result in environmental justice related issues and does not, therefore, require special consideration under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since the Agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the APA or any other statute (see Unit IV.), this action is not subject to provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA.

This final rule will not have substantial direct effects on the States or on one or more Indian tribes, on the relationship between the national government and the States or one or more Indian tribes, or on the distribution of power and responsibilities among the various levels of government or between the Federal government and Indian tribes. As such, this action 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), or any ''federalism implications '' as described in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999).

This action does not involve any technical standards that require the Agency's 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). In issuing this final rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings '' issued under the Executive Order. For information about the applicability of the regulatory assessment requirements to the final rule that was issued on July 14, 2000 (64 FR 43704), please refer to the discussion in Unit VIII. of that document.

VI. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: July 23, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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, 371.

2. Section 180.570 is amended by revising paragraph (a) to read as follows:

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) *General*. Tolerances that expire as indicated in the table below are established for residues of isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, CAS No. 163520–33–0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benezenepropanenitrile when in the commodities listed below. This safener will be used only in conjunction with the active ingredient fenoxaprop-*p*-ethyl, at a rate of 0.17 pound of safener per acre.

Commodity	Parts per million	Expiration/ Revocation date
Rice, bran	0.80	6/21/04
Rice, grain	0.10	6/21/04
Rice, hulls	0.50	6/21/04
Rice, straw	0.25	6/21/04

* * * * *

[FR Doc. 01–19326 Filed 8–1–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301148; FRL–6791–7]

RIN 2070–AB78

Tepraloxydim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3- (tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on canola, seed;

cotton, undelinted seed; cotton, gin byproducts; soybean, seed; soybean, hulls; and soybean, aspirated grain fractions; and the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on milk; meat of cattle, goats, hogs, horses, and sheep; meat byproduct (except kidney) of cattle, goats, hogs, horses, and sheep; kidney of cattle, goats, hogs, horses, and sheep; fat of cattle, goats, hogs, horses, and sheep; poultry, meat; poultry, meat byproducts (except liver), poultry, fat; poultry, liver, and eggs. Nippon Soda Company, Ltd requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 2, 2001. Objections and requests for hearings, identified by docket control number OPP–301148, must be received by EPA on or before October 1, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301148 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; telephone number: (703) 305–5697 ; and 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	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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301148. 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 December 22, 1999 64 FR 71774) (FRL–6398–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F4945) for tolerance by BASF Corporation, acting as agent for Nippon Soda Company, Ltd., P.O. Box 13528, Research Triangle Park, NC 27709–3528. This notice included a summary of the petition prepared by Nippon Soda, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the herbicide tepraloxydim, (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) (calculated as the herbicide) in or on the raw agricultural commodities cotton, seed at 0.2 part per million (ppm); cotton meal at 0.2 ppm, cotton gin trash at 3.0 ppm; soybean seed at 5.0 ppm; soybean hulls, poultry meat and fat at 0.5 ppm; and poultry, liver at 1.0 ppm; and eggs at 0.2 ppm.

During the course of the review, the Agency determined that the available data support the following tolerances: tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on cotton, undelinted seed at 0.2 ppm; cotton, gin byproducts at 3.0 ppm; soybean, seed at 6.0 ppm; soybean, hulls at 8.0 ppm; and soybean, aspirated grain fractions at 1200 ppm; and the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on milk at 0.1 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.2 ppm; meat byproduct (except kidney) of cattle, goats, hogs, horses, and sheep at 0.2 ppm; kidney of cattle, goats, hogs, horses, and sheep at 0.5 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.15 ppm; poultry, meat at 0.2 ppm; poultry, meat byproducts (except liver)

