Implementation'' add in numerical order entries ''142.14(e)–(g)'' and ''142.16(a)''.

§ 9.1 OMB approvals under the Paperwork Reduction Act.

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40 CFR citation	OMB control No.
* * * * * * *	
National Primary Drinking Water Regulations	
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141.31(d)	2040–0090
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141.80–141.91	2040–0204
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141.153–141.154	2040–0090
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National Primary Drinking Water Regulations Implementation	
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142.14(e)–(g)	2040–0090
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142.16(a)	2040–0090
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[FR Doc. 04–19137 Filed 8–19–04; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0200; FRL–7673–6]

DCPA; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of DCPA, dimethyl tetrachloroterephthalate, and its metabolites in or on basil, dried leaves; basil, fresh leaves; celeriac; chicory, roots; chicory, tops; chive; coriander, leaves; dill; ginseng; marjoram; parsley, leaves; parsley, dried leaves; radicchio and radish, oriental. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 20, 2004. Objections and requests for hearings must be received on or before October 19, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0200. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epamail.epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

II. Background and Statutory Findings

In the **Federal Register** of May 6, 2004 (69 FR 25384) (FRL–7356–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E6442) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway 1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petition prepared by IR-4, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.185 be amended by establishing tolerances for residues of the herbicide DCPA or chlorthal dimethyl, dimethyl tetrachloroterephthalate, in or on oriental radish, basil, coriander, dill, marjoram, chives, ginseng, celeriac, chicory, mradicchio, parsley (fresh) and parsley (dried) at 2.0, 5.0, 5.0, 5.0, 5.0, 5.0, 2.0, 2.0, 5.0, 2.0, 5.0 and 15 parts per million (ppm), respectively. The proposed tolerances were corrected to conform to Food and Feed Commodity Vocabulary database (*http://www.epa.gov/pesticides/foodfeed/*) and to include its metabolites to read as follows: Combined residues of the herbicide DCPA (or chlorthal dimethyl), dimethyl tetrachloroterephthalate, and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalate (TPA) (calculated as dimethyl tetrachloroterephthalate) in or on basil, dried leaves at 5.0 ppm, basil, fresh leaves at 20.0 ppm, celeriac at 2.0 ppm, chicory, roots at 2.0 ppm, chicory, tops at 5.0 ppm, chive at 5.0 ppm, coriander, leaves at 5.0 ppm, dill at 5.0 ppm, ginseng at 2.0 ppm, marjoram at 5.0 ppm, parsley, leaves at 5.0 ppm, parsley, dried leaves at 20 ppm, radicchio at 5.0 ppm, and radish, oriental at 2.0 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of DCPA, dimethyl tetrachloroterephthalate, and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalate (TPA) (calculated as dimethyl tetrachloroterephthalate) in or on basil, dried leaves at 5.0 ppm, basil, fresh leaves at 20.0 ppm, celeriac at 2.0 ppm, chicory, roots at 2.0 ppm, chicory, tops at 5.0 ppm, chive at 5.0 ppm, coriander, leaves at 5.0 ppm, dill at 5.0 ppm, ginseng at 2.0 ppm, marjoram at 5.0 ppm, parsley, leaves at 5.0 ppm, parsley, dried leaves at 20 ppm, radicchio at 5.0 ppm, and radish, oriental at 2.0 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 DCPA are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed. Data bearing on the toxicity of tetrachloroterephthalic acid (TPA), a degradate of DCPA, is presented in Table 2.

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

Guideline No.	Study Type	Results
870.3100	28–day oral toxicity—rodents (rats)	NOAEL < 215 lowest dose tested (LDT) milligrams/kilogram/day (mg/kg/day) LOAEL = 215 mg/kg/day based on hepatic hypertrophy. At 1,720 mg/kg/day thyroid follicular cell hyperplasia in males
870.3100	90–day oral toxicity—rodents (rats)	NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on centrilobular hypertrophy. At 1,000 mg/kg/day there were gross and microscopic lesions of lungs and kidneys; microscopic lesions in thyroids; and increased liver weights.

