Commodity	Parts per million
Goat, liver	1.0
Goat, meat	0.01
Goat, meat byproducts, except liver	0.10
Hog, fat	0.01
Hog, liver	0.10
Hog, meat	0.01
Hog, meat byproducts, except liver	0.01
Horse, fat	0.01
Horse, liver	1.0
Horse, meat	0.01
Horse, meat byproducts, except liver	0.10
Milk	0.01
Sheep, fat	0.01
Sheep, liver	1.0
Sheep, meat	0.01
Sheep, meat byproducts, except liver	0.10
Poultry, liver	0.10

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of amicarbazone [4-amino-4, 5-dihydro-N-(1,1-dimethylethyl)-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and its metabolites DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide] and iPr-2-OH DA amicarbazone [N-(1,1-dimethylethyl)-4,5-dihydro-3-(1-hydroxy-1-methylethyl)-5-oxo-1H-1,2,4-triazole-1-carboxamide], calculated as parent equivalents, in or on the following commodities when present therein as a result of application of amicarbazone to the growing crops in paragraph (a) of this section:

Commodity	Parts per million
Alfalfa, forage	0.05
Alfalfa, hay	0.10
Cotton, gin byproducts	0.30
Cotton, undelinted seed	0.07
Soybean, forage	1.50
Soybean, hay	5.0
Soybean, seed	0.80
Wheat, forage	0.50
Wheat, grain	0.10
Wheat, grain, milled by-products	0.15
Wheat, hay	1.0
Wheat, straw	0.50

[FR Doc. 05–18951 Filed 9–22–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0267; FRL–7738–6]

Pyridaben; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridaben in or on hop, dried cones; papaya; star apple; sapote, black; mango; sapodilla; sapote, mamey; canistel, fruit, stone, group 12; strawberry; and tomato. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). EPA is also deleting certain pyridaben tolerances that are no longer needed as result of this action.

DATES: This regulation is effective September 23, 2005. Objections and requests for hearings must be received on or before November 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0267. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of July 3, 2003 (68 FR 39942) (FRL–7315–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (0E6068, 1E6226, 1E6303, 2E6457, and 2E6460) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The

petitions requested that 40 CFR 180.494 be amended by establishing tolerances for residues of pyridaben, 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one in or on the following raw agricultural commodities: Strawberry at 2.5 parts per million (ppm) (PP 0E6068); hop, dried cones at 10.0 ppm (PP 1E6226); tomato at 0.2 ppm (PP 1E6303); fruit, stone, group at 2.5 ppm (PP 2E6457); papaya, black sapote, canistel, mamey sapote, mango, sapodilla, and star apple at 0.1 ppm (PP 2E6460). The tomato petition was subsequently amended to propose a tolerance at 0.15 ppm. Registration for tomato will be limited to greenhouse grown tomato based on the available residue data. The petitioner also proposed that established tolerances for nectarine, peach, plum, and prune at 2.5 ppm be deleted since they will be superceded by the tolerance for fruit, stone, group 12 at 2.5 ppm. That notice included a summary of the petition prepared by BASF Corporation, the registrant. The Agency received one comment expressing support for this action.

EPA is also deleting the apricot, sweet cherry and tart cherry tolerances in § 180.494(a) since they expired on June 30, 2004, and will also be superceded by the tolerance for fruit, stone, group 12.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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 of FFDCA 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) at *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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) of FFDCA, for a tolerance for residues of pyridaben, 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one in or on hop, dried cones at 10.0 ppm; papaya at 0.10 ppm; star apple at 0.10 ppm; sapote, black at 0.10 ppm; mango at 0.10 ppm; sapodilla at 0.10 ppm; sapote, mamey at 0.10 ppm; canistel at 0.10 ppm; fruit, stone, group 12 at 2.5 ppm; strawberry at 2.5 ppm; and tomato at 0.15 ppm. EPA's assessment of 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 Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity--rats	NOAEL in males: = 4.94 mg/kg/day and NOAEL in females: 2.64 mg/kg/day LOAEL = 11.55 mg/kg/day based on decreased body weight (bwt) gain, food consumption, food efficiency and altered clinical pathology parameters in males and a LOAEL of 5.53 mg/kg/day based on decreased body weight gain and food efficiency in females
870.3100	90–Day oral toxicity mice	NOAEL = males: 4.07 and females: 4.92 mg/kg/day LOAEL = males: 13.02 and females: 14.65 mg/kg/day based on decreased body weight gain
870.3150	90–Day oral toxicity--non-rodents	NOAEL = 1.0 mg/kg/day LOAEL = 4.0 mg/kg/day based on increased incidence of clinical signs and decreased body weight gain in both sexes
870.3150	90–Day oral toxicity--non-rodents	NOAEL = < 2.4 mg/kg/day LOAEL ≤ 2.4 mg/kg/day based on increased incidence of clinical signs and depletion of fat in all treated animals
870.3200	21–Day dermal toxicity	NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on decreased body weight gain observed in females
870.3465	30–Day inhalation toxicity	NOAEL = 0.001 mg/L LOAEL = 0.003 mg/L based on increased incidence of clinical signs and clinical chemistry changes in both sexes and decreased body weight gain in females

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental oral toxicity - rodents	Maternal NOAEL = 4.7 mg/kg/day Maternal LOAEL = 13 mg/kg/day based on decreased body weight, body weight gain and food consumption Developmental NOAEL = 13 mg/kg/day Developmental LOAEL = 30 mg/kg/day based on deceased fetal body weight and incomplete ossification of bones
870.3700	Prenatal developmental dermal toxicity - non-rodents	Maternal NOAEL = 70 mg/kg/day Maternal LOAEL = 170 mg/kg/day based on deceased body weight and food consumption Developmental NOAEL = 170 mg/kg/day Developmental LOAEL = 450 g/kg/day based on increased incidence of fetuses with retarded growth (incompletely ossified skull)
870.3700	Prenatal developmental oral toxicity - non-rodents	Maternal NOAEL = 5 mg/kg/day Maternal LOAEL = 15 mg/kg/day based on decreases in body weight, body weight gain, food consumption and abortions Developmental NOAEL = 15 mg/kg/day (HDT). No toxicity was observed at any dose, therefore, the NOAEL is equal to or greater than highest dose tested Developmental LOAEL = > 15 mg/kg/day
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = males: 2.20 and females: 2.41 mg/kg/day Parental/Systemic LOAEL = males: 6.31 and females: 7.82 mg/kg/day based on decreased body weight, body weight gains, and food efficiency Offspring NOAEL = 2.2 mg/kg/day Offspring LOAEL = 6.3 mg/kg/day based on decreased pup body weight and body weight gain Reproductive NOAEL = males: 6.31 and females: 7.82 mg/kg/day (HDT). No reproductive toxicity was observed at any dose Reproductive LOAEL = males: > 6.31 and > 7.82 mg/kg bwt/day (HDT)
870.4100	Chronic toxicity-dogs	NOAEL = Not established LOAEL = 0.5 mg/kg/day based on increased clinical signs of toxicity in both sexes and decreased body weight gain in females
870.4100	Chronic toxicity--dogs	NOAEL = Not established LOAEL = 1.0 mg/kg/day based on increased clinical signs of toxicity in both sexes and decreased body weight gain in females
870.4200	Carcinogenicity--rats	NOAEL = males: 1.13 and females: 1.46 mg/kg/day LOAEL = males: 5 and females: 6.52 mg/kg/day based on decreased body weight and body weight gain observed in males and females, and decreased alanine transferase in males There was no evidence of carcinogenicity
870.4300	Carcinogenicity--mice	NOAEL = 2.78 mg/kg/day (males and females) LOAEL = males: 8.88 and females: 9.74 mg/kg/day) based on decreased body weight gain, decreased food efficiency and changes in organ weights and histopathology (males) No evidence of carcinogenicity
870.5100	Gene mutation - *Salmonella*	Negative
870.5300	Gene mutation in Chinese hamster cultured V-79	Negative
870.5380	Mutagenic- structural chromosome aberration -*in vitro* cytogenetics - Chinese hamster	Negative
870.5385	Mutagenic - structural chromosome aberration - micronucleus - mouse	Negative
870.5500	Mutagenic- DNA damage/ repair- *E. Coli*	Negative

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.6200	Acute oral neurotoxicity - rat	NOAEL = 44 mg/kg (both sexes) LOAEL = 80 mg/kg/day based on increased incident of piloerection, hypoactivity, tremors, partially closed eyes, and decreases in body weight gain and food consumption No neuropathological effects were observed
870.6200	Subchronic neurotoxicity screening battery	NOAEL = males: 8.5 and females: 9.3 mg/kg/day LOAEL = males: 28.8 and females: 31.1 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency in both sexes No neuropathological effects were observed
870.7485	Metabolism and pharmacokinetics	Rapidly metabolized. Gastrointestinal tract was the major site for distribution, and elimination. Highest residues were found in liver, pancreas, spleen, kidney, lymph node and fat. Parent compound was metabolized to 20 - 30 metabolites and were resolved in urine and feces

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm*.