at 0.2 ppm; poultry, fat at 0.3 ppm; poultry, liver at 1.0 ppm; and eggs at 0.20 ppm. The available data also support the establishment of a tolerance with regional registration, as defined in § 180.1(n) for the combined residues of tepraloxydim and its metabolites convertible to GP and OH-GP, calculated as tepraloxydim in or on the raw agricultural commodity canola, seed at 0.5 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[s] for the combined residues of tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on cotton, undelinted seed at 0.2 ppm; cotton, gin byproducts at 3.0 ppm; soybean, seed at 6.0 ppm; soybean, hulls at 8.0 ppm; soybean, aspirated grain fractions at 1200 ppm; and the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on milk at 0.1 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.2 ppm; meat byproduct (except kidney) of cattle, goats, hogs, horses, and sheep at 0.2 ppm; kidney of cattle, goats, hogs, horses, and sheep at 0.5 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.15 ppm; poultry, meat at 0.2 ppm; poultry, meat byproducts (except liver) at 0.2 ppm; poultry, fat at 0.3 ppm; poultry, liver at 1.0 ppm; and eggs at 0.20 ppm; and a tolerance with regional registration, as defined in § 180.1(n) for the combined residues of tepraloxydim and its metabolites convertible to GP and OH-GP, calculated as tepraloxydim, in or on the raw agricultural commodity canola, seed at 0.5 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 tepraloxydim 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.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity in rats	NOAEL = M=22, F=26 mg/kg/day LOAEL = M=223, F=257 mg/kg/day based on decreased body weight/body weight gain, changes in kidney proximal tubule, and changes in clinical chemistry parameters indicative of liver and kidney impairment.
870.3150	90–Day oral toxicity in dogs	NOAEL = M=12.9, F=14.3 mg/kg/day LOAEL = M=63.3, F=68.0 mg/kg/day based on increased liver and thyroid weights and histopathology of spleen.
870.3200	28–Day dermal toxicity in rats	NOAEL = 1,000 mg/kg/day (limit dose) LOAEL = Not determined.
870.3700a	Prenatal developmental in rats	Maternal NOAEL = 120 mg/kg/day LOAEL = 360 mg/kg/day based on decreased body weight and food consumption. Developmental NOAEL = 40 mg/kg/day LOAEL = 120 mg/kg/day based on decreased fetal body weight, retarded ossification, and hydroureter.
870.3700b	Prenatal developmental in rabbits	Maternal NOAEL = 60 mg/kg/day; LOAEL = 180 mg/kg/day based on decreased body weight and food consumption. Developmental NOAEL = ≥ 180 mg/kg/day (HTD) LOAEL = >180 mg/kg/day based on no developmental effects at the HTD.
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = M=50.6, F=55.0 mg/kg/day

