ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300612; FRL–5770–4]

RIN 2070–AB78

Bacillus thuringiensis subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for its Production in Corn; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a temporary exemption from the requirement of a tolerance for residues of the insecticide, *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn for feed use only; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

DATES: This regulation is effective April 10, 1998. Objections and requests for hearings must be received by EPA on or before June 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300612], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300612], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300612]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: Room CS15–W29, 2800 Jefferson Davis Highway, Arlington, VA, 703–308–8715, e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Plant Genetic Systems (America), Inc., 7200 Hickman Road, Suite 202, Des Moines, IA 50322 has requested in pesticide petition (PP 7G4921) the establishment of an exemption from the requirement of a tolerance for residues of the insecticide *Bacillus thuringiensis* subspecies *tolworthi* Cry9C and the genetic material necessary for its production in corn for feed use only. A notice of filing (FRL–5753–3) was published in the **Federal Register** (62 FR 63168, November 26, 1997), and the notice announced that the comment period would end on December 26, 1997; no comments were received. This temporary exemption from the requirement of a tolerance will permit the marketing of the above feed and food commodities when treated in accordance with the provisions of experimental use permit 70218–EUP–1, as amended and extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170.

I. Risk Assessment and Statutory Findings

A. Use Practices

The experimental program will be conducted in the states of Alabama, New York, California, North Carolina, Colorado, Ohio, Delaware, Pennsylvania, Florida, Puerto Rico, Georgia, South Dakota, Hawaii, Tennessee, Illinois, Texas, Indiana, Virginia, Iowa, Wisconsin, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, and Nebraska. Corn containing this plant-pesticide are to be protected from the European corn borer.

B. Product Identity/Chemistry

The Cry9C gene was originally isolated from a *Bacillus thuringiensis* subsp. *tolworthi* strain. The gene was then synthesized with plant preferred codons before it was stably inserted into corn plants to produce a truncated and modified Cry9C protein. The tryptic core of the microbially produced Cry9C delta-endotoxin is similar to the Cry9C protein found in event CBH351 save for a single amino acid substitution in the internal sequence and the addition of two amino acids to the N-terminus. The Cry9C protein was produced and purified from a bacterial host to utilize in the mammalian toxicity studies due to the bacterium's greater production potential. Product analysis that compared the Cry9C protein from the two sources included: SDS-PAGE, Western blots, N- terminal amino acid sequencing, glycosylation tests (for possible post- translational modifications) and insect bioassays. No analytical method was included since this petition requests an exemption from the requirement of a tolerance.

C. Mammalian Toxicological Profile

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

Additionally, section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

A high-dose acute oral toxicity study (3,760 mg/kg body weight) showed no mortalities. Transient weight losses were seen in three female treated animals, with one not recovering her pre-dosing, pre-fast weight at 14 days after dose administration. The treated males showed no weight losses. Transient weight loss has been observed in similar studies conducted on other

purified Cry proteins as well as microbial pesticides containing Cry proteins and is not considered a significant adverse effect.

The *in vitro* digestibility study showed the Cry9C protein to be stable to pepsin digestion at pH 2.0 for 4 hours. The Cry9C protein is also heat stable, not being affected by incubation at 90° C for 10 minutes. The Cry9C protein in corn is the trypsin resistant core and is therefore stable to typtic digest.

A search for amino acid homology did not reveal any significant homology with known toxins or allergens.

The genetic material necessary for the production of the plant-pesticide active ingredient is the nucleic acids (DNA) which comprise genetic material encoding the Cry9C protein and its regulatory regions. Regulatory regions are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant-pesticide have been adequately characterized by the applicant and supports EPA's conclusion that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the Cry9C protein.

D. Aggregate Exposure

The available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the Cry9C protein residue include dietary exposure and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the Cry9C plant-pesticide is contained within plant cells essentially eliminating these exposure routes or reducing these exposure routes to negligible. Drinking water is unlikely to be significantly contaminated with Cry9C protein due to the low expression of the protein in corn tissue, degradation of plant materials in the soil and low leaching potential of a protein from a soil matrix. Minimal to non-existent oral exposure could occur from ingestion of meat, poultry, eggs or milk from animals fed corn containing the plant-pesticide and from drinking water. While unlikely, meat, eggs or milk from animals fed corn containing the plant-pesticide could contain negligible but finite residues. This is viewed as a remote possibility due to the low Cry9C expression level in corn tissue (12 to 225 µg/gm fresh weight), the anticipated degradation and elimination of the Cry9C protein by the animal or the lack of uptake of such a large protein by the animal's intestinal tract. It is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues. However, the best available information on the uptake of intact proteins from the diet would indicate that the intact Cry9C protein would not be available in products from animals fed corn products containing Cry9C protein.

The use sites are all agricultural for control of lepidopteran insects under the associated experimental use permit. Therefore, exposure via residential or lawn use is not expected.

E. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on adults as well as on infants and children of such residues and other substances with a common mechanism of toxicity. Since there is no indication of mammalian toxicity to the Cry9C protein from the studies submitted, there is no reason to believe there would be cumulative toxic effects.

F. Safety Determination

The temporary tolerance exemption is limited to residues of the Cry9C protein resulting from feed use only. The basis of safety for this temporary tolerance exemption includes both the results of the acute oral study at high doses indicating no toxicity and the anticipated minimal to nonexistent human dietary exposure of the Cry9C protein via animal feed use.

Bt microbial pesticides, containing Cry proteins other than Cry9C, have been applied for more than 30 years to food and feed crops consumed by the U.S. population. There have been no human safety problems attributed to the specific Cry proteins. An oral dose of the tryptic core Cry9C protein of at least 3,760 mg/kg was administered to 10 animals without mortality demonstrating a high degree of safety for the protein. Transient weight loss in three female rodents was observed, but not in any males. Transient weight loss has been observed in similar studies conducted on other purified Cry proteins as well as microbial pesticides and this is not considered a significant adverse effect.

A comparison of the amino acid sequence of the Cry9C protein with those found in the PIR, Swiss-Prot and HIV AA data bases did not reveal any significant homology with known toxins or allergens.

The *in vitro* digestibility study showed the Cry9C protein to be stable to pepsin at pH 2.0. The Cry9C protein was shown to be stable to heat at 90 degrees C for 10 minutes and the Cry9C protein in corn is the trypsin resistant core and is therefore stable to tryptic digest.

The best available information to date would indicate that edible products derived from animals such as meat, milk and eggs, intended for human consumption, have not been shown to be altered in their allergenicity due to changes in the feed stock utilized. This information would include no transfer of allergenic factors from cattle fed soybeans to the derived meat or milk eaten by individuals with food sensitivity to soybeans.

G. Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children.

In this instance, based on all the available information, the Agency concludes that infants and children will consume only minimal, if any, residues of this plant-pesticide and that there is a finding of no toxicity.

Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply.

H. Other Considerations

1. *Analytical method.* The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation;therefore, the agency has concluded that an analytical method is not required for enforcement purposes for this plant-pesticide.

2. *Effects on the endocrine systems.* EPA does not have any information

regarding endocrine effects for these kinds of pesticides at this time. The Agency is not requiring information on the endocrine effects of these plant-pesticides at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

I. Existing Tolerances

No tolerances or tolerance exemptions have been granted for the *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

II. Conclusion

Based on the toxicology data cited and the limited exposure expected with animal feed use, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, the temporary tolerance exemption is limited to feed use only. The conclusion of safety is supported by the lack of toxicity after administration of a high oral dose (3,760 mg/kg), the lack of homology to known toxins or allergens, and the minimal to nonexistent exposure via dietary and non-dietary routes. As a result, EPA establishes a temporary exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn, on the condition that *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn be used in accordance with the experimental use permit 70218–EUP–1, with the following provisions:

The total amount of the active ingredients to be used must not exceed the quantity authorized by the experimental use permits. Plant Genetic Systems (America) must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration (FDA).

This temporary exemption from the requirement of a tolerance expires and is revoked January 31, 1999. Residues remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the corn containing the plant-pesticide was legally planted during the term of, and in accordance with, the provisions of the amended experimental use permit and temporary exemption from the requirement of a tolerance.

This temporary exemption from the requirement of a tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

EPA will publish a document in the **Federal Register** to remove the revoked temporary exemption from the Code of Federal Regulations.

III. Objections and Hearing Requests

The new FFDAC section 408(g) provides essentially the same process for persons to ''object'' to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person 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, 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 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).

IV. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300612] (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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services, Division (7502C), 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.

V. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 26, 1998.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

PART 180—[AMENDED]

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

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

2. Section 180.1192 is added to read as follows:

§ 180.1192 Bacillus thuringiensis subspecies tolworthi Cry9C protein and the genetic material necessary for its production in corn; exemption from the requirement of a tolerance.

The plant-pesticide *Bacillus thuringiensis* subspecies *tolworthi* Cry9C and the genetic material necessary for its production in corn is temporarily exempted from the requirement of a tolerance for residues, only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed. This temporary exemption from the requirement of a tolerance will permit the use of the feed commodities and the marketing of animals fed such feed in this paragraph when treated in accordance with the provisions of experimental use permit 70218–EUP–1, which is being amended and extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked January 31, 1999. This temporary exemption from the requirement of a tolerance may be revoked at any time if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

[FR Doc. 98–9245 Filed 4–9–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300619A; FRL–5784–5]

RIN 2070–AB78

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of Prometryn in or on carrots to harmonize tolerances with Canada under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective April 10, 1998. Objections and requests for hearings must be received by EPA on or before June 9, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300619A], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300619A], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests 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 hearing requests must be submitted as an ASCII file avoiding the use of special characters and any from of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300619A]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: