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 considered the environmental impact of this rule and concluded under Figure 2–1, paragraph 34(g) of Commandant Instruction M16475.1D, 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), Reports 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—[AMENDED]

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.T07–139 is added to read as follows:

§ 165.T07–139 Security Zone; Tampa Bay, Florida.

(a) *Regulated area.* The Coast Guard is establishing temporary fixed security zones in all waters extending 100 feet around all bridge supports and rocky outcroppings at the base of the supports for the Sunshine Skyway Bridge in Tampa Bay, located at approximate position 27° 37′12″ N Latitude, 82°39′20″ W Longitude.

(b) *Regulations.* In accordance with the general regulations in § 165.33 of this part, entry into these zones is prohibited except as authorized by the Captain of the Port, or his designated representative. The Captain of the Port will notify the public via Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 13 and 16 (157.1 MHz).

(c) *Dates.* This section becomes effective at 6 p.m. (EST) on December 7, 2001 and will remain in effect until 6 p.m. (EDT) on June 15, 2002.

(d) *Authority.* The authority for this section is 33 U.S.C. 1226; 49 CFR 1.46.

Dated: December 4, 2001.

A. L. Thompson, Jr.,

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

[FR Doc. 01–31524 Filed 12–20–01; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301184; FRL–6806–7]

RIN 2070–AB78

Fluthiacet-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluthiacet-methyl in or on field corn grain, field corn forage, field corn stover, pop corn grain, pop corn stover, sweet corn, kernels plus cob husk removed (K+CWHR), sweet corn forage, and sweet corn stover. K-I Chemical, U.S.A. Inc., 11 Martine Avenue, 9th Floor, White Plains, New York 10606 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 December 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301184, must be received by EPA on or before February 19, 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–301184 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@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/. 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–301184. 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 April 14, 1997 (62 FR 18116) (FRL–5599–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the of FQPA 1996 (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by K-I Chemical U.S.A., Inc., 11 Martine Avenue, 9th Floor, White Plains, NY 10606. This notice included a summary of the petition prepared by K-I Chemical U.S.A. Inc., the registrant. There were no comments received in response to the notice of filing. In the **Federal Register** of October 6, 1998 (63 FR 53656) (FRL–6033–8), EPA issued a notice pursuant to the same Acts, announcing an amendment to the petition. There were no comments received in response to the notice of filing. Addition tolerances for residues of fluthiacet-methyl per se in or on cottonseed and cotton gin by products were requested; however, a revised Section F to the petition was submitted in which these tolerances were not requested.

The petition requested that 40 CFR 180.551 be amended by establishing a tolerance for residues of the herbicide, fluthiacet-methyl, acetic acid, [2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1H,3H-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester), in or on corn, field, grain at 0.010 part per million (ppm); corn, field, forage at 0.050 ppm; corn, field, stover at 0.050 ppm; corn, pop, grain at 0.010 ppm; corn, pop, stover at 0.050 ppm; corn, sweet, forage at 0.050 ppm; corn, sweet, K + CWHR at 0.010 ppm; and corn, sweet, stover at 0.050 ppm.

