NEW CHEMICAL

ENVIRONMENTAL FATE AND EFFECTS SCIENCE CHAPTER

Environmental Fate and Ecological Risk Assessment

For

FLUOXASTROBIN (PC 028869)
E-[2-[[6-(2chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl]
(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone-O-methyloxime

and End Use Product:

HEC 480 SC (40.3% active ingredient)

E-isomer

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I. EXECUTIVE SUMMARY

A. Predicted Environmental Exposure

1. Nature of Chemical Stressor

Fluoxastrobin (HEC 5725) is a new "leaf-systemic" strobilurin fungicide developed by Bayer CropScience for use as a foliar spray to control leaf spot diseases and also as a seed treatment to suppress seed-borne disease and early season damping-off.

This report focused on assessing and characterizing potential risks resulting from the proposed agricultural uses of fluoxastrobin on peanuts, potato and tuber vegetables, leafy vegetables, and fruiting vegetables crops; on the recreational use on turf; and on the seed treatment use on potato (seed piece), peanut, and turf.

Terrestrial risk assessment was based on the EFED's ELL-Fate and Terr-Plant models. Since fluoxastrobin is a new chemical and no monitoring data is available, water resource assessment was also based on modeling. To simulate the most conservative surface water contamination for ecological risk assessment (ERA) purpose, standard PRZM/EXAMS scenarios associated with states having the highest US planted acreage and the highest exposure were selected for each crop: for *peanuts*, a standard North Carolina scenario was chosen; for *potato*, a standard Idaho and a standard Maine scenario; for *cabbage*, a standard Florida scenario; for *tomato*, a standard California and a standard Florida scenario; for *pepper*, a standard Florida scenario; and for *turf*, a standard Florida and a standard Pennsylvania scenario. To simulate the most conservative surface and ground water contamination for human health drinking water assessment (DWA), FIRST and SCI-GROW2, respectively, were modeled on turf, since turf has the highest application rate among all proposed uses.

Environmental Fate

Based on laboratory studies, direct photolysis in clear buffered solutions is the major route of degradation for fluoxastrobin (half-life of 20 - 28 days). However, caution must be used in extrapolating laboratory photolysis data to the environment, since photodegration in turbid and/or deeper waters may be limited by the attenuation of sunlight due to unfavorable conditions. Fluoxastrobin could persist for several months in non-sand soils to several years in sandy type soils. Fluoxastrobin is expected to have low to medium mobility, as it absorbs strongly to all tested soils. Under field conditions of intended use areas in the US, fluoxastrobin was shown to persist for over a year, however, did not seem to leach underground. This is in agreement with the SCI-GROW2 ground water modeling results; for fluoxastrobin use at the maximum allowable rate (turf, 4 applications per year, 0.55 lb ai/A), only negligible amount (less than one ppb) of this chemical is expected to reach the ground water system.

The slow biodegradation of fluoxastrobin compounded with low mobility in soils will increase fluoxastrobin potential to reach surface water via runoff. Furthermore, although foliar interception may reduce the amount of fluoxastrobin available for runoff, fluoxastrobin could also reach surface waters through spray drift, penetration of the canopy to the soil surface at application, and foliar washoff followed by runoff. PRZM/EXAMS modeling for ecological risk assessment and FIRST for drinking water assessment estimate peak fluoxastrobin concentrations in surface water of 39 ppb and 71 ppb, respectively.

The two major laboratory soil metabolites of fluoxastrobin were identified: HEC5725-E-des-chlorophenyl (HEC 7155) and HEC5725-carboxylic acid (HEC 7180). The only major water degradate was HEC5725-oxazepine, which forms through direct photolysis in water. However, a non guideline photolysis study performed in natural water/sediment systems indicates that the majority of applied fluoxastrobin adsorbed onto the sediment and no photolytic formation of oxazepine was observed under natural conditions. Under field conditions, only HEC5725-E-des-chlorophenyl was detected, at concentration below 10% of total applied. This metabolite was also detected in the deeper soil layers, but at less than 1% of total applied. This concurs with the laboratory findings of higher mobility of the metabolites compared to the parent. *Modeling of water resource contamination from the metabolites was not required by the HED RARC committee, due to their expected low concentration in the environment*.

Volatilization from soil and water is not expected to contribute significantly to the dissipation of fluoxastrobin into the environment, considering its low vapor pressure and Henry's Law constant. In addition, fluoxastrobin has low potential to bioaccumalate in fish.

B. Potential Risk to Non-target Organisms

The results of the risk assessment suggest the potential for direct effects to endangered freshwater fish, and both endangered and non-endangered freshwater invertebrates, estuarine/marine invertebrates, and mollusks. Specifically, RQ values for the following taxonomic groups exceed levels of concern established by the Agency for the screening-level risk assessment:

- Freshwater fish: RQs exceed acute endangered species LOCs.

- Freshwater invertebrates: RQs exceed acute restricted use and endangered species LOCs.