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

Guideline No.	Study Type	Results
870.3100	13–week oral toxicity—rodents (mice)	NOAEL = 406 mg/kg/day (males) and 1,049 mg/kg/day (females) LOAEL = 1,235 mg/kg/day (males) and 2,198 mg/kg/day (females) based on centrilobular hepatocyte enlargement.
870.3200	21/28–day dermal toxicity	NOAEL ≥ 1,000 mg/kg/day highest dose tested (HDT)
870.3700	Prenatal developmental—rodents (rats)	Maternal NOAEL ≥ 2,000 mg/kg/day (HDT) Developmental NOAEL ≥ 2,000 mg/kg/day (HDT)
870.3700	Prenatal developmental—nonrodents (rabbits)	Maternal NOAEL = 250 mg/kg/day Maternal LOAEL = 500 mg/kg/day based on maternal mortality Developmental NOAEL ≥ 500 mg/kg/day (HDT)
870.3800	Reproduction and fertility effects (rats)	Parental/Systemic NOAEL = 50 mg/kg/day Parental/Systemic LOAEL = 250 mg/kg/day based on body weight decrements, gross and microscopic changes in kidneys and lungs, and microscopic changes in liver and thyroids. Reproductive NOAEL ≥ 1,000 mg/kg/day (HDT) Offspring NOAEL = 50 mg/kg/day Offspring LOAEL = 250 mg/kg/day based on pup body weight decrements during the lactation period.
870.4300	Chronic toxicity and Carcinogenicity—rodents (rats)	NOAEL = 1 mg/kg/day LOAEL = 10 mg/kg/day based on decreased T4 hormone and thyroid and liver histological changes. Increases in thyroid follicular cell adenomas and carcinomas, hepatocellular adenomas and carcinomas, and hepatocholangiomas in females Q_1^* = 1.5 x 10^{-3} based upon the three combined types of liver tumors in female rats (3/4 scaling factor)
870.4300	Carcinogenicity—mice	NOAEL = 510 mg/kg/day LOAEL = 1,141 mg/kg/day based on elevated liver enzymes and increased liver weight in females. Increases in hepatic adenomas (females) and carcinomas (males, females).
870.5300	Mouse lymphoma assay	Negative for forward mutations
870.5375	Cytogenetic assay in CHO cells	Negative for clastogenicity
870.5550	UDS assay	Negative
870.5915	SCE in CHO cells	Negative
870.7485	Metabolism and pharmacokinetics (rats)	In 6 separate metabolism studies, ^{14}C-DCPA was given as single or multiple oral gavage doses to rats at 1 or 1,000 mg/kg/day. There were no significant sex differences in any of the studies. Absorption was rapid and essentially complete by 48 hours. Absorption was more efficient at 1 mg/kg/day (79%-86% of administered dose) than at 1,000 mg/kg/day (6-9%). Urine was the major route of excretion. Less than 1% of radiolabel was found in bile, so compound in feces represents unabsorbed compound. The major compound found in urine was the mono-methyl metabolite, 4-carbomethoxy-2,3,5,6-tetrachlorobenzoic acid. The di-acid metabolite, TPA, represented approximately 1% of radioactivity in urine. No DCPA was found in urine. Radiolabel did not bioaccumulate in tissues following repeated treatment. Although a high percentage of the administered dose was found in fat 12 hours after discontinuance of dosing (12% of dose in low-dose animals), radiolabel had rapidly depleted by 168 hours (0.03%). Concentration of radiolabel in the thyroid increased at 36 hours postdosing when compared to the 12 hour time period, however, radiolabel in the thyroid rapidly depleted by 168 hours. By 168 hours, highest concentration of radiolabel in both dose groups was in the kidney.
870.7600	Dermal penetration	22% including compound on skin at 47.5 μg/cm^2

TABLE 2.—TPA (TETRACHLOROTEREPHTHALIC ACID) DEGRADATE OF DCPA SUBCHRONIC TOXICITY

Guideline No.	Study Type	Results
N/A	30–day Intubation toxicity—rodents (rats)	NOAEL = 500 mg/kg/day LOAEL = 2,000 mg/kg/day based on soft stools and occult blood in urine.

