Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (32)(e), of Commandant Instruction M16475.lC, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 117 Bridges

Temporary Regulations.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—[AMENDED]

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From 7:25 a.m. through 8:15 a.m. on May 21, 2000, in § 117.261, paragraphs (u) and (v) are suspended and new paragraphs (rr) and (ss) are added to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(rr) *Flagler Memorial (SR A1A) bridge, mile 1021.9 at Palm Beach.* The draw shall open on signal; except that, from 7:25 a.m. to 7:45 a.m. on May 21, 2000, the draw need not open.

(ss) *Royal Park (SR 704) bridge, mile 1022.6 at Palm Beach.* The draw shall open on signal; except that, from 7:25 a.m. to 8:15 a.m. on May 21, 2000, the draw need not open.

Dated: April 18, 2000.

T.W. Allen

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 00–10943 Filed 5–2–00; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300989; FRL–6550–9]

RIN 2070–AB78

Pyridate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyridate in or on peppermint tops, spearmint tops, Brassica, head and stem subgroup, and collards. The Interregional Research Project Number 4 and Novartis Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 3, 2000. Objections and requests for hearings, identified by docket control number OPP–300989, must be received by EPA on or before July 3, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300989 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300989. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information

and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of January 24, 2000 (65 FR 3682) (FRL–6399–6), and August 5, 1998 (63 FR 41835) (FRL–6017–1), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP) 9E6025 and 6F4754 for tolerances by the Interregional Research Project Number 4, New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, NJ 08903, and Novartis Crop Protection Inc., 18300 Greensboro, NC 27419–8300, respectively. These notices included a summary of petitions prepared by Novartis Crop Protection Inc., the registrant. There were no comments received in response to the notice of filing.

These petitions requested that 40 CFR 180.462 be amended by establishing tolerances for combined residues of the herbicide pyridate, [*O*-(6-chloro-3-phenyl-4-pyridazinyl)-*S*-octyl-carbonothioate and the metabolite CL–9673 (6-chloro-3-phenyl-pyradazine-4-ol), and conjugates of CL–9673], in or on peppermint tops and spearmint tops at 0.20, Brassica, head and stem subgroup, and collards at 0.03 parts per million (ppm).

Section 408(b)(2)(A)(i) of the 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) 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) 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 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), 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), for tolerances for combined residues of pyridate on peppermint tops and spearmint tops at 0.20 ppm, Brassica, head and stem subgroup, and collards at 0.03 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 pyridate are discussed in Unit II.A. of the Final Rule on Pyridate Pesticide Tolerance published in the **Federal Register** on October 7, 1998 (63 FR 53837) (FRL 6036–2).

B. Toxicological Endpoints

1. *Acute toxicity*. The acute dietary endpoint selected for the acute dietary risk assessment was 20 milligrams/kilogram/day (mg/kg/day) based on the subchronic (90–day) dog study with a no observed adverse effect level (NOAEL) of 20 mg/kg/day. The lowest observed adverse effect level (LOAEL) was 60 mg/kg/day based on ataxia and emesis observed within 1–3 hours of dosing beginning on the first day. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variations) was used to determine the acute Reference Dose (RfD) of 0.2 mg/kg/day. The acute Population Adjusted Dose (aPAD) is equal to the acute RfD divided by the FQPA Safety Factor. Since the FQPA Safety Factor was reduced to 1X, the aPAD is equal to the acute RfD.

2.*Chronic toxicity*. EPA has established the chronic RfD for pyridate at 0.11 mg/kg/day. This RfD is based on a NOAEL of 10.8 mg/kg/day from the chronic/carcinogenicity study in rats where decreased body weight gain was reported at the LOAEL of 67.5 mg/kg/day. This dose was supported by the results of the 3-generation reproduction toxicity study. The NOAEL was 10.8 mg/kg/day based on the reported decrease in pup weights at 67.5 mg/kg/day on postnatal day 14 and 21 in both generations. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variation) was used to determine the chronic Reference Dose (cRfD) of 0.11 mg/kg/day. The chronic Population Adjusted Dose (cPAD) is equal to the chronic RfD divided by the FQPA Safety Factor. Since the FQPA Safety Factor was reduced to 1X, the cPAD is equal to the chronic RfD.

