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

The Congressional Review Act, 5 U.S.C. 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective May 7, 2002 unless EPA receives adverse written comments by April 8, 2002.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 7, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: February 28, 2002.

Norman Niedergang,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, part 62, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 62—[AMENDED]

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

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

Subpart P—Indiana

2. A new center heading and § 62.3645 are added to read as follows:

Emissions From Small Municipal Waste Combustion Units With the Capacity to Combust at Least 35 Tons Per Day of Municipal Solid Waste But No More Than 250 Tons Per Day of Municipal Solid Waste and Commenced Construction on or Before Aust 30, 1999

§ 62.3645 Identification of plan—negative declaration.

On November 7, 2001, and December 3, 2001, the State of Indiana certified to the satisfaction of the United States Environmental Protection Agency that no sources categorized as small Municipal Waste Combustors are located in the State of Indiana.

[FR Doc. 02–5598 Filed 3–7–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301219; FRL–6827–1]

RIN 2070–AB78]

2,4-D; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extending the time-limited tolerance for residues of 2,4-D 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 (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire on December 31, 2004.

DATES: This regulation is effective March 8, 2002. Objections and requests for hearings, identified by docket control number OPP–301219 must be received by EPA on or before May 7, 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–301219 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@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_180/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–301219. 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 October 24, 2001 (66 FR 53791) (FRL–6803–5), 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 FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by the Industry Task Force II on 2,4-D Research Data, McKenna and Cuneo, 1900 K Street, 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. The Agency received one public comment in response to this notice from the World Wildlife Fund (WWF) in a letter from K. Thayer et al dated November 21, 2001 (Docket No. PF–1045). The WWF's comment concerned the size of the FQPA Safety Factor and are further discussed in the Safety Factor for Infants and Children section below.

The petition requested that 40 CFR 180.142 be amended by extending the time-limited tolerance for residues of the herbicide 2,4-D, 2,4-dichlorophenoxyacetic acid, in or on soybeans at 0.02 part per million (ppm). The tolerance will expire on December 31, 2004.

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 November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of 2,4-D on soybeans at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by 2,4-D are discussed below as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

An oral LD_{50} of 2,4-D acid is 699 milligrams/kilograms (mg/kg) in the rat. The dermal LD_{50} in the rabbit is > 2,000 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 NOAEL of 227 mg/kg for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kg with a LOAEL 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 LOAELs 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 LOAEL 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 a LOAEL of 100 mg/kg/day. The LOAEL 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 LOAEL 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 LOAEL 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 LOAEL 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 LOAEL 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

The dose at which 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, 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 intra species 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 refrence dose (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 and 10X 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 (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-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'' 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 2,4-D used for human risk assessment is shown in the following Table 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 2,4-D FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA* SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13–50 years of age)	NOAEL = 25 mg/kg/day UF = 100 Acute RfD = 0.25 mg/kg/day	FQPA SF = 3 aPAD = 0.083 mg/kg/day	LOAEL = 75 mg/kg/day based on skeletal variations, reduced ossification of the vertebral arches, and unossified sternebrae observed in the prenatal developmental study in rats
Acute Dietary (general population including infants and children)	NOAEL = 67 mg/kg/day UF = 100 Acute RfD = 0.67 mg/kg/day	FQPA SF = 3 aPAD = 0.22 mg/kg/day	LOAEL = 227 mg/kg/day based on increased incidence of incoordination and slight gait abnormalities in both sexes on Day 1 FOB measurements in the acute neurotoxicity study in rats