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

Guideline No.	Study Type	Results
		LOAEL = M= 260.0, F= 276.0 mg/kg/day based on decreased body weight/ weight gain and food consumption. Reproductive NOAEL = ≥ 260 mg/kg/day LOAEL = > 260 mg/kg/day based on no reproductive effects. Offspring NOAEL = M=50.6, F=55.0 mg/kg/day LOAEL = M= 260.0, F= 276.0 mg/kg/day based on reduced pup body weight gain and lower pup body weight during lactation.
870.4100b	Chronic toxicity in dogs	NOAEL = M=11.5, F=12.5 mg/kg/day LOAEL = M=56.0, F=60.6 mg/kg/day based on reduced epididymal and prostate activities, transitional epithelial hyperplasia of the urinary bladder, and abnormal liver function and liver foci.
870.4200	Carcinogenicity in rats	NOAEL = M=5, F=38 mg/kg/day LOAEL = M=30, F=272 mg/kg/day based on hepatic lesions in both sexes, increased incidences of hepatocellular adenoma/carcinoma in females, adrenal medullary tumors in females, and uterine schwannoma in females. Some evidence of carcinogenicity in females
870.4300	Carcinogenicity in mice	NOAEL = M=37, F=52 mg/kg/day LOAEL = M=332, F=490 mg/kg/day based on decreased body weight/gain, increased relative liver weight in males, and uterine sclerosis. Female mice developed liver tumors at an excessively toxic dose.
870.5100	Gene Mutation	Ames test: Negative at all doses; cytotoxic at HTD of 5,000 μg/ml. Mammalian (CHO/HPRT): Negative; HTD = 3,000 μg/ml (limit of solubility = 1000 μg/ml).
870.5395 and 870.5375	Cytogenetics	*In vivo* (mouse bone marrow): Negative; HTD = 500 mg/kg. *In vitro* (chromosomal aberration in CHO cells): Negative; HTD = 1,000 μg/ml (limit of solubility).
870.5550	Other Effects	UDS in primary male rat hepatocytes: Negative; HTD = 500 μg/ml; cytotoxic at ≥ 100 μg/ml.
870.6200a	Acute neurotoxicity screening battery (unacceptable)	NOAEL = < 500 mg/kg LOAEL = 500 mg/kg based on decreased motor activity.
870.6200b	Subchronic neurotoxicity screening battery (unacceptable)	NOAEL = M=103, F=124 mg/kg/day LOAEL = M=428, F=513 mg/kg/day based on increased motor activity, and decreased body weight, food consumption, food efficiency.
870.7485	Metabolism and pharmacokinetics	In pharmacokinetics/metabolism studies in the rat, tepraloxydim was readily and almost completely absorbed after oral administration (single dose of 30 or 300 mg/kg), but was rapidly excreted mainly via the urine (65–80%). Excretion was nearly 2–3 fold higher in the bile than the feces, which suggests enterohepatic recirculation. The rat plasma half life of radiolabeled tepraloxydim is nearly 4.4 and 10 hours at the low and high dose, respectively. No accumulation of radioactivity was observed in any tissue at 120 hours post-dosing. A large number of metabolites were detected in the urine, feces, and bile; the main metabolic pathway being oxidation at the pyran ring to the lactone via a hydroxy metabolite, and cleavage of the oxime ether group with the imine and oxazol as products. At near plasma t_{max} (one hour post dosing), the plasma, liver, and kidney almost exclusively contained the parent compound. The results indicate that the distribution, metabolism, and excretion of tepraloxydim is independent from dose levels, sex, route of administration (oral vs. i.v.), or site of label (pyran vs. cyclohexanone).
870.7600	Dermal penetration (unacceptable)	The available rat dermal absorption study is considered unacceptable. A dermal absorption rate of 36% was derived based on the results of a 28–day dermal toxicity study in rats and developmental toxicity study in rats.

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 intra species differences.

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for tepraloxydim used for human risk assessment is shown in the following Table 2:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TEPRALOXYDIM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg/day), Uncertainty Factor (UF)	Population (if applicable); Endpoint	Study and Toxicological Effects
Acute Dietary	NOAEL = 40; UF = 100; FQPA* = 3X; Females 13–50 ONLY.	Females 13–50: Reduced fetal body weight, reduced ossification indicative of delayed maturation, and the occurrence of hydroureter at 120 mg/kg/day (LOAEL). General Population: This risk assessment is not required. No appropriate single dose end-point. Acute RfD = 0.4 mg/kg Acute PAD = 0.13 mg/kg/day (Females 13–50 ONLY)	Developmental Toxicity-Rat
Chronic Dietary	NOAEL = 5 UF = 100; FQPA = 1X	NOAEL = 100 ppm (5 mg/kg/day) based on male liver microscopic lesions (eosinophilic foci) at 600 ppm (30 mg/kg/day). Chronic RfD = 0.05 mg/kg/day	Carcinogenicity-Rat
Incidental Oral, Short-Term	NOAEL = 120; FQPA = 1X	Reduced maternal body weight gain and food consumption at 360 mg/kg/day (LOAEL).	Developmental Toxicity-Rat
Incidental Oral, Intermediate-Term	NOAEL = 22; FQPA = 1X	NOAEL = 300 ppm (males 22, females 26 mg/kg/day) based on reduced body weight/body weight gain, proximal tubule kidney changes in males, and clinical chemistry changes indicative of hepatic and kidney impairment in both sexes at 3000 ppm (223 and 257 mg/kg/day.	Subchronic Oral Toxicity-Rat
Dermal, Short- and Intermediate-Term	NOAEL = 40	Reduced fetal body weight, reduced ossification indicative of delayed maturation, and the occurrence of hydroureter at 120 mg/kg/day (LOAEL). The dermal absorption factor of 36% should be used for route-to-route extrapolation.	Developmental Toxicity-Rat
Dermal, Long-Term	NOAEL= N/A	This risk assessment is not required due to the seasonal use of the chemical.	N/A
Inhalation, Short-and Intermediate-Term	NOAEL= 40	Reduced fetal body weight, reduced ossification indicative of delayed maturation, and the occurrence of hydroureter at 120 mg/kg/day (LOAEL). Use route-to-route extrapolation and a 100% absorption rate (default value).	Developmental Toxicity-Rat
Inhalation, Long-Term	NOAEL = N/A	This risk assessment is not required due to the seasonal use of the chemical.	N/A

