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 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 23, 2002.

L. John Iani,

Regional Administrator, Region 10.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

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

Subpart C—Alaska

2. Subpart C is amended by adding § 52.73 to read as follows:

§ 52.73 Approval of plans.

(a) Carbon monoxide.

(1) Anchorage.

(i) EPA approves as a revision to the Alaska State Implementation Plan, the Anchorage Carbon Monoxide Attainment Plan (Volume II, Section III.B of the State Air Quality Control Plan adopted December 20, 2001, effective January 27, 2002 and Volume III.B.3, III B.10 and III.B11, III B.12 of the Appendices adopted December 20, 2001, effective January 27, 2002) submitted by the Alaska Department of Environmental Conservation on January 4, 2002.

(ii) [Reserved]

(2) Fairbanks. [Reserved]

(b) *Lead.* [Reserved]

(c) *Nitrogen dioxide.* [Reserved]

(d) *Ozone.* [Reserved]

(e) *Particulate matter.* [Reserved]

(f) *Sulfur dioxide.* [Reserved]

[FR Doc. 02–23083 Filed 9–17–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0190; FRL–7196–7]

Triclopyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) in or on fish and shellfish. Dow Agrosciences LLC requested this tolerance 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 September 18, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0190, must be received on or before November 18, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket identification (ID) number OPP–2002–0190 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0190. 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 February 25, 1998 (63 FR 9519) (FRL–5768–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–

170), announcing the filing of a pesticide petition (PP 1F3935) by Dow Agrosciences LLC, 9330 Zionville Rd, Indianapolis, IN 46268–1054. This notice included a summary of the petition prepared by Dow Agrosciences LLC, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.417 be amended by establishing a tolerance for combined residues of the herbicide triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP), in or on fish at 3.0 parts per million (ppm) and shellfish at 3.5 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) on fish at 3.0 ppm and shellfish at 3.5 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 triclopyr are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—ACUTE TOXICITY OF VARIOUS FORMS OF TRICLOPYR

Guideline No.	Study Type	Results
Acute Toxicity of triclopyr acid, technical grade		
870.1100	Acute oral	Lethal dose (LD_{50}) = 729 milligram/kilogram (mg/kg) Male (M); 630 mg/kg Female (F) Category III
870.1200	Acute dermal	LD_{50} > 2,000 mg/kg Category III
870.1300	Acute inhalation	Not available
870.2400	Primary eye irritation	Not available
870.2500	Primary skin irritation	Not available
870.2600	Dermal sensitization	Not available
870.6200	Acute neurotoxicity	Not available
Acute toxicity of triclopyr triethylamine salt		
870.1100	Acute oral	LD_{50} = 1,847 mg/kg (M & F) Category III
870.1200	Acute dermal	LD_{50} > 2,000 mg/kg Category III
870.1300	Acute inhalation	LC_{50} > 2.6 mg/liter (L) Category III
870.2400	Primary eye irritation	Corrosive Category I
870.2500	Primary skin irritation	Not irritating Category IV
870.2600	Dermal sensitization	sensitizer

TABLE 1.—ACUTE TOXICITY OF VARIOUS FORMS OF TRICLOPYR—Continued

Guideline No.	Study Type	Results
870.6200	Acute neurotoxicity	Not available
Acute toxicity of triclopyr butoxyethyl ester		
870.1100	Acute oral	LD_{50} = 803 mg/kg (M & F) Category III
870.1200	Acute dermal	LD_{50} > 2,000 mg/kg Category III
870.1300	Acute inhalation	LC_{50} > 4.8 mg/L Category III
870.2400	Primary eye irritation	Minimally irritating Category III
870.2500	Primary skin irritation	Not irritating Category IV
870.2600	Dermal sensitization	sensitizer
870.6200	Acute neurotoxicity	Not available

