VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 FFDCA, such as the tolerance 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 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.

VIII. 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 180

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

Dated: March 30, 2006.

Lois Rossi,

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. 321(q), 346a and 371.

■ 2. Section 180.361 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin, Tolerance for Residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	0.4
* * * * *	
Carrots	0.5
* * * * *	
Citrus, oil	0.5
* * * * *	
Fruit, citrus, group 10	0.1
* * * * *	
Nut, tree, group 14	0.1
* * * * *	
Peppermint, oil	1.0
Peppermint, tops	0.2
* * * * *	
Spearmint, oil	1.0
Spearmint, tops	0.2

* * * * *

[FR Doc. 06–3460 Filed 4–11–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0486; FRL–7765–1]

FD&C Blue No. 1 PEG Derivatives; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes two exemptions from the requirement of a tolerance for residues of FD&C Blue No. 1 Polyethylene Glycol (PEG) Derivative and FD&C Blue No. 1, Methyl-PEG Derivative when used as inert ingredients (dye or coloring agent) in a seed-treatment pesticide product. Milliken 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 FD&C Blue No. 1, PEG Derivative and FD&C Blue No. 1, Methyl-PEG Derivative.

DATES: This regulation is effective April 12, 2006. Objections and requests for hearings must be received on or before June 12, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0486. All documents in the docket are listed on the *www.regulations.gov* website. EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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/*.

II. Background and Statutory Findings

In the **Federal Register** of August 29, 1997 (62 FR 45804) (FRL–5738–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 5E4597) by Milliken and Company, Box 1927, Spartanburg, SC 29304–1927. That notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR 180.1001(c) now redesignated as 40 CFR 180.910 be amended by establishing exemptions from the requirement of a tolerance for residues of three PEG-modified dyes to impart color to pesticidally-treated seeds. The two dyes subject to this final rule are poly(ethylene glycol) modified FD&C Blue No. 1 and methyl-poly(ethylene glycol) modified FD&C Blue No. 1. The third dye has been withdrawn by the petitioner. In the **Federal Register** of October 8, 1997 (62 FR 52563) (FRL–5746–7), EPA issued a notice of correction to specify that the concentration of the dyes in a formulated pesticide product would not ''exceed 1 to 5% of the final formulation.''

Methyl-polyethylene glycol modified FD&C Blue No. 1 is also known as FD&C Blue No. 1 methyl-PEG derivative or poly(oxy-1,2-ethanediyl), α, α′, α″, α‴-[[2-sulfophenyl)methyliumylidene]bis[(3-methyl-4,1-phenylene)nitrolodi-2, 1-ethanediyl]]tetrakis[.omega.-hydroxy-, chloride, monosodium salt. (CAS Reg. No. 9079–34–9).

Polyethylene glycol modified FD&C Blue No. 1 is also known as FD&C Blue No. 1 PEG derivative or poly(oxy-1,2-ethanediyl), α, α′, α″, α‴-[[2-sulfophenyl)methyliumylidene]bis[(4,1-phenylene)nitrolodi-2, 1-ethanediyl]]tetrakis[.omega.-hydroxy-, chloride, monosodium salt. (CAS Reg. No. 9079–33–8).

There were no comments received in response to the notice of filing or the notice of correction.

Most pesticide products that are applied to field crops do not contain a dye or coloring agent. Dyes or colorants that are incorporated into pesticide products used on field crops are often used as alerting agents. For example, a dormancy breaker pesticide product may be colored so that the applicator can see which branches have been sprayed and which have not. Another use of dyes in a pesticide product is to color pesticidally-treated seeds. Under 40 CFR 153.155 seed-treatment pesticide products must contain a dye ''to impart an unnatural color to the seed'' so that the treated seed is not confused with food or feed stocks. The use pattern requested by the petitioner is very limited, that of seed-treatment and at a concentration in the pesticide product that is not to exceed 5%. The Agency has determined to establish this tolerance exemption in 40 CFR 180.920 (pre-harvest uses only), as this is a more appropriate placement for a chemical that is only to be used as a seed-treatment.

Both of the FD&C Blue No. 1 derivatives are manufactured via the attachment of varying lengths of polyethylene glycol side-chains to FD&C Blue No. 1. This process results in a polymeric-type of matrix.