A summary of the toxicological endpoints for pyridaben used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIDABEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	NOAEL = 44 mg/kg/day UF = 100 Acute Reference Dose (RfD) = 0.44 mg/kg/day	Special FQPA SF = 1X Acute Population Adjusted Dose (aPAD) = acute RfD/Special FQPA SF = 0.44 mg/kg/day	Acute Neurotoxicity-Rat LOAEL = 80 mg/kg/day based on an increased incidence of piloerection, hypoactivity, tremors and partially closed eyes, decreased body weight gain and food consumption
Chronic dietary (all populations)	LOAEL = 0.5 mg/kg/day UF = 100 Chronic RfD = 0.005 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = .005 mg/kg/day	Chronic Feeding-Dog LOAEL = 0.5 mg/kg/day based on an increased incidence of ptyalism, emesis and soft stools, and decreased body weight gain in females. EPA determined that this LOAEL could be used in risk assessment without an additional safety factor because the effects seen were minimal
Cancer (oral, dermal, inhalation)	Pyridaben has been classified as a Group E chemical (i.e. evidence of non-carcinogenicity for humans) based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice		

C. Exposure Assessment

1. *Dietary exposure 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 including nectarine, peach, plum, and prune at 2.5 ppm. Tolerances have also been established for milk and fat, meat, and meat byproducts for cattle, goat, hog, horse, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from pyridaben in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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 United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each

commodity. The following assumptions were made for the acute exposure assessments: A Tier 3, acute dietary-exposure assessment (probabilistic) was conducted for pyridaben. The probabilistic assessment was based upon residue distribution files or anticipated-residue estimates derived from crop field trial data for most commodities; processing factors from processing studies were utilized for most processed commodities; and percent crop-treated estimates and projected market-share estimates were utilized for most crops.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 2, partially-refined, chronic dietary-exposure assessment was conducted for pyridaben. Anticipated-residue estimates were utilized to account for the residues of concern for risk assessment derived from proposed and established tolerance levels; and percent crop-treated estimates and projected market-share estimates were utilized for most crops.

iii. *Cancer*. Pyridaben has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative exposure assessment was not conducted to assess cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA 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 pursuant to section 408(f)(1) 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. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

4% almonds, 20% apples, 34% apricots, 25% cherries, 10% cranberry, 35% grapefruit, 10% grapes, 4% lemons, 8% oranges, 8% peaches, 22% pears, 8% plums and prunes, 15% nectarines, 1% pistachios, 25% strawberry, 25% tangerines, 8% tomatoes, and 35% for meat and milk. The following PCT data were used in the chronic dietary exposure analysis: 2.5% almonds, 10% apples, 34% apricots, 2.5% cherries, 10% cranberry, 15% grapefruit, 5% grapes, 2.5% lemons, 5% oranges, 5% peaches, 15% pears, 5% plums and prunes, 19% strawberry, 15% tangerines, and 4% tomatoes.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent 6 years.

EPA projects PCT for a new insecticide use by assuming that the PCT for the insecticide's initial 5 years will not exceed the average PCT of the dominant insecticide (the one with the largest PCT) within all insecticides over three latest available years. The PCTs included in the average may be each for the same insecticide or for different insecticides since the same or different insecticides may dominate for each year selected. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is non-proprietary and directly available without computation.

This method of projecting PCT for a new insecticide use, with or without regard to specific pest(s), produces an upper-end projection that is unlikely, in most cases, to be exceeded in actuality because the dominant insecticide is well-established and accepted by farmers. Factors that bear on whether a projection based on the dominant insecticide could be exceeded are whether the new insecticide is more efficacious or controls a broader spectrum of pests than the dominant insecticide, whether it is more cost-effective than the dominant insecticide, and whether it is likely to be readily accepted by growers and experts. These factors have been considered for this insecticide new use, and they indicate that it is unlikely that actual PCT for this new use will exceed the PCT for the dominant insecticide in the next 5 years.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyridaben in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyridaben. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of pyridaben for acute exposures are estimated to be 12 parts per billion (ppb) for surface water and 0.007 ppb for ground water. The EECs for chronic exposures are estimated to be 2.2 ppb

for surface water and 0.007 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyridaben is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyridaben and any other substances and pyridaben does not appear to produce a toxic metabolite produced by other substances. EPA has also evaluated comments submitted that suggested there might be a common mechanism among pyridaben and other named pesticides that cause brain effects. EPA concluded that the evidence did not support a finding of common mechanism for pyridaben and the named pesticides. 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 on toxicity and exposure unless EPA determines based on reliable data 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 uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no quantitative and/or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to pyridaben. There is no evidence of increased quantitative and/or qualitative susceptibility to pyridaben following prenatal exposure in a 2–generation reproduction study in the rat. There are no concerns or residual uncertainties for prenatal/postnatal toxicity.

Pyridaben elicited weak clinical signs (piloerection, hypoactivity, tremors) in an acute neurotoxicity study and a transient effect on the righting reflex in a subchronic feeding study. These signs were initially judged to be evidence of neurotoxicity and a Developmental Neurotoxicity (DNT) study was required. However, further evaluation of the entire weight of evidence has led to the conclusion that these signs are non-specific in nature and not indicative of a direct effect on the nervous system.

Pyridaben has weak neurotoxicity signs as demonstrated in the acute neurotoxicity study in rats. Piloerection, hypoactivity, tremors, and partially closed eyes were observed in animals in the 100 mg/kg bwt group. In the subchronic neurotoxicity study, transient poorly coordinated righting reflex was observed in high dose males (28.8 mg/kg bwt/day) in the absence of other neurotoxicity or neuropathology in the subchronic neurotoxicity study. Inhibition of plasma cholinesterase activity occurred at the highest dose (27.68 mg/kg bwt/day) in females only in the 90–day rat feeding study.

The Agency has determined that the DNT study is no longer required based on the following:

- The lack of evidence for abnormalities in the development of the fetal nervous system including the prenatal developmental toxicity studies in either rats (oral gavage up to 1,000 mg/kg/day) or rabbits (oral greater than 15 mg/kg/day and dermal up to 450 mg/kg/day) and the 2–generation reproduction study in rats (up to 6.31 mg/kg/day).
- The levels at which effects occurred in the acute and subchronic neurotoxicity studies were the highest doses tested where significant toxicity, other than neurotoxic signs were noted. Transient piloerection and hypoactivity were noted in the mid dose males (100 mg/kg/day) and piloerection, hypoactivity, tremors and partially closed eyes were observed in animals in the 200 mg/kg bwt group (highest dose tested) in the acute neurotoxicity study in rats. There was also transient (only 1 week), poorly coordinated righting reflex in highest dose tested (28.8 mg/kg/day) in males only in the subchronic neurotoxicity study. No neuropathology was noted in either study.
- Inhibition of plasma (butyryl and acetyl) cholinesterase activity at the highest dose tested (27.68 mg/kg/day, females) in the standard 90–day rat feeding study, this was not seen in the reversibility phase of the study. Pyridaben may have some flexibility and charge characteristics which would allow it to interact with the cholinesterase receptor in some tissues, but this response is not indicative of a neurotoxic mode of action.
- Only transient (appearing at only week 8, but not at weeks 4 or 13), poorly coordinated righting reflex in high dose males (28.8 mg/kg bwt/day) was observed in the absence of neurotoxicity in the subchronic neurotoxicity study.
- No other study of any duration showed evidence of neurotoxic effects (clinical signs, organ weights, histopathology) and the studies were tested high enough to elicit frank toxicity (other than neurotoxicity).
- The 2–generation reproduction study in rats included developmental and neurotoxicity assessments. The observations included a comprehensive evaluation of clinical signs, onset and completion of pinna (ear) unfolding, hair growth, tooth eruption, eye opening, auditory and visual function assessed using the startle response and examination of pupil closure along with assessment of the visual placement response. No effects were noted up to and including the highest dose tested (6.31 mg/kg/day). No effects were noted on reproductive parameters. The observed effects in the 2–generation reproduction study were minimal in nature involving only body weight and food consumption.

