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).

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: September 21, 2000.

Susan B. Hazen,

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), (346a) and 371.

2. Section 180.564 is added to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the insecticide indoxacarb [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-enantimomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple	1.0
Apple, wet pomace	3.0
Brassica, head and stem, subgroup	5.0
Cattle, goat, horse, sheep and hog fat	0.75
Cattle, goat, horse, sheep and hog meat	0.03
Cattle, goat, horse, sheep and hog meat byproducts	0.02
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husk removed	0.02
Corn, sweet, stover	15
Cotton gin byproducts	15
Cotton, undelinted seed	2.0
Lettuce, head	4.0
Lettuce, leaf	10
Milk	0.10
Milk fat	3.0
Pear	0.20
Vegetables, fruiting, group	0.50

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00–25052 Filed 9–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301058; FRL–6746–2]

RIN 2070–AB78

Halosulfuron–methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of halosulfuron–methyl in or on the squash/cucumber subgroup. The Interregional Research Project 4 (IR–4) 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 September 29, 2000. Objections and requests for hearings,identified by docket control number OPP–301058, must be received by EPA on or before November 28, 2000.

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–301058 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7610; and e-mail address: jackson.sidney@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

Categories	NAICS codes	Examples of potentially affected entities
	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 the 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–301058. 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 August 23, 2000 (65 FR 51314) (FRL–6738–9), 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 (0E6085) for tolerance by IR–4, 681 U.S. Highway 1 South, North Brunswick, New Jersey 08902–3390. This notice included a summary of the petition prepared by Monsanto Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.479 be amended by establishing a tolerance for residues of the herbicide halosulfuron-methyl, methyl 5-(4,6-dimethoxy-2-pyrimidinyl)amino carbonylaminosulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, in or on the squash/cucumber subgroup at 0.5 parts per million (ppm).

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of halosulfuron-methyl on squash/cucumber subgroup at 0.5 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 halosulfuron-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. Acute toxicological studies placed the technical–grade halosulfuron-methyl in Toxicity Category III for acute dermal toxicity and in Category IV for all other types of acute toxicity.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	90–day oral toxicity rodents	NOAEL = 116 males/147 females milligrams/kilograms/day (mg/kg/day)

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

Guideline No.	Study type	Results
		LOAEL = 497 males/640 females mg/kg/day based on decreased body weight gain, decreased absolute weights of adrenal, liver, thymus, heart, and kidneys, decreased cholesterol, bilirubin, total protein, albumin, and calcium; increases in MCH, ALT, and creatinine; and vacuolated livers and pigmented kidney tubules.
870.3200	21/28–day dermal toxicity (rats)	NOAEL = 100 (males), 1,000 (females) mg/kg/day LOAEL = 1,000/>1,000 mg/kg/day male/female (M/F) based on dose–related decrease in total body weight gain in males.
870.3700a	Prenatal developmental in rodents (rat)	Maternal NOAEL = 250 mg/kg/day Maternal LOAEL = 750 mg/kg/day (increased incidence of clinical observations; and reduced body weight gains, food consumption, and food efficiency) Developmental NOAEL= 250 mg/kg/day Developmental LOAEL = 750 mg/kg/day (decreased mean litter size, increased number of resorptions, decreased mean fetal body weight, increases in fetal and litter incidences of dilation of the lateral ventricles and other anomalies in the development of the fetal nervous system, and skeletal variations such as anomalies or delays in ossification in the thoracic vertebrae, sternebrae, and ribs)
870.3700b	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL = 50 mg/kg/day Maternal LOAEL = 150 mg/kg/day (decreased body weight gain, food consumption, and food efficiency) Developmental NOAEL= 50 mg/kg/day Developmental LOAEL = 150 mg/kg/day (decreased mean litter size, increased number of resorptions and increased post implantation loss)
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 50.5 / 58.7 mg/kg/day M/F Parental/Systemic LOAEL = 223.2 / 261.4 mg/kg/day M/F - reductions in body weight, body weight gains, and food consumption during the premating period in both sexes) Offspring NOAEL > 261.4 mg/kg/day highest dose tested (HDT).
870.4100b	Chronic toxicity dogs	NOAEL (systemic) = 10 mg/kg/day LOAEL (systemic) = 40 mg/kg/day (decreased body weight gains and changes in hematological and blood chemistry parameters in females)
870.4200	Carcinogenicity mice	NOAEL (systemic) = 410 / 1214.6 mg/kg/day M/F LOAEL (systemic) = 971.9 / 1214.6 mg/kg/day M/F - decreased mean body weight in males, increased incidence of microconcentration/mineralization in the testis and epididymides) No evidence of carcinogenicity
870.4300	Combined toxicity/carcinogenicity rats	NOAEL (systemic) = 108.3 / 56.4 mg/kg/day M/F LOAEL (systemic) = 225.2 / 138.6 mg/kg/day M/F - marginal decreases in body weight gains) No evidence of carcinogenicity

