

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. Congressional Review Act

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 23, 2003.

**James Jones,**

*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 180.588 is added to subpart C to read as follows:

#### § 180.588 Quinoxifen; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide quinoxifen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline in or on the following raw agricultural commodities:

Commodity	Parts per million
Cherry, sweet .....	0.30
Cherry, tart .....	0.30
Hop, dried cones .....	3.0
Grape .....	0.60

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

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

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

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP–2003–0315; FRL–7328–6]

#### Sethoxydim; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on corn, sweet, forage; corn, sweet, stover; junberry; lingonberry; pistachio; salal; and safflower and increases the tolerance on cattle, meat by products;

corn, sweet, kernels plus cob with husk removed; goat, meat byproducts; hog, meat byproducts; horse, meat byproducts; milk; and sheep, meat byproducts. BASF Corporation requested the tolerances for corn, sweet, forage; corn, sweet, stover and the increase in tolerance for corn, sweet, kernels plus cob with husk removed; milk; and meat products under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). Interregional Project #4 (IR-4) requested the tolerances on junberry, lingonberry, pistachio, salal, and safflower under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). **DATES:** This regulation is effective September 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0315, must be received on or before November 28, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Jim Tompkins, Registration Division

(7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

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

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by

this action, you should carefully examine the applicability provisions in Unit II. If you have any 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 Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0315. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the **Federal Register** of January 18, 2000 (65 FR 2612) (FRL-6486-4), August 7, 2002 (67 FR 51267) (FRL-7191-3), and September 11, 2002 (67 FR 57593) (FRL-7198-11), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of pesticide petitions (9E6012, 9E6021, and 0E6150) by the Interregional Research Project Number 4, Technology Centre and Rutgers State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 and pesticide petition (2F4075) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709-3528. These notices included summaries of the petitions prepared by BASF Corporation, the registrant. There were no comments received in response to these notices of filing.

These petitions requested that 40 CFR part 180 be amended to establish tolerances for cyclohexen-1-one moiety (calculated as the herbicide), in or on corn, sweet, forage at 3.0 parts per million (ppm); corn, sweet, stover at 3.5 ppm; lingonberry at 5.0 ppm; juneberry at 5.0 ppm; pistachios at 0.2 ppm; safflower at 15.0 ppm and salal at 5.0 ppm, and increase the tolerance in cattle, meat byproducts from 0.2 ppm to 1.0 ppm; corn, sweet, kernels plus cob with husk removed from 0.2 ppm to 0.4 ppm; goat, meat byproducts from 0.2 ppm to 1.0 ppm; horse, meat byproducts from 0.2 ppm to 1.0 ppm; milk from 0.05 ppm to 0.5 ppm, and sheep, meat byproducts from 0.2 ppm to 1.0 ppm. The tolerance increases were a result of a 15-day reduction in the pre-harvest interval for sweet corn requested by the registrant.

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) of the FFDCA 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) of the FFDCA 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 of the FFDCA 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) of the FFDCA, 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) of the FFDCA, for a tolerance for combined residues of the herbicide sethoxydim, (2-[1-(ethoxymino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide), in or on corn, sweet, kernels plus cob with husk removed at 0.4 ppm; corn, sweet, forage at 3.0 ppm; corn, sweet, stover at 3.5 ppm; lingonberry at 5.0 ppm; juneberry at 5.0 ppm; milk at 0.5 ppm; cattle, meat byproducts at 1.0 ppm; goat, meat byproducts at 1.0 ppm; hog, meat byproducts at 1.0 ppm; horse, meat byproducts at 1.0 ppm and sheep meat byproducts at 1.0 ppm; pistachio at 0.2 ppm; safflower at 15.0 ppm and salal at 5.0 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 natures of the toxic effects caused by sethoxydim are discussed in Table 1 of this unit 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.—TOXICOLOGY PROFILE FOR SETHOXYDIM TECHNICAL

