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Fenoxaprop-p-ethyl Summary Document
Registration Review: Initial Docket
August 29, 2007

Approved By:

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Steven Bradbury, Ph.D
Director, Special Review and
Reregistration Division

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I. PRELIMINARY WORK PLAN

Introduction:

The Food Quality Protection Act of 1996 amendments to the Federal Fungicide Insecticide and Rodenticide Act (FIFRA) mandated a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by the United States Environmental Protection Agency (the Agency) based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

This document opens the first reevaluation of fenoxaprop-p-ethyl under Registration Review. The Agency plans to review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state clearly what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of fenoxaprop-p-ethyl (FPE).

Anticipated Risk Assessment and Data Needs:

The Agency anticipates updating and revising the ecological risk assessment for FPE (including an endangered species risk assessment), and updating and revising the human health risk assessment. Additional data that the Agency may need to complete these assessments are specified below.

Ecological Risk:

The Agency has determined that a revised risk assessment is necessary for FPE under registration review, to bring the assessment in line with current standards, policies, and registered use patterns. This will include an assessment of potential risk to endangered and threatened species (referred to as listed species). Please refer to Section III of this document, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated ecological risk assessment needs. A summary follows:

- There are data gaps in the toxicity database for FPE. However, available data for racemic fenoxaprop-ethyl will be used for acute toxicity aquatic organism studies because available toxicity data indicate that fenoxaprop-ethyl and FPE have similar acute toxicity to aquatic organisms.

- The technical registrant has recently submitted 23 mammalian toxicology studies conducted with FPE with the intent to show equivalent toxicity with fenoxaprop-ethyl. These studies are being reviewed. If review of these studies indicates that fenoxaprop-ethyl and FPE are not similarly toxic to mammals, additional FPE studies for mammals will be required by DCI for the human health risk and ecological risk assessments. In addition, if the mammalian data do not show similar toxicity between the two active ingredients, chronic avian toxicity studies will also be required for the ecological risk assessment.

- The planned ecological risk assessment will allow the Agency to determine whether use of FPE has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. If the assessment indicates that FPE "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of FPE is “likely to adversely affect” the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate.

Human Health Risk:

The Agency has determined that a revised risk assessment is necessary for FPE under registration review, to bring the assessment in line with current standards, policies, and registered use patterns. This revised assessment will include 1) an assessment of the similarity of the toxicities of fenoxaprop-ethyl and FPE and 2) an assessment of whether the potential carcinogenicity of FPE should be assessed by the linear or threshhold /margin of exposure (MOE) method. Please refer to Section IV, the Human Health Effects Scoping Document for a detailed discussion of the anticipated risk assessment and/or data needs for human health. A summary follows:

- The Agency plans to review the newly received FPE developmental toxicity studies and any other studies deemed relevant, and compare these studies to the analogous studies conducted on fenoxaprop-ethyl. The Agency will make a decision as to whether the entire fenoxaprop-ethyl database, notably the chronic, cancer, and reproductive toxicity studies, may be bridged to FPE. If complete bridging is agreed on, then no FPE toxicity data are likely to be required. If partial or no bridging is permitted, then the FPE toxicity studies that must be required will be identified.

- The Agency will schedule an evaluation of the carcinogenic potential of fenoxaprop-ethyl/FPE by the Agency's HED Cancer Assessment Review Committee (CARC). The CARC will determine whether a mechanism and threshold effect/MOE approach is more appropriate for the carcinogenicity assessment for FPE than the low dose extrapolation method (Q1*). If the MOE approach is not appropriate, the CARC will recalculate the Q1* based on current data and methods. If the carcinogenicity assessment changes from the previous assessment, cancer risk estimates for dietary and occupational exposure will be revised.

- The Agency will prepare an updated human health risk assessment including-
  a) New risk assessments which aggregate food, drinking water and residential exposures.
  b) Occupational handler inhalation assessments for cotton, soybeans, rice, or peanuts, and for various turf uses (sod farms, commercial and residential turf), ornamentals, and rights-of-way.

Timeline:

The timeline below reflects the time that will be needed for registration review of FPE if additional data are deemed necessary for the human health and ecological effects risk assessments. If review of the FPE mammalian toxicity studies indicate that bridging between fenoxaprop-ethyl and FPE toxicity studies is appropriate, additional data will not need to be called in, and the overall risk assessment timeline will shorten to three years.

Activities	Estimated Month/Year (Example - quarters are calendar year)
Open docket	Aug. 2007
Public comment	Nov. 2007
Final Work Plan	1st Quarter 2008
Issue DCI	4th Quarter 2008
Data Submission	4th Quarter 2010
Preliminary Risk Assessment	2nd Quarter 2012
Public Comment Period	3rd Quarter 2012
Proposed Registration Review Decision	4th Quarter 2012
Public Comment Period	1st Quarter 2013
Final Registration Review Decision & Begin Post-Decision Follow-up	2013
Total (years)	6

Guidance for Commenters:

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the FPE case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Stakeholders are also specifically asked to provide information and data in the following areas:

1. Confirmation on the following label information.
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates
    e. frequency of application, application intervals, and maximum number of applications per season and per year
    f. geographic limitations on use
2. Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses).
3. Use history.
4. Median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state and county.
5. Application timing (date of first application and application intervals) by use – national, state, and county.
6. Sub-county crop location data.
7. Usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals).
8. Directly acquired county-level usage data (not derived from state level data).
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
9. Typical application interval (days).
10. State or local use restrictions.
11. Ecological incidents specific to FPE (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
12. Monitoring data.
13. FPE is not identified as a cause of impairment for any water body listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. However, the Agency invites submission of any other existing water quality data. To the extent possible, data elements outlined in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Water Quality & Impaired Water Body Data in OPP's Registration Review Risk Assessment & Management Process," should be provided. To ensure the data can be used quantitatively

or qualitatively in pesticide risk assessments, see http://www.epa.gov/oppsrrd1/reregistration_review/water_quality.htm.

