# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY <br> WASHINGTON D.C., 20460 

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## MEMORANDUM

SUBJECT: Section 18 Ecological Risk Assessment for the Use of Flusilazole to Control Asian Soybean Rust

TO: $\quad$ Carmen Rodia, Chemical Review Manager Daniel Rosenblatt, Risk Manager Emergency Response and Minor Use Section Registration Division (7505C)

FROM:
 Environmental Risk Branch IV Environmental Fate and Effects Division (7507C)

## THRU:

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## APPROVED

BY:
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## I. RISK ASSESSMENT SUMMARY AND CONCLUSIONS

EFED has reviewed the environmental fate and effects data submitted in support of the emergency exemption Section 18 request to use the fungicide, flusilazole, to control Asian rust (Phakopsora pachyrhizi) on soybeans. The proposed label formulations of flusilazole are Punch ( $37.8 \%$ ai. by weight) and Charisma ( $9.7 \%$ ai. by weight; with famoxadone). This risk assessment is based on Punch, the formulation with the highest application rate of flusilazole. Both proposed liquid formulations may be applied by both ground and aerial methods. The proposed treatment rate for soybeans is 0.103 lb a.i./acre applied no more than two times per 12month period in 14 to 21 -day intervals.

There were no acute risk levels of concern (DOCs) exceeded for any taxa evaluated. Chronic risk LOCs were exceeded by up to three-fold for freshwater fish. The chronic avian risk LOC was exceeded for species foraging on short grass $(\mathrm{RQ}=1.7$; $\mathrm{LOC}=1$ ). Chronic mammalian LOCs were exceeded for all size classes foraging on short grass, tall grass or broadleaf plants and
small insects. These exceedances are considered further in the Risk Description section of this risk assessment.

## II. KEY UNCERTAINTIES AND INFORMATION GAPS

The following uncertainties and information gaps were identified:

- The registrant did not submit toxicity data for estuarine/marine organisms or terrestrial plants. These taxa were not included in this assessment, and risks cannot be precluded..
- Avian and mammalian chronic risk quotients were calculated based on the upper-bound estimated residue concentration (derived from the Kenaga nomogram) and the default foliar dissipation half-life value of 35 days. These inputs resulted in exceedances of the chronic LOC for several forage items. Fewer exceedances result when mean residues are used. Use of the default residue half-life presents uncertainty in the RQ. Submission of a foliar dissipation study that estimated a true residue half-life on soybeans will reduce the risk quotients, if it is less than the assumed value.
- There appears to be potential for endocrine disruptor related effects based on observations in mammalian and avian reproduction toxicity studies using flusilazole. This risk assessment has not included an evaluation of the risk of flusilazole for endocrine disruption and, as such, is a source of uncertainty in this assessment.
- Contrary to expectations, the aquatic EEC's were greater for the longer application interval (21-days), possibly due to timing of the application dates and the rainfall events. While the modeling for this Section 18 used the Mississippi soybean scenario, the results of the risk characterization are applied to numerous other sites in the United States. Because application may occur over a relatively long timeframe (months), and because rainfall events will vary in size and timing both temporally and geographically, environmental concentrations may be expected to vary as well. The extent to which environmental concentrations may vary with site constitutes an uncertainty.
- There is much uncertainty regarding the environmental fate of the triazole degradate. While not detected in two laboratory aerobic soil metabolism studies, 1,2,4-triazole was detected at approximately $8 \%$ of the parent flusilazole in a field soil metabolism study. This suggests that under normal use conditions, triazole formation occurs. Currently HED and EFED are working on "1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds", which, when available, will evaluate the environmental fate of triazole. However, further data may still be needed to address the uncertainties surrounding triazole degradates and their parent compounds.


## III. USE CHARACTERIZATION

Flusilazole, a systemic fungicide, is a member of the triazole class of pesticides. Its mode of action is the inhibition of ergosterol biosynthesis, a structural component of fungal cell walls. Flusilazole is proposed for a Section 18 registration for use on Asian soybean rust (Phakopsora pachyrhizi). The label formulations of flusilazole proposed for Section 18 registration are Punch ${ }^{\text {TM }}$, containing $37.9 \%$ flusilazole, and Charisma ${ }^{T M}$, containing $9.73 \%$ flusilazole and $9.12 \%$ famoxadone, for use on soybeans in Minnesota and South Dakota (Table 2). Famoxadone
technical and its formulated product, Tanos, are currently registered (EPA Reg. Nos. 352-605 and 352-604) for use on cucurbits, head lettuce, peppers, potatoes and tomatoes to control various diseases, including anthracnose and downy mildew. Section 3 registration application for flusilazole was submitted in 1986 for the formulation Nustar (File Symbol 352-LNU) for use on apples and grapes (PP Nos. 7F3491 and 7H5530). In 1987, an application for an import tolerance on bananas (PP No. 7E3515) was submitted. Both applications were withdrawn by the registrant (DuPont Crop Protection).

The current risk assessment is based on the Punch formulation at the highest application rate to produce a more conservative screening assessment. The proposed formulation, an emulsifiable concentrate (EC), can be applied by ground and aerial methods as well as through chemigation. The proposed treatment rate for foliar application to soybeans is as high as 0.103 lb a.i./A applied no more than two times per 12 month period at 14 to 21 -day intervals (Table 1). Some of the data used in this risk assessment is from summary information reviewed by the European Union Review Programme for Existing Active Substances.

Table 1. Application Rates for Flusilazole Formulated Products.

| Active Ingredient | flusilazole | flusilazole + famoxazone |
| :--- | :--- | :--- |
| Trade Name | Punch ${ }^{\text {TM }}$ | Charisma |
| Formulation | Emilsifiable Concentrate | Emulsifiable Concentrate |
| \% Active Ingredient | $37.8 \%$ a.i. by weight $(3.3$ <br> lb/gal) | $9.73 \%$ a.i. 0.9 lb. gal) flusilazole $+9.12 \%$ a.i. <br> $(0.8 \mathrm{lb} / \mathrm{gal})$ famoxazone |
| Rate of Application <br> (formulated product) | $3-4 \mathrm{fl} \mathrm{oz} / \mathrm{A}$ | $8-10 \mathrm{oz} / \mathrm{A}$ |
| Rate of Application <br> (flusilizole) | $0.077-0.103 \mathrm{lb}$ a.i./A | 0.070 lb a.i./A |
| Maximum Number <br> of Applications/12 <br> Months | 2 | 2 |
| Application Interval | 14-21 days |  |

## IV. ANALYSIS

## A. Exposure Characterization

## 1. Environmental Fate and Transport Characterization

Based on the submitted environmental fate data, its physical-chemical properties, and the proposed use patterns, flusilazole is a non-volatile compound that is, in general, expected to be persistent and to have low mobility in soil. Flusilazole is stable to hydrolysis and to aqueous photolysis, but undergoes slow degradation via microbially mediated metabolism, with much of the apparent loss of the compound attributed to the formation of non-extractable residues. Microbially mediated cleavage of the parent at the methylene bridge yields the minor degradates [bis(4-fluorophenyl)methyl]silanol (silanol) and 1H-1,2,4-triazole (triazole); there are no major degradates. In anaerobic flooded sediments, flusilazole undergoes very slow transformation, with relatively rapid dissipation from the water column to the sediment phase, where it remains as parent and bound residues. In aerobic flooded sediments, flusilazole is essentially stable to degradation, but partitions to the sediment phase. While the silanol degradate has low to moderate mobility in soil, the triazole has very high mobility. However, both degradates appear to degrade more rapidly than they are formed, and do not reach major degradate levels ( $\geq 10 \%$ ) in the laboratory studies. Bioconcentration factors (BCF) for flusilazole in bluegill sunfish ranged
from 160 to 250 , indicating a high potential for bioconcentration. However, in untreated water, approximately $80 \%$ of the residue burden depurated within 14 days. Physical and chemical properties for flusilazole are presented in Table 2.

There is much uncertainty regarding the environmental fate of the triazole degradate. While not detected in two laboratory aerobic soil metabolism studies, 1,2,4-triazole was detected at approximately $8 \%$ of the parent flusilazole in a field soil metabolism study. This suggests that under normal use conditions, that triazole formation occurs. Currently HED and EFED are working on "1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds", which, when available, will evaluate the environmental fate of triazole. However, further data may still be needed to address the uncertainties surrounding triazole degradates and their parent compounds.

Table 2. Physical Chemical Properties and Environmental Fate Source Data for Flusilazole.

| Property | Value | Source and/or Comments |
| :---: | :---: | :---: |
| Chemical Name | $\begin{gathered} \hline(1-[\operatorname{Bis}(4- \\ \text { fluorophenyl)methyl)silyl] methyl- } \\ 1 H, 1,1,4 \text {-triazole } \\ \hline \end{gathered}$ | -- |
| Molecular Weight | 315.1 | Registrant |
| Solubility in Water (20C) | $41.9 \mathrm{mg} / \mathrm{L}$ | EU Monograph; Oct. 2000 Addendum |
| Vapor Pressure (25C) | $2.9 \times 10^{-7} \mathrm{~mm} \mathrm{Hg}$ | MRIDs 40804705, 41088306 |
| Hydrolysis Half-life (pH 5, 7, 9; 25C) | stable | Accession \# 252481 |
| Aqueous Photolysis Half-life $(\mathrm{pH} 7)$ | stable | 40042143, 41088304 |
| Soil Photolysis Half-life (days) | >30,97 | 40042144, 40042145 |
| Aerobic Soil Metabolism Halflife (days) | 330, 545 | Accession \# 144214; Registrant data reviews, $2005^{1,2}$ |
| Anaerobic Soil Metabolism Half-life (days) | -- | -- |
| Aerobic Aquatic Metabolism Half-life | ${ }^{--}$ | $\stackrel{--}{ }$ |
| Anaerobic Aquatic Metabolism Half-life (days) | 345, 1169 | 40042146, 41088301 |
| Organic Carbon-Normalized Soil Partition Coefficient (Koc) | $\begin{gathered} 985,1701,1844,2038 \text { (mean } \\ 1642 \text { ) } \end{gathered}$ | Registrant data reviews, 2005 ${ }^{\text {1,2 }}$ |
| Soil Adsorption Coefficient (Kd) | 12, 13, 46, 74 (mean 36) | Registrant data reviews, $2005^{\text {1,2 }}$ |
| Log Kow (pH7) | 3.87 | Registrant data reviews, $2005^{1.2}$ |
| Henry's Law Constant | -- | --- |
| Bioconcentration Factor in Fish (BCF) | 160-250X | EU Monograph; Oct. 2000 Addendum |

${ }^{1}$ Singles, Suzanne K. Environmental fate data available for Section 18 and Section 3 registration submissions for flusilazole. (Position Paper) June 29, 2005. DuPont Project Identification DuPont-17756. E.I. du Pont de Nemours and Company, Newark, DE.
${ }^{2}$ Russell, Mark H. and Amy Ritter. Calculation of the laboratory and field degradation kinetics and sorption behavior of flusilazole and its degradation products. (Position Paper) June 24, 2005. DuPont Project Identification DuPont-17756. E.I. du Pont de Nemours and Company, Newark, DE.

## 2. Aquatic Organism Exposures

There are no monitoring data for flusilazole in the U.S., as the pesticide is not yet registered for use in the U.S. Estimated Environmental Concentrations (EECs) for aquatic ecosystems assessments were estimated based on EFED's Tier II aquatic models: PRZM (Pesticide Root Zone Model) and EXAMS (EXposure Analysis Modeling System). PRZM is used to simulate pesticide transport as a result of runoff and erosion from an 10-ha agricultural field and EXAMS considers the environmental fate and transport of pesticides and predicts EECs in an adjacent small water body ( $10,000-\mathrm{m}^{2}$ pond, $2-\mathrm{m}$ deep with no outlet), with the assumption that the small field is cropped at $100 \%$. The model is designed to estimate pesticide concentrations found in water at the edge of the treated field. As such, it provides high-end values of the pesticide concentrations that might be found in ecologically sensitive environments following pesticide application. PRZM-EXAMS is a multi-year runoff model that also accounts for spray drift from multiple applications. The location of the field is specific to the crop being simulated using site-specific information on the soils, weather, cropping, and management factors associated with the scenario. The crop/location scenario is intended to represent a high-end exposure site on which the crop is normally grown. Based on historical rainfall patterns, the water body receives multiple runoff events during the years simulated.

Calculations are carried out with the linkage program shell - PE4VO1.pl - which incorporates the standard scenarios developed by EFED. Additional information on these models can be found at: http://www.epa.gov/oppefed1/models/water/index.htm. The input parameters used in this assessment were selected from the environmental fate data submitted by the registrant and in accordance with US EPA-OPP EFED water model input parameter selection guidelines, Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version II, February 28, 2002.

Input parameters used in the Tier II PRZM/EXAMS model for ecological assessment of flusilazole in surface water sources were based on the proposed application rate for soybean rust and the fate properties of flusilazole. Foliar applications via both aerial and ground spray methods were considered (Table 3). Aquatic exposure characterization was based on a Mississippi soybean application scenario that was selected to represent a wide range of soil and environmental conditions of the growing area. The application date was modeled as June 1.

