specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing state plan submissions, our role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), we have no authority to disapprove a state plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state plan submission, to use VCS in place of a state plan submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, we have taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 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. We will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 12, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects 40 CFR Part 62

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Lead, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: June 20, 2000.

Michael Sanderson,

Acting Regional Administrator, Region 7.

Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart R—Kansas

2. Subpart R is amended by adding § 62.4179 and an undesignated center heading to read as follows:

Air Emissions From Existing Hospital/Medical/Infectious Waste Incinerators

§ 62.4179 Identification of plan.

(a) Identification of plan. Kansas plan for the control of air emissions from hospital/medical/infectious waste incinerators submitted by the Kansas Department of Health and Environment on May 4, 2000.

(b) Identification of sources. The plan applies to existing hospital/medical/infectious waste incinerators constructed on or before June 20, 1996.

(c) Effective date. The effective date of the plan is September 12, 2000.

[FR Doc. 00–17872 Filed 7–13–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301013; FRL–6593–1]

RIN 2070–AB78

Pyridaben; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-choropyridazin-3(2H)-one] in or on citrus; citrus pulp, dried; citrus oil; apple; apple pomace, wet; pear; tree nuts; almond hulls; pistachio; peach (and nectarine); plum; prune; grape; and cranberry. Time-limited tolerances are established for residues of pyridaben on apricot and cherry (sweet and tart) which will expire and are revoked on June 30, 2004. This regulation also establishes tolerances for residues of pyridaben and its metabolites PB–7 and PB–9 in or on the following ruminant commodities: milk, and milk-by-product, fat, and meat of cattle, goat, hog, and sheep. BASF Corporation and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective July 14, 2000. Objections and requests for hearings, identified by docket control number OPP–301013, must be received by EPA on or before September 12, 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–301013 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Melody A. Banks, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone

number: 703–305–5413; and e-mail address: Banks.Melody@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	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–301013. 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 9, 1998 (63 FR 1457) (FRL–5762–6) and February 13, 1998 (63 FR 7414) (FRL–5768–9), EPA issued a notice 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 a pesticide petition (PP 7F4881) for a tolerance by BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by BASF Corporation, Agricultural Products. Also, in the **Federal Register** of December 22, 1999 (64 FR 71767) (FRL–6396–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP 9E6002) for a tolerance by IR-4, Center for Minor Crop Pest Management, North Brunswick, NJ 08902–3390. There were no comments received in response to either notice of filing.

The petition requested that 40 CFR 180.494 be amended by establishing a tolerance for residues of pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio-4-choropyridazin-3(2H)-one], in or on the following crops and crop groups: peach and nectarine at 2.4 ppm; plum and prune (fresh) at 0.7 ppm; prune (dried) at 2.2 ppm; cherry and apricot at 0.05 ppm; grape at 1.4 ppm; and tree nut crops at 0.05 ppm. IR-4 proposed a tolerance for cranberry at 0.50 ppm in support of regional registration. Registration for use on cranberry will be geographically limited based on the available residue data to the states of Maine, New Jersey, Rhode Island, Massachusetts, New York, Connecticut, New Hampshire, Vermont, and Delaware. Persons seeking broader registration should contact the appropriate EPA product manager concerning additional residue data required to expand the use area.

Time-limited tolerances currently exist in 40 CFR 180.494 for pyridaben on apple, pear, almond, and citrus. After further reassessment of the data base in lieu of additional data submitted by the petitioner for tolerances originally established for pyridaben on the forementioned commodities, BASF petitioned EPA to reestablish tolerances for pyridaben on apple and pear. As a result of additionally submitted crop field trial data, EPA is proposing that the tolerances be adjusted as follows: apple from 0.6 ppm to 0.5 ppm and pear from 0.75 ppm to 0.6 ppm; tolerances for citrus and almond will remain the same. Currently, a separate tolerance exists in 40 CFR 180.494(a) for pyridaben on almond. Since the crop group, tree nuts, includes almond, the existing almond tolerance is being removed. However, the existing tolerance for almond hulls at 4.0 ppm will remain the same.