Next Steps:

After the comment period closes in November 2007 and the comments are reviewed, the Agency will prepare a Final Work Plan for this pesticide.

II. FACT SHEET

Background

- FPE (case number: 7209) is undergoing registration review. FPE is the r-isomer enriched (95%) formulation of fenoxaprop-ethyl, which is the racemic mixture of the r- and s- isomers (ratio 50:50).
- Technical registrant: Bayer CropScience
- FPE: PC Code 129092, CAS # 71283-80-2
- Fenoxaprop-ethyl: PC Code 128701, CAS # 66441-23-4
- Fenoxaprop-ethyl no longer has any registered products.
- A Reregistration Eligibilty Decision (RED) was not conducted for FPE because the pesticide was registered after 1984 and was, therefore, not subject to reregistration.
- There are 16 FIFRA Section 3 active registrations and several FIFRA 24 (c) Special Local Needs registrations.
- Ecological risk and exposure assessments that serve as the basis for the ecological risk assessment problem formulation include the following:

    - FIFRA Section 3 new use risk assessment of proposed uses on wheat, soybeans, cotton, peanuts, and conservation reserves (DP barcode 164986; Feb. 14, 1996)
    - Four FIFRA Section 18 risk assessments for uses on barley and rice from 1997 to 2001;
    - One FIFRA Section 18 risk assessment (DP barcode 338410) for use on grass grown for seed in 2007.
    - A drinking water assessment (DP barcode 239618; Oct. 3, 1997)

- Chemical Review Manager: Kylie Rothwell
- Product Managers: Eugene Wilson and Joanne Miller

Use and Usage

- FPE is a selective postemergence herbicide of the aryloxyphenoxy propionate group that controls annual and perennial grass weeds.
- FPE is used on rice, barley, soybeans, cotton, peanuts, and wheat. It is also used for sod farms, commercial and residential turf, highway rights of way, acreage conservation reserve (set-aside) and ornamentals. There are also consumer use products.

- FPE is formulated as an emulsifiable concentrate, a soluble concentrate/liquid, and as a liquid ready-to-use product.
- Screening-level estimates indicate that approximately 700,000 pounds of active ingredient are used annually.
- The estimates of current usage indicate minimal usage on cotton and rice, with approximately 5% of the crop treated for soybeans, approximately 25% for wheat, and less than 1% for cotton.
- Use information, such as application rates and number of applications specified on product labels, is found in Appendix A in the docket.

Recent Actions

- Four FIFRA Section 18 risk assessments for uses on barley and rice were performed from 1997 to 2001.
- The concentration of the r- isomer was increased from 89% to 95% in the MP compound in 2002.
- Risk assessments were performed for an emergency exemption which was requested for use of FPE on grass seed in Oregon in March 2007.

Ecological Risk Assessment Status

To meet current standards, a new ecological risk assessment (including listed species) is needed for all registered outdoor uses. However, based on the results of previous risk assessments, and screening model results presented in the attached Ecological Risk Assessment Problem Formulation:

- Risk quotients for labeled uses of FPE are unlikely to exceed the acute levels-of-concern (LOCs) for birds, mammals and aquatic plants.
- Risk quotients for labeled uses of FPE may exceed the acute LOC for estuarine/marine invertebrates and terrestrial monocot plants; the chronic LOC for birds, mammals, and freshwater and estuarine/marine fish and invertebrates; and the endangered species LOC for birds, mammals, terrestrial monocot plants, and freshwater and estuarine/marine fish and invertebrates.
- 78 reports of adverse field effects to non-target plants have been received. The Agency considers the cause to be uncertain in 39 cases in which several herbicides were used. There are no incident reports involving contamination of ground or surface water.

Human Health Risk Assessment Status

To meet current standards, and to incorporate data not considered in the most recent risk assessment (1998), new human health risk assessments are needed. The conceptual model of risk to human health will also be revisited, both by considering the appropriateness of bridging between toxicity data for fenoxaprop-ethyl and FPE and by evaluating whether the cancer risk assessment should be conducted using the linear Q_1^* or the MOA approach. Please refer to

Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. Below is a summary of the findings:

Dietary (Food and Drinking Water):

- There are no dietary risks that exceed the Agency's level of concern (LOC).

Residential

- A homeowner "handler" risk assessment has not yet been conducted.
- There are currently several registered homeowner products containing FPE. To assess risks to homeowners, a short-term residential handler inhalation assessment should be conducted for lawn and ornamental use based on inhalation exposure only; dermal exposure would not be assessed because of the negative results of the dermal toxicity studies.
- Also, by current standards, children's "incidental" oral exposure (to treated turf) would be assessed based on an existing oral toxicity study of the appropriate exposure duration.

Occupational

- Occupational handler risk assessment was completed for the 1997 and 1998 barley and wheat tolerance petitions based on inhalation exposure, only.
- Dermal exposure was not assessed based on the negative results of the dermal toxicity studies.
- Occupational handler inhalation assessments have not been conducted for cotton, soybeans, rice, or peanuts, or for various turf uses (sod farms, commercial and residential turf), ornamentals, and rights-of-way.
- Carcinogenic risk estimates were completed for workers based on their specific function (such as aerial applicator and ground applicator). The highest carcinogenic risk estimated was 10^{-6} and was based on the mixer/loader function for aerial applications.

Carcinogenicity Assessments

- The most recent assessment in 1998 used an interim Q_1^* of 9.1×10^{-2}, which was based on increases in adrenal tumors in male mice.
- The upper-bound (food only) carcinogenic risk estimate was 9.1×10^{-7}.