TABLE 2.—TPA (TETRACHLOROTEREPHTHALIC ACID) DEGRADATE OF DCPA SUBCHRONIC TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity—rodents (rats)	NOAEL ≥ 500 mg/kg/day (HDT)
870.3700	Prenatal developmental—rodents (rats)	Maternal NOAEL = 1,250 mg/kg/day Maternal LOAEL = 2,500 mg/kg/day based on soft stools and salivation Developmental NOAEL ≥ 2,500 mg/kg/day (HDT)

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the '' default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 DCPA used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DCPA FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An endpoint of concern attributable to a single dose (exposure) was not identified from the available studies. An acute RfD was not established		
Chronic Dietary (All populations)	NOAEL= 1 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.01 mg/kg/day	Combined chronic/carcinogenicity study in rats LOAEL = 10 mg/kg/day based on decreased thyroxine levels and liver and thyroid histological changes in males
Long-Term Dermal (several months to lifetime) (Residential)	Dermal (or oral) study NOAEL= 1 mg/kg/day (dermal absorption rate = 22 % when appropriate)	LOC for MOE = 100 (Residential)	Combined chronic/carcinogenicity study in rats LOAEL = 10 mg/kg/day based on decreased thyroxine levels and liver and thyroid histological changes in males

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DCPA FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short and Intermediate-Term Inhalation (1 day to 6 months) (Residential)	Inhalation (or oral) study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	90–day feeding study in rats LOAEL = 100 mg/kg/day based on based on increased incidence of hepatocellular hypertrophy
Long-Term Inhalation (several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL= 1 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Combined chronic/carcinogenicity study in rats LOAEL = 10 mg/kg/day based on decreased thyroxine levels and liver and thyroid histological changes in males
DCPA Cancer (oral, dermal, inhalation)	Classification: Group C, possible human carcinogen. Q1* = 0.0015 $(mg/kg/day)^{-1}$ based upon three combined types of liver tumors in female rats.		

C. Toxicological Endpoints for TPA

A summary of the toxicological endpoints for TPA used for human risk assessment is shown in Table 4 of this unit:

TABLE 4.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TPA FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment and UFs	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An endpoint of concern attributable to a single dose (exposure) was not identified from the available studies. An acute RfD was not established		
Chronic Dietary (All populations)	NOAEL= 500 mg/kg/day UF = 1,000 Chronic RfD = 0.5 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/Special FQPA SF = 0.5 mg/kg/day	90-day feeding study in rats NOAEL = 500 mg/kg/day (HDT)
Cancer (oral, dermal, inhalation)	TPA is not likely to be a carcinogen for humans because no liver and thyroid precursor events occurred after treatment with TPA at very large doses, and because neither TPA nor DCPA are mutagens.		

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.185) for the combined residues of DCPA, dimethyl tetrachloroterephthalate, and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalate (TPA) (calculated as dimethyl tetrachloroterephthalate) in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from DCPA and its metabolites tetrachloroterephthalate (MTP) and tetrachloroterephthalate (TPA) (calculated as dimethyl tetrachloroterephthalate) 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.

An effect of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies including the developmental toxicity studies in rat and rabbits.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA1989–1992 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: Anticipated residues for currently registered crops and tolerance level used for the proposed crops and the percent crop treated (PCT) data were used for currently registered crops and 100 % of the crop treated for the proposed uses.

iii. *Cancer.* In conducting this cancer risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA1989–1992 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 cancer risk assessments: Anticipated residues for currently registered crops and tolerance level used for the proposed crops and the percent crop treated (PCT) data were used for currently registered crops and 100 % of the crop treated for the proposed uses.

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

The Agency used PCT information in Table 5 as follows:

TABLE 5.—PERCENT CROP TREATED (PCT) FOR REGISTERED DCPA USES.

Crop	Acreage	PCT	Lbs ai/A[1]	Lbs.a.i
Broccoli	145,000	24	4.6	150,000
Cabbage	78,000	6	5.0	20,000
Cantaloupes	100,000	1	7.7	5,000
Cauliflowers	45,000	15	5.0	30,000
Collards	12,000	20	8.0	20,000
Cucumbers	130,000	1	8.0	1,000
Dry beans	190,000	1	5.0	8,000
Eggplant	5,000	1	6.9	500
Onions	160,000	15	6.7	150,000
Sweet peppers	39,000	5	7.41	15,000
Radishes	21,000	5	7.3	5,000
Summer squash	60,000	1	9.0	1,000
Strawberries	55,000	2	6.4	5,000
Tomatoes	415,000	1	5.0	3,000
Turf	250,000	2	5.4	31,000
Total				444,500

Sources: USDA, EPA 1995–2000.

[1]No reported use of DCPA on cotton. Assume 1% Crop Treated for: Green and dry beans, peach, green and succulent peas, potato, sweet potatoes, honeydew melons, watermelons, winter squash, yams. Assume 100% Crop Treated for: Brussels sprouts, garlic, horseradish, hot pepper, turnips, upland cress.

