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).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the plant pesticide active ingredients Bacillus thuringiensis CryIA(b) delta-endotoxin 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. This regulation eliminates the need to establish a maximum permissible level for residues of these plant pesticides in all plant raw agricultural commodities.

EFFECTIVE DATE: Effective on August 2, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number [PP 5F4473/R2270] 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 docket 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 Highway, 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.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 5F4473/R2270]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed 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: Monsanto has genetically modified corn plants to produce a truncated version of the pesticidal CryIA(b) delta-endotoxin protein (derived from the soil microbe *Bacillus thuringiensis*). EPA issued a notice, published in the Federal Register of October 25, 1995 (60 FR 54689)(FRL–4982–4), which announced that the Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198 had submitted a pesticide petition (PP) 5F4473 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 *Bacillus thuringiensis* subsp. kurstaki Insect Control Protein (CryIA(b)) as produced in plant cells. EPA has described the active ingredients covered by this description as *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in all plants. ''Genetic material necessary for its production'' means the genetic material which comprise (1) genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, 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 5F4473.

Product Analysis

Data was presented which showed that the truncated CryIA(b) toxin can be extracted from corn leaf tissue and this purified material displays characters and activities similar to that produced in *E. coli* which has been transformed to produce CryIA(b). The similarities are shown for the tryptic core proteins in molecular weight after SDS-PAGE, immunorecognition in Western blots and ELISA, partial amino acid sequence analysis, lack of glycosylation and bioactivity against either European corn borer or corn earworm. This analysis justifies the use of the microbially produced toxin as an analogue for the plant produced protein in mammalian toxicity testing.

Toxicology Assessment

Toxicity

The toxicology data provided are sufficient to demonstrate that there are no foreseeable human health hazards likely to arise from the use of *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in all plants.

The data submitted regarding potential health effects include information on the characterization of the expressed CryIA(b) delta-endotoxin in corn, the acute oral toxicity, and *in vitro* digestibility of the delta-endotoxin. In an acute oral toxicity test of bacterially-derived CryIA(b) protein, no test substance related deaths occurred at a dose of 4,000 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, as demonstrated.

The data submitted by Monsanto support the prediction that the CryIA(b) 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 CryIA(b) delta-endotoxin is not considered acutely toxic. Adequate information was submitted to show that the test material derived from microbial cultures were biochemically and insecticidally similar to the delta-endotoxin as produced by the plant-pesticide in corn. Production of microbially produced CryIA(b) delta-endotoxin was chosen in order to obtain sufficient material for testing. In addition, the *in vitro* digestibility studies indicate the delta-endotoxin would be rapidly degraded following ingestion.

The genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta-endotoxin are the nucleic acids (DNA) which comprise (1) genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, 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 *Bacillus thuringiensis* CryIA(b) delta-endotoxin in any plants.

Allergenicity

Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, are glycosylated and present at high concentrations in the food. Monsanto has submitted data demonstrating that the CryIA(b) delta-endotoxin is rapidly degraded by gastric fluid *in vitro* and is non-glycosylated.

Studies submitted to EPA done in laboratory animals also have not indicated any potential for allergic reactions to *Bacillus 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,* unlike known food allergens that tend to be resistant to degradation.

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 to the delta-endotoxin itself despite significant oral, dermal and inhalation exposure to the microbial product. Several reports under FIFRA section 6(a)2 have been made for various *Bacillus thuringiensis* products claiming allergic reactions. However, the Agency determined these reactions were not due to *Bacillus thuringiensis* itself or any of the cry toxins.

Residue Chemistry Data

Residue chemistry data were not required because of the lack of mammalian toxicity of this active ingredient. In the acute mouse oral toxicity study, the CryIA(b) delta-endotoxin was shown to have an LD_{50} greater than 4,000 mg/kg. 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 CryIA(b) delta-endotoxin is not considered acutely. This is similar to the Agency position regarding toxicity and the requirement 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, further toxicity testing to verify the observed effects and clarify the source of the effects (Tiers II and III) and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study.

The genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta-endotoxin are the nucleic acids (DNA) which comprise: (1) Genetic material encoding the CryIA(b) delta-endotoxin and (2) its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, such as promoters, terminators, and enhancers. As stated above, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the *Bacillus thuringiensis* CryIA(b) delta-endotoxin in any plant. Therefore, no residue data are required in order to grant an exemption from the requirements of a tolerance for the plant pesticides, *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in plants.

Conclusions

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 rule making. 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 5F4473/R2270] (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 (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 certification statement to this effect 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 record keeping 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 new § 180.1173, to read as follows:

§ 180.1173 Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in all plants.

Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production in all plants are exempt from the requirement of a tolerance when used as plant pesticides in all plant raw agricultural commodities. ''Genetic material necessary for its production'' means the genetic material which comprise genetic material encoding the CryIA(b) delta-endotoxin and its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the CryIA(b) delta-endotoxin, such as promoters, terminators, and enhancers.

[FR Doc. 96–19811 Filed 8–1–96; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 406, 407, 408, and 416

[BPD–752–FC]

RIN 0938–AH33

Medicare Program: Special Enrollment Periods and Waiting Period

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rules with comment period.

SUMMARY: These rules provide an additional way for certain disabled individuals under age 65 to qualify for special enrollment periods (SEPs); extend from 1991 through 1998 the period during which certain disabled individuals under age 65 who are covered under large group health plans (LGHPs) may qualify for SEPs; and make clear that a second 24-month waiting period is not required for disability-based reentitlement if the current impairment is the same as, or directly related to, the impairment on which the previous period of entitlement was based.

The changes made by these rules conform the HCFA regulations to certain provisions of the Omnibus Budget Reconciliation Acts of 1987, 1989, 1990, and 1993 (commonly referred to as OBRA '87, OBRA '89, OBRA '90, and OBRA '93, respectively), and the Social Security Act (SSA) Amendments of 1994 (Pub. L. 103–432).

In OBRA '93, Congress amended section 1862(b) of the Social Security Act (the Act), to extend through September 30, 1998 the Medicare Secondary Payer (MSP) provisions for disabled beneficiaries. Congress did not make a conforming amendment to section 1837(i) of the Act, which authorizes SEPs for disabled beneficiaries who stop working. However, the SSA Amendments of 1994 made the conforming change to section 1837(i), retroactive to the OBRA '93 effective date.

The purpose of the special enrollment period amendments is to ensure that a disabled individual under age 65 who meets the conditions for enrollment in Medicare Part B will be able to enroll as soon as his or her group health plan coverage based on current employment ends; and to extend until September 30, 1998 the protection afforded by the special enrollment periods to disabled individuals covered under LGHPs.

DATES: *Effective date:* These rules are effective on September 3, 1996.

Comment date: We will consider comments received by October 1, 1996.

ADDRESSES: Please mail original and 3 copies of your comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–752–FC, P.O. Box 26688, Baltimore, Maryland 21207.

If you prefer, you may deliver original and 3 copies of your comments to either of the following addresses:

Room 309–G, 200 Independence Avenue, S.W., Washington, DC 20201,

Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–752–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone: (202) 690–7890).

Although we cannot respond to individual comments, if we revise these rules as a result of comments, we will discuss all timely comments in the preamble to the revised rules.

FOR FURTHER INFORMATION CONTACT: Margaret Jefferson, (410) 786–4482.

SUPPLEMENTARY INFORMATION:

I. Background

A. Amendments to the Statute: Special Enrollment Periods and Waiting Period

1. Section 4033 of OBRA '87 (Pub. L. 100–203) amended section 226(f) of the Act to provide that, effective as of March 1988, a second 24-month waiting period is not required for disability-based reentitlement if the current impairment is the same as, or directly related to, the impairment on which the