- Estuarine/marine invertebrates: RQs exceed acute high risk, restricted use, and endangered species LOCs. RQs also exceed chronic LOCs. Chronic effects for estuarine/marine invertebrates include reduced adult survival and reductions in wet weight of surviving adults, following a 28-day exposure duration.

- Estuarine/marine mollusks: RQs exceed chronic LOCs (based on an estimated NOAEC value).

Based on the risk characterization, the following hierarchy of sensitivity to fluoxastrobin exists for aquatic receptors: estuarine/marine invertebrates > freshwater invertebrates > freshwater fish. There is a high degree of uncertainty associated with the risk characterization for estuarine/marine mollusks, due to a lack of chronic toxicity data for these receptors.

Available acute toxicity information on the fluoxastrobin metabolites, HEC 7155 and HEC 7180, indicates that these metabolites are not a concern for aquatic animals or plants. In addition, potential risks associated with exposure of terrestrial and aquatic plants, birds, earthworms, and honeybees to the parent fluoxastrobin are not likely because all associated RQ values are well below levels of concern. Acute risks to mammals are also not likely.

Based on the high level of chronic and acute risk for estuarine/marine invertebrates and acute risks for freshwater invertebrates, there may be potential indirect effects to species of estuarine/marine and freshwater fish, amphibians, and/or water birds that depend on pelagic invertebrates as a source of food. Of particular concern, would be fish populations that rely on mysids as a primary source of food.

Chronic and acute exposure from multiple applications of fluoxastrobin was estimated using a 35-day foliar half-life, a default value used for terrestrial assessments in the absence of data. Although fluoxastrobin could persist in soils over a few months, according to Willis and McDowell (1987), the 35-day foliar half-life value could still result in overestimates of exposure of fluoxastrobin.

Major uncertainties associated with this assessment include the assumption of stability of the anaerobic aquatic metabolism due to “unacceptable” submitted data. Furthermore, the “unacceptable” status of the aerobic aquatic study also led to the assumption that this half-life is two times greater than that of the aerobic soil. In addition to persistence, there is uncertainty on which degradates may form under aerobic and anaerobic conditions, at what ratio, and where they predominantly partition (i.e., water column or sediment). Both of these assumptions may result in an overestimation of the surface water EECs.

Estimated chronic effects for estuarine/marine mollusks are uncertain because no chronic data were submitted by the registrant; therefore, the NOAEC value was estimated based on the acute-to-chronic ratio for mysid shrimp. The uncertainties associated with predicted risks to estuarine/marine mollusks could be reduced if chronic toxicity data on fluoxastrobin were provided to the Agency.

As previously mentioned, sediment-bound fluoxastrobin is persistent, and concentrations in suspended or bottom sediments are likely to be higher than those of the sediment interstitial pore water and/or water column. Given the potential risks to freshwater and estuarine/marine invertebrates based on fluoxastrobin concentrations in the water column, acute (10-day) and chronic (28-day) sediment toxicity testing, as described in the OPPTS 850.1735 and 850.1740 protocols, are recommended in order to evaluate risks to freshwater and estuarine/marine sediment dwelling organisms.

II. PROBLEM FORMULATION

A. Stressor Source and Distribution

1. Chemical and Physical Properties

Proposed Common Name:	Fluoxastrobin
Synonyms:	HEC5725
Chemical Name (CAS):	[2-[[6-(2chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl] (5,6-dihydro-1,4,2-dioxazin-3-yl)methanone-O-methyloxime
CAS Registry No.	(1E): 361377-29-9 (*E*-, *Z*-): 193740-76-0
Molecular Formula:	$C_{21}H_{16}ClFN_4O_5$
Molecular Weight:	458.8
Physical State:	White, slight crystalline solid
Vapor Pressure (@ 20 °C):	5.63 x 10^{-10} Pa
Henry Law Constant (@ 20 °C):	1.01 x 10^{-7} Pa x m^3 / mole
Solubility in water (@ 20 °C):	2.29 mg/L in pH 7 2.56 mg/L in unbuffered solution
Partition Coefficient in Octanol Water (log P_{ow}):	2.86 +/- 0.01
Dissociation Constant	no acidic or basic properties in water between pH 4 and 9

2. Mode of Action

Fluoxastrobin is a new “leaf-systemic” strobilurin fungicide developed by Bayer CropScience. Strobilurin fungicides are site-specific compounds that provide significant control of plant diseases caused by pathogens. They work by interfering with respiration in plant-pathogenic fungi. These types of fungicides also possess translaminar activity, therefore enabling them to move through treated leaves and providing control on both leaf surfaces. Fluoxastrobin is also shown to be effective in inhibiting spore germination and mycelial growth.

3. Use Characterization

If approved, fluoxastrobin technical will be formulated as a soluble concentrate, HEC 480 SC (40.3% ai). HEC 480 SC will be used as a foliar spray to control leaf spot diseases (*Phytophthora infestans, Alternaria solani, Rhynchosporium secalis, Pyrenophora teres, P. tritici-repentis, ...*), rusts, and mildew in plants and also as a seed treatment to suppress seed-borne disease and early season damping-off caused by Rhizoctonia solani. This is the first application for a seed treatment containing a strobilurin. **Table 1** summarizes the proposed use information for fluoxastrobin.

