FOAM BLOWING—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Comments
All foam end-uses: —Rigid polyurethane and polyisocyanurate laminated boardstock —Rigid polyurethane appliance —Rigid polyurethane spray and commercial refrigeration, and sandwich panels —Rigid polyurethane slabstock and other foams —Polystyrene extruded insulation boardstock and billet —Phenolic insulation board and bunstock —Flexible polyurethane —Polystyrene extruded sheet **Except for:** [1] —Space vehicle —Nuclear —Defense —Research and development for foreign customers	HCFC–141b	Unacceptable	Alternatives exist with lower or zero = ODP.

[1] Exemptions for specific applications are identified in the list of acceptable substitutes.

[FR Doc. 04–21809 Filed 9–29–04; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–2004–0249; FRL–7372–6]

Bacillus thuringiensis var. aizawai strain PS811 (Cry1F insecticidal protein); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis var. aizawai* strain PS811 (Cry1F insecticidal protein) and the genetic material necessary for its production in cotton when applied/used as a plant-incorporated protectant. DowAgro Sciences, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis var. aizawai* strain PS811 (Cry1F insecticidal protein) and the genetic material necessary for its production in cotton when used as a plant-incorporated protectant.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0249. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology, that may develop and market plant-incorporated protectants. Potentially affected entities may include, but are not limited to:

- Seed companies (NAICS code 111)
- Pesticide manufacturers (NAICS code 32532)
- Establishments involved in research and development in the life sciences (NAICS code 54171)
- Colleges, universities, and professional schools (NAICS code 611310).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A

frequently updated electronic version of 40 CFR part 174 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of August 11, 2004 (69 FR 48870) (FRL–7673–2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 3F6785) by DowAgro Sciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268–1054. The petition requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis var. aizawai* strain PS811 (Cry1F insecticidal protein) and the genetic material necessary for its production in cotton when used as a plant-incorporated protectant.

This notice included a summary of the petition prepared by the petitioner DowAgro Sciences, LLC. Comments were received by The National Cotton Council and cotton grower groups. All comments were in support of this tolerance exemption.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that 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.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the 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.

Data have been submitted to the Agency demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry1F protein. These data demonstrate the safety of the Cry1F protein at levels well above maximum possible exposure levels that are reasonably anticipated in the crops. 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-incorporated protectant was derived. See 40 CFR 158.740(b)(2)(i). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study to verify the observed effects and clarify the source of these effects (Tier II and Tier III). The acute oral toxicity data submitted support the prediction that the Cry1F protein would be non-toxic to humans. Thus, although Cry1F expression level data were required for an environmental fate and effects assessment, residue chemistry data were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity.

Male and female mice (5 of each) were dosed with 15% (w/v) of the test substance, which consisted of *Bacillus thuringiensis var. aizawai* Cry1F protein at a net concentration of 11.4%. Two doses were administered approximately an hour apart to achieve the dose totaling 33.7 milliliter/kilogram body weight (mL/kg bwt). Outward clinical signs and body weights were observed and recorded throughout the 14–day study. Gross necropsies performed at the end of the study indicated no findings of toxicity. No mortality or clinical signs were noted during the study. A lethal dose $(LD)_{50}$ was estimated at >5,050 milligram (mg)/kg bwt of this microbially produced test material. The actual dose administered contained 576 mg Cry1F protein/kg bwt. At this dose, no LD_{50} was demonstrated as no toxicity was observed. Cry1F maize seeds contain 0.0017 to 0.0034 mg of Cry1F/gram of cotton kernel tissue. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al., *Toxicological Considerations for Protein Components of Biological Pesticide Products*, Regulatory Toxicology and Pharmacology 15L, 3–9 (1992). Therefore, since no effects were shown to be caused by the plant-pesticides, even at relatively high dose levels, the Cry1F protein is not considered toxic. Further, amino acid sequence comparisons showed no similarity between Cry1F protein to known toxic proteins available in public protein databases. Finally, regarding toxicity to the immune system, the acute oral toxicity data submitted support the prediction that the Cry1F protein would be non-toxic to humans.

Since Cry1F is a protein, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, and may be glycosylated and present at high concentrations in the food. Data has been submitted which demonstrates that the Cry1F protein is rapidly degraded by gastric fluid *in vitro* and is non-glycosylated. In a solution of Cry1F: Pepsin at a molar ratio of 1:100, complete degradation of Cry1F to amino acids and small peptides occurred in 5 minutes. A heat lability study demonstrated the loss of bioactivity of Cry1F protein to neonate tobacco budworm larvae after 30 minutes at 75 °C. This indicates that the protein is highly susceptible to digestion in the human digestive tract and that the potential for adverse health effects from chronic exposure is virtually nonexistent. Furthermore, studies submitted to EPA done in laboratory animals have not indicated any potential for allergic reactions to *Bacillus thuringiensis* or its components, including the endotoxin of the crystal protein. Additionally, a comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Cry1F, even at the level of 8 contiguous amino acids residues. Accordingly, the potential for the Cry1F protein to be a food allergen is minimal.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectants chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates or reduces these exposure routes to negligible. Oral exposure, at very low levels, may occur from ingestion of processed cotton products and, potentially, drinking water. However, such exposures are unlikely to be problematic because of the demonstrated lack of mammalian toxicity and the digestibility of the Cry1F protein. Also, the protein is not likely to be present in drinking water because the protein is deployed in minute quantities within the plant, and studies demonstrate that Cry1F protein is rapidly degraded in soil. Finally, the use sites for the Cry1F protein are all agricultural for control of insects. Therefore, exposure via residential or lawn use to infants and children is not expected. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity demonstrated for the Cry1F protein.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA 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.'' These considerations include the possible cumulative effects of such residues on infants and children.

Common modes of toxicity are not relevant to a consideration of cumulative exposure to the *Bacillus thuringiensis* Cry1F insect control protein. The product has demonstrated low mammalian toxicity and *Bt* insecticidal crystal proteins are known to bind to specific receptors in the insect gut, such that biological effects do not appear to be cumulative with any other known compounds.

Thus, the Agency does not expect any cumulative or incremental effects from exposure to residues of the Cry1F protein and the genetic material necessary for its production in cotton when applied/used as a plant-incorporated protectant as directed on the label and in accordance with good agricultural practices.

VI. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of the Cry1F protein and the genetic material necessary for its production in cotton due to its use as a plant-incorporated protectant. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the Cry1F protein include the characterization of the expressed Cry1F protein in cotton, as well as the acute oral toxicity, heat stability, and *in vitro* digestibility of the protein. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered. Adequate information has been submitted to show that the Cry1F test material derived from microbial cultures was biochemically and functionally similar to the protein produced by the plant-incorporated protectant ingredients in cotton. Production of microbially produced protein was chosen in order to obtain sufficient material for testing. The acute oral toxicity data submitted supports the prediction that the Cry1F protein would be non-toxic to humans.

Both (1) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers, including infants and children); and (2) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data were not evaluated. The lack of mammalian toxicity at high levels of exposure to the Cry1F protein demonstrates the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-incorporated protectant active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the proteins. DNA and RNA are 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 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 subject active plant pesticidal ingredients.

B. Infants and Children Risk Conclusions

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(b)(2)(C) 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 prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either by (1) using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans, or (2) using a margin of exposure analysis.

In this instance, due to the anticipated agricultural use pattern for the product, non-dietary exposure to infants and children is not anticipated. Moreover, because all available information concerning the Cry1F protein and the genetic material necessary for its production demonstrates low to no

mammalian toxicity, a lack of allergenic potential, and a high degree of digestability, dietary exposure is anticipated to be at very low levels and, even then, is not anticipated to pose any harm to infants and children. Thus, the Agency concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of the Cry1F protein and the genetic material necessary for its production in cotton, and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues of the Cry1F protein and the genetic material necessary for its production in cotton. Accordingly, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under FFDCA section 408(p), as amended by FQPA, to develop a screening process to determine whether pesticide chemicals (and any other substance that may have an effect that is cumulative to an effect of a pesticide chemical) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Advisory Committee (EDSTAC), EPA determined that there was no scientific basis for including, as part of the program, the androgen-and thyroid hormone systems, in addition to the estrogen hormone systems. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been determined, Cry1F proteins may be subjected to additional screening and/or testing to better characterize any effects related to endocrine disruption.

To date, however, and based on the weight of available data, the Agency has no information to suggest that the Cry1F protein and the material necessary for its production in cotton has an effect on the endocrine system. The Cry1F pesticidal active ingredient is a protein, derived from sources that are not known and not expected to exert an influence on the endocrine system. Similarly, given the rapid digestibility of the Cry1F insecticidal crystal protein, no chronic effects are expected. Accordingly, there is no impact via endocrine-related effects on the Agency's safety finding as set forth in this final rule for the Cry1F protein and the genetic material necessary for its production in cotton when applied/used as a plant-incorporated protectant. Therefore, the Agency is not requiring information on the endocrine effects of this plant-incorporated protectant at this time.

B. Analytical Method(s)

A validated method for extraction and direct enzyme linked immunosorbent assay analysis of Cry1F in cotton meal, cotton seed oil, and cotton by products has been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exists for the plant-incorporated protectant *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in cotton.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0249 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 29, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). 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.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0249, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-

mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Pesticides and pests, Plant-incorporated protectant, Reporting and recordkeeping requirements.

Dated: September 23, 2004.

James Jones,

Director, Office of Pesticides Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136 - 136y; 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 174.455 is added to subpart W to read as follows:

§ 174.455 Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in cotton; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in food and feed commodities of cotton. ''Genetic material necessary for its production'' means the genetic material which comprise: Genetic material encoding the Cry1F protein and its regulatory regions. ''Regulatory regions'' are the genetic material, such as

promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry1F protein.

[FR Doc. 04–21877 Filed 9–29–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0318; FRL–7680–8]

Dichlormid; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the inert ingredient (herbicide safener) dichlormid (Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) in or on sweet corn commodities at 0.05 parts per million (ppm). Dow AgroSciences requested this tolerance under the Federal Food, Drug, and Cosmetic Act, (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire on December 31, 2005.

DATES: This regulation is effective September 30, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. After submitting your original written objection or hearing request as instructed in Unit VI., you can use EDOCKET or regulations.gov to submit the requested copy (see also Unit VI.A.2.). EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0318. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305– 6304; e-mail *address:boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Industry (NAICS 111), e.g., Crop Production, e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Industry (NAICS 112), e.g., Animal Production, e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Industry (NAICS 311), e.g., Food Manufacturing, e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Industry (NAICS 32532), e.g., Pesticide Manufacturing, e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at*http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of November 21, 2003 (68 FR 65708) (FRL–7333–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6676) by Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow AgroSciences, the petitioner.

The petition requested that 40 CFR 180.469 be amended by establishing time-limited tolerances for residues of the herbicide safener dichlormid, (*N,N*-diallyl-2,2-dichloroacetamide or Acetamide, 2,2-dichloro-*N,N*-di-2-propenyl-) (CAS Reg. No. 37764 –25–3), in or on sweet corn commodities at 0.05 parts per million (ppm). There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other