Commodity	Parts per million	Expiration/ Revocation Date
* * *	* *	*
Cattle, meat	0.05	None
* * *	* *	*
Cherimoya	0.30	None
* * *	* *	*
Citrus, dried pulp	7.5	None
Citrus, oil	80	None
* * *	* *	*
Custard, apple ..	0.30	None
Feijoa	0.30	None
Fruit, Citrus, Group 10	2.5	None
Fruit, Pome, Crop Group 11	4.0	None
* * *	* *	*
Goat, kidney	0.05	None
Goat, meat	0.05	None
* * *	* *	*
Guava	0.30	None
* * *	* *	*
Hog, kidney	0.05	None
Hog, meat	0.05	None
* * *	* *	*
Horse, kidney	0.05	None
Horse, meat	0.05	None
* * *	* *	*
Ilama	0.30	None
Jaboticaba	0.30	None
* * *	* *	*
Lettuce, head	5.0	None
Lettuce, leaf	13.0	None
Mamey sapote ..	0.30	None
Mango	0.30	None
* * *	* *	*
Papaya	0.30	None
Passion fruit	0.30	None
Peach	9.0	None
* * *	* *	*
Sapodilla	0.30	None
* * *	* *	*
Sheep, kidney ...	0.05	None
Sheep, meat	0.05	None
* * *	* *	*
Soursop	0.30	None
* * *	* *	*
Star apple	0.30	None
Starfruit	0.30	None
Sugar apple	0.30	None
* * *	* *	*
Vegetable, Cucurbit, Group 9	0.50	None
Wax jambu	0.30	None

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0054; FRL–7701–6]

Triflumizole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of triflumizole in or on parsley, leaves; dandelion, leaves; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese, napa; broccoli; and coriander, leaves (cilantro). 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 parsley; dandelion; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese, napa; broccoli; and coriander, leaves (cilantro). This regulation establishes maximum permissible levels for residues of triflumizole in these food commodities. These tolerances will expire and are revoked on June 30, 2008.

DATES: This regulation is effective April 8, 2005. Objections and requests for hearings must be received on or before June 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0054. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *Sec-18-Mailbox@epamail.epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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 be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing time-limited tolerances for combined residues of the fungicide triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on parsley, leaves at 9.0 parts per million (ppm); dandelion, leaves at 7.0 (ppm); swiss chard at 7.0 (ppm); collards at 9.0 ppm; kale at 9.0 ppm;

kohlrabi at 9.0 ppm; mustard greens at 9.0 ppm; cabbage, chinese, napa at 9.0 ppm; broccoli at 1.0 ppm; and coriander, leaves (cilantro) at 9.0 ppm. These tolerances will expire and are revoked on June 30, 2008. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Triflumizole on Various Commodities and FFDCA Tolerances

Texas has declared a crisis exemption under FIFRA section 18 for the use of triflumizole on parsley; dandelion; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese, napa; broccoli; and coriander, leaves (cilantro) for control of powdery mildew. Texas states the effective control of powdery mildew over the 70 to 90–day growing season requires two additional applications of a systemic pesticide beyond those permitted on the currently registered alternative labels.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of triflumizole in or on parsley; dandelion; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese napa; broccoli; and coriander, leaves (cilantro). In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary time-limited tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these time-limited tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on June 30, 2008, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on parsley, leaves; dandelion, leaves; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese napa; broccoli; and coriander, leaves (cilantro) after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether triflumizole meets EPA's registration requirements for use on parsley; dandelion; swiss chard; collards; kale; kohlrabi; mustard greens; cabbage, chinese napa; broccoli; and coriander, leaves (cilantro) or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of triflumizole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Texas to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for triflumizole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of triflumizole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for time-limited tolerances for combined residues of triflumizole in or on parsley, leaves at 9.0 parts per million (ppm); dandelion, leaves at 7.0 (ppm); swiss chard at 7.0 (ppm); collards at 9.0 ppm; kale at 9.0 ppm; kohlrabi at 9.0 ppm; mustard greens at 9.0 ppm; cabbage, chinese, napa; at 9.0 ppm; broccoli at 1.0 ppm; and coriander, leaves at 9.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. 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 endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members

of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

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). The Food Quality Protection Act of 1996 (FQPA) added to FFDCA section 408(b)(2)(C) an additional safety factor to protect children's health. Where this additional FQPA safety factor is retained, 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 level of concern (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 x 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 triflumizole used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLUMIZOLE FOR USE IN HUMAN RISK ASSESSMENT[1]