Table 3. PRZM/EXAMS Input Parameters for Flusilazole Use

| Parameter | Input Value and Unit | Source | Comments |
| :--- | :--- | :--- | :--- |
| Maximum Application Rate | 0.103 lb a.i./A/applic. | Punch label |  |
| Maximum Number of Applications | 2 | Punch label |  |
| Method of Application | aerial and ground spray | Punch label |  |
| Application Efficiency | 0.95 (aerial) | Input Parameter Guidance |  |
| Spray Drift Fraction | 0.99 (ground spray) |  |  |
| Type of Application | 0.05 (aerial) | Input Parameter Guidance |  |
| Date of Application | 0.01 (ground) |  |  |
| Minimum Interval between Applications | 14 and 21 days | Punch label |  |
| Organic-Carbon Normalized Partition | $1642 \mathrm{mg} / \mathrm{L}$ | Punch label |  |


| Coefficient K |  | $2005^{1.2}$ |  |
| :--- | :--- | :--- | :--- |
| Henry's Law Constant | -- | -- |  |
| Hydrolysis | 0 days (stable) | Accession \# 252481 |  |
| Aerobic Soil Metabolism Half-life (days) | 768.5 | Accession \# 144214 | represents $90^{\text {th_ }}$ <br> percentile value |
| Aerobic Aquatic Metabolism Half-life <br> (days) | 1537 | Accession \# 144214; <br> Registrant data review | In absence of data, <br> default value is <br> twice input value <br> for aerobic soil <br> metabolism |
| Anaerobic Aquatic Metabolism Half-life <br> (days) | 2025.3 | MRIDs 40042146, 41088301 | represents 90 <br> percentile value |
| Aqueous Photolysis Half-life (days) | 0 days (stable) | MRIDs 40042143, 41088304 |  |
| Vapor pressure | $2.9 \times 10^{-7}$ torr | MRIDs 40804705, 41088306 |  |
| Solubility in water (pH 7,20 | EU Monograph; Oct. 2000 <br> Addendum |  |  |
| Molecular Wt. | $41.9 \mathrm{mg} / \mathrm{L}$ | Registrant data reviews, <br> $2005^{1,2}$ |  |

${ }^{1}$ Singles, Suzanne K. Environmental fate data available for Section 18 and Section 3 registration submissions for flusilazole. (Position Paper) June 29, 2005. DuPont Project Identification DuPont-17756. E.I. du Pont de Nemours and Company, Newark, DE.
${ }^{2}$ Russell, Mark H. and Amy Ritter. Calculation of the laboratory and field degradation kinetics and sorption behavior of flusilazole and its degradation products. (Position Paper) June 24, 2005. DuPont Project Identification DuPont-17756. E.I. du Pont de Nemours and Company, Newark, DE.

Two application interval scenarios are presented: 14 and 21 days. There is a slight increase in the estimated concentration as the application interval increases from 14 to 21 days for both aerial and ground spray applications. This may be due to the timing of rain events occurring after the application date. Thus, there is some uncertainty in the results associated with the application date and rain events in the model.

The model results are presented in Table 4. Acute EEC values were used to determine acute risks. The 21 -day average EEC values were used to determine chronic risks to aquatic invertebrates. The 60 -day average EEC values were used to determine chronic risks to aquatic fish. The PRZM/EXAMS output files from the ecological exposure assessment are presented in Appendix A.

Table 4. PRZM/EXAMS Estimated Concentrations of Flusilazole in Surface Water Resulting Aquatic Exposure from Use on Soybeans (Mississippi Soybean Scenario).

| Application Method | Application \#/Interval | Acute Conc. <br> $\mathbf{( p p b )}$ | 21-day Conc. <br> $(\mathbf{p p b})$ | $\mathbf{6 0}$-day Conc. <br> $(\mathbf{p p b})$ |
| :---: | :---: | :---: | :---: | :---: |
| Aerial Spray | 2/14-day | 10.03 | 9.88 | 9.62 |
| Aerial Spray | 2/21-day | 10.20 | 9.98 | 9.74 |
| Ground Spray | 2/14-day | 8.97 | 8.81 | 8.55 |
| Ground Spray | 2/21-day | 9.11 | 8.94 | 8.67 |

## 3. Terrestrial Organism Exposures

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals emphasizing a dietary exposure route for uptake of pesticide residues on vegetative matter and insects. These exposures also apply to terrestrial-phase amphibians as well as reptiles. For exposure to terrestrial organisms, 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. The residue estimates from spray applications are based on a nomogram by Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994) that correlated residue levels, based on application rate, on various terrestrial items immediately following application in the field. The upper-bound and mean residue concentration for each food group was derived from literature and tolerance data. Specifically, for every 1 lb ai/acre of application, the resulting upper-bound concentration on short grass is 240 ppm , on tall grass is 110 ppm , on broad-leaved plants/small insects is 135 -ppm, and on seeds/large insects is 15 ppm . For every 1 lb ai/acre of application, the resulting mean concentration on short grass is 85 ppm , on tall grass is 36 ppm , on broad-leaved plants/small insects is 45 ppm , and on seeds/large insects is 7 ppm .

Determination of residue dissipation over time on food items following single and multiple applications are predicted using a first-order residue degradation half-life with EFED's "T-REX_v1.2.3" model. The risk assessment uses a default foliar dissipation half-life estimate of 35 days. This half-life is used in lieu of representative foliar dissipation data for flusilazole. The screening-level risk assessment for flusilazole uses upper-bound predicted residues as the measure of exposure to estimate risk. The predicted upper-bound residues of flusilazole that may be expected to occur on selected avian or mammalian food items immediately following application (at the maximum annual or seasonal label rate) for soybeans is presented in Table 5.

Table 5. Estimated Environmental Concentrations (EECs) of flusilazole for avian and mammalian food items following two applications at 0.103 lb ai/A with a 14-day interval between applications.

| Food Items | EEC (ppm) <br> Upper-bound Predicted <br> Residue | EEC (ppm) <br> Mean Predicted Residue |
| :--- | :---: | :---: |
| Short grass | 43.45 | 15.39 |
| Tall grass | 19.92 | 6.52 |
| Broadleaf/forage plants and small <br> insects | 24.44 | 8.15 |
| Fruits, pods, seeds, and large insects | 2.72 | 1.27 |

The residues, or estimated environmental concentrations (EECs) on food items, are compared both directly with subacute dietary toxicity data and converted to an ingested whole body dose (single oral dose), as is the case for small mammals and birds. The EEC is converted to oral dose by multiplying the EEC by the percentage of body weight consumed as estimated through allometric relationships. These consumption-weighted EECs (i.e. EEC equivalent dose) are determined for each food source and body size for mammals ( 15,35 , and 1000 g ) and birds ( 20,100 , and 1000 g ). The EEC equivalent doses for birds and mammals are given in Tables 6 and 7, respectively.

Table 6. Avian EEC equivalent dose adjusted for body weight for flusilazole application on soybeans twice per year (Upper-bound Predicted Residue).

| EEC equivalent dose ( $\mathrm{mg} / \mathrm{kg}$-body weight) | Avian Classes and Body Weights |  |  |
| :---: | :---: | :---: | :---: |
|  | small | medium | large |
|  | 20 g | 100 g | 1000 g |
| Percent Body Weight Consumed | 114\% | 65\% | $29 \%$ |
| Will | $11 / 5$ | *i11 | , |
| Short Grass | 49.49 | 28.22 | 12.64 |
| Tall Grass | 22.68 | 12.93 | 5.79 |
| Broadleaf plants/small insects | 27.84 | 15.87 | 7.11 |
| Fruits/pods/large insects | 3.09 | 1.76 | 0.79 |

Table 7. Mammalian EEC equivalent dose adjusted for body weight for flusilazole application on soybeans twice per year.

| EEC equivalent dose <br> (mg/kg-body weight) | Mammalian Classes and Body Weight |  |  |  |  |  |  |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Herbivores/ Insectivores |  | Granivores |  |  |  |  |
|  | 15 g | 35 g | 1000 g | 15 g | 35 g | 1000 g |  |
| Percent Body Weight <br> Consumed | $95 \%$ | $66 \%$ | $15 \%$ | $21 \%$ | $15 \%$ | $3 \%$ |  |
|  |  | 41.43 | 28.63 | 6.64 |  |  |  |
| Short Grass | 18.99 | 13.12 | 3.04 |  |  |  |  |
| Tall Grass | 23.30 | 16.11 | 3.73 |  |  |  |  |
| Broadleaf plants/sm Insects | 2.59 | 1.79 | 0.41 | 0.58 | 0.40 | 0.09 |  |

## B. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an animal or plant. This characterization is generally based on registrant-submitted studies, to the Agency and/or the OECD, that describe acute and chronic effects information for various aquatic and terrestrial animals.

Toxicity testing reported in this section represents all species of birds, mammals, or aquatic organisms. However, 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. Estuarine/marine organisms were not evaluated. For mammals, toxicity studies are limited to the laboratory rat. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that avian and reptilian and terrestrial-phase amphibian toxicities are similar. The same assumption is used for fish and aquatic-phase amphibians. No terrestrial plant data was available for this assessment; one green alga study represents potential toxicity to all aquatic plant species. The information reported in this section reflects the toxicity endpoints used in the Risk Estimation section. More information is provided in Appendix B.

## 1. Aquatic Animals <br> a. Acute Effects <br> Fish

A warmwater fish study, following GLP, was submitted to the Agency (Bear, 1992; MRID 422430-01). The study, categorized acceptable, established an $\mathrm{LC}_{50}$ for channel catfish (Ictalurus punctatus) of 0.42 mg ai/ $/$. Flusilazole is categorized as highly toxic to fish.

## Invertebrates

An acute study evaluating the toxicity of flusilazole to the freshwater invertebrate, Daphnia magna, was conducted by Hutton and Hall, 1983 (MRID 137633), establishing an $\mathrm{EC}_{50}$ of 3.4 mg ai $/ \mathrm{l}$. The study was categorized as acceptable. Flusilazole is categorized as moderately toxic to aquatic invertebrates.
b. Chronic Effects

Fish
A fish early life-stage test (Hoke, 2000; MRID 451077-01) using rainbow trout (Onchorhynchus mykiss), reviewed by the OECD but not yet reviewed by the Agency, established a NOAEC of 3.3 ppb . The NOAEC was based on reduced length and weight of survivors and larval abnormalities.

## Invertebrates

A life-cycle test was conducted with Daphnia magna to determine the chronic toxicity of flusilazole to aquatic invertebrates. The study was submitted to the Agency as Hutton, 1985 (MRID 400421-41) and established the NOAEC as 0.27 mg ai/l. The OECD assessment cites a study as Hutton, 1986, which yielded the same end point, based on reduction in daphnid length and in number of young produced.

Table 8. Summary of endpoints used in aquatic risk estimation.

| Species | Acute Toxicity |  |  |
| :--- | :---: | :---: | :---: |
|  |  |  |  |
| Channel catfish <br> Ictalurus punctatus <br> 96 hr static unaerated | $\mathrm{LC}_{50}$ | 0.42 mg ai/l | Moderately Toxic <br> (Bear, 1992) <br> MRID 422430-01 <br> Acceptable |
| Water flea <br> Daphnia magna <br> 48 hr static unaerated |  |  | Moderately Toxic |
|  |  |  |  |

## 2. Terrestrial Animals <br> a. Mammalian <br> Acute Oral

The acute oral toxicity of flusilazole was tested in $\mathrm{Cr}!\mathrm{CD}$ rats. The study, conducted in 1983 (cited as Wylie, 1984), is reported to have been in compliance with GLP and conformed to the OECD 401 guideline. Ten rats of each sex, per level, were given a single dose by gavage of flusilazole (as INH-6573-49; 97\% pure), using a corn oil carrier. Males received doses of 200, $500,900,1100$ or $1300 \mathrm{mg} / \mathrm{kg}$ and females received doses of $500,700,800,1000,1300$ or 1500 $\mathrm{mg} / \mathrm{kg}$. Deficiencies reported were that clinical signs and necropsy results were inadequately documented. Otherwise, the study was considered acceptable. The study concludes that the $\mathrm{LD}_{50}$ is $1110 \mathrm{mg} / \mathrm{kg}$ for male rats and $674 \mathrm{mg} / \mathrm{kg}$ for females.

## Chronic 2-generation rat study

A study was conducted in 1990, and cited as Mullin 1990. This study was reviewed by the OECD and was consistent with guideline EC B36. In the, flusilazole (as DPX H6573-193; $94 \%$ pure) was added to the diet of 30 (per sex, per dose) Crl:CDBR rats. Test concentrations of $0,5,50$ and 250 ppm were administered from the start of a 73 -day pre-mating period and continued through the breeding of second generation litters. Parental effects reported significant body weight reductions post-delivery in F0 females at the 50 and 250 ppm levels. No clinical signs of toxicity were observed. An increased gestation length was observed in all matings at the highest dose. A total of 11 dams died periparturition, and they were considered treatment related. The reported NOAEC is 50 ppm , based on increased gestation length, periparturient mortality and reduced viability of pups.
b. Avian

Acute Oral Toxicity
To evaluate the acute oral toxicity of flusilazole on birds, a study by Beavers, 1983 (ID number 112-141) was submitted to the EPA for review. Groups of five male and five female mallard ducks (Anas platyrhynchos) were dosed by oral gavage at $0,398,631,1000,1590$ and 2570 mg ai $/ \mathrm{kg}$ body weight. The study was conducted under EPA guideline $71-1$ in 1982, prior to implementation of GLP, and was considered acceptable. Flusilazole ( $97.3 \%$ pure) was administered in a corn oil carrier, and birds were observed for 14 days. Effects were reported as a dose-related reduction in food consumption ( $9-58 \mathrm{~g}$ ) between $0-3$ days. Over the next four days, food consumption increased back to levels comparable to the control. The reduction of food consumed resulted in reduction of body weights in the 1000 mg and greater doses over the first three days, though body weights were unaffected by study termination. One mortality occurred in the $1590 \mathrm{mg} / \mathrm{kg}$ dose group on day four, although no other signs of toxicity were reported for this group. Regurgitation was noted in 'some' birds at the $2570 \mathrm{mg} / \mathrm{kg}$ dose. The $\mathrm{LD}_{50}$ was taken to be $>1590 \mathrm{mg} / \mathrm{kg} \mathrm{bw}$, since it was the highest dose that regurgitation did not occur.

