Dated: February 26, 1999.

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), 346a and 371.

§ 180.175 [Amended]

2. In § 180.175, by amending the table in paragraph (b) for all of the commodities by changing the date ''9/30/99'' to read ''9/30/00''.

[FR Doc. 99–5960 Filed 3–9–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300800; FRL–6065–3]

RIN 2070–AB78

2,4-D; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid in or on soybeans. Industry Task Force II on 2,4-D Research Data requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire on December 31, 2001.

DATES: This regulation is effective March 10, 1999. Objections and requests for hearings must be received by EPA on or before May 10, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300800], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300800], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300800]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 235, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–6224, miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 11, 1998 (63 FR 68455) (FRL–6043–3), 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) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Industry Task Force II on 2,4-D Research Data, McKenna & Cuneo, 1900 K St., NW, Washington, DC 20006–1108. This notice included a summary of the petition prepared by Industry Task Force II on 2,4-D Research Data, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.142 be amended by establishing a time-limited tolerance for residues of the herbicide 2,4-dichlorophenoxyacetic acid, in or on soybeans at 0.02 part per million (ppm). This tolerance will expire on December 31, 2001.

I. Background and Statutory Findings

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).

II. 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 2,4-D and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid on soybeans at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 2,4-D are discussed in this unit.

An oral LD_{50} of 2,4-D acid is 699 miligrams/kilograms (mg/kg) in the rat.

The dermal LD_{50} in the rabbit is >2000 mg/kg. The acute inhalation LC_{50} in the rat is >1.8 mg/liter. A primary eye irritation study in the rabbit showed severe irritation. A dermal irritation study in the rabbit showed moderate irritation. A dermal sensitization study in the guinea pig showed no skin sensitization. An acute neurotoxicity study in the rat produced a no observed advers effect level (NOAEL) of 227 mg/kg for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kg with a lowest observed effect level (LOEL) of 227 mg/kg.

Mutagenicity studies including gene mutation, chromosomal aberrations, and direct DNA damage tests were negative for mutagenic effects.

A 2-generation reproduction study was conducted in rats with NOAELs for parental and developmental toxicity of 5 mg/kg/day. The LOELs for this study are established at 20 mg/kg/day based on reductions in body weight gain in F_0 and F_{2b} pups, and reduction in pup weight at birth and during lactation. A teratology study in rabbits given gavage doses at 0, 10, 30, and 90 mg/kg on days 6 through 18 of gestation was negative for developmental toxicity at all doses tested. A teratology study in rats given gavage doses at 0, 8, 25, and 75 mg/kg on days 6 through 15 of gestation was negative for developmental toxicity at all doses tested. A NOAEL for fetotoxicity was established at 25 mg/kg/day based on delayed ossification at the 75 mg/kg dose level. The effects on pups occurred in the presence of parental toxicity.

A subchronic dietary study was conducted with mice fed diets containing 0, 1, 15, 100, and 300 mg/kg/day with a NOAEL of 15 mg/kg/day. The LOEL was established at 100 mg/kg/day based on decreased glucose and thyroxine levels, increases in absolute and relative kidney weights, and histopathological lesions in the liver and kidneys. A 90-day dietary study in rats fed diets containing 0, 1, 15, 100, or 300 mg/kg/day resulted in a NOAEL of 15 mg/kg/day and an LOEL of 100 mg/kg/day. The LOEL was based on decreases in body weight and food consumption, alteration in clinical pathology, changes in organ weights, and histopathological lesions in the kidney, liver, and adrenal glands of both sexes of rats. A 90-day feeding study was conducted in dogs fed diets containing 0, 0.3, 1, 3, and 10 mg/kg/day with a NOAEL of 1 mg/kg/day. The LOEL was established at 3 mg/kg/day based on histopathological changes in the kidneys of male dogs.