TABLE 2.—TOXICITY PROFILE OF TRICLOPYR

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents with acid - rat	NOAEL = 5 mg/kg/day in males and females LOAEL = 20 mg/kg/day in males and females based on degeneration of the proximal tubules of the kidneys
870.3100	90–Day oral toxicity rodents with ester - rat	NOAEL = 7 mg/kg/day in males and < 7 mg/kg/day in females LOAEL = 28 mg/kg/day in males, 7 mg/kg/day based on increased relative kidney weight (M) and decreased red blood cell content, hemoglobin content, and packed cell volume (F). Degeneration of the proximal tubules of the kidneys was seen in males at 70 and 350 mg/kg/day and females at 350 mg/kg/day highest dose tested (HDT).
870.3150	183–Day oral toxicity non-rodents - dog	NOAEL ≤ 2.5 mg/kg/day (HDT) in males and females LOAEL > 2.5 mg/kg/day in males and females based on toxicologically non-significant decreased rate of phenolsulfothalein (PSP) due to competition between triclopyr and PSP for renal excretion.
870.3200	21–Day dermal toxicity - rabbit	NOAEL = 1,000 mg/kg/day (males and females) LOAEL > 1,000 mg/kg/day. Decreased alkaline phosphatase in both sexes of rabbits at 1,000 mg/kg/day and increased absolute and relative liver weight in males at 1,000 mg/kg/day were considered marginal and not of toxicological significance.
870.3700	Prenatal developmental with ester - rats	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on mortality, clinical signs, necropsy findings, decreased body weight gains, decreased food consumption, increased water consumption, and increased relative kidney and liver weight. Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 300 mg/kg/day based on increased incidence of hydrocephalus, cleft palate, microphthalmia/anophthalmia, retinal folds, thin diaphragm/protrusion of the liver, decreased fetal weight and visceral and skeletal anomalies and variants.
870.3700	Prenatal developmental with ester - rabbits	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 100 mg/kg/day based on mortality Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 100 mg/kg/day based on decreased total live fetuses and increased total fetal deaths, as well as increased fetal and/or litter incidence of skeletal anomalies and variants.

TABLE 2.—TOXICITY PROFILE OF TRICLOPYR—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental with salt - rabbit	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 100 mg/kg/day based on mortality, abortions, decreased body weight gain, decreased food efficiency, increased liver and kidney weight. Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 100 mg/kg/day based on decreased live fetuses and increased embryonic deaths due to abortions.
870.3700	Prenatal developmental with salt - rat	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on mortality Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 300 mg/kg/day based on decreased fetal weight, increased fetal and litter incidence of skeletal anomalies, increased fetal incidence of unossified sternebrae.
870.3700	Prenatal developmental with acid - rat	Maternal NOAEL = < 50 mg/kg/day Maternal LOAEL = 50 mg/kg/day based on increased clinical signs Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 200 mg/kg/day based on increase incidence of fetuses and litters with retarded ossification of skull bones, and two litters (one fetus per litter) with cleft palate and brachycephaly.
870.3800	Reproduction and fertility effects with acid - rat	Parental/Systemic NOAEL = 5 mg/kg/day in males and in females Parental/Systemic LOAEL = 25 mg/kg/day in males and females based on increased incidence of proximal tubular degeneration in male and female P1 and P2 rats. Reproductive/Offspring NOAEL = 5 mg/kg/day in males and females Reproductive/Offspring LOAEL = 25 based on increased incidence of F2 pups with exencephaly and ablepharia.
870.4100a	228–Day toxicity study - acid - dogs	NOAEL = 10 mg/kg/day in males and females LOAEL = 20 mg/kg/day in males and females based on decreased body weight gain (M), decreased hematological parameters (M), changes in clinical chemistry (both sexes), and liver histopathology (both sexes).
870.4100b	Chronic toxicity (1 year) - acid - dogs	NOAEL ≤ 5 mg/kg/day in males and females LOAEL > 5 mg/kg/day in males and females based on changes in clinical chemistry which are due not to toxicity, but a physiologic response of the dog based on limited ability of the dog to excrete organic acids at higher plasma concentrations.
870.4300	Chronic/carcinogenicity - acid - rats	NOAEL = 12 mg/kg/day in males, ≤ 36 mg/kg/day in females LOAEL = 36 in males, > 36 mg/kg/day in females based on marginal increases in proximal tubular degeneration at 6 months. Increase in adrenal gland pheochromocytoma in males and significant trend (< 0.05) for mammary gland adenocarcinomas in females.
870.4300	Carcinogenicity - acid - mice	NOAEL = 84 mg/kg/day in males, 109.5 mg/kg/day in females LOAEL = 143 mg/kg/day in males, 135 mg/kg/day in females based on decreased weight gain No evidence of carcinogenicity in males, but females had a significant trend (< 0.05) for mammary gland adenocarcinomas
870.5265	Gene mutation	Triclopyr BEE was non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535 and TA1537.
870.5265	Gene mutation	Triclopyr acid was non-mutagenic when tested up to 10,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538.
870.5300	Gene mutation	In the rec - assay, triclopyr acid produced no evidence of growth inhibition for the repair competent (H17) or repair deficient (M45) *B. subtilis* bacterial strains when tested up to 2,000 μg/disk.
870.5300	Gene mutation	In the host-mediated assay, triclopyr acid was negative for mutagenicity at doses up to 70 mg/kg in ICR random bred mice when tested against indicator organisms
870.5395	*In Vivo* Cytogenetic assay - rats	Triclopyr acid was negative for chromosomal aberrations in the cytogenetic assay when administered singly or for 5 days to Sprague-Dawley rats up to 70 mg/kg/day
870.5395	*In vivo* Mouse micronucleus	Triclopyr BEE was not clastogenic in the mouse micronucleus test up to 600 mg/kg (HDT)