Data Call-In (DCI) Status

- No DCIs were issued for fenoxaprop-ethyl or FPE.

Tolerances:

- Permanent tolerances were established for the combined residues of fenoxaprop-ethyl and its metabolites, 40 CFR Section 180.430(a). Because fenoxaprop-ethyl and FPE are chemically similar, the tolerances established for fenoxaprop-ethyl are used for FPE. Tolerances for fenoxaprop-ethyl were reassessed in 1998 under the Food Quality Protection Act in conjunction with a risk assessment for new use on barley. If the

Agency determines that fenoxaprop-ethyl and FPE are toxicologically equivalent, the tolerance expression will remain the same. The fenoxaprop-ethyl tolerances for barley, wheat, rice, cottonseed and soybean have been set at 0.05 ppm.

- The Codex Alimentarius has not established maximum residue levels (MRLs) for fenoxaprop-ethyl and FPE. However, the Pest Management Regulatory Association (Canada) has an MRL of 0.03 ppm for fenoxaprop-ethyl in milk. There are FPE MRLs for rice (0.05 ppm), barley (0.05 ppm), and wheat (0.05 ppm) in Mexico.

Fenoxaprop-p-ethyl Registrations:

Table 1. Current FPE Section 3 product labels.

Product Name	Company	Registration #	Uses
Fusion Herbicide	Syngenta Crop Protection	100-1059	cotton, rights-of-way, soybeans
Whip 360 Herbicide	Bayer CropScience	264-647	conservation reserves, rice, soybeans
Silverado Herbicide	Bayer CropScience	264-650	conservation reserves, cotton, peanuts, soybeans, wheat
Fenoxaprop-p-ethyl technical	Bayer CropScience	264-653	
Puma 1EC Herbicide	Bayer CropScience	264-666	barley, wheat
Ricestar Herbicide	Bayer CropScience	264-682	rice
Acclaim Extra Herbicide	Bayer Environmental Science	432-950	ornamentals, rights-of-way, turf
Preclaim EW Herbicide	Bayer Environmental Science	432-957	ornamentals, rights-of-way, turf
Preclaim Crabgrass Killer & Weed Preventer	Bayer Environmental Science	432-958	ornamentals (residential), turf (residential)
Preclaim Herbicide	Bayer Environmental Science	432-959	ornamentals, rights-of-way, turf
Triway + Phenoxaprop Ready-to-Spray Herbicide	Bayer Advanced	72155-62	turf (residential)
Triway + Fenoxaprop Concentrate Herbicide	Bayer Advanced	72155-63	turf (residential)
Triway + Phenoxaprop Ready-to-Use Herbicide	Bayer Advanced	72155-66	turf (residential)
Crabgrass Killer R-T-S Herbicide	Bayer Advanced	72155-74	ornamentals (residential), turf (residential)
Bayer Advanced Lawn Herbicide 3F Concentrate	Bayer Advanced	72155-77	turf (residential)
Bayer Advanced Lawn Herbicide 3F RTU	Bayer Advanced	72155-78	turf (residential)

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

July 30, 2007

PC Code: 129092
DP Barcode: 338163

MEMORANDUM

Subject: Registration Review – REVISED Preliminary Problem Formulation for the Ecological Risk Assessment of Fenoxaprop-p-ethyl

To: Kylie Rothwell, Chemical Review Manager
Kevin Costello, Team Leader
Reregistration Branch
Special Review and Reregistration Division
Office of Pesticide Programs

From: Kristina Garber, Biologist
Greg Orrick, Environmental Scientist
Environmental Risk Branch 4
Environmental Fate and Effects Division
Office of Pesticide Programs

Through: Elizabeth Behl, Chief
Environmental Risk Branch 4
Environmental Fate and Effects Division
Office of Pesticide Programs

Attached is the revised preliminary problem formulation for the ecological risk assessment to be conducted as part of the Registration Review of the herbicide fenoxaprop-p-ethyl (FPE).

REGISTRATION REVIEW

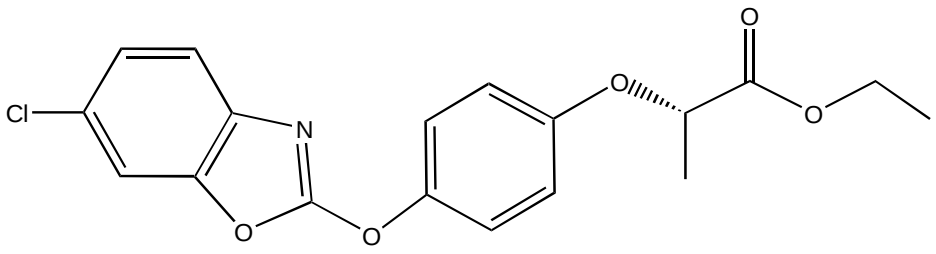
ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION FOR:

Fenoxaprop-p-ethyl

(+)-Ethyl 2-(4-((6-chloro-2-benzoxazolyl)oxy)phenoxy)propanoate

CAS Registry Number: 71283-80-2

PC Code: 129092



Prepared by:

Kristina Garber, Biologist
Greg Orrick, Environmental Scientist

Reviewed by:

R. David Jones, Senior Agronomist
Brian Kiernan, Biologist
Elizabeth Behl, Branch Chief

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

1. STRESSOR SOURCE AND DISTRIBUTION

Fenoxaprop-p-ethyl [FPE; (+)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate] is a selective aryloxyphenoxypropionate herbicide used to control grass plants after emergence. Aryloxyphenoxypropionate herbicides are mobile in the phloem and work by inhibiting acetyl coenzyme A carboxylase, which effectively inhibits lipid synthesis in target plants (Martin, 2000). FPE is the R-enantiomer (or d-isomer) of the racemate fenoxaprop-ethyl (PC Code 128701). The racemate is no longer registered by EPA, as FPE appears to be more efficacious than the S-enantiomer (l-isomer). Submitted studies contain enriched isomeric mixtures of 85:15 d:l, 89:11 d:l, or 97:3 d:l and currently registered products contain FPE at the 97:3 d:l mixture. Submitted studies and existing labels loosely refer to these enriched mixtures as FPE regardless of the purity.