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

DCPA may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for DCPA and its environmental degradate TPA in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of DCPA and TPA.

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

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

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

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of DCPA for acute exposures are estimated to be 22 parts per billion (ppb) for surface water and 0.17 ppb for ground water and of TPA for acute exposures are estimated to be 116 parts per billion (ppb) for surface water and 192 ppb for ground water. The EECs for chronic exposures of DCPA are estimated to be 22 ppb for surface water and 0.17 ppb for ground water and of TPA are estimated to be 116 ppb for surface water and 192 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

DCPA is currently registered for use on the following residential non-dietary sites: Garden vegetables and turf. The risk assessment was conducted for exposure to the active ingredient DCPA and manufacturing impurity hexachlorobenzene (HCB) using the following residential exposure assumptions:

1. *Garden vegetables*. Significant post application exposures are not anticipated for garden vegetables because the applications are made to freshly cultivated soil using only the granular products. The risks of acute oral exposures due to granular ingestion by children were not assessed because adverse effects were not seen following a single dose.

2. *Turf*. Significant post application exposures are anticipated for turf because broadcast applications are made to prevent the growth of weeds throughout the lawn. These exposures are anticipated to be short term because only one or two applications are made per growing season and the label recommended application interval is two months or longer. Only incidental oral exposures were assessed for toddlers because a dermal endpoint for short/intermediate term exposures was not selected.

A Turf Transferable Residue (TTR) study involved the application of dacthal W-75 to Kentucky bluegrass turf plots in Ohio. Three of the treated plots were irrigated with 0.5 water immediately following sampling at one hour after treatment and 0.18 of rain occurred at day after treatment (DAT) six. Irrigation reduced the residue from an initial value of 4.2 µg/cm^2 at DAT 0.04 to 1.6 µg/cm^2 at DAT 0.08. The residue then dissipated at rate of 6.1 percent per day from DAT 1 until the last day of the study (DAT 14).

The Margins of Exposure (MOEs) calculated for toddler post application turf exposure are presented in Table 6.

TABLE 6.—INCIDENTAL ORAL MOES FOR TODDLER POST APPLICATION TURF EXPOSURE

DAT	Application Rate	Hand to Mouth MOE	Object to Mouth MOE	Soil Ingestion MOE	Aggregate MOE
0	15 lb ai acre	220	890	6,6000	180

The cancer risks for adults exposed to treated and irrigated turf were calculated using standard assumptions and the TTR data averaged over 14 days. The data were normalized to an average application rate of 12.5 lbs ai/acre. It was assumed four days of exposure to turf that was treated within 14 days would occur per year.

The cancer risks calculated for adult post application turf exposure are presented in Table 7.

TABLE 7.—CANCER RISKS FOR ADULT POST APPLICATION TURF EXPOSURE[1]

Turf Transferable Residue Level[2](µg/cm^2)	Days Per Year Exposure	DCPA LADD[3] (mg/kg/day)	DCPA Cancer Risk[4]	HCB LADD[3] (mg/kg/day)	HCB Cancer Risk[5]
0.64 (DCPA)	4	2.3e-04	3.4e-07	1.1e-08	1.1e-08

TABLE 7.—CANCER RISKS FOR ADULT POST APPLICATION TURF EXPOSURE[1]—Continued

Turf Transferable Residue Level[2](μg/cm[2])	Days Per Year Exposure	DCPA LADD[3] (mg/kg/day)	DCPA Cancer Risk[4]	HCB LADD[3] (mg/kg/day)	HCB Cancer Risk[5]
0.0026 (HCB)					

[1]Average over 14 days after an application of 12.5 lb ai/acre immediately followed by irrigation.
[2]Assuming heavy yard work with a transfer coefficient (TC) of 7300 cm^2/hour.
[3]LADD = TTR x TC x 0.001 mg/μg x DA x 2 hours exposure/day x (1/70 kg) x 4/365 x 50 years /70 years
[4]DCPA Cancer Risk = LADD x Q_1* where Q_1* = 0.0015 mg/kg/$day^{-1}$for DCPA
[5] HCB Cancer Risk = LADD x Q_1* where Q_1* = 1.0 mg/kg/day^{-1} for HCB