TABLE 2.—TOXICITY PROFILE OF TRICLOPYR—Continued

Guideline No.	Study Type	Results
870.5550	Unscheduled DNA synthesis	Triclopyr BEE did not cause DNA damage or inducible repair in the rat hepatocyte unscheduled DNA synthesis
870.5550	Unscheduled DNA synthesis	Triclopyr acid did not produce any evidence of unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), in rat primary hepatocyte cultures exposed up to cytotoxic levels.
870.5450	Dominant lethal assay - mice	Triclopyr acid was negative for the dominant lethal mutagenic effect in treated male rats which were fed for 9 consecutive weeks at doses up to 70 mg/kg/day and mated to virgin females.
870.5450	Dominant lethal assay - rats	Triclopyr acid was negative for the dominant lethal mutagenic effect in treated male rats at doses up to 70 mg/kg/day given by oral intubation followed by mating to 2 untreated females per week for 7 weeks
870.7485	Metabolism and pharmacokinetics - rat	In a rat metabolism with C14-triclopyr acid at doses of 3 mg/kg (single, low dose), 3 mg/kg x 14 days (repeated low dose) and 60 mg/kg (high dose), triclopyr was well absorbed and rapidly excreted at the low dose or repeated low dose. At 60 mg/kg, excretion was decreased between 0–12 hours due to saturation of renal excretion mechanisms (attainment of zero order kinetics). Unmetabolized parent represented > 90% of the urinary radioactivity, with the remainder present as primarily TCP.
870.7500	Dermal penetration study in humans	In an oral and dermal pharmacokinetics study of triclopyr in human volunteers, triclopyr was administered orally and dermally to six human volunteers. More than 80% of the administered dose was found as unchanged triclopyr in the urine. An average of 1.65% of the dermally applied dose was recovered in the urine and represented dermal penetration of triclopyr.

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 LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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

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 triclopyr used for human risk assessment is shown in the following Table 3:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRICLOPYR IN HUMAN RISK ASSESSMENTS[1]

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary General population	NOAEL = 100 mg/kg/day UF = 100 acute RfD = 1.0 mg/kg/day	FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 1.0 mg/kg/day	Developmental toxicity study with BEE- rat LOAEL = 300 mg/kg/day based on clinical signs on GD 7

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRICLOPYR IN HUMAN RISK ASSESSMENTS[1]—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary Females 13–50 years old	NOAEL = 5 mg/kg/day UF = 100 acute RfD = 0.05 mg/kg/day	FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 0.05 mg/kg/day	2–Generation reproduction study with acid - rat LOAEL = 25 mg/kg/day based on increased incidence of F2 pups with exencephaly and ablepharia
Chronic dietary All populations	NOAEL= 5.0 mg/kg/day UF = 100 Chronic RfD = 0.05 mg/kg/day	FQPA SF = 1X cPAD = cRfD ÷ FQPA SF = 0.05 mg/kg/day	2–Generation reproduction study with acid - rat LOAEL = 25 mg/kg/day based on increased incidence of proximal tubular degeneration in male and female P1 and P2 rats
Short-term incidental, oral (1–30 days) Swimmer, residential	Oral NOAEL = 100 mg/kg/day	LOC for MOE = 100	Developmental rat studies with BEE and TEA (co-critical) LOAEL = 300 mg/kg/day based on mortality (both studies), clinical signs (red and/or green staining) beginning on GD 7 (BEE study) and GD 15 (TEA study) and decreased body weight gain on GD 6–20 (BEE study)
Intermediate-term incidental, oral (1–6 months) Residential	Oral NOAEL = 5.0 mg/kg/day	LOC for MOE = 100	Subchronic toxicity (feeding) with acid - rat LOAEL = 20 mg/kg/day based on histological changes in the kidney (degeneration of the proximal renal tubule)
Short-term dermal (1–30 days) (Occupational/residential)	Oral NOAEL = 5.0 mg/kg/day Dermal absorption = 2%	LOC for MOE = 100	2–Generation reproduction study with acid - rat LOAEL = 25 mg/kg/day based on increased incidence of F2 pups with exencephaly and ablepharia
Intermediate-term dermal (1–6 months) Occupational/residential	Oral NOAEL = 5.0 mg/kg/day Dermal absorption = 2%	LOC for MOE = 100	2–Generation reproduction study with acid - rat and 90–day feeding study with acid - rat (co-critical) LOAEL = 20 mg/kg/day (90 day study) and 25 mg/kg/day (2–generation rat reproduction study) based on histological changes in the kidney in both studies (degeneration of the proximal renal tubules)
Long-term dermal (6 months-lifetime) (Occupational/residential)	Oral NOAEL = 5.0 mg/kg/day Dermal Absorption = 2%	LOC for MOE = 100	2–Generation reproduction study with acid - rat LOAEL = 25 mg/kg/day based on increased incidence of proximal tubular degeneration in male and female P1 and P2 rats
Short-term inhalation (1–30 days) (Occupational/residential)	Oral NOAEL = 5.0 mg/kg/day Inhalation absorption rate = 100%	LOC for MOE = 100	2–Generation reproduction study with acid - rat LOAEL = 25 mg/kg/day based on increased incidence of F2 pups with exencephaly and ablepharia
Intermediate-term inhalation (1–6 months) Occupational/residential	Oral NOAEL = 5.0 mg/kg/day Inhalation absorption rate = 100%	LOC for MOE = 100	2–Generation reproduction study with acid - rat and 90 Day feeding study with acid - rat (co-critical) LOAEL = 20 mg/kg/day (90 day study) and 25 mg/kg/day (2–generation rat reproduction study) based on histological changes in the kidney in both studies (degeneration of the proximal renal tubules)