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

Guideline No.	Study type	Results
870.7485	Metabolism and pharmacokinetics	Radiolabelled technical was administered to 5 rats/sex/group as a single low–dose (5 mg/kg), single high–dose (250 mg/kg), or repeated low–dose (5 mg/kg/day x 14 days). Absorption was rapid, incomplete sic, and similar in both sexes. Elimination was via urine and feces within 72 hours, and appeared to be independent of dose and sex. Desmethyl halosulfuron-methyl and its 5–hydroxy derivative were the major urinary and fecal metabolites.
	Genotoxicity	Bacterial/mammalian microsomal mutagenicity assays were performed and halosulfuron-methyl was found not to be mutagenic. Two mutagenicity studies were performed to test gene mutation and found to produce no chromosomal aberrations or gene mutations in cultured Chinese hamster ovary cells. An in vivo mouse micronucleus assay did not cause a significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow cells. A mutagenicity study was performed on rats and found not to induce unscheduled DNA synthesis in primary rat hepatocytes.
	Endocrine disruption	No specific tests have been conducted with halosulfuron-methyl to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity tests, i.e., teratology and multi- generation reproduction studies, which would suggest that halosulfuron-methyl produces effects characteristic of the disruption of the estrogenic hormone.

B. Toxicological Endpoints

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

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

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

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

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

Exposure scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute dietary females 13-50 years of age, infants and children.	NOAEL = 50 mg/kg/day, UF = 100 acute RfD = 0.5 mg/kg/day	FQPA SF = 1X, aPAD = acute RfD FQPA SF = 0.5 mg/kg/day	Developmental rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size and increases in resorptions and post–implantation loss.
Chronic dietary all populations	NOAEL = 10 mg/kg/day UF = 100, Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1X, cPAD = chronic RfD FQPA SF = 0.1 mg/kg/day	Chronic toxicity - dog LOAEL = 40 mg/kg/day based on decrease in bodyweight gain and alterations in hematology and clinical chemistry parameters.
Short–term dermal (1 to 7 days) (Residential)	oral NOAEL = 50 mg/kg/day, (dermal absorption rate = 75%)	LOC for MOE = 100 (Residential)	Developmental - rabbit LOAEL = 150 mg/kg/day based on decreased mean litter size and increases in resorptions, and post- implantation loss.
Interme diate–term dermal (1 week to several months) (Residential)	oral NOAEL = 10 mg/kg/day, (dermal absorption rate = 75%	LOC for MOE = 100 Residential	Chronic toxicity dog LOAEL = 40 mg/kg/day based on decrease in bodyweight gain and alterations in hematology and clinical chemistry parameters.
Long–term dermal (several months to lifetime) (Residential)	oral NOAEL= 10 mg/kg/day (dermal absorption rate = 75%	LOC for MOE = 100 (Residential)	Chronic toxicity - dog LOAEL = 40 mg/kg/day based on decreased body weight gain and alterations in hematology and clinical chemistry parameters.

