on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. 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 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 the rule in the **Federal Register**. This 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: August 11, 1999.

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), 346(a) and 371.

§ 180.353 [Amended]

2. In § 180.353, by amending the table in paragraph (b) by changing the date for the two commodities ''red beet roots'' and ''red beet tops'' from ''8/31/99'' to read ''12/31/00''.

[FR Doc. 99–21831 Filed 8–24–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300905; FRL–6094–7]

RIN 2070–AB78

Pyridate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol in or on peppermint tops (leaves and stems) and spearmint tops (leaves and stems). 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 peppermint and spearmint. This regulation establishes a maximum permissible level for residues of pyridate in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective August 25, 1999. Objections and requests for hearings must be received by EPA on or before October 25, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300905], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300905], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300905]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 284, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, Madden.Barbara@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a,

is establishing tolerances for combined residues of the herbicide pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate, the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol, in or on peppermint tops (leaves and stems) and spearmint tops (leaves and stems) at 0.3 part per million (ppm). These tolerances will expire and are revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA 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 an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Pyridate on Peppermint and Spearmint and FFDCA Tolerances

Redroot pigweed and kochia have become serious pest concerns for Idaho, Indiana, Montana, Oregon, Washington and Wisconsin mint growers. The lack of any post-emergence chemical weed control have created an emergency situation. Currently, terbacil is the only herbicide registered for post-emergence weed control in mint, but resistance of pigweed and kochia has been well documented. Not only will the presence of these weeds result in mint yield losses but mint oil quality is adversely effected as well. EPA has authorized under FIFRA section 18 the use of pyridate on peppermint and spearmint for control of redroot pigweed and kochia in Idaho, Indiana, Montana, Oregon, Washington and Wisconsin. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of pyridate in or on peppermint and spearmint. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peppermint and spearmint after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether pyridate meets EPA's registration requirements for use on peppermint and spearmint or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of pyridate by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Idaho, Indiana, Montana, Oregon, Washington and Wisconsin to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for pyridate, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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) .

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 pyridate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-

pyridazine-4-ol on peppermint and spearmint at 0.3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyridate are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. An acute dietary reference dose (acute RfD) of 0.20 milligrams/kilograms/day (mg/kg/day) has been identified. The acute RfD is derived from the systemic no observable adverse effects level (NOAEL) of 20 mg/kg/day based on neurotoxic effects (ataxia and emesis) seen at the lowest observable adverse effects level (LOAEL) of 60 mg/kg/day in the 90–day feeding study in dogs and an uncertainty factor of 100 (10x for interspecies differences and 10x for intraspecies variations). EPA has determined that the 10x factor to account for enhanced susceptibility of infants and children, as required by FFDCA section 408(b)(2)(C), can be removed. The acute Population Adjusted Dose (aPAD) is a modification of the acute RfD to accommodate the FQPA Safety Factor. The aPAD is equal to the acute RfD divided by the FQPA Safety Factor. Therefore, since EPA has determined that the 10x factor to account for enhanced susceptibility of infants and children can be removed, the aPAD and acute RfD are the same (0.20 mg/kg/day).

2. *Short- and intermediate-term toxicity.* For short- and intermediate-term dermal and inhalation exposures, the systemic NOAEL of 20 mg/kg/day from the 90–day feeding study in dogs based on clinical signs of neurotoxicity at the LOAEL of 60 mg/kg/day was identified as the short- and intermediate-term endpoint to be used in risk assessments. Since an oral dose was selected for dermal risk assessments, the Agency has determined that a dermal penetration factor of 20% is appropriate. The same oral dose (20 mg/kg/day) was also selected for inhalation risk assessments. Therefore, for inhalation exposure the following are appropriate: (i) Converting inhalation exposure in mg/Liter (L) to mg/kg/day (route-to-route extrapolation using 100% inhalation absorption); (ii) combining the converted exposure with dermal exposure (using 20% dermal absorption) and (iii) comparing the combined total to the appropriate oral NOAEL chosen for the short- and intermediate-term exposure scenario (NOAEL = 20 mg/kg/day).

3. *Chronic toxicity*. EPA has established the chronic RfD for pyridate at 0.11 mg/kg/day. This chronic RfD is derived from a NOAEL of 10.8 mg/kg/day based on decreased body weight gain in males seen at 67.5 mg/kg/day (LOAEL) in a 2–year feeding study in rats and an uncertainty factor of 100 (10x for interspecies differences and 10x for intraspecies variations). EPA has determined that the 10x factor to account for enhanced susceptibility of infants and children, as required by FFDCA section 408(b)(2)(C), can be removed. The chronic Population Adjusted Dose (cPAD) is a modification of the chronic RfD to accommodate the FQPA Safety Factor. The cPAD is equal to the chronic RfD divided by the FQPA Safety Factor. Therefore since the EPA has determined that the 10x factor to account for enhanced susceptibility of infants and children can be removed, the cPAD and chronic RfD are the same (0.11 mg/kg/day).