There are 18 Section 3 product registrations that currently contain FPE (**Table 1**), which include agricultural and non-agricultural uses. Agricultural uses include barley, cotton, peanuts, rice, soybeans, and wheat. Non-agricultural uses include conservation reserves, ornamentals, rights-of-way, and turf. Applications of FPE to ornamentals and to turf can be in residential and commercial settings. FPE products are flowable and are applied by ground or aerial methods; applications by chemigation are prohibited. For more details on the use information of FPE, including application rates, methods and timing, see **Appendix A**.

As of 7/18/07, EFED was notified that registrations 264-649 and 264-654 were cancelled. Therefore, these labels were not considered in this problem formulation.

Table 1. Current FPE Section 3 product labels.

Product Name	Registration #	Uses
Fusion Herbicide	100-1059	cotton, rights-of-way, soybeans
Whip 360 Herbicide	264-647	conservation reserves, rice, soybeans
Silverado Herbicide	264-650	conservation reserves, cotton, peanuts, soybeans, wheat
Puma 1EC Herbicide	264-666	barley, wheat
Ricestar Herbicide	264-682	rice
Acclaim Extra Herbicide	432-950	ornamentals, rights-of-way, turf
Preclaim EW Herbicide	432-957	ornamentals, rights-of-way, turf
Preclaim Crabgrass Killer & Weed Preventer	432-958	ornamentals (residential), turf (residential)
Preclaim Herbicide	432-959	ornamentals, rights-of-way, turf
Triway + Phenoxaprop Ready-to-Spray Herbicide	72155-62	turf (residential)
Triway + Fenoxaprop Concentrate Herbicide	72155-63	turf (residential)
Triway + Phenoxaprop Ready-to-Use Herbicide	72155-66	turf (residential)
Crabgrass Killer R-T-S Herbicide	72155-74	ornamentals (residential), turf (residential)
Bayer Advanced Lawn Herbicide 3F Concentrate	72155-77	turf (residential)
Bayer Advanced Lawn Herbicide 3F Ready-to-Use	72155-78	turf (residential)

2. INTEGRATION OF AVAILABLE INFORMATION

The risk assessments that serve as the basis for this problem formulation include the following (for details, see **Appendix B**):

- 1 Section 3 New Use (S3NU) Risk Assessment of proposed uses on wheat, soybeans, cotton, peanuts, and conservation reserves (DP barcode 164986; Feb. 14, 1996)
- 1 Drinking Water Assessment (DP barcode 239618; Oct. 3, 1997)
- 4 Section 18 Risk Assessments for uses on barley and rice from 1997 to 2001
- 1 Section 18 Risk Assessment (DP barcode 338410+) for use on grass grown for seed in 2007

3. ECOLOGICAL EFFECTS

Registrant submitted data for exposures of aquatic and terrestrial organisms to FPE are available. At this time, several data gaps exist for the toxicity of FPE to aquatic and terrestrial organisms. In order to fill these data gaps, available data for fenoxaprop-ethyl will be used in this ecological risk assessment. Available toxicity data for fenoxaprop-ethyl indicate that the racemic mixture has similar acute toxicity to aquatic organisms when compared to FPE (**Appendix C).** In this assessment, it will be assumed that the R- and S-enantiomers are of equivalent toxicities. In cases where toxicity data are available for both FPE and fenoxaprop-ethyl, the most conservative endpoint (*i.e.* the lowest toxicity value) will be used, regardless of whether or not it relates to FPE or fenoxaprop-ethyl, for deriving RQs for FPE. Toxicity data for aquatic and terrestrial organisms that will be used in deriving RQs are defined below. The full set of available ecological effects data for FPE and fenoxaprop-ethyl, including data from additional studies, is described in **Appendix D**. In some cases, only draft DERs are available for ecotoxicity studies. These data are considered provisional at this time. Data are also available for exposures of organisms to formulated products containing FPE or fenoxaprop-ethyl. These data will not be considered quantitatively in this assessment.

The ECOTOXicology database (ECOTOX), was searched in order to provide additional ecological effects data. No data were located in ECOTOX for FPE. For fenoxaprop-ethyl, toxicity data are available for aquatic (30 records) and terrestrial (107 records) organisms. These data will be evaluated at a later time for their possible value added to this risk assessment.

3.1. Effects to aquatic organisms

On an acute exposure basis, FPE is considered very highly toxic (LC_{50} <0.1 mg/L) to estuarine/marine invertebrates, highly toxic (LC_{50} 0.1-1 mg/L) to freshwater fish, and moderately toxic (LC_{50} >1-10 mg/L) to freshwater invertebrates and estuarine/marine fish. Provisional chronic toxicity data for rainbow trout indicate a NOEC of 0.022 mg/L. Available chronic toxicity data for mysid shrimp indicate a NOEC of 0.01095 mg/L. FPE is moderately toxic (LC_{50} >1-10 mg/L) to aquatic vascular plants and highly toxic (EC_{50}>0.1-1 mg/L) to aquatic non-

vascular plants. Summaries of the most sensitive data from submitted aquatic toxicity data for FPE are located in **Table 2**.