Guideline No.	Study Type	Results
870.1100	Acute oral—rats	LD <sub>50</sub> = male (M): 3,125 milligram/kilogram (mg/kg); female (F) 2,676 mg/kg (category III)
870.1200	Acute dermal—rats	LD <sub>50</sub> = > 5,000 mg/kg (category III)
870.1300	Acute inhalation—rats	LC <sub>50</sub> = M: 6.03 meter/Liter (m/L); F 6.28 m/L (category III)
870.2400	Primary eye irritation—rabbits	No irritation (category IV)
870.2500	Primary skin irritation—rabbits	No irritation (category IV)
870.2600	Dermal sensitization—guinea pigs	Waived based on lack of sensitization in guinea pigs with a formulated product
870.3100	90-Day oral toxicity rodents (rats)	<i>Males</i> NOAEL = 60.4 LOAEL = 196.3 mg/kg/day <i>Females</i> NOAEL = 66.2 LOAEL = 200.5 mg/kg/day Based on decreases in body weight, body weight gain, and food efficiency
870.3100	90-Day oral toxicity rodents (mice)	<i>Males</i> NOAEL = 45.6 LOAEL = 137.1 mg/kg/day <i>Females</i> NOAEL = 52.7 LOAEL = 164.4 mg/kg/day based on increased liver weight and histopathological evidence of hepatocellular hypertrophy
870.3150	90-Day oral toxicity (non-rodents-dogs)	<i>Males and females</i> NOAEL not identified LOAEL = 3.4 mg/kg/day (tentative) based on possible treatment-related clinical findings of cystitis of urinary bladders
870.3200	21-Day dermal toxicity (rabbits)	<i>Males and females</i> NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL not established. No localized or systemic effects
870.3465	4-Week inhalation toxicity (rats)	<i>Males and females</i> NOAEL = 0.3 mg/L (81 mg/kg/day) LOAEL of 2.4 mg/L (651 mg/kg/day), based on increased liver weight, clinical chemistry (increased total serum bilirubin), and liver histopathology
870.3700	Prenatal developmental toxicity (rats)	<i>Maternal</i> NOAEL = 180 mg/kg/day LOAEL = 650 mg/kg/day (irregular gaits, decreased activity, excessive salivation, and anogenital staining) <i>Developmental</i> NOAEL = 180 mg/kg/day LOAEL = 650 mg/kg/day (21–22% decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral, and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum, and/or transverse processes, sternebrae and/or metatarsals, and pubes)
870.3700	Prenatal developmental toxicity (rabbits)	<i>Maternal</i> NOAEL = 320 mg/kg/day LOAEL = 400 mg/kg/day, (based on 37% reduction in body weight gain without significant differences in group mean body weights, and decreased food consumption during dosing) <i>Developmental</i> NOAEL 320 mg/kg/day LOAEL = 400 mg/kg/day HDT based on an increase in the incidence of incompletely ossified 6th sternebrae