Table 1. Proposed Use Information for Fluoxastrobin

Crop (Application type)	**lb ai/A/appl.**	**No. of Applications**	**Min Intervals (days)**	**PHI**	**Max lb ai/A/yr**
Peanut (ground)	0.18	4	14	14	0.72
Potato & Tuber Vegetables (ground/aerial)	0.12	6	7	7	0.72
Leafy Vegetables (ground)	0.18	4	7	3	0.72
Fruiting Vegetables (ground)	0.12 - 0.18	4 - 6	7	3	0.72
Turf (ground)	0.27 - 0.55	4-8 (2 typical)	21-28		2.2
Seed treatment	0.005 - 0.010 lb ai/CWT				0.72

Foliar spray ground application is proposed for all crops, except for potato and tuber vegetables where aerial application is also allowed.

B. Assessment Endpoints

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

Ecosystems Potentially at Risk

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

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

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

The ecological relevance of selecting the above-mentioned assessment endpoints is as follows: 1) complete exposure pathways exist for these receptors; 2) the receptors may be potentially sensitive to pesticides in affected media and in residues on plants, seeds, and insects; and 3) the receptors could potentially inhabit areas where pesticides are applied, or areas where runoff and/or spray drift may impact the sites because suitable habitat is available.

2. Ecological effects

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

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

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

- Acute laboratory toxicity data on non-guideline freshwater invertebrates including midges, copepods, mayflies, amphipods, and aquatic sowbugs,
- Acute laboratory contact and oral toxicity on honeybees, and
- Subchronic laboratory toxicity data on earthworms.

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

Table 2. Summary of Assessment and Measurement Endpoints

Assessment Endpoint	**Measurement Endpoint**
1. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of birds	1a. Bobwhite quail acute oral LD_{50} 1b. Bobwhite quail and mallard duck subacute dietary LD_{50} 1c. Bobwhite quail and mallard duck chronic reproduction NOAEC and LOAEC
2. Abundance (i.e., survival, reproduction, and growth) of individuals and populations of mammals	2a. Laboratory rat acute oral LD_{50} 2b. Laboratory rat developmental and chronic NOAEC and LOAEC
3. Survival and reproduction of individuals and communities of freshwater fish and invertebrates	3a. Rainbow trout and bluegill sunfish acute LC_{50} 3b. Rainbow trout chronic (early-life) NOAEC and LOAEC 3c. Water flea (and other freshwater invertebrates) acute EC_{50} 3d. Water flea chronic (life-cycle) NOAEC and LOAEC
4. Survival and reproduction of individuals and communities of estuarine/marine fish and invertebrates	4a. Sheepshead minnow acute LC_{50} 4b. Estimated chronic NOAEC and LOAEC values based on the acute-to-chronic ratio for freshwater fish 4c. Eastern oyster and mysid shrimp acute LC_{50} 4d. Mysid shrimp chronic (life-cycle) NOAEC and LOAEC 4e. Estimated NOAEC and LOAEC values for mollusks based on the acute-to-chronic ratio for mysids
5. Perpetuation of individuals and populations of non-target terrestrial and semi-aquatic species (crops and non-crop plant species)	5a. Monocot and dicot seedling emergence and vegetative vigor EC_{25} values
6. Survival of beneficial insect populations	6a. Honeybee acute contact LD_{50}
7. Abundance (i.e., survival, reproduction, and growth) of earthworm populations	7a. Acute and subchronic earthworm LC_{50} values
8. Maintenance and growth of individuals and populations of aquatic plants from standing crop or biomass	8a. Algal and vascular plant (i.e., duckweed) EC_{50} values for growth rate and biomass measurements

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

C. Conceptual Model

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

Ecological receptors that may potentially be exposed to fluoxastrobin and its degradates include terrestrial and semiaquatic wildlife (i.e., mammals, birds, and reptiles), terrestrial and semi-aquatic plants, and soil invertebrates. In addition to terrestrial ecological receptors, aquatic receptors (e.g., freshwater and estuarine/marine fish and invertebrates, amphibians) may also be exposed to potential migration of pesticides from the site of application to various watersheds and other aquatic environments via runoff and spray drift.

All potential routes of exposure are considered and are presented in the conceptual site model (**Figure 1 and Figure 2**).

The source and mechanism of release of fluoxastrobin are ground application via foliar spray, treated seeds, and chemigation to agricultural crops. In addition, fluoxastrobin may also be applied aerially (for potatoes and tuber vegetables only). Surface water runoff from the areas of application is assumed to follow topography. Additional release mechanisms include spray drift, and wind erosion, which may potentially transport site-related contaminants to the surrounding air. Potential emission of volatile compounds is not considered as a viable release mechanism for fluoxastrobin, since volatilization is not expected to be a significant route of dissipation for this chemical. The conceptual site models shown in **Figure 1** and **Figure 2** generically depict the potential source of fluoxastrobin, release mechanisms, abiotic receiving media, and biological receptor types.

