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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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September 13, 2004

MEMORANDUM

SUBJECT: EFED Ecological Risk Assessment for the Section 3 Registration of the New Chemical Penoxsulam for Uses on Rice
CAS Registry Number: 219714-96-2
Products: Technical Penoxsulam (XDE-638), 98% ai; and
Manufacturing Use Penoxsulam, 50% ai; and
End Use Products:
Granite SC-SL (21.7% ai); and
GRASP or GF-443-SC (21.7% ai); and
Granite - granule/waterseeded rice-G (0.24% ai); and
GF-947- granule/waterseeded rice-G (0.24% ai)
Company: Dow AgroSciences, LLC

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This memorandum transmits the ecological and environmental risk conclusions for the herbicide, Penoxsulam, and the Environmental Fate and Ecotoxicity Assessments for its proposed uses on rice crops as either a foliar spray for exposed target plants or a granular application to submerged target plants to control a variety of broad leaf and/or grassy weeds. Both formulations may be ground or air applied. A single application per season is contemplated.

Environmental Fate

Penoxsulam is expected to be very mobile, but not very persistent, in either aqueous or terrestrial environments. Penoxsulam exists almost exclusively in a disassociated state at pH values normally found in rice paddy water, but not in terrestrial environments where lower pH values may be found. Penoxsulam degrades by two different transformation mechanisms, producing thirteen different identified transformation products, eleven of which meet the criteria to be classified as major degradates[1]. Six of these transformation products reached peak concentrations at study termination, indicating a greater degree of persistence than penoxsulam and a potential to reach concentrations even greater than those reported at study termination. Penoxsulam is anticipated to primarily enter the environment through release of paddy water to aquatic and semi-aquatic areas and through spray drift in application.

Although penoxsulam is not expected to be persistent in the environment, its rate of degradation in the paddy will be highly dependent upon sunlight exposure as photolysis is the principal degradation pathway. With variations in sunlight exposure, longer residence times may be required to dissipate penoxsulam beneath levels of potential concern to non-target aquatic and terrestrial plants. In terrestrial environments, penoxsulam is expected to dissipate through soil photolysis and biotic degradation. Considering its low vapor pressure and Henry's Law constant, volatilization from soil and water is not expected to contribute significantly to the dissipation of penoxsulam the environment. Penoxsulam also has low potential to bioaccumulate in fish or sediments.

EFED does not currently have an approved model for estimating chronic aqueous concentrations resulting from pesticide use on rice crops. An interim policy has been applied to estimate peak screening-level concentrations in water. Estimates of penoxsulam half life in the water have also been developed to provide a basis for estimating the holding times which ensure penoxsulam would not be present in excess of levels of concern. These half lives do not consider the potential phytotoxicity of degradates. In both cases, RQ estimates apply to both liquid and granular formulations.

Spray drift from the aerial and ground application of liquid formulations was modeled using the AgDrift model to provide estimates of buffer zones for various application practices. Granular application is not anticipated to pose a risk to the surrounding environment and has not been modeled.

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[1]BSA, 2-amino-TP, TPSA, BSTCA methyl, BSTCA, 2-amino-TCA, 5-OH-penoxsulam, SFA, sulfonamide, 5,8-di-OH and 5-OH 2 amino TP.

Risk Conclusions

The results of the screening-level risk assessment suggest that penoxsulam will not pose a threat to aquatic or terrestrial animals, however, this conclusion must be tempered by the fact that testing has not been conducted on several major degradates. Because penoxsulam is an ALS inhibitor, it is not anticipated that it would pose a threat. Nevertheless, penoxsulam is a member of the sulfonamide family which includes antimicrobial agents.

Penoxsulam application at proposed maximum levels does pose a potential risk to aquatic and terrestrial plants. Specifically, seedling emergence risk quotients for terrestrial plants exceeded Levels of Concern for eight out of ten crops studied, although half of those exceedances resulted from a failure to test at a sufficiently high rate. The peak RQ for monocots was 44 for non-endangered species and 120 for endangered terrestrial plants based on studies with onions. The peak RQ for dicots was 15 for non-endangered species and 41 for endangered species, both based on studies with sugar beets. These endpoints are applicable to the Tier 1 estimate for terrestrial plants in terrestrial and semi-aquatic settings from application of either the liquid or granular formulation.

Vegetative vigor risk quotients for terrestrial plants resulted in exceedances for eight out of ten crops for endangered species and six out of ten crops for non-endangered species. The peak RQ for dicots was 13 for non-endangered plants based on studies with the soybean and of 41 for endangered species based on studies with the soybean, sugar beet, and tomato. The peak RQ for monocots was 2.9 for non-endangered species and 120 for endangered plants, both based on studies with ryegrass. Shoot weight was the sensitive endpoint for all of these risk quotients. These endpoints form the Tier 1 estimates for non-target, terrestrial plant exposure due to spray drift.

For aquatic plants, the vascular plant RQs are based on the response of Duckweed (*Lemna gibba*). It generates an RQ of 15 for non-endangered species and of >45 of endangered species. For non-target, non-vascular aquatic plants, the green alga (*Selenastrum capricornutum*) had an RQ of 9 for endangered species when stressed with technical grade penoxsulam and an RQ of 5 for endangered species when stressed with the end-use product GF-443. risk quotients (RQs) for the following taxonomic groups exceed levels of concern for the screening-level risk assessment. These estimates apply to all application practices.

As indicated earlier, spray drift and half life assessments have been provided to the risk managers to inform risk management discussions. A detailed evaluation has also been performed of the DOW generated endangered species assessment. Species for which there is, on a screening basis, the potential for exposure have been identified.

Data Requirements

There are eleven major degradates of penoxsulam. It is possible that some of them pose additional phytotoxicity concerns. In the absence of such information, estimates of required holding times to avoid non-target effects are severely constrained. To eliminate this uncertainty, vegetative vigor and seedling emergence data would be needed on all major degradates (see the footnote on the previous page). In addition, the registrant did not test terrestrial plants using the end use products. Rather, they tested a mixture of 16% penoxsulam in crop oil. Data on the end use products would enhance the accuracy of the risk assessment. The value of both pieces of information is high, although aquatic plant testing and ECOSAR analyses provide some assurance that certain degradates may be considerably less toxic and, consequently, the value of those data would be medium.

The report also identifies a handful of degradates for which aquatic vascular plant testing of the active ingredient would improve the quality of the risk assessment. The value of this information is dependent upon whether holding time is to be used as a potential risk mitigation approach. If it is, the value of the information is high.

Finally, should any additional plant testing suggest any degradate is toxic to the extent suggested by parent testing, additional fate information may be needed.

Labeling Recommendations

None

NEW CHEMICAL

ENVIRONMENTAL FATE AND EFFECTS SCIENCE CHAPTER

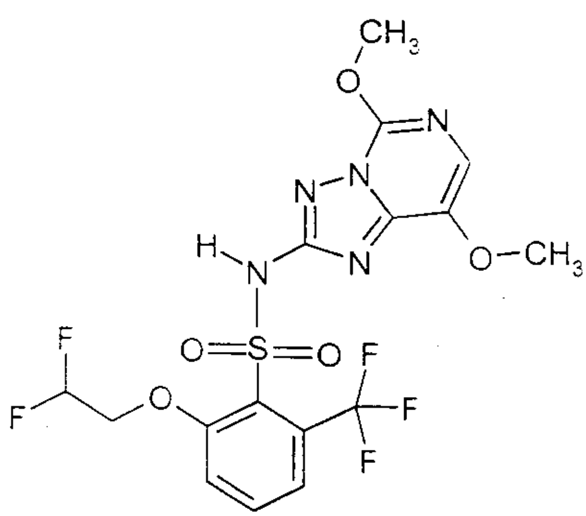
Environmental Fate and Ecological Risk Assessment

For

PENOXSULAM
(CAS No. 219714-96-2, Company Code: XDE-638)

IUPAC Name
3-(2,2-Difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide

CAS Name
2-(2,2-Difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide



Environmental Fate and Effects Division Team Members
Jim Goodyear, Biologist
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Branch Chief Approval
Ben Smith

Date of Approval

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Appendices

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I. EXECUTIVE SUMMARY

A. Predicted Environmental Exposure

1. Nature of Chemical Stressor

Penoxsulam is a new post-emergence, acetolactate synthase (ALS) inhibitor herbicide developed by Dow AgroSciences to be used as a foliar spray on dry-seeded rice crops, or as either a foliar spray or a granular formulation on water-seeded rice crops in order to control broadleaf weeds, aquatic plants, and certain grasses.

This report focused on the proposed agronomic practices associated with the use of penoxsulam on rice crops in the main rice growing regions of the United States – the Gulf Coast, the lower Mississippi Valley, and central California. Penoxsulam comes in liquid and granular formulations. Foliar application is recommended for use of the liquid formulation of penoxsulam on both dry- and water-seeded crops. For water-seeded rice, the application practice is to lower the paddy water depth sufficiently to expose at least 50% of the target plant before spraying. The granular formulation of penoxsulam is only recommended for use on flooded paddies. In its application, the water depth is raised sufficiently to completely submerge the target plants. Although rice paddies are typically constructed to limit the amount of water escaping into the open environment, penoxsulam can reach surface waters through spray drift and particulate drift during application, or by subsequent release of paddy water.

2. Environmental Fate

Screening level environmental fate assessments of pesticides being applied directly to water typically assume a water body depth and use the application rate to estimate potential environmental concentrations. A similar approach was taken in this risk assessment. For assessing the risk to aquatic plants and terrestrial plants in semi-aquatic settings, an approved interim modeling approach for rice was used to estimate both peak concentrations and holding periods which would ensure released paddy water would not exceed levels of concern.

The major route of dissipation for penoxsulam is through direct aqueous photolysis in clear and shallow surface water under favorable light conditions, a common condition in rice paddies where the crop canopy has not yet fully developed. Penoxsulam is somewhat persistent in aerobic soil environments. Although Penoxsulam is very mobile, the design of paddies to maintain a permanent flood and the lack of persistence in paddy water limit the ability to leach to ground water. Considering its low vapor pressure and Henry's Law constant, volatilization from soil and water is not expected to contribute significantly to the dissipation of penoxsulam into the environment. Penoxsulam has low potential to bioaccumulate in fish.

Eleven major degradation products have been identified[1] [BSTCA, 2-amino-TCA, 5-OH-penoxsulam, SFA, sulfonamide, 5,8-di-OH-penoxsulam, BSA, 2-amino-TP, TPSA, BSTCA methyl, and 5-OH 2 amino TP]. Data are not available to fully characterize these degradates and their respective degradation pathways. The uncertainty introduced by this absence of information

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[1]see **Table A6** in **Appendix A** for the structures and full Chemical Abstract Service Names of the penoxsulam transformation products.

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was addressed in the screening assessment by using the acute penoxsulam concentration as the chronic concentration for risk quotient determination. This approach ensures that the assessment addresses the potential threat posed by degradates as long as they are not significantly more toxic or persistent than the parent. Based on a limited analysis using the Office of Toxic Substance's ECOSAR program (described in greater detail in Chapter IV under uncertainties), it is believed that this is a valid assumption. Additional information on the toxicity of all major degradates to terrestrial plants and to Duckweed would improve confidence in this risk assessment. The latter would be especially useful for assessing the paddy holding times that would provide greater confidence that levels of concern (LOCs) were not exceeded upon water release.

B. Potential Risks to Non-Target Organisms in the Rice Use Pattern

As an acetolactate synthase (ALS) inhibitor, the expected potential direct risks to be posed by penoxsulam would be to aquatic and terrestrial plants. Indirect effects due to habitat loss or alteration were not addressed.

Terrestrial plants

Tests of terrestrial plants were not conducted with the end use product. Rather, studies were done on a number of plants using only the technical grade active ingredient in a crop oil concentrate. Data should be provided based on testing of the end use product. Penoxsulam use poses potential acute risk to non-target terrestrial and aquatic plants. Tier 1 screening level risk quotients (RQs) for terrestrial plants exceeded levels of concern (LOCs) for four out of ten crops tested[2] for seedling emergence with peak RQs of 44 for non-endangered and 120 for endangered terrestrial plants based on testing of onions. Vegetative vigor testing resulted in exceedances for eight out of ten crops tested with peak RQs of 13 for non-endangered plants based on testing of soybean and 120 for endangered plants based on testing of ryegrass. Shoot weight was the sensitive endpoint for each of these risk quotients. Because potential levels of concern for terrestrial plants were exceeded. AgDrift modeling was conducted to provide estimates of required buffer zones to reduce drift below levels of concern. The results of these analyses are detailed in Chapter IV. Chapter IV also details threatened and endangered species potentially at risk if they are present inside of the indicated buffer zones.

For exposure of terrestrial plants in semi-aquatic settings, seedling emergence is one of two endpoints to be addressed by a risk assessment. Release and run off to these areas of paddy water could pose residual phytotoxicity concerns if paddy water was released too soon after treatment or if degradates have analogous toxicity to the parent. No degradate seedling emergence data were provided. ECOSAR does not provide estimates of relative terrestrial plant phytotoxicity, so this remains an uncertainty in the risk assessement. As a minimum, Tier 1 seedling emergence and vegetative vigor tests should be completed for all major degradates. with Tier 2 testing conducted as needed.

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[2]Four out of ten seedling emergence tests were not conducted at sufficiently high concentrations to unequivocally rule out exceedances for non-threatened or endangered plants.

Aquatic plants

Test data on aquatic plants were provided with some tests utilizing the technical and other tests using the end-use product or selected degradates. The technical grade product produced screening level exceedances for endangered vascular plants (RQ of 45) and non-endangered aquatic vascular plants (RQ of 15). RQs for endangered nonvascular aquatic plants using the technical grade product and the end-use product were 9 and 5, respectively.

Based on evaluation of penoxsulam fate data, computations were made to estimate the paddy water holding time which would provide sufficient penoxsulam degradation to not pose a potential threat to aquatic plants upon release. Computations detailed later in the report suggest this would take 13 to 23 days to address all Level of Concern issues.

It is important to note, however, that this estimate does not consider the potential impacts of non-tested degradates. In particular, BSTCA methyl,5,8-di-OH-penoxsulam, and SFA are untested degradates for which ECOSAR projects analogous toxicity to the parent. These degradates should be tested on Duckweed.

Terrestrial and aquatic animals

Penoxsulam is practically nontoxic to terrestrial and aquatic vertebrates and practically nontoxic to moderately toxic to aquatic invertebrates. No RQ for liquid penoxsulam exceeded a LOC for an animal. The results of screening-level risk assessments are interpreted to mean that liquid penoxsulam has little potential to cause direct effects to these animals at proposed application rates. However, data were not provided to EFED on the effects of degradates on mammals and birds. Without this information, it is impossible to establish the potential of the degradates, some of which are more persistent than the parent, to pose a risk through contaminated foliage or small insect consumption.

II. PROBLEM FORMULATION

This environmental fate and effects risk assessment is intended to support the Registration Division risk management decision for both the liquid and the granular formulations of a new post-emergence chemical herbicide, penoxsulam. This first-time use of penoxsulam is being proposed for the food crop, rice. In this document, EFED has characterized the potential risk of ecological effects from use on rice grown under both dry- and water-seeded conditions. The new chemical screen package requesting review of the supporting data was submitted under DP barcode #288160. Proposed product labels have been submitted under the following DP barcodes:

#298227 for the Granite SC-SL (21.7%) label,

#298401 for the GRASP or GF-443-SC (21.7%) label,

#298489 for the Technical (98%) label,

#298490 for the Granite - granule/waterseeded rice-G (0.24%) label,

#298491 for the GF-947- granule/waterseeded rice-G (0.24%) label, and

#298492 for the manufacturing use product (50%) label.

A. Stressor Source and Distribution

1. Chemical Properties

Penoxsulam's chemical names or other designations and a table of selected physicochemical properties are given below in Table 1.