TABLE 1.—TOXICOLOGY PROFILE FOR SETHOXYDIM TECHNICAL—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rats)	<i>Systemic</i> NOAEL $\geq$ 150 mg/kg/day LOAEL >150 mg/kg/day <i>Reproductive</i> NOAEL $\geq$ 150 mg/kg/day LOAEL >150 mg/kg/day <i>Offspring</i> NOAEL = 30 mg/kg/day LOAEL = 150 mg/kg/day, based on decreased body weight in F2b pups during lactation and tail abnormalities seen in F1a and F1b offspring
870.4100	Chronic toxicity (dogs)	<i>Males</i> NOAEL = 17.5 mg/kg/day LOAEL = 110 mg/kg/day <i>Females</i> NOAEL = 19.9 mg/kg/day LOAEL = 129 mg/kg/day, based on increase hemosiderosis in the spleen and depressed myeloid erythropoiesis in the sternal bone marrow, increased absolute and relative liver weights, increased alkaline phosphatase and ALT levels
870.4200	Carcinogenicity (mice)	<i>Males</i> NOAEL = 13.8 mg/kg/day LOAEL = 41.2 mg/kg/day, based on early onset of liver effects including hepatocellular hypertrophy and fatty degeneration in male mice. No evidence of carcinogenicity
870.4300	Combined chronic/carcinogenicity (rats)	<i>Male</i> NOAEL = 12 mg/kg/day LOAEL = 48 mg/kg/day, based on liver toxicity (centrilobular hepatocellular hypertrophy) <i>Females</i> NOAEL = 66 mg/kg/day LOAEL = 204 mg/kg/day, based on decreased body weight, body weight gain, liver toxicity (centrilobular hepatocellular hypertrophy), and lung lesions (heart failure cells and interstitial fibrosis) No evidence of carcinogenicity
870.5100	Bacterial reverse mutation	<i>Negative</i> Concentrations 313–5,000 $\mu$ g/plate
870.5300	<i>In vitro</i> mammalian cell gene mutation	<i>Negative</i> Concentrations 500–5,000 $\mu$ g/mL
870.5300	<i>In vitro</i> mammalian cell gene mutation	Negative 10,000 mg/kg
870.5300	<i>In vitro</i> mammalian cell gene mutation	<i>Negative</i>
870.5550	Unscheduled DNA synthesis (rat hepatocyte cells)	<i>Negative</i> Concentrations 10 to 507 $\mu$ g/mL
870.5915	<i>In vivo</i> sister chromatid exchange (chinese hamster bone marrow)	<i>Negative</i> Dose 0, 0.5, 1.67, 5 gram (g)/kg
870.7485	Metabolism and pharmacokinetics (rats)	Excretion is extremely rapid and tissue accumulation is negligible, assuming DMSO vehicle does not affect excretion or storage of NP-55, 78% excreted into urine and 20.1% in feces
870.7485	Metabolism and pharmacokinetics (rats)	Administration of radioactively labeled NP-55 yielded 0.8% radioactivity in urine identified as hydroxymetabolites represented by 6-OH M2SO2 and 2 other metabolites found by mass spectrometry were MSO and M1SO

### 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. A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences. Acceptable developmental toxicity studies were performed in rats and rabbits, with evidence of neurotoxicity in the rat study, and an acceptable 2-generation reproduction study in rats. The developmental toxicity rabbit study did not exhibit either quantitative or qualitative susceptibility. Neurotoxicity studies are not available. Although, the Agency has concluded that there is a concern for prenatal and/or postnatal toxicity resulting from exposure to sethoxydim, the concern is reduced

because the fetal effects in the developmental rat study were seen only at the high dose. Concern is also low because the LOAEL for offspring toxicity for the 2-generation reproduction rat study is based on conservative determinations of offspring toxicity. However, due to lack of subchronic and developmental neurotoxicity studies with evidence of developmental (tail) abnormalities in the rat developmental and reproductive studies the additional 10X FQPA safety factor (SF) in the form of a data base UF was retained.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the reference dose (RfD) is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional SF 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 SF.

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  $1 \times 10^{-6}$  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 ( $\text{MOE}_{\text{cancer}} = \text{point of departure/exposures}$ ) is calculated. A summary of the toxicological endpoints for sethoxydim used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment <sup>k</sup>	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age and including infants and children)	NOAEL = 180 mg/kg/day UF = 1,000 Acute RfD = 0.18 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.18 mg/kg/day	Rat developmental toxicity <i>Developmental</i> LOAEL = 650 mg/kg/day based on decreased fetal body weight, tail abnormalities, delayed ossification
Acute dietary (General population)	NOAEL = 180 mg/kg/day UF = 1,000 Acute RfD = 0.18 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.18 mg/kg/day	Rat developmental toxicity <i>Maternal</i> LOAEL = 650 mg/kg/day based on irregular gait that was observed in 12/34 dams on the first day of dosing
Chronic dietary (All populations)	NOAEL = 14 mg/kg/day UF = 1,000 Chronic RfD = 0.014 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.014 mg/kg/day	Mouse carcinogenicity study LOAEL = 41 mg/kg/day based on liver hypertrophy and fatty degeneration
Short-term Incidental oral (1–30 days)	NOAEL = 180 mg/kg/day	<i>Residential</i> LOC for MOE = 1,000	Rat developmental toxicity <i>Maternal</i> LOAEL = 650 mg/kg/day based on irregular gait that was observed in 12/34 dams on the first day of dosing
Intermediate-term Incidental oral (1–6 months)	NOAEL = 45.6 mg/kg/day	<i>Residential</i> LOC for MOE = 1,000	90-Day mouse oral toxicity LOAEL = 137 mg/kg/day based on increased liver weight and hepatocellular hypertrophy

