Dated: May 8, 1998.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. In § 180.1001, in paragraph (c), the table is amended by alphabetically adding the inert ingredient ''hydroxyethylidine diphosphonic acid (HEDP)'' to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Hydroxyethylidine diphosphonic acid (HEDP) (CAS Reg. No. 2809–21–4).	For use in antimicrobial pesticide formulations at not more than 1 percent.	Stabilizer, chelator
* * *	* * *	*

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[FR Doc. 98–13603 Filed 5–21–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300659; FRL–5790–3]

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 amends an exemption from the requirement of a tolerance for resid ues 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. Plant Genetic Systems (America), Inc. submitted a petition to the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the 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 or on corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

EFFECTIVE DATE: This regulation is effective May 22, 1998. Objections and requests for hearings must be received by EPA on or before July 21, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300659], 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–300659], 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–300659]. 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 7F4826) the establishment of an 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 in or on all raw agricultural commodities. A notice of filing (FRL–5739–9) was published in the **Federal Register** (62 FR 49224, September 19, 1997), and the notice announced that the comment period would end on October 20, 1997; no comments were received. Plant Genetic Systems (America), Inc. submitted an amendment to their petition on April 24, 1998 to request the establishment of an 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 only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed. This exemption from the requirement of a tolerance will permit the marketing of feed corn containing the plant-pesticide; as well as meat, poultry, milk, or eggs resulting from animals fed such feed. 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. 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.

B. 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 tryptic 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.

C. 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 (3 to 250 µg/gm dry 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.

D. 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.

E. Safety Determination

The tolerance exemption is limited to residues of the Cry9C protein resulting from feed use only. The basis of safety for this 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 ° 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.

F. 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.

G. 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.

H. Existing Tolerances

A temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in corn, only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed was established on April 10, 1998 under 40 CFR 180.1192 [63 FR 69]. The exemption from the requirement of a tolerance in this rule makes permanent the temporary tolerance exemption of 40 CFR 180.1192.

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

III. Objections and Hearing Requests

The new FFDCA 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 by June 22, 1998, 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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

IV. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300659] (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 Virginia 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: May 11, 1998.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.1192 is revised 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 protein and the genetic material necessary for its production in corn is 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.

[FR Doc. 98–13604 Filed 5–21–98; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–7244]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Associate Director for Mitigation reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The modified base flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).