Table 2. Summary of most sensitive endpoints of submitted toxicity studies for aquatic organisms exposed to FPE. All data are relevant to exposures of organisms to FPE, unless otherwise noted (by "").**

Species (common name)	Taxa Represented	End-point	Duration (hours)	Mean concentration (mg a.i./L)	Study Classification	Ref. (MRID)
Lepomis macrochirus (Bluegill Sunfish)	Freshwater fish and amphibians	LC_{50}	96	0.31**	Acceptable	00130337
Oncorhynchus mykiss (Rainbow Trout)		NOEC	91 (days)	0.022*	Provisional	44786801
		LOEC		0.036*		
Daphnia magna (Water Flea)	Freshwater Invertebrates	EC_{50}	48	>1.058	Supplemental	44664002
Cyprinodon variegatus (Sheepshead minnow)	Estuarine/ Marine Fish	LC_{50}	96	>1.0**	Supplemental	00163779
Mysidopsis bahia (Mysid shrimp)	Estuarine/ Marine Invertebrates	LC_{50}	96	0.098**	Acceptable	00163777
		NOEC	28 (days)	0.01095	Provisional	44786802
		LOEC		0.03265		
Lemna gibba (duckweed)	Aquatic vascular plants	EC_{50}	14 (days)	>3.00	Supplemental	44664003
		NOEC		3.00		
Selenastrum capricornutum (Green algae)	Aquatic non-vascular plants	EC_{50}	120	0.43	Supplemental	42009609
		NOEC		0.027		

* Based on nominal concentrations.
**Based on exposures of organisms to fenoxaprop-ethyl

No data are available to characterize chronic exposures of freshwater invertebrates or estuarine/marine fish to either FPE or fenoxaprop-ethyl. In light of these data gaps, the Acute to Chronic Ratio (ACR) approach will be used to estimate the chronic toxicity of FPE to these organisms. Available toxicity data for mysid shrimp exposed to FPE include a 96-h LC_{50} of 0.107 mg/L and a 28 day NOEC of 0.01095 mg/L. The result is an ACR of 9.77 for invertebrates. Application of this ratio to available acute toxicity data for daphnia (>1.058 mg/L), results in an estimated chronic NOEC value of 0.108 mg/L. Available toxicity data for rainbow trout exposed to FPE include a 96-h LC_{50} of 0.46 mg/L and a 91 day NOEC of 0.022 mg/L. The result is an ACR of 20.9 for fish. Application of this ratio to available acute toxicity data for sheepshead minnow (>1.0 mg/L), results in an estimated chronic NOEC value of 0.0478 mg/L. Given that the available acute toxicity values for freshwater invertebrates and

estuarine/marine fish are indiscreet, there is uncertainty associated with the estimated NOAEC values defining the effects of chronic exposures to these organisms.

3.2. Effects to terrestrial organisms

Data are available to assess the toxicity of FPE to terrestrial plants. A tier 1 seedling emergence test with dicot species (carrot, soybean, cabbage, lettuce, tomato and cucumber) yielded an EC_{25} >0.1 lb a.i./A. As expected based on the target organisms (*i.e.* grasses) of this herbicide, FPE was more toxic to monocots in a seedling emergence test. Corn was the most sensitive of the tested monocots, with an EC_{25} and NOEC of 0.002 and <0.0006 lbs a.i./A, respectively. No toxicity data were submitted to assess the effects of FPE to the vegetative vigor of dicots. Available vegetative vigor toxicity data for monocots indicated corn as the most sensitive monocot species tested, with EC_{25} and NOEC of 0.0025 and <0.0006 lbs a.i./A, respectively. These data are summarized in **Table 3**.

Table 3. Summary of submitted toxicity studies for terrestrial organisms exposed to FPE.

Species (common name)	Measure of effect	End-point	Mean Concentration	Test Substance (% a.i.)	Study Classification	Reference (MRID)
Dicot	Seedling Emergence (Tier 1)	EC_{25}	>0.1 lb a.i./a	7.2 (D-isomer)	Acceptable	41276904
Corn	Seedling Emergence (Tier 2)	EC_{25}	0.002 lbs a.i./A	7.2 (D-isomer)	Acceptable	41276905
		NOEC	<0.0006 lbs a.i./A			
Corn	Vegetative vigor (Tier 2)	EC_{25}	0.0025 lbs a.i./A	7.2	Acceptable	41276907
		NOEC	<0.0006 lbs a.i./A			

No data are available at this time to characterize the effects of exposures of FPE to birds, mammals or to terrestrial invertebrates; however, these data are available for fenoxaprop-ethyl. Therefore, available data for fenoxaprop-ethyl are used to fill these data gaps. Equivalent toxicities of FPE and fenoxaprop-ethyl are presumed for both mammals and birds.

Fenoxaprop-ethyl (and thus, FPE) is classified practically nontoxic to mammals (LD_{50} >2000 ppm), birds (LD_{50} >2000 mg/kg, LC_{50} >5000 mg/kg), and terrestrial insects (LD_{50} >11µg/bee) on an acute exposure basis. Chronic exposures to rats in a reproduction study indicate a NOAEL for reproduction and parental effects of 5 ppm (0.25 mg/kg/day). Chronic exposures to bobwhite quail in reproduction studies indicate effects to hatching, with a NOAEC of 30 ppm. No data are available to assess the toxicity of exposures of fenoxaprop-ethyl to terrestrial plants. Summaries of the most sensitive data from submitted terrestrial toxicity data for fenoxaprop-ethyl are located in **Table 4**.

Table 4. Summary of submitted toxicity studies for terrestrial organisms exposed to fenoxaprop-ethyl. Since it is assumed that FPE and fenoxaprop-ethyl are of equivalent toxicities to these organisms, these values are utilized for estimating the toxicities of FPE.

