pursuant to 552a(j)(2) and (k)(2). This system of records is maintained by the DOJ Joint Automated Booking System (JABS) Program Office and entitled ''Nationwide Joint Automated Booking System, DOG–005.'' Information in this system of records relates to matters of law enforcement, and the exemptions are necessary to avoid interference with law enforcement responsibilities and to protect the privacy of third parties. The reasons for the exemptions are set forth in the text below.

EFFECTIVE DATE: This final rule is effective August 8, 2001.

FOR FURTHER INFORMATION CONTACT: Mary Cahill—(202) 307–1823.

SUPPLEMENTARY INFORMATION: On April 23, 2001 (66 FR 20410) a proposed rule was published in the **Federal Register** with an invitation to comment. No comments were received.

This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby stated that the order will not have ''a significant economic impact on a substantial number of small entities.''

List of Subjects in 28 CFR Part 16

Administrative Practices and Procedures, Courts, Freedom of Information Act, Government in the Sunshine Act, Privacy.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, Title 28 of the Code of Federal Regulations, Part 16 is amended as set forth below.

PART 16—[AMENDED]

1. The authority for Part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534, 31 U.S.C. 3717, 9701.

2. Add to subpart E, § 16.131 to read as follows:

§ 16.131 Exemption of Department of Justice (DOJ)/Nationwide Joint Automated Booking System (JABS), DOJ–005.

(a) The following system of records is exempt from 5 U.S.C. 552a(c)(3) and (4), (d), (e)(1), (2), (3), (4)(G) and (H), (e)(5) and (8), (f) and (g): Nationwide Joint Automated Booking System, Justice/DOJ–005. These exemptions apply only to the extent that information in the system is subject to exemption pursuant to 5 U.S.C. 552a(j)(2) and (k)(2). Where compliance would not interfere with or adversely affect the law enforcement process, the DOJ may waive the exemptions, either partially or totally.

(b) Exemption from the particular subsections are justified for the following reasons:

(1) From subsections (c)(3), (c)(4), and (d) to the extent that access to records in this system of records may impede or interfere with law enforcement efforts, result in the disclosure of information that would constitute an unwarranted invasion of the personal privacy of collateral record subjects or other third parties, and/or jeopardize the health and/or safety of third parties.

(2) From subsection (e)(1) to the extent that it is necessary to retain all information in order not to impede,compromise, or interfere with law enforcement efforts, e.g., where the significance of the information may not be readily determined and/or where such information may provide leads or assistance to Federal and other law enforcement agencies in discharging their law enforcement responsibilities.

(3) From subsection (e)(2) because, in some instances, the application of this provision would present a serious impediment to law enforcement since it may be necessary to obtain and verify information from a variety to sources other than the record subject to ensure safekeeping, security, and effective law enforcement. For example, it maybe necessary that medical and psychiatric personnel provide information regarding and the subject's behavior, physical. health, or mental stability, etc. to ensure proper care while in custody, or it may be necessary to obtain information from a case agent or the court to ensure proper disposition of the subject individual.

(4) From subsection (e)(3) because the requirement that agencies inform each individual whom it asks to supply information of such information as required by subsection (e)(3) may, in some cases, impede the information gathering process or otherwise interfere with or compromise law enforcement efforts, e.g., the subject may deliberately withhold information, or given erroneous information.

(5) From subsection (4)(G) and(H) because the application of these provisions would present a serious impediment to law enforcement efforts.

(6) From subsection (e)(5) because in the collection of information for law enforcement purposes it is impossible to determine in advance what information is accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance and the accuracy of such information can only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability to collect information for law enforcement purposes, may prevent the eventual development of the necessary criminal intelligence, or otherwise impede law enforcement or delay trained law enforcement personnel from timely exercising their judgment in managing the arrestee.

(7) From subsection (e)(8) to the extent that such notice may impede, interfere with, or otherwise compromise law enforcement and security efforts.

(8) From subsection 5 U.S.C. 552a(f) to the extent that compliance with the requirement for procedures providing individual access to records, compliance could impede, compromise, or interfere with law enforcement efforts.

(9) From subsection (g) to the extent that this system is exempt from the access and amendment provisions of subsection (d).

Dated: July 30, 2001.

Janis A. Sposato,

Acting Assistant Attorney General for Administration.

[FR Doc. 01–19896 Filed 8–7–01; 8:45 am]

BILLING CODE 4410–FB–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301155; FRL–6793–2]

RIN 2070–AB78

Ethalfluralin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of ethalfluralin in or on safflower seed. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on safflower. This regulation establishes a maximum permissible level for residues of ethalfluralin in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective August 8, 2001. Objections and requests for hearings, identified by docket control number OPP–301155, must be received by EPA on or before October 9, 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 VII of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301155 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and e-mail address: madden.barbara@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

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

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301155. 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, 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

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 a tolerance for residues of the herbicide ethalfluralin, [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4(trifluoromethyl)benzenamine], in or on safflower seed at 0.05 part per million (ppm). This tolerance will expire and is revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance 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 and the new safety standard 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) 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. . . .''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (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.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Ethalfluralin on Safflower and FFDCA Tolerances

The applicants state that there are no herbicides registered for use on safflower that effectively control kochia and ALS-resistant kochia. Kochia resistant to sulfonylurea herbicides, 2,4-D, and dicamba are found throughout the state. Research data and grower experience indicate that Treflan (trifluralin) only provides suppression of kochia and can result in three times more kochia density than Sonalan (ethalfluralin). Kochia (especially ALS resistant biotypes) has become a very serious weed problem that farmers have had difficulty controlling. The problem has become particularly noticeable since 1998. No specific economic data has been generated to study safflower yield impacts from kochia competition. However, research conducted in several other crops has documented that yield

reductions of 25 to 75 percent can result from kochia competition.

Safflower is an annual oil seed crop that is most productive when seeded early in the spring. Annual grasses and broadleaf weeds that compete with safflower germinate and emerge along with safflower seedlings. Although delayed seeding and or tillage can reduce weed abundance, it is not a compatible practice in safflower production. Safflower is not very competitive with weeds in the early vegetative stages. In-crop cultivation is not viable for weed control. Harrowing after planting with a light spike tooth or light coil spring may control some weeds, but damage to the emerging safflower can occur and some plants will be buried.

EPA has authorized under FIFRA section 18 the use of ethalfluralin on safflower for control of kochia and ALS-resistant kochia in North Dakota and Montana. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of ethalfluralin in or on safflower. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) 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 this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on safflower seed 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 this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether ethalfluralin meets EPA's registration requirements for use on safflower or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of ethalfluralin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than North Dakota and Montana to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for ethalfluralin, 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 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), 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 ethalfluralin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of ethalfluralin in or on safflower seed at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor 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 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 1×10^{-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 ethalfluralin used for human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for RiskAssessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age	NOAEL = 75 mg/kg/day UF = 100 Acute RfD = 0.75 mg/kg/day	FQPA SF = 3 aPAD = acute RfD ÷ FQPA SF = 0.25 mg/kg/day	Oral developmental toxicity study in rabbits LOAEL = 150 mg/kg/day based on an increased number of resorptions and increased sternal and cranial variations.
Acute dietary general population including infants and children	None	None	None
Chronic dietary all populations	NOAEL = 4.0 mg/kg/day UF = 100 Chronic RfD = 0.04 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.04 mg/kg/day	1–year oral toxicity study in dogs LOAEL = 20 mg/kg/day based on altered red cell morphology and urinary bilirubin.
Short-term dermal (1 to 7 days) Intermediate-term dermal (1 week to several months)	None	None	A dermal penetration study with Rhesus monkeys indicated that 2.8 % of a dermal dose was absorbed through the skin. Although the developmental and fetotoxic effects (refer to toxicological effects for acute dietary for females above) would normally be used for this assessment, the dermal absorption rate of 2.8% precludes the need. Dermal absorption is too low to cause concern.
Short-term inhalation (1 to 7 days) Intermediate-term inhalation (1 week to several months) Long-term inhalation (several months to lifetime) (Residential)	None	None	Ethalfluralin has a low inhalation toxicity category (III). The maximum attainable concentration (gravimetric) was tested in an acute inhalation toxicity study, and no deaths occurred to exposed rats. Clinical signs included hypoactivity, dyspnea, ataxia, chromodacryorrhea, poor grooming, and yellow urine; these were reversible after 4 days (LC_{50} >0.94 mg/L). This maximum attainable concentration is considered to be non-lethal. An inhalation risk assessment is not required
Cancer (oral, dermal, inhalation)	Ethalfluralin has been classified as a possible human carcinogen (Group C). Q_1* = 8.9 x 10^{-2} $(mg/kg/day)^{-1}$	10^{-6}	2–year chronic carcinogenicity study in rats, showing an increased incidence of mammary gland fibroadenomas and combined adenomas/fibroadenomas in female rats.