## Acute Dietary Toxicity

A five-day feeding study (EPA guideline 71-2), conducted by Beavers, 1983, was submitted to the Agency for review (ID number 112-139). Twelve-day-old bobwhite quail (Colinus virginianus) were exposed to nominal dietary concentrations of $562,1000,1780,3160$ and $5620 \mathrm{ppm}, 10$ birds per concentration level. Symptoms of toxicity were observed in the 1000 ppm level and greater. Most birds were reported asymptomatic from day five, though symptoms persisted in some birds through day eight. Food consumption was reduced with increasing concentration. The $\mathrm{LC}_{50}$ was established as $>5620 \mathrm{ppm}$ with the NOAEL for the study 562 ppm .

A second five-day feeding study (EPA guideline 71-2), also conducted by Beavers, 1983, was submitted to the Agency for review (ID number 112-140). Ten-day-old mallard ducks (Anas platyrhynchos) were exposed to nominal dietary concentrations of $562,1000,1780,3160$ and $5620 \mathrm{ppm}, 10$ birds per concentration level. Seven mortalities occurred at the 1780 ppm level, and mortality was a $100 \%$ in the 3160 and 5620 ppm levels. A concentration-related reduction in food consumption was observed with increasing severity with concentration. The LC $\mathrm{C}_{50}$ was established at 1584 ppm with a NOAEL undetermined due to symptoms at the lowest dose tested.

## Chronic Toxicity

To evaluate chronic toxicity of flusilazole to birds, a one-generation reproduction study was conducted by Beavers, 1985 (MRID 400421-36) and submitted to the Agency for review. Sixteen bobwhite quail (Colinus virginianus) of each sex per level were fed feed containing 0,25 , 125 or 625 mg ai/ kg diet ( ppm ) with a $0.03 \%$ corn oil carrier. No signs of adult toxicity were observed and adult body weights were unaffected. Two incidental deaths were reported, one in the control and one at the 125 ppm level. Effects on reproductive parameters were observed at the 125 ppm level and above, with number of cracked eggs, number of hatchlings and 14-day survivors being affected. The NOAEC was established at 25 ppm .

Another reproduction study was submitted to the Agency for review (Beavers, 1985; MRID 400421-37). Sixteen mallard ducks (Anas platyrhynchos) of each sex per level were fed feed containing $0,25,125$ or $625 \mathrm{mg} \mathrm{ai} / \mathrm{kg}$ diet ( ppm ) with a $0.03 \%$ corn oil carrier. No signs of adult toxicity were observed and adult body weights were unaffected. Reproductive effects were increased number of cracked eggs and a decrease in eggshell thickness at both the 125 and 625
ppm levels. The NOAEC was established at 25 ppm , however the Agency reviewer noted appreciable eggshell thinning at the lowest dose. While not statistically significant, the thinning may be of biological relevance and a confirmatory study was requested.

Table 9. Summary of endpoints used in terrestrial risk estimation.

| Species | Acute Toxicity |  |  |  | Chronic Toxicity |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\mathbf{L D}_{50}$ | Acute Oral Toxicity | $\mathrm{LC}_{50}$ | Subacate Dietary Toxicity | NOAEC(L) | Affected <br> Endpoints |
| Northern Bobwhite Quail (Colinus virginianus) | -- | -- | $\underset{\substack{>5620 \\ \mathrm{mg} \text { aiet } \\ \text { diet }}}{ }$ | practically nontoxic (Beavers, 1983) Acceptable | $\begin{gathered} 25 \\ \mathrm{mg} \mathrm{ai} / \mathrm{kg} \text { diet } \end{gathered}$ | offspring survival <br> (Beavers, 1985) <br> Acceptable |
| Mallard duck <br> (Anas <br> platyrhynchos) | $\begin{aligned} & >1590 \\ & \mathrm{mg} / \mathrm{kg}- \end{aligned}$ bwl | practically nontoxic (Beavers, 1983) Acceptable | $1584 \mathrm{mg}$ ai/kg-diet | slightly toxic <br> (Beavers, 1983) <br> Acceptable | $\begin{gathered} 25 \\ \mathrm{mg} \mathrm{ai} / \mathrm{kg} \text { diet } \end{gathered}$ | Egg shell thickness, increases in cracked eggs (Beavers, 1985) Acceptable |
| Laboratory rat (Rattus norvegicus) female | 674 <br> $\mathrm{mg} / \mathrm{kg}-$ bw | slightly toxic (Wylie, 1984) OECD review | -- | -- | $\begin{gathered} 50 \\ \mathrm{mg} \mathrm{ai} / \mathrm{kg} \text { diet } \end{gathered}$ | increased gestation length, reduced pup viability (Pastoor, 1986) OECD review |

## 3. Plants

a. Terrestrial Plants

There have been no studies submitted to the Agency or reported by the OECD, which evaluate the toxicity of flusilazole to terrestrial plants. Risk to terrestrial plants or the animals that depend upon them is not evaluated in this assessment; risks cannot be precluded.
b. Aquatic Plants

The green algae Selenastrum capricornutum was again tested for toxicity to flusilazole (Thompson, 1995; MRID 438787-01), and the study was classified as acceptable. This study established an $\mathrm{EC}_{50}=0.20 \mathrm{mg}$ ai$/ 1$, though a NOEC was not established ( $<0.17 \mathrm{mg}$ ai $/ \mathrm{l}$ ), the $\mathrm{EC}_{05}$ was calculated to be 0.09 mg ai $/ I$. Both the OECD and the EPA consider flusilazole to be algistatic, rather than algicidal, based on the results of the respective studies.

## C. Risk Characterization

## 1. Risk Estimation

Exposure and toxicity effects data are used to evaluate the potential risk to non-target species from the use of flusilazole. For the assessment of flusilazole, 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 B contains additional
information on the TREX model. Appendix C of this document summarizes the LOCs used in this risk assessment.

## a. Nontarget Aquatic Animals

Based on the available data, no acute RQs (Table 10) for aquatic animals exceeded the LOCs. The acute LOC for aquatic animals is 0.5 . A safety factor of 10 is built into the 0.05 LOC for threatened and endangered species. Chronic risk RQs for freshwater fish exceeded the LOC by a factor of up to three, though invertebrate RQs did not exceed the level of concern. For chronic risk to aquatic animals, the LOC is 1.0 . The 60 -day EECs were compared to chronic toxicity endpoints (NOAEC values) to derive chronic RQs for fish, and 21-day EECs were compared to chronic toxicity endpoints for invertebrates.

Table 10. Acute and Cbronic RQs for aquatic animals resulting from use of flusilazole on soybeans at 0.103 lb ai/A.

| Application | Fish |  | Invertebrates |  |
| :--- | :---: | :---: | :---: | :---: |
| Aerial | Acute | Chronic | Acute | Chronic |
| $2 / 14^{\text {a }}$ | 0.02 | $\mathbf{2 . 9 2}$ | 0.003 | 0.04 |
| $2 / 21$ | 0.02 | $\mathbf{2 . 9 5}$ | 0.003 | 0.04 |
| Ground |  |  |  |  |
| $2 / 14$ | 0.02 | $\mathbf{2 . 5 9}$ | 0.003 | 0.03 |
| $2 / 21$ | 0.02 | $\mathbf{2 . 6 3}$ | 0.003 | 0.03 |

${ }^{2}$ number of applications/interval (days)
b. Nontarget Terrestrial Animals

Avian
The EEC's for terrestrial exposure were derived from the Kenaga nomograph, as modified by Fletcher et al. (1994), based on a large set of field residue data. The EECs were calculated by the T-REX Version 1.2.1 model and corresponding avian acute and chronic risk quotients are based on the most sensitive subacute dietary $\mathrm{LC}_{50}$, single oral dose $\mathrm{LD}_{50}$, and NOAEC for birds. Single-oral dose acute studies represent the upper range of the quantity of pesticides birds could potentially ingest with their diet. Subacute dietary studies represent the lower range of the quantity of pesticide potentially ingested.

Calculations for oral dose risk quotients are based on a mallard duck oral acute $\mathrm{LD}_{50}$ of $>1590 \mathrm{mg} / \mathrm{kg}$ body weight. RQs for oral dose-based scenarios are calculated by dividing the consumption-weighted equivalent dose (Table 6) by the body weight-adjusted $\mathrm{LD}_{50}$. The avian $\mathrm{LD}_{50}$ is adjusted for body weight according to the following equation:

Adjusted Avian $\mathrm{LD}_{50}(\mathrm{mg} / \mathrm{kg} \mathrm{bw})=\mathrm{LD}_{50}(\mathrm{mg} / \mathrm{kg} \mathrm{bw}) *\left(\frac{\mathrm{AW}(\mathrm{g})}{\mathrm{TW}(\mathrm{g})}\right)^{\mathrm{x}-1}$
where x is Mineaux Scaling Factor. Default is 1.15 .
The assessed weight (AW) is the body weight of the wildlife species of concern. An adjusted $\mathrm{LD}_{50}$ is calculated for three weight classes of birds ( 20,100 , and 1000 g ). The test weight (TW) is the body weight of the species used in the toxicity study. In this case, the mean weight of the mallard duck is estimated to be 1580 g . The adjusted $\mathrm{LD}_{50}$ is 826,1051 , and $1485 \mathrm{mg} / \mathrm{kg}$ bw for
the weight classes 20,100 , and 1000 g birds, respectively. The acute RQs for birds based on single-oral dose oral studies are summarized in Table 12.

Calculations for acute and chronic dietary-based risk quotients are based on a mallard duck subacute dietary $\mathrm{LC}_{50}$ of $1584 \mathrm{mg} / \mathrm{kg}$ diet and a Northern bobwhite quail chronic NOAEC of $25 \mathrm{mg} / \mathrm{kg}$ diet. These endpoints are not adjusted for body weight.

The acute LOC for both birds and mammals is 0.5 . A safety factor of five is built into the 0.1 LOC for threatened and endangered species. For chronic risk to terrestrial animals the LOC is 1.0. The upper-bound single day residue estimation is used for both the acute and chronic RQ calculations.

For birds, no acute RQs exceeded the LOCs (Table 11). Please note that only dietarybased RQs are presented here. There were no exceedances using dose-based EECs for avian acute risk. The chronic risk LOC for birds was exceeded for birds foraging on short grass (1.74). Chronic risk to birds is only calculated using dietary-based EECs.

Table 11. Dietary-based RQs for avian acute and chronic risk estimation resulting from use of flusilazole on soybeans at 0.103 lb ai/A.

| Forage Item | Acute | Chronic |
| :--- | :---: | :---: |
| Short Grass | 0.03 | $\mathbf{1 . 7 4}$ |
| Tall Grass | 0.01 | 0.80 |
| Broadleaf Plants/Small Insects | 0.02 | 0.98 |
| Fruits/Pods/Seeds/Large Insects | $<0.01$ | 0.11 |

Mammalian
Oral dose-based RQ values were calculated by dividing the consumption-weighted equivalent dose by the body weight-adjusted $\mathrm{LD}_{50}$. The mammalian $\mathrm{LD}_{50}$ is adjusted for body weight using the same equation above. The assessed weight (AW) is the body weight of the wildlife species. An adjusted $\mathrm{LD}_{50}$ is calculated for each weight class of mammal ( 15,35 , and 1000 g ). The test weight (TW) is the weight of the species used in the toxicity study. In this case, the weight of the laboratory rat ( 350 g ) is used because the original $\mathrm{LD}_{50}$ has been already adjusted for body weight. For chronic dose-based RQ calculations, the NOAEC ( $50 \mathrm{mg} / \mathrm{kg}$ bw) was adjusted for body weight using the same procedure.

$$
\begin{equation*}
\text { Adjusted Mammalian } \mathrm{LD}_{50}(\mathrm{mg} / \mathrm{kg} \mathrm{bw})=\mathrm{LD}_{50} *\left(\frac{\mathrm{TW}(\mathrm{~g})}{\mathrm{AW}(\mathrm{~g})}\right)^{0.25} \tag{USEPA,1993}
\end{equation*}
$$

No acute risk LOCs were exceeded for mammals (Table 12). However, dose-based chronic RQs exceeded LOCs for all size classes for short grass, tall grass and broadleaf plants/small insects, ranging from 1.94-7.54. However, dietary-based chronic RQs did not exceed the LOCs.

