Federal Register, file written objections to the 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 above (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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, a summary of any evidence relied upon by the objector as well as the other materials required by 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 genuine and substantial issue of fact; there is 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).

EPA has established a record for this rulemaking under docket number [PP 5E4517/R2271] (including any comments and data submitted electronically). 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 Room 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.

Electronic comments may 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 will be kept in paper form. Accordingly, 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 which will also include all comments 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, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A statement containing the factual basis for this certification was published in the Federal Register of May 4, 1981 (46 FR 24950).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), 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 the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: July 30, 1996.

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 § 180.1175, to read as

§ 180.1175 Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production (plasmid vector pZ01502) in corn; exemption from the requirement of a tolerance.

Phosphinothricin acetyltransferase (PAT) and the genetic material necessary for its production (plasmid vector pZ01502) in corn is exempt from the requirement of a tolerance when used as a plant pesticide inert ingredient in all raw agricultural commodities of field corn, sweet corn, and popcorn. ''Genetic material necessary for its production'' means the genetic material which comprise genetic material encoding the phosphinothricin acetyltransferase and its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the phosphinothricin acetyltransferase, such as promoters, terminators, and enhancers.

[FR Doc. 96–19812 Filed 8–01–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 5E4516/R2269; FRL–5391–2]

RIN 2070–AB78

Plant Pesticide Inert Ingredient CP4 Enolpyruvylshikimate-3-D and the Genetic Material Necessary for Its Production in All Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient CP4 Enolpyruvylshikimate-3-D (CP4 EPSPS) and the genetic material necessary for its production in all plants. A request for an exemption from the requirement of a tolerance was submitted by Monsanto Company (Monsanto). This

regulation eliminates the need to establish a maximum permissible level for residues of these plant pesticide inert ingredients in all plants.

EFFECTIVE DATE: Effective on August 2, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 5E4516/R2269], 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 Resources 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: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP 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 [PP 5E4516/R2269] . 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. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Michael L. Mendelsohn, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, Telephone No. 703–308–8715; e-mail: mendelsohn.michael@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of October 25, 1995 (60 FR 54689)(FRL–4984–4), which announced that Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198, had submitted a pesticide petition (PP) 5E4516 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 inert ingredient CP4 EPSPS and the genetic material necessary for the production of this protein in or on all raw agricultural commodities when used as a plant pesticide inert ingredient. EPA has assigned these inert ingredients the name CP4 EPSPS and the genetic material necessary for its production in plants. ''Genetic material necessary for its production'' means the genetic material which comprise (1) genetic material encoding the CP4 EPSPS and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CP4 EPSPS, such as promoters, terminators, and enhancers.

There were no adverse comments, or requests for referral to an advisory committee received in response to the notice of filing of the pesticide petition 5E4516.

Toxicology Assessment

Product Characterization

CP4 EPSPS protein produced in *E. coli* gave SDS-PAGE, western blot, N-terminal amino acid sequence and enzyme activity similar to the reference standard. The *E. coli* preparation lacked detectable glycosylation based on the staining reaction compared to transferritin and horseradish peroxidase positive controls.

CP4 EPSPS protein as expressed in either *E. coli* or corn line 523–06–1 were compared by SDS-PAGE, western blot, N-terminal amino acid sequence and specific enzyme activity against shikimate-3-phosphate and shown to have essentially equivalent characteristics save the specific activity which was lower in the plant preparation. The similarity of the CP4 EPSPS expressed in corn line 523–06–1 and MON80100 were shown to yield identical banding patterns indicating similar molecular weight and immunoreactivity.

Western blot and enzymatic activity assays indicate that CP4 EPSPS is readily degraded in less than 2 minutes by incubation in simulated gastric fluid. In simulated intestinal fluid the enzyme activity and immunoreactivity lasts longer being still detectable at 10 minutes and undetectable by 270 minutes.

CP4 EPSPS is an enzyme involved in aromatic amino acid synthesis. CP4 EPSPS is not closely related in amino acid homology to other described EPSPS enzymes. CP4 EPSPS is no more than 51.1% similar and 26.0% identical to EPSPS in plants and 59.3% similar and 41.1% identical to EPSPS in other bacteria. The unique character of CP4 EPSPS is its ability to function in the presence of glyphosate which is a competitive inhibitor with PEP for the active site of other EPSPS enzymes.

Toxicology

In an acute oral toxicity test of bacterially-derived CP4 EPSPS protein, no test substance related deaths occurred at a dose of 572 mg/kg.

The Agency expects that proteins with no significant amino acid homology to known mammalian protein toxins and which are readily inactivated by heat or mild acidic conditions and are readily degraded in an *in vitro* digestibility assay would have little likelihood for displaying oral toxicity.

The data submitted and cited by Monsanto support the prediction that the CP4 EPSPS protein would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels [Sjobald, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3-9 (1992)]. Therefore, since no significant acute effects were observed, even at relatively high dose levels, the CP4 EPSPS is not considered acutely or chronically toxic. Adequate information was submitted to show that the test material derived from microbial cultures was biochemically similar to the CP4 EPSPS as produced by the plant-pesticide in corn. Production of microbially produced protein was chosen in order to obtain sufficient material for testing.

The genetic material necessary for the production of the CP4 EPSPS are the nucleic acids (DNA) which comprise (1) genetic material encoding the CP4 EPSPS and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding CP4 EPSPS, 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. 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 CP4 EPSPS in any plant.

Conclusion

Based on the information considered, the Agency concludes that establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the 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 above (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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, a summary of any evidence relied upon by the objector as well as the other materials required by 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 genuine and substantial issue of fact; there is 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 the docket number [PP 5E4516/R2269] (including any comments and data submitted electronically). 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 Room 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 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 will be kept in paper form. Accordingly, 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 rule-making record which will also include all comments 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, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C . 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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 exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A statement contianing the factual basis for this certification was published in the Federal Register of May 4, 1981 (46 FR 24950).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), 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 the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: July 30, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

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. In subpart D, by adding new § 180.1174, to read as follows:

§ 180.1174 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) and the genetic material necessary for its production in all plants.

CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant pesticide inert ingredients in all raw agricultural commodities. ''Genetic material necessary for its production'' means the genetic material which comprise genetic material encoding the CP4 EPSPS and its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CP4 EPSPS, such as promoters, terminators, and enhancers.

[FR Doc. 96–19813 Filed 8–1–96; 8:45 am]
BILLING CODE 6560–50–F

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40 CFR Part 180

[PP 5F4473/R2270; FRL–5391–3]

RIN 2070–AB78

Bacillus Thuringiensis CryIA(b) Delta-Endotoxin and the Genetic Material Necessary for Its Production in All Plants; Exemption from Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).