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

EPA does not have, at this time, available data to determine whether DCPA has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to DCPA and any other substances and DCPA 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 DCPA has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. The toxicology database for DCPA is complete for FQPA purposes and there are no residual uncertainties for pre-/post-natal toxicity. Based on the quality of the exposure data, EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed based on the following:

i. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to DCPA in developmental toxicity studies. There is no quantitative or qualitative evidence of increased susceptibility to DCPA following pre-/post-natal exposure to a 2–generation reproduction study.

ii. There is no concern for developmental neurotoxicity resulting from exposure to DCPA. A developmental neurotoxicity study (DNT) study is not required.

iii. The toxicological database is complete for FQPA assessment.

iv. The dietary food exposure assessment is based on average field trial values corrected by percent crop treated.

v. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

vi. Submitted turf transferable residue (TTR) data will be used along with the Residential Standard Operating Procedures to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by DCPA.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

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

future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An effect of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies including the developmental toxicity studies in rat and rabbits. No acute risk is expected from exposure to DCPA.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to DCPA from food will utilize 0.97 % of the cPAD for the U.S. population, 1.1 % of the cPAD for Children (1 - 6 years old). Based on the garden and turf use patterns, chronic residential exposure to residues of DCPA is not expected. In addition, there is potential for chronic dietary exposure to DCPA 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 Table 8 of this unit:

TABLE 8.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DCPA

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb),	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.01	0.97	22	0.17	350
All Infants	0.01	0.85	22	0.17	99
Children 1- 6	0.01	1.1	22	0.17	99
Females 13 - 50	0.01	0.88	22	0.17	300

Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to TPA from food will utilize 0.02% of the cPAD for the U.S. population, and all infants and children subgroups. Based on the garden and turf use patterns, chronic residential exposure to residues of TPA is not expected. In addition, there is potential for chronic dietary exposure to TPA in drinking water.After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate chronic exposure to TPA to exceed 100% of the cPAD, as shown in Table 9 of this unit:

TABLE 9.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO TPA

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.5	0.02	116	192	17,500
All Infants	0.5	0.02	116	192	5,000
Children 1- 6	0.5	0.02	116	192	5,000
Females 13 - 50	0.5	0.02	116	192	15,000

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).

DCPA 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 DCPA.

Short-term DWLOCs were calculated and compared to the EECs for chronic exposure of DCPA in ground and surface water based on chronic food exposure plus the residential handler exposure for adults and the chronic food exposure alone for toddlers. 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 Table 10 of this unit:

TABLE 10.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO DCPA

Population Subgroup	Aggregate Exposure (mg/kg/day) (Food + Residential)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	0.001697	22	0.17	17,500
All Infants	0.000085	22	0.17	5,000
Children 1- 6	0.00011	22	0.17	5,000
Females 13 - 50	0.001688	22	0.17	15,000

Short term DWLOCs for TPA were calculated based upon food alone because there is no residential non-food exposure to TPA. 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 Table 11 of this unit:

TABLE 11.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO TPA

Population Subgroup	Aggregate Exposure (mg/kg/day) (Food + Residential)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	0.000097	116	192	17,500
All Infants	0.000085	116	192	5,000
Children 1- 6	0.00011	116	192	5,000
Females 13 - 50	0.000088	116	192	15,000

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of DCPA, the endpoints and uncertainty factors for intermediate term exposures are identical to short term. The risks are identical to short term exposure in Table 10. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* DWLOCs were calculated using food alone, and together with residential exposure data. The handler exposure scenario which resulted in the greatest risk (Scenario 1, Hand or Shaker Can Application to Garden Vegetables) was used in the calculation. DWLOC values were calculated and the results are shown in Table 12. The DWLOC for food alone scenario and Food and Home Gardener Handler (Hand Application) scenario are greater than the EEC which means that the cancer risks are expected less than 3.0×10^{-6} for the aggregate exposure to food, water and residential exposure. EPA believes that a risk estimate of this level generally represents a negligible risk, as EPA has traditionally applied that concept. EPA has commonly referred to a negligible risk as one that is in the range of 1 in 1 million (1×10^{-6}). Quantitative cancer risk assessment is not a precise science. There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Thus, EPA generally considers numerical estimates as high as 3.0×10^{-6} to be within the range of 1 in 1 million. Therefore, EPA considers the carcinogenic risk from DCPA to be negligible within the meaning of that standard as it has been traditionally applied by EPA.