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

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.416) for the residues of ethalfluralin, in or on a variety of raw agricultural commodities. Permanent tolerances for residues of ethalfluralin are established for dry beans and peas, cucurbits, peanuts, soybeans, sunflower seeds, and goats (fat, meat, and meat byproducts). These tolerances are all 0.05 ppm. A 0.05 ppm time-limited tolerance associated with a section 18 request is also established for canola. Risk assessments were conducted by EPA to assess dietary exposures from ethalfluralin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has

indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The dietary exposure evaluation model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA (1989–1992) nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance-level residues were used for cucurbit vegetables, canola oil, safflower oil, and goat commodities. All other plant commodities for which there are ethalfluralin tolerances are considered to be blended. For these commodities anticipated residues (ARs) were used. The ARs used for this analysis are the same as those used for the March 1995 reregistration eligibility decision (RED) document prepared for ethalfluralin. No percent crop treated (PCT) adjustment was made therefore, 100% crop treated was assumed. Further refinements (such as percent crop-treated adjustments and/or Monte Carlo analysis) would yield even lower estimates of acute dietary exposure.

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: Tolerance-level residues were used for cucurbit vegetables, canola oil, safflower oil, and goat commodities. All other plant commodities for which there are ethalfluralin tolerances are considered to be blended. For these commodities ARs were used. The ARs used for this analysis are the same as those used for the March 1995, RED document. In addition, weighted average PCT data were used for dry beans and peas, melons, cantaloupe, cucumbers, watermelons and soybeans.

iii. *Cancer*. In conducting this cancer dietary risk assessment the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA (1989–1992) nationwide CSFII. The following assumptions were made for the cancer exposure assessments: Tolerance-level residues were used for cucurbit vegetables, canola oil, safflower oil, and goat commodities. All other plant commodities for which there are ethalfluralin tolerances are considered to be blended. For these commodities ARs were used. The ARs used for this analysis are the same as those used for the March 1995, RED document. In addition, weighted average PCT data were used for dry beans and peas, melons, cantaloupe, cucumbers, watermelons and soybeans.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the ARs levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to ARs to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 34% of dry beans and peas treated; 4% melons and cantaloupes treated; 16% cucumbers treated; 15% watermelons treated and 1% soybeans treated.

The Agency believes that the three conditions listed 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 under estimate 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 under estimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an under estimation. 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 ethalfluralin 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 ethalfluralin 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 ethalfluralin.

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 ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The

GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a 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 ethalfluralin they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of ethalfluralin for acute exposures are estimated to be 2.3 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.052 ppb for surface water and 0.02 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). Ethalfluralin 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 ethalfluralin 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, ethalfluralin 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 ethalfluralin 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).

C. Safety Factor for Infants and Children

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

2. *Developmental toxicity studies*. In the developmental toxicity study in rats, the maternal (systemic) NOAEL was 50 milligrams/kilograms/day (mg/kg/day), based on decreased body weight gain and dark urine at the LOAEL of 250 mg/kg/day. The developmental (fetal) NOAEL was 1,000 mg/kg/day the highest dose tested (HDT).

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 75 mg/kg/day, based on abortions and decreased food consumption at the LOAEL of 150 mg/kg/day. The developmental (fetal) NOAEL was also 75 mg/kg/day, based on a slightly increased number of resorptions, abnormal cranial development, and increased sternal variants at the LOAEL of 150 mg/kg/day.

3. *Reproductive toxicity study*. In a 3–generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 12.5 mg/kg/day, based on decreased mean body weight gains in males in all generations at the LOAEL of 37.5 mg/kg/day. The reproductive (pup) NOAEL was 37.5 mg/kg/day the HDT.

In a 7–month multi-generation bridging study in rats, the parental NOAEL of 20 mg/kg/day was based on increased liver weights at the LOAEL of 61 mg/kg/day. The reproductive (pup) NOAEL was ≥ 61 mg/kg/day the HDT.