For chronic dermal and inhalation exposures, the NOAEL of 10.8 mg/kg/day from a 2–year feeding study in rats based on decreased body weight gain at the LOAEL of 67.5 mg/kg/day, was identified as the chronic endpoint to be used in dermal and inhalation risk assessments. Since an oral dose was selected for dermal risk assessments, the Agency has determined that a dermal penetration rate of 20% is appropriate. The same oral dose (20 mg/kg/day) was also selected for chronic inhalation risk assessments. Therefore, for inhalation exposure the following are appropriate: (i) Converting inhalation exposure in mg/L to mg/kg/day (route-to-route extrapolation using 100% inhalation absorption); (ii) combining the converted exposure with dermal exposure (using 20% dermal absorption); and (iii) comparing the combined total to the appropriate oral NOAEL chosen for the chronic exposure scenario (NOAEL = 10.8 mg/kg/day).

4. *Carcinogenicity*. Pyridate has not been designated a cancer classification by the Agency to date. However, there is no evidence of a tumorigenic response in the 2–year rat feeding study and the mouse carcinogenicity study with pyridate.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.462) for the combined residues of pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate, the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol, in or on cabbage, corn, and peanuts. Risk assessments were conducted by EPA to assess dietary exposures and risks 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. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. At the 95th percentile exposure level, assuming 100 percent crop treated (PCT) and tolerance level residues for all commodities, less than 1% of the aPAD was utilized for the U.S. Population and children (1–6 years old), the subgroup with the highest exposure. The results of this analysis indicate that the acute dietary risk associated with existing uses and the proposed use of pyridate is below the Agency's level of concern.

ii. *Chronic exposure and risk*. In conducting chronic dietary risk assessments, the following conservative assumptions have been made: (a) all of the crops having pyridate tolerances will contain pyridate residues and (b) those residues will be at the level of the tolerance. This results in an overestimation of human dietary exposure. Thus, in making safety determinations for the peppermint and spearmint tolerances, the Agency is taking into account these conservative exposure assumptions. The combined pyridate tolerances (currently published and the section 18 tolerances established by this action) result in a Theoretical Maximum Residue Contribution (TMRC) that is less than 1% of the RfD for the U.S. population and all population subgroups, including non-nursing infants, the subgroup with the highest exposure. The results of this analysis indicate that the chronic dietary risk associated with existing uses and the proposed use of pyridate is below the Agency's level of concern.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive

drinking water exposure analysis and risk assessment for pyridate. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on Generic expected environmental concentration (GENEEC) and EPA's Pesticide Root Zone Model (PRZM^3)/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and Screening Concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. None of these models include consideration of the impact processing 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. Based on the GENEEC and SCI-GROW models, the acute drinking water concentration values are estimated to be 97 parts per billion (ppb) for surface water and 4.4 ppb for ground water. The chronic drinking water concentration values are estimated to be 25 ppb for surface water and 4.4 pbb for ground water.

In the absence of monitoring data for pesticides, drinking water levels of comparison (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, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to pyridate they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Pyridate is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore, EPA expects only dietary and occupational exposure from the use of pyridate.

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 more 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.* Using the exposure assumptions of 100 PCT and tolerance level residues for all commodities, at the 95th percentile, less than 1% of the aPAD was utilized for the U.S. Population. The major identifiable subgroup with the highest aggregate exposure is children, 1–6 years old (discussed below). EPA generally has no concern for exposures below 100% of the aPAD. Despite the potential for exposure to pyridate in drinking water, after calculating a DWLOC (7,000 ppb) for the U.S. population and comparing it to conservative model estimates of acute concentrations of pyridate in surface and ground water (97 ppb and 4.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to pyridate from food will utilize less than 1% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (discussed below). 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, after calculating a DWLOC (3,800 ppb) for the U.S. population and comparing it to conservative model estimates of concentrations of pyridate in surface and ground water (25 ppb and 4.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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 other indoor and outdoor non-occupational exposure. Since there are no non-dietary, non-occupational exposures expected from the use of this chemical, no short- and intermediate-term risk assessments were conducted.

4. *Aggregate cancer risk for U.S. population.* Pyridate has not been designated a cancer classification by the Agency to date. However, there is no evidence of a tumorigenic response in the 2–year rat feeding study and the mouse carcinogenicity study with pyridate. Therefore, no aggregate cancer risk assessments were conducted.

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 during 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 MOE and 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.* In a prenatal developmental toxicity study in rats, the maternal NOAEL was 165 mg/kg/day and the LOAEL was 400 mg/kg/day based on mortality, significant decreases in mean body weight and food consumption as well as clinical signs (ventral body position, dyspnea, sedation, and loss of reaction to external stimuli). The developmental NOAEL was 165 mg/kg/day and the developmental LOAEL was 400 mg/kg/day, based on increased incidences of missing and/or unossified sternebrae and a dose-related decrease in mean fetal body weight.