Figure 1 - Conceptual model depicting ecological risk based on the proposed fluoxastrobin application to foliage

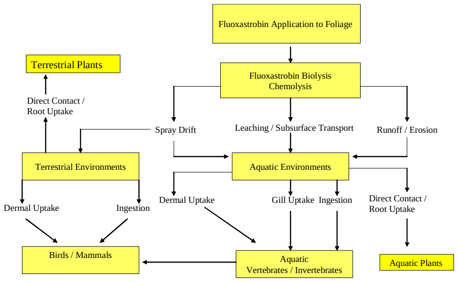
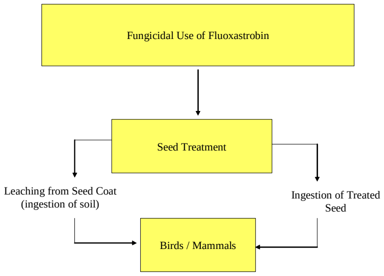


Figure 2 - Conceptual model depicting ecological risk based on the proposed fluoxastrobin application to seeds



D. Key Uncertainties and Information Gaps

The following uncertainties and information gaps were identified as part of the problem formulation:

- Chronic data for estuarine/marine fish were not submitted by the registrant; therefore, measurement endpoints were estimated based on the acute-to-chronic NOAEC ratio for freshwater fish.

- Chronic data for estuarine/marine mollusks were not submitted by the registrant; therefore, measurement endpoints were estimated based on the acute-to-chronic NOAEC ratio for mysids.

- Inhalation and dermal pathways for terrestrial mammals and birds **were not evaluated** because these routes of exposure are considered to be negligible compared to the dietary ingestion pathways. Uncertainties associated with exposure pathways for terrestrial animals are discussed in greater detail in Section IV.D.3.

- Risks to semiaquatic wildlife via consumption of pesticide-contaminated fish **were not evaluated**. However, given that bioaccumulation of fluoxastrobin is low, ingestion of fish by piscivorus wildlife is not likely to be of concern.

- Risks to top-level carnivores **were not evaluated** due to a lack of data for these receptors. Ingestion of grass, plants, fruits, insects, and seeds by terrestrial wildlife was considered; however, consumption of small mammals and birds by carnivores was not evaluated. In addition, food chain exposures for aquatic receptors (i.e., fish consumption of aquatic invertebrates and/or aquatic plants) were also not considered.

- Exposure and associated risks to fluoxastrobin in sediment **were not evaluated** for aquatic receptors and/or semiaquatic wildlife. Because sediment-bound fluoxastrobin is persistent (half-life of 141 days in soil), and concentrations in sediment may be higher than those present in the water column, there are uncertainties associated with risks to benthic organisms.

- Surrogates were used to predict potential risks for species with no data (i.e., reptiles and amphibians). It was assumed that use of surrogate effects data is sufficiently conservative to apply the broad range of species within taxonomic groups. If other species are more or less sensitive to fluoxastrobin and its degradates than the surrogates, risks may be under or overestimate, respectively.

- Aerobic and anaerobic aquatic metabolism studies are needed to determine the level of bacterial biolysis in the water column and in the benthic sediment, respectively. These studies were submitted; however data were deemed "unacceptable" and were not used in the aquatic exposure modeling. Alternatively, according to EFED's water model parameter selection guideline, *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version II, February 28, 2002, an assumption was made for the aerobic aquatic half-life to be two times the aerobic soil half-life, and for the anaerobic aquatic half-life to be stable. These assumptions could result in overestimating the exposure of fluoxastrobin residues to the aquatic species.

- The high soil/water partitioning values indicate that the concentrations of fluoxastrobin in sediment may be higher than those in sediment pore water and/or the water column. Consequently, the use of water toxicity tests to characterize potential adverse effects associated with freshwater and estuarine/marine benthic invertebrate exposure to fluoxastrobin in sediment may result in an underestimation of risk.

- Most of the laboratory studies were conducted with a mixture of the *E*- and *Z*-isomers at a ratio of approximately 98:2. Conversion of the *E*- into the *Z*- isomer was observed in some of the laboratory studies, at a rate of less than 5%, with the exception of the soil photolysis study, where as much as 20% of *Z*-isomer was detected. This risk assessment was based on combined *E* and *Z*- data, with the assumption that the toxicity of *Z*-isomer is equal or less than the *E*-isomer.

III. ANALYSIS

A. Exposure Characterization

Environmental Fate and Transport Characterization

Fluoxastrobin exists in a white slight crystalline solid. Based on a solubility in water of 2.3 mg/L, a vapor pressure of 5.63×10^{-10} Pa at 20 °C, and a melting point of 103 - 108°C, volatilization may not be a significant dissipative pathway for fluoxastrobin in the environment. A Log P_{ow} of 2.86 ± 0.05 and a BCF value of 18 also indicate that the bioaccumulation potential of this chemical in fish could be low.

