ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301111; FRL–6773–7]

RIN 2070–AB78

Ethametsulfuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of ethametsulfuron methyl (methyl 2- ((((4-ethoxy-6- (methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate) in or on canola, crambe, and rapeseed. E.I. DuPont de Nemours and Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 6, 2001. Objections and requests for hearings, identified by docket control number OPP–301111, must be received by EPA on or before June 5, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301111 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; and e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180._00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301111. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 17, 1997 (62 FR 66083) (FRL–5759–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 1F4032) for tolerance by E.I. du Pont de Nemours and Company, Barley Mill Plaza, Walker's Mill Bldg. 37, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide ethametsulfuron methyl (methyl 2- ((((4-ethoxy-6- (methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate) in or on canola seed at 0.1 part per million (ppm). During the course of the review, EPA determined that the available residue data supported tolerances of 0.02 ppm in or on the raw agricultural commodities canola, crambe, and rapeseed at 0.02 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of ethametsulfuron methyl on canola, crambe, and rapeseed at 0.02 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 ethametsulfuron 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 rodents - rats	NOAEL = 365/453 mg/kg/day (m/f) highest dose tested (HDT) LOAEL = not determined, supplementary due to lack of toxic response (inadequate dose levels)
	mice	NOAEL = >686/916 mg/kg/day (m/f) HDT LOAEL = not determined
870.3150	90-Day oral toxicity in nonrodents - dogs	NOAEL = >390/383 mg/kg/day (m/f) LOAEL = not determined; lack of a toxic response (inadequate dose levels)
870.3700a	Prenatal developmental in rodents - rats	Maternal NOAEL = 1,000 mg/kg/day LOAEL = 4,000 mg/kg/day based on decreased body weight and decreased food consumption. Developmental NOAEL = 1,000 mg/kg/day LOAEL = 4,000 mg/kg/day based on reduced fetal body weight gain, increased skeletal variations
870.3700b	Prenatal developmental in nonrodents - rabbits	Maternal NOAEL = 250 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased relative liver weight. Developmental NOAEL = 1,000 mg/kg/day LOAEL = 4,000 mg/kg/day based on increased resorptions (early fetal death), decreased litter size
870.3800	Reproduction and fertility effects	Parental/systemic NOAEL = 395/449 (m/f) mg/kg/day LOAEL = 1,582/1,817 (m/f) mg/kg/day based on reduced body weight and body weight gain in parent and Fla males and females Reproductive NOAEL = 1582/817 (m/f) mg/kg/day LOAEL = not determined
870.4100a	Chronic toxicity rodents	NOAEL = 210/267 mg/kg/day LOAEL = not determined
870.4100b	Chronic toxicity dogs	NOAEL = 87.3/386.9 (m/f) mg/kg/day LOAEL = 478/483 (m/f) mg/kg/day based on reduced body weight gain, and food efficiency, decrease in mean serum values
870.4200	Carcinogenicity rats	NOAEL = 210/267 mg/kg/day LOAEL = not determined. (no) evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 705/930 mg/kg/day LOAEL = not determined. (no) evidence of carcinogenicity
870.5300	Gene mutation	*In vitro* gene mutation in CHO cells. Negative for mutagenicity
870.5395	Gene mutation	*In vivo* micronucleus assay in mice did not induce bone marrow toxicity
870.5300	Gene mutation	*In vivo* rat bone marrow assay did not induce bone marrow did not induce a clastogenic response
870.5550	Gene mutation	*In vitro* UDS assay did not induce a genotoxic effect
870.5100	Gene mutation	*S. typhimurium*/mammalian microsome assay did not induce a genotoxic effect

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

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	Submitted study unacceptable by current guidelines. New study required as a condition of registration
870.7600	Dermal penetration	No studies available. Not required since a dermal risk assessment is not required

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 intraspecies differences.

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

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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 ethametsulfuron methyl used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary	A dose and endpoint were not selected because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose).		
Chronic dietary	NOAEL = 449 mg/kg/day UF = 100x	FQPA SF = 1x cPAD = 4.5 mg/kg/day	2-Generation reproduction study in rats.
	Chronic RfD = 4.5 mg/kg/day		LOAEL = 1817 mg/kg/day based on decreased body wt. and body wt. gain in parental animals and F1a and F1b generations.
Short-, intermediate and long-term dermal	No endpoints were selected for exposure scenarios by the dermal route, since the dermal toxicity study in rats was waived based on lack of systemic toxicity in oral toxicity studies, thereby making the potential for risk negligible.		
Inhalation (any time period)	No endpoint was selected, based on the low toxicity, use pattern and method of application, there is no concern for potential exposure/risk via this route.		
Cancer (oral, dermal, inhalation)	The carcinogenic potential of ethametsulfuron could not be evaluated since the highest dose tested in mice and rats did not elicit systemic toxicity. However, EPA noted that ethametsulfuron, is structurally-related to other sulfonylurea herbicides and does not show evidence of carcinogenicity or mutagenicity. Therefore, a quantitative risk assessment is not warranted.		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. A time-limited tolerance has been established for the residues of (methyl 2- ((((4-ethoxy-6-(methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate), in or on canola in connection with FIFRA section 18 emergency programs authorized in the 2000 growing season. Risk assessments were conducted by EPA to assess dietary exposures from ethametsulfuron 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. A Dietary Exposure Evaluation Model (DEEM) acute exposure analysis was not performed since an appropriate endpoint attributable to a single exposure was not selected.

