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 M1647.1C, 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

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; 40 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 Monday, May 21, 2000, the draw shall not open.

§ 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.


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.

ADDITIONAL INFORMATION: 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 Section 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: Shaia 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.shaia@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:

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS codes</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>111</td>
<td>Crop production</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>Animal production</td>
</tr>
<tr>
<td></td>
<td>311</td>
<td>Food manufacturing</td>
</tr>
<tr>
<td></td>
<td>32532</td>
<td>Pesticide manufacturing</td>
</tr>
</tbody>
</table>

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 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 www.epa.gov/fedrgrstr/.

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 ppm, 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
risk assessment was based on the
subchronic (90–day) dog study with a
no observed adverse effect level
(NOEL) 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 variation) was used to
determine the chronic Reference
Dose (RfD) of 0.11 mg/kg/day. The
chronic Population Adjusted Dose
cPAD) is equal to the chronic RID
divided by the FQPA Safety Factor.
Since the FQPA Safety Factor was
reduced to 1X, the cPAD is equal to the
chronic RID.

2. Chronic toxicity. EPA has
established the chronic RID for pyridate
at 0.11 mg/kg/day. This RID 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.
EPA has established the chronic RID
for 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 general 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 degrade 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 (GENECC) 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 GENECC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment. 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 GENECC 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 GENECC and SCI-GROW models the EECs in drinking water for chronic exposures are estimated to be 25 ppb for surface water and 5 ppb 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>
<thead>
<tr>
<th>Population Subgroups</th>
<th>% aPAD</th>
<th>Food Exposure</th>
<th>SCI-GROW</th>
<th>GENECC</th>
<th>DWLOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. population (48 contiguous states)</td>
<td>&lt;1</td>
<td>0.000151</td>
<td>5</td>
<td>97</td>
<td>7,000</td>
</tr>
<tr>
<td>Non-nursing infants</td>
<td>&lt;1</td>
<td>0.000278</td>
<td>5</td>
<td>97</td>
<td>2,000</td>
</tr>
<tr>
<td>Children 1–6 yrs. old</td>
<td>&lt;1</td>
<td>0.000303</td>
<td>5</td>
<td>97</td>
<td>2,000</td>
</tr>
<tr>
<td>Females 13+ yrs. old (nursing) (60 kg body weight assumed)</td>
<td>&lt;1</td>
<td>0.000149</td>
<td>5</td>
<td>97</td>
<td>7,000</td>
</tr>
<tr>
<td>Males 13–19 yrs. old</td>
<td>&lt;1</td>
<td>0.000141</td>
<td>5</td>
<td>97</td>
<td>7,000</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>U.S. population (48 contiguous states)</th>
<th>cPAD mg/kg/day</th>
<th>Food Exposure mg/kg/day</th>
<th>SCI–GROW (ppb)</th>
<th>GENEEC (ppb)</th>
<th>DWLOC (ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-nursing infants</td>
<td>&lt;1</td>
<td>0.000048</td>
<td>5</td>
<td>25</td>
<td>3.900</td>
</tr>
<tr>
<td>Children 1–6 yrs</td>
<td>&lt;1</td>
<td>0.00121</td>
<td>5</td>
<td>25</td>
<td>1.100</td>
</tr>
<tr>
<td>Females 13+ (nursing)</td>
<td>&lt;1</td>
<td>0.00114</td>
<td>5</td>
<td>25</td>
<td>1.100</td>
</tr>
<tr>
<td>Males 13–19 yrs.</td>
<td>&lt;1</td>
<td>0.000046</td>
<td>5</td>
<td>25</td>
<td>3.900</td>
</tr>
</tbody>
</table>

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 chromatography. 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 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 178.27). 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.

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.”

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 13045, 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 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.


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) * * * *

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brassica, head and stem sub-group</td>
<td>0.03</td>
</tr>
<tr>
<td>Collards</td>
<td>0.03</td>
</tr>
<tr>
<td>Peppermint tops</td>
<td>0.20</td>
</tr>
<tr>
<td>Spearmint tops</td>
<td>0.20</td>
</tr>
</tbody>
</table>

[FR Doc. 00–10813 Filed 5–2–00; 8:45 am]
BILLING CODE 6560–50–F

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