In a prenatal developmental toxicity study in rabbits, the maternal NOAEL was 300 mg/kg/day and the LOAEL was 600 mg/kg/day, based on decreased body weight and body weight gain, decreased food consumption, increased incidence of dried feces, and increased abortions. For developmental toxicity, the NOAEL was equal to or greater than 600 mg/kg/day, the highest dose tested. A developmental LOAEL was not established.

iii. *Reproductive toxicity study.* In a 3–generation reproduction study in rats, the parental systemic NOAEL was 10.8 mg/kg/day and the LOAEL was 67.5 mg/kg/day based on depression of maternal body weight gain. The NOAEL for offspring was 10.8 mg/kg/day and the LOAEL was 67.5 mg/kg/day based on decreased pup weight gains (at postnatal day 14 and 21 in the first litters for both generations).

iv. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for pyridate is complete with respect to current data requirements. There are no prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2–generation rat reproductive toxicity study.

v. *Conclusion.* There is a complete toxicity database for pyridate and exposure data are complete or are estimated base on data that reasonably accounts for potential exposures.The Agency concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, rather than the standard 1,000-fold margin/factor, to protect infants and children. Therefore, the 10x factor to account for enhanced susceptibility of infants and children, as required by FFDCA section 408(b)(2)(C), can be removed.

2. *Acute risk.* Using the exposure assumptions of 100 PCT and tolerance level residues for all commodities, at the 95th percentile, less than 1% of the aPAD was utilized for children 1–6 years old, the subgroup with the highest aggregate exposure. EPA generally has no concern for exposures below 100% of the aPAD. Despite the potential for exposure to pyridate in drinking water, after calculating a DWLOC (2,000 ppb) children 1–6 years old and comparing it to conservative model estimates of acute concentrations of pyridate in surface and ground water (97 ppb and 4.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

3. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to pyridate from food will utilize less than 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, after calculating a DWLOC (1,100 ppb) for non-nursing infants, the subgroup with the highest aggregate exposure and comparing it to conservative model estimates of concentrations of pyridate in surface and ground water (25 ppb and 4.4 pbb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

4. *Short- or intermediate-term risk.* There are no non-dietary, non-occupational exposures expected from the use of pyridate therefore, no short- and intermediate-term risk assessments were conducted.

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 pyridate residue in plants and ruminants is adequately understood. The total toxic residue consists of pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate), its metabolite 6-chloro-3-phenyl-pyridazine-4-ol, and conjugates of that metabolite, all expressed as pyridate.

B. Analytical Enforcement Methodology

A total residue method using ultraviolet detection/high pressure liquid chromatography (UV/HPLC) is available for residue data gathering and enforcement purposes. The method has been adequately validated by recovery data, has passed a successful method trial, and has been forwarded to FDA for publication in PAM-II. The limit of quantitation is 0.03 ppm. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues of pyridate, its metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of that metabolite all expressed as pyridate are not expected to exceed 0.3 ppm in/on peppermint, tops (leaves and stems) and spearmint, tops (leaves and stems). Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

D. International Residue Limits

There are no CODEX, Mexican, or Canadian MRLs established for pyridate in/on mint. Therefore, no compatibility problems exist for the proposed tolerances.

E. Rotational Crop Restrictions

A confined accumulation in rotational crops study with pyridate has previously been reviewed. Pyridate residues metabolize rapidly in soil. No crop rotation label restrictions are needed.

V. Conclusion

Therefore, the tolerance is established for combined residues of pyridate (O-(6-chloro-3-phenyl-4-pyridazinyl)-S-octyl-carbonothioate), the metabolite 6-chloro-3-phenyl-pyridazine-4-ol and conjugates of 6-chloro-3-phenyl-pyridazine-4-ol in or on peppermint

tops (leaves and stems) and spearmint tops (leaves and stems) at 0.3 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by October 25, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300905] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of

affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. 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 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 the rule in the **Federal Register**. This 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: August 11, 1999.

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 adding paragraph (b) to read as follows:

§ 180.462 Pyridate; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for the residue of the herbicide pyridate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. This tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Peppermint, tops (leaves and stems).	0.3 ppm	12/31/01
Spearmint, tops (leaves and stems).	0.3 ppm	12/31/01

* * * * *

[FR Doc. 99–21832 Filed 8–24–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6427–2]

North Carolina: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: North Carolina has applied for Final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). North Carolina's revision consists of provisions promulgated between July 1, 1995 and June 30, 1997. The EPA has reviewed North Carolina's applications and determined that its hazardous waste program revision satisfies all of the requirements necessary to qualify for Final authorization. EPA is authorizing the state program revision through this immediate final action. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial action and does not anticipate adverse comments. However, in the proposed rules section of this **Federal Register**, EPA is publishing a separate document that will serve as a proposal to authorize the revision should the Agency receive adverse comment. Unless EPA receives adverse written comments during the review and comment period, the decision to authorize North Carolina's hazardous waste program revision will take effect as indicated in the Dates section.

DATES: This Final authorization for North Carolina will become effective without further notice on October 25, 1999, unless EPA receives adverse comment by September 24, 1999. Should EPA receive such comments the Agency will publish a timely withdrawal informing the public that the rule will not take effect.

ADDRESSES: Send written comments to Narindar Kumar, Chief RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, SW Atlanta, GA, 30303–3104. Copies of the North Carolina program revision applications and the materials which EPA used in evaluating the revision are available for inspection and copying during normal business hours at the following addresses: North Carolina Department of Environment, Health and Natural Resources, P.O. Box