Table 12. Acute and chronic RQs for terrestrial mammal risk estimation resulting from use of flusilazole on soybeans at 0.103 lb ai/A.

|  | Dose-based |  |  |  |  |  | Dietary- <br> based |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | 15 g |  | 35 g |  | 1000 g |  |  |
| Forage Item | Acute | Chronic | Acute | Chronic | Acute | Chronic | Chronic |
| Short Grass | 0.03 | $\mathbf{7 . 5 4}$ | 0.02 | $\mathbf{6 . 4 4}$ | 0.01 | $\mathbf{3 . 4 5}$ | 0.87 |
| Tall Grass | 0.01 | $\mathbf{3 . 4 6}$ | 0.01 | $\mathbf{2 . 9 5}$ | 0.01 | $\mathbf{1 . 5 8}$ | 0.40 |
| Broadleaf Plants/Small <br> Insects | 0.02 | $\mathbf{4 . 2 4}$ | 0.01 | $\mathbf{3 . 6 2}$ | 0.01 | $\mathbf{1 . 9 4}$ | 0.49 |
| Fruits/Pods/Seeds/Large <br> Insects | $<0.01$ | 0.47 | $<0.01$ | 0.40 | $<0.01$ | 0.22 | 0.05 |
| Seeds | $<0.01$ | 0.10 | $<0.01$ | 0.09 | $<0.01$ | 0.05 | - |

## c. Nontarget Plants

There are no data currently available to estimate the potential risk to nontarget terrestrial plants from exposure to flusilazole. In the absence of data, risk to at least some plant species cannot be precluded.

Based on the green algae study (Selenastrum capricornutum), comparing the $\mathrm{EC}_{50}$ of 200 ppb with the peak EEC of 10.03 results in an acute RQ of 0.05 , which does not exceed the LOC for plants of 1.0 . Using the $\mathrm{EC}_{05}$ for estimating risk to endangered algae, calculated to be 90 ppb , the resulting RQ of 0.11 also does not exceed the LOC of 1.0. Due to lack of data, risk to other aquatic plants cannot be estimated, and cannot be precluded.

## 2. Risk Description

## a. Nontarget Aquatic Animals and Invertebrates

Estimated environmental concentrations (EECs) in surface water from flusilazole use on soybeans were predicted with the Tier II models PRZM/EXAMS. Aquatic exposure characterization was based on a Mississippi soybean scenario. The proposed rate is 0.103 lb a.i./acre for two applications during the growing season, applied at 14-21 day intervals. Foliar applications via both aerial and ground spray were considered.

The EECs are highest based on the 21-day application interval; therefore, these values were used for the aquatic screening assessment. Acute EECs were compared to acute toxicity endpoints to derive acute RQs. The 60-day EECs were compared to chronic toxicity endpoints (NOAEC values) to derive chronic RQs for fish, and 21 -day EECs were compared to chronic toxicity endpoints for invertebrates.

Estuarine/marine toxicity studies were not submitted for flusilazole. Given that soybeans are grown in areas proximal to estuarine/marine environments, these studies are necessary to assess risk to these organisms.

## Acute Aquatic

No acute LOCs are exceeded for freshwater fish and invertebrates. While no acute risk to aquatic animals is indicated from the proposed use of flusilazole, there is some uncertainty whether the submitted studies represent the most sensitive species likely to be exposed. While this uncertainty cannot be quantified, both the channel catfish and rainbow trout studies indicate similar levels of toxicity, and the bluegill sunfish study indicates less sensitivity (Appendix B).

## Chronic Aquatic

While no freshwater invertebrate RQs exceed the chronic LOC, the RQs for freshwater fish exceed the chronic LOC by up to a factor of three. There is some uncertainty surrounding the chronic endpoints used in this assessment. A review of one fish early life stage test by Agency scientists found that a NOAEC was not established based on statistically significant reductions in length ( $8.5 \%$ at 30 ppb ). The endpoint used in the RQ calculation is from a second fish early life-stage study, which establishes the NOAEC an order of magnitude lower than the a fish full life-cycle study submitted to the OECD. That study established a NOAEC of 25 ppb , based on a statistically significant $3 \%$ reduction in offspring length at 48 ppb . The most sensitive endpoint of these studies was used in this risk assessment, but since the first early life stage study did not determine a NOAEC, it could potentially be well below 30 ppb .

## b. Nontarget Terrestrial Animals <br> Avian Risk

There were no exceedances of the avian acute LOCs when comparing $95^{\text {th }}$ percentile upper bound EECs with current toxicological endpoints, indicating flusilazole poses minimal acute risk based on the Agency's screening-level models.

Avian chronic risk quotients, calculated from the dietary NOEC, result in exceedances for short grass and the RQ for broadleaf plant/small insect forage items, 0.98 , is nearing the LOC. Although at this time appropriate conversion factors are unavailable, it is possible that RQs calculated in a dose-based manner would result in higher RQs. Dose-based RQs are calculated using a body weight adjusted and consumption-weighted equivalent dose. The adjustments account for the fact that smaller-sized animals have to consume more food in terms of their body weight than larger animals and that differential amounts of food have to be consumed depending on the water content and nutritive value of the food. By expressing the Kenaga nomogram estimated residues in terms of daily equivalent dose, estimated environmental concentrations could then be compared to the dose-based NOAEC. Weight adjustments for chronic RQs are currently only available for mammals. Dietary-based RQs based on mean Kenaga values do not exceed the LOC. Avian chronic RQs are not exceeded when calculated using the mean exposure values.

Dose-based and dietary-based acute RQs are provided to risk managers whenever effects data allow. There are limitations to each approach. The dose-based approach assumes that the uptake and absorption kinetics of a gavage toxicity study approximate the absorption associated with uptake from a dietary matrix. Toxic response is a function of duration and intensity of exposure and the importance of absorption kinetics across the gut and the importance of enzymatic activation/deactivation of a toxicant may be important and are likely variable across chemicals and species. For many compounds a gavage dose represents a very short-term high
intensity exposure, where dietary exposure may be of a more prolonged nature. The dietarybased approach assumes that animals in the field are consuming food at a rate similar to that of confined laboratory animals. Energy content in food items differs between the field and the laboratory as does the energy requirements of wild and captive animals. Therefore, laboratory studies may underestimate sensitivity.

The $95^{\text {th }}$ percentile upper bound Kenaga EECs exceed the NOAEC for 23 days on short grass and matches the NOAEC for only one day on broadleaf plants and small insects. In the reproduction studies, birds were exposed to flusilazole for 20 weeks. Therefore, environmental exposure may not be sufficient to induce the effects seen in studies, although it is not known whether even a single exposure of sufficient intensity could cause the observed effects. The most sensitive endpoints in both studies were increases in the number of cracked eggs, with reduced eggshell thickness noted in the mallard study and reduction in 14-day survivors in the bobwhite study.

Further complicating the risk picture for birds is that, while originally categorized as 'Acceptable', it is possible that the mallard reproduction study did not identify a true no-effect level. There appears to be a dose-related, though not statistically significant, six percent reduction in eggshell thickness at the lowest dose tested ( $25 \mathrm{mg} / \mathrm{kg}$ ). The statistically significant reduction in eggshell thickness at $125 \mathrm{mg} / \mathrm{kg}$ was eight percent. The registrant was asked to provide a confirmatory study and has requested a waiver. The argument made by the registrant and the study's authors is that there were an increased number of thick eggs in the control compared to a review of historical controls. The Agency evaluates the response level in each study compared to the control within that study. Furthermore, statistics rely on natural variation and rarely is it statistically valid to remove observations from the dataset. Therefore unexpected control results cannot be discounted, thus there is still the possibility that effects in sensitive birds species are possible at lower exposure levels than RQs calculated with the NOAEC may indicate.

Given the design of avian reproduction studies, a new study using mallard may not alleviate the uncertainty. Laboratory studies with DDT, an acknowledged shell-thinning pesticide, using mallard and bobwhite quail did not demonstrate the environmental risk posed to carnivorous birds eventually discovered. Acute sensitivities among species have been shown to vary by 100 -fold. While not well documented, sensitivity in reproductive endpoints may vary similarly, or even to a greater extent.

The small insect RQ calculated from the mallard study was 0.98 . If an insectivorous bird were more sensitive to flusilazole than the mallard, then the LOC would be exceeded by the same magnitude as the increased sensitivity. Using the BCF of 250, lower trophic-level aquatic organisms may subject higher trophic-level organisms, such as piscivorous birds, to flusilazole concentration of 2.5 ppm , given the persistence of the compound. However, the BCF of 250 in fish, with depuration to about $20 \%$ of peak liver values in 14 days, and a low $\mathrm{K}_{\text {ow }}$ may indicate that in open water systems, not accounted for in our models, a fairly low probability of bioaccumulation exists. Nevertheless, the potential effects should not be minimized. Othèr bird species, such as American kestrel, could be tested to help reduce the uncertainty surrounding the potential of flusilazole to disrupt avian reproduction.

## Mammalian Risk

There were no exceedances of the mammalian acute LOCs when comparing $95^{\text {th }}$ percentile upper bound EECs with current toxicological endpoints indicating flusilazole poses minimal acute risk based on the Agency's screening-level models.

Chronic risk to mammals is estimated using the NOAEC ( $50 \mathrm{mg} / \mathrm{kg}$ diet) used in prior assessments. In addition, in accordance with the overview document, the dietary-based NOEC is converted to a dose-based NOEL using the standard USFDA laboratory rat conversion, which can be scaled to different mammalian size classes. The dose-based RQs are calculated using a body weight adjusted and consumption-weighted equivalent dose. The adjustments account for the fact that smaller-sized animals have to consume more food in terms of their body weight than larger animals and that differential amounts of food have to be consumed depending on the water content and nutritive value of the food. By expressing the Kenaga nomogram estimated residues in terms of daily equivalent dose, estimated environmental concentrations could then be compared to the dose-based NOEC. However, both dietary- and dose-based RQs are presented the Risk Estimation section.

Chronic dosed-based RQs exceed the LOC for mammals foraging on short grass, tall grass and broadleaf plants/small insects. While these RQs account for physiological differences between mammals, dietary-based RQs did not exceed LOCs for any forage item. The true estimate of chronic risk probably falls in between these two estimates. The toxicological endpoint used in these calculations is based on the rat. The extent to which other mammals are similar in their sensitivity to flusilazole is uncertain.

For this risk assessment, the risk quotients that were compared to the LOCs were calculated using $95^{\text {th }}$ percentile upper bound EECs. Risk quotients were also calculated based on mean EECs for both single and double annual applications. There were no mammalian acute or chronic exceedances for either oral- or dietary-based scenarios when using the mean EECs (data not shown).

## 3. Risk to Non-target Terrestrial and Aquatic Plants

There is currently no data submitted to the Agency regarding the toxicity of flusilazole to nontarget terrestrial plants. Recently submitted data accepted by the OECD were not available for this assessment.

Based on the one algae study submitted, there is no indication of risk to aquatic plants. However, the extent to which the one species (Selanastrum capricornutum) is representative of all aquatic plant species is unknown.

## 4. Other Non-Target Animals

EFED currently does not quantify risks to terrestrial non-target insects. Risk quotients are therefore not calculated for these organisms. However, flusilazole is categorized as practically non-toxic to honey bees, so it seems unlikely flusilazole will have adverse effects on pollinators and other beneficial insects. Similarly, flusilazole does not appear to be highly toxic to earthworms given the OECD-accepted NOEC of 100 mg ai$/ \mathrm{kg}$ soil.

## V. ENDOCRINE DISRUPTION POTENTIAL

Chronic exposure to flusilazole resulted in increased numbers of eggshells cracked in birds, reduced hatching success in fish and reduced numbers of neonate invertebrates per adult reproductive day in aquatic invertebrates. There is uncertainty regarding whether these effects on a broad range of taxonomic groups are indicative of flusilazole's capacity to act on endocrinemediated processes; however, the sublethal effects observed in chronic toxicity studies are sufficient to trigger concerns regarding the endocrine disrupting potential of flusilazole.

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, flusiazole may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

## VI. THREATENED AND ENDANGERED SPECIES CONCERN

## A. Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are co-located with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that the listed species are located within an assumed area that has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area. This risk assessment presents the use of flusilazole on soybeans fields in the proposed seven states and establishes initial co-location of species with treatment areas.

If the assumptions associated with the screening-level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects upon listed species that depend upon the taxonomic group covered by the RQ as a resource. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of
these species, and the locations of use sites could be considered to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps could consider how this information would impact the action area for a particular listed organism and may potentially include areas of exposure that are downwind and downstream of the pesticide use site.

## B. Taxonomic Groups Potentially at Risk

Based on available screening level information, it is unlikely that flusilazole will have acute toxic effects on endangered or threatened aquatic or terrestrial organisms. However, risk to plants cannot be precluded. However the chronic LOCs are exceeded for birds and mammals consuming various forage items. Threatened and Endangered birds and mammals could potentially be affected through chronic exposure. Risk to estuarine/marine organisms cannot be estimated nor precluded.

Should estimated exposure levels occur in proximity to listed resources, the available screening level information suggests a potential concern for chronic effects on some listed species associated with the proposed use of flusilazole. This screening assessment is based on the initial assumption that listed species within the taxonomic groups of concern are actually present in areas for which the estimated exposure levels used for RQ calculation can be expected to occur. A specific determination of "may affect" for any RQ in excess of listed species LOCs cannot be made without further refinement of the co-occurrence of listed species in soybean use areas where flusilizole is allowed.

The LOCATES database was used to identify those U.S. counties that both grow soybeans and have Federally listed endangered or threatened species. A summary of listed taxa that have been known to occur in those areas is presented in Appendix D, by State. Further refinements to the risk assessment must be made for the Agency to be in compliance with the Endangered Species Act and to determine the need for consultation with the Services.