A 1-year dietary study was conducted in the dog using doses of 0, 1, 5, and 7.5 mg/kg/day. The NOAEL was 1 mg/kg/day and the LOEL was 5 mg/kg/day based on clinical chemistry changes and histopathological lesions in the liver and kidney. A 2-year feeding/carcinogenicity study was conducted in mice fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/kg/day. The systemic LOEL was established at 15 mg/kg/day based on increased kidney and adrenal weights and homogeneity of renal tubular epithelium due to cytoplasmic vacuoles. No carcinogenic effects were observed under the conditions of the study at any dosage level tested. A second 2-year oncogenicity study was conducted in mice fed diets containing 0, 5, 62.5, and 125 mg/kg/day (males) and 0, 5, 150, and 300 mg/kg/day (females). No treatment-related oncogenicity was observed. A 2-year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg kg/day. Although there appeared to be a slight treatment-related incidence of benign brain tumors (astrocytomas) in male rats fed diets containing 45 mg/kg/day, two different statistical evaluations found no strong statistical evidence of carcinogenicity in male rats. There were no carcinogenic effects observed in female rats. A second 2-year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 5, 75, and 150 mg/kg/day. The NOAEL was 5 mg/kg/day and the LOEL was 75 mg/kg/day based on decreased body weight, body weight gain and food consumption; clinical chemistry changes; organ weight changes and histopathological lesions. No treatment-related carcinogenic effects or increased incidences of astrocytomas were observed.

The metabolism of phenyl ring labeled ^{14}C–2,4-D was studied in the rat following a single intravenous or oral dose of approximately 1 mg/kg/day. At 48 hours after treatment, recovery of radioactivity in urine was in excess of 98%. Parent 2,4-D was the major metabolite (72.9% to 90.5%) found in the urine.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA has used an acute neurotoxicity study in rats for endpoint for acute toxicity. The NOAEL of 67 mg/kg/day was based on the increased incidence of incoordination, slight gait abnormalities, and decreased motor activity in both sexes at the lowest observed adverse effect (LOAEL) of 227 mg/kg/day. This risk assessment will evaluate acute dietary risk to all population subgroups.

2. *Short - and intermediate-term toxicity*. For short-term dermal Margin of Exposure (MOE) calculations, EPA used the maternal NOAEL of 30 mg/kg/day from an oral developmental toxicity study in rabbits. The MOE is a measure of how close the high end of exposure comes to the NOAEL (or LOAEL, as the case may be) and is calculated as the ratio of the NOAEL to the exposure. The LOAEL of 90 mg/kg/day was based on abortions, clinical signs (ataxia, decreased motor activity, and cold extremities during gestation), and decreased body weight gain. For acute toxicity, EPA decided that FQPA factor of 10 should be reduced to 3 for females 13 years old and older (13+) and removed for all other population subgroups. As the short-term and acute endpoints are based on the oral developmental toxicity study, this decision is also applicable to the short-term, nonoccupational assessment. Therefore, based on this recommendation, the MOE needed for females 13+ is 300.

For intermediate-term dermal MOE calculations, EPA used the NOAEL of 1.0 mg/kg/day from a 90-day oral toxicity study in dogs. The LOAEL of 3 mg/kg/day was based on clinical chemistry changes (increased BUN and creatinine levels) and lesions in the kidneys. An MOE of 100 is required.

3. *Chronic toxicity*. EPA has established the RfD for 2,4-D at 0.01 mg/kg/day. This RfD is based on a 1-year oral toxicity study in dogs with a NOAEL of 1 mg/kg/day and an uncertainty factor (UF) of 100, based on alterations in serum chemistry with corroborative histopathological lesions in the liver and kidneys.

4. *Carcinogenicity*. EPA has classified 2,4-D as a Group D chemical (''not classifiable as to human carcinogenicity'') on the basis that ''the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect''.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.142) for the residues of 2,4-dichlorophenoxyacetic acid, in or on a variety of raw agricultural commodities. A time limited tolerance of 0.1 ppm was previously established for residues of 2,4-D on soybeans resulting from the preplant use of 2,4-D ester or amine 40 CFR 180.142(a)(11). In order for EPA to recommend favorably for the establishment of permanent tolerances on soybeans, additional field trial data and processing data were required. In response, the Industry Task Force II on

2,4-D Research Data (Task Force II) submitted field residue data on soybeans. EPA reviewed these data and concluded that a tolerance of 0.02 ppm was appropriate for soybean seed. Task Force II has thus proposed to extend the soybean tolerance to December 31, 2001 at a level of 0.02 ppm. Risk assessments were conducted by EPA to assessed dietary exposures from 2,4-D as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–91 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Each analysis assumes uniform distribution of 2,4-D in the commodity supply.