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment <sup>k</sup>	Study and Toxicological Effects
Short-term dermal (1 to 30 days)	Dermal (or oral) study NOAEL= NA	<i>Residential</i> LOC for MOE = NA	Quantification of dermal exposure risk assessment is not required because of lack of dermal and pre-natal toxicity in rabbits, and the low dermal absorption physical and chemical properties of sethoxydim
Intermedia-term dermal (1 to 6 months)	Dermal (or oral) study NOAEL = NA	<i>Residential</i> LOC for MOE = NA	Quantification of dermal exposure risk assessment is not required because of lack of dermal and prenatal toxicity in rabbits, and the low dermal absorption physical and chemical properties of sethoxydim
Long-term dermal > 6 months)	Dermal (or oral) study NOAEL= NA	<i>Residential</i> LOC for MOE = NA	Quantification of dermal exposure risk assessment is not required because of lack of dermal and prenatal toxicity in rabbits, and the low dermal absorption physical and chemical properties of sethoxydim
Short-term Inhalation (1 to 30 days)	Inhalation study NOAEL= 81 mg/kg/day	<i>Residential</i> LOC for MOE = 1,000	28-Day rat inhalation LOAEL = 651 mg/kg/day based on increased liver weight, clinical chemistry (increased total serum bilirubin), and liver histopathology
Intermediate-term Inhalation (1 to 6 months)	Inhalation study NOAEL = 81 mg/kg/day	<i>Residential</i> LOC for MOE = 1,000	28-Day rat inhalation LOAEL = 651 mg/kg/day based on increased liver weight, clinical chemistry (increased total serum bilirubin), and liver histopathology
Cancer (oral, dermal, inhalation)	"Not likely human carcinogen" based on the lack of evidence of carcinogenicity in rats and mice		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population-adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.412) for the combined residues of sethoxydim and its metabolites, in or on a variety of raw agricultural commodities. Tolerances are also currently established for secondary residues in meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm (except 2.0 ppm in poultry meat byproducts); eggs at 2.0 ppm, and milk at 0.05 ppm. Time limited tolerances (to expire by 12/31/03) are established for residues in milk at 0.5 ppm and the meat byproducts of cattle, goats, hogs, horses, and sheep at 1.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from sethoxydim 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. This acute assessment used tolerance level residues for most of the crops but limited refinement was obtained though the incorporation of field trial data and experimental processing factors for some of the crops expected to be more highly associated with dietary exposure to sethoxydim. Specifically, field trial data were incorporated for apples, pears, and other pome fruits, grapes, oranges, potatoes, strawberries, peaches, succulent green peas, succulent green beans, and succulent lima beans. Empirical processing data for apples, grapes, tomatoes, potatoes and oranges were also used. The processing data for orange juice was also translated to other citrus juices. Percent crop treated (PCT) information was available for most crops and was used wherever possible to refine the assessment. Tolerance level residues were used for meat, poultry, milk and eggs. With the refinements

incorporated in this assessment, the acute dietary analyses for sethoxydim show that the estimated risks from acute dietary exposure to sethoxydim are below <100% aPAD for the U.S. population.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (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: The chronic analyses (limited refined dietary risk assessment) used tolerance level residues for all crops and the PCT for many crops. For the chronic analyses, refinement was obtained by calculation of anticipated residues for meat and

milk, and without using field trial data. The results of this analysis indicate that the chronic dietary risk (food only) associated with existing uses of sethoxydim is below <100% cPAD for the U.S. population.

iii. *Cancer.* Sethoxydim is classified as “not likely to be a human carcinogen”. Therefore, a quantitative assessment of aggregate cancer risk was not performed.