Fluoxastrobin (*E* + *Z* isomers, 98:2 isomer ratio) is stable toward abiotic hydrolysis in sterile buffered solutions at pH 4, 7, and 9 at 50° C. In contrast, direct aqueous photodegradation under laboratory conditions is rapid, with an average half life of 4.1 days (24 hour irradiation) and formation of HEC5725-oxazepine. This laboratory half-life corresponds to a predicted environmental half life of 20.1 summer sunlight in Phoenix, Arizona (33° N) and 28.3 days in Edmondton, Alberta, Canada (53°N). Photodegradation on soils is much slower at a predicted environmental rate of 146 days.

Biodegradation under aerobic conditions could take several months to several years, depending on the soil texture (half life of 29.4 days in sandy loam to 393 days in loamy sand; average half-life of 141 days). The degradation was primarily mediated by microbial processes, with biomineralization to CO_2 (less than 10% total applied), via HEC5725-*E*-des-chlorophenyl. This degradate is a hydroxy degradate (fluropyrimidine ring) formed by cleavage of the -O-bond.

The organic carbon adsorption coefficients $K_{oc\text{-}ads}$ range from 420 (loamy sand) to 1580 (silty clay loam), indicating that fluoxastrobin has medium to low leaching potential (based on the Mc Call et al. mobility classification). The organic carbon desorption coefficients $K_{oc\text{-}des}$ range from 645 (loamy sand) to 1440 (silty clay loam). The 1/N values associated with the Freundlich K values were below 0.9 for all test soils following adsorption (1/n = 0.8356 to 0.8749) and desorption (1/n = 0.8645 to 0.8922).

Based on its low mobility and persistence in soils, fluoxastrobin has potential to reach and contaminate surface water resources in the vicinity of the treated areas. For crops treated via foliar spray, interception may reduce the amount of fluoxastrobin available for runoff. However, it is believed that fluoxastrobin could also reach surface waters through spray drift, penetration of the canopy to the soil surface at application, and foliar washoff followed by runoff. Considering fluoxastrobin’s strong binding ability to soils, runoff may be more by dissolution as opposed to adsorption on eroding soil. In water, the dissipation of this chemical is likely to be dependent on physical components of the water (e.g., sediment loading, depth, etc.) which have an effect on sunlight penetration. Since direct aqueous photolysis is rapid, fluoxastrobin is anticipated to be less persistent in clear shallow water bodies, but will probably be more persistent in turbid and/or deeper waters, particularly those with long hydrological residence times. The high soil/water partitioning values compounded with findings in the non-guideline water/sediment photolysis study indicate that the concentrations on suspended or bottom sediments should be higher than those of sediment pore water and water column. Sediment bound fluoxastrobin can potentially desorb into the dissolved water column. However, dissolved fluoxastrobin is not expected to bioaccumalate in fish tissues. Sediment bound fluoxastrobin is also expected to be persistent as suggested by its persistence in aerobic soils. Although acceptable data for aerobic and anaerobic aquatic metabolism are not available for use in this assessment, it is very likely that sediment bound fluoxastrobin could also be persistent under anaerobic conditions. The high soil/water partitioning values also indicate that fluoxastrobin has low capability to leach through soil layers and contaminate ground water resources.

Under field conditions of intended use areas in the US, fluoxastrobin was shown to persist for over a year, but did not seem to leach underground. When applied on turf plots at the turf label rate, fluoxastrobin dissipated with half lives ranging from 239 days (California sandy loam) to 347 days (New York loamy sand). On bare ground, fluoxastrobin seems to be more persistent (578 days for California sandy loam and 533 days for New York loamy sand). No detection of the parent above the LOQ was observed below the 0-6 inch level.

The two major soil metabolites of fluoxastrobin were identified: HEC5725-E-des-chlorophenyl (HEC 7155) and HEC5725-carboxylic acid (HEC 7180). The only major degradate in water is HEC5725-oxazepine, formed by a series of photolytic reactions in clear buffered solution. However, an additional photolysis study performed in natural water/sediment systems indicated that photolytic degradation is insignificant, as no degradate, including oxazepine, was formed. This could be explained by the strong adsorption tendency of fluoxastrobin onto the sediment, which limits the amount of this chemical available for photodegradation. These three metabolites were monitored in the field studies. Only HEC5725-E-des-chlorophenyl was detected, at a maximum concentration of 7% of total applied at day 28 after last treatment (top soil layer of the California turf plot). Residues of this metabolite were also observed in the deeper soil layers, reaching the 36-48 inches layer on day 423, but at less than 1% of total applied. This is consistent with the laboratory adsorption/desorption studies, which indicate that major metabolites of fluoxastrobin are more mobile and more susceptible to leaching than parent fluoxastrobin. The *Z*-isomer of the parent was also detected in all fields, however only in the top soil layers and at less than 10% of total applied.

Table 3 summarizes the environmental fate data of fluoxastrobin and its degradates. Detailed information regarding the environmental fate studies cited in this report can be found in **Appendix A**.

