(8) Reserve or resource distribution by reservoir.

* * * * *

24. In § 203.87, paragraphs (a)(1) and (d) are revised to read as follows:

§ 203.87 What is in an engineering report?

* * * * *

(a) * * *

(1) Its size along with basic design specifications and drawings; and

* * * * *

(d) A discussion of any plans for multi-phase development which includes the conceptual basis for developing in phases and goals or milestones required for starting later phases.

* * * * *

25. In § 203.89, paragraph (a) is revised to read as follows:

§ 203.89 What is in a deep water cost report?

* * * * *

(a) Sunk costs. Report sunk costs in dollars not adjusted for inflation and only if you have documentation.

* * * * *

26. In § 203.91, a new last sentence is added to read as follows:

§ 203.91 What is in a post-production development report?

* * * Also, you must have this report certified by an independent CPA according to § 203.81(c).

[FR Doc. 02–438 Filed 1–14–02; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301199; FRL–6816–4]

RIN 2070–AB78

Fenbuconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the combined residues of the fungicide fenbuconazole [*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis* and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], expressed as fenbuconazole, in or on the stone fruit (except plums and prunes) crop group at 2.0 parts per million (ppm), pecans at 0.1 ppm, and bananas at 0.3 ppm until December 31, 2004, at which time they will expire and be revoked. Dow AgroSciences LLC (then Rohm and Haas Company) requested that these temporary tolerances be made permanent under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective January 15, 2002. Objections and requests for hearings, identified by docket control number OPP–301199, must be received by EPA on or before March 18, 2002.

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–301199 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager 22, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' 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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301199. 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 March 23, 2001 (66 FR 16226) (FRL–6767–3), 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 pesticide petitions (PP 1F3989, 1F3995, and 2F4154) to make temporary tolerances permanent by Dow AgroSciences LLC,

9330 Zionsville Road, Indianapolis, IN 46268–1054. This notice included a summary of the petitions prepared by Rohm and Haas Company, now a part of Dow AgroSciences LLC, whose name and address are provided herein. There were no comments received in response to the notice of filing. The existing time-limited tolerances will expire on December 31, 2001.

The petitions requested that 40 CFR 180.480 be amended by making time-limited tolerances for combined residues of the fungicide fenbuconazole [*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis* and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], expressed as fenbuconazole in or on the stone fruit (except plums and prunes) crop group at 2.0 parts per million (ppm), pecans at 0.1 ppm, and bananas at 0.3 ppm permanent. However, the Agency has determined that it is more appropriate to extend them until December 31, 2004, while the Agency completes its review of data submitted to support the continued registration of fenbuconazole.

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 extension of time-limited tolerances for combined residues of fenbuconazole [*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis* and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], expressed as fenbuconazole in or on the stone fruit (except plums and prunes) crop group at 2.0 ppm, pecans at 0.1 ppm, and bananas at 0.3 ppm until December 31, 2004. EPA's assessment of exposures and risks associated with extending the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects, and the no observed adverse effect levels (NOAEL) and the lowest observed adverse effect levels (LOAEL) from the fenbuconazole toxicity studies are discussed below.

1. The acute toxicological tests of the technical product produced the following results. In the acute oral toxicity study the lethal dose 50% (LD_{50}) was greater than 2 grams per kilogram (g/kg) body weight. The acute dermal toxicity study produced an LD_{50} of greater than 5 g/kg body weight. The acute inhalation lethal concentration 50% (LC_{50}) was greater than 2.1 milligrams per liter (mg/L). In both the primary eye irritation and primary skin irritation studies technical fenbuconazole was classified as non-irritating, and also tested negative for dermal sensitization.

2. A 13–week rat feeding study produced a NOAEL of 20 ppm (1.3 milligrams per kilogram per day (mg/kg/day) for males and 1.5 mg/kg/day for females) and a LOAEL of 80 ppm (5.1 mg/kg/day for males and 6.3 mg/kg/day for females), the endpoint effect being liver histopathology changes.

3. In a 3–month mouse feeding study there was a NOAEL of 20 ppm (3.8 mg/kg/day for males and 5.7 mg/kg/day for females) and a LOAEL of 60 ppm (11.1 mg/kg/day for males and 17.6 mg/kg/day for females), based on liver histopathology changes.

4. A 3–month dog feeding study produced a NOAEL of 100 ppm (3.3 mg/kg/day for males and 3.5 mg/kg/day for females) and a LOAEL of 400 ppm (13.3 mg/kg/day for males and 14.0 mg/kg/day for females), the end point effect being liver histopathology changes.

5. A 21–day rat dermal study produced a NOAEL of 1,000 mg/kg/day (the limit dose) and therefore a LOAEL greater than 1,000 mg/kg/day. Poor dermal absorption was indicated.

6. In a 78–week dietary carcinogenicity study in mice, the NOAEL was 10 ppm (1.43 mg/kg/day); males had a LOAEL of 200 ppm (28.6 mg/kg/day) and females had a LOAEL of 650 ppm (92.9 mg/kg/day), based on hepatocellular enlargement and a greater incidence and severity of hepatocellular vacuolation. There was also evidence of carcinogenicity based on the occurrence of an increased trend for malignant liver tumors in males and an increase in benign and malignant liver tumors in females.

7. A 24–month rat chronic feeding/carcinogenicity study with a systemic NOAEL of 80 ppm (3.03 mg/kg/day for females and 4.02 mg/kg/day for males) and a systemic LOAEL of 800 ppm (30.62 mg/kg/day for males and 43.07 mg/kg/day for females), based on decreases in body weight gains in females, hepatocellular enlargement and vacuolization in females, increases in thyroid weight in both males and females, and histopathological lesions in the thyroid glands in both sexes. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors in males.

8. A 24–month male rat chronic feeding/carcinogenicity study that had a NOAEL of less than 800 ppm and a LOAEL of 800 ppm (30.41 mg/kg/day), based on decreased body weight gain and increased liver and thyroid/parathyroid weights and lesions. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors in males.

9. A 1–year dog chronic feeding study with a NOAEL of 15 ppm (0.38 mg/kg/day) for females and 150 ppm (3.75 mg/kg/day) for males. The LOAEL, 150 ppm for females and 1,200 ppm (30 mg/kg/day) for males, was based on decreases in body weight gain and on adaptive changes in the liver which reflected increased metabolic activity.

10. A 2–generation rat reproduction study with a parental NOAEL of 4 mg/kg/day (80 ppm) and LOAEL of 40 mg/kg/day (800 ppm), based on decreased body weight and food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increases in adrenal and thyroid/parathyroid weights. The reproductive NOAEL was 40 mg/kg/day (800 ppm; the highest dose tested).

11. A developmental toxicity study in rabbits produced a maternal NOAEL of 10 mg/kg/day, a developmental NOAEL of 30 mg/kg/day, an undeterminable developmental LOAEL and a maternal LOAEL of 30 mg/kg/day.

12. A developmental rat toxicity study with a maternal and developmental NOAEL of 30 mg/kg/day, a maternal LOAEL of 75 mg/kg/day due to a decrease in maternal body weight compared to controls, and a developmental LOAEL of 75 mg/kg/day due to an increase in post-implantation loss and a decreased number of live fetuses per dam.

13. Mutation studies showed the following. There was no evidence of gene mutation in a test for induction of gene mutation at the HGPRT locus in Chinese hamster ovary cells, no increase in the number of cells with aberrations or observations per cell in an *in vivo* cytogenetics assay using bone marrow from treated rats, and no increase in unscheduled DNA synthesis in a rat primary hepatocyte study.

14. In a rat metabolism study radiolabeled fenbuconazole was rapidly absorbed, distributed, and excreted following oral administration in rats. Biliary excretion data indicted that systemic absorption of fenbuconazole was high for all dosing groups. The feces were the major route of excretion. Tissue distribution and bioaccumulation of fenbuconazole appeared to be minimal.

B. Toxicological Endpoints

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences multiplied by 10X to account for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q1*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q1* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q1* is calculated and used to estimate risk, which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' (threshold) is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fenbuconazole used for human risk assessment follows.

1. *Acute exposure*. For acute dietary risk assessments a reference dose (acute RfD) of 0.3 mg/kg/day was established for females 13+ years old, the population subgroup of concern, based on the developmental toxicity study in the rat, which had a NOAEL of 30 mg/kg/day based on an increase in post-implantation loss and a significant decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day. A UF of 100 was used. No appropriate endpoint was available for analyzing the acute exposure of the overall U.S. population.

2. *Short- and Intermediate-term Exposure*. Short- and intermediate-term endpoints were not identified. Fenbuconazole also has no residential uses. Therefore, an aggregate risk assessment was not done for these endpoints.

3. *Chronic exposure*. The reference dose (chronic RfD) of 0.03 mg/kg/day was based on the chronic toxicity study in the rat, which had a NOAEL of 3.03 and 4.02 mg/kg/day in males and females, respectively, based on decreased body weight gains (females), hepatocellular enlargement and vacuolation (females), increases in thyroid weight (both sexes), and histopathological lesions in the liver and thyroid glands (both sexes) at the LOAEL of 30.62/43.04 mg/kg/day in males and females, respectively. A UF of 100 was used.

4. *Cancer*. The Agency has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in both mice and rats and has classified fenbuconazole as a Group C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** (51 FR 33992, September 24, 1986), and recommended that for the purpose of risk characterization a low-dose extrapolation model applied to the experimental animal tumor data should be used for quantification of human risk (Q1*). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomas-carcinomas in male rats in two studies, both by pair-wise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the Q1* of 3.59 x 10^{-3} $(mg/kg/day)^{-1}$ in human equivalents.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.480) for the combined residues of the fungicide fenbuconazole [*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis* and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], expressed as fenbuconazole, in or on several agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fenbuconazole in food as follows. In addition to the agricultural commodities that are the

subjects of this final rule, the dietary risk analysis included published FIFRA section 18 temporary tolerances on blueberry; grapefruit; the fat, kidney, liver, meat, meat byproducts, and other organ meats of cattle, goats, hogs, and sheep; and horses, meat. The need for and, if so, results of these analyses follow.

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity consumed. The following assumptions were made for the acute exposure assessments: An acute RfD of 0.3 mg/kg/day was used for the females 13+ years old, the population subgroup of concern, based on the developmental rat toxicity study. This study had a NOAEL of 30 mg/kg/day, based on a decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day and an uncertainty factor of 100. Neither percent crop treated (PCT) nor anticipated residue data were used in the acute exposure/risk analysis.

ii. *Short- and intermediate-term exposure*. Short- and intermediate-term endpoints were not identified. Fenbuconazole also has no residential uses. Therefore, an aggregate risk assessment was not performed for these endpoints.

iii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity consumed. The following assumptions were made for the chronic exposure assessments: A chronic RfD of 0.03 mg/kg/day was used and was based on the rat chronic toxicity study. This study had NOAELs of 3.03 and 4.02 mg/kg/day in males and females, respectively, based on decreased body weight gains (females), hepatocellular enlargement and vacuolation (females), increases in thyroid weight (both sexes), and histopathological lesions in the liver and thyroid glands (males) at the LOAELs of 30.62 and 43.04 mg/kg/day in males and females, respectively. An UF of 100 was again used. Anticipated residues were not used in the exposure/risk analysis; the only adjusted PCT datum used was 12.8% for the stone fruit (except plums and prunes) crop group. This percentage was derived from an annual production cap for fenbuconazole for use on the stone fruit (except plums and prunes) crop group of 38,000 lb of the Indar 75 WSP product (EPA Registration Number 62719–421; the only fenbuconazole product registered for use on stone fruits), equal to 28,500 lb of active ingredient. This amount was calculated by the Agency in 1995 as being equivalent to treating 12.8% of the total United States acreage of apricots, cherries, nectarines, and peaches with fenbuconazole and was made a condition of the registration of this product. The identical production cap is still in place and no additional fenbuconazole products have been registered for use on stone fruits.

iv. *Cancer*. The Agency has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in both mice and rats and has classified fenbuconazole as a Group C carcinogen (possible human carcinogen with limited evidence of carcinogenicity in animals). A low-dose extrapolation model was applied to the experimental animal tumor data used for quantification of human risk (Q1*). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomas-carcinomas in male rats in two studies, both by pair-wise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the Q1* of 3.59×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents. Anticipated residues were not used in the exposure/risk analysis; the only adjusted PCT datum used was 12.8% for the stone fruit (except plums and prunes) crop group. This percentage was derived from an annual production cap for fenbuconazole for use on the stone fruit (except plums and prunes) crop group of 38,000 lb of the Indar 75 WSP product (EPA Registration Number 62719–421; the only fenbuconazole product registered for use on stone fruits), equal to 28,500 lb of active ingredient. This amount was calculated by the Agency in 1995 as being equivalent to treating 12.8% of the total United States acreage of apricots, cherries, nectarines, and peaches with fenbuconazole and was made a condition of the registration of this product. The identical production cap is still in place and no additional fenbuconazole products have been registered for use on stone fruits.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(F) 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), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows. For chronic toxicity and carcinogenicity a PCT value of 12.8% was used for the stone fruit (except plums and prunes) crop group. No other PCT data were used for fenbuconazole exposure/risk analysis.

When fenbuconazole was first registered, a condition of the registration of the fenbuconazole-containing product Indar 75 WSP (EPA Registration Number 62719–421), the only such product being registered for use on the stone fruit (except plums and prunes) crop group, was that only 38,000 lb of it (28,500 lb of the active ingredient) could be manufactured for this use annually. The Agency calculated, in 1995, that this was equivalent to treating 12.8% of the total United States acreage of apricots, cherries, nectarines, and peaches with fenbuconazole. That value has been directly applied to the analysis of dietary exposure and risk as the PCT for fenbuconazole on the stone fruit (except plums and prunes) crop group. Since then, this production cap has remained continuously in place at that same value, and no additional fenbuconazole products have been registered or labeled for use on this crop group.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described above for fenbuconazole used on the stone fruit (except plums and prunes) crop group is reliable and has a valid basis. Fenbuconazole's use on this crop group is unlikely to exceed the calculated PCT because of the rigid production cap and restriction of this use to the one product with the production cap. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into

account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which fenbuconazole may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenbuconazole 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 fenbuconazole.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the Screening Concentration in Ground Water (SCI-GROW) model to predict pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/ EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporates an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

Based on the GENEEC model, the maximum EEC of fenbuconazole in surface water, based on aerial application of the highest labeled annual use rate of 0.75 lb of active ingredient per acre (ai/A), is 6.7 parts per billion (ppb) for acute exposures and 3.6 ppb for chronic exposures. Based on the SCI-GROW model, the maximum EEC of fenbuconazole in ground water, for both acute and chronic exposure, is 0.03 ppb. Since the ground water EECs for fenbuconazole are so much lower than the surface water EECs, only the surface water EECs were used for the purpose of comparisons with the calculated DWLOCs.

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). Fenbuconazole is not registered for use on any sites that would result in residential exposure.

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, at this time, have available data to determine whether fenbuconazole has a common mechanism of toxicity with other substances or to determine how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based upon common mechanism of toxicity, fenbuconazole does not appear to produce a toxic metabolite produced by other substances. For purposes of this tolerance action, EPA has not assumed that fenbuconazole has a common mechanism of toxicity with other substances. For further 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. Safety Factor for Infants and Children

1. *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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. The applicable studies are as follows.

2. *Prenatal and postnatal sensitivity*. A 2-generation rat reproduction study with a parental NOAEL of 4 mg/kg/day (80 ppm) and LOAEL of 40 mg/kg/day (800 ppm), based on decreased body weight and food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increases in adrenal and thyroid weights.The reproductive NOAEL was 40 mg/kg/day HDT.