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 a tolerance for residues of pyridaben in or on peach at 2.5 ppm; nectarine at 2.5 ppm; plum at 0.75 ppm; cherry, sweet at 0.05 ppm; cherry, tart at 0.05 ppm; apricot at 0.05 ppm; crop group 14, tree nuts at 0.05 ppm; pistachio at 0.05 ppm; grape at 1.5 ppm; prune at 2.5 ppm; and cranberry at 0.5 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 pyridaben are discussed in this unit.

Pyridaben belongs to the pyridazinone class of pesticides. Other active ingredients that belong to this class of pesticides include pyrazon and norflurazon. EPA does not currently have data available to determine with certainty whether pyridaben has a common mechanism of toxicity with any other substances. For the purposes of this human health risk assessment, EPA has not assumed that pyridaben has a common mechanism of toxicity with other pesticides.

In general, the acute toxicology studies conducted on technical grade pyridaben demonstrate that it has moderate to mild toxic effects. It was classified as Toxicity Category III based upon the acute oral LD_{50} of 1,100 milligrams/kilograms (mg/kg) in male rats and 570 mg/kg in female rats. The dermal LD_{50}, in rabbits was greater than or equal to 2,000 mg/kg (Toxicity Category III) and the inhalation LC_{50} was 0.66/0.64 milligram/liter (mg/L) in male/female rats, respectively (Toxicity Cateogry III). The eye irritation study (rabbits) produced slight ocular irritation (Toxicity Cateogry III). Pyridaben was not a dermal irritant (Toxicity Cateogry IV) or sensitizer.

There are guideline acute and subchronic neurotoxicity studies. The neurological symptoms in the available neurotoxicity studies and some of the other studies, were seen only at relatively high doses. The neurotoxic effects (piloerection, hypocricturty, tremors, partially closed eyes) were weak, sporadic, transient and/or non-reproducible with no neuropathological effects. In a 90–day rat study, plasma cholinesterase enzyme (ChE) was statistically-significantly inhibited in the females at the highest dose tested (HDT) of 350 ppm (25.71 mg/kg/day for males or 27.68 mg/kg/day for females). Based on these neurotoxic effects, EPA has required that a developmental neurotoxicity study be submitted. There are developmental toxicity studies in rats and rabbits (by the oral or dermal routes), and a multi-generation reproduction study in rats. The developmental and reproduction toxicity studies showed no effect on reproduction and no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to pyridaben as demonstrated by a higher developmental lowest observed adverse effect level (LOAEL) than those observed to produce maternal toxicity.

The most common toxicity endpoint across the various studies and tested species was decreased body weight/decreased body weight gain followed by decreased feed consumption and/or feed efficiency. These effects were observed in 13–week feeding studies in mice, rats, and dogs, in a 21–day dermal toxicity study in rats, in a 28–day inhalation toxicity study in rats, in a 13–week neurotoxicity study in rats, in 1-year feeding studies in dogs, in a 78–week feeding/carcinogenicity study in mice, in developmental toxicity studies in rats and rabbits, in a 2-generation reproduction study in rats, and in a 2-year feeding/carcinogenicity study in rats. It is noteworthy that the LOAELs were always based on decreases in body weight gain/decreases in body weight or decreases in food consumption. Other effects were sporadic and involved changes in certain clinical chemistry values or increases or decreases in organ weights. There is no evidence of increased susceptibility of infants and children to any of these endpoints.

In an acceptable rat metabolism study by the oral route, pyridaben was mainly eliminated in feces where 80–97% of the administered dose was excreted regardless of dose or site of label (pyridazinone or benzyl ring). Nearly 20% of the excreted residue in the feces was unmetabolized parent compound and there was some evidence of glucuronide conjugate(s) in the bile. The plasma levels following a single low oral dose (3 mg/kg) peaked at 2–3 hours while peak levels at the high dose (30 mg/kg) were at approximately 24 hours post-dose due, at least in part, to enterohepatic circulation where nearly 22–30% of an administered radioactive dose is excreted in bile within a period of 24 hours. Residual radioactivity was at or near background levels for most tissues by 72 to 168 hours. Generally, there seemed to be increased distribution to fat over time and, compared to other tissues, fat seemed to have relatively more residual radioactivity. Several metabolites, totaling up to 20–30, were resolved in urine and feces and some were structurally identified.

B. Toxicological Endpoints

1. *Acute toxicity.* An acute reference dose (RfD) of 0.13 mg/kg/day NOAEL = 13 mg/kg/day, uncertainty factor (UF) = 100 for use in assessing acute dietary risk for females 13 years and older. This acute RfD is based upon the developmental toxicity study with rats in which developmental effects (decreased fetal body weight and increased delayed bone ossification) were observed at the development LOAEL of 30 mg/kg/day. The acute population adjusted dose (PAD) = acute RfD/FQPA factor (1x) = 0.13 mg/kg/day for females 13 years older.

An acute RfD of 0.50 mg/kg/day (NOAEL = 50 mg/kg/day, UF = 100) was selected for use in assessing acute dietary risk for the general population. This acute RfD is based upon the acute oral neurotoxicity study with rats in which the following effects were observed at the LOAEL of 100 mg/kg/day: clinical signs of toxicity, decreased food consumption, and decreased body weight gain. The acute PAD = acute RfD/FQPA factor (1x) = 0.5 mg/kg/day for the U.S. population.

2. *Short-term and intermediate-term toxicity.* A NOAEL of 100 mg/kg/day was selected based on a 21–day dermal toxicity study in rats that resulted in decreased body weight gain in female rats at 300 mg/kg/day (LOAEL). A margin of exposure (MOE) of 100 or

greater is adequate since the FQPA factor was reduced to 1X.

EPA concluded that for short-term and intermediate-term aggregate exposure risk assessment the MOEs cannot be combined since the toxicological endpoints were different via the oral, dermal, and inhalation routes (i.e., no common endpoint of concern).

3. *Long-term dermal toxicity*. A long-term dermal endpoint was not selected as the use pattern does not indicate a potential for long-term exposure.

4. *Chronic toxicity*. A chronic RfD of 0.005 mg/kg/day (NOAEL = < 0.50 mg/kg/day; UF = 100) was selected for use in assessing chronic dietary risk. This chronic RfD is based on the chronic toxicity study in dogs, in which the following effects were observed at the LOAEL of 0.5 mg/kg/day: increased incidence of clinical signs in both sexes and decreased body weight gain in females. An additional uncertainty factor (3x, for not establishing a NOAEL) was not applied to the chronic RfD because the toxic response observed was very minimal and was considered to be a threshold effect. The 100x UF for use in assessing chronic dietary risk was considered to be adequate. The chronic cPAD = chronic RfD/FQPA factor (1x) = 0.005 mg/kg/day.

5. *Carcinogenicity*. Based on the lack of evidence of carcinogenicity in acceptable studies in male and female rats and mice, pyridaben was classified as a ''not likely'' human carcinogen based upon the proposed EPA Weight-of-the-Evidence Categories. Also, there was no indication that pyridaben is mutagenic in acceptable *in vitro* and *in vivo* studies.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.494) for the residues of pyridaben, in or on a variety of raw agricultural commodities. Pyridaben is currently registered for use on almond, apple, citrus fruit, and pear. Time-limited tolerances are established in conjunction with these uses. Additionally, a time-limited tolerance for pyridaben in/on cranberries is established in conjunction with a section 18 request. BASF Corporation has proposed to make the tolerances for pyridaben in/on citrus fruit and pear permanent. Additionally, in today's action, tolerances will be established for pyridaben in/on tree nuts, pistachio, peach, nectarine, plum, prune, apricot, cherry, grape, and cranberry.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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.

EPA used the Dietary Exposure Evaluation Model (DEEM) software for conducting a Tier 1 acute dietary (food only) risk analysis. DEEM is a dietary exposure analysis system developed by Novigen Sciences, Inc. that is used to estimate exposure to a pesticide chemical in foods comprising the diets of the U.S. population, including population subgroups. DEEM contains food consumption data as reported by respondents in the Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals conducted in 1989-1992. The assumptions of the Tier 1 acute dietary exposure analysis are tolerance level residues and 100 percent crop-treated estimates. The tolerance levels were adjusted to account for organosoluble residue content.

The acute DEEM analysis indicates the resulting dietary food exposures (at the 95th percentile) occupy up to 19% of the acute PAD for population subgroups exclusive to females 13 years and older. The highest exposed subgroup for females 13 years and older is females (13+/nursing). The analysis also shows that the resulting dietary food exposures (at the 95th percentile) occupy up to 18% of the acute PAD for population subgroups not specific to females 13 years and older. The highest exposed subgroup for population subgroups not specific to females 13 years and older is all infants (< 1-year).

ii. *Chronic exposure and risk*. EPA used DEEM software for conducting a Tier 2 chronic (non-cancer) dietary (food only) risk analysis. The assumptions of the Tier 2 chronic dietary exposure analysis are anticipated residue estimates and 100% crop-treated estimates. The chronic DEEM analysis indicates that the most highly exposed population subgroup is non-nursing infants which occupy up to 64% of the chronic PAD.

2. *From drinking water*. The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for pyridaben. Therefore, the Agency is presently relying on computer-generated Estimated Environmental Concentrations (EECs). GENEEC and/or PRZM/EXAMS (both produce estimates of pesticide concentration in a farm pond) are used to generate EECs for surface water and SCI-GROW (an empirical model based upon actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EECs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing 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 assessing whether a pesticide is likely to be present in drinking water at concentrations which would exceed human health levels of concern.

For any given pesticide, the SCI-GROW model generates a single EEC value of pesticide concentration in ground water. That EEC is used in assessments of both acute and chronic dietary risk. It is not unusual for the ground water EEC to be significantly lower than the surface water EECs. The GENEEC model generates several time-based EECs of pesticide concentration in surface water, ranging from 0–days (peak) to 56-days (average). The GENEEC peak EEC is used in assessments of acute dietary risk; the GENEEC 56–day (average) EEC is used in assessments of chronic (non-cancer and cancer) dietary risk. PRZM/EXAMS provides longer duration (up to 36 years) values of pesticide concentration in surface water and is mainly used when a refined EEC is needed.

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative

EECs provided by computer modeling (SCI-GROW, GENEEC < PRZM/EXAMS).

EPA back-calculates DWLOCs by a two-step process: exposure food + (if applicable) residential is subtracted from the PAD to obtain the maximum acceptable exposure allowed in drinking water; DWLOCs are then calculated using that value and default body weight and drinking water consumption figures. In assessing human health risk, DWLOCs are compared to EECs. When EECs are less than DWLOCs, HED considers the aggregate risk from food + water + (if applicable) residential exposures to be acceptable.

EPA conducted its Tier II screening-level assessments using the simulation models SCI-GROW and PRZM/EXAMS to generate EECs for ground and surface water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for pyridaben (0.5 lbs active ingredient (ai/acre) x 2 applications/acre/year on apples). The EECs are summarized in Table 1 below.

TABLE 1.—ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECS)

SCI-GROW [1] (µg/L) [2]	PRZM/EXAMS [3] (µg/L)	
0.006 (acute & chronic)	0.215 (peak)	0.020 (long-term mean)

[1] SCI-GROW (Screening Concentration in Ground Water) is an empirical model for predicting pesticide levels in ground water. The value from SCI-GROW is considered an upper bound concentration estimate.
[2] µg/L = parts per billion (ppb).
[3] PRZM (Pesticide Root Zone Model—simulates the transport of a pesticide off the agricultural field) and EXAMS (Exposure Analysis Modeling System—simulates fate and transport of a pesticide in surface water. PRZM/EXAMS can substantially overestimate true pesticide concentrations in drinking water.

i. *Acute exposure and risk*. Drinking Water Levels of Comparison (DWLOCs). The DWLOCs value are shown in Table 2. For each population subgroup listed, the acute PAD and the acute dietary (food only) exposure for that subgroup were used to calculate the acute DWLOC for the subgroup, using the formulas in footnotes 1 and 2 of Table 2.

TABLE 2.—DWLOCS FOR ACUTE DIETARY EXPOSURE

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day) [1]	SCI-GROW (µg/L)	PRZM/EXAMS Peak EEC (µg/L)	DWLOC (µg/L) [2,3,4]
U.S. Population (all seasons)	0.50	0.023	0.48	0.006	0.215	1.6×10^4
Females 13+ [5]	0.13	0.024	0.11			3.2×10^3
Infants/Children [5]	0.50	0.091	0.41			4.1×10^3
Other [5]	0.50	0.029	0.47			1.6×10

[1] Maximum Water Exposure (mg/kg/day) = Acute PAD (mg/kg/day)—Acute Food Exposure + Acute Residential Exposure (mg/kg/day). Pyridaben has no registered residential uses.
[2] DWLOC (µg/L) = Maximum Water Exposure (mg/kg/day) x body wt (kg) (10^{-3} mg/µg) x water consumed daily (L/day). µ/L = ppb.
[3] Default body weights are: general U.S. Population, 70 kg; males (13+ years old), 70 kg; females (13+ years old), 60 kg; other adult populations, 70 kg; and, all infants/children, 10 kg.
[4] Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[5] Within each of these subgroups, the subpopulation with the highest (acute) food exposure was selected; namely, females (13+/nursing); all infants (< 1-year); and, the non-Hispanic other, respectively.

ii. *Chronic exposure and risk.—Chronic (Non-Cancer) Dietary (Drinking Water) Exposure—Drinking water levels of comparison (DWLOCs)*. The DWLOC value are shown in Table 3. For each population subgroup listed, the chronic PAD (0.005 mg/kg/day) and the chronic dietary (food only) exposure for that subgroup were used to calculate the chronic DWLOC for the subgroup, using the formulas in footnotes 1 and 2 of Table 3.

TABLE 3.—DWLOCS FOR CHRONIC (NON-CANCER) DIETARY EXPOSURE

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day) [1]	SCI- GROW (µg/L)	PRZM/EXAMS Chronic EEC (µg/L)	DWLOC (µg/L) [2,3,4]
U.S. population (48 contiguous States, all seasons)	0.0050	0.00073	0.0043	0.006	0.020	1.4×10^2
Females 13+ [5]		0.0011	0.0039			1.2×10^2
Infants/children [5]		0.0032	0.0018			18

TABLE 3.—DWLOCS FOR CHRONIC (NON-CANCER) DIETARY EXPOSURE—Continued

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day) [1]	SCI- GROW (µg/L)	PRZM/EXAMS Chronic EEC (µg/L)	DWLOC (µg/L) [2,3,4]
Other [5]		0.00094	0.0041			1.4 x 10

[1] Maximum Water Exposure (mg/kg/day) = Chronic PAD (mg/kg/day)—Chronic Food Exposure + Chronic Residential Exposure (mg/kg/day). Pyridaben has no registered residential uses.
[2] DWLOC (µg/L) = Maximum Water Exposure (mg/kg/day) x body weightt (kg) (10^{-3} mg/µg) x water consumed daily (L/day). µg/L = ppb.
[3] HED default body weights are: General U.S. population, 70 kg; males (13+ years old), 70 kg; females (13+ years old), 60 kg; other adult populations, 70 kg; and, all infants/children, 10 kg.
[4] HED default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[5] Within each of these subgroups, the subpopulation with the highest (chronic) food exposure was selected; namely, females (13+/nursing); non-nursing infants (< 1-year); and the Pacific Region, respectively.

3. *From non-dietary exposure*. At present, there are no registered or proposed residential uses of pyridaben. Thus, a residential exposure assessment is not required. There is a potential for occupational exposure to pyridaben during mixing, loading, and application activities. However, risks from these routes of exposure are considered negligible.

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 pyridaben 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, pyridaben 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 pyridaben 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 and Infants and Children.

1. *Acute risk*. Acute aggregate risk is the sum of exposures resulting from acute dietary food + acute drinking water. This acute aggregate risk assessment was conducted for all population subgroups, and the acute PAD of 0.13 mg/kg/day is applied to all population subgroups exclusive to females 13 years and older and the acute PAD of 0.50 mg/kg/day is applied to all other population subgroups.

EPA used DEEM software for conducting a Tier 1 acute dietary (food only) risk analysis. The assumptions of the Tier 1 dietary exposure analysis are tolerance level residues and 100% crop-treated estimates. The tolerance levels were adjusted to account for organosoluble residue content.

The resulting dietary food exposures (at the 95th percentile) occupy up to 19% of the acute PAD for population subgroups exclusive to females 13 years and older (females (13+/nursing)). The resulting dietary food exposures (at the 95th percentile) occupy up to 18% of the acute PAD for population subgroups not specific to females 13 years and older (all infants (< 1-year)).

The EECs for assessing acute aggregate dietary risk are 0.006 ppb (in ground water, based on SCI-GROW) and 0.215 ppb (in surface water, based on the PRZM/EXAMS). The back-calculated DWLOCs (Table 2) for assessing acute aggregate dietary risk range from 3.2 x 10^3 ppb for the most highly exposed population subgroup (females 13 years and older/nursing) to 1.6 x 10^4 ppb for the U.S. population (all seasons) and non-Hispanic others.

The SCI-GROW and PRZM/EXAMS acute EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for pyridaben residues in drinking water as a contribution to acute aggregate exposure. EPA thus concludes with reasonable certainty that residues of pyridaben in drinking water will not contribute significantly to the aggregate acute human health risk and that the acute aggregate exposure from pyridaben residues in food and drinking water will not exceed the Agency's level of concern (100% of the acute PAD) for acute dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the acute PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

2. *Chronic risk*. Chronic (non-cancer) aggregate risk is the sum of exposures resulting from chronic dietary food + chronic drinking water + chronic residential uses. Pyridaben has no registered residential uses. Therefore, this risk assessment is the aggregate of chronic dietary food + chronic drinking water exposures only. This chronic aggregate risk assessment was conducted for all population subgroups, and the chronic PAD is applied to all population subgroups.

EPA used DEEM software for conducting a Tier 2 chronic (non-cancer) dietary (food) exposed analysis. Tier 2 assumptions are anticipated residue levels and 100% crop-treated estimates.

The resulting dietary food exposures occupy up to 64% of the chronic PAD for the most highly exposed population subgroup, non-nursing infants. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated information and/or additional refinements of the anticipated residue estimates would yield even lower estimates of chronic dietary exposure.

The EECs for assessing chronic aggregate dietary risk are 0.006 ppb (in ground water, based on SCI–GROW) and 0.020 ppb (in surface water, based on the PRZM/EXAMS). The back-calculated DWLOCs for assessing chronic aggregate dietary risk range from 18 ppb for the most highly exposed population subgroup (non-nursing infants, < 1-year old) to 1.4 x 10^2 ppb for the U.S. population (48 contiguous States—all seasons).

The SCI–GROW and PRZM/EXAMS chronic EECs are less than the Agency's

level of comparison (the DWLOC value for each population subgroup) for pyridaben residues in drinking water as a contribution to chronic aggregate exposure. EPA thus, concludes with reasonable certainty that residues of pyridaben in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from pyridaben residues in food and drinking water will not exceed the Agency's level of concern (100% of the chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

Cancer aggregate risk is based on the sum of exposures resulting from chronic dietary food + chronic drinking water + chronic residential uses. Pyridaben is classified as a ''not likely'' human carcinogen based upon the proposed EPA Weight-of-the-Evidence Categories. Thus, pyridaben does not pose a cancer risk.

3. *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 pyridaben residues.

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

1. *Safety factor for infants and children*—i. *In general*. 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 MOE analysis or through using UF in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard UF (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/UF 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. *Conclusion*. There is a complete toxicity data base for pyridaben and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor to protect infants and children should be removed. The FQPA factor is removed because:

a. The toxicity data base is complete for the assessment of the effects following *in utero* and /or postnatal exposure to pyridaben.

b. The toxicity data provided no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

c. Although a developmental neurotoxicity study is required, this requirement is not based on criteria reflecting some special concern for developing fetuses or the young which are generally used for requiring a developmental neurotoxicity study and retention of the FQPA safety factor; and, therefore, does not warrant retention of the FQPA safety factor.

d. The exposure assessments will not underestimate the potential dietary (food and water) exposures for infants and children from the use of pyridaben (currently no residential exposure is expected).

2. *Acute risk*. The resulting dietary food exposures (at the 95th percentile) occupy up to 19% of the acute PAD for population subgroups exclusive to females 13 years and older (females (13+/nursing). The resulting dietary food exposures (at the 95th percentile) occupy up to 18% of the acute PAD for population subgroups not specific to females 13 years and older (all infants < 1-year).

The EECs for assessing acute aggregate dietary risk are 0.006 ppb (in ground water, based on SCI-GROW) and 0.215 ppb (in surface water, based on the PRZM/EXAMS). The back-calculated DWLOCs for assessing acute aggregate dietary risk range from 3.2×10^3 ppb for the most highly exposed population subgroup (females 13 years and older/ nursing) to 1.6×10^4 ppb for the U.S. population (all seasons) and non-Hispanic others.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyridaben from food will utilize 64% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD 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 pyridaben in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short-term or intermediate-term risk*. These aggregate risk assessments take into account chronic dietary exposure from food and water (considered to be a background exposure level) plus (short-term, intermediate-term, or long-term, as applicable) indoor and outdoor residential exposure. Since pyridaben is not registered for residential uses, short-term and intermediate-term, and long-term aggregate risk is captured by the assessment for aggregate chronic risk.

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 pyridaben residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

1. *Nature of residues in plants*. EPA concludes that the tolerance expression for plant commodities will include pyridaben only and that all organosoluble residues may be presumed to be of comparable toxicity to the parent. Thus, the risk assessment for human dietary consumption of pyridaben-treated plant commodities will include all organosoluble residues. EPA has calculated a ratio of pyridaben to organosoluble residues based upon the low dose pyridaben apple and orange metabolism studies. These studies were chosen because they approximate the proposed use of pyridaben on citrus and apples. For dietary exposure analysis, tolerance levels of pyridaben in/on plant commodities will be multiplied by the ratio of organosoluble residues to pyridaben.

2. *Nature of residues in animals*. EPA concludes that the tolerance expression for ruminant commodities will include pyridaben and its metabolites PB–7 and PB–9 and that all organosoluble residues may be presumed to be of comparable toxicity to the parent. Thus, the risk assessment for human consumption of ruminant commodities will also include all organosoluble residues. For liver, EPA will calculate a ratio of pyridaben, PB–7 and PB–9 residues to organosoluble residues based upon the ruminant metabolism study. For milk and other tissues, best estimates of residues of concern for risk assessment may need to be based on total organosoluble residues in the goat metabolism study. Dietary exposure of

poultry to pyridaben residues is not expected as a result of the proposed uses.

3. *Enforcement analytical methods—Plants—Apple, pear, peach, plum, cherry, apricot, grape, pistachio and tree nuts.* BASF Method D9312A: For solid samples, residues of pyridaben are extracted by blending the sample with a solution of acetone/water (8:2 v/v). For juice, residues are extracted by mixing the sample with 80% acetone/water (v/v). Following filtration to remove the sample material, the solvent is exchanged to water and an aliquot of the extract is applied to a mini-C18 silica gel column. Residues are eluted with 80% methanol/water (v/v) and the solvent is exchanged to toluene for analysis. Residues of pyridaben are quantified by analysis of the sample extracts by gas chromatography (GLC) utilizing an electron capture detector (63Ni—ECD) and a fused silica column. The method has been validated to a quantification limit of 0.05 p.m. This method has been independently validated for use with apple and pear commodities as per PR Notice 88-5.

BASF Method D9312 has been adequately validated in both apples and almonds. The submitted method is adequate for the enforcement of the proposed tolerances for residues of pyridaben in/on apples, pears, and almonds. This method has been validated by EPA and was submitted to the Food and Drug Administration (FDA) for inclusion in PAM, Volume II.

4. *Citrus BASF Method D9309B* BASF Method D9309B is briefly described as follows: whole fruit are homogenized and then blended with acetone:water. Sodium chloride is added to the extract and the residues are partitioned into dichloromethane, dried by evaporation, dissolved in DCM:hexane (3:7, v/v) and cleaned up on a silica gel column eluted with DCM:hexane (11:9, v/v). The samples are then dried, dissolved in toluene, and analyzed by GC/ECD. This method has been independently validated for use with citrus commodities as per PR Notice 88-5. The submitted method is adequate for enforcement of permanent tolerances for residues of pyridaben in/on citrus and will be forwarded to the Food and Drug Administration for publication in PAM Vol. II.

