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List of Subjects

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

Dated: May 14, 2004.

James Jones,
Director, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0090; FRL-7348-1]

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of imidacloprid, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in or on blueberry. Interregional Research Project Number 4 (IR-4) 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 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-2004-0090. 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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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 (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 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.gov/opptsfrs/home/guidelin.htm>.

II. Background and Statutory Findings

In the **Federal Register** of February 5, 2003 (68 FR 5880) (FRL-7287-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1E6268, 1E6254, 1E6237, 1E6225, 0E6203, 2E6403, 2E6406, 2E6409, 2E6417, 2E6421, 2E6435, 2E6414, 2E6458, and 2E6506) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Bayer CropScience, the registrant. One comment was received in response to the notice of filing of February 5, 2003, from an individual who requested that information about pesticide tolerances be available in grocery stores next to the food labels.

Pursuant to section 408(o), the Consumer Right to Know provision of the FFDCA as amended by FQPA, the Agency distributes information on the risks and benefits of pesticide chemical residues in or on food to large retail grocers for public display. Copies of this EPA brochure entitled, “Pesticides and Food: What You and Your Family Need to Know” (Publication No. 735-F-98-00) may be obtained at no cost (<http://www.epa.gov/pesticides/food/>) or viewed in its entirety at http://www.pueblo.gsa.gov/cic_text/food/pesticides-andfood/food.html.

The petitions requested that 40 CFR 180.472 be amended by establishing

tolerances for combined residues of the insecticide imidacloprid, (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine), and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on blueberry at 3.5 part per million (ppm), in addition to a variety of raw agricultural commodities previously established in the **Federal Register** of June 13, 2003 (68 FR 35303) (FRL-7310-8). EPA received objections to a time-limited tolerance it established for residues of imidacloprid on blueberries in connection with an emergency exemption for such use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* published in the **Federal Register** of January 18, 2002 (67 FR 2580) (FRL-6817-6). The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. NRDC's objections raise complex legal, scientific, policy, and factual matters. Elsewhere in today's **Federal Register** EPA has denied NRDC's objections to the now-expired blueberry tolerance as moot. Because NRDC's objections are relevant to this rulemaking establishing a new tolerance on blueberries, EPA has treated NRDC's objections as comments on the petition to re-establish the blueberry tolerance and taken them into account in the current action. EPA's detailed response to NRDC is included in the document denying its objections. Individual commodity tolerances for other members of the bushberry subgroup (currant, elderberry, gooseberry and huckleberry) were established in the **Federal Register** of June 13, 2003 (68 FR 35303).

Section 408(b)(2)(A)(i) of 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 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 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 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 FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of imidacloprid, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent on blueberry at 3.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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 imidacloprid as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in Unit III.A. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303).

B. Toxicological Endpoints

A summary of the toxicological endpoints for imidacloprid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 13, 2003 (68 FR 35303). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**. Acute, chronic, and short-term aggregate risk assessments are

appropriate for imidacloprid and were performed by EPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.472) for the combined residues of imidacloprid, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from imidacloprid in a variety of raw agricultural commodities. Acute and chronic exposure assessments conducted by EPA to assess dietary exposures from imidacloprid are discussed in Unit III.C.1. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**. The proposed tolerance for blueberry at 3.5 ppm was included in the imidacloprid risk assessment of June 13, 2003.

2. *Dietary exposure from drinking water.* FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Groundwater (SCI-GROW) model estimated environmental concentrations (EECs) for imidacloprid for acute and chronic exposures are discussed in Unit III.C.2. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**.

3. *From non-dietary exposure.* Imidacloprid is currently registered for use on the following residential non-dietary sites: Granular products for application to lawns and ornamental plants; ready-to-use spray for application to flowers, shrubs and house plants; plant spikes for application to indoor and outdoor residential potted plants; ready-to-use potting medium for indoor and outdoor plant containers; liquid concentrate for application to lawns, trees, shrubs and flowers; and ready-to-use liquid for directed spot application to cats and dogs. In addition, there are numerous registered products intended for use by commercial applicators to residential sites. These include gel baits for cockroach control; products intended for commercial ornamental, lawn and turf pest control; products for ant control; and products used as

preservatives for wood products, building materials, textiles and plastics. The non-dietary exposure assessment is discussed in the Final Rule on Imidacloprid Pesticide Tolerance published in Unit III.C.3. of the **Federal Register** of June 13, 2003 (68 FR 35303). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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."

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 imidacloprid and any other substances and imidacloprid 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 imidacloprid 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 web site at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In

applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* These issues are discussed in Unit III.D.2. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**.

3. *Conclusion.* There is a complete toxicity data base for imidacloprid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 3X. For further discussion, see Unit III.D.3. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303) (FRL-7310-8). These issues are also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates drinking water levels of concerns (DWLOCs) which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (milligrams/kilogram/day) = chronic population adjusted dose - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values

as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kilogram (kg) (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* The acute risk assessment for imidacloprid is discussed in Unit III.E.1. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303).

2. *Chronic risk.* The chronic risk assessment for imidacloprid is discussed in Unit III.E.2. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303).

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Imidacloprid is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for imidacloprid. The short-term risk assessment for Imidacloprid is discussed in Unit III.E.3. of the Final Rule on Imidacloprid Pesticide Tolerance published in the **Federal Register** of June 13, 2003 (68 FR 35303).

4. *Aggregate cancer risk for U.S. population.* There is no evidence of carcinogenicity to humans based on carcinogenicity studies in male and female rats and mice. The Agency concludes that pesticidal uses of

imidacloprid are not likely to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to imidacloprid residues. EPA's safety finding is also discussed in EPA's response to the concerns voiced by NRDC in its objections to the prior imidacloprid blueberry tolerance. EPA's response is published elsewhere in today's **Federal Register**.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of imidacloprid residues of concern in plant (Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200) and livestock commodities (Bayer GC/MS Method 00191). These methods have undergone successful EPA petition method validations (PMVs), and the registrant has fulfilled the remaining requirements for additional raw data, method validation, independent laboratory validation (ILV), and an acceptable confirmatory method (high performance liquid chromatography/ultraviolet (HPLC/UV) Method 00357). The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for imidacloprid in/on blueberries.

V. Conclusion

Therefore, the tolerance is established for combined residues of imidacloprid, (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine), and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid in or on blueberry at 3.5 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA

by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 FFDCA, as was provided in the old sections 408 and 409 of 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-2004-0090 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 VI.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-2004-0090, 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 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).

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.

■ 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 180.472 is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million	Revocation/Expiration Date
* * *	* * *	*
Blueberry	* * *	*
	3.5	None

* * *

Dated: May 11, 2004.

Lois Rossi,

*Director, Registration Division, Office of
Pesticide Programs.*

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