## Appendix A. Tier II Aquatic Modeling Outputs from PRZM/EXAMS

## 1. Aerial spray foliar application to soybeans with a 14-day interval.

```
stored as flul4aer.out
Chemical: flusilazole
PRZM environment: MSsoybeanC.txt modified Satday, 12 October 2002 at
17:07:44
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at
16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20
Nater segment concentrations (ppb)
Year Peak 96 hr 21 Day 60 Day 90 Day Yearly
1961 1.269 1.223 1.097 0.8405 0.642 0.2563
1962 1.629 1.603 1.545 1.478 1.446 1.168
1963 2.284 2.241 2.111 1.962 1.912 1.659
1964 2.873 2.853 2.781 2.55 2.483 2.22
1965 3.649 3.599 3.459 3.28. 3.211 2.925
1966 3.697 3.667 3.568 3.48 3.484 3.377
1967 4.305 4.262 4.192 4.058 4.032 3.816
1968 5.185 5.116 4.946 4.743 4.738 4.422
1969 5.711 5.649 5.5 5.249 5.156 4.946
1970 5.962 5.918 5.819 5.72 5.655 5.481
1971 6.132 6.095 5.967 5.792 5.756 5.618
1972 6.989 6.908 6.702 6.532 6.424 6.023
1973 7.108 7.059 6.915 6.784 6.747 6.577
1974 7.482 7.433 7.309 7.258 7.217 7.001
1975 7.401 7.369 7.265 7.166 7.116 7.061
1976 7.808 7.753 7.573 7.408 7.381 7.187
1977 7.688 7.646 7.522 7.406 7.356 7.282
1978 8.666 8.605 8.452 8.045 7.924 7.674
1979 8.632 8.587 8.492 8.347 8.261 8.173
1980 9.918 9.816 9.488 9.32 9.149 8.621
1981 9.222 9.176 9.07 8.902 8.823 8.759
1982 9.527 9.502 9.356 9.194 9.117 8.967
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1984 9.528 9.492 9.371 9.315 9.314 9.24
1985 9.535 9.493 9.385 9.295 9.254 9.107
1986 9.788 9.741 9.536 9.335 9.114 8.936
1987 10.01 9.958 9.519 9.384 9.194 9.08
1988 10.18 10.12 9.973 9.646 9.531 9.415
1989}10.5710.57 10.5 10.3 10.08 9.975 9.774
1990}10.03 9.996 9.912 9.815 9.771 9.693
Sorted results
Prob. Peak 96 hr 21 Day 60 Day 90 Day Yearly
0.032258064516129 10.57 10.5 10.3 10.08 9.975 9.774
0.0645161290322581 10.18 10.12 9.973 9.815 9.771 9.693
0.0967741935483871 10.03 9.996 9.912 9.646 9.531 9.415
0.129032258064516 10.01 9.958 9.62 9.384 9.314 9.24
0.161290322580645 9.918 9.816 9.536 9.335 9.254 9.107
0.193548387096774 9.813 9.755 9.519 9.32 9.194 9.095
0.225806451612903 9.788 9.741 9.488 9.32 9.161 9.08
0.258064516129032 9.535 9.502 9.385 9.315 9.149 8.967
```



Inputs generated by pe4.pl - 8-August-2003
Data used for this run:
Output File: flul4aer
Metfile: w13893.dvf
PRZM scenario: MSsoybeanC.txt
EXAMS environment file: pond298.exv
Chemical Name: flusilazole
Description Variable Name Value Units Comments
Molecular weight mwt $315.1 \mathrm{~g} / \mathrm{mol}$
Henry's Law Const. henry atm-m^3/mol
Vapor Pressure vapr 2.9E-7 torr
Solubility sol $41.9 \mathrm{mg} / \mathrm{L}$
$\mathrm{Kd} \mathrm{Kd} \mathrm{mg} / \mathrm{L}$
Koc Koc $1642 \mathrm{mg} / \mathrm{L}$
Photolysis half-life kdp 0 days Half-life
Aerobic Aquatic Metabolism kbacw 1537 days Halfife
Anaerobic Aquatic Metabolism kbacs 2025 days Halfife
Aerobic Soil Metabolism asm 769 days Halfife
Hydrolysis: pH 50 days Half-life
Hydrolysis: pH 70 days Half-life
Hydrolysis: pH 90 days Half-life
Method: CAM 2 integer See PRZM manual
Incorporation Depth: DEPI 0 cm
Application Rate: TAPP $0.115 \mathrm{~kg} / \mathrm{ha}$
Application Efficiency: APPEFF 0.95 fraction
Spray Drift DRFT 0.05 fraction of application rate applied to pond
Application Date Date $01-06 \mathrm{dd} / \mathrm{mm}$ or $\mathrm{dd} / \mathrm{mmm}$ or $\mathrm{dd}-\mathrm{mm}$ or $\mathrm{dd}-\mathrm{mmm}$

Interval 1 interval 14 days Set to 0 or delete line for single app.
Record 17: FILTRA
IPSCND 3
UPTKF
Record 18: PLVKRT
PLDKRT
FEXTRC 0.5
Flag for Index Res. Run IR Pond
Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)

## 2. Ground spray foliar application to soybeans with a 14-day interval.

stored as flu14ground.out
Chemical: flusilazole
PRZM environment: MSsoybeanC.txt modified Satday, 12 October 2002 at 17:07:44
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20 Water segment concentrations (ppb)

| Year | Peak | 96 hr | 21 Day |  | 60 Day | 90 | Day | Yearly |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1961 | 1.179 | 1.132 | 1 | 0.7327 |  | 0.5252 | 0.1646 |  |
| 1962 | 1.416 | 1.389 | 1.329 | 1.261 | 1.229 | 0.9784 |  |  |
| 1963 | 1.756 | 1.729 | 1.632 | 1.551 | 1.527 | 1.365 |  |  |
| 1964 | 2.493 | 2.473 | 2.397 | 2.156 | 2.085 | 1.837 |  |  |
| 1965 | 3.187 | 3.136 | 2.993 | 2.811 | 2.741 | 2.467 |  |  |
| 1966 | 3.108 | 3.094 | 2.998 | 2.92 | 2.93 | 2.842 |  |  |
| 1967 | 3.671 | 3.644 | 3.589 | 3.418 | 3.378 | 3.21 |  |  |
| 1968 | 4.35 | 4.306 | 4.182 | 4.079 | 4.077 | 3.761 |  |  |
| 1969 | 4.992 | 4.929 | 4.778 | 4.527 | 4.434 | 4.234 |  |  |
| 1970 | 5.004 | 4.974 | 4.92 | 4.852 | 4.808 | 4.725 |  |  |
| 1971 | 5.286 | 5.25 | 5.126 | 4.959 | 4.892 | 4.807 |  |  |
| 1972 | 6.021 | 5.947 | 5.84 | 5.707 | 5.592 | 5.175 |  |  |
| 1973 | 6.211 | 6.162 | 6.063 | 5.915 | 5.866 | 5.701 |  |  |
| 1974 | 6.458 | 6.422 | 6.333 | 6.26 | 6.225 | 6.101 |  |  |
| 1975 | 6.376 | 6.364 | 6.314 | 6.241 | 6.226 | 6.119 |  |  |
| 1976 | 6.839 | 6.783 | 6.601 | 6.437 | 6.412 | 6.213 |  |  |
| 1977 | 6.543 | 6.525 | 6.468 | 6.37 | 6.371 | 6.28 |  |  |
| 1978 | 7.716 | 7.653 | 7.494 | 7.067 | 6.938 | 6.664 |  |  |
| 1979 | 7.443 | 7.41 | 7.348 | 7.248 | 7.191 | 7.158 |  |  |
| 1980 | 8.872 | 8.772 | 8.449 | 8.239 | 8.09 | 7.605 |  |  |
| 1981 | 8.229 | 8.181 | 8.073 | 7.902 | 7.818 | 7.738 |  |  |
| 1982 | 8.542 | 8.516 | 8.363 | 8.12 | 8.041 | 7.934 |  |  |
| 1983 | 8.819 | 8.758 | 8.617 | 8.304 | 8.168 | 8.048 |  |  |
| 1984 | 8.463 | 8.438 | 8.355 | 8.295 | 8.28 | 8.181 |  |  |
| 1985 | 8.323 | 8.288 | 8.214 | 8.111 | 8.1 | 8.026 |  |  |
| 1986 | 8.745 | 8.697 | 8.485 | 8.277 | 8.044 | 7.838 |  |  |
| 1987 | 8.975 | 8.921 | 8.459 | 8.319 | 8.117 | 7.979 |  |  |
| 1988 | 9.14 | 9.073 | 8.922 | 8.581 | 8.483 | 8.318 |  |  |
| 1989 | 9.348 | 9.286 | 9.104 | 8.878 | 8.798 | 8.678 |  |  |
| 1990 | 8.964 | 8.928 | 8.83 | 8.757 | 8.714 | 8.581 |  |  |

Sorted results


| Hydrolysis: pH 70 | days Half-life |  |
| :---: | :---: | :---: |
| Hydrolysis: pH 90 | days Half-life |  |
| Method: CAM 2 | integer | life See PRZM manual |
| Incorporation Depth: | DEPI 0 | cm |
| Application Rate: TAPP | $0.115 \mathrm{~kg} / \mathrm{ha}$ |  |
| Application Efficiency: | APPEFF | 0.99 fraction |
| Spray Drift DRFT 0.01 | fraction of | application rate applied to pond |
| Application Date Date | $01-06 \mathrm{dd} / \mathrm{mm}$ | or $\mathrm{dd} / \mathrm{mmm}$ or $\mathrm{dd}-\mathrm{mm}$ or $\mathrm{dd}-\mathrm{mmm}$ |
| Interval 1 interval app. | 14 days | Set to 0 or delete line for single |
| Record 17: FILTRA |  |  |
| IPSCND 3 |  |  |
| UPTKF |  |  |
| Record 18: PLVKRT |  |  |
| PLDKRT |  |  |
| FEXTRC 0.5 |  |  |
| Flag for Index Res. Run | IR Pond |  |
| Flag for runoff calc. <br> total (average of entire | RUNOFF <br> run) | none none, monthly or |

## 3. Aerial spray foliar application to soybeans with a 21-day interval.

stored as flu2laer.out
Chemical: flusilazole
PRZM environment: MSsoybeanC.txt modified Satday, 12 October 2002 at 17:07:44
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20
Water segment concentrations (ppb)

| Year | Peak | 96 | hr | 21 | Day | 60 Day |  | 90 Day |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| 1961 | 1.28 | 1.234 | 1.106 | 0.8477 | 0.6472 | 0.2561 |  |  |
| 1962 | 1.633 | 1.606 | 1.545 | 1.475 | 1.441 | 1.159 |  |  |
| 1963 | 2.093 | 2.055 | 1.934 | 1.843 | 1.817 | 1.618 |  |  |
| 1964 | 2.886 | 2.866 | 2.792 | 2.556 | 2.488 | 2.214 |  |  |
| 1965 | 3.666 | 3.616 | 3.475 | 3.295 | 3.224 | 2.934 |  |  |
| 1966 | 3.666 | 3.648 | 3.556 | 3.496 | 3.494 | 3.389 |  |  |
| 1967 | 4.354 | 4.308 | 4.212 | 4.088 | 4.058 | 3.831 |  |  |
| 1968 | 5.258 | 5.185 | 5.001 | 4.769 | 4.764 | 4.442 |  |  |
| 1969 | 5.745 | 5.683 | 5.532 | 5.279 | 5.185 | 4.971 |  |  |
| 1970 | 6.039 | 5.992 | 5.879 | 5.748 | 5.676 | 5.507 |  |  |
| 1971 | 6.203 | 6.164 | 6.027 | 5.843 | 5.794 | 5.652 |  |  |
| 1972 | 7.086 | 7.001 | 6.79 | 6.593 | 6.483 | 6.076 |  |  |
| 1973 | 7.174 | 7.124 | 6.974 | 6.845 | 6.809 | 6.634 |  |  |
| 1974 | 7.498 | 7.457 | 7.384 | 7.293 | 7.262 | 7.058 |  |  |
| 1975 | 7.422 | 7.393 | 7.301 | 7.224 | 7.179 | 7.132 |  |  |
| 1976 | 7.91 | 7.852 | 7.666 | 7.494 | 7.466 | 7.26 |  |  |
| 1977 | 7.652 | 7.616 | 7.519 | 7.425 | 7.427 | 7.347 |  |  |
| 1978 | 8.796 | 8.734 | 8.575 | 8.154 | 8.03 | 7.762 |  |  |
| 1979 | 8.705 | 8.659 | 8.521 | 8.443 | 8.363 | 8.282 |  |  |
| 1980 | 10.1 | 9.992 | 9.651 | 9.482 | 9.303 | 8.743 |  |  |
| 1981 | 9.362 | 9.315 | 9.208 | 9.037 | 8.958 | 8.893 |  |  |
| 1982 | 9.675 | 9.649 | 9.492 | 9.246 | 9.182 | 9.075 |  |  |
| 1983 | 9.938 | 9.88 | 9.743 | 9.442 | 9.288 | 9.216 |  |  |
| 1984 | 9.61 | 9.575 | 9.486 | 9.431 | 9.423 | 9.356 |  |  |

```
\begin{tabular}{lllllll}
1985 & 9.566 & 9.526 & 9.438 & 9.357 & 9.323 & 9.203 \\
1986 & 9.895 & 9.848 & 9.641 & 9.436 & 9.214 & 9.031 \\
1987 & 10.15 & 10.09 & 9.641 & 9.502 & 9.305 & 9.179 \\
1988 & 10.3 & 10.24 & 10.09 & 9.763 & 9.655 & 9.532 \\
1989 & 10.73 & 10.66 & 10.45 & 10.19 & 10.09 & 9.89 \\
1990 & 10.2 & 10.15 & 10.01 & 9.938 & 9.893 & 9.803
\end{tabular}
Sorted results
Prob. Peak 96 hr 21 Day 60 Day 90 Day Yearly
0.032258064516129 10.73 10.66 10.45 10.19 10.09 9.89
0.0645161290322581 10.3 10.24 10.09 9.938 9.893 9.803
0.0967741935483871 10.2 10.15 10.01 9.763 9.655 9.532
0.129032258064516 10.15 10.09 9.743 9.502 9.423 9.356
0.161290322580645 10.1 9.992 9.651 9.482 9.323 9.216
0.193548387096774 9.938 9.88 9.641 9.442 9.305 9.203
0.225806451612903 9.895 9.848 9.641 9.436 9.303 9.179
0.258064516129032 9.675 9.649 9.492 9.431 9.288 9.075
0.290322580645161 9.61 9.575 9.486 9.357 9.214 9.031
0.32258064516129 9.566 9.526 9.438 9.246 9.182 8.893
0.354838709677419 9.362 9.315 9.208 9.037 8.958 8.743
0.387096774193548 8.796 8.734 8.575 8.443 8.363 8.282
0.419354838709677 8.705 8.659 8.521 8.154 8.03 7.762
0.451612903225806 7.91 7.852 7.666 7.494 7.466 7.347
0.483870967741936 7.652 7.616 7.519 7.425 7.427 7.26
0.516129032258065 7.498 7.457 7.384 7.293 7.262 7.132
0.548387096774194 7.422 7.393 7.301 7.224 7.179 7.058
0.580645161290323 7.174 7.124 6.974 6.845 6.809 6.634
0.612903225806452 7.086 7.001 6.79 6.593 6.483 6.076
0.645161290322581 6.203 6.164 6.027 5.843 5.794 5.652
0.67741935483871 6.039 5.992 5.879 5.748 5.676 5.507
0.709677419354839 5.745 5.683 5.532 5.279 5.185 4.971
0.741935483870968 5.258 5.185 5.001 4.769 4.764 4.442
0.774193548387097 4.354 4.308 4.212 4.088 4.058 3.831
0.806451612903226 3.666 3.648 3.556 3.496 3.494 3.389
0.838709677419355 3.666 3.616 3.475 3.295 3.224 2.934
0.870967741935484 2.886 2.866 2.792 2.556 2.488 2.214
0.903225806451613 2.093 2.055 1.934 1.843 1.817 1.618
0.935483870967742 1.633 1.606 1.545 1.475 1.441 1.159 *
```



```
0.1 10.195 10.144 9.9833 9.7369 9.6318
    9.5144
    6.51483666666667
```

