



# Reregistration Eligibility Decision (RED) for Sethoxydim

**September 30, 2005**



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data related to the risk assessments for the herbicide sethoxydim. The enclosed Reregistration Eligibility Decision (RED), which was signed on September 30, 2005, summarizes the Agency's risk assessments for sethoxydim and its conclusions concerning the potential human health and environmental risks of the current product uses, and conditions under which these uses and products will be eligible for reregistration.

In this RED, the Agency has determined that all uses of sethoxydim will be eligible for reregistration.

This RED also contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. **Note, registrants of sethoxydim must respond to DCIs issued by the Agency within 90 days of receipt of this letter. For Product Reregistration, the second set of required responses is due 8 months from receipt of this letter.** Registrants may avoid Agency enforcement action, specifically suspension of their sethoxydim products registration(s), by submitting complete and timely responses.

A Notice of Availability for the Reregistration Eligibility Decision for sethoxydim is being published in the *Federal Register*. Electronic copies of the RED and all supporting documents are available on the Internet. See [www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm). To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805.

Please note that the sethoxydim risk assessments and the attached RED concern only this particular pesticide. 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 shares 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 of EPA's website at  
<http://www.epa.gov/pesticides/cumulative/>.

If you have questions on this document, please contact the Special Review and Reregistration Division representative, Patrick Dobak, at (703) 308-8180. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact the Product Reregistration Chemical Review Manager, Venus Eagle, at (703) 308-8045.

Sincerely,

Debra Edwards, Ph.D.  
Director  
Special Review and Reregistration Division

Attachment

**Reregistration Eligibility Decision**

**for**

**Sethoxydim**

**List [B]**

**Case No. 2600**



# **Sethoxydim Reregistration Eligibility Decision Team**

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## Glossary of Terms and Abbreviations

|                  |  |
|------------------|--|
| AGDCI            | Agricultural Data Call-In  |
| ai               | Active Ingredient  |
| aPAD             | Acute Population Adjusted Dose   |
| AR               | Anticipated Residue  |
| BCF              | Bioconcentration Factor  |
| CFR              | Code of Federal Regulations  |
| cPAD             | Chronic Population Adjusted Dose   |
| CSF              | Confidential Statement of Formula  |
| CSFII            | USDA Continuing Surveys for Food Intake by Individuals   |
| DCI              | Data Call-In   |
| DEEM             | Dietary Exposure Evaluation Model  |
| DFR              | Dislodgeable Foliar Residue  |
| DWLOC            | Drinking Water Level of Comparison.  |
| EC               | Emulsifiable Concentrate Formulation   |
| EEC              | Estimated Environmental Concentration  |
| EPA              | Environmental Protection Agency  |
| EUP              | End-Use Product  |
| FDA              | Food and Drug Administration   |
| FIFRA            | Federal Insecticide, Fungicide, and Rodenticide Act  |
| FFDCA            | Federal Food, Drug, and Cosmetic Act   |
| FQPA             | Food Quality Protection Act  |
| FOB              | Functional Observation Battery   |
| G                | Granular Formulation   |
| GENEEC           | Tier I Surface Water Computer Model  |
| GLN              | Guideline Number   |
| HAFT             | Highest Average Field Trial  |
| IR               | Index Reservoir  |
| LC <sub>50</sub> | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.       |
| LD <sub>50</sub> | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LOC              | Level of Concern   |
| LOD              | Limit of Detection   |
| LOAEL            | Lowest Observed Adverse Effect Level   |
| MATC             | Maximum Acceptable Toxicant Concentration  |
| $\mu\text{g/g}$  | Micrograms Per Gram  |
| $\mu\text{g/L}$  | Micrograms Per Liter   |
| mg/kg/day        | Milligram Per Kilogram Per Day   |
| mg/L             | Milligrams Per Liter   |

|                  |  |
|------------------|--|
| MOE              | Margin of Exposure   |
| MRID             | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| MUP              | Manufacturing-Use Product  |
| NA               | Not Applicable   |
| NAWQA            | USGS National Water Quality Assessment   |
| NPDES            | National Pollutant Discharge Elimination System  |
| NR               | Not Required   |
| NOAEL            | No Observed Adverse Effect Level   |
| OP               | Organophosphate  |
| OPP              | EPA Office of Pesticide Programs   |
| OPPTS            | EPA Office of Prevention, Pesticides and Toxic Substances  |
| PAD              | Population Adjusted Dose   |
| PCA              | Percent Crop Area  |
| PDP              | USDA Pesticide Data Program  |
| PHED             | Pesticide Handler's Exposure Data  |
| PHI              | Preharvest Interval  |
| ppb              | Parts Per Billion  |
| PPE              | Personal Protective Equipment  |
| ppm              | Parts Per Million  |
| PRZM/EXAMS       | Tier II Surface Water Computer Model   |
| Q <sub>1</sub> * | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model              |
| RAC              | Raw Agriculture Commodity  |
| RED              | Reregistration Eligibility Decision  |
| REI              | Restricted Entry Interval  |
| RfD              | Reference Dose   |
| RQ               | Risk Quotient  |
| SCI-GROW         | Tier I Ground Water Computer Model   |
| SAP              | Science Advisory Panel   |
| SF               | Safety Factor  |
| SLC              | Single Layer Clothing  |
| SLN              | Special Local Need (Registrations Under Section 24(c) of FIFRA)                                  |
| TGAI             | Technical Grade Active Ingredient  |
| TRR              | Total Radioactive Residue  |
| USDA             | United States Department of Agriculture  |
| USGS             | United States Geological Survey  |
| UF               | Uncertainty Factor   |
| UV               | Ultraviolet  |
| WPS              | Worker Protection Standard   |



## I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data to the EPA. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of sethoxydim, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. As a result of this review, EPA has determined that all products solely containing the active ingredient sethoxydim are eligible for reregistration. The completion of the sethoxydim RED does not result in any additional tolerances being reassessed since all existing tolerances (85) were reassessed at the time a new food use was established for sethoxydim [63FR54066 (10/8/1998)].

Risks summarized in this document are those that result only from the use of sethoxydim. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency should consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." 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. Therefore, EPA has not assumed that sethoxydim shares 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 of toxicity on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

## II. Use Profile

Sethoxydim [2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]3-hydroxy-2-cyclohexen-1-one] is a member of the *cyclohexanedione or cyclohexenone* class of herbicides. The mode of action for this herbicide is lipid biosynthesis inhibition. Sensitivity has been demonstrated to be due to a greater susceptibility at the acetyl-CoA carboxylase (ACCase) enzyme of grass species. These grass species are killed by the inhibition of the ACCase *enzyme*, which is a key enzyme in the lipid biosynthetic pathway.