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

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

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 fluthacet-methyl on corn, field, grain at 0.010 ppm; corn, field, forage at 0.050 ppm; corn, field, stover at 0.050 ppm; corn, pop, grain at 0.010 ppm; corn, pop, stover at 0.050 ppm; corn, sweet, forage at 0.050 ppm; corn, sweet, K + CWHR at 0.010 ppm; and corn, sweet, stover at 0.050 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fluthiacet-methyl 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, rats and mice	Rats: NOAEL = 6.19 milligrams/kilograms day (mg/kg/day) in males 6.80 mg/kg/day in females LOAEL = 216 mg/kg/day in males 249 mg/kg/day in females Mice: NOAEL = 1.3 mg/kg/day in males 1.6 mg/kg/day in females LOAEL = 66 mg/kg/day in males 83 mg/kg/day in females Based on decreased body weight gains as well as effects on hematology, clinical chemistry, urinalysis parameters, liver weights and microscopic pathology in rats; and on effects on the erythropoietic system and liver in mice.
870.3150	6–week oral toxicity in dogs	NOAEL = 236 mg/kg/day in males 77.7 mg/kg/day in females LOAEL = 709 mg/kg/day in males 232 mg/kg/day in females based on decreased body weight gain.
870.3200	28–day dermal toxicity in rats	NOAEL = 1,000 mg/kg/day, the highest dose tested (HDT).
870.3700	Prenatal developmental in rats and rabbits	Maternal in rats: NOAEL = 1,000 mg/kg/day, HDT Maternal in rabbits: NOAEL = 1,000 mg/kg/day, HDT Developmental in rabbits: NOAEL = 300 mg/kg/day Developmental in rabbits: LOAEL of 1,000 mg/kg/day based on slight non-significant increased incidence of irregularly shaped sternebrae attributed to a delay in fetal development. (See section D., 2.)
870.3800	2-generation Reproduction and fertility effects	Parental/systemic NOAEL = 1.59 mg/kg/day in males LOAEL = 31.8 mg/kg/day in males NOAEL = 1.73 mg/kg/day in females LOAEL = 35.2 mg/kg/day in females based on reduction in male body weights/gains and hepatic pathology Reproductive in males: NOAEL = 31.8 mg/kg/day LOAEL =313 mg/kg/day Reproductive in females: NOAEL = 37.1 mg/kg/day LOAEL = 388 mg/kg/day based on decreases in mean litter body weights.
870.4100	Chronic toxicity dogs	NOAEL in males = 57.6 mg/kg/day LOAEL in males = 582 mg/kg/day NOAEL in females = 30.3 mg/kg/day LOAEL in females = 145 mg/kg/day The LOAELs were based on effects observed in the erythropoietic system and liver.
870.4200	Carcinogenicity rats	NOAEL in males = 2.1 mg/kg/day LOAEL in males = 130 mg/kg/day NOAEL in females = 2.5 mg/kg/day LOAEL in females = 154 mg/kg/dayIn males there were decreased body weight, liver toxicity, pancreatic toxicity and microcytic anemia. In females there were liver toxicity, uterine toxicity and slight microcytic anemia. In males only at 130 and 219 mg/kg/day there was respectively, an increase in the trend toward pancreatic exocrine adenomas and pancreatic islet cell adenomas.

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

Guideline No.	Study Type	Results
870.4300	Carcinogenicity mice	NOAEL in males and females = 0.1 mg/kg/day LOAEL in males and females = 0.1 and 1.2 mg/kg/day, respectively, based on non-neoplastic liver findings. In males, and possibly females, at 10 mg/kg/day for males and 12 mg/kg/day for females; and at 32 gm/kg/day for males and 37 mg/kg/day for females, there was an increase in the number of mice with hepatocellular adenomas, carcinomos and or adenomas/carcinomas.
870.1000	Gene mutation	Flutiacet-methyl was negative for mutagenic/genotoxic effects in bacterial or cultured mammalian cells and did not cause DNA damage in bacterial or primary rat hepatocytes.
870.5375	Cytogenetics	*In vitro* cytogenetic assays performed with two different mammalian cell lines demonstrated that fluthiacet-methyl is clastogenic both in the presence and absence of S9 activation.
870	Other effects	Flutiacet-methyl was negative for micronuclei induction in mouse bone marrow, a significant increase in micronuclei was seen in stimulated rat liver cells following *in vivo* exposure.
870.6200	Acute neurotoxicity screening battery in rats	NOAEL = 2,000 mg/kg/day, with no effects at HDT
870.6200	Subchronic neurotoxicity screening battery in rats	NOAEL in males = 0.576 mg/kg/day (systemic) LOAEL in males = 556 mg/kg/day based on decreased body weight and food consumption NOAEL in females = 1,345 mg/kg/day (HDT) (systemic) NOAEL in males = 1,128 mg/kg/day (neurotoxicity) NOAEL in females = 1,345 mg/kg/day (neurotoxicity)
870.7485	Metabolism and pharmaco-kinetics in rats	Fluthiacet-methyl was absorbed rapidly at both low and high dosages in both male and female rats. Repeated oral dosing had no effect on extent of absorption. Tissue levels of radio active fluthiacet-methyl in single and repeated low dose groups did not exceed 0.018 ppm in any tissue. At the single high dose, female rats showed higher levels of radioactivity in tissues than males except for muscle, brain, fat and plasma. Excretion in males was predominantly in feces for all dose groups, with between 67 to 87% of administered radioactivity excreted by this route. In females, the percentage of administered radioactivity in urine across all dose groups 40 to 48% was approximately equivalent to the percent excreted in feces, 39 to 52%. The greater fecal excretion in males was based on a greater percentage excretion in bile for males, 37% vs. females 19%.
870.7600	Dermal penetration	No dermal penetration studies were submitted.
	Special studies	There were no required special studies