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been not established (40 CFR part 180) for the combined residues of tepraloxydim and its metabolites, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from tepraloxydim 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 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: For acute risk assessments, a food consumption distribution is calculated for each population subgroup of interest based on 1 day consumption data. The only population subgroup of concern for this risk assessment is females (13–50 years old). The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier I/II type) exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment. Exposure estimates are expressed in mg/kg bw/day and as a percent of the aPAD.

In conducting this acute dietary risk assessment, the Agency has made highly conservative assumptions. Default concentration factors were used for the processed commodities. One hundred percent of the proposed crops are assumed to be treated with tepraloxydim and residues were assumed to be at tolerance levels. This is expected to result in an overestimate of dietary exposure. Therefore, this acute dietary (food only) risk assessment should be viewed as a highly conservative risk estimate. The percent aPAD that would be above EPA's level of concern would be 100%. Percent crop treated (PCT) and/or anticipated residues were not used. A DEEM acute analysis was performed using proposed and recommended tolerance levels for the combined residues of tepraloxydim and its metabolites for females (13–50 years old). Based on the results of this analysis, exposure to tepraloxydim from food will utilize 4.4% of aPAD for females (13–50 years old), the only population subgroup of concern.

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: For chronic dietary risk assessment, residue estimates for foods (e.g. apples) or food-forms (e.g. apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg/day and as a percent of the cPAD.

In conducting this chronic dietary risk assessment, the Agency has made highly conservative assumptions which result in an overestimate of human dietary exposure. A DEEM chronic exposure analysis was performed using the proposed tolerance level residues and 100% of the crop treated to estimate the exposure for the general population and subgroups of interest. This is expected to result in an overestimate of dietary risk. Therefore, this chronic dietary (food only) risk assessment should be viewed as a highly conservative risk estimate. Thus, in making a safety determination for these tolerances, EPA takes into account this highly conservative exposure assessment. The Agency is generally concerned with chronic exposures that exceed 100% of the cPAD or chronic RfD. Percent crop and/or anticipated residues were not used. Based on this analysis the exposure to tepraloxydim from food will utilize 6.8% cPAD for the general population, 31% cPAD for all infants (>1 year old), 15% cPAD for children (1–6 old), 10% cPAD for children (7–12 old), 7.4% cPAD for males (13–19 old), and 5.0% for females (13–50 old) and males (20+ years old).

iii. *Cancer*. Tepraloxydim has been reviewed by the Agency for carcinogenicity classification. In accordance with the EPA Draft Guidelines for Carcinogenic Risk Assessment (July, 1999), the Agency has classified tepraloxydim as data are inadequate for an assessment of human carcinogenic potential because some evidence is suggestive of carcinogenic effects, but other equally pertinent evidence does not confirm a concern. The Agency concluded that quantification of human cancer risk is not required because although there was some evidence of carcinogenicity in female rats based on an increased incidence of liver tumors at the high dose, this finding was not supported by the results of the chronic study. The Agency also concluded that female mice developed liver tumors at an excessively toxic dose, and although male mice had non-neoplastic liver changes similar to or exceeding those seen in female mice at the same dose, there was no increase in liver tumor incidence in males. Further more tepraloxydim was not mutagenic in a battery of assays. Therefore a cancer risk assessment was not performed.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of

comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to tepraloxydim they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of tepraloxydim for acute exposures are estimated to be 17.6 µg/L for surface water and 0.0015 µg/L parts per billion (ppb) for groundwater. EECs for chronic exposures are estimated to be 10.3 µg/L ppb for surface water and 0.0015 µg/L 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).

