this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b) (2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Environmental

The Coast Guard has considered the environmental impact of this rule and concluded that under figure 2–1, paragraph 34(g), of Commandant Instruction M14475.1D that this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationships between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or use. We have determined that it is not a ''significant energy action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165, as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T07–135 is added to read as follows:

§ 165.T07–135 Security Zone; HOVENSA Refinery, St. Croix, U.S. Virgin Islands.

(a) *Regulated area.* All waters 3 miles seaward of the HOVENSA facility waterfront outlined by the following coordinates: 64°45′09″ West, 17°41′32″ North, 64°43′36″ West, 17°38′30″ North, 64°43′36″ West, 17°38′30″ North and 64°43′06″ West, 17°38′42″ North.

(b) *Regulations.* In accordance with the general regulations in § 165.33 of this part, no vessel may enter the regulated area unless specifically authorized by the Captain of the Port San Juan or a Coast Guard commissioned, warrant, or petty officer designated by him or unless authorized by the HOVENSA Port Captain who can be reached on VHF Marine Band Radio Channel 11(156.6 Mhz). The Captain of the Port will notify the public of any changes in the status of this zone by Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 16 (156.8 Mhz).

(c) *Effective dates.* This section is effective from 6 p.m. on December 19, 2001 until 11:59 p.m. on June 15, 2002.

Dated: December 19, 2001.

J.A. Servidio,

Commander, U.S. Coast Guard, Captain of the Port.

[FR Doc. 02–1253 Filed 1–16–02; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301208; FRL–6818–6]

RIN 2070–AB78

Ethalfluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethalfluralin in or on canola seed and safflower seed. IR-4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective January 17, 2002. Objections and requests for hearings, identified by docket control number OPP–301208, must be received by EPA on or before March 18, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301208 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9368; and e-mail address: Jamerson.Hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301208. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 14, 2001 (66 FR 57082) (FRL–6808–9), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of pesticide petitions (PP 9E5037, 1E6326, and 1E6345) for tolerances by Interregional Research Project Number 4 (IR–4), 681 U.S. Highway Number 1, South, North Brunswick, New Jersey 08902–3390. This notice included a summary of the petitions prepared by Dow AgroSciences, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.416 be amended by establishing tolerances for residues of the herbicide ethalfluralin, [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, in or on canola seed and safflower seed at 0.05 part per million (ppm).

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of ethalfluralin on canola seed and safflower seed at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by ethalfluralin are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	NOAEL = 68 mg/kg/day LOAEL = 136 mg/kg/day based on low bilirubin and low kidney weights in males.

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

Guideline No.	Study Type	Results
870.3150	90–Day oral toxicity in nonrodents	NOAEL = 27.5 mg/kg/day LOAEL = 80 mg/kg/day based on elevated alkaline phosphatase, slight fatty metamorphosis of the liver, increase cholesterol, and increased blood urea nitrogen (BUN).
870.3200	21–Day dermal toxicity in rabbits	NOAEL = 1,000 mg/kg/day - highest dose tested (HDT) LOAEL =>1,000 mg/kg/day no systemic effects were seen at the HDT.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on decreased body weight gain and dark urine. Developmental NOAEL = 1,000 mg/kg/day no systemic effects were seen at the HDT. LOAEL = >1,000 mg/kg/day no systemic effects were seen at the HDT.
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 75 mg/kg/day LOAEL = 150 mg/kg/day based on abortions and decreased food consumption. Developmental NOAEL = 75 mg/kg/dayLOAEL = 150 mg/kg/day based on slightly increased resorptions, abnormal cranial development, and increase sternal variants.
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = 12.5 mg/kg/day LOAEL = 37.5 mg/kg/day based on decreased mean body weight gains in males in all generations. Reproductive NOAEL = 37.5 mg/kg/day HDT LOAEL = >37.5 mg/kg/day no systemic effects were seen at the HDT.
870.4100	Chronic toxicity dogs	NOAEL = 4 mg/kg/day LOAEL = 20 mg/kg/day based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow.
870.4300	Combined chronic toxicity/carcinogenicity in rats	NOAEL = 32.3 mg/kg/day HDT LOAEL = > 32.3 mg/kg/day no systemic effects were seen at the HDT. Mammary gland fibroadenomas were found in dosed female rats at statistically significant incidences in mid and high doses.
870.4300	Combined chronic toxicity/carcinogenicity in mice	NOAEL = 10.3 mg/kg/day LOAEL = 41.9 mg/kg/day based on focal hepatocellular hyperplasia in both sexes and increased liver, kidney, and heart weights in females. No increase in of neoplasms was attributed to the treatment.
870.5100	Bacterial reverse mutation test	Ethalfluralin was weakly mutagenic in activated strains TA1535 and TA100 of *Salmonella typhimurium*, but not in strains TA1537, TA1538, and TA98 in an Ames assay. In a modified Ames assay with *Salmonella typhimurium* and *Escherichia coli*, ethalfluralin was weakly mutagenic in strains TA1535 and TA100, with and without activation, and in strain TA 98 without activation, at the highest dose.
870.5300	*In vitro* mammalian cell mutation test	No mutagenicity was found in the mouse lymphoma assay for forward mutation.
870.5550	Unscheduled DNA synthesis in mammalian cells in culture	Ethalfluralin did not induce unscheduled DNA synthesis in rat hepatocytes.
870.5375	*In vitro* mammalian chromosome aberration test	In Chinese hamster ovary cells, ethalfluralin was negative without S9 activation, but it was clastogenic with activation.