For use in pesticide products, the Agency has determined that the molecular weight of these PEG derivatives of FD&C Blue No. 1 must be greater than 1,000 amu. It is possible for

a polyethylene glycol chain to act as a surfactant, but only if the chain is shortened. If the PEG side chains that are attached to the FD&C Blue No. 1 are too short, then there is the possibility that these dyes could begin to act as a surfactant. The Agency has considered the use of these chemicals only as dyes or coloring agents, and does not intend for their use as surfactants. The Agency believes that the molecular weight limitation of greater than 1,000 amu will assure that the side-chains are of adequate length.

Section 408(b)(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 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. 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. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. 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. The nature of the toxic effects caused by FD&C Blue No. 1 PEG derivative and FD&C Blue No. 1 methyl-PEG derivative are discussed in this unit.

The two chemicals considered today in this final rule are derived from FD&C Blue No. 1 via the attachment of side-chains which are composed of multiple (repeating) units of ethylene glycol. For this action FD&C Blue No. 1 is used as surrogate data for these PEG derivative chemicals. Both of the derivatives of FD&C Blue No. 1 are considered to be no more toxic and as explained below are likely to be even less toxic than that of FD&C Blue No. 1, *per se*.

A. Toxicity of FD&C Blue No. 1

FD&C Blue No. 1 (CAS Reg. No. 3844–45–9) is also known as CI Acid Blue 9, disodium salt; CI No. 42090; and Brillant Blue FCF. FD&C Blue No. 1 has been extensively studied over a number of years in different toxicity studies using different routes of exposure. A search of the open literature was conducted for EPA by the Department of Energy's Oakridge National Laboratory (ORNL). ORNL prepared summaries of that information which served as the basis for the Agency's December 2005 assessment of FD&C Blue No. 1 for the purpose of tolerance reassessment.

The petitioner for this action submitted to the Agency two FDA memos dated January 12, 1968 and May 10, 1982 which contain the results of FDA's review and analysis of the data which were used to support the 1982 Acceptable Daily Intake (ADI). Comparison of these memos to the information from the open literature indicate that the database used by EPA for the purposes of tolerance reassessment and the database used by FDA are much the same.

Table 1 summarizes various oral toxicity studies reviewed and evaluated by the Food and Drug Administration (FDA), BIBRA, and the World Health Organization, as well as summaries taken from open literature. The two FDA memos, FDA's final rule on FD&C Blue No. 1 published in the **Federal Register** of September 28, 1982 (47 FR 42563), and EPA's Tolerance Reassessment Document are all placed in the docket for this action. (see *http://www.regulations.gov*).

TABLE 1.—FD&C BLUE NO. 1 TOXICITY STUDIES

Study Type	Results
2–year (oral) rat	Test animals received 0.0, 0.5, 1.0, 2.0, or 5.0% of FD&C Blue No. 1 in the diet. The 5% FD&C Blue No. 1 was a ''no effect level'' Note that 5% (50,000 ppm) in the diet is approximately equivalent to 2.5 g/kg/day. This study served as the basis for the WHO ADI.
75–week (oral) rat	Test animals received 0.0, 0.03, 0.3, or 3.0% of Brillant Blue FCF in the diet. The color had no adverse effect on food consumption, food efficiency, and growth
1–year (oral) dog	FD&C Blue was fed in the diet at levels of 0, 1, or 2%. The 2% FD&C Blue No. 1 was a ''no effect'' level. Note that 2% (20,000 ppm) in the diet, is approximately equivalent to 500 mg/kg/day.