Species (common name)	Taxa Represented	End-point	Mean Concentration	Test Substance (% a.i.)	Study Classification	Reference (MRID)
Rattus norvegicus (laboratory rat)	Terrestrial mammals	LD_{50}	2357 mg/kg (males) 2500 mg/kg (females)	Technical	Acceptable	00130010 00130011
		NOAEL	5 ppm (0.25 mg/kg/day)	97.2	Acceptable	0014847
		LOAEC	30 ppm* (1.5 mg/kg/day)			
Anas platyrhynchos (Mallard Duck)	Birds, terrestrial phase amphibians and reptiles	LC_{50}	>5620 ppm	96.6±0.9	Acceptable	00130333
Colinus virginianus (Northern Bobwhite Quail)		LD_{50}	>2510 mg/kg	96.6±0.9	Acceptable	00130330
		LC_{50}	>5620	96.6±0.9	Acceptable	00130334
		NOAEC	30 ppm	95.5	Acceptable	00155304
		LOAEC	180 ppm**			
Apis mellifera (Honey Bee)	Terrestrial invertebrates	LD_{50}	>100 µg/bee	Technical	Acceptable	00130641

*Based on decreased blood lipids in parent, and reduced pup body weights.
**Based on effects to hatching.

4. INCIDENT REPORTS

The Agency has received 78 reports of adverse field effects to non-target plants that have been linked to the use of FPE. All of these incidents involved damage to a grain crop (barley, corn, rice, or wheat). The Agency considered the cause to be uncertain in 39 cases because more than one herbicide was applied to the crop. In the remaining 36 cases, the Agency considers FPE to be the probable cause. Most of the incidents were reports of crop damage that occurred following application of the herbicide directly to the crop, although three incidents occurred from carryover effects of applications made to another crop in a previous growing season. None of the incidents involved damage to crops or other plants outside the treatment site.

The Agency has received one report linking FPE to adverse field effects to wild animals. In 1998, Approximately 200 fish died in a pond in White County, Illinois following application of FPE, along with two other herbicides (fluazifop-p-butyl and fomesafen sodium), on a nearby soybean field. Because FPE is highly toxic to fish and was applied in close proximity to the pond, the Agency believes that exposure to this herbicide was a probable cause or contributing factor to the fish mortality.

The Agency has received no report of adverse field effects to non-target animals or plants that have been attributed to the use of fenoxaprop-ethyl. The Agency also has no incident report from pesticide registrants concerning fenoxaprop-ethyl contamination of ground or surface water.

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

5. EXPOSURE CHARACTERISTICS

FPE residues bioconcentrate in fish and can be moderately mobile in soil. The majority of the environmental fate and transport data submitted for FPE are provisional and currently in review. The submitted data indicate that, as an ester, FPE rapidly de-esterifies ($t_{1/2}$ range = 1-3 days) to fenoxaprop-p acid (AE F088406, (D+)-2-[4-(6-chloro-2-benzoxazolyloxy)phenoxy] propanoate), which is also biologically active (USEPA, 1997). The environmental fate and transport data set submitted for fenoxaprop-p acid is poor, consisting of a hydrolysis study conducted at 50-65°C with extrapolated values for environmental temperatures (MRID 44659603) and a batch equilibrium study (MRID 44768101), both of which are in review.

For current assessments, exposure is assessed in terms of the residues of concern of fenoxaprop-p-ethyl, which include the parent (AE F046360), fenoxaprop-p acid (AE F088406), and the hydrolytic product AE F054014 (USEPA, 2007). FPE residues of concern are expected to degrade slowly, as they are stable to photolysis, hydrolyze with a half-life of 269 to 717 days, and biodegrade with a half-life of 4-9 months under a range of conditions. However, a provisional rice paddy dissipation study indicated that residues of FPE dissipated with a half-life of 3.6 days before the paddy was reflooded.

Environmental fate-related data submitted in support of the no longer supported racemic mixture, fenoxaprop-ethyl (PC code 128701), will not be used in current assessments because the environmental fate characteristics of the two mixtures have not been bridged. Chemical properties of FPE and environmental fate parameters of FPE and its residues of concern are listed in **Table 5**.

Table 5. General chemical properties and environmental fate parameters of fenoxaprop-p-ethyl (based on provisional sources).		
Chemical/Fate Parameter	**Value**	**Source**
Chemical name	(D+)-ethyl-2-[4-(6-chloro-2-benzoxazolyloxy)phenoxy]propanoate	MRID 44676401 (provisional)
Molecular mass	361.8 g/mol	MRID 44676401 (provisional)
Vapor pressure (20°C)	1.4 x 10^{-8} torr	Acc. # 412-03-0113
Water solubility (pH 5.8; 20°C)	0.7 mg/L	MRID 44676401 (provisional)
Octanol-water partition coefficient (K_{OW})	38,000	MRID 44659601
Fish Bioconcentration Factor	129 (edible) 1021 (non-edible) 510 (whole fish)	MRID 41567707
Soil-water distribution coefficient (K_d) [1]; Organic carbon partitioning coefficient (K_{OC})[1]	12.6 L/kg; 5420 L/kg$_{OC}$ 176 L/kg; 6670 L/kg$_{OC}$ 213 L/kg; 26200 L/kg$_{OC}$ 443 L/kg; 17400 L/kg$_{OC}$	MRID 42915001 (provisional)
Total residues Freundlich soil-water distribution coefficient (K_F) [2]; Total residues Freundlich organic carbon partitioning coefficient (K_{FOC}) [2]	4.10 (1/n=1.00); 1770L/kg$_{OC}$ 5.91 (1/n=1.00); 223 L/kg$_{OC}$ 6.55 (1/n=1.00); 807 L/kg$_{OC}$ 9.77 (1/n=1.00); 383 L/kg$_{OC}$	MRID 42915001 (provisional)
Hydrolysis half-life; Total residues half-life (pH 5, 25°C)	37.5 d; 269 d	MRID44659602 (provisional)
Hydrolysis half-life; Total residues half-life (pH 7, 25°C)	75.1 d; 717 d	
Hydrolysis half-life; Total residues half-life (pH 9, 25°C)	5.64 d; 649 d	
Aqueous photolysis half-life	No evidence of degradation	MRID 44676401 (provisional)
Aerobic soil metabolism half-life; Total residues half-life	2.5 d; 188 d	MRID 43400602 (provisional)
Anaerobic aquatic metabolism half-life; Total residues half-life	0.44 d, <1 d; 116 d, 267 d	MRID 45081601 (provisional)
Terrestrial field dissipation half-life; Total residues half-life	<1 d; 3.6 d	MRID 43066404 (provisional)

[1] Point estimates at 0.35 ppm dosing concentration.
[2] 1/n is the Freundlich exponent that describes curvilinearity.