2. Mode of Action

Penoxsulam is a systemic, post-emergence herbicide belonging to the triazolopyrimidine sulfonamides chemistry family. The mode of action upon susceptible weeds is by inhibition of acetolactate synthase (ALS), the first enzyme in the biosynthetic pathway for the amino acids leucine, valine, and isoleucine.

3. Use Characterization

End-Use Products

Dow AgroSciences is petitioning for the registration of the post-emergence herbicide penoxsulam for use on rice when formulated into the end-use products:

> GF-443 SC SF and Grasp SC, (liquid products containing 21.7% active ingredient);
> GF-947 Granule SF and Grasp GR (granular products containing 0.24% active ingredient); and
>
> Granite GR and Granule CA (granular products formulated for use in California containing 0.24% active ingredient).

The proposed label recommends application rates for the end-use products of 2.8 fl. oz./acre for the liquid formulations, and 18.5 lbs./acre for the granular formulations. The one seasonal application allowed for the formulated product on each of these labels is equivalent to an annual application rate for the active ingredient of 0.044 lb./acre (49 g/ha).

Table 1. Physical-Chemical Properties of Penoxsulam

PARAMETER	VALUE
Chemical name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide
Chemical Abstract Service number	219714-96-2
Molecular weight	483.4
Solubility in water	5.7 mg/L (pH 5), 410 mg/L (pH 7), 1500 mg/L (pH 9)
pK_a	5.1
Vapor pressure at 25°C	9.55×10^{-14} Pa
Octanol-water partition coefficient (log K_{ow})	1.1 (pH 5), -0.60 (pH 7), -1.4 (pH 9)
Hydrolysis half-life (pH 5, pH 7, pH 9)	stable
Aqueous photolysis half-life	$t_{1/2}$ = 1.5 - 14 days
Soil photolysis half-life	$t_{1/2}$ = 19 - 109 days
Aerobic metabolism half-lives	$t_{1/2}$ = 12 - 118 days
Anaerobic metabolism half-lives	$t_{1/2}$ = 6.6 - 11 days
Soil-water distribution coefficient (K_d)	13 - 305 (1130 sediment) mL/g

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Application Methods

The proposed label for penoxsulam would allow both ground and aerial application from the one leaf stage of the rice up to 60 days prior to harvest, the specific timing of the application dependant upon the type of weeds requiring treatment. It is recommended not to apply penoxsulam through any type of irrigation system.

In the United States, rice is grown primarily in two regions. The Southern region consists of the Gulf Coast of Texas and Louisiana and the Mississippi River Valley in Louisiana, Mississippi, Arkansas, and Missouri. The remainder of domestic rice production is located in the Sacramento Valley and San Joaquin Valley in California.

The irrigation of rice paddies in association with rice cultivation follows a variety of practices. At the one extreme, there is dry seeding wherein seeds are grown in dry beds several weeks before establishing a permanent flood in the paddy. Small amounts of water are used to assist seed germination, but the field is left dry until the rice has sprouted and begun to grow. This is the most common practice in the Southern region of the United States.

There also is "pin point" flood culture, where sprouted rice is aerially applied to flooded fields. The fields are drained a few days after seeding, and then flooded several days later. Water is released from the paddy then re-flooded primarily to inhibit red rice growth by draining after pre-spouted rice has become established but before the red rice has pegged (put down roots) and to reduce arsenic concentrations which can affect grain formation through a condition known as "straight-heading". When rice is water seeded in the Southern region, the "pin-point flood" culture is the preferred method. Applying pre-sprouted rice to a field is known as wet seeding.

At the other end of the continuum are practices such as continuous flood, where there is a steady flow of aerobic water through the paddy. In California, the majority of rice production is water seeded with a continuous flood.[3] Further discussion in this risk assessment will refer to the first practice as "dry seeding", the second practice as "wet seeding", and the latter practice as "water seeding".

When a liquid formulation (either GF-443 SC SF or Grasp SC) is applied preflood to dryseeded rice crops, it is recommended to flush the field first if moisture stressed, then drain to expose at least 50% of weed. When applied postflood, it is also recommended to drain enough water to expose at least 50% of weed. It is specified that either a surfactant or a crop oil concentrate other than organosilicone must be added to liquid formulated penoxsulam.

When a granular formulation (GF-947 Granule SF, Grasp GR, Granite GR, Granule CA) is applied, paddies are pre-flooded to a depth of 2 to 4 inches, completely submerging the weeds prior to application. The 2 to 4 inch water depth is maintained for 10 days post application for optimum weed control, but may be increased to provide coverage of the target plants. Treated land should not be rotated with crops other than rice for three months following application. The

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[3]Breithaupt, James; February 2001 RED Science Chapter for Molinate; Appendix A - Use Profile; edited for generic rice crops

labels for the granular formulations indicate that penoxsulam provides some residual weed control to susceptible weed species.

The label indicates penoxsulam can be applied to fields used for crayfish production. However, the label advises not to fish, or commercially grow fish, shellfish or other crustaceans on treated acres during the year of treatment. There is no indication on the label that a safener is present in the formulated products.

Target Crops and Pests

The proposed label for penoxsulam would allow only one application (ground or aerial) between the one leaf stage of rice crops and 60 days prior to rice harvest, depending on the type of weeds requiring treatment. This herbicide is intended to control broadleaf weeds, aquatic plants and certain grasses, all at differing developmental stages depending upon the specific target weed.

As indicated earlier in the use characterization portion of this chapter, rice may be dry seeded, water seeded, or wet seeded. In any case, there are scenarios under which penoxsulam and its transformation products will eventually have the potential for release to non-target aquatic environments. The amount which will be released will be dependent on a variety of factors, most significantly whether there is a period between pesticide application and field flooding and the time between pesticide contact with the water and its subsequent release[4]. For the purposes of acute aquatic exposure assessment to the liquid form of the pesticide, it has been assumed that the pesticide is directly applied to paddy water and immediately released. This assumption most closely tracks the principal agronomic practice used in California. Terrestrial plants in terrestrial settings are assumed to be exposed only to spray drift while terrestrial plants in semi-aquatic settings are assumed to be exposed to both aqueous runoff (release) and spray drift.

To better quantify the uncertainty introduced by this approach in other application scenarios, modeling is conducted to assess the relative reduction in released penoxsulam concentration that might be anticipated with various holding times in the paddy prior to release. This second approach will enable the risk assessment to bracket the range of expected concentrations which might be observed as a result of coupling water holding times with typical agronomic practices.

4. Environmental Fate

Penoxsulam is expected to be very mobile, but not persistent, in both aqueous and terrestrial environments. Penoxsulam exists almost exclusively in a disassociated state at pH values normally found in rice paddy water, but not in terrestrial environments where lower pH values may be found. Penoxsulam degrades by two different transformation mechanisms,

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[4]The continuous flow of water normally maintained through rice paddies to ensure aerobic conditions is interrupted when holding times are required. Release of the paddy water after a holding time means that the continuous flow is reinstated, allowing paddy water from adjacent fields to mix. Paddies are not drained after holding times unless otherwise indicated by normal agronomic practices.

producing thirteen different identified transformation products, for photolytic and biotic degradation.

Persistence

Penoxsulam is not expected to be persistent in the environment. In aqueous environments, penoxsulam is expected to be stable to hydrolysis, but to dissipate rapidly through aqueous photolysis in clear shallow waters, and somewhat more slowly through biotic degradation when sunlight has a limited ability to penetrate turbid waters, or when waters are shaded by trees, riparian vegetation, and/or crop canopies. In terrestrial environments, penoxsulam is expected to dissipate through soil photolysis and aerobic soil degradation.

Transport

Penoxsulam is expected to be very mobile in both aqueous and terrestrial environments, not binding strongly to either soil or sediment. Submitted mobility data for three penoxsulam degradation products (BSTCA, 5-OH-penoxsulam, and BST) indicate environmental mobility roughly equivalent to the parent compound. However, there are no data regarding the mobility of the remaining transformation products nor of combined parent/degradate residues. Penoxsulam has low volatility indicating that atmospheric transport is, at best, a very minor route of transportation.

Transformation

Data are not available to fully characterize the complex, potential degradation pathways of penoxsulam. Submitted laboratory studies demonstrate that penoxsulam transforms by competing mechanisms, through several generations of degradation products. Examination of the specific transformation products formed in the submitted laboratory studies suggests that the more rapid photolytic transformation proceeds primarily through cleavage of the parent molecule on, or adjacent to, the sulfonamide bridge. The slower biotic degradation pathway proceeds primarily through fragmentation of the pyrimidine ring or its residues. This complex degradation pathway of penoxsulam produces a large number of degradation products.

Only limited fate data are available for the penoxsulam transformation products. Six of the thirteen identified transformation products failed to reach peak concentrations at study termination: 2-amino-TP, BSTCA, 2-amino-TCA, SFA, sulfonamide and 5,8-di-OH penoxsulam. These six compounds are potentially more persistent than the parent compound, and would probably have reached even greater concentrations with time. Eleven of the thirteen penoxsulam transformation products reported in laboratory studies are considered major degradates: BSA, 2-amino-TP, TPSA, BSTCA methyl, BSTCA, 2-amino-TCA, 5-OH-penoxsulam, SFA, sulfonamide, 5,8-di-OH and 5-OH 2 amino TP. Two of the thirteen penoxsulam transformation products are considered minor degradates: di-FESA and BST.(see **Table 6A** in **Appendix A** for the structure and full Chemical Abstract Service Names of the penoxsulam transformation products).

Bioaccumulation

Bioconcentration in fish data are not available for either parent or degradates, but submitted supplemental data do not suggest that penoxsulam will bioconcentration. Further, what accumulation that was observed in testing of crayfish was followed by rapid depuration. Given penoxsulam's proposed single annual application, this is unlikely to be an issue.

B. Assessment Endpoints

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

1. Ecosystem(s) Potentially At Risk

Ecosystems potentially at risk are expressed in terms of the selected assessment endpoints. The typical assessment endpoints for screening-level pesticide ecological risks are reduced survival, and reproductive and growth impairment for both aquatic and terrestrial animal species. Aquatic animal species of potential concern include freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and amphibians. Terrestrial animal species of potential concern include birds, mammals, beneficial insects, and earthworms. For both aquatic and terrestrial animal species, direct acute and direct chronic exposures are considered. Although these endpoints are measured at the individual level, they provide insight about risks at higher levels of biological organization (*e.g.* populations and communities). For example, pesticide effects on individual survivorship have important implications for both population rates of increase and habitat carrying capacity.

For terrestrial and semi-aquatic plants, the screening assessment endpoint is the perpetuation of populations of non-target species (crops and non-crop plant species). Existing testing requirements have the capacity to evaluate emergence of seedlings and vegetative vigor. Although it is recognized that the endpoints of seedling emergence and vegetative vigor may not address all terrestrial and semi-aquatic plant life cycle components, it is assumed that impacts at emergence and in active growth have the potential to impact individual competitive ability and reproductive success.

For aquatic plants, the assessment endpoint is the maintenance and growth of standing crop or biomass. Measurement endpoints for this assessment endpoint focus on algal and vascular plant (*i.e.*, duckweed) growth rates and biomass measurements.

The ecological relevance of selecting the above mentioned assessment endpoints is as follows: 1) complete exposure pathways exist for these receptors; 2) the receptors may be potentially sensitive to pesticides in affected media and in residues on plants, seeds, and insects;

and 3) the receptors could potentially inhabit areas where pesticides are applied, or areas where runoff and/or spray drift may impact the sites because suitable habitat is available.

2. Ecological Effects

Each assessment endpoint requires one or more "measures of ecological effect," which are defined as changes in the attributes of an assessment endpoint itself or changes in a surrogate entity or attribute in response to exposure to a pesticide. Ecological measurement endpoints for the screening-level risk assessment are based on a suite of registrant-submitted toxicity studies performed on a limited number of organisms in the following broad groupings:

- Birds (mallard duck and bobwhite quail) used as surrogate species for terrestrial-phase amphibians and reptiles,
- Mammals (laboratory rat),
- Freshwater fish (bluegill sunfish and rainbow trout) used as a surrogate for aquatic phase amphibians,
- Freshwater invertebrates (*Daphnia magna*),
- Estuarine/marine fish (Silverside),
- Estuarine/marine invertebrates (*Crassostrea virginica* and *Americamysis bahia*),
- Terrestrial plants (corn, onion, ryegrass, wheat, cucumber, soybean, tomato, sugar beets, cotton, and kale), and
- Algae and aquatic plants (*Selenastrum capricornutum* and *Lemna gibba*).

Within each of these very broad taxonomic groups, an acute and chronic endpoint is selected from the available test data, as the data sets allow. Additional ecological effects data were available for other taxa and have been incorporated into the risk characterization as other lines of evidence. These data include:

- Acute laboratory toxicity data on non-guideline freshwater invertebrates including midges, and amphipods and
- Acute laboratory contact and oral toxicity on honeybees.

A complete discussion of all toxicity data available for this risk assessment and the resulting measurement endpoints selected for each taxonomic group are included in Section III.B of this document. A summary of the assessment and measurement endpoints selected to characterize potential ecological risks associated with exposure to penoxsulam and its degradates is provided in Table 2.

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Table 2. Summary of Assessment and Measurement Endpoints

Assessment Endpoint	Measurement Endpoint
1. Abundance (*i.e.*, survival, reproduction, and growth) of bird populations	1a. Bobwhite quail acute oral LD_{50} 1b. Bobwhite quail and mallard duck subacute dietary LD_{50} 1c. Bobwhite quail and mallard duck chronic reproduction NOAEC and LOAEC
2. Abundance (*i.e.*, survival, reproduction, and growth) of mammal populations	2a. Laboratory rat acute oral LD_{50} 2b. Laboratory rat developmental and chronic NOAEC and LOAEC
3. Survival and reproduction of freshwater fish and invertebrate communities	3a. Rainbow trout and bluegill sunfish acute LC_{50} 3b. Rainbow trout chronic (early-life) NOAEC and LOAEC 3c. Water flea (and other freshwater invertebrates) acute EC_{50} 3d. Water flea chronic (life-cycle) NOAEC and LOAEC
4. Survival and reproduction of estuarine/marine fish and invertebrate communities	4a. Sheepshead minnow acute LC_{50} 4b. Estimated chronic NOAEC and LOAEC values based on the acute-to-chronic ratio for freshwater fish 4c. Eastern oyster and mysid acute LC_{50} 4d. Mysid chronic (life-cycle) NOAEC and LOAEC
5. Perpetuation of populations of non-target terrestrial and semi-aquatic species (crops and non-crop plant species)	5a. Monocot and dicot seedling emergence and vegetative vigor EC_{25} values
6. Survival of beneficial insect populations	6a. Honeybee acute contact LD_{50}
7. Maintenance and growth of standing crop or biomass of aquatic plant populations	7a. Algal and vascular plant (*i.e.*, duckweed) EC_{50} values for growth rate and biomass measurements

LD_{50} = Lethal dose to 50% of the population.
NOAEC = No observed adverse effect level.
LOAEC = Lowest observed adverse effect level.
LC_{50} = Lethal concentration to 50% of the population.
EC_{50}/EC_{25} = Effect concentration to 50%/25% of the population.

C. Conceptual Model

In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a contaminant moves in the environment from a source to an ecological receptor. For an ecological exposure 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. In addition, the potential mechanisms of transformation (*i.e.*, which degradates may form in the environment, in which media, and how much) must be known, especially for a chemical whose metabolites/degradates are of greater toxicological concern. The assessment of ecological exposure pathways, therefore, includes an examination of the source and potential migration pathways for constituents, and the determination of potential exposure routes (*e.g.*, ingestion, inhalation, dermal absorption).