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR 2,4-D FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA* SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (all Populations)	NOAEL = 1 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 3 cPAD = 0.0033 mg/kg/day	LOAEL = 5 mg/kg/day based on alterations in serum chemistry with corroborative histopathological lesions in the liver and kidneys in the chronic dog study
Short-Term Incidental Oral (1 day to 1 month)	NOAEL = 25 mg/kg/day UF = 100	FQPA SF = 3 LOC for MOE = 300	LOAEL = 75 mg/kg/day based on non-significant decrease in body weight gain during the dosing period (maternal effects) in the rat developmental study
Intermediate-Term Incidental Oral (1 month to 6 months)	NOAEL = 1 mg/kg/day UF = 100	FQPA SF = 3 LOC for MOE = 300	LOAEL = 5 mg/kg/day (see chronic dietary)
Short-Term Dermal (1 day to 1 month)	NOAEL = 25 mg/kg/day UF = 100 Dermal absorption rate = 5.8%	FQPA SF = 3 (residential) LOC for MOE = 300 (residential) LOC for MOE = 100 (worker)	LOAEL = 75 mg/kg/day (see acute dietary f 13-50)
Intermediate-Term Dermal (1 month to 6 months)	NOAEL = 1 mg/kg/day UF = 100 Dermal absorption rate = 5.8%	FQPA SF = 3 (residential) LOC for MOE = 300 (residential) LOC for MOE = 100 (worker)	LOAEL = 5 mg/kg/day (see chronic dietary)
Short- and Intermediate-Term Inhalation	N/A	N/A	Not required based on $LC_{50} \leq 1.79$ mg/L and Toxicity Category III
Cancer	N/A	N/A	Classified as a Group D chemical (not classifiable as to human carcinogenicity)

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.142) for the residues of 2,4-D, 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 has reviewed these data and concluded that a temporary tolerance of 0.02 ppm is appropriate for soybean. Task Force II has thus proposed to extend the soybean tolerance to December 31, 2004 at a level of 0.02 ppm. Risk assessments were conducted by EPA to assess dietary exposures from 2,4-D in food as follows:

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 one 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. The following assumptions were made for the acute exposure assessments: The acute exposure analysis for all subgroups was performed using tolerance-level residues (with the exception of anticipated residues on citrus) and 100 percent crop treated. Using these assumptions, acute dietary exposure from food to 2,4-D will occupy 7.3% of the acute population adjusted dose (aPAD) for the U.S. population, 12% of the aPAD for females 13 years and older, 9.4% of the aPAD for infants less than 1 year old, 12% of the aPAD for children 1 – 6 years old, and 8.8% of the aPAD for children 7 – 12 years old.

ii. *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 Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic exposure analysis for all subgroups was performed using anticipated residues on the most highly consumed food items (and tolerance-level residues on the remaining food items) and percent crop treated data for various crops. Using these assumptions, chronic dietary exposure to 2,4-D from food will utilize 24% of the chronic popolation adjusted dose (cPAD) for the U.S. population, 20% for females 13 years and older, 19% of the cPAD for infants less than 1 year old, 46% of the cPAD for children 1 – 6 years old, and 36% of the cPAD for children 7 – 12 years old.

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.

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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows.

Crop	Percent crop treated
Asparagus	13
Barley	37
Corn (pop)	15
Corn (sweet)	9
Barley	37
Grapefruit	2
Lemons	1
Oats	15
Oranges	4
Rice	14
Rye	1
Sorghum	13
Sugarcane	35
Tangerines	4
Wheat	34
Wheat germ oil	55

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. 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 2,4-D may be applied in a particular area.

2. *Dietary exposure from drinking water*. Information is available from the U.S. Geological Survey (USGS) National Water Quality Assessment (NAWQA) program concerning residues of 2,4-D in water. Regarding groundwater, USGS-NAWQA monitoring data indicate a maximum 2,4-D concentration in groundwater of 14.8 ppb. Therefore, the exposure value of 14.8 ppb will be used in both the chronic aggregate risk and acute aggregate risk assessments for groundwater. Regarding surface water, an assessment of USGS-NAWQA monitoring data indicate a maximum ambient 2,4-D concentration of 15.0 ppb in rivers and streams. Therefore, the exposure value of 15 ppb will be used for chronic aggregate risk assessment for surface water. For acute aggregate risk assessment for surface water, however, calculations indicate that direct water application of 2,4-D will yield the highest water concentrations for all labeled 2,4-D use patterns. The value for the water concentrations calculated from direct water application of 2,4-D is 1,561 ppb; therefore, the exposure value of 1,561 ppb will be used in acute aggregate risk assessment for surface water.

Drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the 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 2,4-D, they are further discussed in the aggregate risk sections below.

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).