5.1 Transport and mobility

FPE is partially soluble in water, dissolving at 0.7 mg/L at 20°C and pH 5.8 (MRID 44676401). The compound is not expected to volatilize significantly due to its low vapor pressure of 1.4 x 10^{-8} torr (20°C; Acc. # 412-03-0113). The octanol-water partition coefficient of FPE is 38,000

(MRID 44659601), which is indicative of the relatively high bioconcentration factor (BCF) observed in fish viscera (1021x) relative to the BCF observed in edible fish portions (129x; MRID 41567707). The BCF for whole fish portions was 510x, which does not exceed reporting thresholds for concern for bioconcentration (64 FR 58665, Oct. 29, 1999).

FPE is slightly to hardly mobile (K_d of 12.6 to 443); however, its degradates fenoxaprop-p acid and AE F054014 are mobile (K_d of 1.8 to 25 and 2.0 to 3.8, respectively), according to a provisional batch equilibrium study (MRID 42915001). Therefore, FPE total residues of concern (TRC), which include FPE and these two degradates, are moderately mobile overall. The mobility of the FPE combined residues of concern is of interest relative to that of FPE alone due to the rapid degradation of FPE; Freundlich soil-water partitioning coefficients (K_F) for the combined residues calculated within the same provisional batch equilibrium study range from 4.10 (1/n=1.00) to 9.77 (1/n=1.00) (MRID 42915001). Mobility of the total residues is not well explained by affinity to organic matter, as the coefficient of variation (CV) across four soils for K_{FOC} (87%) is greater than that for K_F (36%). In general, compounds, such as fenoxaprop-p acid and HOE 054014, with K_F values less than five are mobile enough to potentially present a ground water concern in some soils.

A provisional study specifically on fenoxaprop-p acid appears to confirm that it has greater mobility than FPE (K_F range = 1.17 (1/n=0.88) to 8.76 (1/n=0.73); MRID 44768101).

5.2 Degradation

FPE is hydrolyzed moderately in acidic conditions ($t_{½}$ = 37.5 d at pH 5), slowly in neutral conditions ($t_{½}$ = 75.1 d at pH 7), and quickly in alkaline conditions ($t_{½}$ = 5.64 d at pH 9; MRID 44659602). Three major hydrolysis degradates were identified: fenoxaprop-p acid, AE F054014 (6-chloro-2,3-dihydro-benzoxazol-2-one), and AE F096918 (2-(4-hydroxyphenoxy)propanoate). Fenoxaprop-p acid is the primary degradate at up to 63.6% of applied radioactivity in the hydrolysis study (14 days after treatment (DAT); MRID 44659602); both FPE and fenoxaprop-p acid may hydrolyze to AE F054014, which was observed in the hydrolysis study at up to 35.8% of the applied (21 DAT); fenoxaprop-p acid moderately hydrolyzes to both AE F054014 and AE F096918 at equal molar amounts; AE F096918 was observed at up to 42.0% of the applied (64 DAT) in the anaerobic aquatic metabolism study (MRID 45081601). There is no evidence of degradation of FPE by photolysis (MRID 44676401).

FPE was quickly biodegraded in aerobic soils ($t_{½}$ = 2.5 d; MRID 43400602) and in anaerobic aquatic systems ($t_{½}$ < 1 d; MRID 45081601). The four major degradates observed in the these two metabolism studies were fenoxaprop-p acid at up to 65.8% and 100.8% of the applied (2-3 DAT), AE F096918 at up to 42.0% of the applied (64 DAT) in the anaerobic aquatic metabolism study, M3 (an unidentified degradate in the aerobic soil metabolism study) at up to 10.2% of the applied (59 DAT), and carbon dioxide at up to 14.5% (98 DAT) and 29.9% (238 DAT) of the applied, in the aerobic soil metabolism and anaerobic aquatic metabolism studies, respectively.

5.3 Field studies

A terrestrial and aquatic field dissipation study of FPE was conducted with the end use product Whip® (HOE 46360 75 EW; MRID 43066404). Whip® was broadcast at 0.41 lbs a.i./A onto subplots of clay loam soil in a drained rice patty in California with rice seedlings grown to the 1- to 4-leaf stage. At 4 DAT, the paddy was flooded with 6 inches of canal water and flood irrigated through 60 DAT. Soil samples (0-12 inch depth) were collected through 60 DAT. The limit of quantitation for residues of FPE was 10 ppb (10 µg/kg); samples containing ≥50 ppb of FPE residues were analyzed for individual compounds. FPE residues of concern (FPE, fenoxaprop-p acid, and AE F054014) dissipated in the drained soil (0-3 inch depth) with a half-life of 3.6 days. This dissipation rate is faster than expected regarding the degradation rates in the submitted fate and transport studies; therefore, there is some uncertainty as to whether the major routes of dissipation for this compound have been well characterized.