Ecological receptors that may potentially be exposed to penoxsulam and its degradates include terrestrial and semi-aquatic wildlife (*i.e.*, mammals, birds, and reptiles), terrestrial and semi-aquatic plants, and soil invertebrates. In addition to terrestrial ecological receptors, aquatic receptors (*e.g.*, freshwater and estuarine/marine fish and invertebrates, amphibians) may be exposed to potential migration of pesticides from the site of application to various watersheds and other aquatic environments via release or granular/spray drift. However, because penoxsulam is an ALS inhibitor, it is not anticipated to be very toxic to aquatic or terrestrial animals.

The main sources in the environment for the stressor, the post-emergence herbicide penoxsulam, are through direct application to either wet- or dry-seeded rice crops, and through spray drift. Unlike terrestrial row crops, the major growth and development phases for a rice crop take place in a flooded field, or paddy. A paddy is typically designed to capture and maintain a uniform depth of irrigation (flood) water. This design minimizes aquatic transport via levee overflow, breaching, and leaching (also known as deep percolation).

Surface water contamination by penoxsulam is assumed to occur through drift or designed release to a stream or pond. Potential emission of volatile compounds is not considered as a viable release mechanism, since volatilization is not expected to be a significant route of dissipation for this chemical. Likewise, because paddies are generally designed to effectively retain water, the potential for ground water contamination is considered low. Exposure to terrestrial animals could occur through consumption of drift-contaminated vegetation on berms and adjoining fields or direct consumption of the granular.

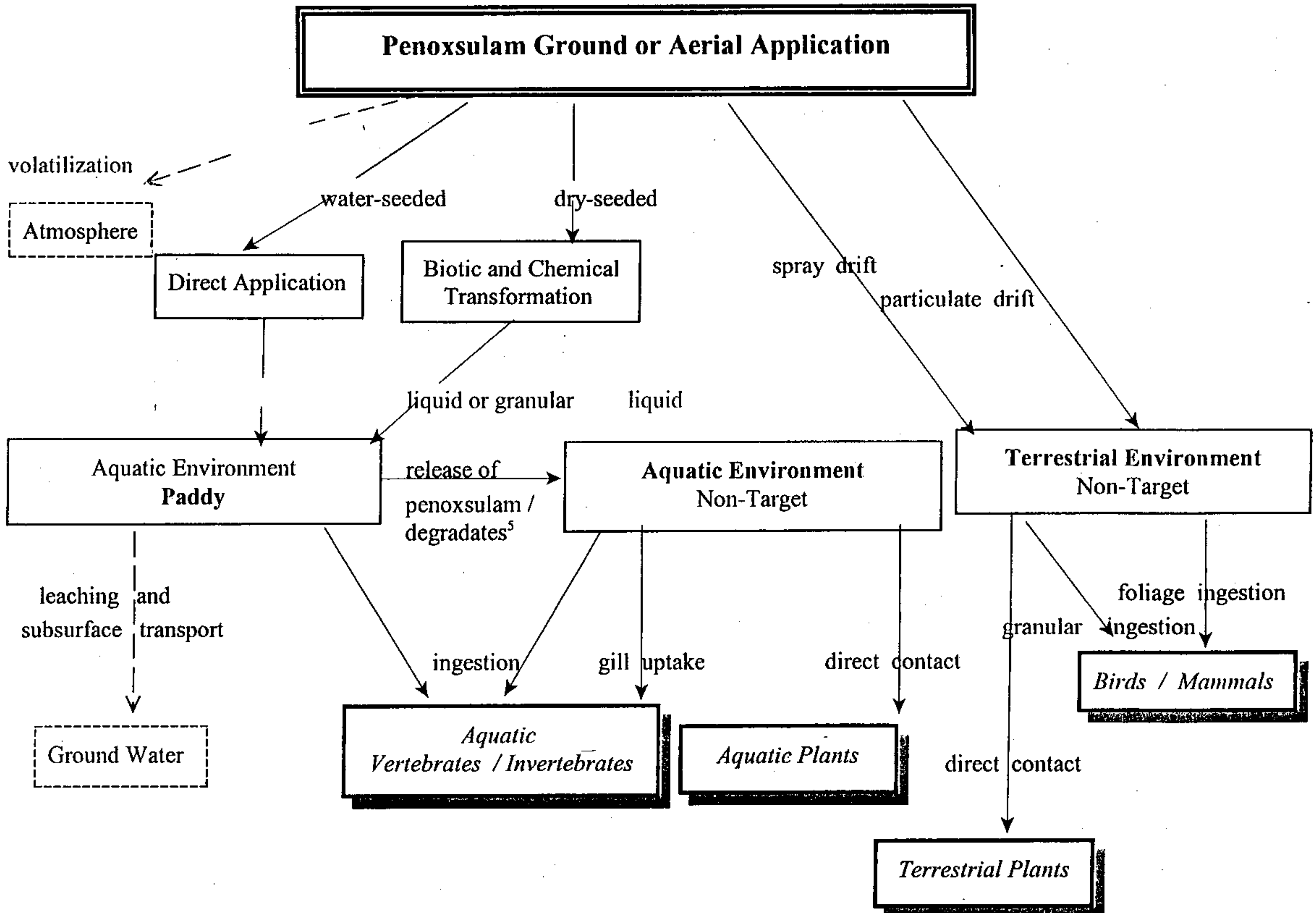
For terrestrial plants in terrestrial settings, exposure is assumed to occur through direct spraying or drift. The assessment endpoints considered are vegetative vigor and seedling emergence. For terrestrial plants in semi-aquatic settings, the possibility of exposure from release of paddy water to low lying areas cannot be ruled out. This release is modeled based on the presumption that one acre of paddy water is released onto one acre of non-target plants. The endpoint evaluated is seedling emergence. Spray drift is modeled as for terrestrial settings.

For aquatic plants, exposure is assessed as a consequence of immediate release of paddy water because at least some cultivation practices involve continuous flow through and the label does not specify a minimum holding time post treatment. From an efficacy standpoint, some holding interval is likely. Modeling is also conducted to ascertain the holding period which would drop paddy water concentrations beneath levels of concern.

A cursory review of the physical and chemical properties of penoxsulam, as outlined in Table 1, indicates that fairly rapid transformation can be expected for penoxsulam in the environment. These properties, coupled with the extremely low application rate of penoxsulam suggest limited need to consider long term or indirect effects. In addition, food chain accumulation is not expected.

The conceptual site model is shown in Figure 1.

Figure 1: Transport Pathway for Combined Penoxsulam and Transformation Product Residues



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[5] **Biotic Degradates** - BSTCA, BSTCA methyl, 5-OH penoxsulam, BST, SFA, sulfonamide, 5,8-di OH
Chemical Transformation Products - BSTCA, BSTCA methyl, BSA, 2-amino TP, TPSA, 5-OH 2-amino TP, TCA, di-FESA

D. Key Uncertainties and Information Gaps

There is currently no peer-reviewed modeling approach within EFED that takes into account transformation and/or degradation processes while estimating chronic pesticide concentrations in rice paddy water. Dow AgroSciences has submitted a document (MRID 458308-11) that addressed the modeling of chronic surface water concentrations of penoxsulam from the proposed use on rice. With some modification, Dow used an approach similar to modeling methods used for the propanil RED and cyhalofop butyl Section 3 documents. EFED also used the interim rice model with appropriate modification of input parameters, as is discussed later in the document.

A potentially major gap in this risk assessment is a lack of fate and ecological effects information on many of the degradates. On the one hand, only one treatment per season was proposed and it is recommended on the label that other crops not be grown in a field for at least three months after application of penoxsulam. On the other, there are eleven major degradates and the parent is expected to be relatively short lived in the paddy environment. The combination of these two pieces of information would suggest at least some of the degradates may provide some of the needed phytotoxicity. Studies were not submitted for many of the degradates.

From a fate perspective, six penoxsulam transformation products (BSTCA, BST, 2-amino-TP, 2-amino TCA, 5,8-diOH , and sulfonamide) reached peak concentrations at study termination. Laboratory data are not available to quantitatively determine degradation rates, and therefore the degree of persistence, for these transformation products under environmental conditions. Furthermore, mobility data submitted for three penoxsulam transformation products (BSTCA, BST, and 5-OH-penoxsulam) indicated mobility roughly equivalent to that of the parent compound, penoxsulam. However, laboratory data are not available to quantitatively determine the degree of mobility for seven identified transformation products under environmental conditions.

III. Analysis (*Selection and Evaluation of Data For Risk Characterization*)

A. Exposure Characterization

1. Evaluation of Aquatic and Terrestrial Fate Studies

Identification of Endpoints

A reported vapor pressure of 9.55×10^{-14} Pa at 25°C indicates that volatilization is not expected to be significant for penoxsulam in the environment.

In aqueous environments, penoxsulam is stable to hydrolysis at pH 5, pH 7 and pH 9. Penoxsulam is expected to dissipate in clear shallow waters through aqueous photolysis. Laboratory data indicate that the four photolytic half-lives reported for penoxsulam in water range from 1.5 to 3.1 days between pH 7 and pH 8, and 14 days at pH 5.8. A reported pK_a value of 5.1 suggests that pH may have an effect upon the photolytic half-life. However, the paddy

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water in a cropped plot is known to rapidly equilibrate to at or above a pH 7 within a few hours of flooding, so pH should not significantly impact photolysis. Penoxsulam is expected to dissipate more slowly through biotic degradation when sunlight has a limited ability to penetrate colored or turbid waters, or when waters are shaded by trees, riparian vegetation, and/or crop canopies.

In terrestrial environments, penoxsulam is expected to dissipate through soil photolysis and biotic degradation. Penoxsulam has photolytic half-lives of 19 and 109 days, on the two soils studied at pH 6 ± 0.2. Aerobic soil metabolism was studied in three soils. The resulting three half-lives calculated through linear regression of log transformed data were 34 days, 43 days, and 118 days. Aerobic aquatic metabolism, the principal biotic degradation mechanism in rice paddies, was studied in six soil/water test systems. The six total system half-lives calculated through linear regression of log transformed data ranged from 16 to 38 days. Anaerobic aquatic metabolism, a degradation mechanism only anticipated in non-target environmental compartments, was studied in three soil/water test systems. The three total system half-lives calculated through linear regression of log transformed data were 5 days, 7 days, and 11 days.

Penoxsulam is expected to be very mobile in the environment. The soil to water partitioning coefficients (K_d) derived from the seventeen soils and one sediment studied ranged from 0.13 to 4.69, with an average value of 0.92 and a standard deviation of 1.07. However, if one excludes sand, volcanic, and Canadian soils which are not typical of rice growing regions, K_d values range from 0.13 to 1.96, with an average value of 0.62 and a standard deviation of 0.53.

Submitted mobility data for three penoxsulam degradation products, BSTCA, 5-OH-penoxsulam, and BST, indicate environmental mobility roughly equivalent to that of the parent compound. The soil to water partitioning coefficients (K_d) for BSTCA derived from the six soils studied ranged from 0.085 to 4.4. The soil to water partitioning coefficients (K_d) for 5-OH-penoxsulam, derived from the eight soils studied ranged from 0.14 to 1.4. The soil to water partitioning coefficients (K_d) for BST derived from the eight soils studied ranged from 0.075 to 0.61. However, there are no data regarding the degradation rates of other penoxsulam degradation products or the mobility of the remaining transformation products or of combined parent/degradate residues. Table 3 summarizes the environmental fate properties of penoxsulam. Information regarding the environmental fate studies used in this report is detailed in Appendix A. Table 4 summarizes the penoxsulam transformation products identified in the submitted data.

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Table 3 - Summary of Environmental Fate Properties of Penoxsulam Used in Assessment

Study Type	Value	Test System	Study MRID	Study Status
Hydrolysis -- $t_{1/2}$	stable	pH 5, 7, 9 buffers / natural waters	45830721	acceptable
Photodegradation in Water -- $t_{1/2}$	1.5 days, 1.5 days, 3.1 days, 14 days	pH 7 buffer, pH 7.8 natural waters, pH 7 AR pond water, pH 5.8 flooded soil	45834801, 45830722	supplemental, supplemental
Photodegradation on Soil -- $t_{1/2}$	19 days, 109 days	flooded silt loam, silty clay loam	45830723	supplemental
Aerobic Soil Metabolism -- $t_{1/2}$	34 days, 43 days, 118 days	AR silt loam CA clay loam, ND loam	45830724	acceptable
Anaerobic Aquatic Metabolism -- $t_{1/2}$ (total system)	5 days, 11 days, 7 days	AR pond water / silt loam clay sediment, AR pond water / silt loam soil, distilled water / silty loam soil (Italy)	45830725	acceptable
Aerobic Aquatic Metabolism -- $t_{1/2}$ (total system)	16 days, 29 days, 12 days, 38 days, 30 days, 31 days	AR pond water / silt loam clay sediment, AR pond water / silt loam soil, Italian channel water / loam sediment, French lake water / sand sed., HPLC water / volcanic loam soil (Japan), HPLC water / loam soil (Japan)	45830726	acceptable
Adsorption/Desorption -- K_d	0.37, 0.56, 0.49, 0.45, 1.96, 0.48, 0.16, 0.32, 1.4, 0.51, 0.64, 0.13	AR Silt loam Sandy clay loam (Japan), CA Clay loam ND Loam, (ND, USA) Silty clay loam (Italy), Silty clay loam (France), Sandy clay loam (UK), Sandy loam (Italy), AR Silty clay sediment Sandy loam (Brazil), Clay loam (Brazil), Sandy clay loam (Brazil)	45830801, 45834802, 45830802	acceptable, supplemental, (aged column mobility study of limited value) supplemental (BSTCA, BST, 5-OH-penoxsulam)
Bioconcentration in Aquatic, Non-Target Organisms - BCF	0.02 mL/g	crayfish (*Procambarus clarkii*), 14 days, at 0.5 ppm under flow-through conditions	45830001	acceptable
Aquatic Field Dissipation -- $t_{1/2}$ (total system)	16 days, 16 days, 5 days, 10 days, 4 days	AR bareground plot, dry seeded (liquid), AR cropped plot, dry seeded (liquid), CA bareground plot, water seeded (liquid), CA cropped plot, water seeded (liquid), CA cropped plot, water seeded (granular)	45830804, 45830805	supplemental, acceptable

Table 4 - Summary of Penoxsulam Transformation Products from Environmental Fate Data

Study Type	Degradates	Maximum % Applied	Major / Minor	Maximum at Study Termination*	Study MRID
Photodegradation in Water	BSA, 2-amino TP, TPSA, 2-amino-TCA, 5-OH, 2-amino TP, BSTCA methyl, BSTCA, di-FESA	36%, 18%, 56%, 85%, 32%, 12%, 7.2%, 7.6%	major, major, major, major, major, minor, minor, minor	no, no, no, yes, no, no, no, no	45834801, 45830722
Photodegradation on Soil	BSTCA, 2-amino TP, BSA, $^{14}CO_2$	11%, 10%, 8.1%, 3.2%	major, major, minor, minor	no, yes, no, yes	45830723
Aerobic Soil Metabolism	BSTCA, 5-OH-penoxsulam, SFA, sulfonamide, $^{14}CO_2$, BSTCA methyl, BST	37%, 63%, 15%, 33%, 16%, 1.4%, 6.3%	major, major, major, major, major, minor, minor	yes, no, yes, yes, yes, no, no	45830724
Anaerobic Aquatic Metabolism	BSTCA, BSTCA methyl, 5-OH-penoxsulam, 5,8-di OH, BST, $^{14}CO_2$	25%, 13%, 42%, 11%, 4.8%, 1.2%	major, major, major, major, minor, minor	no, no, no, yes, no, yes	45830725
Aerobic Aquatic Metabolism	5-OH-penoxsulam, BSTCA, $^{14}CO_2$	40%, 39%, 2.4%	major, major, minor	no, yes, yes	45830726

*Maximum % of applied reported at study termination indicates that amounts may have continued to increased with time

Study Classification

All three of the submitted photodegradation studies, the aged soil column leaching study, and one of the two aquatic field dissipation studies have been classified as supplemental. In the soil photolysis studies, the mass balance was not acceptable, the temperature and the soil moisture were not adequately maintained. In the supplemental aqueous photolysis studies, either the test systems were not sterile, the study author had not adequately identified or described all

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degradates >10% of applied, the mass balance for each test system was not adequate, and/or the CO_2 data were contradictory. In the aged soil column leaching study, only two soils and one label were used in one portion of the study, and insufficient water was used. In the aquatic field dissipation study, it could not determine whether the penoxsulam degradation products of toxicological concern which formed in the paddy water partitioned into the sediment or degraded. However, in spite of these deficiencies, no additional environmental fate data are required at this time.