2,4-D is currently registered for use on the following residential non-dietary sites: ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. The risk assessment was conducted using the following residential exposure assumptions: 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 was not conducted because there is no chronic exposure scenario for this use.

ii. *Short- and intermediate-term exposure and risk*. For short-term dermal margin of exposure (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 reduced the FQPA factor of 10 to 3 for females 13+ and removed the FQPA factor 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. Since there are no intermediate residential exposures, intermediate risk assessment is not required.

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

EPA does not have, at this time, available data to determine whether 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. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for 2,4-D is complete with respect to current data requirements. There are no prenatal toxicity concerns for infants and children based on the lack of evidence of quantitative or qualitative increased susceptibility in the prenatal developmental toxicity studies in rats and rabbits or in the 2-generation reproduction study in rats.

The WWF commented that the 10x FQPA Safety Factor should be retained based on two rationales: (1) Evidence of quantitative susceptibility in the developmental rat study and (2) evidence of qualitative susceptibility because it is a thyroid endocrine disruptor. Therefore, the Agency has reevaluated the results of the developmental toxicity study in rats to assess the potential for increased susceptibility to infants and children following exposure to 2,4-D.

Regarding evidence of quantitative susceptibility in the developmental toxicity study in rats, the initial review of this study concluded that for maternal toxicity, the NOAEL was 25 mg/kg/day and the LOAEL was 75 mg/kg/day based on decreases in body weight gain in the maternal animals during the dosing period (gestation days 6 through 15). When compared to the vehicle control group, maternal body weight gain decreases were: -43% during gestation days 6 through 10 and -21% during days 6 through 15 at the 75 mg/kg/day group. Although these decreases were not statistically significant, they are biologically significant and attributed to treatment because decreases in body weight gain were also seen in the 2-generation reproduction study in the same strain of rats at a comparable dietary dose level (75 mg/kg/day). Additionally, the fact that the maternal animals regained their body weight following cessation of exposure (dosing) indicated that the decreases were indeed due to treatment with 2,4-D. EPA reconfirmed that maternal toxicity was seen at 75 mg/kg/day, the LOAEL.

With regard to the developmental toxicity, fetal effects are manifested as skeletal variations (not malformations) at the same dose that caused maternal toxicity. The skeletal variations included: presence of 7th cervical rib; presence of 14th rudimentary rib; mal-aligned sternebrae; reduced ossification of the vertebral arches and unossified sternebrae. These effects were not considered to be severe in nature because: (1) The presence of ribs indicate extra ossification; (2) malaligned sternebrae, reduced ossification of the vertebral arches and unossified sternebrae which are delays in ossification, were also seen in the controls; (3) there was no dose-response relationship for any of the variations; (4) the incidences were not statistically significant when compared to the vehicle control; (5) no increases were seen when litter incidences were considered; (6) fetal variations were seen in the presence of maternal toxicity; and (7) no malformations were seen at any dose level.

Based on these results, EPA reconfirmed that there is no evidence for increased susceptibility since the mild fetal effects were seen in the presence of maternal toxicity. This conclusion is supported by the lack of evidence for either quantitative or qualitative susceptibility in the developmental toxicity study in rabbits or in the 2-generation reproduction study. In rabbits, no developmental toxicity was seen at the highest dose tested. In the two-generation reproduction study, offspring toxicity (decreased pup body weight during lactation in F_{1b} pups) was seen in the presence of parental/systemic toxicity (degeneration of male kidney tubule and decreased weight gain in females) at the same dose. In addition, no evidence of susceptibility was seen in the developmental toxicity studies conducted with the salts and esters of 2,4-D; in these studies, the developmental toxicity occurred either at the same dose levels or higher dose levels that caused maternal toxicity.

Regarding evidence of qualitative susceptibility as potential thyroid endocrine disruptor, the thyroid effects seen in the subchronic (decreases in T4, follicular cell hypertrophy) and chronic (decreases in T4, increase in thryoid weights) toxicity study in rats occurred only at high doses. These effects were seen in the presence of other systemic (liver or kidney) toxicity, and there was no evidence of thyroid toxicity in dogs. No evidence of endocrine disruptions were seen in the appropriate parameters that evaluated this effect in the two-generation reproduction study.

