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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM **Date: 9/9/09**

SUBJECT: **Revised EFED Problem Formulation for Sulfentrazone Registration Review.**
PC Code No.129081; DP Barcode: D363522.

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The following document is the EFED revised problem Formulation for the Registration Review of Sulfentrazone. The original EFED problem Formulation for the Registration Review of Sulfentrazone was completed on July 29, 2009.

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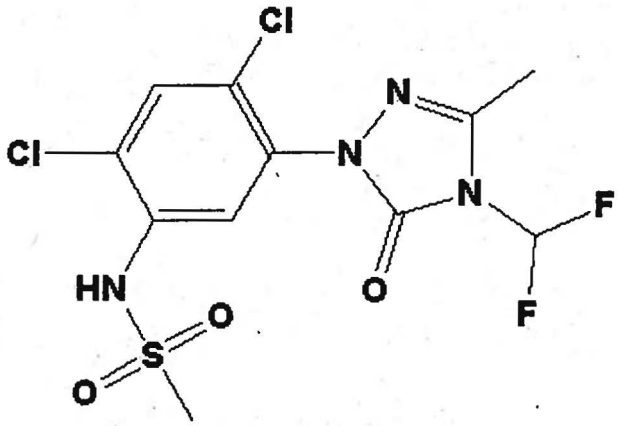
PESTICIDES, AND TOXIC SUBSTANCES

Problem Formulation
For The
Environmental Fate And Effects Division Registration Review of Sulfentrazone



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Problem Formulation

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment being conducted for Sulfentrazone. As such, it articulates the purpose and objectives of the risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998).

A. Nature of Regulatory Action

This document covers the Environmental Fate and Effects Division's (EFED) Registration Review of Sulfentrazone. Previously, a number of registrations have been submitted for this chemical. The most recent ecological risk assessment was conducted on July 1, 2008 for the uses on Head/Stem Brassica Subgroup 5A, Leafy Greens Subgroup 5B, Melon Subgroup 9A, Fruiting Vegetable Group 8, Okra, Succulent Pea, Strawberry and Tuberous/Corm Vegetable Subgroup 1C. These past assessments will serve as the basis for the current Registration Review Problem Formulation.

B. Stressor Sources and Distribution

1. Nature of the Chemical Stressor

In this assessment, Sulfentrazone is considered to be the only stressor as it is the active ingredient of the insecticide under consideration. Sulfentrazone belongs to the phenyl pyrazole class of chemicals called protox inhibitors. The chemical works by inhibiting an enzyme in a plant's chloroplasts causing subsequent cell membrane destruction. It is a light-dependent peroxidizing herbicide (LDPH) which acts by blocking heme and chlorophyll biosynthesis resulting in an endogenous accumulation of photo-toxic porphyrins. This class of herbicide is known to have a photo-toxic mode of action in plants and possibly in fish. LDPHs may be more toxic when exposed to natural sunlight, such as exposure conditions in the field.

Sulfentrazone appears to be persistent and mobile, and has a strong potential to leach into groundwater and move offsite to surface water. This chemical has the following characteristics: (1) moderately soluble in water (water solubility = 400 ppm), (2) not susceptible to hydrolysis at acidic, neutral, and alkaline pHs, (3) extremely susceptible to direct photolysis in water, (4) relatively stable to photodegradation on soil, (5) very persistent in sandy loam and silty clay loam soils under aerobic conditions with a half-life of 1.5 years, (6) extremely persistent to anaerobic aquatic metabolism, (7) is expected to be very mobile in soil (K_{ads} <1; or K_{oc} = 43), (8) non-volatile in water and soil (vapor pressure $<10^{-9}$ mmHg; Henry's Law constant = 10^{-12} atm m^3/mol), and (9) does not accumulate in fish (K_{ow} = 10).

The major routes of dissipation in the environment appear to be direct aqueous photodegradation and leaching. Since sulfentrazone is stable to hydrolysis and biodegradation, direct photolysis appears to be the only effective dissipation pathway in

clear shallow waters. Low soil/water partition indicates that most sulfentrazone runoff is via dissolution in runoff water, as opposed to adsorption to eroding soil. It also indicates that most sulfentrazone will be partitioned in the water column instead of in the suspended and bottom sediments.

Results from each of four field dissipation studies suggested that sulfentrazone was very persistent (dissipation half-lives ranged from 4 to 24 months). However, there was no substantial downward movement (detection limit = 1 ppb) at three of the four study sites in Illinois (clay loam), Arkansas (silty clay loam), and in Iowa (silty clay loam). Based on the residues detected in the 0-6 inch soil at the above three study sites, half-lives were estimated to be 1-2 years. Results from the interim report for the fourth field dissipation study (a loamy sand in North Carolina) suggested much more substantial movement of sulfentrazone, being detected in the deeper soil zones (i.e., 6-12, 12-18, 18-24, 24-30, 30-36, 36-42, 42-48 inches) as well as in the shallow groundwater. Based on sulfentrazone detected in the entire 48-inch soil column at the North Carolina site, the dissipation half-life was estimated to be 121 days.

Based on the environmental fate characteristics of sulfentrazone with consideration of the product formulations, application rates, and results of the field studies, EFED believes that use of sulfentrazone is likely to result in contamination of groundwater and surface water in some circumstances.

2. Overview of Pesticide Usage

Sulfentrazone is a systemic selective herbicide for control of certain broadleaf weeds, grasses and sedges. According to the LUIS reports, sulfentrazone can be applied under the following use patterns: terrestrial food/feed/non-food, and residential outdoor. Under the food/feed uses, sulfentrazone can be applied to asparagus, beans, cabbage, catjang, corn, cowpea, garbanzos, guar, horseradish, lentils, mint, peanuts, peas, peppermint, potato, soybeans, spearmint, sugarcane, and sunflower. Under the non-food and non-feed uses, sulfentrazone can be applied to agricultural and nonagricultural rights-of-way/fences/hedgerows, agricultural and nonagricultural uncultivated areas, agricultural/farm premises, airport/landing fields, commercial storages/warehouses premises, commercial/industrial lawns, commercial/institutional/industrial premises, golf course turf, household/domestic dwellings outdoor premises, industrial areas, ornamental shade trees/herbaceous plants/lawns/turf/nonflowering plants/sod farms/woody shrubs/vines, paths/patios, private paved roads/sidewalks, recreation lawns, residential lawns, sewage disposal areas, and tobacco.

Although the highest single application rate on the food/feed uses is 2.25 lb ai/A for soybeans, the maximum seasonal or yearly rate for soybeans was not reported. The maximum single application rates on other food/feed uses are lower than 0.375 lb ai/A. Most of the corresponding maximum application numbers, application intervals, and seasonal application rates for other food/feed uses were not reported.

The highest single application rate on the non-food/non-feed uses is "1" (unit unspecified) for residential lawns. Although sulfentrazone can be applied two times with an application interval of 30 days to residential lawns, the maximum seasonal or yearly rate was not reported. EFED assumed that the maximum seasonal or yearly rate on residential lawns is 2 lb ai/A/season. The maximum single application rates on other non-food/non-feed uses are lower than 0.742 lb ai/A, but some of the corresponding maximum application numbers, and application intervals were not reported. Sulfentrazone can be applied aerially or by the ground equipments, depending on the uses.

A table of agricultural uses is listed below.

January 6, 2009
Screening Level Estimates of Agricultural Uses of SULFENTRAZONE (129081)
Sorted Alphabetically

	Crop	Lbs. A.I.	Percent Crop Tteated.	
			Avg.	Max.
1	Alfalfa +	1,000	<1	2.5
2	Apples +	<500	<1	<2.5
3	Asparagus	1,000	5	10
4	Barley +	<500	<1	<2.5
5	Beans, Green	<500	<1	<2.5
6	Cabbage	<500	<1	<2.5
7	Dry Beans/Peas	10,000	5	15
8	Fallow, Summer	2,000	<1	<2.5
9	Peanuts	1,000	<1	<2.5
10	Peas, Green	<500	<1	<2.5
11	Potatoes	4,000	<2.5	<2.5
12	Pumpkins +	<500	<1	<2.5
13	Rice +	4,000	<1	<2.5
14	Soybeans	300,000	5	10
15	Strawberries +	1,000	5	10
16	Sugarcane	7,000	<2.5	5
17	Sunflowers	100,000	35	50
18	Tobacco	30,000	35	45
19	Wheat +	4,000	<1	<2.5

All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.
'<1' indicates less than 1 percent of crop is treated.

SLUA data sources include: USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service); 2001-2007
Private Pesticide Market Research, 2001-2007
NPUD 2002 (National Pesticide Use Database) of the CropLife America Foundation and California DPR data.
These results reflect amalgamated data developed by the Agency and are releasable to the public.
+ = These crops were not known to be listed on active end use product registrations when this report was run.

Environmental Fate

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that use of sulfentrazone is likely to result in contamination of groundwater and surface water in some circumstances.

C. Receptors

1. Aquatic and Terrestrial Effects

The receptor is the biological entity that is exposed to the stressor (EPA, 1998). Due to the outdoor uses of Sulfentrazone, exposure and effects to non-target aquatic and terrestrial organisms are expected.

Sulfentrazone is practically non- toxic to avian species (LD50 >2250 mg/kg; LC50 >5620 ppm) on an acute basis and causes no reproductive effects to Quail or Ducks (NOAEC = 100 ppm for both species). It is practically non-toxic to mammals (LD50= 711 mg/kg) on an acute basis but causes reproductive effects (reductions in body weight, male fertility, litter size and survival, increased duration of gestation) in this group of animals (NOAEL = 200 ppm). As sulfentrazone is practically non-toxic (LD_{50} > 25.1 ug/bee) to honeybees, low risk is assumed. The terrestrial plant EC50 is 0.00052 lbs ai/A for dry weight in a 21 day vegetative vigor study using the cucumber (a Dicot). The aquatic plant EC50 = 1.8 ppb for marine diatom and 28.8 ppb for green algae.

Sulfentrazone is slightly to practically non-toxic to freshwater fish on an acute basis LC50s fall in the range of 93.8 to >120 ppm. Reproductive effects for freshwater fish were reductions in growth and survival (NOAEC of 2.95 ppm for the fathead minnow). Since the EC50 is 60.4 ppm, the toxicity of technical Sulfentrazone to daphnids can be classified as slightly toxic on an acute basis. The statistically significant treatment related effects for reproduction in freshwater invertebrates were reduction in survival parameters (NOAEC of 0.20 ppm). Since the LC50 is 114 ppm, the toxicity of Sulfentrazone can be categorized as practically non-toxic for estuarine/marine fish on an acute basis. No data were submitted to assess the chronic toxicity to estuarine/marine fish. Since the LC50/EC50's are 1.0 to >10.5 ppm, the toxicity of Sulfentrazone can be categorized as highly to slightly toxic to estuarine/marine invertebrates on an acute basis. No data were submitted to assess the chronic toxicity to estuarine/marine invertebrates.

Consistent with the process described in the Overview Document (EPA, 2004), risk assessments use a surrogate species approach in its evaluation of a pesticide. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings. In the case of Sulfentrazone, the requirements for ecological studies have mostly been fulfilled for its current use patterns. Additionally, any open literature studies would be identified through EPA's ECOTOX database (http://cfpub.epa.gov/ecotox/), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife.

Table II-1 provides a summary of the taxonomic groups and the surrogate species that are usually tested to help understand potential ecological effects of pesticides to these non-target taxonomic groups.

Table II-1 Test species normally evaluated for assessing potential ecological effects and the associated toxicity endpoint classification

Taxonomic Group	*Example(s) of Surrogate Species*	*Toxicity endpoint*
Birds[1]	Mallard (*Anas platyrhynchos*) Bobwhite (*Colinus virginianus*)	Acute Dietary: LC_{50} Chronic: NOAEC
Mammals	Laboratory rat (*Rattus norvegicus*)	Acute Oral: LD_{50} Chronic 2-Generation: NOAEL
Insects	Honey bee (*Apis mellifera L.*)	Acute contact: *ug*/bee
Freshwater fish[2]	Bluegill sunfish (*Lepomis macrochirus*) Rainbow trout (*Oncorhynchus mykiss*)	Acute: LC_{50} Chronic: NOAEC
Freshwater invertebrates	Water flea (*Daphnia magna*)	Acute: LC_{50} Chronic : NOAEC
Estuarine/marine fish	Sheepshead minnow *(Cyprinodon variegates)*	Acute: LC_{50} Chronic: NOAEC
Estuarine/marine invertebrates	Mysid shrimp *(Americamysis bahia)* Eastern oyster (*Crassostrea virginica)*	Acute: LC_{50} Chronic: NOAEC
Terrestrial plants[3]	Monocots – corn (*Zea mays*) Dicots – soybean (*Glycine max*)	lbs ai/A
Aquatic plants and algae	Duckweed (*Lemna gibba*) Green algae (*Selenastrum capricornutum*)	Acute: EC_{50}

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.
[2] Freshwater fish may be surrogates for aquatic-phase amphibians.
[3] Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans.

Incident Reports

The Agency's Ecological Incident Information System (EIIS) does contain reports of damage or adverse effects to non-target organisms attributed to the use of Sulfentrazone.

Incident #	Date	County	State	Certainty	Legal.	Formul.	Appl. Method	Magnitude
Plant Damage								
Corn								
I014702-008	5/12/2002	Grundy	IA	2	UN	N/R	N/R	580 acres
Strawberry								
I016225-001	4/5/2005	Fayette	IL	2	UN	WDG	Spray	1 acre
Soybean								
I013636-021	4/23/2002	Bremer	IA	2	RU			
I013636-020	4/24/2002	Mitchell	IA	2	RU			74 acres
I013636-019	5/2/2002	Black Hawk	IA	2	RU			47 acres
I013636-009	5/6/2002	Mower	MN	2	RU			145 acres
I014104-001	5/1/2003	Randolph	AR	2	RU	WDG		45 acres
I014108-001	5/1/2003	Randolph	AR	2	RU	WDG		228 acres
I014702-057	5/5/2003	Pocahontas	IA	2	RU	EC	Broadcast	251 acres
I014702-056	5/5/2003	Pocahontas	IA	2	RU	EC	Broadcast	253 acres
I014102-001	5/15/2003	Prairie	AR	2	RU	WDG		250 acres

I014103-001	5/15/2003	Arkansas	AR	2	RU	WDG	300 acres
I014106-001	5/15/2003	Arkansas	AR	2	RU	WDG	227 acres
I015175-001	5/10/2004	Ashley	AR	3	RU	WDG Spray	5,000 acres
Soybeans							
I014702-011	4/26/2003	Worth	IA	3	RU	WSP N/R	40 acres
I014702-012	4/28/2003	Emmet	IA	3	RU	WSP N/R	150 acres
I014702-010	5/1/2003	Worth	IA	3	RU	WSP N/R	108 acres

Certainty Code: 0=Unrelated, 1=Unlikely, 2=Possible, 3=Probable, 4=Highly Probable.
Legality Code: RU=Registered Use, M=Misuse, MA=Misuse (Accidental), MI=Misuse (Intentional), U=Unknown.

