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

PC Code: 128820
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MEMORANDUM **September 2, 2011**

Subject: Registration Review: Preliminary Problem Formulation for Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments for Bensulfuron-methyl (Case No. 7216)

To: Maia Tatinclaux, Chemical Review Manager
Patricia Moe (RM 81), Chief RMIB V
Pesticide Re-Evaluation Division (7508P)

From: Brian D. Kiernan, Biologist
Reuben Baris, Environmental Scientist
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

Through: Mark Corbin, Branch Chief
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

The Environmental Fate and Effects Division (EFED) has completed the preliminary problem formulation (attached) for the environmental fate and ecological risk, endangered species, and drinking water assessments to be conducted as part of the Registration Review of the herbicidal active ingredient bensulfuron-methyl (PC Code 128820). Functioning as the first stage of the risk assessment process for Registration Review, this problem formulation provides an overview of what is currently known about the environmental fate and ecological effects associated with bensulfuron-methyl and its degradates. It also describes the preliminary ecological risk hypothesis and analysis plan for evaluating and characterizing risk to non-target species and the environment in support of registration review.

Data Gaps

The available environmental fate and transport data are considered incomplete for the purposes of risk assessment. The following data gaps exist:

- Aerobic soil metabolism (OPPTS guideline # 835.4100). There is no acceptable data for aerobic soil metabolism. The guideline stipulates that results from at least four relevant

soils of different organic carbon content, pH, clay content, and microbial biomass must be submitted in order to characterize the variability in the aerobic biodegradation of bensulfuron-methyl in the environment. This study should specifically identify and characterize the formation and decline of major degradates.

- Aerobic aquatic metabolism (OPPTS guideline # 835.4300). There are no acceptable aerobic aquatic metabolism studies. This study is necessary in order to describe the fate of bensulfuron-methyl in surface water bodies down-gradient from use sites (e.g., rice paddies). The guideline stipulates that at least two different soil:water systems be submitted that are similar to the potential use sites in the United States. There is currently one supplemental study that lacks information on the aerobicity of the soil:water system. A new study should specifically identify and characterize the formation and decline of major degradates.
- Anaerobic aquatic metabolism (OPPTS guideline # 835.4400). Submission of an acceptable anaerobic aquatic metabolism study is necessary to understand the degradation of bensulfuron-methyl in oxygen-limiting environments.
- Aquatic field dissipation (OPPTS guideline # 835.6200). An acceptable aquatic field dissipation study is required for all pesticides with use patterns for aquatic food and nonfood applications. Supplemental to the aquatic field dissipation study is the independent laboratory method validation, and environmental chemistry methods used for the field study.

The available effects data are considered incomplete for the purposes of risk assessment. The following data gaps exist:

- 850.4400. Two aquatic vascular plant studies are under review, one with TGAI and one with TEP. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, aquatic nonvascular plant data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.
- 850.5400. **Data for a pinnate and a centric diatom are necessary for risk assessment.** Additionally, studies with green algae and cyanobacteria (one TGAI and one TEP each) are under review. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, aquatic nonvascular plant data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.
- 850.2100. **An avian oral toxicity study with a passerine is necessary for risk assessment.**
- 850.2300. **An avian reproduction study with northern bobwhite quail is necessary for risk assessment.** Additionally, an avian reproduction study with mallard duck is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- 850.4100 (850.4225). A seedling emergence study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, seedling emergence data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.

- 850.4150 (850.4250). A vegetative vigor study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- Non-guideline. **Terrestrial Plant Reproduction Study** will be necessary for risk assessment.

Additional detail on the current data gaps for environmental fate and effect is provided in Section 8.0.

EPA
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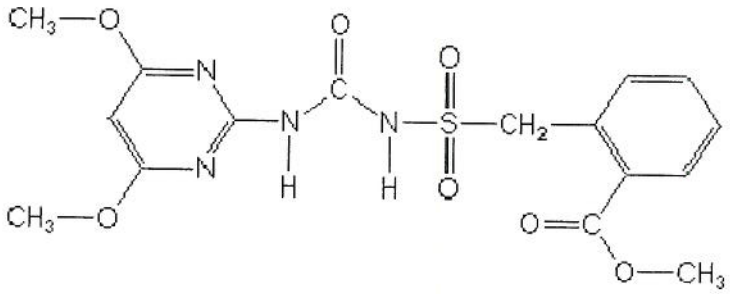
Office of Prevention, Pesticides,
and Toxic Substances

Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Bensulfuron-methyl methyl



methyl 2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]methyl]benzoate
CAS Registry Number: 83055-99-6
PC Code: 128820

Prepared by:
Brian D. Kiernan, Biologist
Reuben Baris, Environmental Scientist

Reviewed by:
Andrew Shelby, Physical Scientist
Mary Frankenberry, Senior Statistician
Stephanie Syslo, RAPL
Mark Corbin, Branch Chief, ERB 6

U. S. Environmental Protection Agency
Office of Pesticide Programs
Environmental Fate and Effects Division
Environmental Risk Branch IV
1200 Pennsylvania Ave., NW
Mail Code 7507P
Washington, DC 20460

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1. Purpose

The purpose of this problem formulation is to provide an understanding of what is known about the environmental fate and ecological effects of the registered uses of bensulfuron-methyl-methyl (PC Code 12880; referred to interchangeably as bensulfuron-methyl). Bensulfuron-methyl belongs to the sulfonylurea class of herbicides and it is applied for selective control of annual and perennial broadleaf weeds and sedges in rice production. This herbicide can be applied as pre-and post-emergence treatments and tank mixed with other compatible herbicides to increase the weed control spectrum. Bensulfuron-methyl-methyl is an acetolactate synthase (ALS) inhibitor. ALS is an important enzyme for the synthesis of branched chain amino acids. This metabolic pathway is present only in plants. Bensulfuron-methyl-methyl is absorbed by the foliage and roots in plants. This document will provide a plan for analyzing data relevant to bensulfuron-methyl and for conducting environmental fate and ecological risk, endangered species, and drinking water assessments for its registered uses. Additionally, this problem formulation is intended to identify data gaps, uncertainties, and potential assumptions used to address those uncertainties relative to characterizing the ecological risk associated with the registered uses of bensulfuron-methyl.

2. Problem Formulation

2.1. Nature of Regulatory Action

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all pesticides distributed or sold in the United States generally must be registered by the Environmental Protection Agency (EPA). As part of determining whether a pesticide can be registered in the U.S., the Agency evaluates its safety to non-target species based on a wide range of environmental and health effects studies. In 1996, FIFRA was amended by the Food Quality Protection Act, and the Agency was mandated to implement a new program for the periodic review of pesticides, *i.e.*, Registration Review (http://www.epa.gov/oppsrrd1/registration_review/). The Registration Review program is intended to ensure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices occur over time. Through the Registration Review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely.

As part of the implementation of the Registration Review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Agency is beginning its evaluation of bensulfuron-methyl to determine whether it continues to meet the FIFRA standard for registration. This problem formulation for the environmental fate, ecological risk, endangered species, and drinking water assessment chapter in support of the Registration Review will be posted in the initial docket, which will open the public phase of the review process.

2.2. Previous Risk Assessments

A document titled "Londax herbicide- Expedited Review of Proposed registration of New Chemical, in Registration Standard Format" was issued in 1988 (Record numbers 190158 and 201782). It reported that Londax would persist in both aquatic and terrestrial environments. While recommending chronic exposure data on aquatic organisms, the report concluded that, because of the low use rate, Londax (bensulfuron-methyl formulation) was not expected to adversely affect nontarget terrestrial organisms.

A document titled "Estimates of ground and surface water concentrations for bensulfuron-methyl" (DP Barcode D239661) was issued in 1997, resulting in acute and chronic surface water estimates of 1.74 and 1.10 pbb, respectively. The groundwater estimate was 0.032 ppb.

Although several other supporting documents for bensulfuron-methyl exist, the two presented here are the primary sources of historical note. No full, Overview Document (USEPA, 2004) compliant risk assessment has been conducted for bensulfuron-methyl.

3. Stressor Source and Distribution

3.1. Mechanism of Action

Bensulfuron-methyl's mode of action is the inhibition of amino acid synthesis in plants through inhibition of acetolactate synthase (ALS). ALS (also known as acetohydroxy acid synthase, or AHAS) is the first common enzyme in the biosynthesis of branched-chain amino acids (valine, leucine and isoleucine). ALS inhibition in plants adversely affects plant growth and reproduction. Although acetolactate is present in mammals, the biosynthesis of branch chain amino acids occurs only in plants. Chlorsulfuron (PC Code 118601), the most studied sulfonylurea (SU), does not affect acetolactate forming enzymes in mammalian cells (Nakata, 1991). In general, SU herbicides are less toxic to animals than plants.

3.2. Overview of Pesticide Use and Usage

Bensulfuron-methyl belongs to the sulfonylurea class of herbicides and it is currently applied for selective control of annual and perennial broadleaf weeds and sedges in aquatic rice production. This herbicide can be applied as pre-and post-emergence treatments and tank mixed with other compatible herbicides to increase the weed control spectrum. Three bensulfuron-methyl-containing products are co-formulated with propanil (PC Code 028201). Bensulfuron-methyl is formulated as water dispersible granules and emulsifiable concentrate. Bensulfuron-methyl may be applied as a direct dry application (without dilution in a liquid carrier). The application rate varies with the formulation used, stage of weed growth, and application timing, but is roughly 0.0625 lbs ai/A (**Table 1**). This herbicide can be applied directly to rice paddies aerially or by using tractor mounted sprayers.

Table 1. Registered products containing bensulfuron-methyl.

Reg#	AI%	Formulation	Product Name	Max App Rate (lb ai/A)	Max # Apps	Seasonal Max (lb ai/A)	Minimum Retreatment Interval	Application Method Type	Application Method	Application Timing
70506-147	60	DF	LONDAX HERBICIDE	.0625	NS	.0625	NS	Broadcast/ Impregnated dry bulk fertilizer treatment.	Air	Foliar.
								Low volume spray (concentrate).	Ground	Foliar.
								Spray.	Air/ground	At permanent flood (of rice).
70506-149	0.32	G	DUPONT LONDAX G HERBICIDE	NDC	NS	.0625	NS	Broadcast.	Sprayer	At permanent flood (of rice).
71085-16	0.62	SC/S	DUET DF RICE HERBICIDE	.0465	NS	.062	NS	Broadcast.	Air/ground	Foliar.
71085-23	0.46	SC/S	DUET 60DF	.046	NS	.0612	NS	Broadcast.	Air/ground	Foliar.
71085-9	0.32	EC	DUET HERBICIDE	.0466	NS	.0622	NS	Broadcast.	Air/ground	Foliar.

NDC = No Dosage Conversion

NS = Not Specified

There are currently five Section 3 registrations, although Londax Herbicide® is available for use as direct dry or foliar spray application, and can be impregnated in fertilizers. The only currently registered use is on rice. According to USDA-NASS data for 2010, Arkansas has the greatest acreage in rice (1,681k acres), followed by Louisiana (560k), California (555k), Mississippi (300k), Missouri (217k) and Texas (199k) (**Figure 1**).

Label information that would help inform the risk assessment include specific maximum application rate (per application and per year), maximum number of applications allowed, defined application intervals, ASABE S-572 droplet size spectra and other drift management language.

According to the Biological and Economic Analysis Division's (BEAD) Screening Level Usage Analysis (SLUA; USEPA 2011), an average of 15,000 lbs of bensulfuron-methyl are applied annually on rice. The SLUA also reports that 49% of all bensulfuron-methyl use is in Louisiana, 26% in Arkansas and 16% in California.