Sethoxydim is used post-emergence for selective control of annual and perennial grass weeds in broadleaf crops. Sethoxydim is currently registered for use in or on at least 86 different agricultural crops such as various grains, fruits, tree nuts, vegetables

and herbs, as well as non-agricultural sites, including ornamentals and flowering plants, recreational areas, right-of-way, along fences, hedgerows, and public and commercial buildings/structures. The principal sethoxydim uses are on soybeans, sunflowers, alfalfa, dry peas/beans, sugar beets, peanuts and corn.

Sethoxydim is formulated as a liquid. Sethoxydim application methods include high and low pressure handwand, backpack, garden hose-end, handgun (lawn) sprayers, groundboom sprayers and aerial equipment. It is applied between 0.09 - 0.47 lbs a.i./A in or on actively growing crops ranging from a min. interval of 10-21 days on annual and perennial grasses (based on the emergence of grass weeds).

Close to a million pounds of the active ingredient sethoxydim are applied each year, with the vast majority being used in the agricultural setting. The principal sethoxydim uses are on soybeans, sunflowers, alfalfa, dry peas/beans, sugar beets, peanuts and corn.

### III. Human Health Risk Assessment

#### A. Toxicology

For more detailed information, see “*Sethoxydim: HED Chapter of the Reregistration Eligibility Decision (RED) Document*”; W. Donovan; 9/27/05.

The toxicity database for sethoxydim is complete and there are no data gaps. The acute toxicity data indicate that sethoxydim is moderately toxic (Category III) via oral, dermal, and inhalation routes of exposure. It is neither irritating to the eye nor the skin (Category IV).

**Table 1: Acute Toxicity Profile for Sethoxydim**

| Guideline No. | Study Type                        | MRIDs #  | Results   | Toxicity Category |
|---------------|-----------------------------------|----------|---|-------------------|
| 870.1100      | Acute Oral- Rats                  | 00045847 | LD <sub>50</sub> = M: 3125 mg/kg, F: 2676 mg/kg   | III               |
| 870.1200      | Acute Dermal- Rats                | 00045848 | LD <sub>50</sub> = > 5000 mg/kg   | III               |
| 870.1300      | Acute Inhalation- Rats            | 00045849 | LC <sub>50</sub> = M: 603 m/L, F: 6.28 m/L<br>Aerosol composed of NP-55 (25%), DMSO (75%).  | III               |
| 870.2400      | Primary Eye Irritation- Rabbits   | 00045850 | No Irritation   | IV                |
| 870.2500      | Primary Skin Irritation- Rabbits  | 00045851 | No Irritation   | IV                |
| 870.2600      | Dermal Sensitization- Guinea pigs | 00045852 | Study waived based on lack of sensitization in guinea pigs treated with an end-use product. Therefore, the EPA does not consider sethoxydim to be a sensitizer. |                   |

The liver appears to be the most significant target organ for sethoxydim exposure in laboratory animals. In a chronic oral dog feeding study, increased absolute and relative liver weights were observed at the higher dose levels, and clinical chemistry and histopathology results also indicate liver effects. In addition, adverse liver effects were observed via the oral route in another species (mice) and via another route of exposure (inhalation) in rats.

The Agency considers the sethoxydim database to be adequate to assess developmental toxicity without the need to require a developmental neurotoxicity (DNT) study. Although the clinical signs following exposure in the rat prenatal developmental toxicity study (MRID 43092902) include irregular gait, decreased activity, excessive salivation, and anogenital staining, which suggest neurotoxicity, the high dose at which these effects occurred suggest a non-specific response and do not justify the need for a DNT study.

Sethoxydim is not likely to be a carcinogenic in humans based on lack of evidence of carcinogenicity in rats and mice; therefore, a dietary cancer exposure analysis was not conducted.

The Agency reduced the default 10X FQPA safety factor for potential special sensitivity in infants and children to 1X because the sethoxydim database includes an acceptable developmental study in rats (MRID 43092902) which showed no concerns for pre- or post-natal toxicity. Further, the study showed a well characterized dose response, and a clear NOAEL/LOAEL. Additionally, no evidence of sensitivity either in dose response or in severity of the effects was observed.

A rat developmental study (MRID 43092902) was used to select the dose and endpoint for establishing the acute reference dose (RfD) of 1.8 mg/kg/day. The acute RfD was calculated by dividing the No-Observed-Adverse-Effect-Level (NOAEL) of 180 mg/kg/day from this study by an uncertainty factor (UF) of 100 [10X for interspecies extrapolation and 10X for intraspecies variation]. Both Maternal effects (gait impairment) and offspring effects (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, sternbrae and/or metatarsals, and pubes in pups) were observed at the LOAEL of 650 mg/kg/day. Since the developmental effects and maternal effects were observed at the same dose level, this RfD is applicable to the general U.S. population as well as females ages 13-50 and all other population subgroups. The acute Population-Adjusted-Dose (aPAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) is equal to the acute RfD divided by the FQPA SF (1X), and therefore the aPAD is equal to the acute RfD (1.8 mg/kg/day).

The mouse combined chronic toxicity/carcinogenicity study was used to select the dose and endpoint for establishing the chronic RfD of 0.14 mg/kg/day. The FQPA SF is 1X, and therefore the chronic Population-Adjusted-Dose (cPAD) is 0.14 mg/kg/day. The NOAEL of 14 mg/kg/day and the LOAEL of 41.2 mg/kg were based on early onset of

liver effects including hepatocellular hypertrophy and fatty degeneration. A 100-fold uncertainty factor (10X interspecies and 10X intraspecies) was applied.

No dermal toxicity endpoints have been established because no dermal or systemic toxicity was seen following repeated dermal applications of sethoxydim at the limit-dose to rabbits. The 21-day dermal study showed no effects at the highest dose tested.

A rat developmental study (the same as was used for assessing acute dietary exposure) was used to select the dose and endpoint for short-term incidental oral exposure. The maternal NOAEL was 180 mg/kg/day and maternal LOAEL was 650 mg/kg/day based on irregular gait observed in dams on the first day of dosing. Intermediate-term incidental oral exposure is not anticipated; therefore, no endpoint was selected.

A rat 28-day inhalation study (MRID 44021202) was used to select the dose and endpoint for inhalation exposure. The NOAEL was 0.3 mg/L (81 mg/kg/day) and LOAEL was 2.4 mg/L (651 mg/kg/day) based on liver weight, clinical chemistry (bilirubin) and histology. This endpoint was used for all inhalation exposure durations.