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

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

EPA does not have, at this time, available data to determine whether tepraloxydim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tepraloxydim 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 tepraloxydim has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. Based on the available data, both quantitative and qualitative evidence of increased susceptibility was observed following *in utero* tepraloxydim exposure to rats. In the prenatal rat developmental toxicity study, the developmental toxicity NOAEL/LOAEL is below the maternal toxicity NOAEL/LOAEL. Additionally, the developmental effects observed (reduced fetal body weights, retarded ossification indicative of delayed maturation, and the occurrence of hydroureter) were considered to be more severe than those observed in maternal animals (decreased body weight gain and food consumption). No evidence of increased susceptibility was seen following pre/post natal exposure in the 2-generation reproduction study.

3. *Conclusion*. The toxicology database for tepraloxydim is complete except for a developmental neurotoxicity study which is required due to evidence of neurotoxicity (effects on motor activity and grip strength) observed in acute and subchronic neurotoxicity studies with adult animals and a 28-day inhalation toxicity study is required because there is no inhalation toxicity available for risk assessment. The exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 3x for tepraloxydim. The Agency concluded that a safety factor is required for tepraloxydim since there is evidence of increased susceptibility of the young demonstrated in the prenatal developmental study in rats. The Committee recommended that the FQPA safety factor be reduced to 3x because: the toxicology database is complete; the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study - and a safety factor (e.g.: neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) - and therefore does not warrant an FQPA safety factor[1]; the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children; and there are currently no residential uses.

The FQPA safety factor for tepraloxydim is applicable to only Females 13–50 years population subgroup for acute dietary risk assessment (there are currently no residential exposure scenarios), since there is concern for increased susceptibility of the young demonstrated in the prenatal developmental study in rats. The developmental effects are presumed to occur following a single exposure of females of child-bearing age and, therefore, are appropriate for risk assessment for females aged 13–50 years old.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative

[1] This is an interim step towards accordance with the proposed OPP Policy on Determination of the Appropriate FQPA Safety Factor(s) for Use in the Tolerance-Setting Process' which was presented to the FIFRA SAP meeting in May, 1999 and placed in the Docket for Public Comment (64 FR 37001, July 8, 1999; Docket No. 37001).

drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to tepraloxydim will occupy 4.4% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to tepraloxydim in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TEPRALOXYDIM

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (µg/L)3	Ground Water EEC (µg/L)3	Acute DWLOC (µg/L)3
Females (13–50 years)	0.13	4.4	17.6	0.0015	3,700

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to teparloxydim from food will utilize 6.8% of the cPAD for the U.S. population, 31% of the cPAD for all infants (< 1 year old and 15% of the cPAD for children (1-6 years old) and 5.0% of the cPAD for females (13–50 years old). There are no residential uses for tepraloxydim that result in chronic residential exposure to tepraloxydim. In addition, there is potential for chronic dietary exposure to tepraloxydim in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TEPRALOXYDIM

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (µg/L)	Ground Water EEC (µg/L)	Chronic DWLOC (µg/L)
U.S. Population	0.05	6.8	10.3	0.0015	1,600
Females (13–50 years old)	0.05	5.0	10.3	0.0015	1,400
All Infants (<1 year)	0.05	31.0	10.3	0.0015	350
Males (13–19 years old)	0.05	5.0	10.3	0.0015	1,600

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).

Tepraloxydim is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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).

