

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 522.970, revise paragraph (b)(2) and add paragraph (b)(4) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(2) See Nos. 057561, 059130, and 061623 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

* * * * *

(4) See No. 055529 for use as in paragraphs (e)(1) and (e)(2) of this section.

* * * * *

Dated: January 4, 2008.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E8-699 Filed 1-15-08; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0733; FRL-8348-1]

Acetamidrid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamidrid in or on bushberry subgroup 13-07B; caneberry subgroup 13-07A; low growing berry subgroup 13-07G; onion, bulb, subgroup 3-07A; and onion, green, subgroup 3-07B. Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2008. Objections and requests for hearings must be received on or before March 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION.**

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0733. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced

Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide 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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C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0733 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 as required by 40 CFR part 178 on or before March 17, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES.** Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0733, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petition for Tolerance

In the **Federal Register** of September 22, 2006 (71 FR 55468) (FRL-8091-9), 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 6F7051) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on bulb vegetables crop group 3 at 3 ppm; edible podded legume vegetables, crop subgroup 6a at 0.5 ppm; succulent shelled peas and beans, crop subgroup 6b, at 0.5 ppm; and berries, crop group 13 at 1 ppm. That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA-HQ-OPP-2006-0733, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of April 2, 2007 (72 FR 16352) (FRL-8119-2), 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 6E7163) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridgeberry at 0.60 parts per million (ppm). That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA-HQ-OPP-2007-0105, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of November 28, 2007 (72 FR 67256) (FRL-8340-6), EPA issued a final rule establishing tolerances for residues of acetamiprid in/on edible-podded legume vegetables and succulent shelled peas and beans but deferred to a later date the decision on the petitioned-for tolerances on the bulb vegetable and berry commodities requested in these petitions. EPA is establishing the bulb vegetable and berry tolerances at this time but has modified the commodity terms and most of the proposed tolerance levels. The reasons for these changes are explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

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. . . ." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 for the petitioned-for tolerance for residues of acetamiprid on bushberry subgroup 13-07B at 1.6 ppm; caneberry subgroup 13-07A at 1.6 ppm; low growing berry subgroup 13-07G at 0.60 ppm; onion, bulb, subgroup 3-07A at 0.02 ppm; and onion, green, subgroup 3-07B at 4.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

As noted above, on November 28, 2007, EPA issued a final rule in the **Federal Register** establishing tolerances for residues of acetamiprid in/on edible-podded legume vegetables and

succulent shelled peas and beans. When the Agency conducted the risk assessments in support of this tolerance action it assumed that acetamiprid residues would be present on bulb vegetables and commodities in the aforementioned berry subgroups as well as on all foods covered by the proposed and established tolerances. Therefore, establishing the bulb vegetable and berry tolerances will not change the most recent estimated aggregate risks resulting from use of acetamiprid, as discussed in the November 28, 2007 **Federal Register**. Refer to the November 28, 2007 **Federal Register** document (72 FR 67256) (FRL-8340-6), available at <http://www.regulations.gov>, 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 November 28, 2007 (72 FR 67256) (FRL-8340-6), 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 acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate residue analytical methods gas chromatography/electron-capture detection (GC/ECD) and high-performance liquid chromatography/ultraviolet detector (HPLC/UV) are available for the enforcement of established and new tolerances for plant and animal commodities. These 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 Codex, Canadian or Mexican MRLs established for acetamiprid on the commodities associated with these petitions.

V. Conclusion

The registrant, Nippon Soda Co., Ltd., petitioned for tolerances on bulb vegetables group 3 and berries group 13 as those crop groups were defined at the time of the petition. IR-4 also petitioned for individual tolerances on strawberry, bearberry, bilberry, lowbush blueberry, cloudberry, cranberry, lingonberry, muntries and partridgeberry (PP 6E7163). In the **Federal Register** of

December 7, 2007 (72 FR 69150) (FRL-8340-6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised bulb vegetables group 3 and berries group 13. Changes to crop group 3 (bulb vegetables) included adding new commodities, creating subgroups for bulb and green onions, and changing the name of one of the representative commodities from "onion, dry bulb" to "onion, bulb". Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a low growing berry subgroup consisting of the commodities requested in PP 6E7163 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL-8126-1) that, for existing petitions for which a notice of filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing tolerances on bushberry subgroup 13-07B; caneberry subgroup 13-07A; low growing berry subgroup 13-07G; onion, bulb, subgroup 3-07A; and onion, green, subgroup 3-07B. The low growing berry subgroup 13-07G consists of the berries for which tolerances were requested in PP 6E7163. The other subgroups include the remaining berries and bulb vegetables for which tolerances were requested in PP 6F7051.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because (1) although the new crop groups/subgroups include several new commodities, the added commodities are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk; and acetamiprid exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action; and (2) the representative commodities for the revised crop groups/subgroups have not changed.

Based upon review of the data supporting PP 6F7051, EPA has also revised the tolerance levels for bushberry subgroup 13-07B and caneberry subgroup 13-07A to 1.6 ppm; onion, bulb, subgroup 3-07A to 0.02 ppm; and onion, green, subgroup 3-07B to 4.5 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field

Trial Data Standard Operating Procedure (SOP).

Therefore, tolerances are established for residues of acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on bushberry subgroup 13-07B at 1.6 ppm; caneberry subgroup 13-07A at 1.6 ppm; low growing berry subgroup 13-07G at 0.60 ppm; onion, bulb, subgroup 3-07A at 0.02 ppm; and onion, green, subgroup 3-07B at 4.5 ppm.

VI. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between

the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: January 8, 2008.

Donald R. Stubbs,

Acting 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 180.578 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

180.578 Acetamiprid; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Berry, low growing subgroups 13-07G	0.60
Bushberry subgroup 13-07B	1.6
Caneberry subgroup 13-07A	1.6
Onion, bulb, subgroup 3-07A	0.02
Onion, green, subgroup 3-07B	4.5

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[FR Doc. E8-683 Filed 1-15-08; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0461; FRL-8346-6]

Mandipropamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide in or on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; okra; vegetable, leafy except brassica, group 4; vegetable, tuberous and corm, subgroup 1C; grape; grape, raisin; onion, dry bulb; onion, green; and potato, wet peel. Syngenta Crop Protection Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 16, 2008. Objections and requests for hearings must be received on or before March 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0461. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in the regulations.gov. Although listed in the

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FOR FURTHER INFORMATION CONTACT: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5611; e-mail address: kearns.rosemary@epa.gov.

SUPPLEMENTARY INFORMATION:

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