Table 2 provides a summary of the toxicological endpoints selected for sethoxydim.

**Table 2: Sethoxydim Endpoint Selection Summary**

| <b>Exposure Scenario</b>                             | <b>Dose &amp; Uncertainty Factor</b>  | <b>Endpoint</b>   | <b>Study/MRID</b>   |
|--|---|---|---|
| Acute Dietary (general population)                   | NOAEL 180 mg/kg/day<br>UF = 100X<br>FQPA SF = 1x<br>Acute PAD = 1.8 mg/kg/day     | Irregular gait that was observed in 12/34 dams on the first day of dosing.                                      | Rat Developmental Toxicity<br>LOAEL = 650 mg/kg/day.<br>MRID No. 43092902               |
| Acute Dietary (females 13-50 years old)              | NOAEL 180 mg/kg/day<br>UF = 100X<br>FQPA SF = 1x<br>Acute PAD = 1.8 mg/kg/day     | Decreased fetal body weight, tail abnormalities, delayed ossification.  | Rat Developmental Toxicity<br>developmental LOAEL = 650 mg/kg/day.<br>MRID No. 43092902 |
| Chronic Dietary (all populations)                    | NOAEL = 13.8 mg/kg/day<br>UF = 100X<br>FQPA SF = 1x<br>Acute PAD = 0.14 mg/kg/day | Early onset of liver effects including Hepatocellular hypertrophy and fatty degeneration in male mice.          | Chronic toxicity/carcinogenicity study in mice.<br>MRID No. 00100527                    |
| Occupational and Residential Inhalation (short-term) | NOAEL = 81 mg/kg/day<br>UF = 100X   | Based on increased liver weight, clinical chemistry (increased total serum bilirubin) and liver histopathology. | 28-day Rat Inhalation<br>LOAEL = 651 mg/kg/day<br>MRID No. 44021202                     |
| Residential Incidental Oral (short-term)             | NOAEL = 180 mg/kg/day<br>UF = 100X<br>FQPA SF = 1x                                | Based on irregular gait observed in 12/34 dams on the first day of dosing                                       | Rat Developmental Toxicity<br>LOAEL = 650 mg/kg/day.<br>MRID No. 43092902               |

Sethoxydim is not a likely human carcinogen based on lack of evidence of carcinogenicity in rats and mice

## B. Dietary Risk from Food

For more detailed information, see “*Sethoxydim: HED Chapter of the Reregistration Eligibility Decision (RED) Document*”; W. Donovan; 9/27/05

The acute dietary exposure was estimated using DEEM-FCID™, Version 1.30, which incorporates food consumption data from USDA’s Continuing Survey of Food Intake by Individuals (CSFII), 1994-1996, 1998. The acute assessment used tolerance level residues for most of the crops. Limited refinement, however, was obtained through the incorporation of field trial data and processing factors for some of the crops expected to be more highly associated with dietary exposure to sethoxydim. Specifically, field trial data were used for pome fruit, grapes, oranges, potatoes, strawberries, peaches, succulent green peas, succulent green beans, and succulent lima beans. Empirical processing factors were used for apples, grapes, tomatoes, potatoes, and oranges. The processing factor for orange juice was translated to other citrus juices. Percent crop treated 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.

Acute dietary risk is calculated based on the toxicity as well as the type and quantity of food eaten in one day and the maximum, or high-end, residue values in the food. A risk estimate that is less than 100% of the aPAD does not exceed the Agency’s level of concern.

Exposure at the 99.9<sup>th</sup> percentile showed an estimated 5.3% of the aPAD for the general US population, and an estimated 9.2% of the aPAD for children 1-2 years old and children 3-5 years old (the two most highly exposed population subgroups). Thus, the acute dietary analysis for sethoxydim shows that the estimated risks from acute dietary exposure to sethoxydim are well below the Agency’s level of concern (<100% of the aPAD) for the general US population and all other population subgroups. Table 3, below, summarizes the acute dietary risks.

**Table 3: Acute Dietary Risk from Sethoxydim\***

| Population Subgroup     | 99.9 <sup>th</sup> Percentile |        |
|-------------------------|-------------------------------|--------|
|                         | Exposure (mg/kg/day)          | % aPAD |
| General U.S. Population | 0.096                         | 5.3    |
| Children 1-2 years old  | 0.165                         | 9.2    |
| Children 3-5 years old  | 0.165                         | 9.2    |

\* Assuming an aPAD of 1.8 mg/kg/day

DEEM™ was also used to calculate the chronic dietary exposure estimates based on average consumption for the U.S. population and population subgroups including infants and children. The chronic analysis (limited refined dietary risk assessment) used tolerance level residues for all crops, percent crop treated for many crops, and anticipated residues for meat and milk. The most highly exposed population subgroup is infants (<1

year old), at an estimated 7.5% of the cPAD. The results of the analysis indicate that the chronic dietary risk (food only) associated with existing uses of sethoxydim is well below the Agency’s level of concern (<100% of the cPAD) for the general U.S. population and all population subgroups. Table 4, below, summarizes the chronic dietary risks.

**Table 4: Chronic Dietary Risk for Sethoxydim\***

| <b>Population Subgroup</b> | <b>Exposure (mg/kg/day)</b> | <b>% cPAD</b> |
|----------------------------|-----------------------------|---------------|
| General U.S. Population    | 0.004                       | 2.7           |
| All Infants (< 1 year old) | 0.010                       | 7.5           |

\* Assuming a cPAD of 0.14 mg/kg/day

### **C. Dietary Risk from Drinking Water**

For more detailed information, see “*Sethoxydim: HED Chapter of the Reregistration Eligibility Decision (RED) Document*”; W. Donovan; 9/27/05

Exposure to pesticides through drinking water can occur as a result of groundwater or surface water contamination. EPA considers both acute (one day) and chronic (multiple year) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of increasing refinement, but is designed to provide high-end estimates of exposure. To determine the maximum allowable contribution from water in the diet, EPA first looks at how much of the overall risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC). The DWLOC represents the maximum allowable contribution to the human diet that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or cPAD.

For sethoxydim, the predominant degradates in soil are the sulfoxide and sulfone derivatives of the parent (MSO and MSO2). These degradates are expected to be found in water along with M1S and M2S. Toxicology data for the four degradates are not available. In the absence of such data, the Agency has assumed that these degradates are as toxic as the parent to ensure that risk will not be underestimated. Therefore, for risk assessment purposes the “total sethoxydim residues” in water should be used instead of the levels for only parent sethoxydim. Modeling estimates were used to quantify possible drinking water exposure. The Estimated Drinking Water Concentrations (EDWCs) were less than the DWLOCs for both acute and chronic exposure to sethoxydim in drinking water, and therefore below the Agency’s level of concern.

The surface water assessment used a Tier 1 model called FIRST (FQPA Index Reservoir Screening Tool), which is a simulation model based on a high runoff scenario (Mississippi cotton) with a storm two days after application. The modeling was performed using the maximum number of applications (four) and maximum application rate of 0.47 pounds active ingredient per acre, assuming a 14-day retreatment interval. The default percent cropped area (PCA) assumed that sethoxydim-treated crops were grown on 87% of the acres of land in the modeled watershed, which is the highest PCA for any watershed in the continental United States and is used as the default value for minor crops. Lower PCA

values could have been applied for the major crops on which sethoxydim is used such as soybeans, cotton and corn. However, because there is such a variety of uses, it is likely that there is usage on major and minor crops in the same watershed, so the crop-specific PCA may not be applicable.

The EDWC for ground water was estimated by the SCI-GROW model, version 2.3. The results of the model for acute and chronic scenarios are 1.5 ppb for parent sethoxydim plus metabolites when assuming a maximum use rate of 1.875 lb ai/A per year.

DWLOCs are calculated by subtracting the contribution of food exposure from the PAD. Because the EDWCs are much less than the DWLOCs, dietary (food plus drinking water) risk is below the EPA’s Level of Concern (LOC). See Table 5, below, for a summary of these findings.

**Table 5: Sethoxydim: Acute and Chronic DWLOC Values Compared to Modeled EDWCs**

| Assessment Type | Most Sensitive Population Subgroup    | DWLOC (ppb) | EDWC (Surface Water) (ppb) | EDWC (Ground Water) (ppb) |
|-----------------|---------------------------------------|-------------|----------------------------|---------------------------|
| Acute           | Children 1-2 yrs. & Children 3-5 yrs. | 16,400      | 130                        | 1.5                       |
| Chronic         | All infants (<1 year)                 | 1,300       | 16                         | 1.5                       |

#### **D. Residential Risk**

Sethoxydim is registered for residential (consumer) use on ornamentals and flowering plants, lawns, recreational areas, and around buildings/structures (outdoor). Homeowners who apply sethoxydim may be exposed for short-term durations through the dermal and inhalation routes of exposure. Children who have contact with sethoxydim-treated turf in recreational or residential settings after a sethoxydim application has occurred (post-application) may be exposed for short-term durations through the dermal and incidental oral routes of exposure. For sethoxydim, however, the dermal route of exposure was not assessed because no toxic effects were seen in the dermal toxicity study. See Table 2 for a summary of the sethoxydim endpoints selected for this RED.

Residential risk is measured by a Margin of Exposure (MOE) which measures how close the residential exposure comes to the NOAEL from animal studies. For sethoxydim, exposure scenarios that yield MOEs that are greater than 100 do not exceed the Agency’s level of concern. This incorporates the standard uncertainty factors of 10x for interspecies variability and 10x for intraspecies variability.

#### Residential Handler Risk:

Inhalation MOEs calculated for residential handler scenarios ranged from 1,400,000 to 1,600,000. These MOEs are greater than 100, and therefore these use scenarios are not of concern to the agency.

Residential Post-application Risk:

Post-application risk scenarios assessed for sethoxydim included the following toddler scenarios: hand-to-mouth activity on turf; object-to-mouth activity on turf; and incidental soil ingestion.

Estimated MOEs for short-term post-application incidental ingestion to toddlers range from 26,000 for hand-to-mouth incidental exposures to 7,600,000 for soil ingestion. These MOEs are above the target MOE of 100 and, therefore, are not of concern to EPA.

**E. Exposure from Use of Tobacco - Health Risk Assessment**

Based on cigarette smoking exposure information, field trial data, a tobacco pyrolysis study, and an assumption that 100% of the sethoxydim will be inhaled and absorbed, EPA estimates that exposure to sethoxydim will not exceed 0.00016 mg/kg/day for males and 0.00018 mg/kg/day for females. The inhalation NOAEL is 81 mg/kg/day and is based on a 28-day inhalation study in the rat. The Agency did not examine the intermediate or long-term exposure to sethoxydim via tobacco due to the severity and quantity of health effects associated with the use of tobacco products. Based on the inhalation NOAEL, the short-term MOE for sethoxydim exposure from the use of tobacco is estimated to be greater than 100 (males = 500,000; females = 440,000). This risk is below the Agency's level of concern for all adult populations.

**F. Aggregate Risk**

In accordance with FQPA, the Agency must consider and aggregate pesticide exposures and risks for varying durations of exposure from the following major sources or pathways: food, drinking water, and residential exposure to homeowners.

In the case of sethoxydim, residential exposure was aggregated with dietary exposures only for the short-term exposure duration. Acute residential exposure was not aggregated with acute dietary exposures because it is extremely unlikely that acute turf exposures would occur concurrently with high-end acute dietary exposures. Likewise, there are no chronic residential scenarios for sethoxydim; therefore, chronic dietary risks were not aggregated with residential risks. As a result, acute and chronic aggregate risks are equal to acute and chronic dietary risks. Section IIIC above presents these results which are below EPA level of concern for the U.S. population and all population subgroups.

Short-Term Aggregate Risk:

Short-term aggregate risk assessments were not calculated for adult handlers because oral and inhalation endpoints lack a common toxicity endpoint. Dermal risks were not assessed because there is no dermal endpoint of concern for sethoxydim.



Short-term aggregate risk assessments are required for children/toddlers because there is a potential for incidental oral post-application exposure resulting from the residential uses of sethoxydim. The children/toddlers 1-2 years of age scenario was chosen because it was the highest estimated food exposure and thus, is also protective of all other children. The MOEs are greater than 100, and therefore the short-term residential risks are below the Agency's level of concern. For surface and ground water, the estimated average concentrations of sethoxydim are less than the Agency's calculated DWLOCs for sethoxydim in drinking water as a contribution to short-term aggregate exposures. Therefore, EPA concludes with reasonable certainty that aggregate risks resulting from exposure to sethoxydim in food, drinking water, and in residential settings do not result in risks of concern. See Table 6 below for a summary of these results.

**Table 6: Short-Term Aggregate DWLOCs for Sethoxydim**

| Population Subgroup                  | NOAEL (mg/kg/day) | Target MOE <sup>1</sup> | Target Maximum Exposure <sup>2</sup> (mg/kg/day) | Estimated Food Exposure (mg/kg/day) | Estimated Residential Exposure (mg/kg/day) | Allowable Water Exposure <sup>3</sup> (mg/kg/day) | Groundwater EDWC (µg/L) <sup>4</sup> | Surface water EDWC (µg/L) <sup>4</sup> | DWLOC <sup>5</sup> (µg/L) |
|--------------------------------------|-------------------|-------------------------|--|-------------------------------------|--|---|--------------------------------------|--|---------------------------|
| Short-term: Children (1-2 years old) | 180               | 100                     | 1.8  | 0.0095                              | 0.0088                                     | 1.7817  | 1.5                                  | 16                                     | 17,800                    |

1 The short-term target MOE for sethoxydim includes the standard intra- and inter-species uncertainty factors of 10X, as well as the FQPA uncertainty safety factor of 1X.

2 Target Max Exposure = NOAEL / Target MOE

3 Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure (mg/kg/day) - Aggregate Food and Residential Exposure (mg/kg/day).

4 Estimate for the highest use rate was chosen.

5 DWLOC (µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10-3 mg/µg) \* water consumed daily (L/day)]. HED standard body weight: All Infants/Children, 10 kg. HED standard daily drinking rate: 1 L/day for children.

## G. Cumulative Risk

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 purpose of this assessment, EPA has not assumed that sethoxydim shares 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 at <http://www.epa.gov/pesticides/cumulative/>.

## H. Occupational Risk

For more detailed information, see "*Sethoxydim: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*"; W. Britton; 6/22/05.

Pesticide handlers are likely to be exposed during the occupational use of sethoxydim in a variety of occupational environments. Since no chemical-specific

handler exposure data are available for sethoxydim, short- and intermediate-term inhalation exposures were assessed using data from the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED data were used with other Agency standard values for areas treated per day, body weight and the level of personal protective equipment (PPE) and engineering controls to assess handler exposures to sethoxydim. Using these assumptions, the calculated occupational handler inhalation risks do not exceed EPA's level of concern (i.e., MOEs > 100) for all exposure scenarios. Short- and intermediate-term inhalation MOEs range from 3,100 (right-of-way sprayer application) to more than 1,900,000 (mixing/loading/applying liquids for low pressure handwand application) at baseline, i.e., no respirator. Dermal exposure was not assessed because a dermal endpoint of concern has not been identified for sethoxydim.

Post-application exposure was not assessed because there is no dermal endpoint of concern and post-application inhalation exposure is expected to be negligible.

#### **IV. Ecological Risk Assessment**

For more detailed information, see "*EFED's Reregistration Eligibility Decision Chapter for Sethoxydim Screening*"; Michael Davy, et al; 6/22/2005.

##### **A. Environmental Fate and Transport**

Sethoxydim has a high solubility and mobility with a low octanol/water partition coefficient. Sethoxydim is unlikely to contaminate ground or surface waters because it is not persistent under most conditions. Under aerobic conditions, half-lives were <1 day. However, the sethoxydim transformation products may be persistent and mobile enough to cause a potential threat to water resources. The transformation mechanisms of parent sethoxydim and residues include: photodegradation; aerobic metabolism in water and soil; and acid-catalyzed hydrolysis in water.

##### **B. Aquatic Organism Risk**

The technical sethoxydim acute LOCs for fish and aquatic invertebrates are not exceeded (at application rate of 0.47 lb/A).

Chronic aquatic data submitted for estuarine fish and invertebrates indicate that chronic risks to estuarine animals are below the Agency's level of concern. Chronic data for freshwater fish and invertebrates are not available to the Agency. Therefore, a risk assessment for freshwater fish and invertebrates can not be conducted at this time.

Sethoxydim is known to be phytotoxic to terrestrial grasses, but aquatic grasses (monocots) were not tested for their response to sethoxydim; thus we cannot make a definitive assessment of the risk to vascular aquatic plants. The tested species (duckweed) is a dicot, and is not expected to be sensitive to sethoxydim (at the maximum exposure rate of 0.47 lb ai/A). However, adverse effects to aquatic monocots cannot be precluded.

### C. Terrestrial Organism Risk

The Agency assessed exposure to terrestrial organisms by first predicting the amount of sethoxydim residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various species of birds and mammals. The amount of residues estimated to be found on animal feed items is based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.) and the current maximum application rate for sethoxydim.

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals, emphasizing a dietary exposure route for uptake of pesticides. These exposures are considered as surrogates for terrestrial-phase amphibians as well as reptiles. For acute exposure to terrestrial organisms, such as birds and small mammals, pesticide residues on food items are estimated, based on maximum application rate and estimated residues at the time of application. Degradation is factored into chronic exposure calculations.

Since sethoxydim is practically non-toxic to birds on an acute basis, we presume that birds are not at acute risk. When maximum EECs are considered, all chronic RQ values for birds exceed the LOC of 1.0 for most food items. However, when mean EECs were considered, the chronic LOC was exceeded only for animals consuming short grass from applications to citrus and tree nut sites. The highest modeled RQs were for citrus and tree nut sites, where the RQ for the short grass scenario based on maximum EECs was >3.12, assuming a default foliar half-life of 35 days. RQs calculated for maximum and mean EECs for various crops and food items are given in Table 7

**Table 7: Avian Organism Chronic Risk Quotient (Chronic Level of Concern = 1)**

| Site (not inclusive)                                 | No. of Apps. | App.Rate (lbs ai/A) | Food Items              | Avian Chronic Risk Quotient based on Max. EEC and NOAEC < 100 ppm <sup>1</sup> | Avian Chronic Risk Quotient based on Mean EEC and NOAEC < 100 ppm |
|--|--------------|---------------------|-------------------------|--|---|
| Citrus, tree nuts                                    | 4            | 0.47                | Short grass             | >3.12  | >1.11   |
|  |              |                     | Tall grass              | >1.43  | >0.47   |
|  |              |                     | Broadleaf plants/Insect | >1.76  | >0.59   |
|  |              |                     | Seeds                   | >0.20  | >0.09   |
| Alfalfa, birdfoot trefoil, sainfoin, clover, cotton, | 3            | 0.47                | Short grass             | >2.63  | >0.93   |
|  |              |                     | Tall grass              | >1.21  | >0.39   |
|  |              |                     | Broadleaf plants/Insect | >1.48  | >0.49   |
|  |              |                     | Seeds                   | >0.16  | >0.08   |
| Fruiting and leafy vegetable crop group              | 3            | 0.28                | Short grass             | >1.57  | >0.56   |
|  |              |                     | Tall grass              | >0.72  | >0.24   |
|  |              |                     | Broadleaf plants/Insect | >0.88  | >0.29   |
|  |              |                     | Seeds                   | >0.10  | >0.05   |

| Site (not inclusive)   | No. of Apps. | App.Rate (lbs ai/A) | Food Items              | Avian Chronic Risk Quotient based on Max. EEC and NOAEC < 100 ppm <sup>1</sup> | Avian Chronic Risk Quotient based on Mean EEC and NOAEC < 100 ppm |
|--|--------------|---------------------|-------------------------|--|---|
| Soybeans, grape, berries, peanut, Head & petiole vegetable crop subgroup, mint, pea, potato, safflower, sugar beets, Christmas tree farms, ornamentals, rights of way, roadsides, turf | 2            | 0.47                | Short grass             | >1.98  | >0.70   |
|  |              |                     | Tall grass              | >0.91  | >0.30   |
|  |              |                     | Broadleaf plants/Insect | >1.12  | >0.37   |
|  |              |                     | Seeds                   | >0.12  | >0.06   |
| Orchard floor middles, strawberry, sunflower   | 1            | 0.47                | Short grass             | >1.13  | >0.40   |

\* Assuming NOAEC <100ppm.

Technical sethoxydim is practically non-toxic to mammals on an acute basis and no risks are expected for maximum label rates. The chronic RQs for mammals did not exceed the LOC of 1.0 with a maximum RQ of 0.5 at the highest exposure level.

Sethoxydim is practically non-toxic to honey bees. Adverse effects to beneficial insects are not expected at maximum label rates.

For terrestrial plants, sethoxydim is selectively toxic to grasses, which are monocot plants, and is not particularly toxic to dicots. Based on the screening risk assessment, there is a risk to non-target grasses.

Based on modeled EECs and the available toxicity data, RQ values for all uses of sethoxydim application scenarios exceed the LOC for listed and non-listed non-target terrestrial plants and terrestrial plants in semi-aquatic areas. RQs resulting from spray drift are not of concern, but RQs resulting from run-off scenarios for non-listed plants range from 1.3 to 3.1 and RQs for listed plants range from 1.7 to 4.1. These risks were calculated from toxicity values from the technical product and not the formulated product. Plant risks are generally calculated from formulated product and, therefore, these RQs may underestimate the risks to terrestrial plants from use of sethoxydim due to presence of solvents in end-use products.

#### **D. Risk Characterization**

The Agency usually assesses ecological risks for animals on the technical active ingredient only. As described in the ecological risk assessment section, the parent compound does not pose a risk to the aquatic environment. However, for sethoxydim, the Agency had some additional aquatic organism toxicity studies conducted with the formulated products which contained two chemical stressors: the first is the active ingredient; sethoxydim and its degradates; and the second stressor is the petroleum solvent used in some end-use formulations including POAST® and POAST® Plus. This solvent is known to contain several percent by weight of naphthalene, which is also a registered active ingredient (PC code 055801). Naphthalene will be considered in a separate reregistration eligibility decision (RED scheduled for March, 2008). In these studies, the Agency assumes that sethoxydim is the stressor responsible for most

observed effects to plants and birds, and the petroleum solvent is the stressor responsible for most observed effects risks to fish and aquatic invertebrates (fresh- and salt-water).

While technical sethoxydim is practically non-toxic to fish and invertebrates on an acute basis, an 18% Typical End-Use product (TEP) is moderately toxic to these organisms. The formulation of the TEP contains a petroleum solvent (CAS Registry. No. 64742-94-5) that is known to contain naphthalene. Acute toxicity data for naphthalene indicate that it has toxicity similar to that of the TEP. Thus, any acute risk to aquatic freshwater or estuarine animals from the use of sethoxydim formulated with this petroleum solvent may be in fact attributable to the solvent. The estuarine chronic studies which resulted in low toxicity were also conducted with formulated products, but the solvent content in these formulations is unknown.

Since, the avian chronic reproduction study with the active ingredient did not achieve a no effect level, chronic avian toxicity may be underestimated. However, RQs were generally not of concern even though conservative exposure assumptions were used for calculation purposes.

The estimated risk to non-target plants may be underestimated due to lack of valid vegetative vigor studies conducted with a Typical End Use product (TEP). Using the TEP in terrestrial plant studies is important because most herbicides use adjuvants to penetrate the plant cuticle and other plant defenses in order to get the active ingredient into the plant to adversely affect the plant. Another tier II vegetative vigor study conducted with a TEP on at least three grass species including corn should be conducted to assess risk to non-target grass species. Although there are currently no data which will allow comparison of toxicity between technical sethoxydim and the TEP, both appear to be phytotoxic to grass species only. There are no data available to the Agency which would allow comparison of toxicity between the technical active ingredient and a TEP.

#### **E. Endangered Species Concerns**

The risk profile for various taxa varies based upon whether assessments were performed using data from studies conducted with the active ingredient or a formulated product. Based on data obtained from studies using the active ingredient, the screening level ecological risk assessment for endangered species resulted in a determination that sethoxydim results in no direct effects, either chronic or acute, to: mammals; aquatic phase amphibians; mollusks; and marine/estuarine fish and crustaceans. There also are no direct acute effects to avian species, freshwater fish and crustaceans, and no direct effects to terrestrial and semi-aquatic dicots. A bee toxicity study indicted that sethoxydim technical is practically non-toxic to bees on an acute contact basis which implies there is likely not a direct acute effect to insects.

The Agency's levels of concern is exceeded for direct chronic effects to birds, and effects to terrestrial and semi-aquatic monocots. Testing on aquatic plants is only required on *Lemna gibba*, a dicotyledonous species, which did not demonstrate effects. However, effects to aquatic grasses can not be ruled out. Reptiles and terrestrial phase

amphibians are not tested but are assumed to have potential effects similar to the effects observed in birds. Based on the exceedence of the LOC for direct chronic effects to bird, effects to reptiles and to terrestrial phase amphibians can not be ruled out based on the screening level assessment. Additionally, there are no data to assess potential chronic effects to freshwater fish and crustaceans and therefore, chronic risk to these species can not be ruled out. Further, indirect effects can not be ruled out for any species that depends upon a taxa that may experience direct effects.

Even given the determinations above, because there are uncertainties regarding the potential toxicity of the TEPs, and the potential exposure from spray drift to shallow bodies of water, direct acute effects can not be precluded at this time to freshwater fish and crustaceans, aquatic phase amphibians, mollusks, marine/estuarine fish and marine/estuarine crustaceans (see section C. **Aquatic Organism Risk to Formulated Product**, above).

These findings are based solely on EPA's screening level assessments and do not constitute "may affect" findings under the Endangered Species Act.

## V. Risk Mitigation Summary

The Agency is not requiring any additional risk-based mitigation measures for sethoxydim at this time. The sethoxydim database is sufficient to perform the necessary risk assessments. The chemical's toxicity, when reviewed in conjunction with the current use patterns, does not result in the need to impose additional label restrictions under FIFRA at this time. However, additional data are required in order to confirm the risk conclusions reached in this document. The tolerance revision actions outlined in Table 8 below are necessary based on the legal requirements of FIFRA, FFDCFA and FQPA, despite the absence of dietary risk. No additional tolerances are considered reassessed as a result of this RED.

For worker risks, per the Worker Protection Standard, a 12-hour restricted entry interval (REI) is required for chemicals classified as acute Toxicity Category III for dermal toxicity and IV for skin and eye irritation. Sethoxydim is classified in Toxicity Category III for acute oral, dermal and inhalation, and Toxicity Category IV for and primary eye and skin irritation; therefore, the current REI of 12 hours is appropriate and will remain on labels. This assessment also confirms that the baseline PPE currently on sethoxydim labels is still adequate for this chemical, and no changes to the labeled PPE statements are required.

### A. Tolerance Reassessment

For more detailed information, see "*Sethoxydim. HED Chemistry Chapter of the Reregistration Eligibility Decision (RED)*"; W. Donovan; 9/27/2005.

Tolerances have been established under 40 CFR §180.412 for the combined residues of sethoxydim [2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 2-cyclohexene-1-one moiety

(calculated as sethoxydim) in or on numerous plant and animal, food and feed commodities. The completion of the sethoxydim RED does not result in any additional tolerances being reassessed since all existing tolerances (85) were reassessed at the time a new food use was established for sethoxydim [63FR54066 (10/8/1998)]. See Table 8, below, for a summary of the sethoxydim tolerances.

**Table 8. Tolerance Reassessment Summary for Sethoxydim**

| Commodity                    | Established Tolerance (ppm) | Tolerance Reassessment (ppm) | Comments (correct commodity definition)   |
|------------------------------|-----------------------------|------------------------------|---|
| Alfalfa forage               | 40                          | 40                           |   |
| Alfalfa hay                  | 40                          | 40                           |   |
| Almond, hulls                | 2                           | 2                            |   |
| Apple, dry pomace            | 0.8                         | 0.80                         | Apple, dried pomace                       |
| Apple, wet pomace            | 0.8                         | Revoke                       | Revoke: not a significant feedstuff       |
| Apricot                      | 0.2                         | 0.2                          |   |
| Artichoke, globe             | 5                           | 5                            | Tolerance with Regional Registration      |
| Asparagus                    | 4                           | 4                            |   |
| Bean, dry, seed              | 20                          | Revoke                       | Included in subgroup 6C                   |
| Bean, forage                 | 15                          | 15                           | Cowpea, forage                            |
| Bean, hay                    | 50                          | 50                           | Cowpea, hay                               |
| Bean, succulent              | 15                          | 15                           |   |
| Beet, garden                 | 1                           | 1                            | Beet, garden, roots                       |
| Beet, sugar, molasses        | 10                          | 10                           |   |
| Beet, sugar, roots           | 1                           | 1                            |   |
| Beet, sugar, tops            | 3                           | 3                            |   |
| Blueberry                    | 4                           | 4                            |   |
| Caneberry subgroup           | 5                           | 5                            | Caneberry subgroup 13A                    |
| Canola/rapeseed              | 35                          | 35                           | Rapeseed, seed                            |
| Canola/rapeseed, meal        | 40                          | 40                           | Rapeseed, meal                            |
| Carrot                       | 1                           | 1                            |   |
| Cattle, fat                  | 0.2                         | 0.2                          |   |
| Cattle, meat                 | 0.2                         | 0.2                          |   |
| Cattle, meat byproducts      | 1                           | 1                            |   |
| Cherry, sweet                | 0.2                         | 0.2                          |   |
| Cherry, tart                 | 0.2                         | 0.2                          |   |
| Citrus, dried pulp           | 1.5                         | 1.5                          |   |
| Citrus, molasses             | 1.5                         | Revoke                       | Revoke: not a significant feedstuff       |
| Clover, forage               | 35                          | 35                           |   |
| Clover, hay                  | 50                          | 55                           | The maximum residue observed was 50.7 ppm |
| Coriander                    | 4                           | 4                            | Coriander, leaves                         |
| Corn, field, grain           | 0.5                         | 0.5                          |   |
| Corn, forage                 | 2                           | 2                            | Corn, field, forage                       |
| Corn, fodder                 | 2.5                         | 2.5                          | Corn, field, stover                       |
| Corn, sweet, forage          | 3                           | 3                            |   |
| Corn, sweet, kernel plus cob | 0.4                         | 0.4                          |   |
| Corn, sweet, stover          | 3.5                         | 3.5                          |   |
| Cotton, seed, soapstock      | 1.5                         | Revoke                       | Revoke: not a significant feedstuff       |
| Cotton, undelinted seed      | 5                           | 5                            |   |
| Cranberry                    | 2                           | 2.5                          | The maximum residue observed was 2.2 ppm  |
| Egg                          | 2                           | 2                            |   |