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 Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For chronic risk assessments, residue estimates for foods or food-forms of interest are multiplied by the average consumption estimate of each food/food-form of each population subgroup. Chronic exposure estimates are expressed in milligram/kilogram body weight/day (mg/kg bw/day) and as a percent of the cPAD. A DEEM chronic exposure analysis was performed using the proposed tolerance level residues (0.02 ppm) and 100% crop treated to estimate the exposure for the general population and subgroups of interest. The percent cPAD that would be above EPA's level of concern would be 100%. Percent crop treated (PCT) and/or anticipated residues were not used. Based on the results of this analysis, exposure to ethametsulfuron methyl from food will utilize <1% of the cPAD for all population groups.

iii. *Cancer*. A DEEM cancer risk assessment is not performed because ethametsulfuron methyl is not expected to pose a cancer concern.

2. *Dietary exposure from drinking water*. The Agency will use monitoring data to assess exposures for a comprehensive dietary exposure and risk assessment when available. Because ethametsulfuron methyl is not registered for use, drinking water monitoring data for use in the dietary exposure and risk assessment are not available. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on modeling taking into account data on the physical characteristics of ethametsulfuron methyl.

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 Concentration 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 ethametsulfuron methyl, they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of ethametsulfuron methyl for acute exposures are estimated to be 0.48 parts per billion (ppb) for surface water and 0.11 ppb for ground water. The EECs for chronic exposures are estimated to be 0.32 ppb for surface water and 0.11 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).

Ethametsulfuron methyl 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 ethametsulfuron 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, ethametsulfuron 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 ethametsulfuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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.

ii. *Prenatal and postnatal sensitivity*. EPA determined that the available Agency Guideline studies indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to ethametsulfuron. In the prenatal developmental toxicity studies in rats and rabbits as well as the 2-generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

iii. *Conclusion*. The toxicity data base for ethametsulfuron methyl is complete except for a general metabolism study. The current metabolism study is not acceptable by current guidelines. A guideline study is required as a condition of the registration. The exposure data are complete or estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor Committee recommended that the 10x factor for protection of infants and children (as required by FQPA) be removed since: (1) The toxicology data base is complete except for the rat metabolism study. Requirements for developmental toxicity studies and reprodction studies are satisfied; (2) there is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data; (3) unrefined dietary exposure estimates are protective since they will exaggerate dietary exposure estimates; (4) EFED will model ground and surface source drinking water exposure assessments, resulting in estimates that are conservative upper-bound concentrations; and (5) there are currently no registered residential uses for ethametsulfuron and therefore, non-dietary exposure to infants and children is not expected.

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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 RfD (aRfD) was not established because a dose and endpoint attributable to a single exposure were not identified from the available oral toxicity studies, including maternal toxicity in the developmental toxicity studies.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to ethametsulfuron methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants (<1 year old) and <1% of the cPAD for children (1-6 years old). There are no residential uses for ethametsulfuron methyl that result in chronic residential exposure to ethametsulfuron methyl. In addition, there is potential for chronic dietary exposure to ethametsulfuron 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 3:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	4.5	<1	0.32	0.11	160,000
Females 13+	4.5	<1	0.32	0.11	140,000
Infants all (<1 year old)	4.5	<1	0.32	0.11	45,000
Children (1-6 years old)	4.5	<1	0.32	0.11	45,000

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).

Ethametsulfuron 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).

Ethametsulfuron 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*. A cancer aggregate risk assessment was not performed because ethametsulfuron methyl is not expected to pose a cancer concern.

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 ethametsulfuron methy residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

There is an analytical method available using high performance liquid chromatography (HPLC) with a photoconductivity detector that has been validated by the petitioner to gather residue data at the 0.02 ppm tolerance. EPA recommends this method be used by analysts having access to a working photoconductivity conductor. An improved analytical method is being validated by EPA's Analytical Chemistry Branch. Prior to publication in PAM II, and upon request, the existing HPLC analytical method for canola commodities will be available from the Analytical Chemistry Branch (ACB), Biological Economic Analysis Division (BEAD) (7503C), Environmental Science Center, 701 Mapes Road, Fort George G. Meade, MD 20755–5350; contact Francis D. Griffith, Jr., telephone (403) 305–2905, e-mail griffith.francis@epa.gov. The analytical standards for this method are also available from EPA's National Pesticide Standard Repository at the same location.

B. International Residue Limits

There are no Codex, Canadian, and Mexican maximum residue levels (MRLs). However, ethametsulfuron methyl is registered in Canada on canola/rape and mustard with a default value of 0.1 ppm, with no published MRL. The use pattern and residue data support a U.S. tolerances of 0.02 on canola, crambe, and rapeseed.

C. Conditions

A general metabolism study performed by current guidelines (870.7485) is being required as a condition of the registration.

V. Conclusion

Therefore, the tolerances are established for residues of ethametsulfuron methyl (methyl 2- ((((4-ethoxy-6- (methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate), in or on canola, crambe, and rapeseed at 0.02 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–301111 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 5, 2001.

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

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

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

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

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

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301111, 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). 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: March 21, 2001.

Anne E. Lindsay,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.563 is amended by adding paragraph (a) to read as follows:

§ 180.563 Ethametsulfuron methyl; tolerances for residues.

(a) *General.* A tolerance is established for residues of ethametsulfuron methyl (methyl 2- ((((4-ethoxy-6-(methylamino)-1,3,5- triazin-2-yl) amino) carbonyl) amino) sulfonyl) benzoate) in or on the following raw agricultural commodities.

Commodity	Parts per million
Canola seed	0.02
Crambe	0.02
Rapeseed	0.02

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