A developmental toxicity study in rabbits produced a maternal NOAEL of 10 mg/kg/day, a developmental NOAEL of 30 mg/kg/day, an undeterminable developmental LOAEL of 60 mg/kg/day (due to increased resorptions), and a maternal LOAEL of 30 mg/kg/day.

A developmental rat toxicity study resulted in a maternal and developmental NOAEL of 30 mg/kg/day, a maternal LOAEL of 75 mg/kg/day due to a decrease in maternal body weight compared to controls, and a developmental LOAEL of 75 mg/kg/day due to an increase in post-implantation loss and a decreased number of live fetuses per dam.

3. *Conclusion*. Therefore, a complete toxicity data base for fenbuconazole exists and exposure data are complete or

are estimated based on data that reasonably account for potential exposures. Based on the developmental and reproductive toxicity studies there is no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to fenbuconazole. In the developmental toxicity studies in rats and rabbits, as well as the 2–generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses and was not judged to be more severe than in the maternal/parental animals. EPA therefore determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because:

i. The toxicology data base is complete.

ii. There is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* or and/or postnatal exposure in the developmental and reproductive toxicity studies.

iii. Dietary (food) exposure estimates are slightly refined (using limited PCT data for the stone fruit (except plum and prune) crop group) but likely result in overestimates of the actual dietary exposure.

iv. Models are used for ground and surface source drinking water exposure assessments, resulting in estimates that are upper-bound concentrations.

v. There are currently no registered residential uses for fenbuconazole and, as a result, this type of infant and children exposure is not expected.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as points of comparison with the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and 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 the USEPA Office of Water, are used to calculate DWLOCs: 2L per 70 kg body weight (adult male), 2L per 60 kg body weight (adult female), and 1L per 10 kg body weight (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. 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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. For the population subgroup of concern, females 13 years old and older, the acute RfD is 0.3 mg/kg/day, the estimated acute food exposure is 0.015 mg/kg/day, the maximum estimated acute water exposure is 0.29 mg/kg/day, the acute DWLOC is 8.6×10^3 microgram/liter (µg/L), and the acute EEC is 6.7 µg/L. Therefore, the Agency concludes with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of acute exposure for which reliable data exist) will not result in unacceptable levels of acute aggregate human health risk estimates for the population subgroup females 13 years old and older.

The Agency generally has no concern for exposures below 100% of the acute RfD (when the FQPA Safety Factor has been removed, as is the case for fenbuconazole) because the acute RfD represents the level at or below which a single daily exposure will not pose appreciable risks to human health. Despite the potential for exposure to fenbuconazole in drinking water, the Agency does not expect the acute aggregate exposure to exceed 100% of the acute RfD for the subpopulation of cencern (females 13 years old and older). The Agency concludes that there is a reasonable certainty that no harm will result to females 13 years old and older from chronic aggregate exposure to fenbuconazole residues.

2. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term endpoints were not identified. Fenbuconazole is also not registered for use on any sites that would result in residential exposure. Therefore, the short-term aggregate risk assessment was not performed.

3. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term endpoints were not identified. Fenbuconazole is also not registered for use on any sites that would result in residential exposure. Therefore, the intermediate-term aggregate risk assessment was not performed.

4. *Chronic risk*. The following values were used or derived in calculations of chronic exposure and risk. The percentages of the chronic RfD that food exposure to fenbuconazole represented were <1.0% for the overall U.S. population, 2.5% for all infants (<1 year old), 1.1% for nursing infants (<1 year old), 3.1% for non-nursing infants (<1 year old), 1.5% for children (1-6 years old), <1.0% for non-Hispanic (other than Black or White), and 1.0% for seniors (55 years old or older). The adult population subgroup with the highest food exposure, non-Hispanic (other than black or white), was the subgroup used in the full analysis. For males the chronic RfD is 0.03, the estimated chronic food exposure is 0.00030 mg/kg/day, the maximum estimated water exposure is 0.030 mg/kg/day, DWLOC is 1.0×10^3 µg/L, and the chronic EEC is 3.6 µg/L. For females the chronic RfD is 0.03, the estimated chronic food exposure is 0.00030 mg/kg/day, the maximum estimated water exposure is 0.030 mg/kg/day, DWLOC is 8.9×10^2 µg/L, and the chronic EEC is 3.6 µg/L.