Inputs generated by pe4.pl - 8-August-2003
Data used for this run:
Output File: flu2laer
Metfile: w13893.dvf
PRZM scenario: MSsoybeanC.txt
EXAMS environment file: pond298.exv
Chemical Name: flusilazole
Description Variable Name Value Units Comments
Molecular weight mwt $315.1 \mathrm{~g} / \mathrm{mol}$
Henry's Law Const. henry atm-m^3/mol
Vapor Pressure vapr $2.9 \mathrm{E}-7$ torr

```
Solubility sol 41.9 mg/L
Kd Kd mg/L
Koc Koc 1642 mg/L
Photolysis half-life kdp 0 days Half-life
Aerobic Aquatic Metabolism kbacw }1537\mathrm{ days Halfife
Anaerobic Aquatic Metabolism kbacs 2025 days Halfife
Aerobic Soil Metabolism asm 769 days Halfife
Hydrolysis: pH 5 0 days Half-life
Hydrolysis: pH 7 0 days Half-life
Hydrolysis: pH 9 0 days Half-life
Method: CAM 2 integer See PRZM manual
Incorporation Depth: DEPI 0 cm
Application Rate: TAPP 0.115 kg/ha
Application Efficiency: APPEFF 0.95 fraction
Spray Drift DRFT 0.05 fraction of application rate applied to pond
Application Date Date 01-06 dd/mm or dd/mmm or dd-mm or dd-mmm
Interval 1 interval 21 days set to 0 or delete line for single
app.
Record 17: FILTRA
    IPSCND 3
    UPTKF
Record 18: PLVKRT
    PLDKRT
    FEXTRC 0.5
Flag for Index Res. Run IR Pond
Flag for runoff calc. RUNOFF none none, monthly or
total(average of entire run)
```


## 4. Ground spray foliar application to soybeans with a 21-day interval.

stored as flu21ground.out
Chemical: flusilazole
PRZM environment: MSsoybeanC.txt modified Satday, 12 October 2002 at 17:07:44
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w13893.dvf modified Wedday, 3 July 2002 at 09:06:20
Water segment concentrations (ppb)


| 1977 | 6.624 | 6.604 | 6.545 | 6.442 | 6.442 | 6.348 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| 1978 | 7.85 | 7.785 | 7.62 | 7.18 | 7.046 | 6.755 |
| 1979 | 7.559 | 7.526 | 7.456 | 7.357 | 7.3 | 7.271 |
| 1980 | 9.047 | 8.943 | 8.61 | 8.392 | 8.239 | 7.732 |
| 1981 | 8.372 | 8.324 | 8.215 | 8.042 | 7.957 | 7.877 |
| 1982 | 8.695 | 8.667 | 8.503 .8 .242 | 8.157 | 8.046 |  |
| 1983 | 8.947 | 8.885 | 8.743 | 8.428 | 8.298 | 8.174 |
| 1984 | 8.589 | 8.563 | 8.479 | 8.419 | 8.404 | 8.301 |
| 1985 | 8.42 | 8.383 | 8.31 | 8.227 | 8.216 | 8.125 |
| 1986 | 8.855 | 8.806 | 8.592 | 8.381 | 8.146 | 7.936 |
| 1987 | 9.117 | 9.062 | 8.583 | 8.439 | 8.23 | 8.082 |
| 1988 | 9.263 | 9.196 | 9.043 | 8.7 | 8.611 | 8.438 |
| 1989 | 9.486 | 9.423 | 9.236 | 9.004 | 8.923 | 8.798 |
| 1990 | 9.047 | 9.012 | 8.957 | 8.883 | 8.839 | 8.696 |

[^0]

## Appendix B. Ecological Effects Characterization

In screening-level ecological risk assessments, effects characterization describes the types of effects a pesticide can produce in an animal or plant. This characterization is generally based on registrant-submitted studies, to the Agency and/or the OECD, that describe acute and chronic effects information for various aquatic and terrestrial animals.

Toxicity testing reported in this section represents all species of birds, mammals, or aquatic organisms. However, 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. Estuarine/marine organisms were not evaluated. For mammals, toxicity studies are limited the laboratory rat. Also, neither reptiles nor amphibians are tested. The risk assessment assumes that avian and reptilian and terrestrial-phase amphibian toxicities are similar. The same assumption is used for fish and aquatic-phase amphibians. No terrestrial plant data was available for this assessment; one green alga study represents potential toxicity to all aquatic plant species.

## 1. Aquatic Animals <br> a. Acute Effects <br> Fish

Two acute fish toxicity studies were submitted to the Agency for review. Agency scientists judged both studies acceptable. OECD used these two studies in their registration assessment for flusilazole. Endpoints used in this risk assessment are summarized in Table 8.

In a study (Hutton and Hall, 1983; MRD 137632) with the coldwater species, rainbow trout (Onchorhynchus mykiss, previously Salmo gairdneri), the $96-\mathrm{hr}_{\mathrm{LC}}^{50}$ was determined by Agency scientists to be 0.39 mg ai $/ l$. The OECD set the $\mathrm{LC}_{50}$ from their rainbow trout study at 1.2 mg ai/l and lists 0.39 mg ai/l as the LOEC. In the other study (Hutton and Hall, 1983; MRID 137631), which used the warmwater bluegill sunfish (Lepomis macrochirus), determined a $96-\mathrm{hr}$ $\mathrm{LC}_{50}$ of 1.7 mg ai $/ \mathrm{l}$, an endpoint accepted by both the Agency and OECD. An additional warmwater fish study, following GLP, was submitted to the Agency (Bear, 1992; MRID 422430 01). The study, considered acceptable, established an $\mathrm{LC}_{50}$ for channel catfish (Ictalurus punctatus) of 0.42 mg ai/l. Flusilazole is categorized as highly toxic to fish, though sensitivity appears to vary. The endpoint used in this risk assessment is the $\mathrm{LC}_{50}$ for the channel catfish, 0.42 mg ai$/ \mathrm{l}$.

## Invertebrates

An acute study evaluating the toxicity of flusilazole to the freshwater invertebrate, Daphnia magna, was conducted by Hutton and Hall, 1983 (MRID 137633), establishing an EC E $_{50}$ of 3.4 mg ai $/ 1$. The study was categorized as acceptable. Flusilazole is categorized as moderately toxic to aquatic invertebrates.

## b. Chronic Effects <br> Fish

A fish early life-stage test, by Forbis, 1985 (MRD 400421-40), was conducted with rainbow trout (Onchorhynchus mykiss, previously Salmo gairdneri). According to Agency reviews, the study does not fulfill guidelines, as a NOAEC was not defined. The LOEC for the study was established as 0.03 mg ai $/ \mathrm{l}$, based on reduced growth (length and weight) of fry after 60 days. Using the same study, OECD concluded that the statistically significant reduction in length
at 0.03 mg ai/l was not biologically significant ( $8.5 \%$ reduction), and thus established the NOAEC at 0.03 mg ai/l. OECD did not detect a significant reduction in fry weight after 60 days at $0.03 \mathrm{mg} \mathrm{ai} / 1(30 \mathrm{ppb})$.

A second fish early life-stage test (Hoke, 2000; MRID 45107701) using rainbow trout (Onchorhynchus mykiss), reviewed by the OECD, established a NOAEC of 3.3 ppb . The NOAEC was based on reduced length and weight of survivors and larval abnormalities. This endpoint was used in this assessment.

The OECD reviewed a fish full life-cycle study. The test was initiated with newly fertilized fathead minnow (Pimephales promelas), at nominal concentrations of 0 (control), 3.1, $6.3,13,25,50$ and $100 \mu \mathrm{gai} / \mathrm{l}$. At initiation, there were 50 embryos per replicate, four replicates per test concentration. The replicates were impartially thinned after 48 hours to 25 individuals per replicate. No statistically significant differences were detected between the control and any test concentration for hatchability or survival in either the F0 or F1 generations. There was no statistically significant effect on growth in the F0 generation at any test concentration, but significant differences were detected at the 48 ppb concentration ( $3 \%$ reduction in length) in the F1 generation.

## Invertebrates

A life-cycle test was conducted with Daphnia magna to determine the chronic toxicity of flusilazole to aquatic invertebrates. The study was submitted to the Agency as Hutton, 1985 (MRID 400421-41) and established the NOAEC as 0.27 mg ai $/ \mathrm{l}$. The OECD assessment cites a study as Hutton, 1986, which yielded the same end point, based on reduction in daphnid length and in number of young produced.

A study on the benthic-dwelling midge (Chironomus riparius) established a NOAEC of $>9.96 \mathrm{ppb}$ over 28 -day continuous exposure. This study was reviewed by the OECD and reported greater than $85 \%$ of nominal concentrations bound to sediments.

Table A. Summary of endpoints used in aquatic risk estimation.

| Species | Acute Toxicity |  |  |
| :---: | :---: | :---: | :---: |
| Channel catfish Ictalurus punctatus 96 hr static unaerated | $\mathrm{LC}_{50}$ | $0.42 \mathrm{mg} \mathrm{ai} / \mathrm{l}$ | Moderately Toxic (Bear, 1992) |
| Water flea Daphnia magna 48 hr static unaerated | $\mathrm{LC}_{50}$ | 3.4 mg ai/l | Moderately Toxic (Hutton and Hall, 1983) <br> MRID 137633 |
|  | Chronic Toxicity |  |  |
| Rainbow Trout Onchorhynchus mykiss <br> Early life-stage | NOEC | $3.3 \mu \mathrm{gai} / \mathrm{L}$ | effects on length and weight of offspring, abnormal young (Hoke, R.A., 2000) not yet reviewed MRID 451077-01 |
| Water flea Daphnia magna Life-cycle | NOEC | $270 \mu \mathrm{gai} / \mathrm{L}$ | reduced number of young produced (Hutton and Hall, 1985 MRID 400421-41) |

2. Terrestrial Animals
a. Mammalian

Acute Oral
The acute oral toxicity of flusilazole was tested in $\mathrm{Crl}: \mathrm{CD}$ rats. The study, conducted in 1983 (cited as Wylie, 1984), is reported to have been in compliance with GLP and conformed to the OECD 401 guideline. Ten rats of each sex, per level, were given a single dose by gavage of flusilazole (as INH-6573-49; 97\% pure), using a corn oil carrier. Males received doses of 200, $500,900,1100$ or $1300 \mathrm{mg} / \mathrm{kg}$ and females received doses of $500,700,800,1000,1300$ or 1500 $\mathrm{mg} / \mathrm{kg}$. Deficiencies reported were that clinical signs and necropsy results were inadequately documented. Otherwise, the study was considered acceptable.

