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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2006-0053; FRL-7766-8]

Imidacloprid; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of imidacloprid in or on oats and rye. Bayer CropScience 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 March 22, 2006. Objections and requests for hearings must be received on or before May 22, 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-2006-0053. 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, 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: Daniel Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7546; e-mail address: kenny.dan@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:

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- 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**.

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II. Background and Statutory Findings

In the **Federal Register** of January 27, 2006 (71 FR 4580) (FRL-7759-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F7020) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.472 be amended by establishing a tolerance 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 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, in or on oats, grain at 0.5 parts per million (ppm); oats, forage at 2.0 ppm; oats, hay at 6.0 ppm; oats, straw at 3.0 ppm; rye, grain at 0.5 ppm; rye, forage at 2.0 ppm; rye, hay at 6.0 ppm; and rye, straw at 3.0 ppm. In order to correct a typographical error in the original petition, the proposed tolerance levels for oats, grain and rye, grain were subsequently revised to 0.05 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

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 the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

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 on oats, grain at 0.05 ppm; oats, forage at 2.0 ppm; oats, hay at 6.0 ppm; oats, straw at 3.0 ppm; rye, grain at 0.05 ppm; rye, forage at 2.0 ppm; rye, hay at 6.0 ppm; and rye, straw at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

The proposed use for imidacloprid on oats and rye involves the registration of imidacloprid as a seed treatment. Imidacloprid is already registered as a seed treatment on barley, corn, sorghum, and wheat. Permanent tolerances for imidacloprid are established for barley, corn, sorghum, and wheat, and seed treatment residue data are available for these crops. These crops are considered to be representative commodities for the cereal grain crop group, which also includes oats and rye. After consideration of the existing data used to support the tolerances discussed above, and provided that the proposed oat and rye seed treatment application rates are similar to the application rates used in the barley, corn, sorghum, and wheat residue studies, EPA concluded that the translation of this data to support tolerances on oats and rye is acceptable and that the highest residues be used for estimation of residues in/on oat and rye.

On June 13, 2003 the Agency published a Final Rule (68 FR 35303, FRL-7310-8) establishing tolerances for residues of imidacloprid in or on acerola; artichoke, globe; avocado; banana (import); canistel; corn, pop, grain; corn, pop, stover; cranberry; currant; elderberry; feijoa; fruit, stone, group 12; gooseberry; huckleberry; guava; jaboticaba; juneberry; lingonberry; longan; lychee; mango; mustard, seed; okra; papaya; passionfruit; persimmon; pulasan; rambutan; salal; sapodilla; sapote, black; sapote, mamey; Spanish lime; star apple; starfruit; strawberry; vegetable, leaves of root and tuber, group 2; vegetable, legume, group 6, except soybean; vegetable, root and tuber, group 1, except sugar beet; watercress; wax jambu. When the Agency conducted the risk assessments in support of this tolerance action, it

assumed that imidacloprid residues would be present on oats and rye (including grain, forage, hay, and straw) as well as on all foods covered by the proposed and established tolerances. Residues on oats and rye were included because there were previously established indirect or inadvertent tolerances for imidacloprid in or on cereal grains, including oats and rye. In assuming the dietary risk from the consumption of treated oats and rye, the most conservative assumptions were used (i.e., 100% of oats and rye crops were treated and residues on the treated commodities were at tolerance levels). Therefore, establishing permanent tolerances in or on oat and rye commodities will not change the most recent estimated aggregate risks resulting from use of imidacloprid, as discussed in the June 13, 2003 **Federal Register**. Refer to the June 13, 2003 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

Based on the risk assessments discussed in the final rule published in the **Federal Register** of June 13, 2003, 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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Bayer Gas Chromatography/Mass Spectrometry (GC/MS) Method 00200 in plant commodities, and Bayer GC/MS Method 00191 in livestock commodities) is available to enforce the tolerance expression. The method 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 maximum residue limits for imidacloprid in or on oats or rye.

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 1-[(6-chloro-3-pyridinyl)methyl]-N-

nitro-2-imidazolidinimine, in or on oats, grain at 0.05 ppm; oats, forage at 2.0 ppm; oats, hay at 6.0 ppm; oats, straw at 3.0 ppm; rye, grain at 0.05 ppm; rye, forage at 2.0 ppm; rye, hay at 6.0 ppm; and rye, straw at 3.0 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 EPA-HQ-OPP-2006-0053 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 May 22, 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 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 **ADDRESSES**. Mail your copies, identified by docket ID number EPA-HQ-OPP-2006-0053, to: Public Information and Records Integrity Branch, Information Technology and Resource Management 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).

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 13, 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 180.472 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a)* * *

| Commodity | Parts per million |
|--------------------|-------------------|
| * * * * | * |
| Oats, forage | a2.0 |
| Oats, grain | 0.05 |
| Oats, hay | 6.0 |
| Oats, straw | 3.0 |
| * * * * | * |
| Rye, forage | 2.0 |
| Rye, grain | 0.05 |
| Rye, hay | 6.0 |
| Rye, straw | 3.0 |

[FR Doc. 06-2712 Filed 3-21-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0168; FRL-7768-3]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of hexythiazox (trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent) in or on grape; citrus fruit, crop group 10 (CA, AZ, TX only); citrus, oil; citrus, dried pulp; fruit, pome, group 11; apple, wet pomace; and cattle, sheep, goat, and horse meat byproducts.

DATES: This regulation is effective March 22, 2006. Objections and requests for hearings must be received on or before May 22, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2006-0168. All documents in the docket are listed on the www.regulations.gov web site. 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: Olga Odiott, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9369; e-mail address: odiott.olga@epa.gov.

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II. Background and Statutory Findings

In the **Federal Register** of December 30, 2005 (70 FR 77363-77371) (FRL-7752-1), EPA issued a proposed rule pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), proposing that 40 CFR Part 180 be amended by establishing tolerances for combined residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent), in or on grape at 0.75 ppm; citrus fruit, crop group 10 (CA, AZ, TX only) at 0.35 ppm; citrus, oil at 0.90 ppm; citrus, dried pulp at 1.5 ppm; fruit, pome, group 11 at 1.7 ppm; apple, wet pomace at 2.5 ppm; and cattle, sheep, goat, and horse meat byproducts at 0.12 ppm. That notice followed a notice of filing (**Federal Register** of June 1, 2005, 70 FR, 31455-31459, FRL-7711-8) of a pesticide petition (PP 3F6569) by Gowan Company, the registrant.

There was one comment received on the proposal. The commenter, B. Sachua, requested that a zero tolerance be set for hexythiazox based on the commenter's generalized criticisms of EPA's risk assessment process and EPA's alleged "poor record on keeping tabs of incident reports of negative reports from use of pesticides. . . ." EPA has responded to B. Sachua's generalized comments on several occasions. (See the **Federal Register** of