The estimated 56–day concentration of fenbuconazole in surface water (3.6 µg/L) is less than the Agency's levels of comparison for fenbuconazole in drinking water as a contribution to chronic aggregate exposure (1.0×10^3 µg/L and 8.9×10^2 µg/L for males and females respectively). Therefore, taking into account the registered uses, the Agency concludes with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of chronic exposure for which the Agency has reliable data) would not result in unacceptable levels of chronic aggregate

human health risk estimates for adult population subgroups.

The Agency generally has no concern for exposures below 100% of the chronic RfD (when the FQPA Safety Factor has been removed, as is the case for fenbuconazole) because the chronic RfD represents the level at or below which average daily lifetime exposure will not pose appreciable risks to human health. Despite the potential for exposure to fenbuconazole in drinking water, the Agency does not expect the chronic aggregate exposure to exceed 100% of the chronic RfD for population subgroups which include adults. The Agency concludes that there is a reasonable certainty that no harm will result to adults from chronic aggregate exposure to fenbuconazole residues.

5. *Aggregate cancer risk for U.S. population*. Fenbuconazole has been classified as a Group C carcinogen with a Q1* of 3.59×10^{-3} $(mg/kg/day)^{-1}$. The group used in this analysis was U.S. population (48 contiguous states), the U.S. population as a whole. The cancer analysis, using all of the existing fenbuconazole tolerances (including section 18 tolerances), results in a cancer risk estimate of 8.3×10^{-7} for food consumption for the U.S. population as a whole. This analysis used 100% crop treatment values except for the stone fruit (except plum and prune) crop group, where a value of 12.8% crop treated was used. Based on the cancer dietary (food only) exposure and using default body weights and water consumption figures, a cancer DWLOC was calculated. The values used or calculated as part of the calculation of the DWLOC are the Q 1* of 3.59×10^{-3} $(mg/kg/day)^{-1}$, a food exposure of 0.00023 mg/kg/day, a maximum water exposure of 4.6×10^{-5} mg/kg/day, a DWLOC of 1.6 µg/L, and a chronic EEC of 3.6 µg/L.

Agency policy states that a factor of three will be applied to GENEEC model values when determining whether or not a level of comparison has been exceeded. If the GENEEC model value is less than or equal to three times the DWLOC, the pesticide is considered to have passed the screen and no further assessment is needed. The estimated 56–day (chronic) concentration of fenbuconazole in surface water (3.6 µg/L) is less than three times the level of comparison ($3 \times 1.6 = 4.8$ µg/L) for fenbuconazole in drinking water as a contribution to chronic (cancer) aggregate exposure. Therefore, it is concluded with reasonable certainty that residues of fenbuconazole in drinking water, when considered along with other sources of chronic (cancer) exposure for which there is reliable data, would not result in unacceptable levels of cancer aggregate human health risk estimates for the overall U.S. population. The chronic food exposure estimate is partially refined. Further refinement would lower the food exposure estimate and result in a higher DWLOC.

The Agency generally has no concern for exposures that result in a cancer risk estimate below 1×10^{-6}. Despite the potential for exposure to fenbuconazole in drinking water, the Agency does not expect the chronic (cancer) aggregate exposure to exceed 1×10^{-6} for the U.S. population as a whole. The Agency concludes that there is a reasonable certainty that no harm will result to the overall U.S. population from chronic (cancer) aggregate exposure to fenbucanazole residues.

6. *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, or to infants and children from aggregate exposure to fenbuconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. This method involves extraction of parent and metabolites into solvent followed by concentration, clean up, separation by gas chromatography, and detection with a nitrogen phosphorus detector. This method was submitted for inclusion in PAM II. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits for fenbuconazole in or on pecans, bananas, and the stone fruit (except plums and prunes) crop group.