*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.* Tolerances have been established (40 CFR 180.479) for the residues of halosulfuron-methyl, in or on various raw agricultural commodities (RACs) with tolerances ranging from 0.05 to 0.8 ppm. Halosulfuron-methyl is currently registered on a variety of use sites, including agricultural crops and residential lawns. Tolerances have been established for plant and animal RACs including field corn at 0.05 ppm, grain sorghum (milo) at 0.05 ppm, sweet corn (kernel + cobs with husks removed) at 0.05 ppm, pop corn grain at 0.05 ppm, sugarcane cane at 0.05 ppm, tree nuts nutmeat at 0.05 ppm, pistachio nuts nutmeat at 0.05 ppm, cotton undelinted seed at 0.05 ppm, and rice grain at 0.05 ppm; and secondary tolerances in meat and meat by–products at 0.1 ppm (cattle, goats, hogs, horses, and sheep). Tolerances are established for indirect or inadvertent residues of halosulfuron-methyl ranging from 0.1 to 0.5 ppm in or on certain soybean and wheat RACs when present therein as a result of the application of halosulfuron-methyl to growing crops. Indirect or inadvertent tolerances including soybean forage at 0.5 ppm, soybean hay at 0.5 ppm, soybean seed at 0.5 ppm, wheat forage at 0.1, wheat grain at 0.1, and wheat straw at 0.2 have also been established for RACs. Tolerances for the fruiting vegetable crop group 8 have been proposed by Gowan Company at 0.05 ppm. An additional tolerance is herein being requested for the crop group 9B, squash/cucumber subgroup of the cucurbit vegetable group, at 0.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from halosulfuron-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 one day or single exposure. The acute dietary endpoint for halosulfuron-methyl was based on developmental effects (decreased mean litter size, increased resorptions, and increased postimplantation loss). The endpoint applies only to subgroups consisting of females (aged 13–50 years), infants and children. The 10X FQPA factor was removed, therefore, the acute RfD of 0.5 mg/kg/day is equal to the aPAD. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: acute dietary exposure analysis was performed assuming tolerance level residues and 100% crop treated for all commodities for which halosulfuron-methyl is registered as well as for crops in the cucumber/squash subgroup (9B), which are being evaluated in this action. Further, standard processing factors were used for all processed commodities. The results of the DEEM analysis indicate that exposure for all applicable subgroups is less than 1% of the aPAD at the 95th percentile.

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: chronic dietary analysis was performed assuming tolerance level residues and 100% crop treated for all commodities for which halosulfuron-methyl is registered as well as for crops in the cucumber/squash subgroup (9B), which are being evaluated in this action. The results of the DEEM analysis indicate that exposure for all applicable subgroups is less than 1% of the cPAD.

The chronic dietary endpoint for halosulfuron-methyl is based on decreased body weight gains, changes in hematological and blood chemistry parameters. Since the 10X FQPA factor was removed, the chronic RfD of 0.1 mg/kg/day is equal to the cPAD.

iii. *Cancer*. Halosulfuron-methyl is classified as a ''not likely'' human carcinogen based on a lack of evidence of carcinogenicity in male and female mice and rats. A cancer risk assessment is not required.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for halosulfuron-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 halosulfuron-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 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 halosulfuron-methyl they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI–GROW models the estimated environmental concentrations (EECs) of halosulfuron-methyl in surface water and ground water for acute exposures are estimated to be 4.73 parts per billion (ppb) for surface water and 0.097 ppb for ground water. The EECs for chronic exposures are estimated to be 1.4 ppb for surface water and 0.097 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).

Halosulfuron-methyl is currently registered for use on the following residential non–dietary site: residential lawns. The risk assessment was conducted using the following residential exposure assumptions: Adults may be dermally exposed after treatments to lawns, and children may be exposed through dermal, hand–to–mouth and incidental oral sources.