The acute exposure analysis for all subgroup was performed using anticipated and tolerance-level residues and 100 percent crop treated. The high end MOE for the subgroup of Females (13+) was 399, and is no cause for concern given the need of a MOE of 300. The high end MOEs for the remaining populations ranged from 214 (infants less than one year old) to 321 (overall U.S. population, 48 states), and demonstrate no cause for concern given the need of a MOE of 100. Therefore, EPA does not consider the acute food risk to exceed the level of concern.

ii. *Chronic exposure and risk.* A chronic dietary risk assessment was performed for 2,4-D using the RfD for the chronic dietary analysis of 0.01 mg/kg bwt/day. Chronic dietary exposure estimates (DEEM) used mean consumption (3 day average) and anticipated or tolerance-level residues for all commodities. Exposure estimates used 25.6% of the RfD for the general U.S. population (48 states) and 49.2% of the RfD for the most exposed population of non-nursing infants (less than one year old). Since estimated exposures did not exceed the RfD for any subgroup, EPA does not consider the chronic food risk to exceed the level of concern.

2. *From drinking water.* A Maximum Contaminant Level (MCL) of 0.07 mg/L and Health Advisories (HAs) as follows are established for 2,4-D in drinking water: for a 10-kg child, a range of 1 mg/L from 1-day exposure to 0.1 mg/L for longer-term exposure up to 7 years; for a 70-kg adult, a range of 0.4 mg/L for longer-term exposure to 0.07 mg/L for lifetime exposure.

Information in the Pesticides in Groundwater Database (EPA 734–12–92–001, 9/92) indicates that 6,142 wells in 32 States were sampled for residues of 2,4-D during the period 1979-91. Detectable residues were reported (0.0079–57.1 g/L) in 2.3% (139) of those sampled wells.

An FQPA water assessment was conducted by the Environmental Fate and Effects Division (EFED) to support an FQPA tolerance reassessment for the use of 2,4-D dimethylamine salt (DMA), 2,4-D ethylhexyl ester (EHE), and 2,4-D (acid) as a soybean burndown product. Since laboratory environmental fate data indicate that 2,4-D DMA and 2,4-D EHE degrade rapidly to form 2,4-D, the water assessment is focused on the environmental fate and transport of the 2,4-D. The strategy assumes that the 2,4-D DMA and 2,4-EHE are not persistent in the environment, and the environmental fate of these compounds is dependent on the fate properties of the degradate 2,4-D.

It is noteworthy that water treatment processes affect the removal of 2,4-D from raw water (Versar, 1992). These treatments include granulated activated carbon (70–100% removal), packed tower aeration (0-29% removal), and ozone oxidation (30–69% removal).

A review of the labels indicate that the highest single application rate in terrestrial environments (e.g., terrestrial noncrop and terrestrial crop use patterns) for 2,4-D occur at 3.74 pounds of active ingredient per acre (lbs ai/A), for 2,4-D EHE occur at 10 lbs ai/A, and for 2,4-D DMA occur at 2 lbs ai/A. These rates represent seasonal maximum application rates as part of 2,4-D exposure reduction agreement to support 2,4-D use on pasture/rangeland, forestry, and residential and turf (excluding sod farm) sites. It is noteworthy that the 10 lbs ai/A rate corresponds to a basal bark spot treatment. Since this type of application cannot be simulated from Tier 1 models, EFED conducted modeling on the label rate from the 2,4-D label.

For groundwater, SCIGROW modeling indicates that the 2,4-D concentration in ground water is not likely to exceed 0.014 µg/L for both peak (acute) and annual average (chronic) concentration. Since this estimation was less than the actual monitoring concentrations noted above, the actual monitoring concentrations were used in the risk assessment.