TABLE 1.—FD&C BLUE NO. 1 TOXICITY STUDIES—Continued

Study Type	Results
Metabolism (oral) rat	Adult rats were given 200 mg/kg FD&C Blue No. 1. Urine and feces were collected for 36 hours. ''The color was almost completely excreted unchanged in the feces, an average of 96 +/−2.16% having been recovered. None of the color was found in the urine.''
3–generation reproductive (oral) rat	No adverse effects observed with dietary doses of up to about 1 g/kg/day
Developmental (stomach tube) rat	Pregnant rats were given 0.2, 0.6, or 2 g/kg/day on gestation days 6 to 15. No convincing signs of maternal or fetal toxicity
2–year chronic (with*in-utero* phase) (oral) rat	Test animals received 0, 0.1, 1.0, or 2.0% Brillant Blue FCF in the diet. There were no significant differences in reproduction/fertility data between control and treated animals A no-effect level of 2% (1,200 mg/kg/day) was determined. FDA determined that FD&C Blue No. 1 is not carcinogenic in the rat after lifetime dietary exposures of 2.0%. This study served as the basis for the FDA ADI
2–year (oral) mouse	Test animals received 0, 0.5, 1.5, or 5.0% Brilliant Blue FCF in the diet. There were no statistically significant effects observed in any of the parameters examined. The no-effect level is 5.0% (7,354 mg/kg/day (male) and 8,966 mg/kg/day (female). FDA determined that FD&C Blue No. 1 is not carcinogenic in the mouse after lifetime dietary exposures of 5.0%.

B. Toxicity of the PEG Derivatives of FD&C Blue No. 1

The petitioner also submitted several toxicity studies conducted using the PEG FD&C Blue No. 1 Derivatives as the test substance. The results of these studies are in Table 2:

TABLE 2.—FD&C BLUE NO. 1 PEG-DERIVATIVE TOXICITY STUDIES

Acute Oral Toxicity in the Rat	The estimated acute oral LD_{50} for FD&C Blue No. 1 methyl-PEG Derivative is greater than 5,000 mg/kg.
Dermal Irritation in the Rabbit	No erythema, edema, or other dermal effects were noted at any of the test sites during the study.
Mutagenicity—*in Vitro* Transformation of Balb/3T3 Cells Assay	The FD&C Blue No. 1 PEG Derivative ''did not induce the appearance of a significant number of transformed foci over the concentration range of 7.2 to 5.38 μL/mL. This concentration range corresponded to approximately 85% to near 10% survival in the preliminary cytotoxicity test.''
Mutagenicity—Mouse Lymphoma Forward Mutation Assay	The FD&C Blue No. 1 PEG Derivative ''did not induce significant increases in the mutant frequency at the TK locus in L5178Y mouse lymphoma cells. The test material was assayed up to 10 μL/mL without inducing significant increases in the background.''
Mutagenicity - *Salmonella*/Mammalian-Microsome Reverse Mutation Assay (Ames Test)	Under the conditions of this study, FD&C Blue No. 1 methyl-PEG derivative, ''did not cause a positive increase in the number of histidine revertants per plate of any of the tester strains either in the presence or absence of'' S9 activation.

C. Toxicity of Polyethylene Glycol (PEG) Side Chains

As previously discussed, the side-chains of the PEG derivatives of FD&C Blue No. 1 are composed of multiple (repeating) units of ethylene glycol. A group of ethylene glycol chemicals represented by the generic structure, HO(CH2CH2O)nH where n = 1-5 has been reviewed and evaluated by the Organization for Economic Cooperation and Development (OECD). The agreed upon conclusions and recommendations of OECD's Screening Information Dataset Initial Assessment Profile (SIAP) are available via the internet (see *http://cs3-hq.oecd.org/scripts/hpv/Home.asp using ethylene glycols as the search term*). The SIAP contains summarized results of OECD's review of various toxicity studies performed using ethylene glycol or a chain of ethylene glycol varying from 2 to 5 units. According to the SIAP, ''[a]vailable data and modeling confirm that as the molecular weight increases, the potential for systemic, reproductive, and developmental toxicity decreases''. Thus, pentaethylene glycol (5 units) would be the least toxic of all the ethylene glycol chemicals evaluated by OECD in this group of chemicals. It is of importance to note that the SIAP also indicated that larger (n= 6-8) ethylene glycol chemicals were deliberately excluded from this category of

chemicals, because at . ''n=6-8, absorption from ingestion decreases.'' Thus, the larger the ethylene glycol chain, the less the toxicity. The Agency believes that the molecular weight limitation of greater than 1,000 amu will assure that the side-chains are of adequate length.