Table 3. Summary of Environmental Fate Properties of Fluoxastrobin and its major degradates

Study	Half-lives, Days	Major Degradates *Minor Degradates*	MRID #	Study Status
Fluoxastrobin				
Hydrolysis	stable at pH 4, 7 , and 9 @ 50C	none	458653-04	Acceptable
Direct Aqueous Photolysis	4.1 days (combined data, both labels, both isomers, corrected for dark control, 24-hr irradiation) 20.1 days and 28.3 days (predicted environmental half-lives for Phoenix, AZ and Edmondton, Canada, respectively)	HEC5725-oxazepine (max 24% at end of study)	458653-06 458654-03	Acceptable
Soil Photolysis	73 days (both isomers, corrected for dark control, 24-hr irradiation) 266 days (predicted environmental half-lives for Phoenix, AZ)	none	458653-08	Acceptable
Aerobic Soil Metabolism	29.4 days (sandy loam) 26.2 and 30.1 (silt) 46.6 days (silt loam) 323 and 393 days (loamy sand) 141 days (**average**) 38 days (**median**)	HEC5725-E-des-chlorophenyl (max 32% at day 30) *HEC5725-4-hydroxyphenyl, HEC5725-amide, and* CO_2	458653-09 458653-10	Acceptable Acceptable

Anaerobic Aquatic Metabolism	187 days (total system)	HEC5725-carboxylic acid (max 23%, end of study, total system) *HEC5725-amide*	458653-12	Unacceptable
Aerobic Aquatic Metabolism	190 days (total system)	None *HEC5725-E-des-chlorophenyl,* *HEC5725-des-chlorophenyl carboxylic acid,* *HEC5725-carboxylic acid,* *HEC5725-amide*	458653-13	Unacceptable
$K_{d\text{-}ads}$ / $K_{d\text{-}des}$ (mL/g) $K_{oc\text{-}ads}$ / $K_{oc\text{-}des}$ (mL/g)	26.26 / 23.91 (silty clay loam), 12.70 / 20.30 (sandy loam), 16.21 / 23.30 (silt), and 3.35 / 5.09 (loamy sand) 1580 / 1440 (silty clay loam), 629 / 1006 (sandy loam), 758 / 1089 (silt), and 424 / 645 (loamy sand)	Not applicable	458653-15	Supplemental
HEC5725-E-des-chlorophenyl (HEC 7155)				
Aerobic Soil Metabolism DT_{50}	34 days (loamy sand), 47 days (silt), and 100 days (silt loam)	Not applicable	458653-09 458653-10	Acceptable Acceptable
$K_{d\text{-}ads}$ / $K_{d\text{-}des}$ (mL/g) $K_{oc\text{-}ads}$ / $K_{oc\text{-}des}$ (mL/g)	3.01 / 3.01 (clay loam), 0.47 / 1.29 (silt), 0.28 / 1.36 (sandy loam), and 0.18 / 1.29 (loamy sand) 181 / 181 (clay loam), 22 / 60 (silt), 14 / 67 (sandy loam), and 23 / 163 (loamy sand)	Not applicable	458653-14	Supplemental
HEC5725-carboxylic acid (HEC 7180)				
$K_{d\text{-}ads}$ / $K_{d\text{-}des}$ (mL/g) $K_{oc\text{-}ads}$ / $K_{oc\text{-}des}$ (mL/g)	1.41 / 5.21 (silt clay), 1.12 / 3.46 (loamy sand), 0.58 / 2.49 (sandy loam), and 0.50 / 2.69 (sandy loam) 87 / 322 (silt clay), 56 / 174 (loamy sand), 56 / 244 (sandy loam), and 37 / 196 (sandy loam)	Not applicable	458653-16	Supplemental

2. Aquatic Resource Exposure Assessment

General Approach

Fluoxastrobin is a new chemical, for which no monitoring data are available. Exposure concentrations for drinking water and aquatic ecosystems assessments were estimated based on EFED’s aquatic models listed below in **Table 4**. 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 parameter selection guidelines, *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version II, February 28, 2002. A detailed aquatic resource exposure assessment is attached in **Appendix B**.

Table 4. Models Used to Estimate Exposure Concentrations for Drinking Water and Aquatic Ecosystem Assessments

Exposure Estimates	Models
Drinking water, Surface water (Tier I)	FIRST (FQPA Index Reservoir Screening Tool) version 1.0, August 1, 2001.
Drinking water Ground water (Tier I)	SCIGROW (version 2.1; November 1, 2001)*
Aquatic ecosystems Surface water (Tier II)	PRZM 3.12 (dated May 7, 1998), named PRZM3.12.EXE EXAMS 2.98.04 (dated July 18, 2002), named EXAMS.EXE, Pond scenario PE4VO1.pl, dated 8/8/03

*While use of this version is provisional, it is expected to produce more accurate estimated values for compounds with longer half-lives. In most cases, a majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to drive the SCIGROW estimates.