TABLE 12.—DWLOC CALCULATIONS FOR DCPA (BASED UPON A TARGET CANCER RISK OF 3.0×10^{-6})

	Food Alone	Food and Home Gardener Handler (Hand Application)
Dietary Food Exposure[A]	0.097 μg/kg/day	0.097 μg/kg/day
Residential Exposure[A]	N/A	0.35 μg/kg/day
Aggregate Cancer Exposure	0.097 μg/kg/day	0.45 μg/kg/day
Target Maximum Exposure[B]	2.0 μg/kg/day	2.0 μg/kg/day
Max Water Exposure[C]	1.9 μg/kg/day	1.6 μg/kg/day
Cancer DWLOC[D]	67 μg/Liter	54 μg/Liter
Surface Water EEC - PA Turf @ 15 lb ai/acre (PCA = 0.87)	33 μg/Liter (36–year mean)	
Surface Water EEC - Florida Cabbage @ 10.5 lb ai/acre (PCA = 0.87)	15 μg/Liter (36–year mean)	
Surface Water EEC - California Onions @ 10.5 lb ai/acre (PCA = 0.87)	19 μg/Liter (36–year mean)	
Ground Water EEC - Any Crop @ 10.5 lb ai/acre	0.17 μg/Liter (90–day average)	
Ground Water EEC - Any Crop @ 15 lb ai/acre	0.25 μg/Liter (90–day average)	

[A]The food and residential exposures are expressed in ug/kg/day rather than mg/kg/day.
[B]Target Maximum Exposure (ug/kg/day) = $3.0 \times 10^{-6} / Q_1^* \times 1{,}000$ ug/mg where $Q_1^* = 1.5 \times 10^{-3}$ mg/kg/day
[C]Maximum Water Exposure (ug/kg/day) = [Target Maximum Exposure - (Food Exposure + Residential Exposure)]
[D]Cancer DWLOC(μg/liter) = [maximum water exposure (μg/kg/day) x body weight (kg)] / [water consumption (liter)]

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

There are no Codex Maximum Residue Levels (MRLs) for DCPA residues; therefore no compatibility issues exist. There are Canadian MRLs ranging from 1-5 ppm in or on leaf crops, cole crops, cucurbits, legumes, root crops, fruiting vegetables, bulb vegetables and strawberries,. The Canadian MRLs appear to only include the parent compound, but are numerically identical to U.S. tolerances.

V. Conclusion

Therefore, tolerances are established for combined residues of the herbicide DCPA, dimethyl tetrachloroterephthalate, and its metabolites monomethyl tetrachloroterephthalate (MTP) and tetrachloroterephthalate (TPA) (calculated as dimethyl tetrachloroterephthalate) in or on basil, dried leaves at 5.0 ppm, basil, fresh leaves at 20.0 ppm, celeriac at 2.0 ppm, chicory, roots at 2.0 ppm, chicory, tops at 5.0 ppm, chive at 5.0 ppm, coriander, leaves at 5.0 ppm, dill at 5.0 ppm, ginseng at 2.0 ppm, marjoram at 5.0 ppm, parsley, leaves at 5.0 ppm, parsley, dried leaves at 20 ppm, radicchio at 5.0 ppm, and radish, oriental at 2.0 ppm.

In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the Federal Food, Drug, and Cosmetics Act (FFDCA) 21 U.S.C. 346a(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required to reassess all tolerances in existence on August 2, 1996 by August 2006. This regulatory action will count for 38 reassessments toward the August 2006 deadline.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0200 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 October 19, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0200, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of

significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 12, 2004.

Lois A. Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.185 is amended to read as follows:

■ i. In paragraph (a), by adding a heading and by alphabetically adding commodities to the table;

■ ii. By redesignating paragraph (b) as paragraph (c) and adding a heading; and

■ iii. By adding and reserving with headings new paragraphs (b) and (d) to read as follows:

§ 180.185 Dimethyl tetrachloroterephthalate; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Basil, dried leaves	5.0
Basil, fresh leaves	20.0
* * * * *	
Celeriac	2.0
Chicory, roots	2.0
Chicory, tops	5.0
Chive	5.0
Coriander, leaves	5.0
* * * * *	
Dill	5.0
* * * * *	
Ginseng	2.0
* * * * *	
Marjoram	5.0
* * * * *	
Parsley, leaves	5.0
Parsley, dried leaves	20.0
* * * * *	
Radicchio	5.0
Radish, oriental	2.0
* * * * *	

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

(c) *Tolerances with regional registrations.* * * *

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

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