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRICLOPYR IN HUMAN RISK ASSESSMENTS[1]—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (6 months-lifetime) Occupational/residential	Oral NOAEL= 5.0 mg/kg/day Inhalation absorption rate = 100%	LOC for MOE = 100	2–Generation reproduction study with acid - rat and 90 Day feeding study with acid - rat (co-critical) LOAEL = 20 mg/kg/day (90 day study) and 25 mg/kg/day (2–generation rat reproduction study) based on histological changes in the kidney in both studies (degeneration of the proximal renal tubules)
Cancer (oral, dermal, inhalation)	Cancer classification (''Group D'')	Risk Assessment not required	Group D chemical

1 UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC= data base for triclopyr is complete and adequate for FQPA assessment; a developmental level of concern, MOE = margin of exposure. The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

In accordance with the Agency's 1999 Guidelines for Carcinogenic Risk Assessment, triclopyr has been classified as a ''Group D'' chemical - not classifiable as to human carcinogenicity (not entirely negative, but yet not convincing). Although increases in the incidence of two tumor types was observed in the acceptable carcinogenicity studies (mammary gland adenocarcinomas in female mice and rats, and benign adrenal pheochromocytomas in male rats), the Agency determined that the Group D classification is appropriate because: (1) The increased incidence of these tumor types was only marginal; (2) statistical significance was not achieved by pairwise comparisons of mammary gland adenocarcinomas in treated female mice to the concurrent controls; (3) a dose-related response in tumor incidence was not apparent in female rat mammary gland adenocarcinomas and in male rat benign adrenal pheochromocytomas following treatment with triclopyr; (4) no evidence of genotoxicity in a full battery of mutagenicity assays conducted with the triclopyr acid, triethylamine salt and the butoxyethyl ester was observed; and (5) data from structural analogs, such as chlorpyrifos, did not provide additional support for carcinogenicity. Experimental data on chlopyrifos demonstrated that this insecticide is not a carcinogen and unlike triclopyr, is more readily metabolized. Given the only marginal indication of carcinogenic potential, EPA does not expect triclopyr to pose a cancer risk to humans.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.417) for the combined residues of triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) in or on grasses, forage and grasses, forage, hay; and the combined residues of triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) in or on rice, grain; rice, straw; eggs; meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry. Risk assessments were conducted by EPA to assess dietary exposures from triclopyr 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A refined acute analysis was performed using anticipated residue levels for rice, fish, shellfish, and livestock commodities, default processing factors, and making use of percent crop treated (PCT) values for all commodities except fish and shellfish. A value of 1% was used wherever values < 1% were reported. For acute dietary risk, HED's LOC is > 100% aPAD. A probabilistic assessment was conducted, using 1,000 iterations in the Monte Carlo analysis.