Drinking Water Resources Modeling: Tier I estimated drinking water concentrations (EDWC) for surface and ground water are calculated using FIRST (FQPA Index Reservoir Screening Tool) and SCI-GROW (Screening Concentration in Groundwater), respectively. **FIRST** model is a screening tool designed to estimate pesticide concentrations in a vulnerable index reservoir. FIRST considers desorption of the pesticide to soil or sediment; incorporation of the pesticide at application, if application; direct deposition of spray drift into the water body, and degradation of the pesticide in soil before runoff and within the water body. Simulation results are also adjusted with a Percentage Crop Adjustment (PCA) value to account for the percentage of the watershed in the crop being assessed. FIRST is expected to be exceeded by measured pesticide concentrations in drinking water only very rarely due to the conservative nature of the model assumptions. It represents a small drinking water reservoir surrounded by a runoff-prone watershed, uses maximum pesticide application rates and assumes that no buffer exists between the reservoir and the treated fields. The simulation also assumes runoff from a single, large rainfall event. The **SCI-GROW2** is based on a regression approach which relates the concentrations found in groundwater in Prospective Groundwater studies to the aerobic soil metabolism rate and soil-water partitioning properties of the chemical. SCI-GROW2 estimates likely groundwater concentrations if the pesticide is used at the maximum allowable rate in areas where groundwater is vulnerable to contamination. Characteristics of such vulnerable areas include high rainfall, rapidly permeable soil, and a shallow aquifer. In most cases, a large majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW2 estimate. Additional information on these models can be found at: http://www.epa.gov/oppefed1/models/water/index.htm.

The EDWCs recommended by EFED for use in the human health risk assessment for fluoxastrobin are presented in **Table 5**. These values were based on the highest proposed use, which is turf at 4 ground applications per year at 0.55 lbs ai/A per application and 21-day interval.

Table 5 - Fluoxastrobin EDWCs in Surface and Ground Water for Use in Human Health Risk Assessment

Surface Water Peak Concentration (Acute)	71 ppb
Surface Water Annual Average Concentration (Chronic)	28 ppb
Ground Water Concentration (Acute and Chronic)	<1 ppb

Aquatic Organism Exposure Modeling: Tier II Estimated Environmental Concentrations (EECs) for were estimated using EFED's 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 environmental fate and transport of pesticides in surface water and predicts EECs in a standard pond (10,000-m^2 pond, 2-m deep), with the assumption that the small field is cropped at 100%. 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 five crops chosen to represent the agricultural uses of fluoxastrobin are peanut, potato (for potato and tuber vegetables), cabbage (for leafy vegetable), tomato and pepper (for fruiting vegetables). Turf represents the recreational use. To simulate these uses, standard scenarios associated with states of the highest US planted acreage (based on the data provided in USDA National Agriculture Statistics Service, "2002 Census of Agriculture, Volume 1 Chapter 2: U.S. State Level Data" at http://www.nass.usda.gov/census/census02/volume1/us/index2.htm and the highest exposure (driven in part by the vulnerability of the soils, the climate, and the agricultural practices) were chosen for the selected crops. Maximum application rates were selected to model environmental concentrations for this screening-level deterministic (risk quotient-based) assessment. Application dates were based on whether fluoxastrobin is applied as a pre- or post-emergent as well as on reported planting dates found in the documentation section of each scenario. Results are tabulated in **Table 6**

Table 6 - Fluoxastrobin EECs in Surface Water for Use in Ecological Risk Assessment

Crop	Use Patterns	Upper 90th Percentile Values (ppb)					
		Peak	**96 Hour**	**21 Day**	**60 Day**	**90 Day**	**Yearly**
Potato ID	6 x 0.12 lbs ai/A @ 7 day interval (aerial)	**8.8**	**8.7**	**8.6**	**8.4**	**8.3**	**7.9**
Potato ID	6 x 0.12 lbs ai/A @ 7 day interval (ground)	**4.3**	**4.3**	**4.1**	**3.9**	**3.9**	**3.6**
Potato ME	6 x 0.12 lbs ai/A @ 7 day interval (aerial)	**32.9**	**32.7**	**31.9**	**30.8**	**30.6**	**29.8**
Potato ME	6 x 0.12 lbs ai/A @ 7 day interval (ground)	**28.7**	**28.6**	**27.8**	**26.7**	**26.5**	**25.8**
Tomato CA	4 x 0.18 lbs ai/A @ 7 day interval (ground)	**8.4**	**8.3**	**8**	**7.6**	**7.5**	**6.8**
Tomato FL	4 x 0.18 lbs ai/A @ 7 day interval (ground)	**21**	**20.8**	**20**	**18.2**	**17.7**	**14.8**
Pepper FL	4 x 0.18 lbs ai/A @ 7 day interval (ground)	**25.2**	**24.9**	**23.6**	**18.5**	**17.8**	**16.1**
Pepper FL	4 x 0.18 lbs ai/A @ 7 day interval (ground/no drift)	**24.6**	**24.3**	**22.9**	**17**	**17.3**	**15.6**
Cabbage FL	4 x 0.18 lbs ai/A @ 7 day interval (ground)	**12.8**	**12.6**	**12.3**	**11.1**	**10.6**	**9.5**
Peanuts NC	4 x 0.18 lbs ai/A @ 7 day interval (ground)	**19.7**	**19.6**	**19.2**	**18.5**	**18**	**16.1**
Turf FL	4 x 0.55 lbs ai/A @ 21 day interval (ground)	**20.9**	**20.6**	**19.6**	**18.5**	**17.9**	**15.4**
Turf FL	2 x 0.55 lbs ai/A @ 21 day interval (ground)	**9.4**	**9.3**	**8.9**	**8.4**	**8.2**	**7**
Turf PA	4 x 0.55 lbs ai/A @ 21 day interval (ground)	**21.6**	**21.3**	**20.7**	**19.8**	**19.7**	**18**
Turf PA	2 x 0.55 lbs ai/A @ 21 day interval (ground)	**10.4**	**10.3**	**10**	**9.6**	**9.6**	**8.6**