For surface water estimates were made using the generic expected environmental concentration (GENEEC) model. GENEEC modeling indicates that 2,4-D concentrations in raw surface water are not likely to exceed 132 µg/L for annual peak (acute) and 48 µg/L for 56 day average (chronic) concentrations. Since Office of Pesticide Program (OPP) policy recommends that the 90/56-day GENEEC value be divided by 3 to obtain a value for chronic risk assessment calculations, the surface water value for use in the chronic risk assessment would be 16 ppb or µg/L.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. OPP uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments. 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. If new uses are added in the future, EPA will reassess the potential impacts of 2,4-D on drinking water as a part of the aggregate risk assessment process.

i. *Acute exposure and risk.* EPA has calculated drinking water levels of comparison (DWLOCs) for acute exposure to 2,4-D in drinking water for the females (13+ years old, nursing) to be 1700 ppb. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the DEEM analysis) was subtracted from the RfD to obtain the acceptable acute exposure to 2,4-D in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures. EPA has determined that the maximum estimated concentrations of 2,4-D in surface and/or ground water is not likely to exceed EPA's levels of consideration for 2,4-D in drinking water as a contribution to acute exposure. EPA concludes with reasonable certainty that residues of 2,4-D 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.

ii. *Chronic exposure and risk.* For chronic (non-cancer), the drinking water levels of concern are 260 and 51 ppb for the U.S. population and non-nursing infants (less than 1 year old), respectively. To calculate the DWLOC for chronic (non-cancer, cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to 2,4-D in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures. EPA has determined that the maximum estimated concentrations of 2,4-D in surface and/or ground water is not likely to exceed EPA's levels of consideration for 2,4-D in drinking water as a contribution to chronic aggregate exposure. EPA concludes with reasonable certainty that residues of 2,4-D 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.

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

3. *From non-dietary exposure.* 2,4-D is currently registered for use on the following residential non-food sites: ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. There are chemical-specific and site-specific data available to determine the potential risks associated with residential exposures from the registered uses of 2,4-D. Dislodgeable residues of 2,4-D taken during exposure sessions showed a rapid decline from 1 hour following application (8%) to 24 hours following applications (1%). No detectable residues were found in urine samples supplied by volunteers exposed to sprayed turf 24 hours following application. Intermediate-term postapplication exposure is thus not expected. The following assessments are based on the available chemical specific data.

i. *Chronic exposure and risk.* Although a chronic endpoint was chosen, this risk assessment is not required because there is no chronic exposure scenario for this use.

ii. *Short- and intermediate-term exposure and risk.* For short-term dermal MOE calculations, EPA used the maternal NOAEL of 30 mg/kg/day from the oral developmental toxicity study in rabbits. The LOAEL of 90 mg/kg/day was based on abortions, clinical signs (ataxia, decreased motor activity, and cold extremities during gestation), and decreased body weight gain. For acute toxicity, EPA reduce the FQPA factor of 10 to 3 for females 13+ and removed for all other population subgroups. As the short-term and acute endpoints are based on the oral developmental toxicity study, this decision is also applicable to the short-term, nonoccupational assessment. Therefore, based on this recommendation, the MOE needed for females 13+ is 300.

For intermediate-term dermal MOE calculations, EPA used the NOAEL of 1.0 mg/kg/day from the 90-day oral toxicity study in dogs. The LOAEL of 3 mg/kg/day was based on clinical chemistry changes (increased BUN and creatinine levels) and lesions in the kidneys. An MOE of 100 is required.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 2,4-D has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 2,4-D does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that 2,4-D has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary MOE was calculated to be 321 for the U.S. population and 399 for females 13+ years/nursing (accounts for both maternal and fetal exposure). These MOE calculations were based on the acute neurotoxicity NOAEL of 67 mg/kg/day. This risk assessment assumed 100% crop-treated with anticipated (blended commodities) or tolerance-level residues on all treated crops consumed, resulting in a significant over estimation of dietary exposure. The acute dietary MOE calculated for the U.S. population and for females 13+ years/nursing provides assurance that there is a reasonable certainty of no harm for acute exposure to 2,4-D.

The maximum estimated concentrations of 2,4-D in surface and ground water are less than EPA's DWLOCs for 2,4-D as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of 2,4-D in drinking water do not contribute significantly to the aggregate acute human health risk at the present time considering the present uses and uses proposed in this action.

EPA bases this determination on a comparison of estimated concentrations of 2,4-D in surface waters and ground waters to levels of comparison for 2,4-D in drinking water. The estimates of 2,4-D in surface and ground waters are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of 2,4-D on drinking water as a part of the aggregate acute risk assessment process.

2. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to 2,4-D from food will utilize 26% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate

exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to 2,4-D residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

The short-term NOAEL for dermal exposure is based on the maternal NOAEL of 30 mg/kg/day from the oral developmental toxicity study in rabbits. After factoring in residential exposure, the high end total MOE for females 13+ was 750, and does not exceed EPA's level of concern.

The intermediate-term NOAEL for dermal exposure is based on the NOAEL of 1.0 mg/kg/day from the 90-day oral toxicity study in dogs. As homeowner use of 2,4-D is not expected to result in intermediate-term dermal exposure, only dietary and water exposures need to be considered in this assessment.

There is a potential for short- and intermediate-term exposure from drinking water. However, as estimated average concentrations of 2,4-D in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short- and intermediate-term exposure should not exceed EPA's levels of concern.

4. *Aggregate cancer risk for U.S. population*. EPA has classified 2,4-D as a Group D chemical (''not classifiable as to human carcinogenicity'') on the basis that ''the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.'' Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to 2,4-D residues.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainity that no harm will result from aggregate exposure to residues of 2,4-D.

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

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of 2,4-D, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In a developmental toxicity study in rats, the maternal (systemic) NOAEL was >75 mg/kg/day at the highest dose tested (HDT). The developmental (fetal) NOAEL was 25 mg/kg/day, based on delayed ossification at the developmental LOAEL of 75 mg/kg/day. In a developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 30 mg/kg/day, based on ataxia, decreased motor activity, cold extremities, and decreased body weight gain at the LOAEL OF 90 mg/kg/day. The developmental (fetal) NOAEL was 90 mg/kg/day (HDT).

iii. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOAEL of 5 mg/kg/day was based on degenerative effects in the kidneys of males and decreased body weight gain in females at the LOAEL of 20 mg/kg/day. The reproductive (pup) NOAEL was 5 mg/kg/day, based on decreased pup weight at the LOAEL of 20 mg/kg/day. The reproductive effects occurred in the presence of parental toxicity.

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for 2,4-D is complete with respect to current data requirements. There are pre-natal toxicity concerns for infants and children, based on the results of the rat developmental toxicity study in which developmental toxicity occurred in the absence of maternal toxicity. Based on the developmental and reproductive toxicity studies discussed above, for 2,4-D there does appear to be an extra sensitivity for pre-natal effects.

EPA decided that the FQPA factor of 10 should be reduced to 3 for females 13+ and removed for all other population subgroups. The recommendation was based on the presence of developmental effects in the absence of maternal effects for 2,4 D in the rat developmental study. There was no indication of increased susceptibility in a rabbit developmental study or a multigeneration reproduction study in rats. Currently, the acute dietary risk assessment is based on the NOAEL results of the acute neurotoxicity study and applies to all population subgroups with an MOE requirement of 100. However, due to the FQPA concerns discussed above, females 13+ will require an MOE of 300 (100 x 3 for FQPA), in contrast to the other population subgroups which will continue to require the usual MOE of 100 (FQPA does not apply). In practical terms, the acute dietary risk assessment will be performed for all population subgroups using the NOAEL from the acute neurotoxicity study. However, only females 13+ will require an MOE of 300 and all other population subgroups will require an MOE of 100.

v. *Conclusion*. There is a complete toxicity database for 2,4-D and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. The acute dietary MOE was calculated to be 214 for infants (less than 1 year old), and 399 for females 13+ years (accounts for both maternal and fetal exposure). These MOE calculations were based on the acute neurotoxicity NOAEL of 67 mg/kg/day. This risk assessment assumed 100% crop-treated with anticipated or tolerance-level residues on all treated crops consumed, resulting in a significant over estimation of dietary exposure. The large acute dietary MOE calculated for females 13+ years and infants (less than 1 year old) provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants or infants and children and post-natal exposure to 2,4-D.

The maximum estimated concentrations of 2,4-D in surface and ground water are less than EPA's DWLOCs for 2,4-D as a contribution to acute aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of 2,4-D in

drinking water do not contribute significantly to the aggregate acute human health risk at the present time considering the present uses and uses proposed in this action.