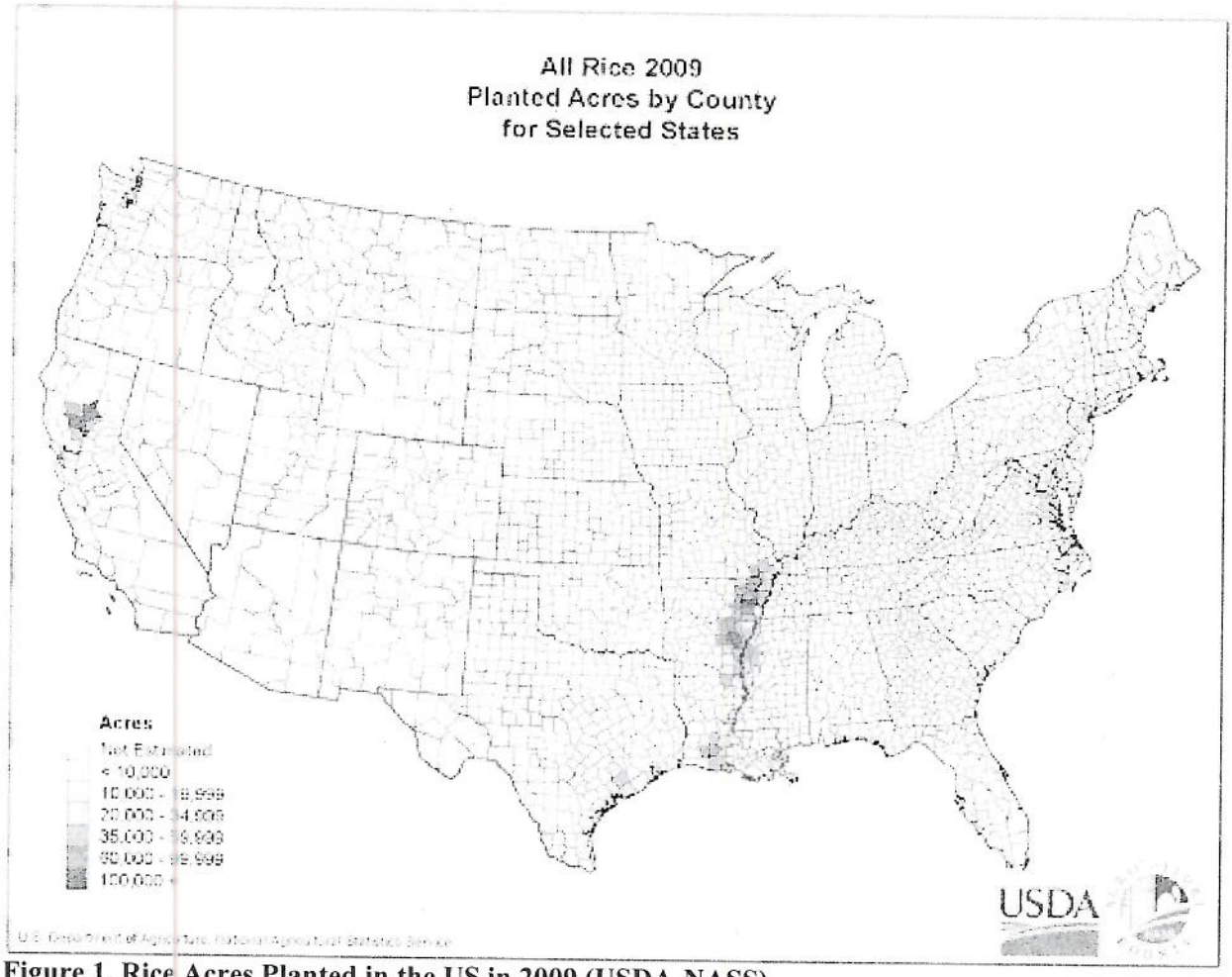

Figure 1. Rice Acres Planted in the US in 2009 (USDA-NASS)

3.3. Environmental Fate and Transport

The Agency has completed a review of all available data submitted by the registrant as part of registration review; the guidelines noted below are considered data gaps. At this time, the following environmental fate guidelines are not fulfilled for bensulfuron-methyl and are considered data gaps. The fate data gaps are:

- Aerobic soil metabolism (835.4100),
- aerobic aquatic metabolism (835.4300),
- anaerobic aquatic metabolism (835.4400), and
- aquatic field dissipation (835.6200).

In absence of these data, conservative assumptions will be made for the risk assessment regarding the fate and transport of bensulfuron-methyl (*e.g.*, stable to aerobic soil metabolism). Physical chemical properties for bensulfuron-methyl have been submitted pursuant to guideline 830 Series Subgroup B (physical/chemical properties) in MRID 40089309. This study is a summary of the relevant physical and chemical properties. Additional detail for each guideline is recommended to inform the risk assessment. For example, EFED has evidence that the dissociation constant (pKa) varies with respect to pH. However, the data in MRID 40089309 only provide a point estimate for pKa. EFED recommends that these data be submitted in order to accurately characterize the fate and transport of bensulfuron-methyl in the environment. Additional detail is provided below.

The following assessment of the environmental fate of bensulfuron-methyl is, in part, based on uncertain data. As a result, the fate, ground and surface water assessments of bensulfuron-methyl may change after review of the additional data that is currently outstanding.

Table 2 summarizes the submitted environmental fate data for bensulfuron-methyl.

TABLE 2. General Chemical Properties and Environmental Fate Properties of Bensulfuron-methyl 1

Parameter	Value		Reference (MRID #) /Comment
Physical/Chemical Parameters			
Cas Registry Number	83055-99-6		40089309
Molecular mass	410.4 g/mol		MRID 40089309 is a summary of data submitted for Group B physical/chemical properties. Additional detail on each guideline is required.
Vapor pressure (25°C)	2.1×10^{-14} mmHg		
Henry's Law Constant	No data		
Water solubility (25°C)	pH 4.8	2.9 mg/L	
	pH 6.9	120 mg/L	
	pH 7.8	1,200 mg/L	
Octanol-water partition coefficient (Log K_{OW})	0.613		
Dissociation Constant (pKa)	5.2		

Parameter	Value	Reference (MRID #) /Comment
Mobility		
Soil Partitioning Coefficient (K_d)	0.56-6.3 (data from four soils)	40767004 00073657
Persistence in Water		
Hydrolysis half-life (25°C, pH 5, 7, & 9)	pH 5, 11 days pHs 7 and 9, stable	00073657
Aqueous photolysis half-life (25°C)	Stable	40089330
Aerobic aquatic metabolism half-life	No acceptable data (assumed stable)	No acceptable data available. Assumed stable to aerobic metabolism (USEPA, 2009)
Anaerobic aquatic metabolism half-life	No acceptable data (assumed stable)	No acceptable data available. Assumed stable to anaerobic metabolism (USEPA, 2009)
Persistence in Soil		
Aerobic soil metabolism half-life (25°C)	No acceptable data (assumed stable)	No acceptable data available. Assumed stable to aerobic metabolism (USEPA, 2009)
Field Dissipation		
Aquatic field dissipation half-life	1-7 days	40089331
Aquatic Bioconcentration		
Bioconcentration Factor (BCF) in fish	Low potential to bioconcentrate (BCF < 3x for edible and non-edible tissues)	00073657
Bioconcentration Factor (BCF) in crayfish	0.6 (whole crayfish) 0.3 (cooked, edible tailmeat)	43256402

The physical and chemical properties of bensulfuron-methyl are uncertain at this time, as no physical/chemical data was submitted pursuant to OPPTS guideline series 830 Group B (Physical/Chemical Properties). In absence of these data, it is uncertain what the environmental fate of this compound is, and the Agency's ability to assess the environmental risks of this compound is diminished. Further, it is uncertain whether bensulfuron-methyl is a weak acid or a strong acid at environmental pHs since there is no available physical-chemical properties data. Available data, as well as open literature data, indicate the dissociation constant is strongly pH dependent (-9.2 at pH 9, 3.2 at pH 5).

The mobility of bensulfuron-methyl varies with soil types, with adsorption correlated with organic matter. Bensulfuron-methyl has a tendency to leach in sandy, inorganic soils, but rice plots (the only labeled use for bensulfuron-methyl) are designed to hold water with some type of confining layer. Bensulfuron-methyl applied when the rice fields are non-flooded will not leach, and any residues remaining at flooding will partition onto the sediment. When the fields are drained, the amount of compound that remains in the water column will remain with the released water, and the chemical sorbed to the sediment in rice paddies will remain on the field, unless the sediment is eroded with the release water. Previous aqueous photolysis studies used in the registration standard reported significant photolytic degradation in water (MRID 40089335,

ACC 073657); however a thorough review of available data and an updated aqueous photolysis study using light intensity comparable to natural sunlight reported negligible photolysis at pHs 7 and 9, and degradation at pH 5 which was attributed to hydrolysis. Therefore bensulfuron-methyl is expected to persist in alkaline and neutral aquatic systems.

The degradation of bensulfuron-methyl in aerobic soil is uncertain. A thorough review of the available data highlighted deficiencies in the aerobic soil metabolism study (variability in the total recovery, generally poor recovery throughout the study duration, and material losses over the duration of the study). Therefore the half-lives reported in this study (ACC 073657) cannot reliably be used for risk assessment. Therefore bensulfuron-methyl is assumed to be stable to aerobic soil metabolism, in absence of these data. The aerobic soil metabolism study does provide supplemental information about the formation of major degradates of bensulfuron-methyl: 2-amino-4,6-dimethoxyprimidine, methyl 2-(aminosulfonyl-methyl)benzoate, and 1H-2,3-benzothiazin-4(3H)-one 2,2-dioxide. However, due to deficiencies in the environmental fate data for bensulfuron-methyl, not all degradates may be accounted for, nor are the quantities at which degradates form known with any certainty.

Degradation of bensulfuron-methyl in aquatic systems is also uncertain. A review of the available aerobic and anaerobic aquatic metabolism data highlighted deficiencies in both aerobic and anaerobic aquatic metabolism studies. The aerobic aquatic metabolism study did not adequately characterize the aerobicity of the system. Although the soil:water system was constantly agitated prior to treatment, aerobic conditions should have existed in the soil prior to treatment, however the redox potential and dissolved oxygen were not measured throughout the study. Therefore it is uncertain if oxidizing conditions were strong or weak or constant during the course of the study, which can greatly affect the metabolism of organic compounds. Further the soils used for this study were from Japan and it is uncertain if they represent soils for the potential use sites in the United States. The anaerobic aquatic metabolism study reported loss of material over the course of the study for both labels, therefore the half-lives from this invalid study (MRID 40089333) cannot be used reliably for risk assessment. In absence of acceptable metabolism data in aquatic systems, the compound is assumed to be stable to aerobic and anaerobic metabolism in aquatic systems for the purposes of risk assessment.

Supplemental aquatic field dissipation data show that bensulfuron-methyl dissipates in aquatic systems in one to seven days (MRID 40089331, 43256402).

The lack of acceptable laboratory and field dissipation data limit the Agency's ability to assess with confidence the environmental fate of bensulfuron-methyl. The above assessment of the environmental fate of bensulfuron-methyl was, in part, based on uncertain data. As a result, the fate, ground and surface water assessments of bensulfuron-methyl may change after review of the additional data being required.

3.4. Bioaccumulation

Available data for the bioconcentration potential of bensulfuron-methyl in fish indicate a low potential for bioconcentration (ACC 00073657). Further, a supplemental field study of

bensulfuron-methyl accumulation in crayfish of a flooded rice paddy showed low bioconcentration factors (BCF) of 0.6x in whole crayfish, 0.3x in edible tailfish (MRID 43256402).

4. Receptors

Consistent with the process described in the Overview Document (USEPA 2004), the risk assessment for bensulfuron-methyl relies on a surrogate species approach. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate the potential effects on a variety of species (receptors) included under these taxonomic groupings.

Acute and chronic toxicity data from studies submitted by the pesticide registrant, along with the available open literature, will be used to evaluate the potential direct and indirect effects of bensulfuron-methyl to aquatic and terrestrial receptors. This includes toxicity on the technical grade active ingredient, degradates, and when available, formulated products (*e.g.*, "Six-Pack" studies). Open literature studies were identified through EPA's publically available ECOTOXicology (ECOTOX) database (November 2010), which employs a literature search engine for locating chemical toxicity data for aquatic and terrestrial plants and wildlife. The evaluation of both sources of data may also provide insight into the direct and indirect effects of bensulfuron-methyl usage on biotic communities from loss of species that are sensitive to the chemical and from changes in structure and functional characteristics of the affected communities.

A brief summary of the aquatic and terrestrial toxicity data available for the species most sensitive to bensulfuron-methyl is provided in Sections 4.1 and 4.2, respectively. A more complete summary of the available data is presented in **Appendix B**. In addition, a summary of ecological incidents associated with bensulfuron-methyl and a description of ecosystems potentially at risk are provided in Sections 4.3 and 4.4, respectively. As noted previously, data on the formation and decline of bensulfuron-methyl degradates are minimal, and there are also no data on the potential toxicity of any degradates. Data on the phytotoxicity of the degradates are necessary for risk assessment.

Toxicity to fish and aquatic invertebrates is categorized using the system shown in **Table 3** (US EPA, 2004). Toxicity to terrestrial fauna (birds and mammals) is categorized using the system shown in **Table 4**. Toxicity categories for plants have not been defined.

Table 3. Categories of Acute Toxicity for Aquatic Animals

LC_{50} (ppm)	Toxicity Category
< 0.1	Very highly toxic
> 0.1 - 1	Highly toxic
> 1 - 10	Moderately toxic
> 10 - 100	Slightly toxic
> 100	Practically nontoxic

Table 4. Categories of Acute Toxicity for Terrestrial Animals

LD_{50} (mg/kg)	LC_{50} (ppm)	Toxicity Category
<10	<50	Very highly toxic
10-50	50-500	Highly toxic
51-500	501 - 1000	Moderately toxic
501-2000	1001 - 5000	Slightly toxic
>2000	>5000	Practically nontoxic

4.1. Effects to Aquatic Organisms

The most sensitive of the available aquatic toxicity data from registrant-submitted studies are provided in **Table 5**. There are several aquatic studies that have been submitted by the registrant and are under review. Until the review is complete, the Agency cannot determine whether these studies are suitable for use in risk assessment. There are several studies available in ECOTOX which will be reviewed for the risk assessment. Based on the available information, bensulfuron-methyl is classified as no more than slightly toxic to fish and invertebrates on an acute exposure basis. Available data indicate both vascular and nonvascular aquatic plants are affected by bensulfuron-methyl; however several of the aquatic plant studies are among those under review and a complete suite of nonvascular plant data is unavailable. Additionally, guideline studies for the two diatoms necessary for risk assessment have not been submitted.

In summary, aquatic data needed or under review:

- 850.1400. A fish early life stage study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- 850.4400. Two aquatic vascular plant studies are under review, one with TGAI and one with TEP. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment.
- 850.5400. Data for a pinnate and a centric diatom are necessary for risk assessment. Additionally, studies with green algae and cyanobacteria (one TGAI and one TEP each) are under review. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment.

Table 5. Aquatic Toxicity Profile for Bensulfuron-methyl

Taxonomic Group	Species (Common Name)	Endpoint (mg ai/L)	Acute Classification	Reference (MRID)
Freshwater Fish	*Lepomis macrochirus* (Bluegill sunfish)	LC_{50}>63	Slightly toxic	40940102
	Oncorhyncus mykiss (rainbow trout)	NOAEC=1.5[a]	--	46361501
Freshwater Invertebrates	*Procambus clarki* (Crayfish)	LC_{50}>71	Slightly toxic	40951403
	Daphnia magna (daphnid shrimp)	NOAEC=17	--	40940108
Estuarine/marine Fish	*Cyprinodon variegatus* (Sheepshead minnow)	LC_{50}>123	Practically nontoxic	40940104[a]
Estuarine/marine Invertebrates	*Americamysis bahia* (mysid shrimp)	LC_{50}>130	Practically nontoxic	40940101
Vascular plants	*Lemna gibba* (duckweed)	--[a]	--[b]	45586703 45586704
Nonvascular plants		--[a,c]	--	--

[a]study is under review
[b]Toxicity categories for plants have not been defined.
[c]complete dataset unavailable; unable to determine most sensitive endpoint

4.2. Effects to Terrestrial Organisms

Table 6 summarizes the most sensitive terrestrial toxicity endpoints for bensulfuron-methyl, based on an evaluation of the submitted data. If open literature studies are identified through ECOTOX, they will be reviewed for the risk assessment. Bensulfuron-methyl is classified as practically nontoxic to terrestrial birds based on the available acute oral and subacute dietary exposure studies; however, an acute oral study with a passerine species is necessary for risk assessment. Bensulfuron-methyl is classified as practically nontoxic to mammals on an acute oral exposure basis. One of two required avian reproduction studies has been submitted. The Agency will review the study but until both studies are submitted and reviewed, it will presume chronic risk to avian species. Bensulfuron-methyl is classified as practically nontoxic to honey bees (*Apis mellifera*) on an acute contact exposure basis.

As expected with an herbicide, bensulfuron-methyl has adverse effects on plants. The required seedling emergence and vegetative vigor studies have been submitted and are in the review process. Until the studies are reviewed, the Agency cannot determine if the data are adequate for risk assessment purposes.

In summary, terrestrial data needed or under review:

- 850.2100. An avian oral toxicity study with a passerine is necessary for risk assessment.
- 850.2300. An avian reproduction study with northern bobwhite quail is necessary for risk assessment. Additionally, an avian reproduction study with mallard duck is under

review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.

- 850.4100 (850.4225). A seedling emergence study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- 850.4150 (850.4250). A vegetative vigor study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.

The guideline numbers for terrestrial plants in the 40 CFR Part 158 were updated to reflect final 850 guidelines and do not reflect the numbers of the Public Draft 850 guidelines. Part 158 lists 850.4100 and 850.4150 (seedling emergence and vegetative vigor, respectively) for both Tier 1 and Tier 2 studies. The Public Draft guidelines 850.4100 and 850.4150 are for Tier 1 and 850.4225 and 850.4250 are for Tier 2.

Table 6. Terrestrial Toxicity Profile for Bensulfuron-methyl.

Taxonomic Group	Surrogate Species (Common Name)	Endpoint	Acute Classification/ Chronic effect	Reference (MRID)
Birds	*Anas platyrhynchos* (mallard)	LD_{50}>2510 mg ai/kg bw	Practically nontoxic	00148303
	Colinus virginianus (Bobwhite quail)	LC_{50}>5620 mg ai/kg diet	Practically nontoxic	00148304
	Passerine bird	No data	No data	--
Mammals	*Rattus norvegicus* (Laboratory rat)	LD_{50}>5000 mg ai/kg bw	Practically non toxic	40089316
	Laboratory rat	LOAEL=7500 mg a1/kg-diet NOAEC=750 mg ai/kg-diet	Adult body weights	40089316
Terrestrial Invertebrates	*Apis mellifera* (Honey bee)	LD_{50}>12.5 µg/bee	Practically nontoxic	00148305
Seedling emergence	--	--[a]	--	42690101
Vegetative vigor	--	--[a]	--	42690102

[a]data under review

Although avian subacute and mammalian acute endpoints are nondefinitive values, preliminary calculation of RQs (not shown) indicate that the highest dose tested (*e.g.* 5000 mg ai/kg-bw) are sufficiently higher than the EECs so that further data are not needed at this time.

4.3. Incident Database Review

A review of the Ecological Incident Information System (EIIS) database for incidents involving bensulfuron-methyl was conducted on March 3, 2011. One incident is reported in the database.

This incident (I008849-001) occurred in April 1999 in Jefferson Davis County, LA. Two oak trees and three unidentified trees were affected by spray drift from a registered use on rice. The incident is considered 'likely' due to bensulfuron-methyl.

Similarly, a search of the Avian Incident Monitoring System (AIMS; http://www.abcbirds.org/abcprograms/policy/toxins/aims/aims/index.cfm), a database administered by the American Bird Conservancy which contains publicly available data on reported avian incidents involving pesticides did not report any incidents for bensulfuron-methyl as of March 3, 2011.

Pesticide registrants report certain types of incidents to the Agency as aggregate counts of incidents occurring per product per quarter. No aggregated incidents have been reported to the Agency associated with bensulfuron-methyl. The lack of incident reports cannot be construed as the absence of incidents as there can be many reasons why the Agency is not notified of adverse effects resulting from the use of a pesticide.

4.4. Ecosystems Potentially at Risk

The ecosystems at risk are often extensive in scope; therefore, it may not be possible to identify specific ecosystems during the development of a nation-wide ecological risk assessment. However, in general terms, terrestrial ecosystems potentially at risk could include the treated field and immediately adjacent areas that may receive drift or runoff. Areas adjacent to the treated field could include cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats and other uncultivated areas.

Aquatic ecosystems potentially at risk include water bodies adjacent to, or downstream from, the treated field and could include impounded bodies such as ponds, lakes and reservoirs, or flowing waterways such as streams or rivers. For uses in coastal areas, aquatic habitat also includes marine ecosystems, including estuaries.

5. Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected."[1] Selection of the assessment endpoints is based on valued entities (*e.g.,* fish, birds), the ecosystems potentially at risk (*e.g.,* waterbodies, riparian vegetation, and upland habitats), the migration pathways of bensulfuron-methyl (*e.g.,* runoff, drift, *etc.*), and the routes by which ecological receptors are exposed to bensulfuron-methyl (*e.g.,* direct contact, *etc.*).

Assessment endpoints for bensulfuron-methyl include direct toxic effects on the survival, reproduction, and growth of the receptors, as well as indirect effects, such as reduction of the prey base or modification of habitat. Each assessment endpoint requires one or more "measures of ecological effect," defined as changes in the attributes of an assessment endpoint or changes in a surrogate entity or attribute in response to exposure to a pesticide. Specific measures of ecological effect are generally evaluated based on acute and chronic toxicity information from

[1] From U.S. EPA (1992). *Framework for Ecological Risk Assessment.* EPA/630/R-92/001.

registrant-submitted guideline tests that are performed on a limited number of organisms. Additional ecological effects data from the open literature will also be considered.

6. 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.

The conceptual model for bensulfuron-methyl provides a written description (risk hypothesis) and visual representation (conceptual diagram) of the predicted relationships between bensulfuron-methyl, 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 (USEPA 1998b).

Based on the available data (including those from uncertain studies, and considering existing data gaps), bensulfuron-methyl is stable in neutral to basic water. Bensulfuron-methyl is hydrolyzed in acidic water. Bensulfuron-methyl is assumed to be stable to aerobic metabolism in soil and water as well as anaerobic aquatic metabolism, due to unacceptable data or existing datagaps. The mobility of bensulfuron-methyl varies with soil types (correlated with organic matter). Bensulfuron-methyl will have a tendency to leach in sandy, inorganic soils, but rice plots (the only labeled use for bensulfuron-methyl) are designed to hold water with some type of confining layer. Therefore the amount of compound that remains in the water column will remain with the released water (when paddy is drained), and the chemical sorbed to the sediment in rice paddies will remain sorbed to sediment particles and will only travel downstream if the sediment is eroded with the release water. Bensulfuron-methyl is not expected to bioaccumulate in aquatic or terrestrial food chains. It is important to note that the solubility, volatility, photolytic adsorption, octanol water partitioning coefficient, are all uncertain at this time as no physical and chemical data has been submitted to the Agency.

6.1. Risk Hypothesis

A risk hypothesis describes the predicted relationship among the stressor, exposure, and assessment endpoint response along with the rationale for their selection. For bensulfuron-methyl, the following ecological risk hypothesis will be employed for the national-level ecological risk assessment:

Given the uses of bensulfuron-methyl and its environmental fate properties, there is a likelihood of exposure to non-target terrestrial and aquatic organisms. When used in accordance with the label, bensulfuron-methyl may result in potential adverse effects upon the survival, growth, and reproduction of non-target terrestrial and aquatic organisms.

6.2. Conceptual Diagram

The conceptual model used to depict the potential ecological risk associated with the use of bensulfuron-methyl (the stressor) assumes that as a pesticide, bensulfuron-methyl can adversely affect terrestrial and aquatic organisms (the receptors) if environmental concentrations exceed toxic thresholds as a result of application according to the label directions (**Figures 2 and 3**). Ecological receptors that may potentially be exposed to bensulfuron-methyl include terrestrial and semi-aquatic wildlife (*e.g.*, mammals, birds, terrestrial-phase amphibians and reptiles), terrestrial and semi-aquatic plants, and terrestrial invertebrates (*e.g.*, honey bees). Additionally, given the mobility of bensulfuron-methyl, aquatic organisms (*i.e.*, freshwater and estuarine/marine fish and invertebrates, aquatic-phase amphibians, and aquatic plants) are potential receptors in adjacent water bodies through off-site transport of bensulfuron-methyl from the application site through runoff, erosion, and spray drift.