Two runs were simulated for Florida Pepper, one with the usual spray drift and one with no drift, in order to gauge the amount fluoxastrobin residues contributed by drift to run off. **Table 4** showed that, in this case, spray drift accounts for only less than 4% of residue that is available for total run off.

Monitoring Information

Because fluoxastrobin is a new active ingredient that has not yet been registered in the

U.S. (nor in any other foreign countries), no monitoring information on this chemical exists.

3. Terrestrial Organism Exposure Modeling

Terrestrial wildlife exposure estimates are typically calculated for bird and mammals, emphasizing a dietary exposure route for uptake of pesticide active ingredients. These exposures are considered as surrogates for terrestrial-phase amphibians as well as reptiles. For exposure to terrestrial organisms, such as birds and small mammals, pesticide residues on food items are estimated, based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario. Application methods for all uses of fluoxastrobin include broadcast spray, aerial application (potato and tuber vegetable only), seed treatment, and chemigation. For this terrestrial exposure assessment, spray applications and seed treatment applications are considered.

Spray Applications and Residues

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

The terrestrial exposure assessment is based on the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). Terrestrial EECs for non granular formulations (**Table 5**) were derived for major crops (potatoes, fruiting vegetables, leafy vegetables, peanuts, and turf) using current application rates and intervals between applications. Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. When data are absent, as in this case, EFED assumes a 35-day foliar dissipation half life, based on the work of Willis and McDowell (1987).

The EECs on food items may be compared directly with dietary toxicity data or converted to an oral dose, as is the case for small mammals. The screening-level risk assessment for fluoxastrobin uses upper bound predicted residues as the measure of exposure. The predicted maximum and mean residues of fluoxastrobin 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 potatoes, fruiting and leafy vegetables, peanuts, and turf are presented in **Table 7.** For mammals, the residue concentration is converted to daily oral dose based on the fraction of body weight consumed daily as estimated through mammalian allometric relationships.

Table 7. Estimated environmental concentrations on avian and mammalian food items (ppm) following label specified applications of fluoxastrobin to potatoes, fruiting vegetables, leafy vegetables, peanuts, and turf.

Crop	**Application Rate lbs. a.i./A (# app / interval, days)**	**Food Items**	**Predicted Maximum Residue EEC (ppm)[1]**	**Predicted Mean Residue EEC (ppm)[2]**
Potatoes	0.12 (6 / 7)	Short grass	126	82
		Tall grass	58	38
		Broadleaf plants/small insects	71	46
		Fruits, pods, seeds, and large insects	7.9	5.1
Fruiting and Leafy Vegetables and Peanuts	0.18 (4 / 7)	Short grass	142	93
		Tall grass	65	42
		Broadleaf plants/small insects	80	52
		Fruits, pods, seeds, and large insects	8.9	5.8
Turf	0.55 (4 / 21)	Short grass	314	170
		Tall grass	144	78
		Broadleaf plants/small insects	177	95
		Fruits, pods, seeds, and large insects	20	11

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

[2] Predicted mean residues from Fletcher et al.: Short grass = 85; Tall grass = 36; Broadleaf plants / insects = 45; and Seeds / fruits = 7

Seed treatment applications

Birds and mammals in the field may be exposed to seed treated with pesticides by ingesting material directly with the diet. They also may be exposed by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, preening activities, and ingestion of drinking water contaminated with pesticide. Only ingestion of treated seed was considered as a route of exposure in this assessment.

Terrestrial EECs and acute risk quotient values were calculated in two different ways for the purposes of assessing risk from fluoxastrobin-treated seeds. The first approach estimates a dietary dose assuming that an organism has been eating only treated seed. This approach uses the acute oral toxicity for the toxicity endpoint (LD_{50}). The second method also uses the acute oral dose for toxicity (LD_{50}), but compares it to the available concentration of pesticide on the basis of pesticide per square foot.

Avian Exposure

The first method of assessing exposure to treated seeds was used to assess risk to the smallest birds that eat seeds, which weigh about 20 g. Small birds tend to eat more per unit body weight; therefore, they are likely to be the most vulnerable. Exposure is estimated from the concentration of fluoxastrobin on treated seed. The maximum application rate (0.01 lbs a.i. per 100 lbs seed) is equivalent to 100 mg a.i. kg^{-1} of seed. Using daily food intake, as estimated by Nagy (1987) (**EQ 1**), a 20-g bird will consume approximately 5.1 g of food (wet weight) based on the allometric equation: