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.

■ 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), 346(a) and 371.

■ 2. Section 180.570 is amended by revising paragraph (a)(2) to read as follows:

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) * * *

(2) Tolerances are established for the residues of isoxadifen-ethyl (3-isoxazolecarboxylic acid, 4,5-dihydro-5,5-diphenyl-, ethyl ester (CAS No. 163520–33–0)), and its metabolites 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benezenepropanenitrile when used as an inert ingredient (safener) in or on the following raw agricultural commodities, when applied at an annual application rate of 0.17 pounds isoxadifen-ethyl/acre.

Commodity	Parts per million
Rice, grain	0.10
Rice, hulls	0.50
Rice, straw	0.25

* * * * *

Dated: May 11, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 04–11561 Filed 5–25–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0056; FRL–7357–6]

Ultramarine Blue; 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 ultramarine blue when used as an inert ingredient in pesticide products. Holliday Pigments Limited 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 ultramarine blue.

DATES: This regulation is effective May 26, 2004. Objections and requests for hearings must be received on or before July 26, 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 ID number OPP–2004–0056. 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., Confidential Business Information (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, 1921 Jefferson Davis Hwy., 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: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0371; e-mail address: *parker.james@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 March 12, 2003 (68 FR 11843) (FRL–7295–3), 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 (3E6549) by Holliday Pigments Limited, Morley Street, Hull, East Yorkshire, England, HU88DN. That notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ultramarine blue, which is also known as C.I. Pigment Blue 29 (CAS Reg. No. 57455–37–5). 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 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 ploymers 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 ultramarine blue are discussed in this unit. Ultramarines are inorganic pigments that are used as dyes. The color of ultramarine (blue, pink, green, red, or violet) is determined by the ratios of the materials used to manufacture the ultramarine pigment.

Ultramarine blue is the manufactured or synthetic form of naturally occurring Lapis Lazuli. It was first manufactured in the early 1800s. The pigment is a complex sulfurized sodium aluminum silicate material having an approximate chemical formula of $Na_7Al_6Si_6O_{24}S_3$. Ultramarine blue is obtained by calcining (thoroughly roasting or burning in the presence of oxygen) a mixture of kaolin, sulfur, sodium carbonate, and a source of carbon at temperatures above 700 °C. The material obtained from this process is crushed, washed, purified, and ground.

Ultramarine blue is known to form a rigid tetrahedra alumino-silicate framework. Ultramarine blue is insoluble in water and organic solvents. Ultramarine blue is stable in alkali (pH 7 or greater) environments but decomposes and releases hydrogen sulfide in acidic environments. When used as a dye, it is non-migratory and bleed-resistant, having excellent light fastness and heat stability.

A. Toxicology Studies

The information available to the Agency consisted of detailed information concerning various pre-1981 studies conducted using ultramarine blue. The summaries provided sufficient detail for Agency evaluation. The available information consisted of the following:

- The acute oral lethal dose $(LD)_{50}$ for ultramarine blue is equal to or greater than 10 grams/kilogram in both rats and mice.
- Ultramarine blue was found to be a non-sensitizer in guinea pigs and non-irritating in rabbits.
- In a short-term (15–day) study, mice were fed ultramarine blue at dose levels of 10,000 milligrams/kilogram/day (mg/kg/day) which resulted in no physiological changes or deaths.
- In a 90–day feeding study of rats and mice to ultramarine blue at levels up to 10,000 mg/kg/day, there were no adverse effects.
- In another 90–day feeding studying, rats were fed 100, 1,000, 10,000, and 100,000 parts per million (ppm) (equivalent to 0.01, 0.1, 1, or 10% of the diet) ultramarine blue, which showed inflammation of the GI (gastrointestinal) tract and the presence of siliceous stones in kidney and bladder at all dose levels were observed. Histologically, no pathological effects were observed in rats after ingestion of 100 or 1,000 ppm ultramarine blue. At higher concentrations, 10,000 and 100,000 ppm, there were increased excretion of silica and sodium, and pathological effects in the kidneys, stomach, intestine and bladder which could be associated with high and prolonged intake of siliceous earth.
- A developmental toxicity study showed no maternal deaths at any of the administered doses (0, 100, 1,000, 10,000, or 100,000 ppm which would be equivalent to 0, 0.01, 0.1, 1, or 10% of the diet). Histologically, no pathological effects were observed at 100 or 1,000 ppm. At higher concentrations (10,000 and 100,000 ppm), there were pathological effects in the kidneys, stomach, intestine and bladder which could be associated with high and prolonged intake of siliceous earth. There was no significant difference in litter size, fetal weights, or resorptions between controls and dose level groups. No malformations were observed in controls or the highest dose group (100,000 ppm). At the 100, 1,000, and 10,000 ppm dose groups, malformations in the hind limbs were observed at a ratio of 2/177, 2/146, and 1/159 fetuses, respectively. These malformations are not statistically significant. In both cases where 2 pups had malformations, they were from the same mother.
- Ultramarine blue was also shown to be non-mutagenic (via Ames assay) using two strains each of *Salmonella typhimurium* and *Escherichia coli.*

Taken together, all of the studies indicate that ultramarine blue is of low or no toxicological concern. This is consistent with the fact that ultramarine blue is insoluble; therefore, it is likely that ultramarine blue would be poorly absorbed by any route. The only effect of concern occurred in those groups of animals that were fed a diet that contained 1% or 10% ultramarine blue. The effects that occurred are consistent with those of the body's being over-whelmed by being fed large amounts of a siliceous earth material, which describes ultramarine blue, a sulfurized sodium aluminum silicate.