| Commodity  | Established Tolerance (ppm) | Tolerance Reassessment (ppm) | Comments (correct commodity definition)   |
|--|-----------------------------|------------------------------|---|
| Flax, meal   | 7                           | Revoke                       | Revoke: Covered by flax, seed tolerance   |
| Flax, seed   | 5                           | 5                            |   |
| Flax, straw  | 2                           | Revoke                       | Revoke: not a significant feedstuff   |
| Fruit, citrus  | 0.5                         | 0.5                          | Fruit, citrus, group 10   |
| Fruit, pome  | 0.2                         | 0.2                          | Fruit, pome, group 11   |
| Goat, fat  | 0.2                         | 0.2                          |   |
| Goat, meat   | 0.2                         | 0.2                          |   |
| Goat, meat byproducts                                    | 1                           | 1                            |   |
| Grape  | 1                           | 1                            |   |
| Grape, raisin  | 2                           | 2                            |   |
| Hog, fat   | 0.2                         | 0.2                          |   |
| Hog, meat  | 0.2                         | 0.2                          |   |
| Hog, meat byproducts                                     | 1                           | 1                            |   |
| Horse, fat   | 0.2                         | 0.2                          |   |
| Horse meat   | 0.2                         | 0.2                          |   |
| Horse, meat byproducts                                   | 1                           | 1                            |   |
| Horseradish  | 4                           | 4                            |   |
| Juneberry  | 5                           | 5                            |   |
| Lentil, seed   | 30                          | Revoke                       | Included in subgroup 6C   |
| Lingonberry  | 5                           | 5                            |   |
| Milk   | 0.5                         | 0.5                          |   |
| Nectarine  | 0.2                         | 0.2                          |   |
| Peach  | 0.2                         | 0.2                          |   |
| Peanut   | 25                          | 25                           |   |
| Peanut, soapstock  | 75                          | Revoke                       | Revoke: not a significant feedstuff   |
| Pea and bean, dried shelled, except soybean, subgroup 6C | ---                         | 25                           | Supported by dry pea and dry bean data and tolerance spreadsheet results  |
| Pea, dry, seed   | 40                          | Revoke                       | Included in subgroup 6C   |
| Pea, field, hay  | 40                          | 40                           |   |
| Pea, field, vines  | 20                          | 20                           | Pea, field, forage  |
| Pea, succulent   | 10                          | 10                           |   |
| Peppermint, tops (stems and leaves)                      | 30                          | 30                           | Peppermint, tops  |
| Pistachio  | 0.2                         | 0.2                          |   |
| Potato, flakes   | 8                           | 8                            | Combine these two tolerance expressions into the following: Potato, granules/flakes<br>Potato, processed potato waste |
| Potato, granules   | 8                           |                              |   |
| Potato waste, processed (wet and dry)                    | 8                           | 8                            |   |
| Poultry, fat   | 0.2                         | 0.2                          |   |
| Poultry, meat  | 0.2                         | 0.2                          |   |
| Poultry, meat byproducts                                 | 2                           | 2                            |   |
| Rhubarb  | 0.3                         | 0.3                          | Tolerance with Regional Registration  |
| Safflower  | 15                          | 15                           | Safflower, seed: Two additional safflower field trials are needed from Region 10.                                     |
| Salal  | 5                           | 5                            |   |
| Sheep, fat   | 0.2                         | 0.2                          |   |
| Sheep, meat  | 0.2                         | 0.2                          |   |
| Sheep, meat byproducts                                   | 1                           | 1                            |   |
| Soybean  | 16                          | 16                           | Soybean, seed   |
| Soybean, hay   | 10                          | 10                           |   |
| Spearmint, tops (stems and                               | 30                          | 30                           | Spearmint, tops   |



| Commodity                                  | Established Tolerance (ppm) | Tolerance Reassessment (ppm) | Comments (correct commodity definition)     |
|--|-----------------------------|------------------------------|---|
| leaves                                     |                             |                              |   |
| Strawberry                                 | 10                          | 10                           |   |
| Sunflower, meal                            | 20                          | 20                           |   |
| Sunflower, seed                            | 7                           | 7                            |   |
| Tomato, concentrated products              | 24                          | Revoke                       | Revoke: not a significant feedstuff         |
| Tomato, dry pomace                         | 12                          | Revoke                       | Revoke: not a significant feedstuff         |
| Tree nut                                   | 0.2                         | 0.2                          | Nut, tree, group 14                         |
| Vegetable, brassica, leafy, group 5        | 5                           | 5                            |   |
| Vegetable, bulb, group 3                   | 1                           | 1                            |   |
| Vegetable, cucurbit, group 9               | 4                           | 4                            | Vegetable, cucurbit, group 9                |
| Vegetable, fruiting, group 8               | 4                           | 4                            | Vegetable, fruiting, group 8                |
| Vegetable, leafy, except brassica, group 4 | 4                           | 4                            | Vegetable, leafy, except Brassica , group 4 |
| Tuberous and corn vegetable crop subgroup  | 4                           | 4                            | Vegetable, tuberous and corm, subgroup IC   |

In an attempt to improve sethoxydim tolerance harmonization between the US and Canada, the Agency has reexamined the residue data and tolerance levels for pulse crops. The residue data for dry peas and dry beans reflect identical use patterns and are sufficient to support a tolerance for crop subgroup 6C, “Pea and bean, dried shelled, except soybean, subgroup 6C”. Inserting the field trial data for dry beans and dry peas into the tolerance spreadsheet devised by the NAFTA Tolerance/MRL Harmonization Workgroup results in a recommended tolerance level of 25 ppm for subgroup 6C. Accordingly, the Agency recommends for the establishment of this tolerance level, while the separate tolerance levels for dry pea, dry bean and lentil are revoked since these crops are covered by the crop subgroup tolerance. Harmonization between the US tolerance and the Canadian MRL is under consideration between EPA and Canada’s Pest Management Regulatory Agency (PMRA). The US use pattern specifies a 30-day PHI while the Canadian use pattern specifies a 60-day PHI.

The limited field accumulation study indicated that residues were below the limit of quantitation (0.1 or 0.2 ppm LOQ) of the enforcement method in all rotational crop RACs at all plantback intervals. Since residues in rotational crops are expected to be below the limit of quantitation of the method, tolerances are not required for rotational crops planted greater than 30 days after the primary crop is treated with sethoxydim. The associated label language for this restriction has been submitted by the registrant and approved by the Agency since the revised risk assessments were completed.

## B. Data Gaps

### Ecological Data Requirements

850.4525 Seedling emergence (using TEP)  
850.2300 Avian Reproductive

- 850.1400 Early-life stage Estuarine Fish (using 40% TEP or the technical sethoxydim)
- 850.1350 Life Cycle Aquatic Invertebrate
- 850.4225 Seedling Emergence
- 850.4250 Vegetative Vigor (Partial)
- 850.SS1 Vascular aquatic plant toxicity for grasses (using TEP)

**Residue Chemistry**

- 860.1500 Two safflower field trials from Region 10

**C. Endangered Species**

Potential risks to listed species from the use of sethoxydim are based on a screening level ecological risk assessment and the findings do not constitute “may affect” findings under the Endangered Species Act. Thus, EPA is not imposing any mitigation at this time. However, should EPA’s endangered species-specific assessment indicate that use of sethoxydim “may affect” listed species, then changes to the registered uses of sethoxydim may need to be made as noted below.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis.

Following this future species-specific analysis, a determination that sethoxydim may affect a listed species or adversely modify its critical habitat may result in: limitations on the use of sethoxydim, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of sethoxydim “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). EPA is not requiring specific sethoxydim label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

#### **D. Conclusions**

The Agency is issuing this Reregistration Eligibility Document (RED) for sethoxydim, as announced in a Notice of Availability published in the *Federal Register*. This RED does not include any requirements to amend sethoxydim product label language. The Agency has determined that all currently registered uses of sethoxydim are eligible for reregistration. The completion of the sethoxydim RED does not result in any additional tolerances being reassessed since all existing tolerances (85) were reassessed at the time a new food use was established for sethoxydim [63FR54066 (10/8/1998)].