Study Variability

The four photolytic half-lives reported for penoxsulam in water had R squared values for the regressed data points from each test system that ranged from 0.95 to 0.99. The two photolytic half-lives for penoxsulam on soil had R squared values for the regressed data points from each test system that ranged from 0.7 to 0.9. The three aerobic degradation half-lives for penoxsulam had R squared values for the regressed data points from each test system that ranged from 0.81 to 0.93, with an average value of 0.89. The six total system, aerobic aquatic degradation half-lives for penoxsulam had R squared values for the regressed data points from each test system that ranged from 0.80 to 0.99, with an average value of 0.91. The three total system, anaerobic aquatic degradation half-lives for penoxsulam had R squared values for the regressed data points from each test system of 0.98.

In some cases, use of non-linear regression to calculate half-lives would have produced a shorter half-life and an overall better fit for the values in that particular data set than linear regression of log transformed data. However, while linear regression of the log transformed data generally underestimates the initial degree of biotic degradation of pesticides in soil systems, non-linear regression generally underestimates the amount of parent material still present after several weeks/months of degradation. Additionally, for the purposes of generating an overall half-life value from multiple data sets, decrease in half-life would generally be offset by an increase in the standard deviation for the data sets.

2. Aquatic Organism Exposure Modeling

General Approach

EFED does not have a peer reviewed model for the assessment of releases from rice paddies. As an interim approach for the evaluation of registration actions, EFED has developed a screening-model for calculating EECs and required holding times to provide a reasonable degree of confidence that levels of concern will not be exceeded. This model is identical to the one which has been used for previous rice pesticide evaluations.

Aquatic concentrations are estimated by applying the total annual application to the paddy[6], partitioning the pesticide between the water and the paddy sediment, then calculating the

[6]Since penoxsulam is a single application pesticide, the maximum single application is the annual application rate.

dissolved concentration occurring in the water column. This concentration represents the maximum concentration expected to be found in water released from the paddy. Degradation processes, dilution with uncontaminated water outside the paddy, and movement of pesticide on suspended sediment are not considered in this calculation.

While this approach is extremely conservative for estimating chronic environmental concentrations for quickly degrading compounds with short half lives, it also helps prevent underestimation in cases where little is known about major degradates and when labels do not contain explicit holding times for treated paddy water. It also provides some margin of safety in acute exposure assessments to reflect the paucity of information relating to the amount of paddy water that could reasonably be expected to impact any given acre of adjoining semi-aquatic areas[7]. It is less conservative than the approach taken to modeling aquatic pesticides where there is direct application to waterways.

The model paddy considered in estimating EECs with the interim method is assumed to have a four inch depth with the pore space in a 1 cm thick sediment interaction zone. A standard assumption is made for the bulk density of surface horizons of mineral soils. K_d and K_{oc} are estimated according to the methods recommended for other surface water models in EFED's Input Parameter Guidance (USEPA, 2002). The equation **(EQ1)** to use for this calculation is:

$$EEC = \frac{10^9 M_T}{V_T + m_{sed} K_d} \qquad \textbf{(EQ 1)}$$

where M_T is the total mass of pesticide in kg applied per ha of paddy, V_T is 1.067×10^6 L ha^{-1} which is the volume of water in a paddy 4 inches (10.16 cm) deep, and includes the pore space in a 1 cm sediment interaction zone. The mass of sediment, m_{sed}, is the amount found in the top 1 cm interaction zone and is 130,000 kg ha^{-1} when the sediment bulk density was assumed to be 1.3 kg L^{-1}, a standard assumption for the bulk density of surface horizons of mineral soils (Brady, 1984; Hillel, 1982). The 10^9 constant converts the units of mass from kg to µg.

When the level of concern in a risk assessment is not exceeded using an EEC calculated by this screening method, there is high confidence that there will be little or no risk above the level of concern from exposure through water resources. The size of the area and the length of time for which the estimate is reasonable depends upon how fast the pesticide degrades, the rate of removal onto uncontaminated bed sediments, the nature of the local stream network, and all of the previously mentioned factors.

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[7]This lack of information is in marked contrast to the conventional PRZM/EXAMS scenarios where one or ten acres of runoff are projected to impinge upon a one acre pond.

As a further refinement to calculating surface water environmental concentrations, the modeling approach used for the refined assessment associated with the propanil RED [8] was utilized. The refinement introduced in the propanil assessment partitions the pesticide between the paddy water and the soil, degrades the pesticide using the rate constant from the dominant mechanism for the environmental compartment, and calculates concentrations which can be useful for suggesting potential holding times of paddy water.

The dominant route of dissipation for penoxsulam in paddy water is expected to be through aqueous photolysis. However, photolysis can be strongly influenced by turbidity, clouds and canopy cover can also contribute to slower degradation rates. Dow, in a study submission (MRID 458308-11), proposed use of total system aquatic field dissipation rates to estimate suggested holding times. Because these rates were generally consistent with laboratory data, EFED also modeled decay using these rates[9].

Criteria For Scenario Selection

The interim approach described in this assessment is substantially independent of the location of US rice production. Consequently, no additional scenario development is required.

Model Results

Applying the method outlined in the current EFED interim policy for calculating estimated environmental concentrations (EECs) and estimated drinking water concentrations (EDWCs) resulting from the use of pesticides on rice crops produced an ***upper bound screening estimation***, using the lowest K_d value (0.13) for a non-sand soil, of ***45 ppb*** (ug/L) ***in paddy waters***. This estimated EEC is used for both acute and chronic EECs, as well as for both aquatic ecological risk assessments and for drinking water exposure (EDWCs) in human health risk assessments. This value changes to 43 ppb (ug/L) if calculated from the average K_d value typical of rice growing regions. EECs for individual penoxsulam transformation products can not exceed the values estimated for the parent, penoxsulam, using the interim method. Individual EECs were not calculated for any transformation product.

Modeling aquatic concentrations using the standard Tier 1 model, SCI-GROW, estimated parent-only ground water concentrations of 0.67 ppb (ug/L). Even so, EFED does not regard ground water contamination from a pesticide applied to rice to be a significant route of dissipation.

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[8]EFED Response to Registrant Request for a Seven (7) Day Holding Period for Propanil Use in Rice Paddies; DP Barcode: D290202; PC Code: 028201; 9/11/03.

[9]Dow estimates for EECs differed significantly from EFEDs due to the use of inappropriate values for both degradation and partitioning, and incorporation of a holding period which is not supported by the current labels.

Estimated Holding Times Necessary to Reduce Aquatic Concentrations of Penoxsulam in Rice Paddy Water to Levels Below Ecological Effects LOCs

Estimated values of residual penoxsulam in paddy water are plotted below considering degradation due to aqueous photolysis only (Figure 2), degradation following the rate reported for the 90% confidence interval in the paddy water phase of submitted aquatic field dissipation studies (Figure 3), and the degradation following the rate reported the total system of submitted aquatic field dissipation studies (Figure 4). Total system aqueous field dissipation rate differs from the aqueous phase dissipation in that the total system dissipation half-lives are calculated from combined percent of applied radiation identified as penoxsulam in both the soil and in the paddy water at each sampling interval. Aqueous phase dissipation rates are calculated from the percent of applied radiation identified as penoxsulam in the paddy water alone. While aqueous photolysis is expected to be the most dominant route of degradation for penoxsulam in rice paddies, environmental factors such as turbidity, canopy cover and atmospheric conditions will reduce the degradation rate by limiting the amount of solar energy impinging upon the aquatic phase of the system. Use of the total system half-lives combines concentrations temperately residing in sediment with concentrations present in paddy water. The most realistic approach is to use the aquatic field dissipation rates in paddy water alone for estimating suggested holding times. The results from the three separate approaches are provided to generate a sense of the potential variability which might be seen under actual conditions.

Figure 2: Estimated Concentrations for Paddy Water for Dry-Seeded Rice Using Photolysis Degradation Rate

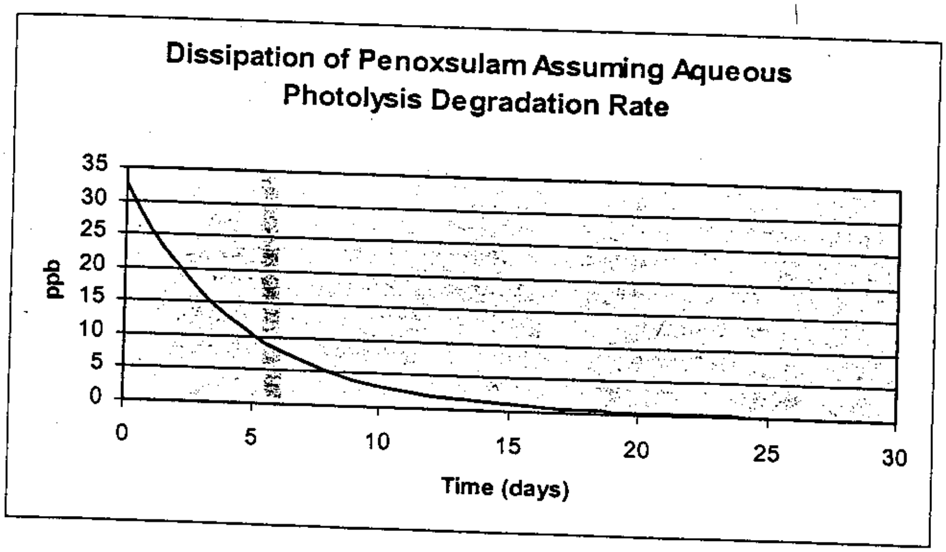

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Figure 3: Estimated Concentrations for Paddy Water for Dry-Seeded Rice Using Aquatic Field Dissipation Paddy Water Degradation Rate

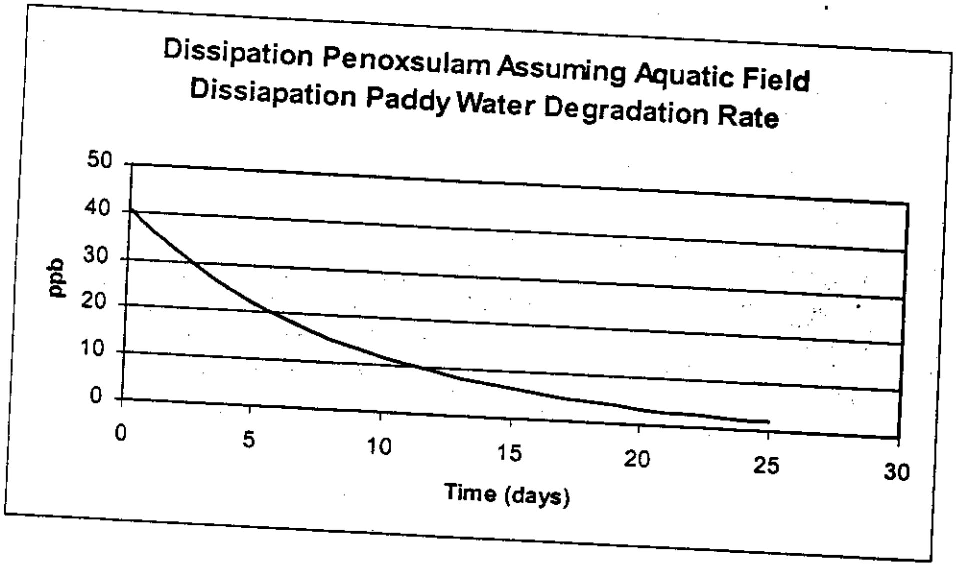
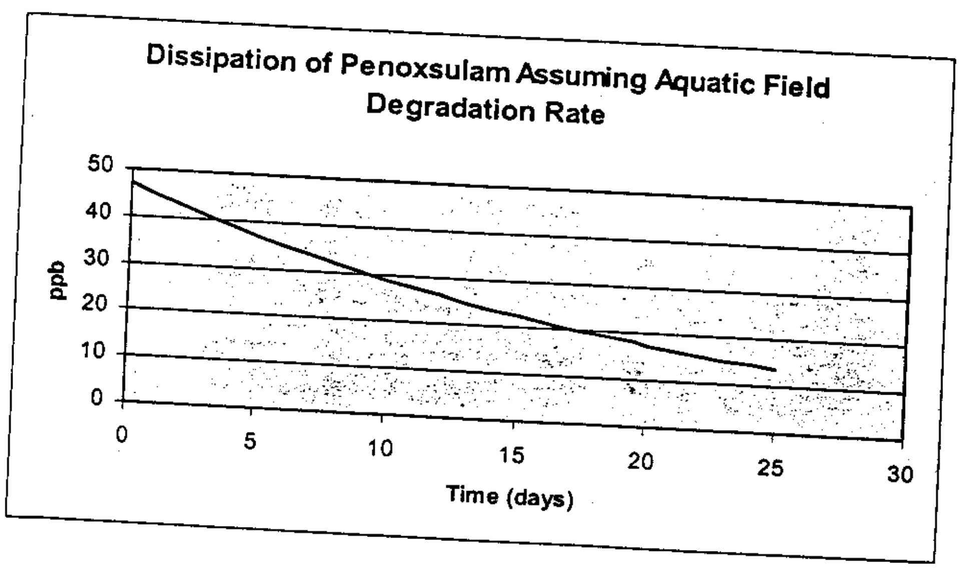


Figure 4: Estimated Concentrations for Paddy Water for Dry-Seeded Rice Using Aquatic Field Dissipation Total System Degradation Rate



Monitoring Information

Penoxsulam is a new chemical being proposed for registration. Therefore, no surface water monitoring data are currently available. Nevertheless, aquatic field dissipation half-lives were generally consistent with submitted laboratory data. Penoxsulam dissipated from dry seeded rice paddies with calculated, total system half-lives of 16 days for each of the two test sites. Penoxsulam dissipated from the three water-seeded test sites where abiotic transformation would be expected to have a more dominant influence with calculated half-lives of 4 days, 5 days and 10 days.

3. Terrestrial Organism Exposure Modeling

General Approach

Terrestrial wildlife exposure estimates are typically calculated for bird and mammals, emphasizing a dietary exposure route for uptake of pesticide active ingredients. These exposures are considered as surrogates for terrestrial-phase amphibians as well as reptiles. For exposure to terrestrial organisms, such as birds and small mammals, pesticide residues on food items are estimated, based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario.

For penoxsulam spray applications, estimation of pesticide concentrations in wildlife food items focuses on quantifying possible dietary ingestion of residues on vegetative matter and insects. The residue estimates are based on a nomogram that relates residues to pesticide application rate. The estimated environmental concentrations (EECs) are generated from a spreadsheet model (EL-FATE) that calculates the decay of a chemical applied to plant surfaces for single or multiple applications.

The terrestrial exposure assessment for liquid-based applications is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). Terrestrial EECs for nongranular formulations (Table 5) were derived using the maximum application rate. Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. When data are absent, EFED assumes a 35-day dissipation half-life, based on the work of Willis and McDowell (1987). For penoxsulam, it can not be determined whether this is a conservative assumption due to lack of information on degradate toxicity.

The EECs on food items may be compared directly with dietary toxicity data or converted to an oral dose. The screening-level risk assessment for penoxsulam uses upper bound predicted residues as the measure of exposure. The predicted maximum and mean residues of penoxsulam are those which may be expected to occur on selected avian or mammalian food items immediately following application (at the maximum annual or seasonal label rate). For mammals, the residue concentration is converted to daily oral dose based on the fraction of body weight consumed daily as estimated through mammalian allometric relationships.