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL 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 fluthiacet-methyl used for human risk assessment is shown in the following Table 2:

TABLE 2. —SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUTHIACET-METHYL FOR USE IN HUMAN RISK ASSESSMENT.

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary	None	No appropriate endpoint attributable to a single dose (exposure) was identified in oral toxicity studies. Therefore, an acute reference dose (RfD) was not established. Thus, an acute exposure/risk assessment was not conducted.	None
		NOT REQUIRED	
Chronic Dietary General population	NOAEL = 0.1 mg/kg/day	Non-neoplastic liver findings (increase in absolute and relative liver weights, fatty changes, chronic inflammation, karyomegaly, single cell necrosis and ceroid/lipofuscin pigmentation).	18-month carcinogenicity in the mouse
	UF = 100 FQPA SF = 1	Chronic RfD = 0.001 mg/kg/day Chronic PAD = 0.001 mg/kg/day	
Short-term and intermediate-term (dermal)	None	No dermal or systemic toxicity was seen at the limit-dose following repeated dermal applications to rats.	28–day dermal in the rat
Long-term (dermal) see footnote 1 below table	NOAEL = 0.1 mg/kg/day	Non-neoplastic liver findings (increase in absolute and relative liver weights, fatty changes, chronic inflammation, karyomegaly, single cell necrosis and ceroid/lipofuscin pigmentation).	18–month carcinogenicity in the mouse
Inhalation (Any time period)	None	The LC^{50} for males and females was >5,048 ± 225 mg/m^3 (>5.0 mg/L). Based on the low acute toxicity (Toxicity Category 4), the composition of the end-use product (5.36%) and the application rate (0.0089 lb ai/acre/season or 4.0 g ai/acre/season), an inhalation exposure/risk assessment was not conducted.	None

TABLE 2. —SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUTHIACET-METHYL FOR USE IN HUMAN RISK ASSESSMENT.—Continued

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Cancer (Chronic)	Q_1^* = 2.07E^{-1} (mg/kg/day)$^{-1}$ (In human equivalents)	The HED, CARC (HED Cancer Assessment Review Committee) recommended a linear low-dose approach (Q_1^*) for human risk characterization and determined that extrapolation should be based on the combined hepatocellular tumors (adenomas and carcinomas) in male mice.	78–week carcinogenicity in the mouse

[1]= *Long-term dermal* Since an oral study was selected and there is no dermal absorption study, a 100% dermal absorption factor (default value) was used.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.551) for the residues of fluthiacet-methyl, in or on a variety of raw agricultural commodities. There are presently no tolerances established for meat, milk, poultry and eggs. Based upon the results of a ruminant feeding study and a goat metabolism study, this Agency concluded that there is no reasonable expectation of finite residues in ruminant tissues and milk. Based upon the results of a poultry metabolism study, fluthiacet-methyl and its metabolite (CGA–300403) are unlikely to occur in poultry or eggs. Risk assessments were conducted by EPA to assess dietary exposures from fluthiacet-methyl 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. There were no toxicological effects that could be attributed to a single oral exposure (dose) in an appropriate toxicological study. Thus, an acute exposure/risk assessment was not conducted for fluthiacet-methyl.

ii. *Chronic exposure.* Percent crop treated (PCT), anticipated market share percentages and tolerance level residues were used.