Reported results indicate mortality among females at all dose levels 2-3 days postadministration. Mortalities among males were limited to concentrations of $900 \mathrm{mg} / \mathrm{kg}$ and higher 2-4 days post-administration. Weight loss, described as slight to severe was seen in surviving females at higher dose levels and in males at all but the lowest dose tested. Clinical signs of toxicity reported are diarrhea, hunched posture, lethargy, weakness, alopecia and ruffled fur. These signs were seen in females at all dose levels, increasing in severity with dosage tested. It was not reported at what dose levels clinical signs of toxicity were observed in males. Necropsies on premature decedents revealed non-specific abnormalities, including discolored lungs, distended stomachs and dark livers. A small number of 'cranial-mengial' hemorrhages were reported, which is thought to mean 'cranial-meningeal'. No abnormalities were reported in the survivors. The study concludes that the $\mathrm{LD}_{50}$ is $1110 \mathrm{mg} / \mathrm{kg}$ for male rats and $674 \mathrm{mg} / \mathrm{kg}$ for females. Endpoints used in terrestrial risk estimation are presented in Table 9.

## Chronic 2-generation rat study

Two 2-generation rat toxicity studies were submitted to OECD for review. One study, cited as Pastoor, 1986, was a sub-study of a two-year feeding study (guideline EC B35). A second study was conducted in 1990, and cited as Mullin 1990. The second study was consistent with guideline EC B36.

The first study, which tested rats at $0,10,50$ and 250 ppm , showed no significant signs of parental toxicity. Reduced 0-4 day viability of pups was observed at the highest dose tested. Increased liver weight was also seen in pups at the highest dose, and the reported NOAEC is 50 ppm.

In the second study, flusilazole (as DPX H6573-193; 94\% pure) was added to the diet of 30 (per sex, per dose) Crl:CDBR rats. Test concentrations of $0,5,50$ and 250 ppm were administered from the start of a 73-day pre-mating period and continued through the breeding of second generation litters. Parental effects reported significant body weight reductions postdelivery in F0 females at the 50 and 250 ppm levels. No clinical signs of toxicity were observed. An increased gestation length was observed in all matings at the highest dose. A total of 11 dams died periparturition, and they were considered treatment related. The reported NOAEC is 50 ppm , based on increased gestation length, periparturient mortality and reduced viability of pups.

## b. Avian <br> Acute Oral Toxicity

To evaluate the acute oral toxicity of flusilazole on birds, a study by Beavers, 1983 (ID number 112-141) was submitted to the EPA for review. Groups of five male and five female mallard ducks (Anas platyrhynchos) were dosed by oral gavage at $0,398,631,1000,1590$ and 2570 mg ai $/ \mathrm{kg}$ body weight. The study was conducted under EPA guideline $71-1$ in 1982, prior to implementation of GLP, and was considered acceptable. Flusilazole ( $97.3 \%$ pure) was administered in a corn oil carrier, and birds were observed for 14 days. Effects were reported as a dose-related reduction in food consumption ( $9-58 \mathrm{~g}$ ) between 0-3 days. Over the next four days, food consumption increased back to levels comparable to the control. The reduction of food consumed resulted in reduction of body weights in the 1000 mg and greater doses over the first three days, though body weights were unaffected by study termination. One mortality occurred in the $1590 \mathrm{mg} / \mathrm{kg}$ dose group on day four, although no other signs of toxicity were reported for this group. Regurgitation was noted in 'some' birds at the $2570 \mathrm{mg} / \mathrm{kg}$ dose. The $\mathrm{LD}_{50}$ was taken to be $>1590 \mathrm{mg} / \mathrm{kg} \mathrm{bw}$, since it was the highest dose that regurgitation did not occur.

## Acute Dietary Toxicity

A five-day feeding study (EPA guideline 71-2), conducted by Beavers, 1983, was submitted to the Agency for review (ID number 112-139). Twelve-day-old bobwhite quail (Colinus virginianus) were exposed to nominal dietary concentrations of 562, 1000, 1780, 3160 and $5620 \mathrm{ppm}, 10$ birds per concentration level. Control birds received a basal diet with $2 \%$ corn oil; all birds received the basal diet during a three-day observation period prior to the study. Symptoms of toxicity were observed in the 1000 ppm level and greater. Symptoms included lethargy and reduced reaction to external stimuli on days 2-4 and toe picking on day five. Nostril picking was observed in many of the birds at the 3160 ppm level. Single mortalities occurred on day four at the 1780 ppm level and day 7 in the 3610 ppm level. At the 5620 ppm level, there were two mortalities (days 2 and 4), and lethargy, reduced reaction, wing droop, lower limb weakness and depression were observed. Most birds were reported asymptomatic from day five, though symptoms persisted in some birds through day eight. A concentration related weight gain reduction of $7-16 \mathrm{~g}$ was observed in bird in the 1000 ppm level and greater. Food consumption was reduced with increasing concentration. The $\mathrm{LC}_{50}$ was established as $>5620 \mathrm{ppm}$ with the NOEL for the study 562 ppm .

A second five-day feeding study (EPA guideline 71-2), also conducted by Beavers, 1983, was submitted to the Agency for review (ID number 112-140). Ten-day-old mallard ducks (Anas
platyrhynchos) were exposed to nominal dietary concentrations of 562, 1000, 1780, 3160 and $5620 \mathrm{ppm}, 10$ birds per concentration level. Control birds received a basal diet with $2 \%$ corn oil; all birds received the basal diet during a three-day observation period prior to the study. Symptoms of toxicity observed in the 562 and 1000 ppm levels were lethargy, increasing in severity through day five, though all birds had recovered by day seven. Seven mortalities occurred at the 1780 ppm level, and mortality was a $100 \%$ in the 3160 and 5620 ppm levels. A concentration-related reduction in food consumption was observed with increasing severity with concentration. The $\mathrm{LC}_{50}$ was established at 1584 ppm with a NOAEL undetermined due to symptoms at the lowest dose tested.

## Chronic Toxicity

To evaluate the chronic toxicity of flusilazole to birds, a one-generation reproduction study was conducted by Beavers, 1985 (MRID 400421-36) and submitted to the Agency for review. Sixteen bobwhite quail (Colinus virginianus) of each sex per level were fed feed containing $0,25,125$ or 625 mg ai$/ \mathrm{kg}$ diet ( ppm ) with a $0.03 \%$ corn oil carrier. No signs of adult toxicity were observed and adult body weights were unaffected. Two incidental deaths were reported, one in the control and one at the 125 ppm level. Reproductive parameters were observed at the 125 ppm level and above, with cracked eggs, hatchlings and 14-day survivors being affected. The NOAEC was established at 25 ppm .

Another reproduction study was submitted to the Agency for review (Beavers, 1985; MRID 400421-37). Sixteen mallard ducks (Anas platyrhynchos) of each sex per level were fed feed containing $0,25,125$ or 625 mg ai $/ \mathrm{kg}$ diet (ppm) with a $0.03 \%$ corn oil carrier. No signs of adult toxicity were observed and adult body weights were unaffected. However, necropsies revealed an increase in egg yolk peritonitis in hens (8/16) and increased fatty degeneration of the liver in drakes $(6 / 16)$ at the 625 ppm level. Reproductive effects were increased number of cracked eggs and a decrease in eggshell thickness at both the 125 and 625 ppm levels. The NOAEC was established at 25 ppm , however the Agency reviewer noted appreciable eggshell thinning at the lowest dose. While not statistically significant, the thinning may be of biological relevance and a confirmatory study was requested.

## c. Other Terrestrial Animals <br> Nontarget Insects

An acute contact study with the honeybee (Apis mellifera) was conducted to evaluate the toxicity of flusilazole to insects. The study, by Meade, 1984 (MRID 400421-42) was considered acceptable by EPA reviewers, who established the $\mathrm{LC}_{50}$ as greater than $150 \mu \mathrm{~g} /$ bee, classifying flusilazole as practically nontoxic to honey bees. The OECD, evaluating the same study, established the $\mathrm{LD}_{50}=165 \mu \mathrm{~g} /$ bee, which was the study author's conclusion using probit analysis. While the study report states that bees were observed for behavioral responses, none were reported.

## Earthworms

Three tess using artificial soils were conducted as part of one study (Meade, 1986) examining the toxicity of flusilazole to earthworms (Eisenia foetida). In all three tests, flusilazole was dissolved in acetone and administered to the soil at rates up to 2000 mg ai $/ \mathrm{kg}$ soil. The results of the three tests lead to different conclusions. In test A , the $\mathrm{LC}_{50}$ was determined to be $34.9 \mathrm{mg} \mathrm{ai} / \mathrm{kg}$ soil. However, in the other two tests, the $\mathrm{LC}_{50}$ was determined to be 387.5 and 388.2 mg ai$/ \mathrm{kg}$. The use of chloroacetamide as a reference substance in all three tests led the

OECD reviewers to discount the test A as aberrant and set the $\mathrm{LC}_{50}=388 \mathrm{mg}$ ai$/ \mathrm{kg}$ soil with a NOEC $=100 \mathrm{mg} \mathrm{ai} / \mathrm{kg}$ soil.

Table B. Summary of endpoints used in terrestrial risk estimation.

| Species | Acute Toxicity |  |  |  | Chronic Toxicity |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\mathbf{L D}_{50}$ | Acute Oral Toxicity | $\mathbf{L C}_{50}$ | Subacute Dietary Toxicity | NOAEC(L) | Affected <br> Endpoints |
| Northern Bobwhite Quail (Colinus virginianus) | -- | -- | $\begin{gathered} >5620 \\ \text { mg ai } / \mathrm{kg} \text { diet } \end{gathered}$ | practically nontoxic (Beavers, 1983) | $25$ <br> mg ai/ kg diet | offspring survival <br> (Beavers, 1985) |
| Mallard duck <br> (Anas <br> platyrhynchos) | $>1590$ $\mathrm{mg} / \mathrm{kg}-$ bwt | practically nontoxic (Beavers, 1983) | 1584 mg ai/kg-diet | slightly toxic (Beavers, 1983) | $25$ <br> mg ai/ kg diet | Egg shell thickness, increases in cracked eggs <br> (Beavers, 1985) |
| Laboratory rat (Rattus norvegicus) female |  | slightly toxic (Wylie, 1984) | -- | -- | $50$ <br> $\mathrm{mg} \mathrm{ai} / \mathrm{kg}$ diet | increased gestation length, reduced pup viability <br> (Pastoor, 1986) |
| 3. Plants <br> a. Terrestrial Plants |  |  |  |  |  |  |

There have been no studies submitted to the Agency or reported by the OECD, which evaluate the toxicity of flusilazole to terrestrial plants. Risk to terrestrial plants or the animals that depend upon them cannot be evaluated in this assessment, and cannot be precluded.
b. Aquatic Plants

In a study by Douglas and Handley, 1987, the green alga species Selenastrum capricornutum was tested for toxicity to flusilazole. The study was reviewed by OECD, which reported that the 120$\mathrm{hr} \mathrm{EC}_{50}$, based on reduced frond numbers, was 7.9 mg ai/l. However, this study (MRID 41534806) was classified as invalid by Agency reviewers due to numerous guideline deviations. In a subsequent study, apparently not reviewed by OECD, Selenastrum capricornutum was again tested for toxicity to flusilazole (Thompson, 1995; MRID 438787-01), and the study was classified as acceptable. This study established an $\mathrm{EC}_{50}=0.20 \mathrm{mg}$ ai $/ \mathrm{l}$, though a NOEC was not established ( $<0.17 \mathrm{mg} \mathrm{ai} / 1$ ), the $\mathrm{EC}_{05}$ was calculated to be 0.09 mg ai $/ \mathrm{l}$. Both the OECD and the EPA consider flusilazole to be algistatic, rather than algicidal, based on the results of the respective studies.

## APPENDIX C: Points to Consider in Development of Risk Description for Birds and Mammals

## Acute and Reproduction Dietary Discussions

The risk assessment includes numerous calculations of dietary exposure for multiple weight classes of animals. However, there are energetic considerations that suggest that some weight class/food item combinations are not likely to naturally occur. For example, there are not likely to be many 15 g mammals or 20 g birds that exclusively feed on vegetation. The risk assessor is urged to consult such texts as the Wildlife Exposure Factors Handbook (USEPA 1993), for more comprehensive approaches to consider energy requirements and energy availability to estimate dietary exposure. In addition, age of individuals may also play an important role in the types and relative amounts of food items selected. This should also be taken into account when describing dietary risks.

## Acute Toxicity RQ Approaches

Dose-based and dietary-based acute RQs should be provided to risk managers whenever effects data allow. There are limitations to each approach. The dose-based approach assumes that the uptake and absorption kinetics of a gavage toxicity study approximate the absorption associated with uptake from a dietary matrix. Toxic response is a function of duration and intensity of exposure and the importance of absorption kinetics across the gut and the importance of enzymatic activation/deactivation of a toxicant may be important and are likely variable across chemicals and species. For many compounds a gavage dose represents a very short-term high intensity exposure, where dietary exposure may be of a more prolonged nature. The dietarybased approach assumes that animals in the field are consuming food at a rate similar to that of confined laboratory animals. Energy content in food items differs between the field and the laboratory as does the energy requirements of wild and captive animals. The Wildlife Exposure Factors Handbook can provide insights into energy requirements of animals in the wild as well as energy content of their diets

## Reproduction RQ Approach

The typical 21-week avian reproduction study does not define the true exposure duration needed to elicit the observed responses. The study protocol was designed to establish a steady-state tissue concentration for bioaccumulative compounds. For other pesticides, it is entirely possible that steady-state tissue concentrations are achieved earlier than the 21-week exposure period. Moreover, pesticides may exert effects at critical periods of the reproduction cycle and so long term exposure may not be necessary to elicit the effect observed in the 21-week protocol. The EFED screening risk assessment uses the single-day upper-bound estimated EEC as a conservative approach. The degree to which this exposure is conservative cannot be determined by the existing reproduction study. However, risk assessment discussions should be accompanied by the graphics from the T-REX model regarding the number of days dietary exposure is above the NOAEC. The greater number of days EECs exceed the NOAEC, the greater the confidence in predictions of reproductive risk concerns.

USEPA. 1993. Wildlife Exposure Factors Handbook. Volume I of II. EPA/600/R-93/187a. Office of Research and Development, Washington, DC 20460.

## APPENDIX D: Risk Quotient Method

The Risk Quotient Method is the means used by EFED to integrate the results of exposure and ecotoxicity data. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values (i.e., RQ = EXPOSURE/TOXICITY), both acute and chronic. These RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. EFED has defined LOCs for acute risk, potential restricted use classification, and for endangered species.

The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories:
(1) acute - there is a potential for acute risk; regulatory action may be warranted in addition to restricted use classification;
(2) acute restricted use - the potential for acute risk is high, but this may be mitigated through restricted use classification
(3) acute endangered species - the potential for acute risk to endangered species is high, regulatory action may be warranted, and
(4) chronic risk - the potential for chronic risk is high, regulatory action may be warranted.
Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) $\mathrm{LC}_{50}$ (fish and birds), (2) $\mathrm{LD}_{50}$ (birds and mammals), (3) $\mathrm{EC}_{50}$ (aquatic plants and aquatic invertebrates), and (4) $\mathrm{EC}_{25}$ (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEL (birds, fish, and aquatic invertebrates), and (2) NOAEL (birds, fish and aquatic invertebrates). The NOAEL is generally used as the ecotoxicity test value in assessing chronic effects.

Risk presumptions, along with the corresponding RQs and LOCs are summarized in Table C.


## Appendix E: Species Taxa Count Report for Crops

## Soybeans for beans (acres)

No species were excluded
Minimum of 1 Acre.
$A L, A K, A Z, A R, C A, C O, C T, D E, D C, F L, G A, H I, I D, I L, I N, I A, K S, K Y, L A, M E, M D$, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY

## Alabama

The taxa Amphibian has 2 species affected by indicated crops.
The taxa Bird has 4 species affected by indicated crops.
The taxa Bivalve has 29 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 15 species affected by indicated crops.
The taxa Gastropod has 10 species affected by indicated crops.
The taxa Mammal has 4 species affected by indicated crops.
The taxa Plant has 14 species affected by indicated crops.
The taxa Reptile has 5 species affected by indicated crops.

## Arkansas

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 5 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 3 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.
The taxa Plant has 3 species affected by indicated crops.

## Colorado

The taxa Bird has 2 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.

## Connecticut

The taxa Bird has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Delaware

The taxa Bird has 2 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 2 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Florida

The taxa Amphibian has 1 species affected by indicated crops.
The taxa Bird has 8 species affected by indicated crops.
The taxa Bivalve has 7 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Mammal has 6 species affected by indicated crops.
The taxa Plant has 26 species affected by indicated crops.
The taxa Reptile has 6 species affected by indicated crops.

## Georgia

The taxa Amphibian has 1 species affected by indicated crops.
The taxa Bird has 5 species affected by indicated crops.
The taxa Bivalve has 15 species affected by indicated crops.
The taxa Fish has 11 species affected by indicated crops.
The taxa Mammal has 4 species affected by indicated crops.
The taxa Plant has 16 species affected by indicated crops.
The taxa Reptile has 2 species affected by indicated crops.

## Hawaii

The taxa Arachnid has 1 species affected by indicated crops.
The taxa Bird has 13 species affected by indicated crops.

The taxa Crustacean has 1 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 85 species affected by indicated crops.
The taxa Reptile has 2 species affected by indicated crops.

## Illinois

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 7 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Insect has 2 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 9 species affected by indicated crops.

## Indiana

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 11 species affected by indicated crops.
The taxa Insect has 2 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 5 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Iowa

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.
The taxa Plant has 6 species affected by indicated crops.

## Kansas

The taxa Bird has 4 species affected by indicated crops.

The taxa Fish has 4 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 2 species affected by indicated crops.

## Kentucky

The taxa Bird has 7 species affected by indicated crops.
The taxa Bivalve has 22 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 5 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 5 species affected by indicated crops.
The taxa Plant has 10 species affected by indicated crops.

## Louisiana

The taxa Bird has 6 species affected by indicated crops.
The taxa Bivalve has 3 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.
The taxa Plant has 2 species affected by indicated crops.
The taxa Reptile has 6 species affected by indicated crops.

## Maine

The taxa Bird has 3 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 3 species affected by indicated crops.

## Maryland

The taxa Bird has 2 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Insect has 2 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.

The taxa Plant has 6 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Massachusetts

The taxa Bird has 2 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Michigan

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Insect has 4 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.
The taxa Plant has 6 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Minnesota

The taxa Bird has 2 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 4 species affected by indicated crops.

## Mississippi

The taxa Bird has 6 species affected by indicated crops.
The taxa Bivalve has 9 species affected by indicated crops.
The taxa Fish has 3 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.
The taxa Plant has 3 species affected by indicated crops.

The taxa Reptile has 6 species affected by indicated crops.

## Missouri

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 6 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 7 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Insect has 3 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 8 species affected by indicated crops.

## Montana

The taxa Bird has 4 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.

## Nebraska

The taxa Bird has 4 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops
The taxa Plant has 2 species affected by indicated crops.

## New Jersey

The taxa Bird has 3 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 5 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## New Mexico

The taxa Bird has 2 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.
New York

The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 6 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## North Carolina

The taxa Arachnid has 1 species affected by indicated crops.
The taxa Bird has 5 species affected by indicated crops.
The taxa Bivalve has 8 species affected by indicated crops.
The taxa Fish has 3 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 7 species affected by indicated crops.
The taxa Plant has 26 species affected by indicated crops.
The taxa Reptile has 6 species affected by indicated crops.

## North Dakota

The taxa Bird has 4 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.

## Ohio

The taxa Bird has 2 species affected by indicated crops.
The taxa Bivalve has 6 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Insect has 4 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 6 species affected by indicated crops.
The taxa Reptile has 2 species affected by indicated crops.
Oklahoma

The taxa Bird has 7 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Fish has 4 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 3 species affected by indicated crops.
The taxa Plant has 2 species affected by indicated crops.

## PennsyIvania

The taxa Bird has 2 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 2 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## Rhode Island

The taxa Bird has 1 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.

## South Carolina

The taxa Amphibian has 1 species affected by indicated crops.
The taxa Bird has 4 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Fish has 1 species affected by indicated crops.
The taxa Mammal has 9 species affected by indicated crops.
The taxa Plant has 20 species affected by indicated crops.
The taxa Reptile has 6 species affected by indicated crops.

## South Dakota

The taxa Bird has 4 species affected by indicated crops.
The taxa Fish has 2 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.

The taxa Mammal has 1 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.

## Tennessee

The taxa Arachnid has 1 species affected by indicated crops.
The taxa Bird has 4 species affected by indicated crops.
The taxa Bivalve has 37 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 15 species affected by indicated crops.
The taxa Gastropod has 3 species affected by indicated crops.
The taxa Mammal has 4 species affected by indicated crops.
The taxa Plant has 20 species affected by indicated crops.

## Texas

The taxa Amphibian has 3 species affected by indicated crops.
The taxa Arachnid has 7 species affected by indicated crops.
The taxa Bird has 13 species affected by indicated crops.
The taxa Crustacean has 1 species affected by indicated crops.
The taxa Fish has 3 species affected by indicated crops.
The taxa Insect has 6 species affected by indicated crops.
The taxa Mammal has 4 species affected by indicated crops.
The taxa Plant has 16 species affected by indicated crops.
The taxa Reptile has 6 species affected by indicated crops.

## Vermont

The taxa Bird has 1 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Mammal has 1 species affected by indicated crops.
The taxa Plant has 1 species affected by indicated crops.

## Virginia

The taxa Amphibian has 1 species affected by indicated crops.
The taxa Bird has 3 species affected by indicated crops.
The taxa Bivalve has 15 species affected by indicated crops.

The taxa Crustacean has 2 species affected by indicated crops.
The taxa Fish has 4 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Insect has 1 species affected by indicated crops.
The taxa Mammal has 6 species affected by indicated crops.
The taxa Plant has 12 species affected by indicated crops.
The taxa Reptile has 1 species affected by indicated crops.

## West Virginia

The taxa Amphibian has 1 species affected by indicated crops.
The taxa Bird has 1 species affected by indicated crops.
The taxa Bivalve has 1 species affected by indicated crops.
The taxa Gastropod has 1 species affected by indicated crops.
The taxa Mammal has 4 species affected by indicated crops.
The taxa Plant has 4 species affected by indicated crops.

## Wisconsin

The taxa Bird has 4 species affected by indicated crops.
The taxa Bivalve has 2 species affected by indicated crops.
The taxa Insect has 3 species affected by indicated crops.
The taxa Mammal has 2 species affected by indicated crops.
The taxa Plant has 6 species affected by indicated crops.


[^0]:    Sorted results
    Prob. Peak 96 hr 21 Day 60 Day 90 Day Yearly
    $0.0322580645161299 .486 \quad 9.423 \quad 9.2369 .004 \quad 8.923 \quad 8.798$
    $\begin{array}{llllllll}0.0645161290322581 & 9.263 & 9.196 & 9.043 & 8.883 & 8.839 & 8.696\end{array}$
    $\begin{array}{llllllll}0.0967741935483871 & 9.117 & 9.062 & 8.957 & 8.7 & 8.611 & 8.438\end{array}$
    $0.1290322580645169 .047 \quad 9.012 \quad 8.7438 .4398 .4048 .301$
    0.1612903225806459 .0478 .9438 .6188 .4288 .2988 .174
    $\begin{array}{lllllll}0.193548387096774 & 8.947 & 8.885 & 8.592 & 8.419 & 8.239 & 8.125\end{array}$
    $\begin{array}{lllllllll}0.225806451612903 & 8.855 & 8.806 & 8.583 & 8.392 & 8.23 & 8.082\end{array}$
    0.2580645161290328 .6958 .6678 .5038 .3818 .2168 .046
    $0.2903225806451618 .5898 .5638 .4798 .242 \quad 8.157 \quad 7.936$
    $\begin{array}{lllllllll}0.32258064516129 & 8.42 & 8.383 & 8.31 & 8.227 & 8.146 & 7.877\end{array}$
    $\begin{array}{lllllllll}0.354838709677419 & 8.372 & 8.324 & 8.215 & 8.042 & 7.957 & 7.732\end{array}$
    $\begin{array}{llllllll}0.387096774193548 & 7.85 & 7.785 & 7.62 & 7.357 & 7.3 & 7.271\end{array}$
    $\begin{array}{llllllll}0.419354838709677 & 7.559 & 7.526 & 7.456 & 7.18 & 7.046 & 6.755\end{array}$
    $0.451612903225806 \quad 6.942 \quad 6.883 \quad 6.694 \quad 6.524 \quad 6.499 \quad 6.348$
    $0.483870967741936 \quad 6.624 \quad 6.604 \quad 6.545 \quad 6.442 \quad 6.442 \quad 6.289$
    $0.516129032258065 \quad 6.529 \quad 6.492 \quad 6.397 \quad 6.324 \quad 6.301 \quad 6.193$
    $\begin{array}{llllllll}0.548387096774194 & 6.462 & 6.448 & 6.396 & 6.32 & 6.286 & 6.16\end{array}$
    $\begin{array}{lllllllll}0.580645161290323 & 6.273 & 6.224 & 6.122 & 5.974 & 5.925 & 5.76\end{array}$
    $0.612903225806452 \quad 6.093 \quad 6.018 \quad 5.903 \quad 5.769 \quad 5.652 \quad 5.231$
    0.6451612903225815 .3525 .3145 .1845 .0094 .9394 .842
    $\begin{array}{lllllllll}0.67741935483871 & 5.042 & 5.011 & 4.954 & 4.883 & 4.838 & 4.752\end{array}$
    $\begin{array}{lllllllll}0.709677419354839 & 5.023 & 4.96 & 4.808 & 4.555 & 4.462 & 4.26\end{array}$
    $0.7419354838709684 .3784 .3334 .2084 .1054 .102 \quad 3.782$
    $\begin{array}{llllllll}0.774193548387097 & 3.69 & 3.664 & 3.609 & 3.436 & 3.396 & 3.226\end{array}$
    $\begin{array}{llllllll}0.806451612903226 & 3.204 & 3.152 & 3.013 & 2.934 & 2.944 & 2.855\end{array}$
    $0.8387096774193553 .123 \quad 3.1093 .008 \quad 2.825 \quad 2.7542 .477$
    $0.8709677419354842 .5062 .485^{\prime} 2.408 \quad 2.161 \quad 2.0891 .831$
    $\begin{array}{llllllll}0.903225806451613 & 1.559 & 1.544 & 1.496 & 1.438 & 1.433 & 1.324\end{array}$
    $\begin{array}{llllllll}0.935483870967742 & 1.42 & 1.391 & 1.328 & 1.257 & 1.223 & 0.97\end{array}$
    $\begin{array}{lllllll}0.967741935483871 & 1.191 & 1.143 & 1.01 & 0.7401 & 0.5305 & 0.1657\end{array}$

    | 0.1 | 9. 11 | 9.057 | 8.9356 | 8.6739 | 8.5903 | 8. |  |  |
    | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
    |  |  |  |  | Average | yearly | ges: |  | . 68989 |

    Inputs generated by pe4.pl - 8-August-2003
    Data used for this run:
    Output File: flu21ground
    Metfile: w13893.dvf
    PRZM scenario: MSsoybeanC.txt