Tepraloxydim is not registered for use on any sites that would result in residential exposure. 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*. Tepraloxydim has been reviewed by the Agency for carcinogenicity classification. In accordance with the EPA Draft Guidelines for Carcinogenic Risk Assessment (July, 1999), the Agency has classified tepraloxydim as data are inadequate for an assessment of human carcinogenic potential because some evidence is suggestive of carcinogenic effects, but other equally pertinent evidence does not confirm a concern. The Agency concluded that quantification of human cancer risk is not required because although there was some evidence of carcinogenicity in female rats based on an increased incidence of liver tumors at the high dose, this finding was not supported by the results of the chronic study. The Agency also concluded that female mice developed liver tumors at an excessively toxic dose, and although male mice had non-neoplastic liver changes similar to or exceeding those seen in female mice at the same dose, there was no increase in liver tumor incidence in males. Further more, tepraloxydim was not mutagenic in a battery of assays. Therefore a cancer risk assessment was not performed.

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 tepraloxydim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Analytical methods (gas chromotography (GC/MS (selected ion monitoring)) have been proposed as analytical enforcement methods by the petitioner for raw agricultural, processed, and livestock commodities. These methods have been validated by the petitioner for gathering residue data. The initial raw agricultural commodity method has a longer completion time than currently permitted by current EPA Guidelines. A shorter, improved method for agricultural commodities and the

livestock commodity methods are being evaluated by EPA's Analytical Chemistry Branch. Prior to publication in PAM II and upon request, the analytical methods will be available from the Analytical Chemistry Branch (ACB), Biological and Economic Analysis Division (BEAD), Environmental Sciences Center, 701 Mapes Road, Fort George C. Meade, MD 20755–5350, contact Frances D. Griffith Jr., telephone (410–305–2905, e-mail griffith,frances@epa.gov. The analytical standards for these methods are also available from EPA's National Pesticide Standard Repository at the same location. Successful completion of method trials for proposed analytical methods are a condition of registration

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for tepraloxydim. Harmonization is not an issue at this time.

C. Conditions

The following are conditions of registration.

1. Successful completion of method trials for the proposed analytical enforcement methods.

2. A regional registration for canola in the states of Minnesota, Montana, North Dakota, and South Dakota.

3. Submission of additional storage stability data are needed to support the ruminant feeding study (samples stored for 217–337 days) and Agency review of storage stability data currently under review.

4. Submission of a developmental neurotoxicity study.

5. Submission of a 28–day inhalation toxicity study.

V. Conclusion

Therefore, the tolerance is established for combined residues of tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3- (tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on cotton, undelinted seed at 0.2 ppm; cotton, gin byproducts at 3.0 ppm; soybean, seed at 6.0 ppm; soybean, hulls at 8.0 ppm; soybean, aspirated grain fractions at 1,200 ppm; and the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim, in or on milk at 0.1 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.2 ppm; meat byproduct (except kidney) of cattle, goats, hogs, horses, and sheep at 0.2 ppm; kidney of cattle, goats, hogs, horses, and sheep at 0.5 ppm; fat of cattle, goats, hogs, horses, and sheep at 0.15 ppm; poultry, meat at 0.2 ppm; poultry, meat byproducts (except liver) at 0.2 ppm; poultry, fat at 0.3 ppm; poultry, liver at 1.0 ppm; and eggs at 0.20 ppm; and a tolerance with regional registration, as defined in § 180.1 (n) for the combined residues of tepraloxydim and its metabolites convertible to GP and OH-GP, calculated as tepraloxydim, in or on the raw agricultural commodity canola, seed at 0.5 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 control number OPP–301148 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 1, 2001.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301148, to: Public Information and Records Integrity Branch, Information Resources and

Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(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). 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 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 a substantial direct effects in one or more Indian Tribes, or the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rule will not have substantial direct effects on tribal governments, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: July 26, 2001.

James Jones,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.573 is added to read as follows:

§ 180.573 Tepraloxydim; Tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of tepraloxydim (2-[1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-3-hydroxy-5-(tetrahydro-2H-pyran-4-yl)-cyclohexene-1-one) and its metabolites convertible to GP (3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid) and OH-GP (3-hydroxy-3-(tetrahydropyran-4-yl)pentane-1,5-dioic acid), calculated as tepraloxydim in or on the following raw agricultural commodities.