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 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis made use of the same assumptions that went into the acute analysis described above, except that average anticipated residue levels were used in a deterministic analysis.

iii. *Cancer.* As described above, given the only marginal evidence supporting triclopyr's carcinogenic potential, EPA has determined qualitatively, based on the weight of the evidence, that triclopyr is not expected to pose a cancer risk to humans and, therefore has not conducted a quantitative analysis.

iv. *Anticipated residue and PCT.* 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 PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 100% fresh-water fish and shellfish; 6% rice; 1% hay.

The Agency believes that the conditions listed in Unit IV. 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 triclopyr 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 triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) 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 triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP).

3. *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.''

TCP, 3,5,6-trichloro-2-pyridinol is a metabolite of triclopyr, chlopyrifos, and chlorpyrifos-methyl. Accordingly, EPA has assessed the risk of triclopyr taking into account aggregate exposure to TCP resulting from triclopyr, chlorpyrifos, and chlorpyrifos-methyl.

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The toxicology data base for triclopyr is adequate according to the Subdivision F Guideline requirements for a food-use chemical. Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2–generation reproduction study in the rat. In determining the degree of concern and residual uncertainties, the Agency examined the need for an additional safety factor to account for the concern. In both the prenatal and postnatal study in rats with triclopyr, there were clearly defined NOAELs and LOAELs for developmental and offspring toxicities. The Agency noted that although the skull malformations (exencephaly and ablepharia) are rare, they occurred at a dose (25 mg/kg/day) above the dose (5mg/kg/day) that is used for acute and chronic dietary and residential exposure risk assessments. The other anomalies seen in the rat following *in utero* exposure occurred even at much higher dose levels (LOAEL = 200 mg/kg/day). The Agency determined that it is unlikely that the occurrence of commonly seen developmental effects would go undetected or under estimated since the rare findings were clearly observed following both prenatal and postnatal exposures.

3. *Conclusion*. There is a complete toxicity data base for triclopyr and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has determined that the Special FQPA SF of 10x can be reduced to 1x because:

i. The toxicology data base is complete for FQPA special SF determination;

ii. There is no susceptibility identified following *in utero* exposure in rabbits;

iii. There is qualitative susceptibility identified following *in utero* as well as prenatal and postnatal exposure of the rat, however, these effects occurred at a dose (25 mg/kg/day) above the dose (5 mg/kg/day) that is used for acute and chronic dietary and residential exposure risk assessments;

iv. The developmental neurotoxicity study is not required for this chemical;

v. There are no residual uncertainties associated with the exposure assessments performed for the dietary food and drinking water or the residential pathway.

In addition, the Agency determined that no traditional additional safety factor (addressing data deficiencies) is needed because: The Agency concluded that the toxicological data base for triclopyr is complete and adequate for FQPA assessment; a developmental neurotoxicity study was not required for triclopyr and no additional safety factors are needed to account for toxicology data deficiencies.

The default FQPA SF of 10X has been retained on TCP because at this time, an individual analysis has not been conducted as to whether a different safety factor would be appropriate.

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

1. *Triclopyr* i.—*Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) will occupy 0.6% of the aPAD for the U.S. population, 11% of the aPAD for females 13 years and older, 0.8% of the aPAD for all infants and 1% of the aPAD for children 1–6 years old. In addition, there is potential for acute dietary exposure to triclopyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRICLOPYR

Scenario/Population Subgroup	aPAD, mg/kg/day	Acute Food Exposure, mg/kg/day	Maximum Acute Water Exposure[1], mg/kg/day	Surface Water EEC[2], ppb	Acute DWLOC[3], ppb
U.S. Population	1.0	0.006245	0.993755	1,000	35,000
All infants (< 1 year old)	1.0	0.000770	0.999230	1,000	10,000
Children (1–6 years old)	1.0	0.009764	0.990236	1,000	9,900
Children (7–12 years old)	1.0	0.006929	0.993071	1,000	9,900
Females (13–50 years old)	0.05	0.005328	0.044672	1,000	1,300
Males (13–19 years old)	1.0	0.008638	0.991362	1,000	35,000
Males (20+ years old)	1.0	0.005200	0.994800	1,000	35,000
Seniors (55+ years old)	1.0	0.005671	0.994329	1,000	35,000

[1] Maximum acute water exposure (mg/kg/day) = aPAD (mg/kg/day) - acute food exposure from DEEM® (mg/kg/day).
[2] 2Peak drinking water estimate based on proposed aquatic uses.
[3] 3The acute DWLOCs were calculated as follows: DWLOC (μ/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/μg.