Adverse effects apparently can occur under routine application conditions from pesticide drift and/or runoff. The incidents of plant (corn, soybean and strawberry) damage listed above were classified as either "possible" or "probable" and most were a result of registered uses.

A lack of reported incidents does not necessarily mean that such incidents have not occurred. In addition, incident reports for non-target plants and animals typically provide information on mortality events only. Reports for other adverse effects, such as reduced growth or impaired reproduction, are rarely received.

2. Ecosystems potentially at Risk

The ecosystems at risk are often extensive in scope, and as a result it may not be possible to identify specific ecosystems during the development of a baseline risk assessment. Relative to the proposed use patterns of Sulfentrazone, terrestrial and aquatic plant ecosystems are expected to be at risk as a result of its current uses.

D. Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected". Defining an assessment endpoint involves two steps: (1) identifying the valued attributes of the environment that are considered to be at risk; and (2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to pesticides.

To estimate exposure concentrations, the ecological risk assessment typically considers a single application at the maximum application rate to fields that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate

treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

E. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between Sulfentrazone, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

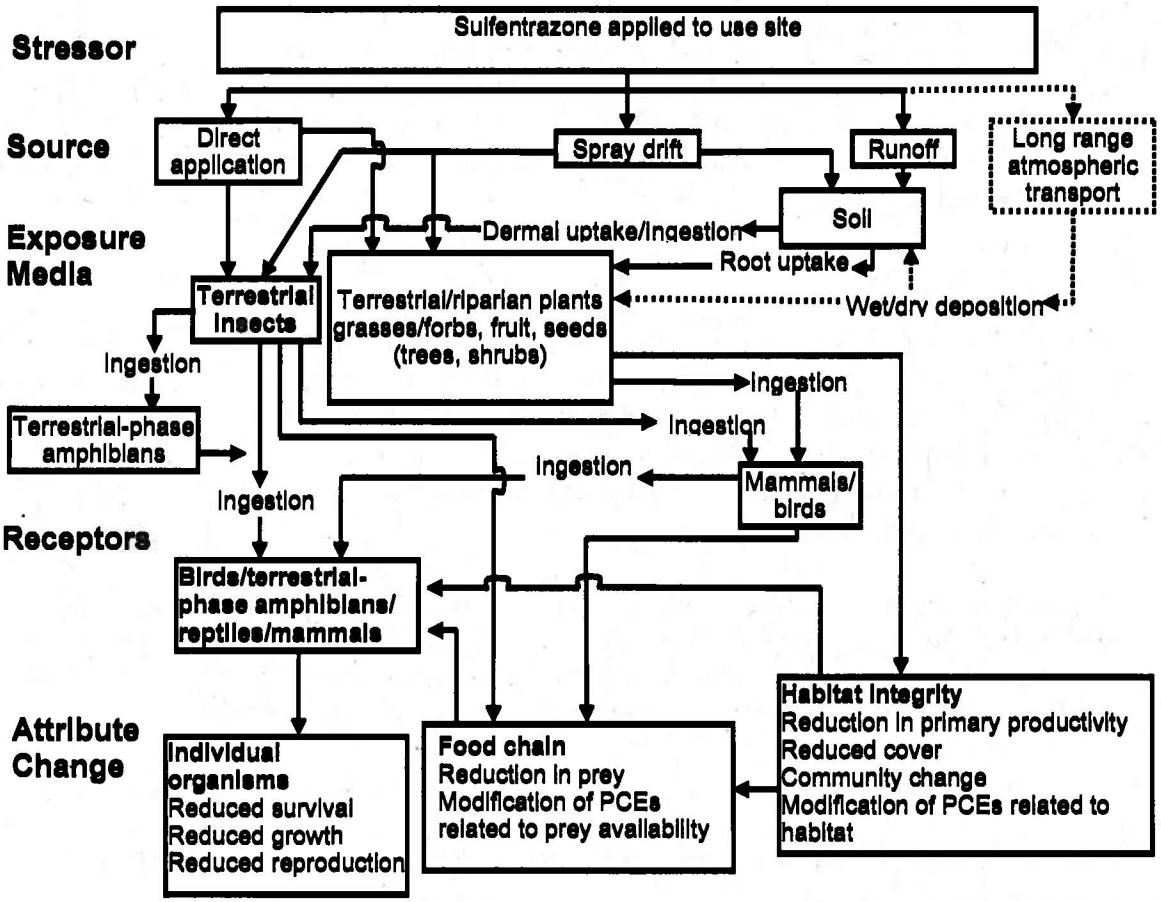
1. Risk Hypotheses

For Sulfentrazone, the following ecological risk hypothesis is being employed for this baseline risk assessment:

Sulfentrazone, when used in accordance with the label, may result in potential adverse effects upon the survival, growth, and reproduction of endangered and non-target terrestrial and aquatic plants.

2. Conceptual Diagram

A conceptual diagram/model is established for chemicals with likely outdoor environmental exposure pathways.


Stressor
Sulfentrazone applied to use site
Source
Direct application
Spray drift
Runoff
Long range atmospheric transport
Exposure Media
Soil
Dermal uptake/ingestion
Root uptake
Terrestrial Insects
Terrestrial/riparian plants grasses/forbs, fruit, seeds (trees, shrubs)
Wet/dry deposition
Ingestion
Ingestion
Terrestrial-phase amphibians
Ingestion
Ingestion
Mammals/ birds
Ingestion
Receptors
Birds/terrestrial-phase amphibians/ reptiles/mammals
Attribute Change
Individual organisms
Reduced survival
Reduced growth
Reduced reproduction
Food chain
Reduction in prey
Modification of PCEs related to prey availability
Habitat integrity
Reduction in primary productivity
Reduced cover
Community change
Modification of PCEs related to habitat

F. Analysis Plan Options

1. Conclusions from Previous Risk Assessments

The most recent ecological risk assessment was conducted on July 1, 2008 for the uses on Head/Stem Brassica Subgroup 5A, Leafy Greens Subgroup 5B, Melon Subgroup 9A, Fruiting Vegetable Group 8, Okra, Succulent Pea, Strawberry and Tuberous/Corm Vegetable Subgroup 1C. Based on previous assessments, Sulfentrazone poses little risk to most terrestrial and aquatic species tested. However, for terrestrial plants adjacent to treatment sites and in semi aquatic areas, RQs exceeded LOCs for monocots and dicots. Also, since sulfentrazone may exhibit photo- and phyto- toxicity, and RQs exceeded LOCs, endangered and non-target terrestrial and aquatic plant species are potentially at additional risk. Species directly using these plants for food and/or cover may be adversely affected through indirect effects.

Since the registrant has committed to clarify the labels, the drinking water assessment completed on April 17, 2003 can be used in place of a new assessment for the uses. The maximum single application and the seasonal/yearly rates (0.375 lbs ai/A and 0.375 lbs ai/A/season (or year), respectively) are the same as for previously assessed uses and risks should be similar. For the current risk assessment, a revised drinking water assessment is not necessary. However, based on the results of the ground water monitoring studies, a new drinking water assessment may be necessary in the future.

2. Preliminary Identification of Data Gaps

Environmental Fate: According to the use patterns for sulfentrazone, the following environmental fate data requirements have not been fulfilled: anaerobic soil metabolism (835.4200) and aerobic aquatic soil metabolism (835.4300). These studies offer information on how, or by what mechanism, the pesticide degrades or dissipates, the rate at which it degrades or dissipates, and what transformation products are formed. Data from these studies are used as inputs to exposure models. These models estimate the expected environmental concentrations of the pesticide and its degradates under various environmental and use conditions. In addition, the registrant must submit the Environmental Chemistry Method (ECM) and Independent Laboratory Validation (ILV) to support the registration review. Data from ECM and ILV studies are very important in evaluating the validity of the terrestrial dissipation, aquatic dissipation, and aquatic non-target organism field accumulation, groundwater studies as well as the risk assessment. The status of the studies submitted by the registrant to support the use of sulfentrazone is summarized below:

Environmental Fate Data Requirements for: Sulfentrazone

Guideline #	Data Requirement	Is Data Requirement Satisfied?	MRID #'s	Study Classification
835.2120	Hydrolysis	yes	41928202	acceptable
835.2240	Photodegradation in Water	yes	43345424 43588601	unacceptable acceptable
835.2410	Photodegradation on Soil	yes	43345425	acceptable
835.4100	Aerobic Soil Metabolism	yes	41922803 42932117	acceptable acceptable
835.4200	Anaerobic Soil Metabolism	no	No study has been submitted	-
835.4300	Anaerobic Aquatic Metabolism	yes	43345426	acceptable
835.4400	Aerobic Aquatic Metabolism	no	No study has been submitted	-
835.1230 835.1240	Adsorption/Desorption/Leaching	yes	41911604 43355903	unacceptable acceptable
835.6100	Terrestrial Field Dissipation	yes	43345427 43651009 43651008 43345434	acceptable acceptable acceptable acceptable (TFD portion)
835.7100	Ground water monitoring	pending	43345434 43926814 46816001 47453602 47453601	under review (GW portion) under review under review under review under review
None	Environmental chemistry method (ECM)	no	No study has been submitted	-
None	Independent laboratory validation (ILV)	no	No study has been submitted	-

Ecological Effects: The environmental toxicity database for Sulfentrazone technical is largely complete and adequate for risk assessment purposes. The Agency has recommended that phototoxicity studies be conducted on herbicides with this mode of action to determine if animals exposed to light-dependent peroxidizing herbicides (LDPHs) and intense light (similar to sunlight) show increased toxicity relative to controls exposed to LDPHs and low intensity light. The results of these studies will help to determine if animals that are exposed to sunlight in LDPH use areas are at higher risk than guideline toxicity studies suggest. EFED understands that a LDPH phototoxicity protocol has been submitted for review by the registrant (Pers. Comm. J. Guerry, PRD, 9/8/2009) and the comments have been provided to LDPH Task Force.

Ecological Effects Data Requirements for: Sulfentrazone

Guideline #	Data Requirement	Is Data Requirement Satisfied	MRID #'s	Study Classification
71-1	Avian Oral LD_{50}	Yes	419116-17	Core
71-2	2 Avian Dietary LC_{50}'s	Yes	419116-18 419116-19	Core Core
71-4	Avian Reproduction (2 species)	Yes	433559-01 433559-02	Supplemental Supplemental
72-1	2 Freshwater Fish $LC_{50's}$ (Tech)	Yes	419116-20 419116-21	Core Core
72-2	Freshwater Invert. Acute LC_{50} (tech)	Yes	419116-22	Core
72-3(a)	Estuarine/Marine Fish LC_{50} (Tech)	Yes	435886-02	Core
72-3(b)	Estuarine/Marine Mollusk EC_{50} (Tech)	Yes	440549-01	Supplemental
72-3(c)	Estuarine/Marine Shrimp EC_{50} (Tech)	Yes	435886-03	Core
72-4(a)	Freshwater Fish Early Life-Stage (tech)	Yes	435886-04	Core
72-4(b)	Estuarine Fish Early Life-Stage	N/A	No data	N/A
72-4(c)	Estuarine Invertebrate Life-Cycle	N/A	No data	N/A
72-4(d)	Freshwater Invert Life-Cycle (Tech)	Yes	435886-05	Core
72-5	Freshwater Fish Full Life-Cycle Estuarine Fish Full Life-Cycle	N/A	No data	N/A
81-1	Acute Mammalian LD_{50}	Yes	419116-06	Core
83-4	2-generation mammalian reproduction	Yes	433454-08	Core
123-1(a)	Tier II Seed Germ./Seedling Emergence	Yes	433454-11	Core
123-1(b)	Tier II Vegetative Vigor	Yes	433454-12	Core
123-2	Tier II Aquatic Plant Growth	Yes	436510-04 436510-05 436510-06 436510-07 433454-13	Core Core Supplemental Core Core
144-1	Honey Bee Acute Contact LD_{50}	Yes	440549-02	Core
850.1730	Accumulation in Fish/ Bioconcentration	Yes	43345433	Acceptable

3. Measures of Effects and Exposure

For a chemical, a number of measures of exposure are used, which are the measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint. Measures of exposure are potentially estimated using models. Aquatic exposure usually consists of aquatic EECs based on a total residue approach and derived using a water-body that is vulnerable and representative of static ponds and first order waterways. Terrestrial exposure is usually estimated using a model that assumes a direct application to a variety of avian, mammal and reptilian food items. Exposure to terrestrial plants is typically estimated using a model that assumes the chemical drifts or moves with runoff to adjacent habitats. Models require quantitative measurements for endpoints to evaluate the effects of the chemicals on the various species. Table II-2 provides a summary of the assessment endpoints previously identified as survival, growth and reproduction along with the measure of effects and exposure.

Table II-2 Measures of ecological effects and exposure for Sulfentrazone.

Assessment Endpoint		*Surrogate Species and Measures of Ecological Effect*[1]	*Measures of Exposure*
Birds[2]	Survival	Quail acute oral LD_{50} > 22.5 ppm Bobwhite & Mallard acute dietary LC_{50} >5620 ppm	Maximum residues on food items
	Reproduction and growth	Bobwhite chronic reproduction NOAEC= 100 ppm Mallard chronic reproduction NOAEC= 100 ppm	Maximum residues on food items
Mammals	Survival	Laboratory rat acute oral LD_{50} = 711 mg/kg	Maximum residues on food items
	Reproduction and growth	Laboratory rat oral reproduction chronic NOAEC = 200 ppm and LOAEC = 500 ppm	Maximum residues on food items
Freshwater fish[3]	Survival	Bluegill sunfish acute LC_{50} = 93.8 ppm Rainbow trout acute LC_{50} > 120 ppm	Peak EEC[4]
	Reproduction and growth	Rainbow trout chronic (early life-stage) NOAEC= 2.95 ppm and LOAEC= 5.93 ppm	60-day average EEC[4]
Freshwater Invertebrates	Survival	Water flea (and other freshwater invertebrates) acute EC_{50} = 60.4 ppm	Peak EEC[4]
	Reproduction and growth	Water flea chronic (life cycle) NOAEC= 0.20 ppm LOAEC= 0.51 ppm	21-day average EEC[4]
Estuarine/ Marine fish	Survival	Silverside acute LC_{50} = 114 ppm	Peak EEC[4]
	Reproduction and growth	No data were submitted	60-day average EEC[4]
Estuarine/ Marine Invertebrates	Survival	Eastern oyster acute EC_{50} > 10.5 ppm and Mysid acute LC_{50} = 1.0 ppm	Peak EEC[4]
	Reproduction and growth	No data were submitted	21-day average EEC[4]

Assessment Endpoint		*Surrogate Species and Measures of Ecological Effect*[1]	*Measures of Exposure*
Terrestrial Plants[5]	Survival and growth	Dicot - Lettuce/tomato 21 day seedling emergence EC_{25} =0.008 lbs ai/A (dry wt); NOAEC = 0.006 (dry wt) Monocot – oat 21 day seedling emergence EC_{25} = 0.017 lbs ai/A (dry wt); NOAEC = 0.019 (dry wt) Dicot - cucumber 21 day vegetative vigor EC_{25} =0.00052 lbs ai/A (dry wt); NOAEC = 0.00044 (dry wt) Monocot – onion 21 day vegetative vigor EC_{25} = 0.0015 lbs ai/A (dry wt); NOAEC = 0.00133 (dry wt)	Estimates of runoff and spray drift to non-target areas
Insects	Survival (not quantitatively assessed)	Honeybee acute contact LD_{50}> 25.1 ug/bee	Maximum application rate
Aquatic Plants and Algae	Survival	Duckweed EC_{50} = 28.8 ppb Green algae EC_{50} = 31.0 ppb Marine diatom EC_{50} = 1.8 ppb Freshwater diatom EC_{50} = 42.1 ppb Blue-green algae EC_{50} = 32.8 ppb	Peak EEC

[1] If species listed in this table represent most commonly encountered species from registrant-submitted studies, risk assessment guidance indicates most sensitive species tested within taxonomic group are to be used for baseline risk assessments.
[2] Birds represent surrogates for amphibians (terrestrial phase) and reptiles.
[3] Freshwater fish may be surrogates for amphibians (aquatic phase).
[4] One in 10-year return frequency.
[5] Four species of two families of monocots - one is corn, six species of at least four dicot families, of which one is soybeans. LD_{50} = Lethal dose to 50% of the test population; NOAEC = No observed adverse effect concentration; LOAEC = Lowest observed adverse effect concentration; LC_{50} = Lethal concentration to 50% of the test population; EC_{50}/EC_{25} = Effect concentration to 50%/25% of the test population.

4. Endangered Species Considerations

Pesticide ecological risk assessments for registration review will address the Endangered Species Act, Section 7(a)(2) obligations. Due to the registered outdoor uses for Sulfentrazone, endangered species may be affected, especially plants.

Path Forward

The planned ecological risk assessment will evaluate the lines of evidence and make a determination of potential effects to endangered species. If the planned ecological risk assessment indicates that Sulfentrazone may affect, either directly or indirectly, listed species or affect critical habitat, the Agency will take steps to refine the assessment to determine whether this pesticide's uses are likely to adversely affect, or are not likely to adversely affect the species. In the case of critical habitat, the Agency will assess whether use of the pesticide may destroy or adversely modify any principle constituent

elements for the critical habitat.

If the Agency's assessment results in a determination that the pesticide may affect but is not likely to adversely affect a listed species or designated critical habitat, the Agency will request concurrence by the USFWS and NMFS (Services) on that determination. If the Services do not concur, the Agency will enter into Formal Consultation with them under the Endangered Species Act. If the Agency's assessment results in a determination that the pesticide is likely to adversely affect a listed species or designated critical habitat, the Agency will initiate Formal Consultation with the Services. Formal Consultation concludes with issuance of a Biological Opinion to the Agency. The Agency may seek to change the terms of registration to address unacceptable risks to a listed species should EPA determine such risks exist.

Other Information Needs

Information is requested for confirmation on the following information:

1. State or local use restrictions
2. Ecological incidents not already reported to the Agency

The analysis plan will be revisited and may be revised depending upon the information submitted by the public in response to the opening of the Registration Review docket.

Summary

- Sulfentrazone belongs to the phenyl pyrazole class of chemicals called protox inhibitors. The chemical works by inhibiting an enzyme in a plant's chloroplasts causing subsequent cell membrane destruction.
- Sulfentrazone is a light-dependent peroxidizing herbicide (LDPH) which acts by blocking heme and chlorophyll biosynthesis resulting in an endogenous accumulation of photo-toxic porphyrins.
- Sulfentrazone appears to be persistent and mobile, and has a strong potential to leach into groundwater and move offsite to surface water.
- The stressor is expected to reach terrestrial and aquatic receptors from application drift, and/or runoff.
- Relative to the outdoor use pattern of Sulfentrazone, terrestrial and aquatic plant ecosystems are expected to be at risk as a result of its current uses.
- The Agency's Ecological Incident Information System (EIIS) does contain reports of damage or adverse effects to non-target plants attributed to the use of Sulfentrazone.
- Ecological toxicity data were available for risk assessment purposes.
- An open literature search will need to be completed if additional information is needed for assessment purposes.

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H. Appendix Data Requirement and DCI Justifications

Ecological Effects Data Requirements for: Sulfentrazone

Guideline #	Data Requirement	MRID #'s	Study Classification
71-1	Avian Oral LD_{50}	419116-17	Core
71-2	2 Avian Dietary LC_{50}'s	419116-18 419116-19	Core Core
71-4	Avian Reproduction (2 species)	433559-01 433559-02	Supplemental Supplemental
72-1	2 Freshwater Fish $LC_{50's}$ (Tech)	419116-20 419116-21	Core Core
72-2	Freshwater Invert. Acute LC_{50} (tech)	419116-22	Core
72-3(a)	Estuarine/Marine Fish LC_{50} (Tech)	435886-02	Core
72-3(b)	Estuarine/Marine Mollusk EC_{50} (Tech)	440549-01	Supplemental
72-3(c)	Estuarine/Marine Shrimp EC_{50} (Tech)	435886-03	Core
72-4(a)	Freshwater Fish Early Life-Stage (tech)	435886-04	Core
72-4(b)	Estuarine Fish Early Life-Stage	No data	N/A
72-4(c)	Estuarine Invertebrate Life-Cycle	No data	N/A
72-4(d)	Freshwater Invert Life-Cycle (Tech)	435886-05	Core
72-5	Freshwater Fish Full Life-Cycle Estuarine Fish Full Life-Cycle	No data	N/A
81-1	Acute Mammalian LD_{50}	419116-06	Core
83-4	2-generation mammalian reproduction	433454-08	Core
123-1(a)	Tier II Seed Germ./Seedling Emergence	433454-11	Core
123-1(b)	Tier II Vegetative Vigor	433454-12	Core
123-2	Tier II Aquatic Plant Growth	436510-04 436510-05 436510-06 436510-07 433454-13	Core Core Supplemental Core Core
144-1	Honey Bee Acute Contact LD_{50}	440549-02	Core
850.1730	Accumulation in Fish/ Bioconcentration	43345433	Acceptable

Environmental Fate Data Requirements for: Sulfentrazone

Guideline #	Data Requirement	Is Data Requirement Satisfied?	MRID #'s	Study Classification
835.2120	Hydrolysis	yes	41928202	acceptable
835.2240	Photodegradation in Water	yes	43345424 43588601	unacceptable acceptable
835.2410	Photodegradation on Soil	yes	43345425	acceptable
835.4100	Aerobic Soil Metabolism	yes	41922803 42932117	acceptable
835.4200	Anaerobic Soil Metabolism	no	No study has been submitted	-
835.4300	Anaerobic Aquatic Metabolism	yes	43345426	acceptable

835.4400	Aerobic Aquatic Metabolism	no	No study has been submitted	-
835.1230 835.1240	Adsorption/Desorption/Leaching	yes	41911604 43355903	unacceptable acceptable
835.6100	Terrestrial Field Dissipation	yes	43345427 43651009 43651008 43345434	acceptable acceptable acceptable acceptable (TFD portion)
835.7100	Ground water monitoring	pending	43345434 43926814 46816001 47453602 47453601	under review (GW portion) under review
None	Environmental chemistry method (ECM)	no	No study has been submitted	-
None	Independent laboratory validation (ILV)	no	No study has been submitted	-

C=Core; S=Supplemental; U=Unnaceptable; W=Waived; N/A=Not Applicable; NA=Not Available

Guideline Number: 835-4200/835-4300
Study Title: Anaerobic Soil Metabolism/Aerobic Aquatic Metabolism

Rationale for Requiring the Environmental Fate Studies Performed in the Laboratory

EPA requires a series of individual laboratory studies to assess the behavior and fate of a pesticide in the environment. Controlled environmental fate and transport laboratory studies are used to determine the persistence and mobility potential of a pesticide active ingredient and its major degradates. The studies offer information on how, or by what mechanism, the pesticide degrades or dissipates, the rate at which it degrades or dissipates, where it goes, and what transformation products are formed. Data from these studies are used as inputs to exposure models. These models estimate the expected environmental concentrations of the pesticide and its degradates under various environmental and use conditions.

Metabolism study includes anaerobic soil metabolism and aerobic aquatic metabolism. The soil microbial metabolism study determines the persistence of the pesticide when it interacts with soil microorganisms under anaerobic and aerobic conditions. The study also identifies the significant degradates that result from biological degradation. Currently no acceptable studies have been submitted.

Practical Utility of the Data