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	Rats were treated orally with a single low dose, a single high dose, or repeated low doses of radiolabeled ethalfluralin. Absorption of ethalfluralin was estimated at 79–87% of the dose for all dose levels. Ethalfluralin was rapidly and extensively metabolized, and 95% of the chemical was excreted in urine and feces by seven days. The major route of elimination for the radiolabel was in the feces, 50.9–63.2%, and the levels remaining in the tissues after 72 hours were negligible.
870.7600	Dermal penetration	A Dermal penetration study with rhesus monkeys indicated that 2.8% of a dermal dose was absorbed through the skin.

B. Toxicological Endpoints

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

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

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

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

TABLE 2.—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 Risk Assessment	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 = 10 aPAD = acute RfD FQPA SF = 0.075 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 = 10 cPAD = chronic RfD FQPA SF = 0.004 mg/kg/day	1–year oral toxicity study in dogs LOAEL = 20 mg/kg/day based on altered red cell morphology and urinary bilirubin.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
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 needed.
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)$^{-1}$	Negligible risk	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. The safety factor of 10X was retained until ethalfluralin is assessed by the Agency's FQPA Safety Factor Committee. Therefore, the 10X is subject to change when ethalfluralin is assessed in an upcoming Tolerance Reassessment Eligibility Decision (TRED).

C. 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. Tolerances for residues of ethalfluralin are established for dry beans and peas, the Cucurbits vegetable subgroup, peanuts, soybeans, sunflower seeds, and fat, meat, and meat by-products of goats. The tolerance level for all these commodities is 0.05 ppm. Time limited tolerances associated with section 18 requests have also been established for canola and safflower. 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 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: 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 were used. The ARs used for this analysis are the same as those used for the 1995 reregistration eligibility decision (RED, 3/95) document prepared for ethalfluralin. No percent crop-treated 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 anticipated residues were used. The ARs used for this analysis are the same as those used for the 1995 reregistration eligibility decision (RED, 3/95) document. In addition, weighted average percent crop treated 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 anticipated residues were used. The ARs used for this analysis are the same as those used for the 1995 reregistration eligibility decision (RED, 3/95) document. In addition, weighted average percent crop treated data were used for dry beans and peas, melons, cantaloupe, cucumbers, watermelons and soybeans.

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

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop-treated (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 dry peas treated; 4% melons and cantaloups treated; 16% cucumbers treated; 15% watermelons treated and 1% soybeans treated.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. 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 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 Screening Concentrations in Ground Water (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 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 0.05 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).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (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 milligram/kilogram/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 are estimated based on data that reasonably accounts for potential exposures.

To date, ethalfluralin has not been assessed by the Agency's FQPA Safety Factor Committee. The Agency is in the preliminary stages of evaluating ethalfluralin for an upcoming Tolerance Reassessment Eligibility Decision (TRED) (Reports on FQPA Tolerance Reassessment Progress and Interim Risk Management Decisions). During this reassessment, the Agency's FQPA Safety Factor Committee will evaluate this chemical.

EPA's preliminary review of the studies bearing on risks to infants and children indicates that an additional safety factor of greater than 10X will not be needed to protect the safety of infants and children. Previously, when time-limited tolerances were established for residues of ethalfluralin in or on canola seed and safflower seed to support specific emergency exemptions the Agency concluded that an additional FQPA safety factor of 3X for assessing acute dietary risk and an additional FQPA safety factor of 1X for assessing chronic dietary risk would be adequate for protecting the safety of infants and children. This was based on a determination made by ad hoc FQPA Safety Factor Committee which based its decision on the results of the oral developmental toxicity study in rabbits.

Accordingly, for the purpose of acting on the petition for tolerances for residues of ethalfluralin in or on canola seed and safflower seed prior to completion of the ethalfluralin TRED, the FQPA safety factor of 10X was retained.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + 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: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, 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 on 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 3:

TABLE 3.—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)	0.075	<1	2.3	0.02	2,200

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 estimated environmental concentrations 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 4:

TABLE 4.—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	0.004	<1	0.05	0.02	140
Females 13–50	0.004	<1	0.05	0.02	120
Children	0.004	<1	0.05	0.02	40
Infants	0.004	<1	3.05	0.02	40

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 estimated environmental concentrations of ethalfluralin in surface and ground water, EPA does not expect the aggregate exposure to pose greater than a negligible risk (the range of 10^{-6}), as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (CANCER) EXPOSURE TO ETHALFLURALIN

Population Subgroup	Q1*	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}	0.05	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.

IV. 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 oilseed and pulse crops, wheat, field crop vegetables, barley, rapeseed, flax, canola, and mustard however, there are no published tolerances.