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 halosulfuron-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, halosulfuron-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 halosulfuron-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 November 26, 1997 (62 FR 62961).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children— 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*. The available data provided no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to halosulfuron-methyl.

3. *Conclusion*. A postnatal developmental neurotoxicity study in rats is required for confirmatory purposes because of evidence of fetal nervous system alterations in rats at 750 mg/kg/day. This requirement is a condition of registration.

Notwithstanding the above study requirement, there is an otherwise complete toxicity data base for halosulfuron-methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X FQPA Safety Factor to protect infants and children should be removed because:

i. There was no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to halosulfuron-methyl. In the prenatal developmental toxicity studies in rats

and rabbits and the two–generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

ii. The committee determined that the requirement of a developmental neurotoxicity study in rats did not warrant an application of additional safety factors because:

a. The alterations observed in the fetal nervous system occurred in only one species (in rats and not in rabbits)

b. The fetal effects which will be investigated in the required developmental neurotoxicity study were seen only at a dose of 750 mg/kg/day which is close to the limit–dose (LTD) (1,000 mg/kg/day).

c. There was no evidence of clinical signs of neurotoxicity, brain weight changes, or neuropathology in the subchronic or chronic studies in rats.

d. The developmental neurotoxicity study is required only as confirmatory data to understand what the effect is at a high exposure (dose) level.

e. Exposure assessments do not indicate a concern for potential risk to infants and children based on the results of the field trial studies and the very low application rate (0.06 lbs. active ingredient (a.i) per acre). Detectable residues are not expected in foods.

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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to halosulfuron-methyl will occupy < 1.0 percent of the aPAD for the U.S. population, < 1.0 percent of the aPAD for females 13 years and older, < 1.0 percent of the aPAD for infant subpopulation and < 1.0 percent of the aPAD for children population. In addition, there is potential for acute dietary exposure to halosulfuron-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 aPAD, as shown in following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HALOSULFURON-METHYL

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
(All Infants)	0.50	<1.0	4.73	0.097	5,000
Female (13–50 years)	0.50	<1.0	4.73	0.097	15,000
Children (1–6 years)	0.50	<1.0	4.73	0.097	5,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to halosulfuron-methyl from food will utilize <1.0% of the cPAD for the U.S. population, for infant subpopulations at greatest exposure and for children subpopulation at greatest exposure]. Based the use pattern, chronic residential exposure to halosulfuron-methyl is not expected. In addition, there is potential for chronic dietary exposure to halosulfuron-methyl in drinking water. After calculating the 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 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON–CANCER) EXPOSURE TO HALOSULFURON-METHYL

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.10	<1.0	1.4	0.097	3,500

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON–CANCER) EXPOSURE TO HALOSULFURON-METHYL—Continued

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
(All Infants	0.10	<1.0	1.4	0.097	990
Children (1–6 years)	0.10	<1.0	1.4	0.097	1,000
Females (13–50 years)	0.10	<1.0	1.4	0.097	2,300
Males (13–19 years)	0.10	<1.0	1.4	0.097	3,500

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). Halosulfuron-methyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short–term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for short–term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 310 and 2,200 for all infants and females (13 to 50 years), respectively. Note that there is no oral residential exposure for adults. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short–term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron-methyl in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short–term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT–TERM EXPOSURE TO HALOSULFURON-METHYL

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Short–term DWLOC (ppb)
(All Infants)	310	100	1.4	0.097	4,900
Females (13–50 years)	2,200	100	1.4	0.097	10,000

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). Halosulfuron-methyl is currently registered for use(s) that could result in intermediate–term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate–term exposures for halosulfuron-methyl.