B. FDA Evaluation

Ultramarine blue is approved by the Food and Drug Administration as a color additive in cosmetics (21 CFR 73.2725), food contact materials (21 CFR 178.3297), and salts intended for animal feed (21 CFR 73.50) when used in

accordance with the following conditions.

1. *Cosmetics.* Ultramarine pigments including ultramarine blue may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye. These pigments are exempt from certification.

2. *Food contact materials.* Ultramarine blue can be used as ''colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.'' In this context ''colorant means a dye, pigment, or other substance that is used to impart color or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye.''

3. *Animal feeds.* Ultramarine blue can be used to color salt intended for ''animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5% by weight of the salt.'' Ultramarine blue is exempt from certification.

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).

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.

Ultramarine blue has been used world-wide for many years as a colorant. It is used to color food-contact plastics and rubber (packaging materials), toys, cosmetics including eye shadows and eye pencils, wallpaper, paints including children's fingerpaints, modeling clays, tile, cement, animal eartags, and salt intended for animal feed. Given its use as a colorant the amount of ultramarine blue that would be incorporated into any product is limited by the need for a certain shade or hue of blue.

A. Dietary Exposure

1. *Food.* Due to the insolubility of ultramarine blue, it is not likely to be absorbed by any route. The available toxicity information indicates that ultramarine blue is of low or no toxicological concern.

2. *Drinking water exposure.* Ultramarine blue is likely to absorb tightly to soil and not migrate to bodies of water. Due to the insolubility of ultramarine blue, it is highly unlikely that it would be found in drinking water.

B. Other Non-Occupational Exposure

Ultramarine blue has many non-food uses including use in: Food-contact plastics and rubber (packaging materials), toys, cosmetics including eye shadows and eye pencils, wallpaper, paints including children's fingerpaints, modeling clays, tile, cement, animal eartags, and salt intended for animal feed.

VI. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.'' 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 as to ultramarine blue and any other substances and ultramarine blue does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ultramarine blue has 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. Additional 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. In a developmental toxicity study, female rats were fed ultramarine blue before and during pregnancy which resulted in no statistically significant malformations and no difference between fetuses in the control and highest dose group. Due to the lack of absorption by all routes of exposure and the expected low toxicity of ultramarine blue, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VIII. Determination of Safety

The available information indicates that ultramarine blue is insoluble in water and is not readily absorbed by any route of exposure. The only effects noted in any of the studies were effects consistent to those of other siliceous earth materials. The available toxicity information indicates that ultramarine blue is of low or no toxicological concern. Additionally, given its use as a colorant, the amount of ultramarine blue that would be incorporated into any pesticide product is limited by the need for a certain shade or hue of blue. Therefore, EPA concludes that use of ultramarine blue in pesticide products as a colorant is not likely to pose a dietary risk under reasonably foreseeable circumstances. There is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to residues of ultramarine blue.

IX. Other Considerations

A. 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.

B. Existing Exemptions

There is an existing tolerance exemption in 40 CFR 180.930, formerly 180.1001(e), for ultramarine blue when used as a dye in animal ear tags.

C. International Tolerances

The Agency is not aware of any country requiring a tolerance for ultramarine nor have any CODEX maximum residue levels been established for any food crops at this time.

D. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL–6807–8)), to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification. Given the available information which indicates that ultramarine blue is insoluble in water and is not readily absorbed by any route of exposure, ultramarine blue (CAS Reg. No. 57455–37–5) is to be classified as a List 4A inert ingredient.

X. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of ultramarine blue (CAS Reg. No. 57455–37–5). Accordingly, EPA finds that exempting ultramarine blue from the requirement of a tolerance will be safe.

Since the tolerance exemption is established under 40 CFR 180.950, the existing tolerance exemption in 40 CFR 180.930 is a duplication, and will be removed.

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. EPA's 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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–2004–0056 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 July 26, 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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0056, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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).

XII. Statutory and Executive Order Reviews

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). 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 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. 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 FFDCA section 408(n)(4). 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.

■ 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 180.950 is amended by adding alphabetically to the table in paragraph (e) the following insert ingredient to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredient.

(e) * * *

Chemical Name	CAS No.
* * * * *	
Ultramarine blue (C.I. Pigment Blue 29)	57455–37–5
* * * * *	

* * * * *

§ 180.930 [Amended]

■ 3. Section 180.930 is amended by removing from the table the entry for ultramarine blue.

Dated: May 14, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 04–11672 Filed 5–25–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 25, 63 and 64

[DA 04–671]

International Bureau Filing System (IBFS)

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (FCC) codifies the use of the International Bureau Filing System (IBFS) as an official method of filing applications related to satellite and international telecommunications services with the Commission. In addition, this document modifies the Commission Rules to reflect mandatory electronic filing