V. Conclusion

Therefore, tolerances are established for residues of ethalfluralin,[*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine], in or on canola seed and safflower seed at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301208 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 March 18, 2002.

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

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

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

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

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

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301208, 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public

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

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: January 3, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.416 is amended as follows:

i. By alphabetically adding entries for the commodities ''canola, seed'' and ''safflower, seed'' to the table in paragraph (a) as set forth below.

ii. The text of paragraph (b) is removed and reserved.

§ 180.416 Ethalfluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Canola, seed	0.05
* * * * *	
Safflower, seed	0.05
* * * * *	

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

* * * * *

[FR Doc. 02–701 Filed 1–16–02; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 82

RIN 0920–ZA00

Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Act of 2000

AGENCY: Department of Health and Human Services.

ACTION: Interim Final Rule; Reopening of Comment Period.

SUMMARY: The Department of Health and Human Services(DHHS), is reopening the comment period for the interim final rule for dose reconstruction for certain claims for cancer under the Energy Employees Occupational Illness Program Act (EEOICPA) that was published in the **Federal Register** of Friday, October 5, 2001. After considering these comments, comments previously received, and comments from the Advisory Board on Radiation and Worker Health (ABRWH) DHHS will publish a final rule.

DATES: Any public written comments not submitted at the meeting of the ABRWH must be received on or before Wednesday, January 23, 2002.

ABRWH must submit any comments and recommendations on the interim final rule to DHHS by Wednesday, February 6, 2002.

ADDRESSES: Submit written comments to: Attention—DoseReconstruction Comments, Department of Health and HumanServices, National Institute for Occupational Safety andHealth (NIOSH), Robert A. Taft Laboratories, MS–C34, 4676Columbia Parkway, Cincinnati, OH 45226, Telephone: (513) 533–8450, Fax: (513) 533–8285, e-mail: *NIOCINDOCKET@CDC.GOV.*

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director,Office of Compensation Analysis and Support, NationalInstitute for Occupational Safety and Health, 4676 ColumbiaParkway, Cincinnati, Ohio 45226, Telephone 513–841–4498(this is not a toll free number). Information requests may also be submitted by e-mail to *OCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION: On October 5, 2001, HHS published an interim final rule establishing methods for radiation dose reconstruction to be conducted for certain cancer claims filed under EEOICPA, Public Law 106–398 [See FR Vol. 66, No. 194, 50978]. The notice included a public comment period that ended on November 5, 2001. However, DHHS is requesting the ABRWH to conduct a review of its dose reconstruction methods. ABRWH will be conducting its review during a meeting of the ABRWH scheduled for Tuesday, January 22, 2002 and Wednesday, January 23, 2002.

To permit HHS to consider the ABRWH review and any comments and recommendations of ABRWH in the rulemaking, DHHS will reopen the public comment period. This will also provide the public with the opportunity to participate in this review. The public comment period will be reopened to include the ABRWH meeting transcript and any statements submitted for the record of that meeting in the docket for this rule. DHHS will also accept additional public written comments submitted to its docket office on or beforeWednesday, January 23, 2002. The record for this rulemaking will close on Wednesday, February 6, 2002, by which time ABRWH must submit any comments and recommendations on the interim final rule to DHHS.

Dated: January 14, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–1318 Filed 1–16–02; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 126

[USCG–2001–10164]

RIN 2115–AG17

Alternate Compliance Program; Incorporation of Offshore Supply Vessels

AGENCY: Coast Guard, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On October 23, 2001, we published a direct final rule (66 FR 53542). The direct final rule notified the public of our intent to incorporate Offshore Supply Vessels (OSVs) into the Alternate Compliance Program (ACP). This action will improve the flexibility of regulations governing OSVs by providing an alternative method for vessel design, inspection, and certification without compromising existing safety standards. We have not received an adverse comment, or notice of intent to submit an adverse comment, on this rule. Therefore, this rule will go into effect as scheduled.

DATES: The effective date of the direct final rule is confirmed as January 22, 2002.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Lieutenant Benjamin Nicholson, United States Coast Guard Office of Design and Engineering Standards (G-MSE), at 202–267–0143, or e-mail him at *BNicholson@comdt.uscg.mil.*

Dated: January 10, 2002.

Joseph J. Angelo,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 02–1251 Filed 1–16–02; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 961030300–1007–05; I.D. 120996A]

RIN 0648–AJ30

Magnuson-Stevens Act Provisions; Essential Fish Habitat (EFH)

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to revise the regulations implementing the essential fish habitat (EFH) provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This rule establishes guidelines to assist the Regional Fishery Management Councils (Councils) and the Secretary of Commerce (Secretary) in the description and identification of EFH in fishery management plans (FMPs), the identification of adverse effects to EFH, and the identification of actions required to conserve and enhance EFH. The regulations also detail procedures the Secretary (acting through NMFS), other Federal agencies, and the Councils will use to coordinate, consult, or provide recommendations on Federal and state actions that may adversely affect EFH. The intended effect of the rule is to promote the protection, conservation, and enhancement of EFH.