ii. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) from food will utilize 0.2 % of the cPAD for the U.S. population, 0.02 % of the cPAD for all infants under 1 year old and 0.2% of the cPAD for Children 1–6 years old. Based the use pattern, chronic residential exposure to residues of triclopyr is not expected. In addition, there is potential for chronic dietary exposure to triclopyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRICLOPYR

Scenario/Population Subgroup	cPAD, mg/kg/day	Chronic Food Exposure, mg/kg/day	Maximum Chronic Water Exposure[1], mg/kg/day	Surface Water EEC[2], ppb	Chronic DWLOC[3], ppb
U.S. Population	0.05	0.000084	0.049916	390	1,700

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRICLOPYR—Continued

Scenario/Population Subgroup	cPAD, mg/kg/day	Chronic Food Exposure, mg/kg/day	Maximum Chronic Water Exposure[1], mg/kg/day	Surface Water EEC[2], ppb	Chronic DWLOC[3], ppb
All infants (< 1 year old)	0.05	0.000008	0.049992	390	500
Children (1–6 years old)	0.05	0.000105	0.049895	390	500
Children (7–12 years old)	0.05	0.000070	0.049930	390	500
Females (13–50 years old)	0.05	0.000082	0.049918	390	1,500
Males (13–19 years old)	0.05	0.000096	0.049904	390	1,700
Males (20+ years old)	0.05	0.000091	0.049909	390	1,700
Seniors (55+ years old)	0.05	0.000079	0.049921	390	1,700

[1] Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM (mg/kg/day).
[2] Chronic drinking water estimate based on aquatic uses.
[3] The chronic DWLOCs were calculated as follows: DWLOC (μ/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption (L/day) x 0.001 mg/μg.

iii. *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).

Triclopyr 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 triclopyr.

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 477 for females 13–50 years old, 5,950 for children 1–6 years old, 9,890 for all infants less than 1 year old, and 11,500 for children 7–12 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of triclopyr 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 LOC, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO TRICLOPYR

Population	Short Term Scenario				
	Target MOE[1]	Aggregate MOE (food and residential)[2]	Max Water Exposure[3] mg/kg/day	Surface Water EEC[4](μg/L)	Short-Term DWLOC[5](μg/L)
All Infants (<1 year)	100	9,890	0.989892	390	9,900
Children 1–6 years old	100	5,950	0.983195	390	9,800
Children 7–12 years old	100	11,500	0.99131	390	9,900
Females 13–50 years old[6]	100	477	0.039518	390	1,200

[1] Basis for the target MOE: interspecies and intraspecies uncertainty factors totaling 100.
[2] Aggregate MOE = NOAEL ÷ (Chronic Food Exposure + Residential Exposure. Home post application & swimming)
[3] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[4] Chronic drinking water estimate based on aquatic uses.
[5] DWLOC(μg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ water consumption (L) x 10^{-3} mg/μg (10 kg body weight assumed, except for Females, 13–50, 60 kg)
[6] Although this dose/endpoint was not specifically identified for use in short-term incidental oral aggregate risk calculations for females 13–50, the Agency believes the use of the acute dieatry endpoint is appropraite to evelauate this senario.

iv. *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).

Triclopyr is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for triclopyr.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 142,000 for all infants less than 1 year of age, 37,900 for children 1–6 years of age, and 51,500 for children 7–12 years of age. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of triclopyr

in surface water. After calculating DWLOCs and comparing them to the EECs for surface water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC, as shown in the following Table 7:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO TRICLOPYR

Population	Intermediate-term Scenario				
	Target MOE [1]	Aggregate MOE (food and residential)[2]	Max Water Exposure[3] mg/kg/day	Surface Water EEC[4] (µg/L)	Intermediate-Term DWLOC[5] (µg/L)
All Infants (< 1 year)	100	142,000	0.049965	390	500
Children 1–6 years old	100	37,900	0.049868	390	500
Children 7–12 years old	100	51,500	0.049903	390	500

[1] Basis for the target MOE: interspecies and intraspecies uncertainty factors totaling 100.
[2] Aggregate MOE = NOAEL ÷ (Chronic Food Exposure + Residential Exposure (toddler soil ingestion only))
[3] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure (toddler soil ingestion only))
[4] Chronic drinking water estimate based on aquatic uses.
[5] DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ water consumption (L) x 10^{-3} mg/µg (10 kg body weight assumed

v. *Cancer*. Given the only marginal indication of carcenogenic potential, EPA does not expect triclopyr to pose a cancer risk to humans.