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-50 years of age)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.1 mg/kg/day	Developmental Toxicity Study - Rat Developmental LOAEL = 35 mg/kg/day based on decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight, and increased incidences of cervical ribs
Acute Dietary (general U.S. population) (including infant and children)	NOAEL = 25 mg/kg/day UF = 100 Acute RfD = 0.25 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.03 mg/kg/day	Acute Neurotoxicity Study - Rat LOAEL = 100 mg/kg/day based on functional observational battery findings (neuromuscular impairment) and decreased locomotor activity
Chronic Dietary (all populations)	NOAEL= 1.5 mg/kg/day UF = 100 Chronic RfD = 0.015 mg/kg/day	FQPA SF = 1X cPAD = chronic/RfD FQPA SF = 0.015 mg/kg/day	Multi-generation Reproduction Study - Rat Reproductive LOAEL = 3.5 mg/kg/day based on increased gestation length in dams of the F_{3a} interval
Short-Term Oral (1-30 days) (Residential)	Oral NOAEL = 8.5 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation
Intermediate-Term Oral (1-6 months) (Residential)	Oral NOAEL = 8.5 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation and decreased body weight and body weight gain in parental animals
Short-Term Dermal (1-30 days) (Occupational/Residential)	Oral NOAEL= 8.5 mg/kg/day (dermal absorption rate = 3.5%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation
Intermediate- and Long-Term Dermal (1-6 months and 6 month or longer) (Occupational/Residential)	Oral NOAEL = 1.5 mg/kg/day (dermal absorption rate = 3.5%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 3.5 mg/kg/day based on increased gestation length in the dams of the F_{3a} interval

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLUMIZOLE FOR USE IN HUMAN RISK ASSESSMENT[1]—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Short-Term Inhalation (1-30 days) (Occupational/Residential)	Oral NOAEL= 8.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 21 mg/kg/day, based on decreased body weight gain in pups during lactation
Intermediate- and Long-Term Inhalation (1-6 months and 6 month or longer) (Occupational/Residential)	Oral NOAEL = 1.5 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Multi-generation Reproduction Study - Rat LOAEL = 3.5 mg/kg/day based on increased gestation length in the dams of the F_{3a} interval
Cancer (oral, dermal, inhalation)	Evidence for non-carcinogenicity for humans	Not applicable	Combined Chronic Toxicity/Carcinogenicity Study - Rat Carcinogenicity Study - Mouse No evidence of carcinogenicity in rats and mice

[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, MOE = margin of exposure, LOC = level of concern.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.476) for the combined residues of triflumizole, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from triflumizole 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 1994–1996 and 1998 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: Tolerance level residues and 100% crop treated for all registered and proposed uses.

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 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A refined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using anticipated residues (ARs) from average field trial residues for apple, grape, pear, cherry, cucurbit, strawberry, and milk commodities; registered and proposed tolerances for all other commodities; percent crop treated (CT) information for apple, grape and pear commodities; and 100% CT information for all other uses.

iii. *Cancer*. Triflumizole has been classified as not likely to be carcinogenic to humans. Therefore, a quantitative exposure assessment was not conducted to assess cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) 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. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

The Agency used PCT information for the registered uses on grape, apple, and pear. EPA based these assumptions on use data for the period 1996 to 1997 and 1998. For all other registered uses as well as these uses, EPA assumed that 100% of the U.S. crop would be treated with triflumizole.

The Agency believes that the three conditions previously discussed 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 triflumizole 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 triflumizole 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 triflumizole.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will generally use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 triflumizole they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of triflumizole for acute exposures are estimated to be 191 parts per billion (ppb) for surface water and 0.12 ppb for ground water. The EECs for chronic exposures are estimated to be 40 ppb for surface water and 0.12 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).

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

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

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

C. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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 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*. There is qualitative evidence of increased susceptibility demonstrated in the oral prenatal developmental toxicity studies in rats. Developmental toxicity resulted in fetal death as compared to maternal toxicity which included decreases in body weight gain and food consumption and increases in placental, spleen and liver weights at the same dosages. No quantitative or qualitative evidence of increased susceptibility was demonstrated in the prenatal developmental toxicity studies in rabbits or the multi-generation reproduction studies in rats. In the rabbit developmental studies, 24–hour fetal survival was decreased at the highest dose tested. This endpoint is not a recommended guideline parameter and is generally believed to have limited value in the assessment of development toxicity; rather, it is more an indicator of fetal endurance in the absence of critical maternal care, following removal from the uterus. The Hazard Identification Assessment Review Committee did not consider this effect to be a measurement of treatment-related effects on fetal viability and, thus, did not consider it to be relevant to the assessment of fetal susceptibility. There was no evidence of quantitative or qualitative susceptibility in the 2–generation reproduction study in rats. In that study, increased gestation length was observed at the study LOAEL. In rats, this alteration in normal reproductive function can result in equally adverse consequences (i.e., mortality) in both dams and offspring.