4. *Prenatal and postnatal sensitivity*. There is qualitative evidence of increased susceptibility following *in utero* exposure to ethalfluralin in the developmental toxicity study in rabbits demonstrated by abortions and a slightly increased number of resorptions, abnormal cranial development, and increased sternal variants in the pups. There was no indication of increased susceptibility following *in utero* exposure to ethalfluralin in the prenatal developmental toxicity study in rats.

5. *Conclusion*. There is a complete toxicity data base for ethalfluralin and exposure data are complete or estimated based on data that reasonably accounts for potential exposures. Based on the oral developmental toxicity study in rabbits, an *ad hoc* FQPA Safety Factor Committee determined that the appropriate safety factor for assessing acute dietary risk is 3X and for assessing chronic dietary risk is 1X.

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 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 US EPA Office of Water

to calculate DWLOCs: 2Liters/70 kilograms (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 ethalfluralin 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 ethalfluralin in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An acute dietary endpoint was only identified for females. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to ethalfluralin will occupy less than 1% of the aPAD for females 13 years and older. In addition, despite the potential for acute dietary exposure to ethalfluralin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of ethalfluralin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–50 years old)	0.25	<1	2.3	0.02	7,500

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to ethalfluralin from food will utilize less than 1% of the cPAD for the U.S. population and all other population subgroups included in DEEM. There are no residential uses for ethalfluralin that result in chronic residential exposure to ethalfluralin. In addition, despite the potential for chronic dietary exposure to ethalfluralin in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of ethalfluralin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.40	<1	0.052	0.02	1,400
Children	0.40	<1	0.052	0.02	400
Infants	0.40	<1	0.052	0.02	400

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). Ethalfluralin 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 were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethalfluralin 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 were previously addressed.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for cancer exposure, EPA has concluded that exposure to ethalfluralin from food will result in an estimated lifetime cancer risk to the U.S. population of 5.8×10^{-7}. Currently there are no uses registered for ethalfluralin that will result in residential exposures. In addition, despite the potential for chronic (cancer) dietary exposure to ethalfluralin in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of ethalfluralin in surface and ground water, EPA does not expect the aggregate exposure to be greater than 1×10^{-6}, as shown in the following Table 4:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (CANCER) EXPOSURE TO ETHALFLURALIN

Population Subgroup	Q_1*	Cancer Risk Estimate (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	8.9×10^{-2} $(mg/kg/day)^{-1}$	5.8×10^{-7}	0.052	0.02	0.18

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 ethalfluralin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GLC-ECD) is available in PAM II to enforce the tolerance expression. The limit of detection in plant commodities is 0.01 ppm.

B. International Residue Limits

There are no Codex maximum residue limits (MRLs) established for ethalfluralin. Mexico has established MRLs of 0.05 ppm in/on squash, cucumber, and melon. Canada has labels for uses on oil seed and pulse crops, wheat, field crop vegetables, barley, rapeseed, flax, canola, and mustard. There are no published tolerances so presumably the Canadian default tolerance of 0.10 ppm applies to these crops.

C. Conditions

Do not exceed 1.15 lbs. active ingredient (ethalfluralin) per acre per crop year.

VI. Conclusion

Therefore, the tolerance is established for residues of ethalfluralin, *N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4(trifluoromethyl)benzenamine, in or on safflower seed at 0.05 ppm.

VII. 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–301155 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 9, 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 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 Unit I.B.2. Mail your copies, identified by the docket control number OPP–301155, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Regulatory Assessment Requirements

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

IX. 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 25, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.416 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.416 Ethalfluralin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Safflower, seed	0.05	6/30/03

* * * * *

[FR Doc. 01–19755 Filed 8–7–01; 8:45 a.m.]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 010413094–1094–01; I.D. 080201C]

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Deep-Sea Red Crab Fishery; Closure

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

ACTION: Closure.

SUMMARY: NMFS announces that, effective 0001 hrs, local time, August 17, 2001, through 2400 hr, local time, November 14, 2001, vessels may not fish for, or possess, red crab harvested from the exclusive economic zone (EEZ) in excess of 100 lb (45.4 kg) per trip. This action is based on a determination that the red crab total allowable catch (TAC) is projected to be reached as of August