EPA bases this determination on a comparison of estimated concentrations of 2,4-D in surface waters and ground waters to levels of comparison for 2,4-D in drinking water. The estimates of 2,4-D in surface and ground waters are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, DWLOCs may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of 2,4-D on drinking water as a part of the aggregate acute risk assessment process.

3. *Chronic risk.* Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to 2,4-D from food will utilize from 11.4% of the RfD for nursing infants less than one year old up to 49.2% of the RfD for non-nursing infants less than one year old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to 2,4-D residues.

4. *Short- or intermediate-term risk.* The short-term NOAEL for dermal exposure is based on the maternal NOAEL of 30 mg/kg/day from the oral developmental toxicity study in rabbits. After factoring in for residential exposure, the calculated MOE or the short-term aggregate risk of the most highly exposed subgroup (non-nursing infants (<1 year old)) is 560, and does not exceed EPA's level of concern.

The intermediate-term NOAEL for dermal exposure is based on the NOAEL of 1.0 mg/kg/day from the 90-day oral toxicity study in dogs. As homeowner use of 2,4-D is not expected to result in intermediate-term dermal exposure, only dietary and water exposures need be considered in this assessment.

There is a potential for short- and intermediate-term exposure from drinking water. However, as estimated average concentrations of 2,4-D in surface and ground water are less than EPA's levels of concern for drinking water as a contribution to chronic aggregate and acute aggregate exposures, contribution to short- and intermediate-term exposure should not exceed EPA's levels of concern either.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to 2,4-D residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is 2,4-D *per se.* The nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies. The residues of concern in animals is 2,4-D, *per se.*

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available (gas chromatography (GC) with electron capture detection (ECD), EN-CAS Method ENC-2/93. This GC/ECD method has undergone successful independent laboratory validation and is available to enforce the time-limited tolerance on soybean seed.

C. Magnitude of Residues

Residues of 2,4-D are not expected to exceed 0.02 ppm in/on soybean seed as a result of this use. Secondary residues are expected in animal commodities as associated with this use. Meat/milk/poultry/egg tolerances have been established as a result of other 2,4-D uses.

D. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for 2,4-D on soybeans.

E. Rotational Crop Restrictions

The confined rotational crop data indicate that no plant-back intervals following 2,4-D application are needed.

IV. Conclusion

Therefore, the tolerance is established for residues of 2,4-dichlorophenoxyacetic acid in soybeans at 0.02 ppm.

V. Objections and Hearing Requests

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

Any person may, by May 10, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify

the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300800] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

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

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

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the 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). 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) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

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

C. Executive Order 13084

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

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

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 the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and

the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 1, 1999.

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. 346a and 371.

2. In § 180.142, by revising paragraph (a)(11) to read as follows:

§ 180.142 2,4-D; tolerances for residues.

(a) *General* . * * *

(11) A tolerance that expires on December 31, 2001 is established for residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid) resulting from the preplant use of 2,4-D ester or amine in or on the food commodity as follows:

Commodity	Parts per million
soybean, seed	0.02

* * * * *

[FR Doc. 99–5961 Filed 3–9–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300798; FRL–6065–1]

RIN 2070–AB78

Carboxin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the fungicide carboxin and its metabolites in or on onions, dry bulb at 0.2 part per million (ppm) for an additional 18-month period.This tolerance will expire and is revoked on June 30, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on onion seed. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective March 10, 1999. Objections and requests for hearings must be received by EPA, on or before May 10, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300798], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300798], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300798]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 271, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of February 3, 1997 (62 FR 4911) (FRL–5584–5), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established a time-limited tolerance for the residues of carboxin and its metabolites in or on onion seed at 0.2 ppm, with an expiration date of January 17, 1998. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of carboxin on onions, dry bulb for this year growing season due to the urgent and non-routine situation resulting from a lack of effective registered pesticides or alternative practices to control onion smut in northern onion producing states. After having reviewed the submission, EPA concurs that emergency conditionsexist. EPA has authorized under FIFRA section 18 the use of carboxin on onion seed for control of onion smut in onions.

EPA assessed the potential risks presented by residues of carboxin in or on onions, dry bulb. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of February 3, 1997 (62 FR 4911) (FRL–5584–5). Based on that data and information considered, the Agency reaffirms that extension of the time-