3. *Conclusion*. In the Agency's previous triflumizole human health risk assessment, the following toxicity studies were determined to be data gaps: A 28–day rat inhalation study Guideline Number (GLN) 870.3465)), acute rat neurotoxicity study (GLN 870.6200), and subchronic rat neurotoxicity study

(GLN 870.6200). The acute and sub-chronic neurotoxicity studies have been submitted, reviewed by the Agency and determined to be acceptable. As a result, the following has changed: (1) Selection of an acute endpoint for the general U.S. population (including infants and children); and (2) the removal of the 3x database uncertainty factor (UFDB). All other aspects of the most recent risk assessment remain unchanged.

As acceptable acute and sub-chronic neurotoxicity studies have been submitted, the Agency has determined that the 3x UFDB should be removed from the acute and chronic RfDs. In addition, the FQPA SFC recommended a special FQPA SF be reduced to 1x. The Agency has re-evaluated the quality of the exposure and hazard data; and, based on these data, concluded that the special FQPA SF remain at 1x. The conclusion is based on the following:

- The toxicity database is complete for FQPA assessment.
- There was no quantitative or qualitative evidence of increased susceptibility in the rabbit fetuses following *in utero* exposure or the rat following prenatal and postnatal exposure in the rat reproduction study.
- There was evidence of qualitative susceptibility in the developmental rat study; however, there are no residual uncertainties, and the use of the developmental NOAEL and the endpoint for the acute RfD for females 13 to 50 would be protective of the prenatal toxicity following an acute dietary exposure.
- There is no evidence of increased quantitative or qualitative susceptibility in the rat developmental neurotoxicity study.
- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The chronic dietary food exposure assessment utilizes ARs and % CT data verified for several existing uses. For all proposed use, tolerance-level residue and 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.
- There are no registered or proposed uses of triflumizole that would result in residential exposure.

D. 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 Populated adjusted dose (PAD)) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational 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: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to triflumizole 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 triflumizole on 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 triflumizole will occupy 6% of the aPAD for the U.S. population, 9% of the aPAD for females 13 to 49 years old, and 21% of the aPAD for children 1 to 2 years old, the population at greatest exposure. In addition, despite the potential for acute dietary exposure to triflumizole in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of triflumizole in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLUMIZOLE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population (total)	0.25	5	191	0.12	8,300
Females, (13–49 years)	0.1	9	191	0.12	2,700
All Infants (<1 year old)	0.25	11	191	0.12	2,200
Children (1–2 years old)	0.25	21	191	0.12	2,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triflumizole from food will utilize 5% of the cPAD for the U.S. population, 4% of the cPAD for all infants (<1 year old) and 13% of the cPAD for children 1 to 2 years old, the subpopulation at greatest exposure.

There are no residential uses for triflumizole that result in chronic residential exposure to triflumizole. In addition, despite the potential for chronic dietary exposure to triflumizole in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of triflumizole in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO TRIFLUMIZOLE

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.015	5	40	0.12	500
Children (1–2 years old)	0.015	13	40	0.12	130
Infants (<1 year old)	0.015	4	40	0.12	140

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure assessments take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For triflumizole, the Agency did not perform short-term or intermediate-term assessments because there are currently no registered or proposed uses for homeowner application and residential post-application exposures are expected to be negligible.

4. *Aggregate cancer risk for U.S. population*. Since triflumizole has been determined not to be carcinogenic, it is not expected to pose a cancer risk.

5. *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 triflumizole residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/mass spectrometry detector (GC/MSD) method (Morse Method METH-115, Revision #3)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for triflumizole residues in/on crop commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this risk assessment.

C. Conditions

The petitioner should submit adequate limited field rotational crop data on wheat at plant-back intervals longer than 120 days. Alternatively, the petitioner has the option of submitting a full set of residue field trials on all intended rotational crops other than leafy and root vegetables.

VI. Conclusion

Therefore, tolerances are established for combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on parsley, leaves at 9.0 ppm; dandelion, leaves at 7.0 ppm; swiss chard at 7.0 ppm; collards at 9.0 ppm; kale at 9.0 ppm; kohlrabi at 9.0 ppm; mustard greens at 9.0 ppm; cabbage, chinese, napa at 9.0 ppm; broccoli at 1.0 ppm; and coriander, leaves at 9.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides that 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–2005–0054 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 June 7, 2005.