A chronic reference dose (RfD) (0.001 mg/kg/day) was identified for fluthiacet-methyl, based on non-neoplastic liver findings (increase in absolute and relative liver weights, fatty changes, chronic inflammation, karyomegaly, single cell necrosis and ceroid/lipofuscin pigmentation). The chronic PAD is the same as the chronic RfD since the FQPA factor was reduced to 1X. The chronic PAD was used to assess chronic risk.

EPA's Office of Pesticide Programs (OPP) Health Effects Division used Dietary Exposure Evaluation Model (DEEM™), version 7.075) software for conducting a chronic dietary (food) exposure analysis. DEEM ™ is a dietary exposure analysis system developed by Novigen Sciences, Inc. that is used to estimate exposure to pesticide residues in foods comprising the diets of the U.S. population, including population subgroups. DEEM™ contains food consumption data as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989–1992.

A Tier 2 chronic DEEM™ analysis was performed. The assumptions of this Tier 2 analysis were tolerance level residues and estimates of PCT for soybeans and projected market-share for corn commodities. The following tolerance levels were used in the analysis: soybeans at 0.01 ppm, sweet corn at 0.01 parts per million (ppm), pop corn at 0.01 ppm, and corn grain (field corn) at 0.01 ppm. These values were also used for corresponding processed commodities since processing studies for soybeans and field corn showed no concentration of residues into processed commodities. Thus, default concentration factors for corn grain, bran; corn grain, endosperm; corn grain, oil; soybean, other; soybeans, sprouted seeds; soybeans, flour (defatted, low fat, and full fat); soybean, oil; and soybean, protein isolate were set to 1X. DEEM™ default processing factors for corn grain/sugar/hfcs (1.5X), and corn grain/sugar-molasses (1.5X) were retained as processing data for these commodities are not available. A PCT value of 1% was used for soybeans and a projected market share value of 1% was used for all types of corn. These estimates of PCT/projected market share were derived based on Agency analysis of information on weed-pests for the use sites.

The chronic dietary exposure (food only) to fluthiacet-methyl for some population subgroups are presented in Table 3. The resulting dietary food exposures occupy <1% of the Chronic PAD for all population subgroups included in the analysis. The results of this dietary exposure analysis should be viewed as partially refined. Refinements such as use of anticipated residue values may yield even lower estimates of chronic dietary exposure.

TABLE 3.—SUMMARY: CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 2)

Population Subgroup[1]	Exposure (mg/kg/day)	% of Chronic PAD[2]
U.S. population (total)	<0.000001	<1.0
All Infants (<1 year)	0.000001	<1.0
Children (1–6 years)	<0.000001	<1.0
Children (7–12 years)	<0.000001	<1.0
Males (20+ years)	<0.000001	<1.0
Females (13–50 years)	<0.000001	<1.0

[1]The subgroups listed are: (1) The U.S. population (total); (2) those for infants and children; and, (3) the most highly exposed of the adult females and males subgroups (in this case, females, 13 to 50 years and males 20+ years).

[2] Percent chronic PAD = (exposure ÷ chronic PAD) x 100%.

Note: There are no other subgroup(s) (other than All Infants) for which the percentage of the Chronic PAD occupied is greater than that occupied by the subgroup U. S. population (total).

iii. *Cancer*. Fluthiacet-methyl has been classified as ''likely to be a human carcinogen'' by EPA. The Office of Pesticide Programs, Heath Effects Division, Cancer Assessment Review Committee recommended a linear low-dose approach (Q_1^*) for human risk assessment. The Q_1^* is 0.207 (mg/kg/day)–1 in human equivalents and is based upon the combined hepatocellular tumors (adenomas and carcinomas) in male mice.