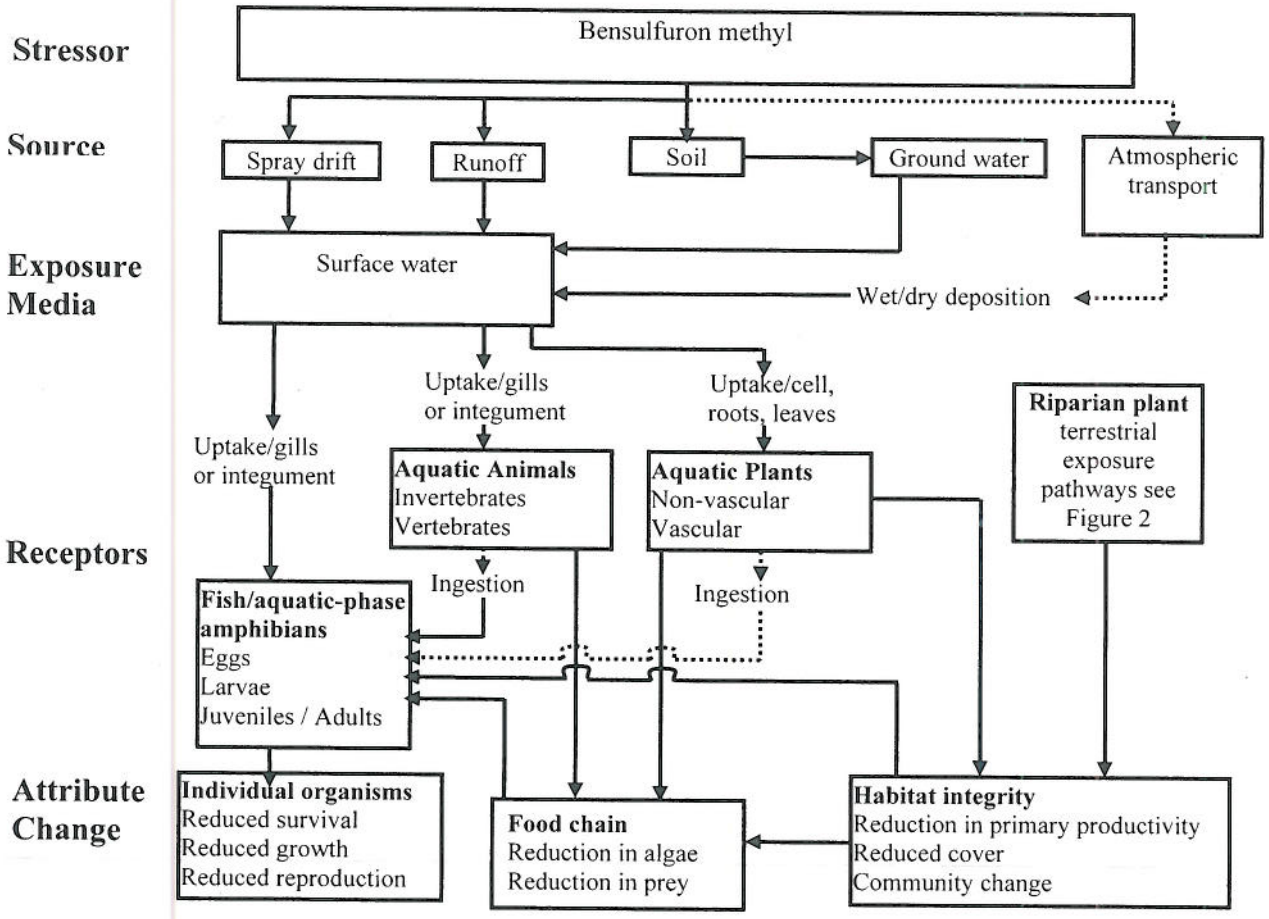

Figure 2. Conceptual model for bensulfuron-methyl exposure to aquatic organisms. Dashed lines indicate route of exposure considered of lower importance for bensulfuron-methyl.

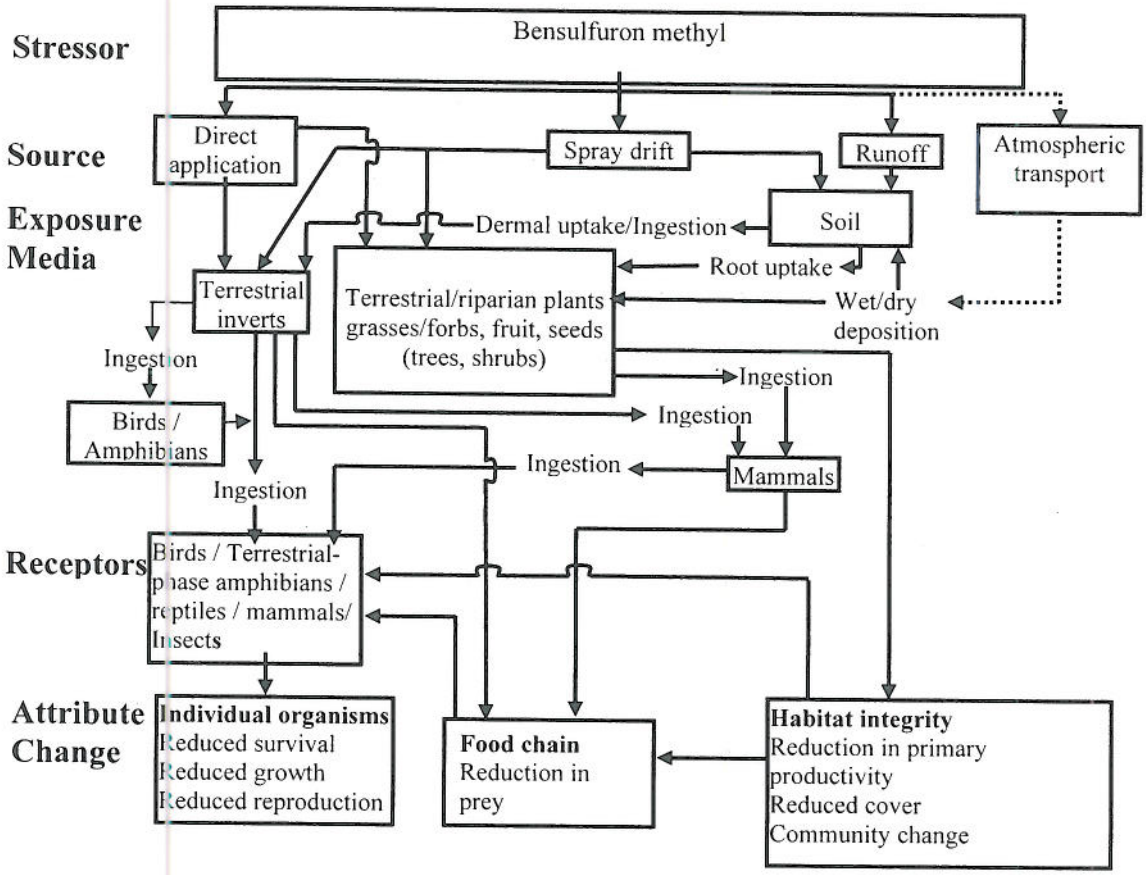

Figure 3. Conceptual model for bensulfuron-methyl exposure to terrestrial organisms. Dashed lines indicate route of exposure considered of lower importance for bensulfuron-methyl.

7. Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment will be estimated. The use, environmental fate, and ecological effects of bensulfuron-methyl will be characterized and integrated to assess the risks. This will be accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA 2004), the likelihood of effects to individual organisms from particular uses of bensulfuron-methyl may be estimated using the probit dose-response slope and either the level of concern (discussed below) or the actual calculated risk quotient value.

This 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 for bensulfuron-methyl.

7.1. Stressors of Concern

The stressor of concern in the assessment will be bensulfuron-methyl. There are three products of specific mixtures of bensulfuron-methyl with propanil, registered and are under the trade names. In its ecological risk assessments, the Agency does not routinely include an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of multiple active ingredients (that is, a registered product containing more than one active ingredient, each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, the data may be used qualitatively or quantitatively in accordance with the Agency's Overview Document and the Services' Evaluation Memorandum (USEPA, 2004; Williams and Hogarth, 2004).

7.2. Measures of Exposure

In order to estimate risks of bensulfuron-methyl exposures in aquatic and terrestrial environments, exposure modeling will be based on maximum application rates and methods cited in **Table 1.** Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) of bensulfuron-methyl. The Tier I Rice Model is used to assess exposure in surface water from released paddy water following use on rice. The model used to predict terrestrial EECs on food items is the Terrestrial Residue Exposure model (T-REX). The model used to derive EECs relevant to terrestrial plants is TerrPlant. These models are parameterized using relevant reviewed environmental fate data from registrant submissions and the literature. Model input values will be consistent with the most recent version of the input parameter guidance (Version 2.1; USEPA 2009).

The Tier I Rice Model relies on an equilibrium partitioning concept to provide conservative estimates of ecological and drinking water exposure resulting from application of pesticides to rice paddies. When a pesticide is applied to a rice paddy, the model assumes that it will instantaneously partition between a water phase and a sediment phase. The model does not account for pesticide degradation, mass transfer between the aqueous phase and the sediment, volatilization, dilution, or other dissipation processes. The Tier I Rice Model was calibrated to generate estimates that are consistent with, or conservative for, the dissolved concentrations measured within rice paddies and in discharged paddy water. The model was not evaluated or calibrated for concentrations measured in sediment and does not account for residues bound to suspended sediment. The model also does not account for dilution that may occur downstream from the rice-growing areas where paddy water is released.

Due to a range of environmental and other factors, the Tier I Rice Model is expected to generate conservative exposure estimates that exceed peak measured concentrations of pesticides in water bodies well downstream of rice paddies by less than one order of magnitude to multiple orders of

magnitude (USEPA, 2007b). Rice paddies are likely to be planted and harvested on or near the same date suggesting that when paddy waters are released, an influx of bensulfuron-methyl residues from multiple locations to the waterways may be expected. Also, exposure estimates are expected to be more conservative downstream of rice paddies in California and inland areas of the Southeastern United States where dilution is expected to occur. Tidal influences in surface waters of the coastal areas of the Southeastern United States may effectively reduce dilution of bensulfuron-methyl residues from discharged paddy water, lengthening the period of chronic residue exposure in waterways influenced by rice paddies.

Exposure estimates for terrestrial organisms assumed to be in the target area or in an area exposed to off-site deposition are derived using the T-REX model (version 1.4.1, 10/09/2008). This model incorporates the Kenaga nomograph, as modified by Fletcher *et al.* (1994), which is based on a large set of field residue data. The upper limit values from the nomograph represent the upper bound of residue values from actual field measurements (Hoerger and Kenaga 1972). The Fletcher *et al.* (1994) modifications to the Kenaga nomograph are based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. Based on these data, T-REX assumes a 35-day foliar dissipation half-life in the absence of other data.

In order to determine if inhalation is a potential pathway of concern for terrestrial organisms, the Screening Tool for Inhalation Risk (STIR v.1.0) was used to calculate an upper bound estimate of exposure using bensulfuron-methyl's vapor pressure and molecular weight for vapor phase exposure as well as the maximum application rate and method of application for spray drift. STIR incorporates results from several toxicity studies including acute oral and inhalation rat toxicity endpoints obtained from the "six-pack" of core studies, which are a series of six guideline studies that are submitted to the Registration Division of the Office of Pesticide Programs for technical and formulated products of a pesticide as well as the most sensitive acute oral avian toxicity endpoint. Based on the results of the STIR model, inhalation exposure alone was not determined to be a potential pathway of concern for avian or mammalian species on an acute exposure basis.

Inhalation exposure via spray drift and/or vapor-phase of the pesticide alone does not appear to be of concern. The analysis of the inhalation route of in STIR does not consider that aggregation with other exposure pathways such as dietary, dermal, or drinking water may contribute to a total exposure that has a potential for effects to non-target animals. However, the Agency does consider the relative importance of other routes of exposure in situations where data indicate that pesticide exposures through other routes may be potentially significant contributors to wildlife risk (USEPA, 2004). The risk assessment will discuss the impact of consideration of other routes of exposure that have been identified as potentially important and the degree of certainty associated with screening-level risk assessment conclusions. Detailed information about STIR v.1.0, as well as the tool, can be found on the EPA's website at:http://www.epa.gov/pesticides/science/models_pg.htm#terrestrial.

The Screening Imbibition Program (SIP v.1.0) was used to calculate an upper bound estimate of exposure using bensulfuron-methyl's solubility, the most sensitive acute and chronic avian and mammalian toxicity endpoints. Drinking water exposure alone was determined to be a not to be

a potential pathway of concern for mammalian species on an acute or chronic exposure basis. Drinking water was also not a concern for avian species on an acute exposure basis, although potential avian chronic concern is assumed due to lack of data.

This pathway will be explored further with the development of SIP v.2.0 in the risk assessment for bensulfuron-methyl. Detailed information about the SIP v.1.0, as well as the tool, can be found on the EPA's website at http://www.epa.gov/pesticides/science/models_pg.htm#terrestrial.

EECs for terrestrial plants are derived using TerrPlant (v.1.2.2). This model uses estimates of pesticides in runoff and in spray drift to calculate EECs. EECs are based upon solubility, application rate and minimum incorporation depth.

The AgDRIFT (v2.01; May 2001) or AgDISP (v. 8.15) spray drift model may be used to assess exposures of organisms to bensulfuron-methyl deposited on terrestrial habitats by spray drift.

7.3. Measures of Effect

Ecological effects data are used as measures of direct and indirect effects to biological receptors. Effects data are obtained from registrant-submitted studies or from literature studies identified by the ECOTOX database.