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

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

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by the docket ID number OPP–2005–0054, to: Public Information and Records Integrity Branch, Information Resources and

Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Statutory and Executive Order Reviews

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 28, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—AMENDED

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

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

■ 2. Section 180.476 is amended by adding text to paragraph (b) to read as follows:

§ 180.476 Triflumizole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for the residues triflumizole (1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino)-2-

propoxyethyl)-1H-imidazole) and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/ revocation date
Broccoli	1.0	6/30/08
Cabbage, chinese, napa	9.0	6/30/08
Collards	9.0	6/30/08
Coriander, leaves	9.0	6/30/08
Dandelion, leaves	7.0	6/30/08
Kale	9.0	6/30/08
Kohlrabi	9.0	6/30/08
Mustard greens	9.0	6/30/08
Parsley, leaves	9.0	6/30/08
Swiss chard	7.0	6/30/08

* * * * *

[FR Doc. 05–7046 Filed 4–7–05; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH44

Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population for Two Fishes (Boulder Darter and Spotfin Chub) in Shoal Creek, Tennessee and Alabama

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), in cooperation with the States of Tennessee and Alabama and with Conservation Fisheries, Inc., a nonprofit organization, plan to reintroduce one federally listed endangered fish, the boulder darter (*Etheostoma wapiti*), and one federally listed threatened fish, the spotfin chub (*Cyprinella* (=*Hybopsis*) *monacha*), into their historical habitat in Shoal Creek (a tributary to the Tennessee River), Lauderdale County, Alabama, and Lawrence County, Tennessee. Based on the evaluation of species' experts, these species currently do not exist in this reach or its tributaries. These two fish are being reintroduced under section 10(j) of the Endangered Species Act of 1973, as amended (Act), and would be classified as a nonessential experimental population (NEP).

The geographic boundaries of the NEP would extend from the mouth of Long Branch, Lawrence County, Tennessee (Shoal Creek mile (CM) 41.7 (66.7 kilometers (km)), downstream to the backwaters of the Wilson Reservoir at Goose Shoals, Lauderdale County, Alabama (approximately CM 14 (22 km)), and would include the lower 5 CM (8 km) of all tributaries that enter this reach.

These reintroductions are recovery actions and are part of a series of reintroductions and other recovery actions that the Service, Federal and State agencies, and other partners are conducting throughout the species' historical ranges. This rule provides a plan for establishing the NEP and provides for limited allowable legal taking of the boulder darter and spotfin chub within the defined NEP area. In addition, we are changing the scientific name for spotfin chub, from *Cyprinella* (=*Hybopsis*) *monacha* to *Erimonax monachus*, to reflect a recent change in the scientific literature, and adding a map to the regulation for a previously created NEP including one of these fishes for the purposes of clarity.

DATES: The effective date of this rule is April 8, 2005.

ADDRESSES: Comments and materials received, as well as supporting documentation used in preparation of this final rule, are available for public inspection, by appointment, during normal business hours at the Tennessee Field Office, U.S. Fish and Wildlife Service, 446 Neal Street, Cookeville, TN 38501.

You may obtain copies of the final rule from the field office address above, by calling (931) 528–6481, or from our Web site at *http://cookeville.fws.gov.*

FOR FURTHER INFORMATION CONTACT: Timothy Merritt at the above address (telephone 931/528–6481, Ext. 211, facsimile 931/528–7075, or e-mail at *timothy_merritt@fws.gov*).

SUPPLEMENTARY INFORMATION:

Background

1. *Legislative:* Under section 10(j) of the Act, the Secretary of the Department of the Interior can designate reintroduced populations established outside the species' current range, but within its historical range, as ''experimental.'' Based on the best scientific and commercial data available, we must determine whether experimental populations are ''essential,'' or ''nonessential,'' to the continued existence of the species. Regulatory restrictions are considerably reduced under a Nonessential Experimental Population (NEP) designation.

Without the ''nonessential experimental population'' designation, the Act provides that species listed as endangered or threatened are afforded protection primarily through the prohibitions of section 9 and the requirements of section 7. Section 9 of the Act prohibits the take of an endangered species. ''Take'' is defined by the Act as harass, harm, pursue, hunt, shoot, wound, trap, capture, or collect, or attempt to engage in any such conduct. Service regulations (50 CFR 17.31) generally extend the prohibitions of take to threatened wildlife. Section 7 of the Act outlines the procedures for Federal interagency cooperation to conserve federally listed species and protect designated critical habitat. It mandates that all Federal agencies use their existing authorities to further the purposes of the Act by carrying out programs for the conservation of listed species. It also states that Federal agencies will, in consultation with the Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 of the Act does not affect activities undertaken on private land unless they are authorized, funded, or carried out by a Federal agency.

With the experimental population designation, a population designated is treated for purposes of section 9 of the Act as threatened regardless of the species' designation elsewhere in its range. Threatened designation allows us greater discretion in devising management programs and special regulations for such a population. Section 4(d) of the Act allows us to adopt whatever regulations are necessary to provide for the conservation of a threatened species. In these situations, the general regulations that extend most section 9 prohibitions to threatened species do not apply to that species, and the special 4(d) rule contains the prohibitions and exemptions necessary and appropriate to conserve that species. Regulations issued under section 4(d) for NEPs are usually more compatible with routine human activities in the reintroduction area.

For the purposes of section 7 of the Act, we treat an NEP as a threatened species when the NEP is located within a National Wildlife Refuge or National Park, and section 7(a)(1) and the