EPA conducted a cancer assessment analysis (food) using DEEM software and Tier 2 chronic dietary exposure assumptions. The assumptions of this Tier 2 chronic dietary analysis are as specified above.

The cancer risk estimate (food only) for the U.S. population (total) is 3.93×10^{-8}. This risk estimate translates to a dietary exposure of 1.90×10^{-7} mg/kg/day. This dietary exposure value was back-calculated based upon the cancer risk estimate and the Q_1^*. As cancer risk = Exposure x Q_1^* Thus, Exposure = cancer risk estimate/ Q_1^* or Exposure = $3.93 \times 10^{-8}/0.207$.

iv. *Anticipated residue and PCT information*. Anticipated residues estimates were not used in the exposure analysis. Tolerance levels were used and a projected market share estimate was used as described in the chronic exposure section above.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: Percent projected market share: Corn, 1% and soybeans, 1%. Currently the largest market share for a pesticide for control of velvetleaf in corn or cotton is less than 20%. While the Agency does not expect the PCT to exceed 1% for corn or soybeans, it would be highly unlikely that the PCT approach the 20% share. EPA has determined that if PCT was to reach 20% there is still a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fluthiacet-methyl residues.

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. EPA believes the PCT used in this analysis is reasonable based on factors used in the analysis; in particular, the number of acres of corn and soybeans currently treated for the control of the weed pest, velvetleaf, the primary target weed pest for which fluthiacet-methyl will be used. This analysis also included competing currently registered herbicides for this market. EPA estimates that currently about 25 million acres of soybeans and 50 million acres of corn are treated for control of velvetleaf. Corn acres are treated with 41 different herbicidal active ingredients (a.i.), and soybeans acres are treated with 34 different herbicidal a.i.. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which fluthiacet-methyl may be applied in a particular area.

1. *Dietary exposure from drinking water*. The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for fluthiacet-methyl. Therefore, the Agency is presently relying on computer-generated estimated environmental concentrations (EECs). The PRZM/EXAMS Index Reservoir (IR) model was used to generate EECs for surface water and the SCI-GROW2 (an empirical model based upon actual monitoring data collected for a number of pesticides that serve as benchmarks) was used to predict EECs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing 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 determining that pesticides residues (and its metabolites) in water are not of concern.

For any given pesticide, the SCI-GROW2 model generates a single EEC value of pesticide concentration in ground water. That EEC is used in assessments of both acute and chronic dietary risk. It is not unusual for the ground water EEC to be significantly lower than the surface water EECs. The PRZM/EXAMS IR model generates several time-based EECs of pesticide concentration in surface water for acute exposure (upper 10^{th} percentile of peak values), non-cancer chronic exposure (upper 10^{th} percentile of 90–day values), and cancer exposure (mean annual value).

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. HED uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative EECs provided by computer modeling.

EPA, OPP, HED back-calculates DWLOCs by a two-step process: exposure [food + residential (if applicable)] is subtracted from the PAD to obtain the maximum acceptable exposure allowed in drinking water; DWLOCs are then calculated using that value and HED default body weight and drinking water consumption figures. In assessing human health risk, DWLOCs are compared to EECs. When EECs are less than DWLOCs, HED considers the aggregate risk from [food + water + residential (if applicable) exposures] to be acceptable.

2. *Environmental profile*. In soil, fluthiacet-methyl and its metabolites are considered to be mobile and persistent (effective or combined aerobic soil half-life of 305 days). The uncertainty of this half-life is large as indicated by a 95% confidence range of roughly 200 to 1,100 days. Due to the large uncertainty a soil half-life of 915 days was used in the models. Fluthiacet-methyl is expected to be a ground and surface water contaminant.

EPA, HED, Metabolism Assessment Review Committee (MARC) determined that the residues of concern for risk assessment purposes in water are residues that comprised greater than or equal to 10% of the total radioactive residues in the environmental fate studies. These residues include, but are not limited to, CGA–300402, CGA–300404, CGA–330057, component E, CGA–300403, CGA–327066, CGA–327067, CGA–330059, A-CFPSA, and ACA-CFPSA.

3. *Estimated environmental concentrations (EECs)*. The modeling results below are based on the combined concentrations of six chemicals. These chemicals are the parent compound and metabolites CGA–300402, CGA–300403, CGA–327066, CGA–327067, and A-CFPSA. The modeling was conducted based on the environmental profile and two applications at the rate of 0.0045 lbs ai/A (or a seasonal rate of 0.009 lbs ai/A).

The EECs are shown in Table 4.

TABLE 4.—EFED ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECS)

SCI-GROW2 (µg/L)[1]	PRZM/EXAMS IR Model (µg/L)
0.08 (acute and chronic)	0.8 (for acute exposure) 0.5 (for chronic (non-cancer) exposure) 0.06 (for cancer exposure)

1 µg/L = parts per billion or ppb.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fluthiacet-methyl 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 fluthiacet-methyl.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC 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.

As 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 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. Because DWLOCs address total aggregate exposure to fluthiacet-methyl they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW 2 models the estimated environmental concentrations (EECs) of fluthiacet-methyl for acute exposures are estimated to be 0.8 ppb for surface water and 0.08 ppb for ground water. The EECs for chronic exposures (non-cancer) are estimated to be 0.5 ppb for surface water and 0.08 ppb for ground water. The EEC for chronic (cancer) exposures are estimated to be 0.08 ppb for ground water and 0.06 ppb for surface water.

4. *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).

Fluthiacet-methyl is not registered for use on any sites that would result in residential exposure.

5. *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 fluthiacet-methyl 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, fluthiacet-methyl 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 fluthiacet-methyl 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. *Prenatal and postnatal sensitivity*. There was no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or prenatal/postnatal exposure to fluthiacet-mthyl. In rabbits, *in utero* exposure did not result in maternal toxicity at 1,000 mg/kg/day. Developmental toxicity, however, was seen at this dose characterized as an increase in irregular sternebrae (a variation which is reversible). The occurrence of developmental toxicity at which no maternal toxicity was noted indicates an apparent increase in susceptibility. The Office of Pesticide Program's Hazard Identification Assessment Review Committee (HIARC), however, determined that the apparent susceptibility is not convincing because of the equivocal nature of the effect based on: (1) The increased incidence of irregular sternebrae was not statistically significant when compared to concurrent controls; (2) the increase occurred at the Limit-Dose (1,000 mg/kg/day; (3) it was the only anomaly seen (i.e., a single variation); (4) the dose response was not strong because there was only a small increase in the litter incidence between the low- (5 mg/kg/day) and the high-dose (1,000 mg/kg/day), with the mid- and high-dose groups having 8 litters with this variation;, and (5) this endpoint is appropriate to establish a LOAEL and not appropriate for risk assessments. Based on these factors, the HIARC concluded that there is no increased susceptibility in the rabbit study. Therefore, the 10X FQPA safety factor to ensure the protection of infants and children was not applied in the risk assessments.

3. *Conclusion*. There is a complete toxicity data base for fluthiacet-methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The 10X FQPA safety factor to protect infants and children was removed based on the lack of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to this chemical.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative 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 the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An acute dietary endpoint for fluthiacet-methyl has not been identified; therefore, fluthiacet-methyl is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fluthiacet-methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year and <1% of the cPAD for all children. There are no residential uses for fluthiacet-methyl that result in chronic residential exposure to fluthiacet-methyl. Based the use pattern, chronic residential exposure to residues of fluthiacet-methyl is not expected. In addition, there is potential for chronic dietary exposure to fluthiacet-methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 5:

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

Population Subgroup	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	<1.0	0.5	0.08	35
All infant	<1.0	0.5	0.08	1.0
Females (13–20 years)	<1.0	0.5	0.08	30

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

Population Subgroup	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Males (20 + years)	<1.0	0.5	0.08	35

Chronic PAD (cPAD) in mg/kg/day is 0.001 for all population subgroups.