Commodity	Parts per million
Cotton, undelinated seed	0.2
Cotton, gin byproducts	3.0
Soybean, seed	6.0
Soybean, hulls	8.0

Commodity	Parts per million
Soybean, aspirated grain fraction	1200.0

(2) Tolerances are established for the combined residues of tepraloxydim and its metabolites convertible to GP, OH-GP, and GL (3-(2-oxotetrahydropyran-4-yl)-1,5-dioic acid), calculated as tepraloxydim in or on the following commodities

Commodity	Parts per million
Cattle, fat	0.15
Cattle, kidney	0.50
Cattle, meat	0.20
Cattle, meat by products (except kidney)	0.20
Eggs	0.20
Goat, fat	0.15
Goat, kidney	0.50
Goat, meat	0.20
Goat, meat by products (except kidney)	0.20
Hog, fat	0.15
Hog, kidney	0.50
Hog, meat	0.20
Hog, meat by products (except kidney)	0.20
Horse, fat	0.15
Horse, kidney	0.50
Horse, meat	0.20
Horse, meat by products (except kidney)	0.20
Milk	0.10
Poultry, fat	0.30
Poultry, liver	1.00
Poultry, meat	0.20
Poultry, meat by products (except liver)	0.20
Sheep, fat	0.15
Sheep, kidney	0.50
Sheep, meat	0.20
Sheep, meat by products (except kidney)	0.20

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

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(n) is established for the combined residues of tepraloxydim and its metabolites convertible to GP and OH-GP, calculated as tepraloxydim in or on the following raw agricultural commodity:

Commodity	Parts per million
Canola, seed	0.50

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

[FR Doc. 01–19325 Filed 8–1–01; 8:45 a.m.]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 072501A]

Atlantic Highly Migratory Species Fisheries; Atlantic Bluefin Tuna

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Adjustment of General category daily retention limit.

SUMMARY: NMFS has determined that the Atlantic bluefin tuna (BFT) General category daily catch limit should be adjusted in order to allow for maximum utilization of the 2001 General category June through August subquota. Therefore, NMFS increases the daily retention limit from one to two large medium or giant BFT for the remainder of the June through August time-period.

DATES: Effective July 30, 2001 through August 31, 2001.

FOR FURTHER INFORMATION CONTACT: Pat Scida or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION:

Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. BFT fishing category quotas and General category effort controls (including time-period subquotas and Restricted-Fishing Days (RFDs)) are specified annually under §§ 635.23(a) and 635.27(a). The 2001 BFT quotas and General category effort controls were implemented July 13, 2001 (66 FR 37421, July 18, 2001).

Adjustment of Daily Retention Limit

Under § 635.23(a)(4), NMFS may increase or decrease the daily retention limit of large medium and giant BFT over a range from zero (on RFDs) to a maximum of three per vessel to allow for maximum utilization of the quota for BFT. Based on a review of dealer reports, daily landing trends, and the availability of BFT on the fishing grounds, NMFS has determined that an increase of the daily retention limit is appropriate and necessary to allow full use of the June through August subquota while ensuring an August fishery. Therefore, NMFS adjusts the daily retention limit for the remainder of the June through August subquota time-period to two large medium or giant BFT per vessel. This adjustment does not affect the previously scheduled RFDs for August (August 11, 12, and 13), on which the daily retention in the General category will be zero, and on which General category vessels may not fish for BFT.

The intent of this adjustment is to allow for maximum utilization of the June through August subquota (specified under § 635.27(a)) by General category participants in order to help achieve optimum yield in the General category fishery, to collect a broad range of data for stock monitoring purposes, and to be consistent with the objectives of the Fishery Management Plan for Atlantic Tunas, Swordfish and Sharks.

While catch rates have been low so far this season, NMFS recognizes that they may increase. In addition, due to the temporal and geographical nature of the fishery, certain gear types and areas are more productive at various times during the fishery. In order to ensure that the June through August subquota is not filled prematurely and to ensure equitable fishing opportunities in all areas and for all gear types, NMFS has not waived the RFDs in August, which correspond to market closures in Japan, and could promote better ex-vessel prices.

Classification

This action is taken under § 635.23(a)(4) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: July 27, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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