Model Results

Table 5. Estimated Environmental Concentrations (EECs) on avian and mammalian food items (ppm) immediately following an application of 0.044 lbs a.i./A. [1]

Food Items	EEC (ppm) Predicted Maximum Residue	EEC (ppm) Predicted mean Residue
Short grass	11	3.7
Tall grass	4.8	1.6
Broadleaf plants / Insects[2]	5.9	2.0
Seeds	0.66	0.31

[1] Predicted maximum and mean residues are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

[2] The surface to volume ratios of broadleaf plants and insects are similar, therefore, the residues may be similar.

<u>*Granular applications*</u>

Birds and mammals in the field may be exposed to seed treated with pesticides by ingesting granular pesticide directly with the diet. They also may be exposed by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, preening activities, and ingestion of drinking water contaminated with pesticide. Traditionally, EFED has only considered ingestion of pesticide granules as a route of exposure. There are two reasons such an analysis was not undertaken for penoxsulam. First, penoxsulam is not being proposed for a seed treatment, nor is it being formulated with a grain or other material attractive to birds or small mammals. Consequently, the chances of more than incidental consumption of the granular are limited. Secondly, acute toxicity was not demonstrated, nor expected, for penoxsulam and its degradates.

B. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an organism or plant. This characterization is based on registrant-submitted studies that describe acute and chronic toxicity effects for various aquatic and terrestrial animals and plants. In addition, other sources of information, including reviews of the open literature and the Ecological Incident Information System (EIIS), may be used to further refine the characterization of potential ecological effects.

Appendix D summarizes the results of the registrant-submitted toxicity studies used to characterize effects for this risk assessment. Toxicity studies reported in this section do not represent all species of birds, mammals, or aquatic organisms. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to Norway rat. Estuarine/marine studies are usually limited to a crustacean, a mollusk, and a fish. Neither reptiles nor amphibians are studied. The risk assessment assumes that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians.

1. Evaluation of Aquatic and Terrestrial Ecotoxicity Studies

Testing of the active ingredient suggest that penoxsulam is practically nontoxic to freshwater fish, birds, mammals, and honeybees on an acute basis. In many tests, no adverse effects were seen at highest tested levels. Consequently, toxicity category labels reflect the highest possible risk nomenclature, rather than a clear demonstration of toxicity at that level. For instance, the degradate TPSA was only tested on the bluegill to a level of 1.4 ppm. An LC50 for the bluegill of 1.4 ppm would result in the toxicity category of "Moderately toxic". In actuality, the LC50 could be much higher and justify a classification of anything up to "Practically nontoxic".

Because penoxsulam is an ALS inhibitor, it does have an effect on plants. For these cases, there is a greater liklihood that indicated classifications are the proper ones. There also is some potential for greater concern with respect to invertebrates. In both of these cases, lack of information on the degradates limits the evaluation of the ecotoxicity of penoxsulam.

Acute Toxicity to Freshwater Fish

Studies using the rainbow trout, carp, and the bluegill sunfish were used to evaluate acute toxicity. The rainbow trout and bluegill sunfish acute studies are consistent with Guideline §72-1(a) and §72-1(c) requirements and are classified as core. The acute study using the common carp is classified as supplemental because this species is not recognized as acceptable for use in acute toxicity studies of freshwater fish. No adverse effects were noted in any of these studies. Information on degradates was not provided. The results are tabulated below in Table 6.

Chronic Toxicity to Freshwater Fish

A freshwater fish early life stage study using the fathead minnow (*Pimephales promelas*) was submitted. No treatment-related effects on hatchability, survival, and/or terminal growth parameters were observed. The NOAEC was 10.2 ppm, the highest level tested. Although this study is scientifically sound, it is classified as supplemental because a LOAEC value was not determined.

Toxicity to Freshwater Invertebrates

The *Daphnia magna*, as well as a midge (*Chironomus sp.*), and an amphipod (*Gammarus* sp.) were used to study the toxicity of technical penoxsulam to freshwater invertebrates. The toxicities of an end-use product and several degradates were studied with the water flea. The 48-hr EC_{50} value for *D. magna* with the technical grade product is >98 ppm. This study fulfills the §72-2 guideline.

Table 6. Freshwater Fish - Acute and Chronic Aquatic Toxicity Data.

Species and Chemical	Acute Toxicity		Chronic Toxicity	
	96-hr LC_{50} (ppm)	Toxic Category (MRID)	NOAEC (mg/L)	Endpoints (MRID)
Rainbow Trout ***Oncorhynchus mykiss***				
Technical grade	>102	Practically Nontoxic (45834804)	None	
Degradates and End-use products	None			
Bluegill sunfish ***Lepomis macrochirus***				
Technical grade	>103	Practically Nontoxic (45831010)	None	
GF-443[1]	>147	Practically Nontoxic (45831011)		
Degradate	None			
Common Carp ***Cyprinus carpio***				
Technical grade	>101	Practically Nontoxic (45831009)	None	
Degradates and End-use products	None		None	
Fathead minnow ***Pimephales promelas***				
Technical grade	None	None	10.2	None (45831027)

[1]GF-443 is the liquid formulation containing 21.7% penoxsulam

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Several studies were submitted on the acute toxicity of the degradates of penoxsulam to *D. magna*. Seven of them, the studies on BSTCA, BST, 5-hydroxy-XDE-638[10], 2-amino-TP, TPSA, (5-OH, 2-amino-TP), and BSA, were acceptable for risk analysis. Their 48-hour EC_{50} values ranged from >1.0 ppm to >100 ppm. Supplemental data on the acute toxicity of penoxsulam to other non-guideline freshwater invertebrates showed that when studied with the amphipod, *Gammarus* sp., penoxsulam had a 48-hr EC_{50} >126 ppm.. The results are tabulated below in Table 7.

Acute Toxicity to Estuarine/Marine Fish

Acute toxicity studies were performed on an estuarine/marine fish, a mollusk and a crustacean. The estuarine/marine fish acute toxicity study on the Silverside (*Menidia beryllina*) was done using the active ingredient. No impacts were observed. The results are tabulated below in Table 8.

Acute Toxicity to Estuarine/Marine Invertebrates

Acute penoxsulam toxicity data are available for the mysid (*Americamysis bahia*) and the Eastern oyster (*Crassostrea virginica*), and are summarized in Table 8. The 96-hour mysid LC_{50} is 114 ppm; therefore, penoxsulam is classified as practically nontoxic to estuarine/marine crustaceans on an acute exposure basis. The acute mysid study is scientifically sound and is consistent with Guideline §72-3(c) requirements.

A study with the eastern oyster found that penoxsulam is practically nontoxic to mollusks, with an LC_{50} of >127 ppm, a NOAEC of 127 ppm. After 96 hours of exposure, there was one mortality in the control and no mortalities in the treatment groups. No statistically significant reductions in shell deposition were observed at any level.

Chronic Toxicity to Estuarine/Marine Fish

No data were submitted. Requirements are reserved.

[10]Also referred to by its common name, 5-OH-penoxsulam.

Table 7. **Freshwater Invertebrates - Acute and Chronic Aquatic Toxicity Data.**

Species and Chemical	Acute Toxicity		Chronic Toxicity	
	48-hr EC_{50} (ppm)	Toxicity Category (MRID)	NOAEC (ppm)	Endpoints (MRID)
Water flea ***Daphnia magna***				
Technical grade	>98	Slightly Toxic (45831012)	3.0	Live young (45831026)
BSTCA	>100	Practically Nontoxic (45831014)		
BST	>96	Slightly Toxic (45831018)		
5-hydroxy-XDE-638	>1	Moderately Toxic (45831013)		
2-amino-TP	>1	Moderately Toxic (45831014)		
TPSA	>1.4	Moderately Toxic (45831018)		
5-OH,2amino-TP	>1	Moderately Toxic (45831016)		
BSA	>1.6	Moderately Toxic (45831017)		
Midge ***Chironomus*** **sp.**				
Technical grade	> 140	Practically Nontoxic (45831102)	7.1	Development (45831102)
Amphipod ***Gammarus*** **sp.**				
Technical grade	>126	Practically Nontoxic (45831021)		

Chronic Toxicity to Estuarine/Marine Invertebrates

Chronic toxicity testing was performed on the mysid (*Americamysis bahia).* Statistically significant effects were seen at all tested levels for male dry weight. At the lowest tested level of 8.1 mg/L, there was a 20% reduction in male body weight versus the controls. At 59 mg/L and higher levels much higher male weight loss was seen and statistically significant reductions in number of young/female/day were also observed. At 119 mg/L, effects were seen on the length of both sexes. Data were not provided on male survival, nor on sex distribution of offspring. Because no NOAEC was identified, the study is classified as supplemental.

Table 8. Estuarine and Marine Animals - Acute and Chronic Toxicity Data.

Species and Chemical	Acute Toxicity		Chronic Toxicity	
	96-hr LC_{50} (ppm)	Toxicity Category (MRID)	NOAEC (mg/L)	Endpoints (MRID)
Silverside *Menidia beryllina*				
Technical grade	>129	Practically Nontoxic (45831022)		
Eastern oyster *Crassostrea virginica*				
Technical grade	>127	Practically Nontoxic (45831023)		
Mysid *Americamysis bahia*				
Technical grade	114	Practically Nontoxic (45831024)	<8.1	Male dry weight

Chronic Toxicity to Freshwater Invertebrates

A freshwater aquatic invertebrate life-cycle study using the TGAI was submitted for penoxsulam using the preferred species *Daphnia magna* and summarized in Table 7. Mortality and immobilization data were not analyzed because less than 50% mortality and immobilization occurred during the test. However, a statistically-significant reduction in the number of live offspring produced was observed at the 9.8 ppm a.i. level. Based on the number of live offspring (the only endpoint affected), the NOAEC and LOAEC values were 3.0 and 9.8 ppm a.i., respectively. The study is scientifically sound, consistent with Guideline §72-4(b), and is classified as core. A chronic study with a midge found an EC_{50} (development rate) of >140 mg a.i./L and a NOAEC of 7.1 mg a.i./L.

Toxicity to Aquatic Plants

Acute plant toxicity data are presented in Table 9 below. Studies using the technical grade product, end-use products, and degradates were submitted for vascular and nonvascular plants. As shall be discussed in greater detail in the uncertainties section, data were not provided on the sulfonamide and SFA degradates.

Table 9. Aquatic Plants - Acute Toxicity Data

Species and Chemical	MRID	Acute EC_{50} (mg/L)	NOAEC (mg/L)	EC_{05} (mg/L)	Affected Endpoint
Vascular plants- Duckweed *Lemna gibba*					
Technical grade	45831120	0.003	0.001	0.0007	Number of fronds
BSTCA	45831106	>10	10	ND	None
5-hydroxy-XDE-638	45831104	>11	0.22	0.095	Number of fronds
BST	45831105	>6.2	<0.1	ND[1]	Number of fronds Growth rate
2-amino-8-methoxy Tier 1	45831108	>1.25	1.25	ND	None
2-amino-TP Tier 1	45831111	>1.0	1.0	ND	None
BSA Tier 1	45831110	>1.6	1.6	ND	None
TPSA Tier 1	45831109	>1.4	1.4	ND	None
Nonvascular plants- Green algae *Selenastrum capricornutum*					
Technical grade	45834805	0.092	0.005	0.007	Cell density
GF-443	45831107	0.094	0.009	0.005	Biomass
BSTCA	45831119	>10	10	ND	None
BST	45831117	>9.6	3.9	ND	Growth rate Biomass
5-hydroxy-XDE-638	45831118	>10	10	ND	None
TPSA	45831113	>1.4	1.4	ND	None
5-OH,2-amino-TP	45831114	>1.0	1.0	ND	None
BSA	45831112	>1.6	1.6	ND	None
2-Amino TP	45831115	>1.0	1.0	ND	None
Nonvascular plants- Freshwater diatom *Navicula pelliculosa*					
Technical grade	45831121	>49.6	49.6	ND	None
Nonvascular plants- Freshwater alga *Anabaena flos-aquae*					
Technical grade	45831122	0.27	0.194	0.027	Cell density Biomass
Nonvascular plants Tier I Saltwater diatom *Skeletonema costatum*					
Technical grade	45831123	>46.7	2.33	0.43	Cell Density Biomass
TPSA	45831113	>1.4	1.4	ND	None
5-OH, 2-amino-TP	45831114	>1.0	1.0	ND	None
2-Amino TP	45831115	>1.0	1.0	ND	None
BSA	45831112	>1.6	1.6	ND	None

[1]Not determined because non-monotonic response.

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Acute Toxicity to Aquatic Plants

Vascular plants

The vascular plant used was duckweed (*Lemna gibba)*. The technical's acute EC_{50} and EC_{05} were 0.003 mg/L and 0.0007 mg/L, respectively. Its NOAEC was 0.001 mg/L. The most sensitive effect for duckweed was the number of fronds. No studies of the effect of the end-use product, GF-443, on a vascular plant were submitted. The toxicities of the degradates BSTCA, 5-hydroxy-XDE-638, BST, 2-amino-8-methoxy , 2-amino-TP, BSA, and TPSA were studied. A NOAEC was not obtained for BST at 0.1 mg/L, but all other toxicities were demonstrated to be less than that of the technical. It is not expected that BST would be more toxic than the technical based on the level of response.

Nonvascular plants

The active ingredient affected the green algae *Selenastrum capricornutum* by reducing its cell density. The EC_{50} was 0.092 mg/L, NOAEC was 0.005 mg/L, and the EC_{05} was 0.007 mg/L. The most sensitive end point was cell density. The end use product, GF-443, had essentially the same toxicity. Its EC_{50}, NOAEC, and EC_{05} values were 0.094, 0.009, and 0.005 mg/L, respectively and the most sensitive end point was biomass. The penoxsulam degradates BSTCA; BST; 5-hydroxy-XDE-638; TPSA; 5-OH,2-amino-TP; BSA; and 2-Amino TP were not as toxic as the parent material.

The effect of the technical grade product was also studied on the diatom *Navicula pelliculosa*, the freshwater alga *Anabaena flos-aquae*, and the saltwater diatom *Skeletonema costatum*. The most sensitive was *Anabaena flos-aquae*, which had a NOAEC of 0.194 mg a.i./L, an EC_{50} of 0.27 mg a.i./L, and an EC_{05} of 0.027 mg/L and affected cell density. Of these species, only *Skeletonema costatum* had study reports for degradates, none of which exhibited a toxic response.

Toxicity to Terrestrial Animals

Eight studies on the toxicity of penoxsulam were submitted and are being used for risk characterization. The results are presented below in Table 10. The registrant submitted two acute and dietary toxicity studies with the technical grade product and one with the end use product GF-443. All found that the stressors were practically nontoxic to birds. The only observed effect in any of the studies was a statistically significant reduction of feed consumption on the first three days of the testing of acute oral toxicity of GF-443 to the bobwhite quail.

Chronic toxicity of the technical grade was tested on both the quail and the duck. An avian dietary study on the bobwhite quail found a NOAEC of 231 ppm. Effects were observed for food consumption and body weight gain. A study on the mallard duck found a NOAEC of 501 mg/kg. The endpoint of concern was male body weight gain. No reproductive effects were observed.

Acute oral toxicity of the technical grade was tested at a dose level of 5000 mg/kg. Five male and 5 female Fischer 344 rats were used in the study. No animals died during the study. Clinical abnormalities were transient and only observed in a few animals. Chronic mammalian testing of the technical grade in a two generation reproductive test of the Norway rat found a NOAEC of 600 ppm. The effect observed was delay of preputial separation in F_1 males. This is a developmental delay effect.

Table 10. Acute and Chronic Toxicity for Terrestrial Animals.

Species and Chemical	Acute Toxicity		Dietary Toxicity		Chronic Toxicity	
	LD_{50} (ppm)	Category (MRID)	LC_{50} (mg/kg)	Category (MRID)	NOAEC (ppm) (MRID)	Endpoints
Northern bobwhite quail ***Colinus virginianus***						
Technical grade	>2,025	Practically Nontoxic (45830928)	>4,411	Slightly Toxic (45831002)	231 (45831006)	Food consumption, Male & female body weight gain
GF-443	>2,190	Practically Nontoxic (45831001)				
Mallard duck ***Anas platyrhynchos***						
Technical grade	>1,900	Practically Nontoxic (45830929)	>4310	Slightly Toxic (45831003)	501 (46276401)	Adult male body weight
GF-443	None					
Norway Rat ***Rattus norvegicus***						
Technical Grade	>5000 mg/kg bw	(45830812)			600 (45830920)	
Honey bee ***Apis meliferus***						
Species Chemical	**Acute Contact (µg/bee contact)**		**MRID**			
Technical grade	>100		45831124			
GF-443	>22		45831127			

Toxicity to Terrestrial Plants

Studies (MRID 45831116) on the toxicity of penoxsulam to terrestrial plants were submitted. The data are presented in Tables 11a and 11b for seedling emergence and vegetative vigor, respectively. Testing was not provided on the end use product. Rather, testing was conducted on a 16% crop oil concentrate of penoxsulam. Both studies were scientifically sound and fulfilled the guideline requirements for seedling emergence and vegetative vigor studies (Guidelines 123-1 (a & b; TIER II)).

Table 11a. Terrestrial Plants- Tier II Data, Seedling Emergence.

Species	Shoot length (g ai/ha)			Shoot weight (g ai/ha)			Most Sensitive Parameter	Slope
	NOAEC	EC_{05}	EC_{25}	NOAEC	EC_{05}	EC_{25}		
Dicots								
Sugarbeet	1.2	2.5	5.5	1.2***	1.1	3.2*	Weight	2.2
Cotton	33	ND	>33	33	ND	>33	None	n/a
Soybean	33	ND	>33	33	ND	>33	None	n/a
Cucumber	33	ND	>33	33	ND	>33	None	n/a
Kale	3.7	3.9	11	3.7	2.3	6.7	Weight	2.1
Tomato	3.7	4.9	18	3.7	3.2	11	Weight	1.8
Monocots								
Onion	3.7	0.28	6.2	0.41****	0.066	1.1**	Weight	0.79
Wheat	100	ND	>100	100	ND	>100	None	n/a
Corn	100	ND	>100	100	ND	>100	None	n/a
Ryegrass	33	ND	>100	33	ND	>33	None	n/a

* Most sensitive EC25 dicot   ** Most sensitive EC25 monocot   *** Most sensitive NOAEC dicot
**** Most sensitive NOAEC monocot

Table 11b. Terrestrial Plants- Tier II, Vegetative Vigor

Species	Shoot length (g ai/ha)			Shoot weight (g ai/ha)			Most Sensitive Parameter	Slope
	NOAEC	EC_{05}	EC_{25}	NOAEC	EC_{05}	EC_{25}		
Dicots								
Soybean	3.7	1.9	4.4	1.2***	2.1	3.9*	Weight	3.7
Sugarbeet	11.1	6.4	20	1.2***	1.7	4.6	Weight	2.3
Tomato	3.7	1.5	8.0	1.2***	3.0	8.1	Length	1.3
Cotton	3.7	11	73	33	35	>100	Length	1.2
Cucumber	33	32	63	33	21	49	Weight	n.d.
Kale	3.7	3.2	10	3.7	3.6	8.6	Weight	2.6
Monocots								
Ryegrass	33	ND	>100	0.41****	0.08	17**	Weight	0.42
Corn	100	ND	>100	100	ND	>100	None	n/a
Wheat	100	ND	>100	100	ND	>100	None	n/a
Onion	3.7	7.8	36	11	20	31	Length Weight	n.d.

* Most sensitive EC25 dicot   ** Most sensitive EC25 monocot   *** Most sensitive NOAEC dicot
**** Most sensitive NOAEC monocot

Seedling emergence

Based on the results of the Tier II terrestrial plant toxicity studies, it appears that both monocot and dicot species of non-target plants are very selective with respect to sensitivity to penoxsulam, particularly for the seedling emergence test. In the seedling emergence test, six out of the ten test species showed no effect at the highest concentration of penoxsulam tested. With the exception of corn and wheat, which were tested at maximum penoxsulam concentrations of 100 g a.i./ ha, the highest test concentration for the other species was 33 g a.i./ha (less than the proposed maximum application rate of 49 g a.i./ha). Out of the six plant species showing no sensitivity to penoxsulam, three were dicots (i.e., cotton, soybean, and cucumber) and three were monocots (wheat, corn, and ryegrass). The most sensitive endpoint for plants that exhibited seedling emergence sensitivity to penoxsulam (onion, sugarbeet, kale, and tomato), as defined by ≥ 25% inhibition, was shoot weight.

Vegetative vigor

In the vegetative vigor test, two monocot species (corn and wheat) showed no sensitivity to penoxsulam at maximum concentrations of 100 g a.i./ha. Of the species that were sensitive to treatment, EC_{25} values for the most sensitive dicot (soybean) and monocot (ryegrass) were 3.9 and 17 g a.i./ha. Both vegetative vigor endpoints were based on shoot weight.

2. Open Literature Review

Because penoxsulam is a new active ingredient, which has not yet been produced, no evaluation of the open literature was conducted.

3. Incident Data Review

Since penoxsulam has never been registered, a search of the incident data base was not performed.

IV. Risk Characterization

Risk characterization is the integration of exposure and effects characterizations to determine the ecological risk from the use of the pesticide and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide use scenarios. The risk characterization provides an estimation and a description of the risk; articulates risk assessment assumptions, limitations, and uncertainties; synthesizes an overall conclusion; and provides the risk managers with information to make regulatory decisions regarding a pesticide.

A. Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of penoxsulam risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide's use as directed on the label has the potential to cause adverse effects on non-target organisms. Appendix E of this document summarizes the LOCs used in this risk assessment. Appendix F provides detailed spreadsheets of all derived RQs for non-target species.

1. Risk Quotient

Nontarget Aquatic Animals and Plants

Surface water concentrations resulting from penoxsulam application to selected crops were predicted with the previously described preliminary rice exposure model. Because of the manner in which rice is grown all EECs were determined to be 0.045 ppm. The peak EEC was 0.045 ppm. The peak EEC was then compared to acute toxicity endpoints to derive acute RQs. This EEC was also compared to chronic toxicity endpoints (NOAEC values) to derive chronic RQs for freshwater and for estuarine/marine organisms. Acute and chronic RQs for freshwater and estuarine/marine organisms are summarized in Tables 12 through 14, respectively.

For aquatic vascular and non-vascular plants, peak EECs were compared to acute EC_{50} and NOAEC toxicity endpoints to derive acute non-endangered and endangered species RQs, respectively. Acute non-endangered and endangered species RQs for aquatic vascular and non-vascular plants are summarized in Table 15.

For the current application rates of penoxsulam to rice, acute LOCs are exceeded only by the technical grade product and the end use product GF-443 on the vascular plant, duckweed (*Lemna gibba*), and the green alga *Selenastrum capricornutum*.

Risk to Freshwater Fish

The acute and chronic risk quotients were determined for freshwater fish. A chronic risk quotient was also determined for one species. The RQs are tabulated below. No freshwater fish acute or chronic LOCs were exceeded. No studies were submitted using a degradate.

Risk to Freshwater Invertebrates

Three species of freshwater invertebrates were studied. The calculated acute and chronic risk quotients are tabulated below. No acute or chronic Levels of Concern were exceeded in the studies on freshwater invertebrates. Studies were done on *Daphnia magna*, the preferred species, but studies were also submitted using an amphipod (*Gammarus* sp.) and a midge (*Chironomus* sp.). Studies using the technical grade product were done for all three species. Several degradates were also assessed using the Daphnid. None of the RQs from these studies exceeded the Level of Concern.

Table 12. Freshwater Fish - Risk Quotients

Species and Chemical	Acute LC_{50} (ppm)	Chronic NOAEC (ppm)	EEC Peak (ppm)	EEC 21-Day Average (ppm)	Acute RQ (ppm) EEC/EC_{50}	Chronic RQ (ppm) EEC/NOAEC
Rainbow trout ***Oncorhynchus mykiss***						
Technical grade	>102		0.045	0.045	<0.001	
GF-443	None					
Degradates	None					
Bluegill Sunfish ***Lepomis macrochirus***						
Technical grade	>103		0.045	0.045	<0.001	
GF-443	>147		0.045	0.045	<0.001	
Degradates	None					
Fathead Minnow ***Pimephales promelas***						
Technical grade		10.2	0.045	0.045		0.004
GF-443	None					
Degradates	None					

Table 13. Freshwater Invertebrates - Acute and Chronic Risk Quotients.

Species and Chemical	Acute EC_{50} (ppm)	Chronic NOAEC (ppm)	EEC Peak (ppm)	EEC 21-Day Average (ppm)	Acute RQ EEC/EC_{50}	Chronic RQ EEC/NOAEC
Daphnia magna						
Technical grade	>98.3	3.0	0.045	0.045	<0.001	0.0015
BSTCA	>100		0.045	0.045	<0.001	
BST	>96		0.045	0.045	<0.001	
5-hydroxy-XDE-638	>1		0.045	0.045	<0.045	
2-amino-TP	>1		0.045	0.045	<0.045	
TPSA	>1.4		0.045	0.045	<0.032	
5-OH,2-amino-TP	>1		0.045	0.045	<0.045	
BSA	>1.6		0.045	0.045	<0.028	
Midge ***Chironomus*** **sp.**						
Technical grade	>140	7.1	0.045	0.045	<0.001	0.006
Amphipod ***Gammarus*** **sp.**						
Technical grade	>126		0.045		<0.001	

Risk to Estuarine and Marine Animals

Three acute and one chronic study on the toxicity of technical grade penoxsulam were submitted. It is not possible to ascertain from the chronic test that the LOC would not be exceeded, however, there is an order of magnitude factor of safety even based on an acute EEC. Given that there was no mortality in the tests and the magnitude of the weight loss endpoint at tested levels, it is viewed as unlikely that the level would be exceeded in repeat testing. No studies on degradates were submitted.

Table 14. Estuarine and Marine Animals - Risk Quotients

Species and Chemical	Acute EC_{50} (ppm)	Chronic NOAEC (ppm)	EEC Peak (ppm)	EEC 21-Day Average (ppm)	Acute RQ EEC/EC_{50}	Chronic RQ EEC/NOAEC
Silverside *Menidia beryllina*						
Technical grade	>129		0.045	0.045	<0.001	
Eastern oyster *Crassostrea virginica*						
Technical grade	>127		0.045	0.045	<0.001	
Mysid *Americamysis bahia*						
Technical grade	114	<8.1	0.045	0.045	<0.001	>.006

Risk to Aquatic Plants

The risk quotients for vascular and nonvascular plants were calculated from the Estimated Environmental Concentration (0.045 ppm) and the EC_{50} for acute risk, and the NOAEC when one exists, or the EC_{05}. The sole exception is in the case of an endangered endpoint for BST where it was not felt the assessment endpoint was reliable enough to estimate an endpoint. The results are tabulated below.

The duckweed study with the technical grade product found an exceedance for both non-endangered and endangered species Levels of Concern (RQs of 15 and >45, respectively). The green alga studies with the technical grade product and an end-use product found RQs of 9 and 4.1, respectively. These RQs exceed endangered species Levels of Concern.

While there were no other LOC exceedances, several major degradates were not tested.

Table 15. Risk Quotients for Aquatic Plants.

Species Chemical	MRID	EEC- PEAK (ppm)	EC_{50} (mg/L)	NOAEC or EC_{05}[1] (ppm)	Risk Quotients: Non-endangered Species EEC/EC_{50}	Risk Quotients: Endangered Species EEC/NOAEC or EC_{05}
Vascular plants- Duckweed *Lemna gibba*						
Technical grade	45831120	0.045	0.003	0.001	15*	>45*
BSTCA	45831106	0.045	>10	10	<0.005	<0.005
5-hydroxy-XDE-638	45831104	0.045	>11	0.22	<0.004	0.49
BST	45831105	0.045	>6.2	<0.1	<0.007	ND[2]
2-amino-8-methoxy Tier 1	45831108	0.045	>1.25	1.25	<0.036	0.036
2-amino-TP Tier 1	45831111	0.045	>1.0	1.0	<0.045	0.045
BSA Tier 1	45831110	0.045	>1.6	1.6	<0.028	0.028
TPSA Tier 1	45831109	0.045	>1.4	1.4	<0.032	0.032
Nonvascular plants- Green algae *Selenastrum capricornutum*						
Technical grade	45834805	0.045	0.092	0.005	0.49	9.0*
GF-443	45831107	0.045	0.094	0.009	0.48	5.0*
BSTCA	45831119	0.045	>10	10	<0.005	0.005
BST	45831117	0.045	>9.6	3.9	<0.005	0.013
5-hydroxy-XDE-638	45831118	0.045	>10	10	<0.005	0.005
TPSA	45831113	0.045	>1.4	1.4	<0.032	0.032
5-OH,2-amino-TP	45831114	0.045	>1.0	1.0	<0.045	0.045
BSA	45831112	0.045	>1.6	1.6	<0.028	0.028
2-Amino TP	45831115	0.045	>1.0	1.0	<0.045	0.045
Nonvascular plants- Freshwater diatom *Navicula pelliculosa*						
Technical grade	45831121	0.045	>49.6	49.6	<0.001	0.001
Nonvascular plants- Freshwater alga *Anabaena flos-aquae*						
Technical grade	45831122	0.045	0.27	0.194	0.17	0.23
Nonvascular plants Tier I Saltwater diatom *Skeletonema costatum*						
Technical grade	45831123	0.045	>46.7	2.33	0.001	0.019
TPSA	45831113	0.045	>1.4	1.4	≤0.032	0.032
5-OH, 2-amino-TP	45831114	0.045	>1.0	1.0	≤0.045	0.045
2-Amino TP	45831115	0.045	>1.0	1.0	≤0.045	0.045
BSA	45831112	0.045	>1.6	1.6	≤0.028	0.028

[1] NOAEC or, if NOAEC isn't available, the EC_{50} *Exceeds LOC

[2] Could not reliably estimate

Non-target Terrestrial Animals

The EEC values for terrestrial exposure from the consumption of foliage, insects, and seeds directly exposed to liquid penoxsulam (Table 16) were derived from the Kenaga nomograph, as modified by Fletcher *et al.* (1994), based on a large set of field residue data. Risk quotients are based on the most sensitive acute LC_{50} (2025 ppm) and chronic NOAEC (231 ppm) for birds and LD_{50} for mammals (based on lab rat studies). Acute and chronic RQs for birds and mammals are summarized in Table 16. Risk quotients were not determined for exposure to the granular because no mortality was seen in any of the bird studies. Although there was mortality in the acute mammalian study, it was at a level much higher than the possible ingestion rate. Furthermore, the granular is not being incorporated into a matrix which would be especially attractive to small mammals and there was some evidence of aversion in the quail study.

Table 16. Acute and Chronic Risk Quotients for Terrestrial Animals.

Species and Chemical	LD_{50} (ppm)	NOAEC (ppm)	Estimated Environmental Concentration (ppm) — Maximum Concentration				Highest RQ	
			Short Grass	Tall Grass	Broadleaves or Insects	Seeds	Acute EEC/LD_{50}	Chronic EEC/NOAEC
Northern bobwhite quail ***Colinus virginianus***								
Technical grade	>2025	231	11	4.8	5.9	0.66	<0.005	0.048
Mallard duck ***Anas platyrhynchos***								
Technical grade	>1,900	501	11	4.8	5.9	0.66	<0.006	0.022
Norway Rat ***Rattus norvegicus***								
Technical grade	>5,000	600	11	4.8	5.9	0.66	0.002	0.018

Nontarget Terrestrial Plants

The Risk Quotients were calculated using an Estimated Environmental Concentration derived from the application rates and acute EC_{25}s (for non-endangered species) and the NOAECs (or, if the NOAECs are not available, the EC_{05}s; in this case, NOAECs were available for all plants) from toxicity studies (MRID 45831116) done on terrestrial crops. Results are summarized below in Table 17.