EPA is currently developing policy, procedures and data requirements for endocrine disruptors. If, as a part of the review under reregistration, 2,4-D is identified as a potential endocrine disruptor, 2,4-D will be assessed according to EPA policy and appropriate data will be requested.

iii. *Conclusion.* There is a complete toxicity data base for 2,4-D and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. An FQPA safety factor is necessary for 2,4-D since there is evidence of neuropathology (retinal degeneration) in female rats at the 1–year measurements made in the chronic neurotoxicity study in rats. This finding triggers the need for a developmental neurotoxicity study and an FQPA safety factor for this data gap. However, the safety factor can be reduced to 3x based on the fact that the

toxicology data base is complete for the core studies required for FQPA assessment, that there is no evidence of quantitative or qualitative increased susceptibility in the prenatal developmental toxicity studies in rats and rabbits or in the 2-generation reproduction study in rats, and that the exposure assessments will not underestimate the potential dietary (food and water) and non-dietary exposure resulting from the use of 2,4-D.

Since there is a concern for neuropathology which triggers a developmental neurotoxicity study, the FQPA safety factor is applicable to all population subgroups for acute and chronic dietary assessments and to residential exposure and risk assessment of all durations. The result of the developmental neurotoxicity study could inform all endpoint selections.

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 a point of comparison against 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/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (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 groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to 2,4-D will occupy 7.3% of the aPAD for the U.S. population, 12% of the aPAD for females 13 years and older, 9.4% of the aPAD for infants less than 1 year old and 8.8% of the aPAD for children 7 – 12 years old. In addition, there is potential for acute dietary exposure to 2,4-D in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO 2,4-D

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.22	7.3	1,561	14.8	7,100
All Infants (< 1 year) old	0.22	9.4	1,561	14.8	2,000
Children 1–6 yrs old	0.22	12	1,561	14.8	1,900
Children 7–12 yrs old	0.22	8.8	1,561	14.8	2,000
Females 13–50 yrs old	0.083	12	1,561	14.8	2,200

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to 2,4-D from food will utilize 24% of the cPAD for the U.S. population, 19% of the cPAD for infants less than 1 year old and 46% of the cPAD for children 1 – 6 years old. Based on the use pattern, chronic residential exposure to residues of 2,4-D is not expected. In addition, there is potential for chronic dietary exposure to 2,4-D in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO 2,4-D

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0033	24	15	14.8	88
All Infants (< 1 year) old	0.0033	19	15	14.8	27
Children 1–6 yrs old	0.0033	46	15	14.8	18
Children 7–12 yrs old	0.0033	36	15	14.8	21
Females 13–50 yrs old	0.0033	20	15	14.8	80

3. *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). 2,4-D is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for 2,4-D. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 853 for the U.S. population, 943 for infants less than 1 year old, 912 for children 1 – 6 years old, and 859 for females 13 years and older. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of 2,4-D in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO 2,4-D

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
US Population	853	300	15	14.8	1,890
All Infants (< 1 year) old	943	300	15	14.8	568
Children 1–6 yrs old	912	300	15	14.8	559
Females 13–50 yrs old	859	300	15	14.8	1,630

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

IV. Other Considerations

A. 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.

B. International Residue Limits

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

C. Conditions

This tolerance with an expiration date was required by EPA to allow the Industry Task Force II on 2,4-D Research Data to submit additional field residue trials, including bridging studies with ester and amine formulations, plant metabolism studies, storage stability data, and oncogenicity studies in two species, rat and mouse preferred. Because the Agency has not completed the regulatory assessment of its scientific findings, EPA is proposing to amend 40 CFR 180.142 to extend the expiration date for these tolerances until December 31, 2004.

V. Conclusion

Therefore, the tolerance is established for residues of 2,4-D, 2,4-dichlorophenoxyacetic acid, in or on soybeans at 0.02 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–301219 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 May 7, 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–301219, 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 establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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, entitled *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: February 26, 2002.

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.

2. Section 180.142 is amended by revising paragraph (a)(11) to read as follows:

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

(a) * * *

(11) A tolerance that expires on December 31, 2004 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 raw agricultural commodity as follows:

Commodity	Parts per million	Expiration/Revocation Date
Soybean, seed	0.02	12/31/04

* * * * *

[FR Doc. 02–5606 Filed 3–7–02; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Parts 59 and 61

RIN 3067–AD16

National Flood Insurance Program (NFIP); Inspection of Insured Structures by Communities

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim final rule.