2. *TCP (3,5,6-trichloro-2-pyridinol)*. TCP is a metabolite of triclopyr, chlorpyrifos, and chlorpyrifos-methyl. Thus, contributions from all three chemicals are needed to adequately estimate the total amount of TCP exposure from food, water and residential sources.

TCP aggregate exposure risk assessments were performed for acute and chronic aggregate exposure (food + drinking water). TCP residential exposure risk assessments were not conducted because triclopyr residential assessments were deemed protective of TCP residential exposures for reasons explained below.

Since the Agency does not have ground and surface water monitoring data to calculate a quantitative aggregate exposure, drinking water levels of concern (DWLOCs) were calculated.

i. *Acute risk*. Because the aPAD for TCP is based on developmental toxicity effects, the only population subgroup of concern for acute dietary exposure is females 13–50 years old. The developmental toxicity study in rabbits had a developmental NOAEL = 25 mg/kg/day based on increased incidence of hydrocephaly and dilated ventricles seen at 100 mg/kg/day (LOAEL).

The Agency's LOC for acute exposure to TCP is for exposures greater than 100% of the aPAD of 0.025 mg/kg/day. An aggregate assessment of TCP resulting from uses of chlorpyrifos, chlorpyrifos-methyl, and triclopyr provides an acute dietary estimate for females 13–50 years old that utilizes 22% of the aPAD when using percent crop treated values for the registered uses and assuming all shellfish and freshwater fish contain triclopyr residues and 90% of the triclopyr residues are present as TCP.

The results of the TCP acute aggregate risk analysis indicate that the acute aggregate dietary risk estimate for the Females 13–50 years old population subgroup does not exceed the Agency's LOC. The aggregate TCP EEC of 510 ppb is less than the DWLOC of 590 ppb. Thus, acute aggregate risk estimates are below the Agency's LOC. Table 8 summarizes the acute aggregate exposure to TCP residues.

TABLE 8.—ACUTE AGGREGATE EXPOSURES TO TCP RESIDUES

Scenario/Population	Subgroup aPAD, mg/kg/day	Acute Food Exposure[1], mg/kg/day	Maximum Acute Water Exposure[2], mg/kg/day	Surface Water EEC[3], ppb	Acute DWLOC[4], ppb
Females (13–50 years old)	0.025	0.005447	0.019553	510	590

[1] Acute aggregate TCP exposure from Table 3.
[2] Maximum acute water exposure (mg/kg/day) = aPAD (mg/kg/day) - acute food exposure from DEEM (mg/kg/day).
[3] Peak drinking water estimate based on sum of TCP levels from chlorpyrifos/chlorpyrifos-methyl and triclopyr uses.
[4] The acute DWLOC was calculated as follows: DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption L/day x 0.001 mg/µg

ii. *Chronic risk*. The Agency's LOC for chronic exposure to TCP is for exposures greater than 100% of the cPAD of 0.012 mg/kg/day from a 1–year chronic dog study with a NOAEL 12 mg/kg/day based on alterations in clinical chemistry levels at 48 mg/kg/day (LOAEL). An aggregate assessment of TCP resulting from uses of chlorpyrifos, chlorpyrifos-methyl, and triclopyr provides an chronic dietary estimate for all infants that utilize 0.5 % cPAD to children 1–6 years old that utilizes 1.5% of the cPAD for TCP when using PCT values for the registered uses and assuming all shellfish and freshwater fish contain triclopyr residues and 90% of the triclopyr residues are present as TCP.

The results of the TCP chronic aggregate risk analysis indicates that the chronic dietary risk estimates for all adult population subgroups do not exceed the Agency's LOC. The aggregate TCP EEC of 340 ppb are less than the DWLOCs for all population adult subgroups. The Agency notes that the chronic aggregate risk assessment for TCP exceeds the Agency's LOC (the

chronic DWLOC) for infants and children.

TABLE 9.—CHRONIC AGGREGATE EXPOSURES TO TCP RESIDUES

Scenario/Population Subgroup	Subgroup cPAD, mg/kg/day	Chronic Food Exposure[1], mg/kg/day	Maximum Chronic Water Exposure[2], mg/kg/day	Surface Water EEC[3], ppb	Chronic DWLOC[4], ppb
U.S. Population	0.012	0.000110	0.011890	340	420
All infants (<1 year old)	0.012	0.000056	0.011944	340	120
Children (1–6 years old)	0.012	0.000185	0.011815	340	120
Children (7–12 years old)	0.012	0.000120	0.011880	340	120
Females (13–50 years old)	0.012	0.000099	0.011901	340	360
Males (13–19 years old)	0.012	0.000098	0.011902	340	420

[1] Chronic aggregate TCP exposure from Table 5.
[2]Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM (mg/kg/day).
[3]Chronic drinking water estimate based on sum of TCP levels from chlorpyrifos/chlorpyrifos-methyl and triclopyr uses (see Table 6).
[4]The chronic DWLOCs were calculated as follows: DWLOC (µg/L) = maximum water exposure (mg/kg/day) x body weight (kg) ÷ consumption L/day x 0.001 mg/µg

Although the generally conservative aggregate risk assessment based on modeling data exceeds the Agency's LOC under the chronic exposure scenario for infants and children, the Agency has biomonitoring data on 416 individuals that include all pathways and routes of exposure (food, water, residential, dermal, oral, and inhalation). The Agency believes that the biomonitoring study represents a worse case scenario since 120 children that were monitored were from households where their residents had been treated with a termiticide containing chlorpyrifos. All adult exposures measured in studies represented less than 8% of the cPAD for TCP. For children 1–6 years old, 95% of the individuals had exposures that utilized 4.5% of the cPAD or less. The Agency feels the biomonitoring studies represent a worst-case scenario and that chronic exposure to TCP for children will be significantly lower than shown through biomonitoring. The Agency reached this conclusion based on the fact that chlorpyrifos and chlorpyrifos methyl were the main source of TCP compared to triclopyr. At the time of the biomonitoring study 35X more chlorpyrifos and chlorpyrifos methyl was being used than triclopyr. With the cancellation of all uses of chlorpyrifos methyl with the exception of the stored grain use, the post-construction use of chlorpyrifos as a termiticide being canceled at the end of 2002, the pre-construction use of chlorpyrifos as a termiticide being canceled in 2004/2005 unless submitted data shows acceptable exposure levels (due to the circumstances of its application significant exposure, is not expected from pre-construction use of chlorpyrifos but data has been required to confirm this assumption), and homeowner applied chlorpyrifos products having been canceled, the chronic exposure to TCP should be significantly lower than shown through the biomonitoring.

iii. *Residential assessment.* A residential assessment was not done for TCP. The residential uses of triclopyr are expected to result in exposure to levels of TCP levels that are approximately 100X less than the estimated triclopyr levels and the short term dermal endpoint for TCP is 5X higher than same endpoint for triclopyr. Residential TCP exposures are not expected from chlorpyrifos or chlorpyrifos-methyl. All chlorpyrifos-methyl uses (stored grain only) should be completely phased out by 2004. For chlorpyrifos, the following reductions are in progress: Pre-construction termiticide uses will be completely phased out by 2004 unless submitted data shows acceptable risks, post-construction termiticide uses will be completely phased out by 2002, homeowner applied products have been canceled, and major reductions in professionally applied residential lawn/ornamental products are expected.

3. *Determination of safety for Triclopyr and TCP.* 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 triclopyr and TCP.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography with mass selective detection (GC/MSD)(GRM 97.02) is available to enforce the tolerance expression. The method may be requested from: Paul Golden, Analytical Chemistry Lab, Office of Pesticide Programs, Environmental Protection Agency, Environmental Science Center, 701 Maples Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2960; e-mail address: golden.paul@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue levels (MRLs) for triclopyr residues. Therefore, harmonization is not an issue at this time.

V. Conclusion

Therefore, the tolerance is established for combined residues of triclopyr and its metabolites, 3,5,6-trichloro-2-pyridinol (TCP) and 2-methoxy-3,5,6-trichloropyridine (TMP) in or on fish at 3.0 ppm and shellfish at 3.5 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 ID number OPP–2002–0190 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 18, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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 ID number OPP–2002–0190, 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 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, *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 record keeping requirements.

Dated: September 9, 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 374.

2. Section 180.417 is amended by alphabetically adding the commodities ''Fish''and ''Shellfish'' to the table in paragraph (a)(1) to read as follows:

§ 180.417 Triclopyr; tolerances for residues.

(a) General. (1) * * *

Commodity	Parts per million
* * *	* *
Fish	3.0
* * *	* *
Shellfish	3.5

* * * * *

[FR Doc. 02–23746 Filed 9–17–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0256; FRL–7274–9]

Indoxacarb; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of indoxacarb in or on cranberry. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberry. This regulation establishes a maximum permissible level for residues of indoxacarb in this food commodity. The tolerance will expire and is revoked on December 31, 2004.

DATES: This regulation is effective September 18, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0256, must be received on or before November 18, 2002.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: conrath.andrea@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 producers (NAICS 111)
- Animal producers (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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