Table 17. Risk Quotients for Terrestrial Plants for Use in Rice Paddy.

Species	EEC	EC_{25}	NOAEC	Risk Quotients: Non-Endangered Species EEC/EC_{25}	Risk Quotients: Endangered Species EEC/NOAEC
Seedling Emergence					
Dicots					
Sugarbeet	49	3.2	1.2	15*	41*
Cotton	49	>33	33	<1.5*	1.5*
Soybean	49	>33	33	<1.5*	1.5*
Cucumber	49	>33	33	<1.5*	1.5*
Kale	49	6.7	3.7	7.3*	13*
Tomato	49	11	3.7	4.4*	13*
Monocots					
Onion	49	1.1	0.41	44*	120*
Wheat	49	>100	100	<0.5	0.5
Corn	49	>100	100	<0.5	0.5
Ryegrass	49	>33	33	<1.5*	1.5*
Vegetative Vigor					
Dicots					
Soybean	49	3.9	1.2	13*	41*
Sugarbeet	49	4.6	1.2	11*	41*
Tomato	49	8.1	1.2	6.1*	41*
Cotton	49	>100	33	<0.5	1.5*
Cucumber	49	49	33	1	1.5*
Kale	49	8.6	3.7	5.7*	13*
Monocots					
Ryegrass	49	17	0.41	2.9*	120*
Corn	49	>100	100	<0.5	0.5*
Wheat	49	>100	100	<0.5	0.5
Onion	49	30	11	1.6*	4.4*

* Exceeds the Level of Concern (RQ = 1)

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B. Risk Description-Interpretation of Direct Effects

1. Level of Concern Exceedances

As expected in the conceptual model, the principal concerns with penoxsulam application relate to plants. Seedling emergence risk quotients for terrestrial plants exceeded Levels of Concern for eight out of ten crops studied, although half of those exceedances resulted from a failure to test at a sufficiently high rate. The peak RQ for monocots was 44 for non-endangered species and 120 for endangered terrestrial plants based on studies with onions. The peak RQ for dicots was 15 for non-endangered species and 41 for endangered species, both based on studies with sugar beets. These endpoints are applicable to the Tier 1 estimate for terrestrial plants in semi-aquatic settings as they presume the release of paddy water to a non-target plant area.

Vegetative vigor risk quotients for terrestrial plants resulted in exceedances for eight out of ten crops for endangered species and six out of ten crops for non-endangered species. The peak RQ for dicots was 13 for non-endangered plants based on studies with the soybean and of 41 for endangered species based on studies with the soybean, sugar beet, and tomato. The peak RQ for monocots was 2.9 for non-endangered species and 120 for endangered plants, both based on studies with ryegrass. Shoot weight was the sensitive endpoint for all of these risk quotients. These endpoints form the Tier 1 estimates for non-target, terrestrial plant exposure due to spray drift.

For aquatic plants, the vascular plant RQs are based on the response of Duckweed (*Lemna gibba*). It generates an RQ of 15 for non-endangered species and of >45 of endangered species. For non-target, non-vascular aquatic plants, the green alga (*Selenastrum capricornutum*) had an RQ of 9 for endangered species when stressed with technical grade penoxsulam and an RQ of 5 for endangered species when stressed with the end-use product GF-443.

2. Refinement of Exposure Estimates

Aquatic Plants

In developing the Tier 1 screening estimates, the simplifying assumption was made that the EEC was equal to the peak concentration in the paddy upon application. This approach provides an estimate which is protective in the absence of information on major degradates. Nevertheless, there is nothing in the degradation pathway analysis to suggest any specific degradate would differentially accumulate over multiple seasons such that its concentration would be expected to substantially exceed that of the parent. So, unless there exist degradates with greater phytotoxicity than that of the parent, the Tier 1 approach is accordingly conservative. In order to provide a more robust estimate of the potential risk to aquatic plants, various estimates of the rate of penoxsulam degradation were developed to assess potential penoxsulam concentrations that might be associated with paddy water release at various holding times. These estimates of the rate of decay of penoxsulam were discussed in Section III.A.2. Combining these concentrations with the EC_{50} for the most sensitive aquatic plant (Duckweed) provides an estimate of what duration would ensure an adequate holding time such that released penoxsulam would not pose a threat to aquatic plants. The non-endangered endpoint was used for this analysis because no threatened or endangered aquatic plants are believed to exist in counties where rice is grown.

The results of this rice modeling approach using the photolysis degradation rate estimates that a holding time of approximately 13 days would be sufficient to bring concentrations in paddy water below any level of concern for aquatic plants[11]. However, if the suggestion by Dow Agroscience in their submitted aquatic modeling assessment (MRID 458308-11) that the degradation rate in *paddy water from the aquatic field dissipation rates* more accurately accounts for competing degradation pathways and environmental processes is used, then an *estimated holding time of approximately 23 days* would be needed. On the other hand, if the total system aquatic field dissipation rate were used, an estimated holding time of approximately 58 days would be required to bring the aquatic concentrations in paddy water below the level of concern. For the Tier 2 assessment, the 23 day holding time is probably adequate to provide a margin of safety for aquatic plants given that the total system holding time accounts for penoxsulam in the interstitial water which would not be released.

Terrestrial Plants

Exposure to non-target terrestrial plants may occur as a consequence of runoff or spray drift. As expressed in the formulation of the conceptual model, separate scenarios are needed for terrestrial and semi-aquatic settings when considering pesticide application to rice. For terrestrial settings, exposure is limited to spray drift.

For semi-aquatic settings, exposure may occur as a consequence of spray drift or release of paddy water. In the former case, vegetative vigor will be the endpoint of concern while seedling emergence will be the primary concern in the latter case. Lacking a model for estimating exposure in the semi-aquatic setting due to runoff, no refinement is attempted for the seedling emergence endpoint resulting from this potential exposure. However, spray drift estimates are refined.

Spray drift estimates

Downwind spray drift buffers or distances required to dissipate penoxsulam spray drift to NOAEC levels were estimated for both monocot and dicot terrestrial plant species using the AgDRIFT model. Spray drift buffers were developed for possible use in mitigating risks for endangered terrestrial plants that grow in close proximity to rice fields treated with liquid spray applications of penoxsulam. Based on the results of the AgDRIFT modeling, the proposed spray buffer distances for aerial and ground application of penoxsulam are 1,400 and 300 feet, respectively (see Appendix F). The proposed buffer distances are based on NOAEC values from the most sensitive species used in Tier II seedling emergence and vegetative vigor toxicity tests. For both the seedling emergence and vegetative vigor toxicity tests, the most sensitive species is a monocot, and the resulting NOAEC value, based on shoot weight, is 0.41 g a.i./ha. The corresponding NOAEC value for dicots, also based on shoot weight, is 1.2 g a.i./ha.

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[11]The concentration evaluated was 3 ppb, the EC_{50} for duckweed. When the concentration in water is beneath 3ppb, the RQ will be less than 1 (the LOC for aquatic plants). Concentrations of penoxsulam are taken from Figures 2 through 4.

Although the label for penoxsulam does not specify release height or droplet size for ground applications, the AgDRIFT model was run for four scenarios (high boom and fine spray, low boom and fine spray, high boom and medium/coarse spray, and low boom and medium/coarse spray) to provide an estimate of the possible range of buffer distances. All drop size descriptions are based on ASAE S-572 standard definitions. High and low boom heights are representative of 4 and 2 foot release heights, respectively. The output of the AgDRIFT model provides distances (in feet) required to dissipate spray drift to the NOAEC and EC_{25} levels. Buffer distances are provided for both types of tests (i.e., seedling emergence (SE) and vegetative vigor (VV)) using the most sensitive monocot and dicot species.

Table 18. Results of AgDRIFT Modeling for Ground Application of Penoxsulam

Species	Test Type	Distance Required to Dissipate Spray Drift to NOAEC/EC_{25} Levels (feet)			
		High boom; fine spray (NOAEC/EC_{25})	Low boom; fine spray (NOAEC/EC_{25})	High boom; med/coarse spray (NOAEC/EC_{25})	Low boom; med/coarse spray (NOAEC/ EC_{25})
Onion (Monocot)	SE	282 / 115	118 / 43	82 / 26	46 / 13
Sugarbeet (Dicot)	SE	105 / 39	39 / 16	23 / 10	13 / 7
Ryegrass (Monocot)	VV	282 / 10	118 / 3	82 / 3	46 / 3
Soybean (Dicot)	VV	105 / 33	39 / 13	23 / 7	13 / 7

The results of the AgDRIFT modeling for ground application of penoxsulam show that a buffer distance of 282 feet is required to dissipate spray drift to NOAEC levels (under worst case conditions of high boom and fine spray) for seedling emergence and vegetative vigor, based on the most sensitive species, which are both monocots. Dissipation distances required for no effects to the most sensitive species are reduced to 118 feet (based on low boom and fine spray), 82 feet (based on high boom and medium/course spray), and 46 feet (based on low boom and medium/course spray). Dissipation distances for dicots are less than those predicted for monocots, with NOAEC-level values ranging from 13 to 105 feet. As expected, ground boom dissipation distances were affected by both droplet size and release height. Therefore, spray drift can be reduced by lowering the release height and/or increasing the spray droplet size. Resulting label language should identify ASAE S-572 as the droplet sizing standard.

For aerial application, the most important factors affecting drift from aerial applications are spray droplet size, release height, and wind speed. The aerial part of the AgDRIFT model predicts mean values based on the inputs provided. Label guidelines for aerial application of penoxsulam specify a medium to coarse droplet size category (per S-572 ASAE standard), and a spray volume of 10 gallons per acre. In addition, the distance between the outer most nozzles on the boom must not exceed two-thirds (2/3) of the wingspan of fixed-wing aircraft (or 3/4 of the helicopter rotor width), and nozzles must always point backward parallel to the air stream and never downward more than 45 degrees. Although the label specifies a medium to coarse droplet size for aerial application of penoxsulam, fixed winged applications (applications made by airplanes) are limited in the coarsest droplet size that can be sprayed. Typical fixed wing aerial application speeds exceed 120 mph. At these speeds, coarse droplets shatter and produce medium or finer sprays. Thus, it is generally inappropriate to model coarse sprays for fixed wing applications without some restriction on flight speed. For the purpose of AgDRIFT modeling, fine to medium spray droplet size was modeled as a high end drift scenario. In addition, other ASAE droplet sizes including medium and medium/coarse sprays were also considered.

Table 19. Results of AgDRIFT Tier II Modeling for Aerial Application of Penoxsulam

Species	Test Type	Distance Required to Dissipate Spray Drift to NOAEC/EC_{25} Levels (feet)		
		Fine to Medium Spray (NOAEC/EC_{25})	Medium Spray (NOAEC/EC_{25})	Medium to Coarse Spray (NOAEC/EC_{25})
Onion (Monocot)	SE	>1,000* / 371	787 / 276	466 / 200
Sugarbeet (Dicot)	SE	341 / 141	259 / 108	187 / 66
Ryegrass (Monocot)	VV	>1,000* / 13	787 / 10	466 / 7
Soybean (Dicot)	VV	341 / 115	259 / 79	187 / 52

* The maximum dissipation distance from the edge of the field in the Tier II aerial model is 1000 feet.

The results of the Tier II aerial AgDRIFT modeling show that a buffer distance of greater than 1,000 feet is required to dissipate spray drift to no effect levels for monocots under worst case conditions of fine to medium spray drift. The dissipation distance for monocot plant species decreases from >1,000 feet to <787 feet, based on the use of a medium to coarse droplet size. Dissipation distances for no effects to dicots are 341 feet for fine to medium sprays and <259 feet for medium to coarse sprays. Tier III modeling makes it possible to estimate buffer distance to points greater than 1000 feet from the field. This modeling verified that the actual distance of the aerial buffer zone for endangered monocots exposed to fine to medium spray is 1385 feet.

C. Threatened and Endangered Species Concerns

1. Taxa Potentially at Risk

Penoxsulam RQs do not exceed any Levels of Concern for animals. The use of penoxsulam on rice at the current rate is not expected to put any animals at risk. The use of penoxsulam on rice produces LOC exceedances for both aquatic and terrestrial plants.

Dow completed an assessment of potential effects on Federally listed threatened and endangered species from the use of penoxsulam in U.S. rice (Dow AgroSciences LLC, 2004) (MRID 458308-11). The report was intended to support EPA's review process by providing an evaluation of potential risks for adverse effects to Federally listed threatened and endangered species related to the proposed use of penoxsulam in rice. In addition, risk mitigation measures were proposed where potential risks to threatened and endangered species exceed EPA's Levels of Concern (LOCs). As part of this effort, Dow completed a Tier I ecological risk assessment and species-specific endangered/threatened species assessment.

The results of the ecological risk assessment were used to select taxa of threatened and endangered species for further evaluation. Consistent with its activity as a herbicide, the results of the Dow Tier I risk assessment concluded that penoxsulam exceeds LOCs for non-target aquatic and terrestrial plants.

Dow used the Information Management System (IMS) developed by the FIFRA Endangered Species Task Force (FESTF) to identify those U.S. rice-producing counties where Federally listed threatened and endangered plant species also occur. For counties where overlap in rice production and endangered species occurred, Geographical Information System (GIS) technology was used to produce cartographic maps that provide detailed spatial information on the proximity of the species' habitat to rice production.

The results of the county-level overlap of rice production with taxa of concern show that there are a total of 33 dicot and 7 monocot Federally listed threatened and endangered plant species that occur in counties where rice is grown. However, none of the species included in this list are aquatic non-vascular or aquatic vascular plants. Consequently, further analysis was limited to endangered terrestrial plants.

Dow's list of threatened and endangered plant species that occur in rice-producing counties are listed in Appendix G. EFED added several additional endangered species as a result of information available from NatureServe and the California Department of Fish and Game Natural Diversity Data Base (CNDDB). In addition, a larger number of counties were included in the endangered species assessment for Missouri.

Federally listed threatened and endangered terrestrial plant species occur in rice-producing counties as follows: 6 Arkansas counties; 13 California counties, 5 Missouri counties; 3 Mississippi counties; and 2 Texas counties. Federally listed threatened and endangered plants were not found to occur in any of the rice-producing counties (parishes) in Louisiana; therefore, no further analysis was required for this state.

In order to assess the potential for endangered species/county crop overlaps, analyses were conducted to determine the proximity of these plants relative to rice fields. A "no effects" determination is made if listed species do not co-occur or are located within 1,400 feet (based on EFED's buffer distance for aerial application of penoxsulam; see Appendix F) of rice crops. For county-species combinations that exceed the Agency's endangered species levels of concern, Dow proposes the use of appropriate protective measures to allow a "Not Likely to Adversely

Affect" determination. These measures include use of the granular formulation of penoxsulam to essentially eliminate drift, or the use of spray buffers when applying the liquid formulation of penoxsulam with aerial or ground equipment. The proposed spray buffer distances for aerial and ground application of penoxsulam are 1,400 feet and 300 feet, respectively (see Appendix F). Effects determinations based on listed species proximity analysis are discussed for each state and sub-county below.

In general, there was greater certainty and precision in the spatial analysis conducted for California than for the other rice-producing states, due to the availability of more detailed cropping and element occurrence (EO) data. EO data for listed species included in the Dow assessment had not been obtained for the states of Arkansas, Mississippi, Missouri, or Texas at the time the analyses were conducted. According to Dow, use of EO data for additional analyses in these states might enable a "No Effect" determination in at least some of the instances where this determination could not be made.