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

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

The Agency used PCT information as follows.

Alfalfa 0.1%; apples 0.1%; apricot 0.02%; asparagus 5%; beans, lima 9%; beans/peas, dried 14%; beets, sugar 8%; broccoli 1%; cabbage 1%; canola 4%; cantaloupe 8%; carrots 2%; cauliflower 2%; cherries 0.4%; collards 2%; corn, field 0.1%; corn, sweet 0.5%; cotton 0.5%; cranberries 8%; cucumbers 6%; eggplant/peppers 5%; flax 38%; grapefruit 1%; grapes 1%; lemons 5%;

lettuce 1%; nectarines 0.1%; oranges 3%; peaches 0.4%; peanuts 5%; peppers, bell 3%; peppers, chili 11%; pears 0.03%; peas, green 2%; potatoes 4%; potatoes, sweet 18%; pumpkins 8%; root/tuber vegetables (other than carrots, potatoes, and sugar beets) 5%; soybeans 2%; spinach 0.3%; squash 8%; strawberries 5%; sunflowers 14%; tomatoes 4%; vegetables, other 6%; watermelons 12%.

The Agency believes that the three conditions listed in Unit IV have been met. With respect to condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which sethoxydim may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a

comprehensive dietary exposure analysis and risk assessment for sethoxydim 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 sethoxydim.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop 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 percent reference dose (%RfD or percent population adjusted dose (%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 sethoxydim they are further discussed in the aggregate risk section Unit III. E.

Based on the FIRST and SCI-GROW models the EECs of sethoxydim for

acute exposures are estimated to be 100 parts per billion (ppb) for surface water and 1 ppb for ground water. The EECs for chronic exposures are estimated to be 20 ppb for surface water and 1 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). Sethoxydim is currently registered for use on the following residential non-dietary sites: Ornamentals and flowering plants, recreational areas, and buildings/structures (non-agricultural-outdoor). The risk assessment was conducted using the following exposure assumptions:

i. *Residential handler.* There is potential sethoxydim exposure to residential handlers who mix, load and apply sethoxydim for use on residential turf and ornamentals. Because dermal toxicity endpoints were not identified, only the following exposure scenarios were assessed:

- Adult inhalation exposure from mixing/loading/applying sethoxydim for spot treatment with a low-pressure handwand.
- Adult inhalation exposure from mixing/loading/applying sethoxydim for spot treatment with a hose-end sprayer.

ii. *Residential post-application.* The labeled use pattern for sethoxydim only suggests spot treatments for non-agricultural sites (e.g., fence lines, at base of ornamental plantings, etc.). The Agency considered the potential residential post-application exposure from spot treatment to be negligible. However, an exposure/risk assessment for broadcast turf treatment, using the applicable endpoints, was included in this assessment because there is no labeled recommendation against broadcast treatment of lawns. Sethoxydim treatment may take up to 3 weeks before visible burnback of turf is seen, and the previous risk assessment for other agricultural use sites included residential post-application exposure from turf use.

Broadcast turf treatment would result in the potential for dermal (adults and children) and incidental oral exposure (children only) during post-application activities. However, because the appropriate dermal toxicity endpoints for sethoxydim were not identified, and because inhalation is considered negligible for post-application exposure, only the following post-application exposure scenarios were assessed:

1. Incidental non-dietary ingestion of pesticide residues on lawns from hand-to-mouth transfer.

2. Incidental non-dietary ingestion of residues from object-to-mouth activities (pesticide-treated turfgrass).

3. Incidental non-dietary ingestion of soil (base of pesticide-treated ornamentals).

Post-application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings.

The exposure via incidental non-dietary ingestion involving other plant material (i.e., resulting from children's handling of treated ornamentals) may occur but is considered negligible.