D. Conclusions

In its Tolerance Reassessment Document, EPA discusses the low toxicity of FD&C Blue No1. This finding was based on the toxicity profile which indicated that via the oral route of exposure that FD&C Blue No. 1 demonstrated no adverse effects in developmental, reproductive, or chronic/carcinogenicity studies. The available information also indicates that FD&C Blue No. 1 is not metabolized in the mammalian body and that almost 100% of the ingested chemical is excreted within 36 hours. The molecular weight of FD&C Blue No. 1 is almost 800 amu. Generally, larger molecules are less well absorbed. Since both of these derivatives of FD&C Blue No. 1 are, in fact, larger than FD&C Blue No. 1, with molecular weights greater than 1,000 amu, and displaying characteristics of a polymeric/matrix nature, it is likely that the derivatives are even less well-absorbed. Therefore, based on their relationship to FD&C Blue No. 1, these PEG derivatives are likely to be even less toxic.

The Agency also notes that these derivatives of FD&C Blue No. 1 contain PEG or methyl-PEG side chains. The Agency has no definitive information on the role of these side-chains in the metabolism of the two chemicals considered today. However, the available information in the SIAP suggests that the PEG side-chains are not readily metabolized.

Given the data in Table 2, FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative are of low oral and dermal acute toxicity. These two chemicals are not mutagenic. Given the available toxicity information on FD&C Blue No. 1 and on chains of polyethylene glycol, the Agency believes that FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative of molecular weight greater than 1,000 amu are not well-absorbed in the mammalian body and therefore are not likely to be carcinogenic, or to cause adverse developmental or reproductive effects.

V. 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).

A. Dietary Exposure

1. *Food.* As part of its review and analysis of FD&C Blue No. 1, FDA not only evaluated various toxicity studies (Table 1), but also estimated ADIs. In 1968, the ADI was estimated as 300 mg/person/day or 5 mg/kg/day. In 1982, as a result of its review of additional toxicity studies, the ADI was re-estimated as 717.6 mg/day or 12 mg/kg/day.

There is the potential for exposures through food and drinking water resulting from the use of FD&C Blue No. 1 PEG derivative and FD&C Blue No. 1 methyl-PEG derivative in a pesticide product. Given the Agency's experience with its generic inert ingredient modeling, as evidenced by the discussion in the FD&C Blue No. 1 Tolerance Reassessment Document, and in light of the low percents in the formulation for dyes that are used in pesticide products, the Agency believes that potential dietary exposures through food would be much less than FDA's ADI for FD&C Blue No. 1.

2. *Drinking water exposure.*Since the PEG-derivatives of FD&C Blue No. 1 are only to be used in seed treatment products, exposures will occur via applications to ground (both surface and subsurface) and subsequent leaching from the seed into the surrounding soil. Transport to ground water via leaching and to surface water via the dissolved and sorbed phase will then occur. The extent to which the substance is available for leaching and runoff will be controlled by the rate of leaching from the seed. It is important to note that the formulation of dyes, such as FD&C Blue No. 1 into a polyethylene glycol matrix is to minimize ''bleeding'' of the dye into the surrounding area.

The environmental fate of FD&C Blue No. 1 PEG derivative and FD&C Blue No. 1 methyl-PEG derivative is highly uncertain because of the polymeric type of matrix, and the varying lengths of the chains of polyethylene glycol incorporated into the matrix. No physical-chemical properties and no environmental transformation and/or occurrence data were located in the readily available open literature. Therefore, the Agency's assessment is based on projected physical/chemical properties, and two modified Zahn-Wellens Ready Biodegradability tests supplied by the petitioner. The results of these two studies indicate that these derivatives of FD&C Blue No. 1 are not expected to rapidly biodegrade in the environment; the studies indicated very little degradation, approximately 20 percent over a 42 day test period. Degradation reached a plateau at about day 28 of the study. Therefore, primary degradation is likely to occur on the order of months and ultimate degradation (mineralization) on the order of many months. Both of these PEG derivatives of FD&C Blue No. 1 are classified as not readily biodegradable.

Because of the difficulties in ascertaining a representative molecular structure, the estimated fate and potential exposures are deemed uncertain; however, the Agency has used a bounding approach that should not under-estimate the potential exposures to the two PEG derivatives of FD&C Blue No. 1. The PEG derivatives of FD&C Blue No. 1 are likely to be dispersible in water, nonvolatile, and not very mobile. Leaching to ground water is not expected to be appreciable. The Agency believes that the likelihood of these two chemicals reaching surface water is limited, and the likelihood of reaching ground water and bioaccumulating in the environment is even more limited.