5. *Enforcement analytical method—Animals—BASF Method D9405 for animal matrices.* BASF Method D9405 is briefly described as follows: macerate animal tissue with acetone/water and milk with acetone. Filter and wash the sample with the same solvent. Methylate a portion of the extract with diazomethane. After adding water, load the methylated sample onto a octadecylsilane column and elute with methanol/water. The sample is then evaporated to dryness, dissolved in acetonitrile and analyzed by GC/ECD. This method has been independently validated for use with milk and liver commodities as per PR Notice 88–5. BASF Method D9405 has been validated in both liver and milk.

B. International Residue Limits

There are no established or proposed Codex, Canadian or Mexican limits for residues of pyridaben in/on plant commodities or for pyridaben and its metabolites (PB–7 and PB–9) in/on livestock commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this risk assessment.

V. Conclusion

Therefore, the tolerance is established for residues of pyridaben, in or on peach at 2.5 ppm; nectarine at 2.5 ppm; plum at 0.75 ppm; cherry, sweet at 0.05 ppm; cherry, tart at 0.05 ppm; apricot at 0.05 ppm; crop group, 14, tree nuts at 0.05 ppm; almond hulls at 4.4 ppm; pistachio at 0.05 ppm; grape at 1.5 ppm; prune at 2.5 ppm; cranberry at 0.5 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–301013 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 September 12, 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, 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 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, 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, 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–301013, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 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 a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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: June 28,2000.

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. Section 180.494 is revised to read as follows:

§ 180.494 Pyridaben; tolerance for residues.

(a) *General.* Tolerances are established for residues of the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the following plants, and of the insecticide pyridaben and its metabolites (2-tert-butyl-5-(4-(1-carboxy-1-methylethyl)benzylthio)-4-chloropyridazin-3(2H)-one] and (2-tert-butyl-5-[4(-1,1-dimethyl-2-hypdroxyethyl)benzylthio-4-chloropyridazinn-3(2H)-one) on animals, as indicated in the following table.

Commodity	Parts per million	Revocation/expiration date
Almond hulls	4.0	None
Apple	0.5	None
Apple, wet pomace	0.75	None
Apricot	0.05	6/30/04
Cattle, fat	0.05	None
Cattle, meat	0.05	None
Cattle, meat by-products	0.05	None
Cherry, sweet	0.05	6/30/04
Cherry, tart	0.05	6/30/04
Citrus, crop group	0.05	None
Citrus, dried pulp	1.5	None
Citrus, oil	10.0	None
Goat, fat	0.0	None
Goat, meat	0.05	None
Goat meat by-products	0.05	None
Grape	1.5	None
Hog, fat	0.05	None
Hog, meat	0.05	None
Hog meat by-products	0.05	None
Horse, fat	0.05	None
Horse meat	0.05	None
Horse meat by-products	0.05	None
Milk	0.01	None
Nectarine	2.5	None
Nut, tree crop group	0.05	None
Peach	2.5	None
Pear	0.75	None
Pistachio	0.05	None
Plum	2.5	None
Prune	2.5	None
Sheep, fat	0.05	None
Sheep, meat	0.05	None
Sheep, meat by-product	0.05	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the insecticide pyridaben [2-tert-butyl-5(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration Date
Cranberry	0.5	None

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00–17619 Filed 7–13–00; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 80, and 90

[WT Docket No. 99–332; FCC 00–220]

Frequency 156.250 MHz Available for Port Operations Purposes in Los Angeles and Long Beach, CA Ports

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Commission's rules to designate marine VHF Channel 05A for port operations communications in Los Angeles and Long Beach, California ports. The effect of this rule is that it will foster reliable marine communications and increase safe vessel transit in the ports. The action will allow the LA/LB Pilots to manage vessel traffic in that area more efficiently and protect the marine environment by preventing collisions and groundings.

EFFECTIVE DATE: August 14, 2000.

FOR FURTHER INFORMATION CONTACT: James Shaffer, Wireless Telecommunications Bureau at (202) 418–0680.

SUPPLEMENTARY INFORMATION:

1. This is a summary of the Commission's *Report and Order* (R&O) FCC 00–220, adopted on June 15, 2000, and released on June 20, 2000. The full text of this *R&O* is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY A257, 445 12th Street, S.W., Washington, D.C. The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, N.W. Washington, D.C. 20037.

Summary of Report and Order

2. By letter the Los Angeles and Long Beach Port Pilots (jointly, LA/LB Pilots) request the assignment of an intership