The exposure and risk estimates for the three residential exposure scenarios are assessed for the day of application (day "0") because it is assumed that toddlers could contact the lawn immediately after application. On the day of application, it was assumed that 5% of the application rate is available from the turf grass as transferrable residue (20% for object-to-mouth activities). Intermediate-term exposure is also expected (up to 6 months) because reapplications are not limited, and may be necessary to continue suppression of grass. The application rates used for turf and ornamental gardens are 0.33 and 0.49 lb active ingredient acres (ai/A) respectively.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA 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 sethoxydim has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sethoxydim and any other substances and sethoxydim 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 sethoxydim 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408 of the FFDCA provides that EPA will 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.* EPA determined that there are no residual uncertainties for prenatal and/or postnatal toxicity based on the following:

i. There was evidence of qualitative susceptibility in the developmental rat study with the occurrence of more severe effects in the fetuses (tail abnormalities and delayed ossification) than the maternal animals (clinical signs of neurotoxicity). Tail abnormalities were also seen in the F1a and F1b offspring of the 2-generation reproduction rat study. However, the degree of concern is low for the fetal effects in the developmental rat study since the fetal anomalies were seen only at the high dose 650 mg/kg/day which is close to the Limit Dose (LTD) (1,000 mg/kg/day). They were seen in the presence of maternal toxicity (clinical signs of neurotoxicity) and clear NOAELs/LOAELs were established for maternal and developmental toxicities.

ii. Evidence of quantitative susceptibility was indicated in the 2-generation reproduction rat study, by a slightly higher decrease (11–13%) in the body weights of offspring during lactation as compared to an 8–10% decrease in the body weights of the parental animals. Again, the degree of concern is also low for the 2-generation reproduction rat study since the LOAEL for offspring toxicity is based on a conservative determination of a minimal response in pup body weight decrements at the same dose that also caused decreases in body weights in the parental animals.



iii. The developmental toxicity study in the rabbits did not exhibit either quantitative or qualitative susceptibility.

3. *Conclusion.* Exposure data for sethoxydim are complete or are estimated based on data that reasonably accounts for potential exposures. The toxicity data base, however, is not complete. Due to evidence of developmental (Tail) abnormalities in the rat developmental and reproductive studies, EPA has required submission of subchronic and developmental neurotoxicity studies. After reviewing the data base, EPA concluded that there was not a reliable basis for establishing an additional safety factor for the protection of children at a value different than the statutory default of 10X. Accordingly, EPA has retained the additional 10X FQPA safety factor in the form of a Data base Uncertainty Factor.

#### *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 U.S. EPA Office of Water are used to calculate DWLOCs: 2 L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the

calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which 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 sethoxydim will occupy 52% of the aPAD for the U.S. population, 92% of the aPAD for children aged 1–2 and 92% of the aPAD for children aged 3–5. In addition, there is potential for acute dietary exposure to sethoxydim 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 the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO SETHOXYDIM

Population Subgroup	aPAD (mg/kg)	Acute Food Exp mg/kg/day	Surface Water EEC (ppb) <sup>1</sup>	Ground Water EEC (ppb) <sup>1</sup>	Acute DWLOC (ppb) <sup>2</sup>
General U.S. population	0.18	0.096	100	1.0	2,940
Children 1–2 years	0.18	0.165	100	1.0	150
Children 3–5 years	0.18	0.165	100	1.0	152

<sup>1</sup> The crop producing the highest risk level was used.

<sup>2</sup> Chronic DWLOC (μg/L) = maximum chronic water exposure (mg/kg/day) x body weight (kg) water consumption (L) x 10<sup>3</sup> mg/μg.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sethoxydim from food will utilize 24% of the cPAD for the U.S. population, and 75% of the cPAD

for infants <1 year old. Based on the use pattern, chronic residential exposure to residues of sethoxydim is not expected. In addition, there is potential for chronic dietary exposure to sethoxydim 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 4:

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

Population Subgroup	cPAD (mg/kg)	Chronic Food Exp mg/kg/day	Surface Water EEC (ppb) <sup>1</sup>	Ground Water EEC (ppb) <sup>1</sup>	Chronic DWLOC (ppb) <sup>2</sup>
General U.S. population	0.014	0.0038	20	1.0	358
Infants (<1 year)	0.014	0.0105	20	1.0	35.3

<sup>1</sup> The crop producing the highest level was used.