B. Other Non-Occupational Exposure

As part of its evaluation, FDA also estimated a maximum (conservative) daily intake of 35.4 mg/person/day (or 0.59 mg/kg/day) for exposure via food, dietary supplements, drugs, and cosmetics for FD&C Blue No. 1.

The available information indicates that neither of these PEG derivatives of FD&C Blue No. 1 are as widely used in consumer products as FD&C Blue No. 1. Therefore, the exposures that could occur from the use of these PEG derivatives in either residential pesticidal or consumer non-pesticidal products is expected to be much less than that estimated for FD&C Blue No. 1.

VI. Cumulative Effects

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative. These chemicals are structurally-related to FD&C Blue No. 1, which is considered over-all to be a chemical of lower toxicity. EPA has assessed exposure and risk to FD&C Blue No. 1 generally. These chemicals do not appear to produce any toxic metabolite produced by other substances. For the

purposes of this tolerance action, therefore, EPA has not assumed that FD&C Blue No. 1, FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concluded that a different margin of safety will be safe for infants and children.

Using the available data on FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative and the surrogate data on FD&C Blue No. 1, these chemicals over-all present as chemicals of lower toxicity. In a FD&C Blue No. 1 reproductive toxicity study reviewed and evaluated by FDA, there were no ''significant differences in reproduction/fertility data between control and treated animals.'' The exposure pattern considered in this final rule is that of seed-treatment only and at a low percent in the formulation. Due to the expected low oral toxicity, and considering the low potential for exposure, a safety factor analysis has not been used to assess the risk of FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative. For the same reasons, the additional tenfold safety factor for the protection of infants and children is unnecessary.

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Based on the available toxicity data, EPA believes that FD&C Blue No. 1, PEG derivative and FD&C Blue No. 1, methyl-PEG derivative are chemicals of lower oral toxicity, and that exposure to residues from these pesticide chemicals under reasonably forseeable circumstances will pose no appreciable risk to human health. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of FD&C Blue No. 1, PEG derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-PEG derivative (CAS Reg. No. 9079–34–9). EPA finds that establishing exemptions from the requirement of a tolerance for FD&C Blue No. 1, PEG derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-PEG derivative (CAS Reg. No. 9079–34–9) will be safe for the general population including infants and children.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect * * * '' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing FD&C Blue No. 1, PEG derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-PEG derivative (CAS Reg. No. 9079–34–9) for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for FD&C Blue No. 1, PEG derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-PEG derivative (CAS Reg. No. 9079–34–9)

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for FD&C Blue No. 1, PEG derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-PEG derivative (CAS Reg. No. 9079–34–9) nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Accordingly, two exemptions from the requirement for a tolerance are established for FD&C Blue No. 1, polyethylene glycol derivative (CAS Reg. No. 9079–33–8) and FD&C Blue No. 1, methyl-polyethylene glycol derivative (CAS Reg. No. 9079–34–9). These exemptions are limited to seed treatment only, the concentration is not to exceed 5% of the formulated pesticide product, and number average molecular weight must be greater than 1,000 amu.

XI. 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 FFDCA 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 EPA–HQ–OPP–2005–0486 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 June 12, 2006.

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 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). 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 XI.A., 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 EPA–HQ–OPP–2005–0486, 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**. 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. 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.

XIII. 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 180

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

Dated: March 27, 2006.

Lois Rossi,

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. 321(q), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
FD&C Blue No. 1, methyl-polyethylene glycol derivative (CAS Reg. No. 9079–34–9).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent
FD&C Blue No. 1, polyethylene glycol derivative (CAS Reg. No. 9079–33–8).	For seed treatment use only; Number average molecular weight (in amu) is greater than 1,000; Not to exceed 5% of the formulated pesticide product.	Dye, coloring agent
* * *	* *	* *

[FR Doc. 06–3307 Filed 4–11–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0212; FRL–7765–4]

Emamectin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of emamectin and its metabolites in or on pome fruit (crop group 11). It also revises the combined residues of emamectin and its metabolites in or on various livestock commodities. Syngenta Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 12, 2006. Objections and requests for hearings must be received on or before June 12, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0212. All documents in the docket are listed on the *www.regulations.gov* website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) 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: Thomas Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), 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