Using the exposure assumptions described in this unit for intermediate–term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,000, 1,700, and 2,000 for all infants, females (13 to 50 years) and males (13 to 19), respectively. It should be noted that there is no oral residential exposure for adults. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate–term DWLOCs were calculated and compared to the EECs for chronic exposure of halosulfuron-methyl in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate–term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE–TERM EXPOSURE TO HALOSULFURON-METHYL

Population subgroup	Aggregate MOE (Food + Residential)(oral)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Intermediate–term DWLOC (ppb)
(All Infants)	1,000	100	1.4	0.097	920
Females (13–50 years	1,700	100	1.4	0.097	2,800
Males (13–19 years)	2,000	100	1.4	0.097	3,300

5. *Aggregate cancer risk for U.S. population*. Halosulfuron-methyl is classified as a ''not likely'' human carcinogen based on a lack of evidence of carcinogenicity in male and female mice and rats.

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 halosulfuron-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The analytical method for cucumber and squash is based on ''Analytical Method for the Determination of MON 12000 and 3-Chlorosulfonamide Acid Producing residues in Field Corn'', Monsanto Doc. No. RES–026–92. This method has been submitted to FDA for publication in the Pesticide Analytical Manual (PAM) II. The analytical method involves sample extraction, acid hydrolysis under reflux to convert halosulfuron-methyl to 3-chlorosulfonamide acid (CSA), and derivatization to convert the CSA to chlorosufonamide ester (CSE). Detection is by GC/ECD (gas chromatography using electron capture detection). Quantitation is expressed in terms of halosulfuron-methyl equivalents. Chromatograms, calibration curves and calculations were included in this submission. The Agency concludes that the GC/ECD method is adequate for enforcement of tolerances and data collection on residues of halosulfuron-methyl in or on squash/cucumber subgroup. Information regarding availability of the method may be requested from: Calvin Furlow, PIRIB, 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, Canadian, or Mexican maximum residue limits (MRL) for halosulfuron-methyl in or on squash/cucumber subgroup. Therefore, international harmonization is not an issue for this tolerance.

C. Conditions

The Agency requires a satisfactory postnatal developmental neurotoxicity study in rats for confirmatory purposes because of evidence of fetal nervous system alterations in rats at 750 mg/kg/day. The study requirement is a condition of this registration.

V. Conclusion

Therefore, the tolerance is established for residues of halosulfuron-methyl, methyl 5-(4,6-dimethoxy-2-pyrimidinyl)amino carbonylaminosulfonyl-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, and its metabolites determined as 3-chloro-1-methyl-5-sulfamoylpyrazole-4-carboxylic acid, in or on the squash/cucumber subgroup at 0.5 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–301058 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 November 28, 2000.

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–301058, 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 file format 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* October 4, 1993 (58 FR 51735). 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 by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* May 19, 1998 (63 FR 27655); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low–Income Populations* February 16, 1994 (59 FR 7629); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). 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* August 10, 1999 (64 FR 43255). 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).

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: September 21, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.479 is amended by alphabetically adding an entry to the table in paragraph (a)(2) for ''squash/cucumber subgroup'' to read as follows:

§ 180.479 Halosulfuron-methyl, tolerances for residues.

* * * * *

(a)* * *

Commodity	Parts per million
* * * * *	
Squash/cucumber subgroup	0.5
* * * * *	

* * * * *

[FR Doc. 00–25048 Filed 9–28–00; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301067; FRL–6748–3]

RIN 2070–AB78

Yucca Extract; 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 the yucca extract on raw agricultural commodities when applied/used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops. EDM Corporation 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 yucca extract.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301067, must be received by EPA on or before November 28, 2000.

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–301067 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Vera Soltero, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9359; e-mail address: soltero.vera@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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301067. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 20, 1998 (63 FR 64494) (FRL–6027–7), 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 (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by, EDM Corporation, 2278 S. Indiana St., Porterville, CA 93257. This notice included a summary of the petition prepared by the petitioner EDM Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(d) be amended by establishing an exemption from the requirement of a tolerance for residues of yucca extract.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this