<sup>2</sup> Chronic DWLOC (μg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)] ÷ [water consumption (L) x 10<sup>−3</sup> mg/μg.]

3. *Short-term risk (1–30 days).* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sethoxydim is currently registered for uses 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 sethoxydim.

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 greater than 1,000 for all exposure scenarios in children aged 1–2 years, which includes oral hand-to-mouth, oral object-to-mouth and soil ingestion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. Short-term aggregate risk assessments were not calculated for adult handlers because oral and inhalation endpoints lack a common toxicity endpoint. The

children 1–2 years-of-age scenario was chosen because it was the highest estimated food exposure and thus, also protective of children 3–5 years of age. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of sethoxydim in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface water 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 SETHOXYDIM

Population Subgroup	Target MOE	Target Maximum Exposure <sup>1</sup> (mg/kg/day)	Surface Water EEC <sup>2</sup> (ppb)	Ground Water EEC <sup>2</sup> (ppb)	Short-Term DWLOC (ppb)
Children 1–2 years old	1,000	0.18	20	1	1,650

<sup>1</sup> Target Maximum Exposure = NOAEL/Target MOE.

<sup>2</sup> Estimate for the highest use rate was chosen.

4. *Intermediate-term risk (1–6 months).* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sethoxydim 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 sethoxydim.

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 greater than 1,000 for all exposure scenarios in children aged 1–2 years old, which includes oral hand-to-mouth, oral object-to-mouth and soil ingestion. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. Intermediate term aggregate risk assessments were not calculated for

adult handlers because oral and inhalation endpoints lack a common toxicity endpoint. The children 1–2 years-of-age scenario were chosen because it was the highest estimated food exposure and thus, also protective of children 3–5 years of age. After calculating DWLOCs and comparing them to the EECs for surface water 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 SETHOXYDIM

Population Subgroup	Target MOE	Target Maximum Exposure <sup>1</sup> (mg/kg/day)	Surface Water EEC <sup>2</sup> (ppb)	Ground Water EEC <sup>2</sup> (ppb)	Intermediate-Term DWLOC (ppb)
Children 1–2 years old	1,000	0.046	20	1	330

<sup>1</sup>Target Maximum Exposure = NOAEL/Target MOE.

<sup>2</sup>Estimate for the highest use rate was chosen.

5. *Aggregate cancer risk for U.S. population.* Sethoxydim is not expected to pose a cancer risk because no evidence of carcinogenicity was found in adequate animal tests in two different species.

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 sethoxydim residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas-liquid chromatography with flame photometric detection (GLC/FPD) in the sulfur mode) is available [BASF Wyandotte Corporation's (BWC's) Method No. 30, 3/15/82; MRID 44864501; Method I, PAM II] to enforce the tolerance expression in plant and livestock commodities.

##### B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits or tolerances for sethoxydim on lingonberry, junberry, salal, or safflower. Therefore, international harmonization is not an issue for the proposed uses of sethoxydim on lingonberry, junberry, salal, pistachio, or safflower.

There are no Codex or Mexican maximum residue limits or tolerances for sethoxydim on sweet corn. There is a Canadian tolerance on corn of 0.5 ppm for sethoxydim and metabolites

containing the cyclohex-2-enone moiety expressed as sethoxydim. The tolerance for the proposed use of sethoxydim on sweet corn is not being harmonized with the Canadian tolerance until the Agency can revise its risk assessment to evaluate the risks of the harmonization with the Canadian tolerance.

### C. Conditions

As a condition of registration, the registrant must submit:

1. *Residue chemistry.* i. To support the proposed use on safflower, storage stability data for sethoxydim, MSO, and 5-OH-MSO<sub>2</sub> in safflower oil (or another oil) stored frozen for 1 year are needed since storage stability data for sethoxydim residues in oil have not previously been submitted.

ii. As recommended in OPPTS 860.1500, five field trials are required for safflower, with suggested distribution in Region 7 (two Trials) and Region 10 (three Trials). Four studies, which were conducted in 1988, were submitted from Region 10 (one study), Region 5 (two studies), and Region 7 (one study). EPA has determined that two additional studies from Region 10 must be submitted.