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).

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

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

5. *Aggregate cancer risk for U.S. population.* Fluthiacet-methyl has been classified as ''likely to be a human carcinogen'' based upon the combined hepatocellular tumors (adenomas and carcinomas in male mice.

6. *Cancer aggregate risk conclusions.* As summarized previously, the cancer risk estimate (food only) for the U.S. population (total) is 3.93×10^{-8}. This risk estimate translates to an exposure of 1.90×10^{-7} mg/kg/day. The results of this dietary exposure analysis should be viewed as partially refined (health protective). Refinements such as use of anticipated residue values may yield even lower estimates of cancer exposure.

The EECs provided by EFED for assessing cancer risk are 0.08 µg/L (for ground water, based on SCI-GROW2) and 0.06 µg/L (for surface water, based on PRZM/EXAMS IR modeling). The back-calculated DWLOC for assessing cancer aggregate dietary risk is 0.17 µg/L for the U.S. population (total).

The SCI-GROW2 and PRZM/EXAMS cancer EECs are less than the Agency's level of comparison for fluthiacet-methyl residues in drinking water as a contribution to chronic (cancer) aggregate exposure. HED thus concludes with reasonable certainty that residues of fluthiacet-methyl in drinking water will not contribute significantly to the aggregate cancer human health risk and that the chronic (cancer) aggregate exposure from fluthiacet-methyl residues in food and drinking water will not exceed the Agency's level of concern ($1X\ 10^{6}$) for the U.S. population. EPA generally has no concern for exposures below which result in cancer risks in the range of 1×10^{-6}, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, very conservative, and protective of human health.

7. *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 fluthiacet-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method AG–603B, MRID No. 442345–02), gas-liquid chromotography with a nitrogen/phosphorus detector, is available to enforce the tolerances for fluthiacet-methyl in or on corn and soybean commodities. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex Alimentarius Commission (Codex), Canadian, or Mexican Maximum Residue Levels (MRLs) for fluthiacet-methyl at this time.

C. Conditions

Conditions for registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) will include Agency monitoring for PCT as addressed within this Final Rule.

V. Conclusion

Tolerances are established for residues of fluthiacet-methyl in or on corn. field, grain at 0.010 ppm; corn, field, forage, at 0.050 ppm; corn, field, stover at 0.050 ppm; corn, pop, grain at 0.010 ppm; corn, pop, stover at 0.050 ppm; corn, sweet, stover at 0.050 ppm; corn, sweet, forage at 0.050 ppm; and corn, sweet, K + CWHR at 0.010 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–301184 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 February 19, 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–301184, 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 prior consultation as specified in Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: December 8, 2001.

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 180.551 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.551 Fluthiacet-methyl; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Corn, field, forage	0.050
Corn, field, grain	0.010
Corn, field, stover	0.050
Corn, pop, grain	0.010
Corn, pop, stover	0.050
Corn, sweet, forage	0.050
Corn, sweet, (K + CWHR)	0.010
Corn, sweet, stover	0.050
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[FR Doc. 01–31497 Filed 12–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301196; FRL–6811–6]

RIN 2070–AB78

Sodium thiosulfate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium thiosulfate when used as an inert ingredient (dechlorinator) in or on growing crops, or when applied to raw agricultural commodities after harvest. Eden Bioscience submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium thiosulfate.

DATES: This regulation is effective December 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301196, must be received by EPA on or before February 19, 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 VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301196 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6304; and e-mail address: boyle.kathryn@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