3. *Carcinogenicity*. Pyridate is not carcinogenic in either the rat or the mouse. Therefore, no carcinogenic endpoint was selected.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.462) for the combined residues of pyridate, in or on a variety of raw agricultural commodities. Permanent tolerances are established for combined residues of pyridate, the metabolite CL–9673, and conjugates of CL–9673 in/on cabbage, corn, and peanut at 0.03 ppm. Risk assessments were conducted by EPA to assess dietary exposures from pyridate as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. Tier 1 acute dietary exposure analyses from food for pyridate were performed with the Dietary Exposure Evaluation Model (DEEM™) using published and proposed tolerance level residues and 100% crop treated (CT) for all commodities. Therefore, the acute risk was analyzed at the 95th percentile. The acute dietary risk estimates from food are less than 1% of the aPAD for the general U.S. population and all population subgroups. The results of the analyses indicate that the acute dietary risks from food associated with the existing and proposed uses of pyridate do not exceed EPA's level of concern for the U.S. population or any population subgroup.

ii. *Chronic exposure and risk*. Tier 1 chronic dietary exposure analyses from food for pyridate were performed with the DEEM™ using published and proposed tolerance level residues and

100% CT for all commodities. The chronic dietary risk from food estimates are less than 1% of the cPAD for the general U.S. population and all population subgroups. The results of the analyses indicate that the chronic dietary risks from food associated with the existing and proposed uses of pyridate do not exceed EPA's level of concern for the U.S. population or any population subgroup

2. *From drinking water*. Although pyridate does not possess the environmental fate parameters associated with a compound that could leach to ground water, the fate parameters of its degradate CL–9673 seem to indicate that it has the potential to leach to ground water especially in soils of low organic matter. In unusual conditions such as flooding, where an aerobic conditions exist in the top soil layers for up to 60 days, CL–9673 could persist and possibly leach to ground water or run off to surface water. Pyridate is not listed in the EPA Pesticides in Ground Water Database, nor is there an EPA Maximum Contaminant Level or health advisory.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI–GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water.

The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end run off scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use the estimates environmental concentration (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparisons (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in 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 from residential uses. Since DWLOCs address total aggregate exposure to pyridate, they are further discussed in the aggregate risk sections below.

EPA has calculated DWLOCs for both acute and chronic risks. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from DEEM was subtracted from the aPAD to obtain the acceptable acute exposure to pyridate in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the cPAD to obtain the acceptable chronic (non-cancer) exposure to pyridate in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

i. *Acute exposure*. Based on the GENEEC and SCI–GROW models the EECs of pyridate in drinking water for acute exposures are estimated to be 97 parts per billion (ppb) for surface water and 5 ppb for ground water.

ii.*Chronic exposure*. Based on the GENEEC and SCI–GROW models the EECs in drinking water for chronic exposures are estimated to be 25 ppb for surface water and 5 pbb for ground water.

3. *From non-dietary exposure*. There are no residential or non- occupational uses for pyridate; therefore, residential exposures are not expected.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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.''

EPA does not have, at this time, available data to determine whether pyridate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyridate 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 pyridate 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. A high-end exposure estimate from residues in food was calculated for the general U.S. population and all population subgroups. The acute dietary exposure from food for all populations subgroups (<1% aPAD) is below EPA's level of concern. The maximum EECs of pyridate in surface and ground water are less than EPA's DWLOCs for pyridate as a contribution to acute aggregate exposure (Table 1).

TABLE 1. AGGREGATE RISK ASSESSEMENT FOR ACUTE EXPOSURE

Population Subgroups	% aPAD mg/kg/day	Food Exposure mg/kg/day	SCI–GROW (ppb)	GENEEC (ppb)	DWLOC (ppb)
U.S. population (48 contiguous states)	<1	0.000151	5	97	7,000
Non-nursing infants	<1	0.000278	5	97	2,000
Children 1–6 yrs. old	<1	0.000303	5	97	2,000
Females 13+ yrs. old (nursing) (60 kg body weight assumed)	<1	0.000149	5	97	7,000
Males 13–19 yrs. old	<1	0.000141	5	97	7,000

Therefore, EPA concludes with reasonable certainty that residues of pyridate in drinking water do not contribute significantly to the aggregate acute human health risk at the present time considering the present uses and uses proposed in this action. Acute risk estimates resulting from aggregate exposure to pyridate in food and water are below EPA's level of concern for all population subgroups.

2. *Chronic risk*. Using the Tier 1 exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyridate from food will utilize <1% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is infants or children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to pyridate in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as indicated in Table 2.