2. *Toxicology.* i. Subchronic neurotoxicity study—rat.

ii. Developmental neurotoxicity study (DNT)—rat.

### V. Conclusion

Therefore, tolerances are established for the combined residues of sethoxydim, (2-[1-(ethoxymino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide), in or on corn, sweet, kernels plus cob with husk removed at 0.4 parts per million (ppm); corn, sweet, forage at 3.0 ppm; corn, sweet, stover at 3.5 ppm; lingonberry at 5.0 ppm; junberry at 5.0 ppm; milk at 0.5 ppm; cattle, meat byproducts at 1.0 ppm; goat, meat byproducts at 1.0 ppm; hog, meat byproducts at 1.0 ppm; horse, meat byproducts at 1.0 ppm; sheep, meat byproducts at 1.0 ppm; pistachio at 0.2 ppm; safflower at 15.0 ppm and salal at 5.0 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. EPA's 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP-2003-0315 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, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

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](mailto: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 20460-0001.

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 20460-0001.

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.1. Mail your copies, identified by docket ID number OPP-2003-0315, 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 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

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

Dated: September 23, 2003.

**Debra Edwards,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. Section 180.412 is amended as follows:

■ i. In the table to paragraph (a) by revising the entries for cattle, meat byproducts; corn, sweet, kernel plus cob with husks removed; goat meat byproducts; hog, meat byproduct; horse, meat byproduct; milk; and sheep, meat byproduct, and by alphabetically adding the commodities corn, sweet, forage; corn sweet, stover, junberry; lingonberry; pistachio; salal; and safflower.

■ ii. By removing the text from paragraph (b) and reserving the paragraph designation and heading.

■ The amended, added, and revised portions of § 180.412 read as follows:

## § 180.412 Sethoxydim; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million	Expiration/Revocation Date
* * *	* * *	*
Cattle, meat by-products .....	1.0	None
* * *	*	*
Corn, sweet, forage .....	3.0	None
Corn, sweet, kernel plus cob with husks removed .....	0.4	None

Commodity	Parts per million	Expiration/Revocation Date
Corn, sweet stor- ver .....	3.5	None
* * *	*	*
Goat, meat by- products .....	1.0	None
* * *	*	*
Hog, meat by- products .....	1.0	None
* * *	*	*
Horse, meat by- products .....	1.0	None
* * *	*	*
Juneberry .....	5.0	None
* * *	*	*
Lingonberry .....	5.0	None
* * *	*	*
Milk .....	0.5	None
* * *	*	*
Pistachio .....	0.2	None
* * *	*	*
Salal .....	5.0	None
Safflower .....	15.0	None
* * *	*	*
Sheep, meat by- products .....	1.0	None
* * *	*	*

(b) Section 18 emergency exemptions.  
[Reserved]

\* \* \*

[FR Doc. 03-24562 Filed 9-26-03; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2003-0256; FRL-7328-8]

#### Indian Meal Moth Granulosis Virus; 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 Indian Meal Moth Granulosis Virus (IMMGV) in or on all food commodities when applied/used in accordance with approved label rates and good agricultural practices. AgriVir, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996

(FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of IMMGV.

**DATES:** This regulation is effective September 29, 2003. Objections and requests for hearings, identified by docket identification number OPP-2003-0256, must be received on or before November 28, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: [cole.leonard@epa.gov](mailto:cole.leonard@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0256. The official public docket consists of the documents

specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the appropriate docket ID number.

##### **II. Background and Statutory Findings**

In the **Federal Register** of July 30, 2003 (68 FR 447804) (FRL-7319-7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 3F6736) by AgriVir, LLC, 1901 L Street, NW., Suite 250, Washington, DC 20036. This notice included a summary of the petition prepared by the petitioner AgriVir, LLC. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1218 be amended by establishing an exemption from the requirement of a tolerance for residues of IMMGV.

##### **III. Risk Assessment**

New section 408(c)(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