C. Conditions

Discuss conditions for registration (i.e., additional residue field trials required), regional registration, etc.

The conditions of registration for fenbuconazole were submissions of the following items. Five additional studies had to be submitted: (1) Fish life cycle, (2) growth and reproduction of aquatic plants, (3) droplet size spectrum, (4) drift field evaluation, and (5) 49–month storage stability study. Several corrections to the labels were required. Mitigation measures to address chronic non-target organism toxicity concerns had to be identified and submitted. Production of the Indar 75 WSP product could not exceed 38,000 lb (28,500 lb ai) for each year of conditional registration and information on its production had to be submitted for the first federal fiscal year during which fenbuconazole was registered for use on stone fruits and pecans. Production information had to be submitted for the Enable 2F product (EPA Registration Number 62719–416) for the first federal fiscal year during which this product was registered for use on pecans. The company has subsequently submitted studies, information, and corrected labels, and participated in task forces, intended to satisfy all these condition-of-registration requirements. All such submissions that have been reviewed have been found to satisfy the appropriate registration condition.

V. Conclusion

Therefore, the tolerances are extended until December 31, 2004 for the combined residues of the fungicide fenbuconazole [*alpha*-(2-(4-chlorophenyl)-ethyl)-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis* and *trans*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], expressed as fenbuconazole, in or on the stone fruit (except plums and prunes) crop group at 2.0 ppm, pecans at 0.1 ppm, and bananas at 0.3 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–301199 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 March 18, 2002.

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 a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 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–301199, 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 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 extends tolerances 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). 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 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). 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. 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: December 26, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

§ 180.480 [Amended]

2. In § 180.480(a)(1) is amended by revising the ''Expiration/Revocation Date'' in the table ''12/31/01'' to read ''12/31/04.'' for the entries ''bananas (whole fruit)''; ''pecans''; and ''stone fruit crop group (except plums and prunes)''.

[FR Doc. 02–962 Filed 1–14–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7125–1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste Final Exclusion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA (also, ''the Agency'' or ''we'' in this preamble) is granting a delisting to Heritage Environmental Services, LLC (Heritage) to exclude treated Electric Arc Furnace Dust (EAFD) produced at Nucor Steel, Division of Nucor Corporation (Nucor) located in Crawfordsville, Indiana from the lists of hazardous wastes.

After careful analysis, the EPA has concluded that the petitioned waste is not a hazardous waste when disposed of in a Subtitle D landfill. Today's action conditionally excludes the petitioned waste from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) only if the waste is disposed of in a Subtitle D landfill which is permitted, licensed, or registered by a State to manage industrial solid waste.

EFFECTIVE DATE: This rule is effective on January 15, 2002.

ADDRESSES: The RCRA regulatory docket for this final rule is located at the U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, and is available for viewing from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding federal holidays. Call Todd Ramaly at (312) 353–9317 for appointments. The public may copy material from the regulatory docket at $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For technical information concerning this document, contact Todd Ramaly at the address above or at (312) 353–9317.

SUPPLEMENTARY INFORMATION: The information in this section is organized as follows:

I. Background

A. What Is a Delisting Petition?

A delisting petition is a request from to exclude waste from the list of hazardous wastes under RCRA regulations. In a delisting petition, the petitioner must show that waste generated at a particular facility does not meet any of the criteria for which EPA listed the waste as set forth in 40 CFR 261.11 and the background document for the waste. In addition, a petitioner must demonstrate that the waste does not exhibit any of the hazardous waste characteristics (that is, ignitability, reactivity, corrosivity, and toxicity) and must present sufficient information for us to decide whether factors other than those for which the waste was listed warrant retaining it as a hazardous waste.

A petitioner remains obligated under RCRA to confirm that the waste remains nonhazardous based on the hazardous waste characteristics even if EPA has ''delisted'' the waste.

B. What Regulations Allow a Waste To Be Delisted?

Under 40 CFR 260.20 and 260.22, a person may petition the EPA to remove