TABLE 2. CHRONIC (NON-CANCER) AGGREGATE RISK ASSESSMENT

	cPAD mg/kg/day	Food Exposure mg/kg/day	SCI–GROW (ppb)	GENEEC (ppb)	DWLOC (ppb)
U.S. population (48 contiguous states)	<1	0.000048	5	25	3,900
Non-nursing infants	<1	0.000121	5	25	1,100
Children 1–6 yrs	<1	0.000114	5	25	1,100
Females 13+ (nursing)	<1	0.000046	5	25	3,900
Males 13–19 yrs.	<1	0.000057	5	25	3,900

EPA concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to pyridate residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Because there are no uses of pyridate that could result in residential exposures, the short- and intermediate-term aggregate risk assessment for pyridate takes into account exposure estimates only from dietary consumption of pyridate (food and drinking water). EPA concludes that there is a reasonable certainty that no harm will result from aggregate short- and intermediate-term exposure to pyridate residues.

4. *Aggregate cancer risk for U.S. population*. Pyridate is not carcinogenic in either the rat or the mouse, and therefore is not expected 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 from aggregate exposure to pyridate residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of pyridate, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 determines 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. The developmental toxicity study in Wistar HAN rats resulted in increased incidences of missing and ossified sternebrae and decreased fetal body weight. Maternal toxicity was characterized by a decrease in the mean body weight and food consumption and clinical signs which were indicative of neurotoxicity (ventral body position, dyspnea, sedation and loss of reaction to external stimuli). Developmental and maternal NOAELs were 165 mg/kg/day. In the developmental toxicity study in New Zealand White rabbits, no developmental effects were reported at the NOAEL of 600 mg/kg/day and maternal toxicity was characterized by decreased body weight and body weight gain, decreased food consumption, increased incidences of dried feces and increased incidences of abortion at the LOAEL of 600 mg/kg/day. The maternal NOAEL was 300 mg/kg/day.

iii. *Reproductive toxicity study*. The 3–generation reproduction study in rats resulted in a decrease in maternal body weight gain and a decrease in pup weight gain at postnatal days 14 and 21. Both parental and offspring toxicity were reported at the high dose of 67.5 mg/kg/day.

iv. *Prenatal and postnatal sensitivity*. The data demonstrated no indication of increased sensitivity *in utero* and postnatal exposure to pyridate.

v. *Conclusion*. There is a complete toxicity data base for pyridate, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency believes that reliable data support using the standard 100-fold safety factor for assessing sensitivity to residues of pyridate and that an additional 10-fold margin of safety for infants and children is not warranted.

2. *Acute risk*. As presented in Table 1 above, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyridate from food will utilize <1% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD,

because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to pyridate in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk*. Because there are no uses of pyridate that could result in residential exposures, the acute aggregate risk assessment for pyridate takes into account exposure estimates only from dietary consumption of pyridate (food and drinking water).

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyridate residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants and ruminant animals is adequately understood. The residue of concern in plants consist of pyridate, the metabolite CL–9673, and conjugates of CL–9673, all expressed as pyridate.

B. Analytical Enforcement Methodology

The analytical method is a total residue procedure using ultraviolet-high pressure liquid chromotography. The method has undergone validation in EPA laboratories and is suitable to enforce tolerances.

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of pyridate in the subject crops. Therefore, a compatibility issue is not relevant to the proposed tolerances.

V. Conclusion

Therefore, the tolerance is established for combined residues of pyridate and its metabolite CL–9673 and conjugates of CL–9673, in or on peppermint tops and spearmint tops at 0.20 ppm, Brassica, head and stem subgroup, and collards at 0.03 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA 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 control number OPP–300989 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 3, 2000.

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 (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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.2. Mail your copies, identified by docket control number OPP–300989, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 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.2. 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 file format 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. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to the petitions 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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: April 17, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[Amended]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. In § 180.462, by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.462 Pyridate; tolerance for residues.

* * * * *

(a) * * *

Commodity	Parts per million
Brassica, head and stem subgroup	0.03
* * * * *	
Collards	0.03
* * * * *	
Peppermint tops	0.20
* * * * *	
Spearmint tops	0.20

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300996; FRL–6554–8]

RIN 2070–AB78

Fludioxonil; Re-Establishment of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for residues of the fungicide fludioxonil in or on apricots, nectarines, peaches, and plums at 5.0 part per million (ppm) for an additional 2-year period. These tolerances will expire and are revoked on December 31, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on apricots, nectarines, peaches, and plums. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under