The acute measures of effect used for animals in this assessment are the LD_{50}, LC_{50} and EC_{50}. LD stands for "Lethal Dose", and LD_{50} is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for "Lethal Concentration" and LC_{50} is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for "Effective Concentration" and the EC_{50} is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC. NOAEL stands for "No Observed-Adverse-Effect-Level" and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (*i.e.*, "No-Observed-Adverse-Effect-Concentration") is the highest test concentration at which none of the observed effects were statistically different from the control. For non-listed plants, only acute exposures are assessed (*i.e.*, EC_{25} for terrestrial plants and EC_{50} for aquatic plants); for listed plants either the NOAEC or EC_{05} is used.

Where available, sublethal effects observed in both registrant-submitted and open literature studies will be evaluated qualitatively. Such effects may include behavioral changes (*e.g.*, lethargy and changes in coloration). However, quantitative assessments of risks, are limited to those endpoints that can be directly linked to the Agency's assessment endpoints of impaired survival, growth and reproduction.

In the absence of taxon-specific data, the assessment of risk for direct effects to non-target organisms makes the assumption that toxicity of bensulfuron-methyl to birds is similar to terrestrial-phase amphibians and reptiles. The same assumption is made for fish and aquatic-phase amphibians. In the absence of data for either acute or chronic effects, the conservative assumption will be to presume that bensulfuron-methyl is toxic.

7.4. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the registered uses of bensulfuron-methyl and the likelihood of direct and indirect effects to non-target organisms in aquatic and terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of bensulfuron-methyl risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's Levels of Concern (LOCs) (USEPA 2004). These criteria are used to indicate when bensulfuron-methyl use, as directed on the labels, has the potential to cause adverse direct or indirect effects to non-target organisms. In addition, incident data from the EIIS will be considered as part of the risk characterization.

7.5. Deterministic and Probabilistic Assessment Methods

The quantitative assessment of risk will primarily depend on the deterministic point-estimate (RQ) based approach described in the risk assessment. An effort will be made to further qualitatively describe risk using probabilistic tools that the Agency has developed. These tools have been reviewed by FIFRA Scientific Advisory Panels (http://www.epa.gov/scipoly/sap/index.htm) and have been deemed as appropriate means of refining assessments where deterministic approaches have identified risks. Newer tools may be available to assess the routes of exposure (*e.g.* TIM and SWAMP models) and will be applied as appropriate in Registration Review.

7.6. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of reregistration decision, EPA will review these data and select the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), bensulfuron-methyl is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required

determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Bensulfuron-methyl is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Accordingly, as part of registration review, EPA will issue future EDSP orders/data call-ins, requiring the submission of EDSP screening assays for bensulfuron-methyl. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

7.7. Endangered Species Assessment

Consistent with the Agency's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to Federally-listed threatened and/or endangered (listed) species from registered uses of bensulfuron-methyl. This assessment will be conducted in accordance with the Overview Document (USEPA 2004), provisions of the ESA, and the Services' *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998).

The assessment of effects associated with the registration of bensulfuron-methyl is based on an action area. The action area is considered to be the area directly or indirectly affected by the federal action, as indicated by the exceedance of Agency Levels of Concern (LOCs) used to evaluate direct or indirect effects. The Agency's approach to defining the action area under the provisions of the Overview Document (USEPA 2004) considers the results of the risk assessment process to establish boundaries for that action area with the understanding that exposures below the Agency's defined LOCs constitute a no-effect threshold. For the purposes of this assessment, attention will be focused on the footprint of the action (*i.e.*, the area where bensulfuron-methyl application occurs), plus all areas where offsite transport (*i.e.*, spray drift, runoff, *etc.*) may result in potential exposure that exceeds the Agency's LOCs. Specific measures of ecological effect that define the action area for listed species include any direct and indirect effects and/or potential modification of its critical habitat, including reduction in survival, growth, and reproduction as well as the full suite of sublethal effects available in the effects literature. Therefore, the action area extends to a point where environmental exposures are below any measured lethal or sublethal effect threshold for any biological entity at the whole organism, organ, tissue, and cellular level of organization. In situations where it is not possible to determine the threshold for an observed effect, the action area will initially be assumed to include all counties where bensulfuron-methyl is used in the United States.

7.8. Drinking Water Assessment

In order to bring the drinking water exposure assessment up to date with current data, models and simulation model guidance, a new drinking water assessment will be conducted to support future human health dietary risk assessments of bensulfuron-methyl. The drinking water exposure assessment will be conducted for the maximum labeled use in support of the human health dietary risk assessment. The drinking water assessment will incorporate model estimates of bensulfuron-methyl alone in surface water and ground water including any residues that are determined to be of toxicological concern. Concentrations of bensulfuron-methyl in surface waters (Estimated Drinking Water Concentrations, or EDWCs) will be estimated using PRZM/EXAMS (see description above) but using the Index Reservoir scenario rather than the standard pond used for assessment of exposure in drinking water.

An EDWC of bensulfuron-methyl in ground water will be estimated using EFED's Tier I aquatic model SCIGROW (Screening Concentration in Ground Water, version 2.3; 8/8/2003). SCIGROW is a regression model used as a screening tool to estimate pesticide concentrations found in ground water used as drinking water. The output of SCIGROW represents the concentrations that might be expected in shallow unconfined aquifers under sandy soils, which is representative of the ground water most vulnerable to pesticide contamination likely to serve as a drinking water source.

7.9. Environmental Monitoring Data

A query of the United States Geological Survey's (USGS) National Water Quality Assessment Program (NAWQA) for detections of bensulfuron-methyl in surface water returned 33 detections out of 2,589 samples analyzed (concentrations ranging from 0.0056 to 1.098 ug/L; detection frequency of 1.3 %; MDL ranged from 0.0058 to 0.06 ug/L). Similarly for groundwater, 6 detections were reported out of 2,442 samples analyzed for bensulfuron-methyl (concentrations ranged from 0.019 to 0.093 ug/L; detection frequency of <1 %). Although the detection frequencies are low for surface water and groundwater, these detections illustrate the potential for both surface water and groundwater contamination resulting from bensulfuron-methyl use. All monitoring data will be considered to characterize the modeling and risk estimations for bensulfuron-methyl in the environment for the ecological and drinking water assessments. States, Tribal Organizations, and other government and non-government organizations are encouraged to submit additional surface water and groundwater monitoring data for bensulfuron-methyl.

8.0. Preliminary Identification of Data Gaps

8.1. Environmental Fate

The studies submitted to fulfill environmental fate data requirements for bensulfuron-methyl are not sufficient to conduct an exposure assessment; five requirements have not been met as stipulated in 40 CFR part 158 Subpart N §158.1300 for all pesticides with use patterns for aquatic food and nonfood applications:

- 835.4100 There is no acceptable data for aerobic soil metabolism. The guideline stipulates that results from at least four relevant soils of different organic carbon content, pH, clay content, and microbial biomass must be submitted in order to characterize the variability in the aerobic biodegradation of bensulfuron-methyl in the environment.
- 835.4300 There are no acceptable aerobic aquatic metabolism studies. This study is necessary in order to describe the fate of bensulfuron-methyl in surface water bodies down-gradient from use sites (e.g., rice paddies). The guideline stipulates that at least two different soil:water systems be submitted that are similar to the potential use sites in the United States.
- 835.4400 Submission of an acceptable anaerobic aquatic metabolism study is necessary to understand the degradation of bensulfuron-methyl in oxygen-limiting environments.
- 835.6200 An acceptable aquatic field dissipation study is required for all pesticides with use patterns for aquatic food and nonfood applications. Supplemental to the aquatic field dissipation study is the independent laboratory method validation, and environmental chemistry methods used for the field study.

Although not necessary for exposure assessment, submission of environmental chemistry methods in water, soil, and sediment as well as associated independent laboratory validations for these methods is also necessary in order to support enforcement and monitoring purposes at the federal, state, and local levels.

Further, there are no physical and chemical data for bensulfuron-methyl pursuant to OPPTS guideline series 830 Group B (Physical/Chemical Properties). Without these data it is difficult to estimate the environmental exposure of bensulfuron-methyl. These data are crucial to predicting the environmental fate and transport of a compound in the environment, without these data there is considerable uncertainty about the fate and transport of bensulfuron-methyl.

Table 7 identifies studies by MRID that offer data for each guideline requirement, as well as study classifications and whether or not further data are needed in order to support risk assessment (*i.e.*, whether there is a data gap).

Table 7. Summary of available environmental fate data.

Guideline	Study Title	MRID / ACC No.	Classification	Data Gap?	Comments
835.2120	Hydrolysis	00073657	**Acceptable**	No	
835.2240	Photodegradation in Water	40448102	**Acceptable**	No	Study was conducted using a light source comparable in intensity to sunlight.
		40089330	**Unacceptable**		Study was conducted using a light source lacking in intensity similar to natural sunlight conditions.
		40089335 ACC 73657	**Supplemental**		Supplemental information for ACC 73657. Study was conducted using a light source lacking in intensity similar to natural sunlight conditions. Degradates were not properly identified.

Guideline	Study Title	MRID / ACC No.	Classification	Data Gap?	Comments
835.2410	Photodegradation on Soil	No data	**No data**	No	Not required for aquatic food use pesticides.
835.4100	Aerobic Soil Metabolism	00073657	**Supplemental**	**Yes**	Study was previously classified acceptable. Two soils were used for calculation of rate. Reviewer noted that an additional two soils are needed for degradation rate calculation. Half-lives from this study should not be used for risk assessment due to variability in material balance, poor recovery, and material losses over the course of the study.
835.4200	Anaerobic Soil Metabolism	No data	**No Data**	**No**	Not required for aquatic food use pesticides.
835.4300	Aerobic Aquatic Metabolism	40089329	**Supplemental**	**Yes**	Study was previously classified acceptable. Study was downgraded to supplemental because the original study did not provide information regarding aerobicity during flooding. Therefore there is uncertainty if the system was sufficiently aerobic during the study. The study did report that the test system was constantly agitated prior to treatment; therefore aerobic conditions should have existed. However this information is missing from the original study.
835.4400	Anaerobic Aquatic Metabolism	40089333	**Unacceptable**	**Yes**	Pattern of material loss over the course of the study.
835.1240, 835.1230	Mobility - Adsorption / Desorption	00073657	**Supplemental**	No	Batch Equilibrium data as Ka (adsorbed) was only provided for unaged soil. Loss of material was reported. DER stated that aged portion of guideline remains open. MRID 40767004 fulfills that requirement.
		40767004 00073657	**Acceptable**		Soil column leaching study, supplement to Batch Equilibrium.
835.6100	Terrestrial Field Dissipation	**No data**	**No data**	No	Conditionally required for aquatic food and nonfood use pesticides where use site is intermittently dry. However, since use pattern is consistent with flooded conditions, and aquatic field studies show dissipation in aquatic system, study is not required at this time.
835.6200	Aquatic Field Dissipation	42184903	**Unacceptable**	**Yes**	Closed pond studies for aquatic uses and aquatic impact uses, as well as accumulation studies for aquatic non-target organisms. Pattern of formation and decline of degradates was not addressed; freezer storage stability data were not provided; description of immunoassay method used to quantify parent was not provided; test site was not completely characterized.
		00073657	**Unacceptable**		Hydrolysis of bensulfuron-methyl methyl occurred during analytical procedure.
		40089331	**Supplemental**		Study was scientifically sound and provides supplemental information on the dissipation of bensulfuron-methyl methyl within diked rice plots. Pattern of formation and decline of degradates was not addressed, analytical method was not reported, test plots and soils were not well characterized (e.g., dimensions, soil properties).

Guideline	Study Title	MRID / ACC No.	Classification	Data Gap?	Comments
		43256402	**Unacceptable**		Stability of bensulfuron-methyl methyl in soil and water during frozen storage was not demonstrated. Irrigation water was not characterized (water quality information was not included). Degradates of bensulfuron-methyl methyl were not monitored in floodwater nor soil samples.
850.1730	Fish Accumulation	00073657	**Acceptable**	No	Biospherics study 1983b (Project No.: 83-E-555C) using Rainbow Trout No bioconentration observed.
		00073657	**Acceptable**		Biospherics study 1983a (Project No.: 83-E-554R) Using Carp. No bioconcentration observed.
		42602501	**Study currently under review**		Study currently under review.
Non-guideline	Field Accumulation in Crayfish	43256402	**Supplemental**	No	Study is scientifically sound and provides supplemental information on the bioaccumulation of bensulfuron-methyl in crayfish caged in floodwater of rice paddies treated with bensulfuron-methyl.

8.2. Ecological Effects

The available ecological effects data for bensulfuron-methyl is incomplete (Tables 8-10). Acute avian toxicity data (850.2100) on a passerine species are necessary, as is an avian reproduction study with bobwhite quail (850.2300). A reproduction study with mallard duck is currently under review; if EFED concludes that the study is sufficient for risk assessment, no further mallard data would be necessary. Data are under review for vascular aquatic plants (*Lemna gibba*) and aquatic nonvascular plants (*Pseudokirchneriella subcapitata* and *Anabaena flos-aquae*); however, data (850.5400) are necessary for both a centric and a pinnate diatom. Available supplemental data indicate that *Nitzschia palea*, a pinnate diatom, may be more sensitive than other aquatic nonvascular plants. Data for terrestrial plants (850.4100 and 850.4150) are under review and if the review concludes that the data are sufficient for risk assessment, no further terrestrial plant data will be necessary.

Terrestrial plants are typically very sensitive to sulfonylurea urea herbicide exposure. There is evidence[2] to suggest plant reproduction may be affected by sulfonylurea herbicides at levels below effects on vegetative growth or visual injury (Fletcher *et al.*, 1993). Uncertainty regarding the potentially greater sensitivity of terrestrial plant reproduction has been discussed extensively in the environmental fate and effects RED assessment for chlorsulfuron (D330621). Therefore, to the extent that terrestrial plant reproduction are more sensitive to bensulfuron-methyl than growth endpoints, risks to terrestrial plants may be underestimated in this risk assessment. Additional information on the reproductive toxicity of bensulfuron-methyl to terrestrial plants is necessary to address this uncertainty.

Known major degradates of bensulfuron-methyl are 2-amino-4,6-dimethoxyprimidine (AE-F092944 or INJ0290 or ADMP), methyl 2-(aminosulfonyl-methyl)benzoate (IN-D1R84), and 1H-2,3-benzothiazin-4(3H)-one 2,2-dioxide. For the latter, data on saccharin will be considered.

[2] Snipes *et al.* 1992, Bansal *et al.* 1999; Fletcher *et al.* 1993, 1995,1996; Bhatti *et al.* 1995; Al-Khatib *et al.* 1992; Boutin *et al.* 2000; Asghari and Evans 1992

Due to deficiencies in the environmental fate data for bensulfuron-methyl, not all degradates may be accounted for, nor are the quantities at which degradates form known with any certainty. Therefore, the following process will be applied to bensulfuron-methyl regarding the need for degradate plant toxicity data. In general, degradates forming at less than 10% of the parent will not need toxicity data. For plants, toxicity data needed for degradates include seedling emergence for terrestrial plants and both vascular and nonvascular aquatic plants. Any degradates that retain the double ring structure of the parent with the sulfonylurea bridge will be assumed equally toxic to the parent. Degradates forming from the ring on the sulfonyl side of the molecule such orthobenzoic acid/ methylorthobenzoate would need toxicity data. Aminodimethoxypyrimidine degradates forming from the ring on the on the amine side of the molecule would also need toxicity data. Further, any urea-type will need to have degradate toxicity data submitted. Toxicity data from similar degradates from other SUs would be considered for bridging provided sufficient justification is provided.

- 850.4400. Two aquatic vascular plant studies are under review, one with TGAI and one with TEP. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, aquatic nonvascular plant data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.
- 850.5400. **Data for a pinnate and a centric diatom are necessary for risk assessment.** Additionally, studies with green algae and cyanobacteria (one TGAI and one TEP each) are under review. Until the reviews are complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, aquatic nonvascular plant data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.
- 850.2100. **An avian oral toxicity study with a passerine is necessary for risk assessment.**
- 850.2300. **An avian reproduction study with northern bobwhite quail is necessary for risk assessment.** Additionally, an avian reproduction study with mallard duck is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- 850.4100 (850.4225). A seedling emergence study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment. Additionally, seedling emergence data on the 2-amino-4,6-dimethoxyprimidine and methyl 2-(aminosulfonyl-methyl)benzoate degradates are necessary, as well as any other degradates as described in Section 8.2.
- 850.4150 (850.4250). A vegetative vigor study is under review. Until the review is complete, EFED cannot be certain the data are sufficient for risk assessment.
- Non-guideline. **Terrestrial Plant Reproduction Study** will be necessary for risk assessment.

TABLE 8. Available ecological effects data for terrestrial animals exposed to bensulfuron-methyl

Guideline	Description	MRID/ Accession	Classification	Data Gap?	Comments
850.2100	Avian oral toxicity	00148303	Acceptable	**Yes**[a]	Avian acute oral toxicity data are not available for passerines, which are required under 40 CFR Part 158.
850.2200	Avian dietary toxicity	ACC 073655	Acceptable	No	
		00148304	Acceptable		
850.2300	Avian reproduction	45668901	In review	**Yes**	Avian reproduction data on bobwhite quail are necessary for risk assessment
850.3020	Honeybee acute contact toxicity	00148305	Acceptable	No	

[a]Bold indicates data necessary for risk assessment

TABLE 9. Available ecological effects data for aquatic animals exposed to bensulfuron-methyl.

Guideline	Description	MRID/ Accession	Classification	Data Gap?	Comments
850.1075	Freshwater fish – Acute toxicity	40940107	Acceptable	No	In the absence of data, risk will be presumed
		40089321	Supplemental		
		40940102	Acceptable		
		40089322	Supplemental		
		40951402	Supplemental		
850.1075	Saltwater fish – Acute toxicity	40940104	Acceptable	No	
850.1010	Freshwater invertebrates – Acute toxicity	40940103	Acceptable	No	
		40951403	Supplemental		
850.1025 850.1035	Saltwater invertebrates –Acute toxicity	40940101	Acceptable	No	
		40940106	Acceptable		
850.1300	Freshwater invertebrate – life cycle test	40940108	Acceptable	No	
850.1350	Saltwater invertebrates – life cycle test	None		Yes	For estuarine/marine chronic endpoints, acute-to-chronic ratios will be used if necessary
850.1400	Freshwater fish – early life stage test	40951401	Acceptable	No	
		46361501	In review		
850.1400	Saltwater fish – early life stage test	None		Yes	

TABLE 10. Available ecological effects data for plants exposed to bensulfuron-methyl.

Guideline	Description	MRID	Classification	Data Gap?	comments
850.4225	Terrestrial Plant toxicity: Tier II seedling emergence	46290101	In review l	**Yes**	Guideline data on the toxicity of bensulfuron-methyl to two diatoms are necessary. Supplemental data indicate a high degree of sensitivity in these taxa
850.4250	Terrestrial Plant toxicity: Tier II vegetative vigor	46290102	In review	**Yes**	
850. 5400	Aquatic Plant Growth: algae	45385201	In review	**Yes**[a]	
		45586701	In review		
		45385202	In review		
		45586702	In review		
		40815104	In review		
		41267901	Supplemental		
850.4400	Aquatic Plant Growth: vascular plants	45586703	In review	**Yes**	
		45586704	In review		
Non guideline	Terrestrial Plant Reproduction Study			**Yes**	Special study; see justification

[a]Bold indicates data necessary for risk assessment

9. References

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Submitted Fate Studies

161-1 Hydrolysis

Accession No. 073657	Friedman, P.L. (1983) Hydrolysis of 14C-DPX-F5384. Laboratory Project ID AMR-143-83. Prepared and Submitted by E.I. du Pont de Nemours and Company, Inc., Wilmington, DE.

161-2 Photodegradation-water

MRID	Citation Reference
40089330	Scott, M. (1986) Photodegradation of [Phenyl(U)[carbon 14]] DPX-F5384 and [Pyrimidine-2-[carbon 14]] DPX-F5384 on Soil: Report No. AMR-512-86. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 42 p.
40448102	Horne, P. (1987) Photodegradation of ?Phenyl (U)-?Carbon 14||DPX-F5384 and ?Pyrimidine-2-?Carbon 14||DPX-F5384 in Water: (Conducted in Sunlight): Laboratory Project ID: AMR-899-87. Unpub- lished study prepared by E. I. du Pont de Nemours & Co., Inc. 46 p.
40089335 ACC 73657	Friedman, P. (1987) Aqueous Photolysis of [Carbon 14]-DPX-F5384: (Response to Reviewer's Comments): Report No. AMR-215-84. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 6 p.

162-1 Aerobic Soil Metabolism

Accession No. 073657	Friedman, P.L. (1984a) Aerobic Soil Metabolism of 14C-DPX-F5384. Laboratory Project ID AMR-216-84. Prepared and Submitted by E.I. du Pont de Nemours and Company, Inc., Wilmington, DE.

162-3 Anaerobic aquatic metab.

MRID	Citation Reference
40089333	Cadwgan, G.; Ryan, T. (1986) Anaerobic Aquatic Metabolism of [Pyrimidine-2-[carbon 14]]DPX-F5384 and [Phenyl(U)-[carbon 14] DPX-H6573 in Water: Laboratory Project ID: AMR-606-86. Unpub- lished study prepared by E. I. du Pont de Nemours & Co., Inc. 40 p.

162-4 Aerobic aquatic metab.

MRID	Citation Reference
40089329	Hunt, O. (1986) Aerobic Aquatic Metabolism of [Phenyl(U)-[carbon 14]] DPX-F5384 and [Pyrimidine-2-[carbon 14]]DPX-F5384: Report No. AMR-475-86. Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 42 p.

163-1 Leach/adsorp/desorption

MRID	Citation Reference
40767004 or ACC 73657	Priester, T. (1985) Batch Equilibrium (Adsorption/Desorption) and Soil Thin-Layer Chromatography Studies with ?Carbon 14|- DPX-F5384: Laboratory Project ID AMR-254-84. Unpublished study prepared by E.I. du Pont de Nemours & Co., Inc. 14 p.
Accession No. 073657	Priester, T.M. (1984a) Batch Equilibrium (Adsorption/Desorption) and Soil Thin-Layer Chromatography Studies with DPX-F5384: Laboratory Project ID AMR-254-84. Prepared and Submitted by E.I. du Pont de Nemours & Company, Inc., Wilmington, DE.
147405 or Accession No. 073657	Neal, L.W. (1984) Soil Column Leaching Studies with [phenyl]-14C(U)]DPX-F5384. Laboratory Project ID AMR-208-84. Prepared and Submitted by E.I. du Pont de Nemours and Company, Inc., Wilmington, DE.
147405	Neal, L.W. (1984) Soil Column Leaching Studies with [phenyl-14C] DPX-F5384. Document No. AMR-208-84. Unpublished Study Prepared and Submitted by E.I. du Pont de Nemours and Company, Inc., Wilmington, DE.

164-1 Terrestrial field dissipation

MRID	Citation Reference
40089331	Ackerson, R.; McIntosh, C. (1987) Aquatic Filed (sic) Soil Dissipation Study with Du Pont Londax 10WP Herbicide: Report No. RC5384-2-86.

Unpublished study prepared by E. I. du Pont de Nemours & Co., Inc. 37 p.

164-2 Aquatic field dissipation

MRID	Citation Reference
42184903	Langeland, K. (1991) Field Dissipation (Closed Pond) Studies of Bensulfuron Methyl for Aquatic Uses and Aquatic Impact Uses and Field Accumulation (Closed Pond) Studies of Bensulfuron Methyl for Aquatic Nontarget Organisms: Lab Project Number: AMR-1350-88: ML89-0135-DUP. Unpublished study prepared by Univ. of Florida, Inst. of Food and Agric. Science, and Morse Labs, Inc. 129 p.
43256401	Slates, R. (1990) Determination of the Freezer Storage Stability of Bensulfuron Methyl Residues in Field Dissipation Study Samples: Lab Project Number: AMR-1258-88: ML88-0062-DUP. Unpublished study prepared by Morse Lab., Inc. 32 p.
43256402	Slates, R.; Larochelle, J. (1990) Aquatic Field Dissipation/Accumulation Studies: Bensulfuron Methyl Residues in Flooded Rice Fields: Lab Project Number: ML88-0053-TUP: AMR-1167-88. Unpublished study prepared by E.I.du Pont de Nemours & Co. Inc. 108 p.
Accession No. 073657	Priester, T.M. (1984) Metabolism of DPX-F5384 [14C-phenyl (U)] in Rice Paddy Ecosystem. Laboratory Project ID AMR-229-84. Prepared and Submitted by E.I. du Pont de Nemours & Company, Inc., Wilmington, DE.
40089332	Johnston, E.F., R.V. Slates and G.P. Griffith (1987) Determination of Rice Herbicide Candidate DPX-F5384 in Rice Paddy Soil. Laboratory Project ID AMR-295-84. Prepared and Submitted by E.I. du Pont de Nemours and Company, Inc., Wilmington, DE.

165-4 Bioaccumulation in fish

MRID	Citation Reference
42602501	McComish, M.; Marquis, J. (1991) Residues of (carbon 14)Bensulfuron Methyl in Channel Catfish: Lab Project Number: 64705 (1-4779R): AMR-1542-89. Unpublished study prepared by Arthur D. Little, Inc. 100 p.
Accession No. 073657	Biospherics, Inc. (1983b) DPX-F5384 [14C-phenyl (U)] Flow-Through Bioconcentration Study with Rainbow Trout. Project Number 83-E-555C.Prepared by Biospherics, Inc., Rockville, MD and Submitted by E.I. du Pont de Nemours and Company, Inc.., Wilmington, DE.
Accession No. 073657	Biospherics, Inc. (1983a) DPX-F5384 [14C-phenyl (U)] Flow-Through Bioconcentration Study with Carp. Project Number 83-E-555C.Prepared by Biospherics, Inc., Rockville, MD and Submitted by E.I. du Pont de Nemours and Company, Inc.., Wilmington, DE.

165-5 Bioaccum-aquatic non-target

MRID	Citation Reference
43256405	Zhou, M. (1993) Magnitude of Bensulfuron Methyl Residues in Crayfish after Application of Bensulfuron Methyl: Lab Project Number: AMR 965-87: AMR 1167-88: AMR 1168-88. Unpublished study prepared by E.I.du Pont de Nemours & Co.; Morse Lab., Inc.; Louisiana State University Ag. Center; University of FL. Center Aquatic Plants. 138 p.
43256403	Romaire, R.; Kleinow, K. (1989) Flow-Through Crayfish Bioconcentration Study with (carbon 14)-Bensulfuron Methyl: Lab Project Number: AMR-965-87: 903-22-6149. Unpublished study prepared by Louisiana State University Ag. Center. 64 p.

Physical/chemical properties

40089309	E. I. du Pont de Nemours & Co., Inc. (1986) Physical and Chemical Characteristics of DPX-F5384 (Technical): Report No. PC5384-12-86. Unpublished study. 6 p.

Submitted Effects Studies

71-1 Avian oral toxicity

MRID	Citation Reference
148303 ACC 73655	Beavers, J. (1984) An Acute Oral Toxicity Study in the Mallard with H # 15,190: Final Report: Project No. 112-151. Unpublished study prepared by Wildlife International Ltd. 14 p. **with Benzoic Acid PC Code 009101**

71-4 Avian Dietary Toxicity

MRID	Citation Reference
148304 ACC 73655	Beavers, J. (1984) A Dietary LC50 Study in the Bobwhite with H # 15,190: Final Report: Project No. 112-149. Unpublished study prepared by Wildlife International Ltd. 12 p. **with Benzoic Acid PC Code 009101**

ACC 073655	Beavers, J. (1984) A Dietary LC50 Study in the Mallard with H # 15,190: Final Report: Project No. 112-150. Unpublished study prepared by Wildlife International Ltd. 12 p.

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71-4 Avian Reproduction

MRID	Citation Reference
45668901	Gallagher, S.; Beavers, J.; Jaber, M. (2002) Bensulfuron Methyl (DPX-F5384) Technical: A One Generation Reproduction Study with the Mallard: Lab Project Number: 5081: DUPONT-5081: 112-501. Unpublished study prepared by Wildlife International, Ltd. 157 p.

72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
40089321	Hutton, D. (1984) 96-Hour LC50 To Rainbow Trout: Londax Herbicide: Report No. HLR-544-84. Unpublished study prepared by Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours & Co., Inc. 9 p.
40089322	Hutton, D. (1984) 96-Hour LC50 To Bluegill Sunfish: Londax Herbicide: Report No. HLR-468-84. Unpublished study prepared by Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours & Co., Inc. 9 p.
40940102	Hutton, D. (1988) Static Acute 96-hour LC50 of IN F5384-85 to Bluegill Sunfish (Lepomis macrochirus): Medical Research Project No. 4581-642: Haskell Laboratory Report No. 626-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 17 p.
40940107	Hutton, D. (1988) Static Acute 96-hour LC50 of IN F5384-85 to Rainbow Trout (Salmo gairdneri): Medical Research Project No. 4581-642: Haskell Laboratory Report No. 654-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 18 p.

40951402	E.I. du Pont de Nemours and Co., Inc. (1986) Static Acute 96-hour LC50 of INF-5284-52 to Channel Catfish (Ictalurus punctatus): Haskell Laboratory Report No. 526-86: MR No. 4581-437. Unpub- lished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 9 p.
147399 ACC 73655	Hall, C. (1985) 96-Hour LC50 to Bluegill Sunfish: [INF-5384-52]: Report No. 468-84. Unpublished study prepared by Haskell Labo- ratory for Toxicology and Industrial Medicine. 3 p. **with Benzoic Acid PC Code 009101**
148306 ACC 73655	Hall, C. (1984) 96-Hour LC50 to Rainbow Trout: [INF-5384-52]: Re- port No. 544-84. Unpublished study prepared by Haskell Labora- tory for Toxicology and Industrial Medicine. 3 p. **with Benzoic Acid PC Code 009101**

72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
40940103	Hutton, D. (1988) Static Acute 48-hour EC50 of IN F5384-85 to Daphnia magna: Medical Research Project No.4581-642: Haskell Laboratory Report No. 625-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 18 p.
40951403	Johnson, I.; Drotter, K. (1988) Acute Toxicity of H-16,441 to the Crayfish (Procambarus clarki): ESE 86-342-0200-2130-41: Du Pont HLO 57-87. Unpublished study prepared by Environmental Science and Engineering, Inc. 37 p.
147398 ACC 73655	Driscoll, R. (1984) 48-Hour LC50 to Daphnia magna: Report No. 564- 83. Unpublished study prepared by Haskell Laboratory for Toxi- cology and Industrial Medicine. 4 p. **Test with Benzoic Acid PC Code 009101**

72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID	Citation Reference
40940101	Boeri, R. (1987) Static Acute Toxicity of Haskell Sample No. 16,985 to the Mysid, Mysidopsis bahia: Enseco Marblehead Laboratory Project D2087. Unpublished study prepared by Enseco, Inc. 21 p.
40940104	Boeri, R. (1988) Static Acute Toxicity of Haskell Sample 16,985. Unpublished study prepared by Enseco, Inc. 20 p. Sheepshead Minnow

study

40940106 Boeri, R. (1988) Static Acute Toxicity of Haskell Sample No. 16,985 to Embryos and Larvae of the Eastern Oyster Crassostrea virgini- ca: Enseco Marblehead Laboratory Project D2287: Du Pont HLO 172- 88. Unpublished study prepared by Enseco, Inc. 19 p.

72-4 Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study

MRID	Citation Reference
40940105	Hutton, D. (1988) Chronic Toxicity of IN F5384-122 to Ceriodaphnia: Medical Research No. 4581-611: Haskell Laboratory Report No. 362-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 21 p.
40940108	Hutton, D. (1988) Chronic Toxicity of IN F5384-122 to Daphnia magna: Medical Research Project No. 4581-652: Haskell Laboratory Report No. 709-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 27 p.
40951401	Hutton, D. (1988) Early Life-stage Toxicity of IN F5384-122 to Fathead Minnows: Medical Research Project No. 4581-611: Haskell Laboratory Report No. 530-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc., Haskell Laboratory for Toxicology and Industrial Medicine. 139 p.
46361501	Samel, A. (2003) Bensulfuron Methyl (DPX-F5384) Technical: Early Life-Stage Toxicity to Rainbow Trout, Oncorhynchus mykiss. Project Number: DUPONT/5446, 13362, 217. Unpublished study prepared by E. I. Du Pont De NeMours And Co, Inc. 114 p.
45595001	Samel, A. (2002) Bensulfuron Methyl (DPX-F5384) Technical: Early Life-Stage Toxicity to Rainbow Trout, Oncorhynchus mykiss: Lab Project Number: 13362: 217: 5446. Unpublished study prepared by E.I. du Pont de Nemours and Company. 110 p.

122-2 Aquatic plant growth

MRID	Citation Reference
41267901	USDA (1989)Effects of Bensulfuron Methyl on Aquatic Plants: Du Pont Study No. F3584-EEB-1. Unpublished study prepared. 18 p.
45385201	Sloman, T. (2001) Bensulfuron Methyl (DPX-F5384) Technical: Influence on Growth and Growth Rate of the Green Alga Selenastrum capricornutum: Lab Project Number: 13362: 5440. Unpublished study

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45385202 Sloman, T. (2001) Bensulfuron Methyl (DPX-F5384) Technical: Influence on Growth and Growth Rate of the Blue-Green Alga Anabaena flos-aquae: Lab Project Number: 13362: 5441. Unpublished study prepared by E.I. du Pont de Nemours and Co. 49 p.

45586701 Sloman, T. (2001) Bensulfuron Methyl (DPX-F5384) 60WG: Influence on Growth and Growth Rate of the Green Alga Selenastrum capricornutum: Lab Project Number: 280: 13381: 5437. Unpublished study prepared by E.I. du Pont de Nemours and Company. 51 p.

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123-1 or 850.4225 4250 Seedling emergence and vegetative vigor

MRID	Citation Reference
46290101 repeated in Tier	Porch, J.; Martin, K. (2004) Bensulfuron Methyl (DPX-F5384) 60WG: A Greenhouse Study to Investigate the Effects on Seedling Emergence

I	and Growth of Ten Terrestrial Plant Species Following Soil Exposure. Project Number: 112/535, DUPONT/12416, 12416. Unpublished study prepared by Wildlife International, Ltd. 186 p.
46290102 repeated in Tier 1	Porch, J.; Martin, K. (2004) Bensulfuron Methyl (DPX-F5384) 60WG: A Greenhouse Study to Investigate the Effects on Vegetative Vigor of Ten Terrestrial Plant Species Following Foliar Exposure. Project Number: 112/536, DUPONT/12417, 12417. Unpublished study prepared by Wildlife International, Ltd. 147 p.

141-1 Honeybee Acute Toxicity

148305	Meade, A. (1984) Acute Contact LD50 Study in Honey Bees (Apis mellifera L.) with INF 5384-52: Final Report: Project No. ABM-84-7. Unpublished study prepared by E. I. du Pont de Nemours and Co. 6 p.

Appendix A Justification for Special Study

Guideline Number: none **Study Titles: Special Study for Non-Target Plant Reproductive Toxicity**
Rationale for Requiring the Data
As stated in the Problem Formulation, investigations/studies have indicated a small percentage of the label application rate of low dose high potency herbicides such as sulfonylureas (e.g. bensulfuron-methyl) may impact the reproduction of non-target terrestrial plants. However, there are no available data on adverse reproductive impacts to terrestrial plants from bensulfuron-methyl residues due to spray drift. Terrestrial plant reproductive toxicity data would help to screen for potential plant risks associated with bensulfuron-methyl use. Plants form the basis of most habitats and contribute significantly to overall environmental quality. The loss of plant reproductive output could potentially have an adverse effect on animals, both invertebrates and vertebrates, as many are dependent on plant reproduction for a food source and for habitat quality and structure. A solid understanding of the potential risks to plants is therefore essential for sound environmental management. A study protocol must be submitted for review and approved by the Agency prior to initiation of the study.
Practical Utility of the Data
How will the data be used? The data will be used to estimate potential reproductive risks to non-target terrestrial plants, including the likelihood of potential risks to endangered species, either by direct effects or by indirect effects, and to reduce uncertainties associated with the current ecological risk assessment. By refining the assessment, the Agency will be able to determine whether current labeling is appropriate and whether further mitigation is necessary. In the absence of this data, risks to terrestrial plants will be presumed. **How could the data impact the Agency's future decision-making?** These data, once submitted, should allow the Agency to characterize the risk posed to plant reproductive processes from bensulfuron-methyl in terrestrial ecosystems. Primary producers (*i.e.* plants) provide food and habitat vital to ecological processes. Therefore, a solid understanding of the potential risks to non-target plants is essential in order to assess the environmental risks the use of bensulfuron-methyl may pose. If the data indicate that bensulfuron-methyl poses significant risks to these non-target plant species, the Agency may explore additional decision options to minimize the risks to these species. The lack of these data will limit the flexibility the Agency and registrants have in complying with the Endangered Species Act and could result in use restrictions for bensulfuron-methyl which may otherwise be avoided, or which are unnecessarily severe.

Appendix B Summary of available effects studies

I. Aquatic

A. Fish

i. Freshwater

Acute

A 96-h acute exposure toxicity test (MRID 40940107) was conducted with rainbow trout (*Onchorhynchus mykiss*, formerly *Salmo gairdneri*). Two replicates of five fish each were exposed to bensulfuron-methyl at concentrations of 0 (negative control), 56, 79, 130, 170 and 270 mg ai/L. No mortality was reported; a single fish at the 170 mg ai/L concentration was reported to have darkened coloration and was swimming at the surface. No other sublethal effects were reported. The NOAEC is 270 mg ai/L and the LC_{50} is >270 mg ai/L. The study is classified as Acceptable and bensulfuron-methyl is classified as practically nontoxic to rainbow trout sunfish on an acute exposure basis.

A second 96-h acute exposure toxicity test (MRID 40089321) is available for rainbow trout. Ten fish each were exposed to bensulfuron-methyl at concentrations of 0 (negative and solvent controls), 1, 10, 100 and 150 mg ai/L. No mortality or sublethal effects were reported. The test concentrations were adjusted to pH 9.0, considerably higher than the maximum recommended pH of 8.5. Despite this major deviation, the lack of effects are notable and together with MRID 40940107 is useful for risk characterization.

A 96-h acute exposure toxicity test (MRID 40940102) was conducted with bluegill sunfish (*Lepomis macrochirus*). Five fish in two replicates each were exposed to bensulfuron-methyl at mean-measured concentrations of 0 (negative control), 12, 19, 23, 32, 40, 49, 53 and 63 mg ai/L. Twenty percent mortality was reported in the lowest concentration. No other mortality or sublethal effects were reported. The NOAEC is 63 mg ai/L and the LC_{50} is >63 mg ai/L. The study is classified as Acceptable and bensulfuron-methyl is classified as no more than slightly toxic to bluegill sunfish on an acute exposure basis.

A second 96-h acute exposure toxicity test (MRID 40089322) is available for bluegill sunfish. Ten fish each were exposed to bensulfuron-methyl at nominal concentrations of 0 (negative and solvent controls), 1, 10, 100 and 150 mg ai/L. No mortality or sublethal effects were reported. The test concentrations were adjusted to pH 9.0, considerably higher than the maximum recommended pH of 8.5. Despite this major deviation, the lack of effects are notable and together with MRID 40940102 is useful for risk characterization.

A 96-h acute exposure toxicity test (MRID 40951402) was conducted with channel catfish (*Ictalurus punctatus*). Ten fish (no replicates) each were exposed to bensulfuron-methyl at nominal concentrations of 0 (negative control and NaOH control), 98, 109, 121, 135 and 150 mg

ai/L. No mortality or sublethal effects were reported. The NOAEC is 150 mg ai/L and the LC_{50} is >150 mg ai/L. The study is classified as Supplemental and bensulfuron-methyl is classified as practically nontoxic to channel catfish on an acute exposure basis.

Chronic

A 36-d early life stage (ELS) study (MRID 40951401) with fathead minnow (*Pimephale promelas*) is available for bensulfuron-methyl. Two replicates of 20 larva each were exposed to mean-measured concentrations of 5.0, 8.8, 14, 34, 55 and 120 mg ai/L for larval survival and growth. Four replicate were used for hatching success, which ranged from 64-72%. Effects on adults were not measured. No dose related effects were reported for any parameter at any concentration tested The NOAEC is 120 mg ai/L. The study is classified as Acceptable.

A second ELS study (MRID 46361501) conducted with rainbow trout is available for bensulfuron-methyl and is under review. Until the review is complete, EFED cannot determine whether these studies are suitable for use in risk assessment. The value reported in the study report is 1.5 mg ai/L, considerably lower than reported in the fathead minnow study.

ii. Estuarine/marine
Acute

A 96-h acute exposure toxicity test (MRID 40940104) was conducted with sheepshead minnow (*Cyprinodon variegatus*). Five fish in four replicates each were exposed to bensulfuron-methyl at mean measured concentrations of 0 (negative control), 78.4, 92.5, 101, 113, and 123 mg ai/L No mortality or sublethal effects were reported. The NOAEC is 123 mg ai/L and the LC_{50} is >123 mg ai/L. The study is classified as acceptable and bensulfuron-methyl is classified as practically nontoxic to sheepshead minnow on an acute exposure basis.

Chronic

No data on the effect of chronic exposure to estuarine/marine fish are available for bensulfuron-methyl. In the absence of specific data, an acute-to-chronic ratio derived from freshwater fish may be used to estimate risk to estuarine/marine fish.

B. Invertebrates

i. Freshwater
Acute

A 96-h acute study (MRID 40940103) with *Daphnia magna* is available for bensulfuron-methyl. Two replicates of ten daphnids each were exposed to mean measured concentrations of 0 (negative control), of 30, 42, 56, 73, and 99 mg ai/L. No mortalities or sublethal effects are reported. The NOAEC is 99 mg ai/L and the LC_{50} is >99 mg ai/L. The study is classified as Acceptable. Bensulfuron-methyl is classified as practically nontoxic to dapnids on an acute exposure basis.

A 96-h acute study (MRID 40951403) with crayfish (*Procambus clarki*) is available for bensulfuron-methyl. Three replicates of ten crayfish each were exposed to mean measured concentrations of 0 (negative control) and 71 mg ai/L. No mortalities or sublethal effects are reported. The NOAEC is 71 mg ai/L and the LC_{50} is >71 mg ai/L. The study is classified as Supplemental. Bensulfuron-methyl is classified as no more than slightly toxic to crayfish on an acute exposure basis.

Chronic

A 21-d chronic study (MRID 40940108) with daphnids is available for bensulfuron-methyl. Three replicate of 5 daphnids each were exposed to mean-measured concentrations of 8.0, 17, 31, 64, and 110 mg ai/L. Survival, reproduction and growth were the reported parameters. Growth was inhibited at 31 mg ai/L, growth and reproduction were significantly inhibited at 64 mg ai/L and all parameters were significantly inhibited at 110 mg ai/L. The NOAEC is 17 mg ai/L. The study is classified as Acceptable.

ii. Estuarine/marine
Acute

A 96-h acute study (MRID 40940101) with mysid shrimp (*Americamysis bahia*, formerly *Mysidopsis bahia*) is available for bensulfuron-methyl. Two replicates of each mean measured concentrations of 0 (negative control), of 85.4, 105, 112, 124 and 130 mg ai/L were tested. Less than 15% mortality was reported at all concentrations and no sublethal effects are reported. The statistical NOAEC is 130 mg ai/L and the LC_{50} is >130 mg ai/L. The study is classified as Acceptable. Bensulfuron-methyl is classified as practically nontoxic to mysid shrimp on an acute exposure baisis.

A 48-h acute study (MRID 40940106) with larval Eastern oyster (*Cassostrea virgina*) is available for bensulfuron-methyl. Three replicates each (four control) of nominal concentrations of 0 (negative control), 40, 60, 100, 125 and 142 mg ai/L were tested. A maximum of 3.9% reduction was reported in the 125 mg ai/L was reported. The NOAEC is 142 mg ai/L and the LC_{50} is >142 mg ai/L. The study is classified as Acceptable. Bensulfuron-methyl is classified as practically nontoxic to Eastern oyster larvae on an acute exposure basis.

Chronic

No data on the effect of chronic exposure to estuarine/marine invertebrates are available for bensulfuron-methyl. The endpoint from the daphid chronic study will be used to estimate risk (via Acute to Chronic ratio (ACR)) to estuarine/marine invertebrates in the absence of specific data.

C. Plants

i. Vascular

There are two aquatic vascular plant studies that are under review for bensulfuron-methyl. Until the review is complete, EFED cannot determine whether these studies are suitable for use in risk assessment. MRIDs 45586703 and 45586704 are studies with *Lemna gibba*. In both of these cases, one study is conducted with TGAI and the other with formulated product.

ii. Nonvascular

There are several aquatic nonvascular plant studies that are under review for bensulfuron-methyl. Until the review is complete, EFED cannot determine whether these studies are suitable for use in risk assessment. MRID 45385201 and 45586701 are studies with *Pseudokirchneriella subcapitata* (formerly *Selanastrum capricornutum*); MRIDs 45385202 and 45586702 are studies with the cyanobacteria *Anabaena flos-aquae*. In each of these cases, one study is conducted with TGAI and the other with formulated product.

A 120-h study (MRID 40815104) with the green alga *Pseudokirchneriella subcapitata* was submitted for bensulfuron-methyl. Three replicates for each concentration of 0 (negative and solvent controls), 0.1, 0.2, 0.4, 0.8 and 1.6 mg ai/L were utilized. A considerable change in all parameters (absorbance, area under the growth curve and percent inhibition) was reported at the two highest concentrations. The study is classified as Supplemental because the initial cell density and the light intensity were both nearly double the guideline recommendation. Nonetheless, the study may be useful for risk assessment purposes. The NOAEC for the study is 0.4 mg ai/L and the EC_{50} is 0.8 mg ai/L.

A supplemental study with several aquatic plants is available (MRID 41267901). EC_{50} values for the species tested were: *Anabaena flos-aquae* 118 ppb, *Pseudokirchneriella subcapitata* 18.4 ppb, *Nitzschia palea* 8.23 ppb, *Skeletonema costatum* >1000 ppb, and *Lemna gibba* 0.01 ppb (day-15). The data are not adequate for risk estimation, although they may be used in characterization.

II. Terrestrial

A. Birds

Acute and Subacute Dietary

The DERs for these studies are found under PC Code 009101, benzoic acid and are from accession #073655. MRIDs are only available for the acute and one subacute study.

An acute oral toxicity study (MRID 00148303) with mallard duck (*Anas platyrhychos*) is available for bensulfuron-methyl. Five males and five females at each dose were exposed to bensulfuron-methyl at 0 (control), 398, 631, 1000, 1590 and 2510 mg ai/kg-bw. No mortalities or sublethal effects were observed at any dose level over the 14 days of the study. The study is classified as Acceptable. The NOAEL is 2510 mg ai/kg-bw and the LD_{50} >2510 mg ai/kg-bw. Bensulfuron-methyl is classified as practically nontoxic to mallard duck on an acute exposure basis.

A subacute dietary study with mallard duck (ACC 073655) is available for bensulfuron-methyl. Ten chicks per treatment level, without regard for sex, were exposed to bensulfuron-methyl at 0

(control), 562, 1000, 1780, 3160 and 5620 mg ai/kg-diet. No mortalities were observed. Concentration related reduction in both food consumption and bodyweight gains were observed at the 1780 and 5620 mg ai/kg-diet levels. The study is classified as Acceptable. The NOAEL is 1000 mg ai/kg-diet and the LC_{50} >5620 mg ai/kg-diet. Bensulfuron-methyl is classified as practically nontoxic to mallard duck on a subacute dietary exposure basis.

A subacute dietary study (MRID 00148304) with bobwhite quail (*Colinus virginianus*) is available for bensulfuron-methyl. Ten chicks per treatment level, without regard for sex, were exposed to bensulfuron-methyl at 0 (control), 562, 1000, 1780, 3160 and 5620 mg ai/kg-diet. No mortality or sublethal effects were observed at any test level. The study is classified as Acceptable. The NOAEL is 5620 mg ai/kg-diet and the LC_{50} >5620 mg ai/kg-diet. Bensulfuron-methyl is classified as practically nontoxic to bobwhite quail on a subacute dietary exposure basis.

Chronic

There is an avian reproduction study (MRID 45668901) conducted with mallard duck available for bensulfuron-methyl. The study is currently under review. Until the review is complete, EFED cannot determine whether this study is suitable for use in risk assessment. However, there is not a study available with an upland game species as required by 40 CFR Part 158. A suitable study consistent with the data requirements and the 850.2300 guidelines should be submitted for bensulfuron-methyl.

B. Mammals

Acute

According to a study reviewed by Health Effect Division (HED; MRID 40089316), single oral doses of bensulfuron-methyl were administered to 5 male and 5 female Crl:CDBR rats (*Rattus norvegicus*) at a rate of 5000 mg ai/kg-bw. No mortalities or clinical signs were reported. The LD_{50}>5000 mg ai/kg-bw. Bensulfuron-methyl is classified as practically nontoxic to rats on an acute exposure basis.

Chronic

In a two generation study with rats is available from HED (MRID 40089316). Concentrations tested were 0 (control), 50, 750 and 7500 mg ai/kg-diet. Based in the results of that study, the NOAEC, based on lower mean body weights in adult females, is 750 mg ai/kg-diet. No effects on reproduction were reported

C. Invertebrates

Acute

A 48-h acute contact study (MRID 00148305) with honeybees (*Apis mellifera*) is available for bensulfuron-methyl. Forty bees each, across four replicates, were exposed to concentrations of 0 (negative and solvent controls), 1.5625, 3.125, 6.25 and 12.5 µg ai/bee. No mortality was observed in any treatment group, with a NOAEC of 12.5 µg ai/bee and an LC_{50} >12.5 µg ai/bee. Bensulfuron-methyl is classified as practically nontoxic to honeybees on an acute contact basis.

D. Plants

Both seedling emergence (MRID 46290101) and vegetative vigor (MRID 46290102) studies have been submitted for bensulfuron-methyl and are currently under review. Until the review is complete, EFED cannot determine whether these studies are suitable for use in risk assessment.