No enforcement actions are expected, based upon the toxicity for this plant pesticide. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/ or a request for a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and 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, and must conform to the other requirements of 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 issue(s) on which a hearing is requested, the requestor's contentions on each such issue, 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 3F4273/R2132] (including copies of any objections and requests for hearings 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

An electronic copy of objections and requests for hearings can be sent directly to EPA at:

opp-Docket@epamail.epa.gov.

A copy of electronic objections and requests for hearings 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 will be kept in paper form. Accordingly, EPA will transfer any copy of objections and requests for hearings received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include any objections and requests for hearings submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant'' regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or (3) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemption from tolerance requirements do not have a significant economic effect on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4,1981 (49 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: April 25, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

2. In subpart D, by adding new § 180.1147, to read as follows:

§ 180.1147 Bacillus thuringiensis CryIIIA delta-endotoxin and the genetic material necessary for its production.

Bacillus thuringiensis CryIIIA delta-endotoxin and the genetic material necessary for its production are exempted from the requirement of a tolerance when used as a plant pesticide in potatoes. ''Genetic material necessary for its production'' means the CryIIIA gene and its regulatory regions. 'Regulatory regions'' are the genetic materials that control the expression of the gene, such as promoters, terminators, and enhancers.

[FR Doc. 95–10864 Filed 4–28–95; 12:21 pm]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 4F4317/R2125; FRL–4949–4]

RIN No. 2070–AB78

Myclobutanil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for the combined residues of the fungicide myclobutanil and a metabolite in or on the raw agricultural