3. *Conclusion*. There is a complete toxicity data base for pyridaben and exposure data are complete. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to pyridaben in developmental studies. There is no quantitative or qualitative

evidence of increased susceptibility to pyridaben following prenatal/postnatal exposure in a 2–generation reproduction study incorporating neurotoxicity measurements. There is no concern for developmental neurotoxicity resulting from exposure to pyridaben. Since there was no observed evidence of potential developmental neurotoxicity in short- and long-term toxicity studies in rats, mice, and dogs, a DNT study is not required.

The dietary exposure scenarios includes metabolites and/or degradates of concern and the dietary food exposure assessment is refined for acute food exposure and partially refined for chronic food exposure. Although refined, the assessments are based on reliable data and will not underestimate exposure/risk. The dietary drinking water assessment (Tier 2 estimates) utilizes values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. There are no residential uses of pyridaben.

Based on these data, the Agency has reduced the FQPA Safety Factor to 1X and a developmental neurotoxicity study will not be required.

E. Aggregate Risks and Determination of Safety

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against EECs. The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. When new uses are added EPA reassesses the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EECs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

There are no existing or proposed uses for pyridaben that would result in residential non-dietary exposure, therefore aggregate acute and chronic risks are based solely on exposure from food and water, which are as follows:

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to pyridaben will occupy 3% of the aPAD for the U.S. population, 2% of the aPAD for females 13 years and older, 4% of the aPAD for all infants < 1 year old, and 6% of the aPAD for children 1–2 years old, the children subpopulation at greatest exposure. In addition, there is potential for acute dietary exposure to pyridaben in drinking water. To estimate total aggregate exposure to a pesticide from food and drinking water the Agency calculated DWLOCs which are used as a point of comparison against EECs. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PYRIDABEN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.44	3	12	0.007	15,000
Females (13-49 years old)	0.44	2	12	0.007	12,900
Children (1-2 years old)	0.44	6	12	0.007	4,100
All infants (< 1 year old)	0.44	4	12	0.007	4,200

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyridaben from food will utilize 13% of the cPAD for the U.S. population, 29% of the cPAD for all infants < 1 year old, and 47% of the cPAD for children 1–2 years old the subpopulation at greatest exposure. In addition, there is potential for chronic dietary exposure to pyridaben in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRIDABEN

Population/Subgroup	cPAD/mg/kg/day	% cPAD/(Food)	Surface Water EEC/(ppb)	Ground/Water EEC/(ppb)	Chronic/DWLOC (ppb)
U.S. population	0.005	13	2.2	0.007	150
Children (1-2 years old)	0.005	47	2.2	0.007	27
All infants (< 1 year old)	0.005	29	2.2	0.007	40

3. *Short-term and Intermediate-term risks*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyridaben is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. Pyridaben has been classified as not likely to be carcinogenic to humans. Therefore, pyridaben is expected to pose at most a negligible cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC/ECD method, BASF D9312) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex MRLs for pyridaben on hops, tropical fruit, stone fruit, strawberry, and tomatoes. Therefore, no compatibility questions exist with respect to Codex.

C. Response to Comments

The Agency received one comment expressing support for this action.

V. Conclusion

Therefore, tolerances are established for residues of pyridaben, 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one in or on hop, dried cones at 10.0 ppm; papaya at 0.10 ppm; star apple at 0.10 ppm; sapote, black at 0.10 ppm; mango at 0.10 ppm; sapodilla at 0.10 ppm; sapote, mamey at 0.10 ppm; canistel at 0.10 ppm; fruit, stone, group 12 at 2.5 ppm; strawberry at 2.5 ppm; and tomato at 0.15 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2005–0267 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 November 22, 2005.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0267, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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: September 19, 2005.

Lois Rossi,

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 amended by removing the entries for ''apricot''; ''cherry, sweet''; ''cherry, tart''; ''nectarine''; ''peach''; ''plum''; and ''prune'' from the table in paragraph (a) and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.494 Pyridaben; tolerance for residues.

(a) * * *

Commodity	Parts per million	Revocation/expiration date
* *	* *	*
Canistel	0.10	None
* *	* *	*
Fruit, stone, group 12.	2.5	None
* *	* *	*
Hop, dried cones.	10.0	None

Commodity	Parts per million	Revocation/expiration date
* *	* *	*
Mango	0.10	None
* *	* *	*
Papaya	0.10	None
* *	* *	*
Sapodilla	0.10	None
Sapote, black	0.10	None
Sapote, mamey.	0.10	None
* *	* *	*
Star apple	0.10	None
Strawberry	2.5	None
Tomato	0.15	None

* * * * *

[FR Doc. 05–19058 Filed 9–22–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL–7973–8]

Ocean Dumping; Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today designates a new Ocean Dredged Material Disposal Site (ODMDS) in the Atlantic Ocean offshore Port Royal, South Carolina, as an EPA-approved ocean dumping site for the disposal of suitable dredged material. This action is necessary to provide an acceptable ocean disposal site for consideration as an option for dredged material disposal projects in the greater Port Royal, South Carolina, vicinity. This site designation is for an indefinite period of time, but the site is subject to continuing monitoring to insure that unacceptable adverse environmental impacts do not occur.

DATES: This rule is effective on October 24, 2005.

ADDRESSES: The file supporting this designation is available for public inspection at the following location: EPA Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Gary W. Collins, (404) 562–9395.

SUPPLEMENTARY INFORMATION:

A. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.*, gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean disposal sites to the Regional Administrator of the Region in which the sites are located. This designation is being made pursuant to that authority.

The EPA Ocean Dumping Regulations promulgated under MPRSA (40 CFR Chapter I, Subchapter H, § 228.4) state that ocean dumping sites will be designated by promulgation in this part 228. This site designation is being published as final rulemaking in accordance with § 228.4(e) of the Ocean Dumping Regulations, which permits the designation of ocean disposal sites for dredged material.

B. Regulated Entities

Entities potentially affected by this action are persons, organizations, or government bodies seeking to dispose of dredged material into ocean waters offshore Port Royal, South Carolina, under the MPRSA and its implementing regulations. This final rule is expected to be primarily of relevance to parties seeking permits from the U.S. Army Corps of Engineers (COE) to transport dredged material for the purpose of disposal into ocean waters and to the COE itself for its own dredged material disposal projects. Potentially regulated categories and entities that may seek to use the proposed dredged material disposal site may include:

Category	Examples of potentially regulated entities
Federal Government	U.S. Army Corps of Engineers Civil Works Projects, U.S. Marine Corps, and Other Federal Agencies.
Industry and General Public	Port Authorities, Marinas and Harbors, Shipyards, and Marine Repair Facilities, Berth Owners.
State, local and tribal governments	Governments owning and/or responsible for ports, harbors, and/or berths, Government agencies requiring disposal of dredged material associated with public works projects.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. To determine whether your organization is affected by this action, you should carefully consider whether your organization is subject to the requirement to obtain an MPRSA permit in accordance with Section 103 of the MPRSA and the applicable regulations at 40 CFR Parts 220 and 225, and whether you wish to use the site subject to today's action. EPA notes that nothing in this final rule alters the jurisdiction or authority of EPA or the types of entities regulated under the MPRSA. Questions regarding the applicability of this final rule to a particular entity should be directed to the contact person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

C. EIS Development

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 *et seq.*, requires that Federal agencies prepare an Environmental Impact Statement (EIS) on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. The object of NEPA is to build into the agency decision making process careful consideration of all environmental aspects of proposed actions. While NEPA does not apply to EPA activities of this type, EPA has voluntarily committed to prepare NEPA documents in connection with ocean disposal site designations. (See 63 FR 58045 [October 29, 1998], ''Notice of Policy and Procedures for Voluntary Preparation of National Environmental Policy Act (NEPA) Documents.'')

EPA, in cooperation with the Charleston District COE, has prepared a Final EIS (FEIS) entitled ''Final Environmental Impact Statement for the Port Royal Ocean Dredged Material Disposal Site Designation.'' On June 25, 2004, the Notice of Availability of the FEIS for public review and comment was published in the **Federal Register** (69 FR 35597 [June 25, 2004]). Anyone desiring a copy of the EIS may obtain one from the address given above. The public comment period on the FEIS closed on July 26, 2004.

EPA received one comment letter on the FEIS from the South Carolina