Arkansas

Six counties in Arkansas produce rice where threatened and endangered plants occur. According to Dow, an inquiry requesting EO location data was not answered by the Arkansas Natural Heritage Inventory. Therefore, the NatureServe database was queried to provide information on USGS hydrologic units and habitat descriptions for the EOs. Of the six county-species combinations for Arkansas, two counties including Drew and Yell yielded an effects finding of "No Effect" because listed species are not located in areas suitable for rice production. The remaining counties, including Clay, Jackson, Lawrence, and Woodruff, include listed species that overlap areas suitable for rice crops. In the absence of more detailed EO data, protections may be needed in these counties to protect pondberry. Therefore, the effects determination for listed species (pondberry) in these counties is "Not Likely to Adversely Affect" if protections are in place. If no protections are in place, then levels of concern are exceeded for pondberry.

Missouri

As previously mentioned, species/county combinations for Missouri were modified to include additional counties based on NatureServe database records. In addition to Butler, Dunklin, and Ripley Counties, additional listed species were also determined to be present in Mississippi and Wayne Counties, where rice is grown. Of the five county-species combinations for Missouri, effects determinations for Mississippi and Wayne counties were classified as "No Effect" because listed species are not co-located with rice crops. Detailed examination of the GIS maps for Butler, Dunklin, and Ripley Counties revealed that listed species occurred in locations with distinctive in-field berms used for water management of rice culture. Therefore, combinations for these counties are classified as "Not Likely to Adversely Affect" if protections are in place. If no protections are in place, then levels of concern are exceeded for endangered plant species in these counties.

Mississippi

Pondberry is found in three Mississippi counties including Bolivar, Sharkey, and Sunflower. According to the USFWS recovery plan for this species, the populations of pondberry in Sharkey County are entirely within the Delta National Forest, and thus are protected by programmatic

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means. Pondberry populations in Bolivar and Sunflower Counties are on private land. Therefore, the effects determination for pondberry in Sharkey County is "No Effect." In the absence of more detailed information, the effects determination for pondberry in Bolivar and Sunflower Counties is "Not Likely to Adversely Affect" if protections are in place. If no protections are in place, then levels of concern are exceeded for pondberry in these counties.

Texas
The Texas Prairie dawn-flower is found in Fort Bend and Harris Counties in Texas where rice production also occurs. According to Dow, an inquiry requesting detailed EO location data from the Texas Natural Heritage Inventory was not answered. Agricultural areas in Fort Bend and Western Harris Counties are located near Buffalo Bayou. Information from the Texas Parks and Wildlife Department indicates that many occurrences of Texas Prairie dawn flower have been observed in the Barker and Addicks Reservoir areas. These reservoirs are large flood control basins for Buffalo Bayou; therefore, rice fields near Buffalo Bayou may require protection for the Texas Prairie dawn flower. The effects determination for Western Harris and Fort Bend Counties is "Not Likely to Adversely Affect" if protections are in place. If no protections are in place in Western Harris and Fort Bend Counties, then levels of concern are exceeded for the Texas Prairie dawn-flower. In Eastern Harris County, the effects determination is "No Effect" because the sparsely vegetated habitat necessary for the Texas Prairie dawn-flower is not present. West of the city of Houston, there appears to be agricultural areas interspersed with grasslands, which could provide habitat for the Texas Prairie dawn-flower. It is unknown if these agricultural areas are used to produce rice; however, if they are, protections may be needed. Therefore, levels of concern for the Texas Prairie dawn-flower are exceeded if no protections are in place. If protections are in place, the effects determination for this portion of Harris County is "Not Likely to Adversely Affect."

California
As previously mentioned, the California endangered species assessment was conducted with a high degree of certainty and precision (as opposed to the other states) due to the availability of more detailed cropping and EO location data. The California Department of Fish and Game Natural Diversity Data Base (CNDDB), a product of the California Natural Heritage Program, was linked with GIS layers to provide spatially-referenced point EO data. Within 13 counties that grow rice in California, 79 county-species combinations were identified. Of the 13 identified counties, "No Effect" determinations were made for 8 counties (Alameda, Fresno, Madera, Merced, Placer, Sacramento, San Joaquin, and Tehama) because listed species are not located in proximity (i.e., greater than 1,400 feet) to rice crops. Effects determinations for the remaining five counties (Butte, Colusa, Glenn, Stanislaus, and Yolo) are discussed below.

In Butte County, occurrences of endangered species in the southern part of the county are close to, and in some cases, adjacent to rice fields. Protections may be necessary for Butte County meadowfoam, Green's tuctoria, Hoover's spruge, and hairy orcutt grass in the southern half of Butte County. These species are all located within 180 feet of rice fields; therefore, proposed buffer distances of 1,400 feet for aerial application and 300 feet for ground application of penoxsulam would not be protective of these species. Slender orcutt grass is over 5,450 ft from the nearest rice field. Levels of concern are exceeded for the occurrences of Butte County meadowfoam, Green's tuctoria, Hoover's spruge, and Hairy orcutt grass in Butte County; with appropriate protections the determination is "Not Likely to Adversely Affect." Because these listed species are located within the proposed buffer zones for both ground and aerial application of penoxsulam, appropriate protections in Butte County would include restrictions on all liquid applications of penoxsulam. The determination for Slender orcutt grass is "No effect."

Species under consideration in Colusa County include Palmate-bracted bird's beak and Colusa grass. Habitat for these two species is found within the Develan and Colusa National Wildlife Refuges. As a protected area, programmatic management programs should be in place for these wildlife refuges. If not, protections may be needed. Therefore, the effects determination for these endangered plant species is "Not Likely to Adversely Affect" if programmatic management practices are in place; if not, then levels of concern for these species are exceeded.

Rice is grown extensively in Glenn County along the Sacramento River. The EOs are confined to the Sacramento National Wildlife Refuge. Because the wildlife refuge is a protected area, programmatic management practices should be in place. If not, protections may be needed for listed species. The effects determination for Hoover's spurge, Palmate-Bracted Bird's-Beak, and Hairy Orcutt Grass are"Not Likely to Adversely Affect" if programmatic management or protections are in place. If programmatic management or protections are not in place, then levels of concern for these listed species are exceeded.

In Stanislaus County, rice is grown in three small areas. The spatial join distance between Greene's Tuctoria and rice fields is 163 meters (535 feet), indicating that some protections (i.e., restrictions on aerial application of penoxsulam) may be needed for this species. The effects finding for Greene's Tuctoria is "Not Likely to Affect" if protections are in effect. If no protections are in place, then levels of concern for Greene's Tuctoria are exceeded. Greene's Tuctoria is located within the proposed 1,400 foot buffer distance required for aerial application of penoxsulam; therefore, this type of application is not recommended in Stanislaus County. For other listed species in the county, the effects finding is "No Effect."

In Yolo County, the rice producing areas are in the center and eastern parts of the county. The closest EO of Palmate-bracted Bird's-Beak is approximately 370 meters (1,214 feet) from the nearest rice field. Therefore, in Yolo County, the effects determination for Palmate-bracted Bird's-Beak is " Not Likely to Affect" with protections (i.e., restrictions on aerial application of penoxsulam). With no protections, levels of concern for Palmate-bracted Bird's-Beak are exceeded. Palmate-bracted Bird's-Beak is located within the proposed 1,400 foot buffer distance required for aerial application of penoxsulam; therefore, this type of application is not recommended in Yolo County. The effects determination for Colusa grass and Crampton's tuctoria is "No Effect."

2. Indirect Effects Analysis

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of nesting habitat. In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-endangered organisms in these taxonomic groups as resources critical to their life cycle. Because screening-level acute RQs for animals were not exceeded, the primary potential indirect effect would be due to loss of habitat. Given penoxsulam's short half life and the limited projected use, it is believed to be unlikely that such effects could occur.

D. Description of Assumptions, Uncertainties, Strengths, and Limitations

1. Assumptions and Limitations Related to Exposure For All Taxa

This screening-level risk assessment assumes that labeled statements concerning the maximum rate of penoxsulam application have been observed. It has not taken into consideration whether there is a lower typical rate of penoxsulam application. A major uncertainty in this assessment is the lack of information on the fate and transport of several major degradates. This uncertainty was addressed through the use of conservative model estimates.

2. Assumptions and Limitations Related to Exposure For Aquatic Species

EFED does not currently have an approved model for estimating chronic aqueous concentrations resulting from pesticides use on rice crops. An interim policy has been issued outlining a method to estimate screening-level concentrations in water in order to support regulatory decisions for pesticides used in rice agriculture that require ecological and human health risk assessments. EECs/EDWCs are estimated by applying the total annual application to the paddy and partitioning the pesticide between the water and the paddy sediment according to a linear or K_d partitioning model.

EECs calculated by this method are screening estimates, and as such are expected to generally exceed the true values found in the environment for chronic exposures and acute exposures when multiple applications are allowed. Penoxsulam is a single application pesticide.

Several simplifying assumptions have been incorporated into the current EFED interim model. Movement of pesticide on suspended sediment is not considered. Dilution by environmental surface water is not considered. Abiotic transformation and biotic degradation of the pesticide are not considered. The resulting screening-level EECs/EDWCs represents both the maximum dissolved concentration occurring in the water column and the maximum concentration in water released from the paddy. In most cases, these screening-level values will overestimate actual concentrations found in the environment.

3. Assumptions and Limitations Related to Exposure For Terrestrial Species

For screening terrestrial risk assessments for listed species, a generic bird or mammal is assumed to occupy either the treated field or adjacent areas receiving pesticide at a rate commensurate with the treatment rate on the field. Spray drift model predictions suggest that this assumption leads to an overestimation of exposure to species that do not occupy the treated field. For screening risk assessment purposes, the actual habitat requirements of any particular terrestrial species are not considered, and it assumed that species occupy, exclusively and permanently, the treated area being modeled. This assumption leads to a maximum level of exposure in the risk characterization. Since penoxsulam has low toxicity for animals, this is of little concern.

4. Assumptions and Limitations Related to Effects Assessment

There are a number of uncertainties associated with the assessment of potential effects of penoxsulam spray drift to plants. It may be possible to further refine this assessment with additional information addressing the following uncertainties:

- The representativeness of tested species for non-target plant species in penoxsulam use areas. It is possible that woody and other perennial plant species may be exposed to spray drift in penoxsulam use areas near rice fields; however, their sensitivity to penoxsulam is uncertain. Toxicity data on a wider range of plants could be used to reduce uncertainty related to the potential effects of penoxsulam on perennial and woody species at field edges and downwind of treated fields.

- The adequacy of laboratory spraying treatments in representing spray drift far from field boundaries. Plants in laboratory studies are exposed to herbicide in volumes of carrier that are adequate to cover the test plants. Plants exposed to spray drift downwind of field boundaries would contact the same amount of herbicides tested in the laboratory, but in much lower volumes of carrier. Plants are exposed to spray drift far away from the field edge in discrete spots where droplets impact the plant foliage, whereas plants are covered with a diffuse coating in lab studies. The effect of small concentrated exposures relative to diffuse exposure is uncertain. Data on the effect of exposure volume on phytotoxicity could be used to refine effect level estimates.

- The results of the seedling emergence toxicity test show that six out of the ten plants tested exhibit no adverse effects when exposed to maximum application rates of penoxsulam. Two out of ten plants exhibit no response in the vegetative vigor test. These facts suggest considerable inter-plant variability in response. Furthermore, the endpoint in all tested cases was changes in shoot weight. Information is not available to document what levels are associated with actual plant death.

- There is uncertainty associated with the use of a spray drift buffer distance that is based on protection of endangered monocot plants because the results of the endangered species assessment (see Appendix G) indicate that potential "May Affect" determinations for all county-species combinations in Arkansas, Missouri, Mississippi, Texas, and Yolo County in California apply to endangered dicots only. However, given the lack of information on how effects from the ten species used in the Tier II terrestrial plant toxicity tests translate to endangered monocots and dicots, the most sensitive species were used as a conservative measure of protection. If endangered monocots/dicots are more or less sensitive to penoxsulam than the 10 species used in the Tier II terrestrial plant toxicity tests, then risks to endangered plant species and resulting downwind spray drift buffer distances may be either underestimated or overestimated, respectively.

Another potentially major gap in this risk assessment is a lack of ecological effects information on many of the degradates. On the one hand, only one treatment per season was proposed and it is recommended on the label that other crops not be grown in a field for at least three months after application of penoxsulam. On the other, there are eleven major degradates and the parent is expected to be relatively short lived in the paddy environment. The combination of these two pieces of information would suggest at least some of the degradates may provide some of the needed phytotoxicity. Studies were not submitted for many of the degradates.

To reduce some of the uncertainty, structure-activity relationships (SARs) were evaluated. SARs have been used by the U.S. Environmental Protection Agency since 1981 to predict the aquatic toxicity of new industrial chemicals in the absence of test data. The acute toxicity of a chemical to fish (both fresh and saltwater), water fleas (daphnids), and green algae have been the focus of the development of SARs, although for some chemical classes SARs are available for other effects. SARs are developed for chemical classes based on measured test data that have been submitted by industry or they are developed by other sources for chemicals with similar structures, e.g., phenols. Using the measured aquatic toxicity values and estimated Kow values, regression equations can be developed for a class of chemicals. Toxicity values for new chemicals may then be calculated by inserting the estimated Kow into the regression equation and correcting the resultant value for the molecular weight of the compound.

To date, over 150 SARs have been developed for more than 50 chemical classes. These chemical classes range from the very large, e.g., neutral organics, to the very small, e.g., aromatic diazoniums. The ECOSAR Class Program is a computerized version of the ECOSAR analysis procedures as currently practiced by the Office of Pollution Prevention and Toxics (OPPT). It has been developed within the regulatory constraints of the Toxic Substances Control Act (TSCA). It is a pragmatic approach to SAR as opposed to a theoretical approach. As individual compounds increasingly differ from those tested, greater and greater uncertainty is introduced into test values. The detailed program runs are provided in Appendix A. Table 20 details the principal results for green algae, the most close analogue to the endpoints of concern (terrestrial and aquatic plants) and the one type of ecological endpoint for which several points of comparison with real data are possible.

Examination of Table 20 suggests a number of interesting results. First and foremost, predicted toxicity of penoxsulam is much less than that observed from testing. Looking at results in terms of relative toxicity, provided EC50 test data on BSA, TPSA, 5-OH-2-amino TP, and BSTCA (see Table 15)agree quite well with ECOSAR projections that these compounds would be relatively non-toxic when compared to the parent penoxsulam. Data on 5-OH-penoxsulam (i.e. 5-hydroxy-XDE-638) suggest slightly greater relative toxicity than supported by testing.[12] Nevertheless, ECOSAR does suggest 5-OH-penoxsulam is considerably more toxic than the previously mentioned degradates. Based on these comparisons, it appears ECOSAR does provide

[12]Comparison of ChV (chronic values) produced by ECOSAR do not track well with experimental results and are not discussed further.

Table 20: ECOSAR Based Projections for Penoxsulam and Major Degradates

class	duration	end point	penoxsulam (ppm)	sulfonamide (ppm)	2-amino TCA (ppm)	SFA (ppm)	5,8-di-OH (ppm)	5-OH 2-amino TP (ppm)	TPSA (ppm)	2-amino TP (ppm)	5-OH penoxsulam (ppm)	BSTCA methyl (ppm)	BSA (ppm)	BSTCA (ppm)
green algae	96 hr	EC50	35	564	31588	168	425 / 0.311 (clogp)	1692	446000 0	207	140	16	62045	12938
green algae	96 hr	ChV	6	39	1105	17	36 / 0.702 (clogp)	33 / 74	23394	14	16	12	2167	769

Notes: ChV is a chronic value estimate
clogp refers to fragment based estimates provided by a subprogram in ECOSAR provided by BioByte Corporation

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