SUMMARY: This interim final rule would amend the NFIP regulations to clarify that areas of Monroe County, Florida that incorporate on or after January 1, 1999, and become eligible for the sale of flood insurance must participate in the inspection procedure as a condition of joining the NFIP. We established the inspection procedure to help the communities of Monroe County and the Village of Islamorada verify that structures comply with the community's floodplain management ordinance, and to ensure that property owners pay flood insurance premiums to the NFIP commensurate with their flood risk.

DATES: 44 CFR 59.30(a) is effective March 8, 2002. The amendments to Appendices (A)(4), (A)(5), and (A)(6) of 44 CFR part 61 are effective on June 6, 2002. Please submit comments on or before June 6, 2002.

ADDRESSES: Please send your comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, 500 C Street, SW., room 840, Washington, DC 20472, (facsimile) 202–646–4536, or (email) *rules@fema.gov*.

FOR FURTHER INFORMATION CONTACT: Donald Beaton, Federal Emergency Management Agency, Federal Insurance and Mitigation Administration, 500 C Street, SW., Washington, DC 20472, 202–646–3442, (facsimile) 202–646–4327 or (email) *donald.beaton@fema.gov*, or Lois Forster, Federal Emergency Management Agency, Federal Insurance and Mitigation Administration, 202–646–2720, (facsimile) 202–646–2577, or (email) *lois.forster@fema.gov*.

SUPPLEMENTARY INFORMATION: We established a pilot inspection procedure and the criteria to implement it under 44 CFR 59.30 in a final rule published in the **Federal Register** on June 27, 2000, 65 FR 39726. The inspection procedure is to help the communities of Monroe County, Florida and the Village of Islamorada, also located within Monroe County, verify that structures comply with the community's floodplain management ordinance, and to ensure that property owners pay flood insurance premiums to the NFIP commensurate with their flood risk. The inspection procedure requires owners of insured buildings to obtain an inspection from community officials and to submit a Community Inspection Report as a condition of renewing the Standard Flood Insurance Policy on the building. Specifically, the inspection procedure is designed to help the communities determine whether buildings with an enclosure comply with the community's floodplain management ordinance.

The community inspection procedure applies only to insured post-FIRM (Flood Insurance Rate Map) buildings located in the Special Flood Hazard Areas of the communities participating in the inspection procedure.

On November 2, 1999, the City of Marathon incorporated and on October 16, 2000 the City became an NFIP participating community. We notified the City of Marathon of the inspection procedure before it applied to join the NFIP. The community agreed to participate in the pilot inspection procedure in a resolution titled, ''A Resolution of the City Council of the City of marathon, Florida, Providing for Approval of the City's Participation in the National Flood Insurance Program's Pilot Inspection Program and Providing for an Effective Date'', which was passed and adopted on September 13, 2000.

In the **SUPPLEMENTARY INFORMATION** in both the proposed rule (published in the **Federal Register** on May 5, 1999, 64 FR 24256) and the final rule (published in the **Federal Register** on June 27, 2000, 65 FR 39726), we stated that as a condition of joining the NFIP the inspection procedure would be undertaken in areas within Monroe County that incorporate and become a separate community on or after January 1, 1999.

We established the following requirement in 44 CFR 59.30(a), Purpose, which requires areas within Monroe County that incorporate after January 1, 1999, to implement the inspection procedure: ''(a) This section sets forth the criteria for implementing a pilot inspection procedure in Monroe County and the Village of Islamorada, Florida. These criteria will also be used to implement the pilot inspection procedure in any area within Monroe County, Florida that incorporates on or after January 1, 1999, and is eligible for the sale of flood insurance.'' The City of Marathon is the only community in Monroe County that has incorporated after January 1, 1999.

This interim final rule would amend 44 CFR 59.30 and Appendices (A)(4), (A)(5), and (A)(6) of 44 CFR part 61 to clarify that areas in Monroe County that become communities by incorporating