FPE residues were detected at a maximum concentration of 350 ppb (15% of the applied concentration; 0-3 inch depth, 0.04 DAT) and at a maximum depth of 6 inches. FPE residues were not detected above the limit of quantitation in flood water. FPE parent was detected at a maximum concentration of 60 ppb (0-3 inch depth; 1-2 DAT); fenoxaprop-p acid was detected at a maximum concentration of 270 ppb (0-3 inch depth; 0.4 DAT); AE F054014 was detected at a maximum concentration of 70 ppb (0-3 inch depth; 4 DAT). Maximum depths of FPE parent, fenoxaprop-p acid, and AE F054014 were not reported.

5.4 Degradates

Major degradates of FPE include fenoxaprop-p acid, AE F054014, AE F096918, M3 (an unidentified compound), and carbon dioxide (chemical names and structures are tabulated in **Appendix E**). One minor degradate has been identified, AE F040356 (4-(6-chloro-2-benzoxazolyloxy)phenol). FPE and its major degradates containing the 6-chloro-2-benzoxazol moiety (fenoxaprop-p acid and AE F054014) are residues of concern for dietary risk assessment and, therefore, for mammals (USEPA, 2007). Toxicity data specific to the two degradates of concern are unavailable. In the absence of data, the FPE degradates of concern are assumed to have similar toxicity to FPE parent. Therefore, a total residues of concern (TRC) approach will be used for current drinking water exposure assessment and aquatic ecological risk assessment to evaluate the potential exposure of humans and aquatic taxa to the residues of risk concern, *i.e.*, FPE, fenoxaprop-p acid, and AE F054014.

6. CHARACTERISTICS OF ECOSYSTEMS POTENTIALLY AT RISK

For FPE and pesticides in general, the ecosystems at greatest risk are those in close proximity to the use areas. These would include agricultural fields growing barley, cotton, peanuts, rice, soybeans and wheat, as well as conservation reserves, rights-of-way, container- and field-grown ornamentals, golf courses, sod farms, other turf areas (*e.g.*, athletic fields), residential areas and water bodies directly adjacent to use sites that may receive chemical residues via drift, runoff, and/or discharged ground water. Within water bodies, the water column, sediments, and pore water are all compartments of concern. Organisms of concern include birds, mammals, reptiles, fish, amphibians, terrestrial and aquatic invertebrates, and plants. The assessment endpoints are intended to reflect population sustainability and community structure within ecosystems and

hence relate back to ecosystems at risk. If risks are expected for given species/taxa based on the screening-level assessment, then risks might be expected to translate to higher levels of biological organization.

7. ASSESSMENT ENDPOINTS

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

To estimate exposure concentrations, an ecological risk assessment considers application(s) at the maximum application rate to use sites that have vulnerable soils. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Guideline toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants.

8. CONCEPTUAL MODEL

The conceptual model used to depict the potential ecological risk associated with FPE assumes that FPE is capable of affecting aquatic and terrestrial organisms provided environmental concentrations are sufficiently elevated as a result of proposed label uses. However, through a preliminary iterative process of examining fate and effects data, the conceptual model, *i.e.*, the risk hypothesis, has been refined to reflect the exposure pathways and the organisms for which risk is most likely. Based on a preliminary risk screening and past assessments indicating that FPE is highly toxic to freshwater fish on an acute exposure basis and causes potential effects in mammals and birds when chronically exposed, the hypothesis for the risks of FPE to non-target animals (depicted in **Figure 1**) focuses on both aquatic and terrestrial environments. Therefore, exposure as a result of direct spray, spray drift, granules, and runoff will be considered. Risk to aquatic plants is also considered in this screening-level assessment. For terrestrial animals, the major route of exposure considered is the dietary route; consumption of food items such as plant leaves or insects that have FPE residues as a result of spraying and drift. For aquatic animal

species, the major routes of exposure are considered to be via the respiratory surface (gills) or the integument. Aquatic plants may be exposed via direct uptake and adsorption.

Estimated exposure concentrations (EEC) for all organisms are obtained through the use of several Agency exposure models. EECs modeled for the preliminary risk screen and the 2007 Section 18 risk assessment used degradation half-lives calculated for the collective residues of risk concern in the submitted environmental fate studies. As shown in **Table 5**, hydrolysis half-lives increased from short—moderate values for FPE alone to relatively persistent values counting TRC and aerobic soil metabolism and anaerobic aqueous metabolism half-lives increased from rapid values for FPE alone to approaching persistent values counting TRC.

8.1. Risk Hypothesis

Risk hypotheses are specific assumptions about potential adverse effects (*i.e.*, changes in assessment endpoints) and may be evaluated on theory and logic, empirical data, mathematical models, or probability models (USEPA, 2004). For this assessment, the risk is stressor-initiated, where the stressor is the release of FPE to the environment. The following risk hypothesis is presumed for this screening level assessment:

> *Based on the application methods, mode of action, and the sensitivity of non-target aquatic and terrestrial species, FPE has the potential to reduce survival, reproduction, and/or growth in terrestrial and aquatic organisms.*

In order for a chemical to pose an ecological risk, its residues of concern must reach non-target organisms at concentrations found to cause adverse effects. The exposure pathway is the way by which a pesticide moves in the environment from the application site to non-target organisms. The assessment of ecological exposure in this assessment includes an examination of the source and potential migration pathways for FPE residues of concern, and the determination of potential exposure routes to non-target species.

8.2. Diagram

Application methods for the use of FPE involve spray using ground or aerial equipment. Ecological receptors that may potentially be exposed to FPE include terrestrial and semi-aquatic wildlife (*i.e.*, mammals, birds, amphibians, terrestrial invertebrates, reptiles and plants). In addition, aquatic receptors (*e.g.*, freshwater and estuarine/marine fish and invertebrates, amphibians, and aquatic plants) may also be exposed as a result of potential migration of FPE via spray drift and/or runoff from the site of application to various aquatic environments. These data form the basis for identifying potential endpoints, stressors, and ecological effects associated with FPE use (**Figure 1**).

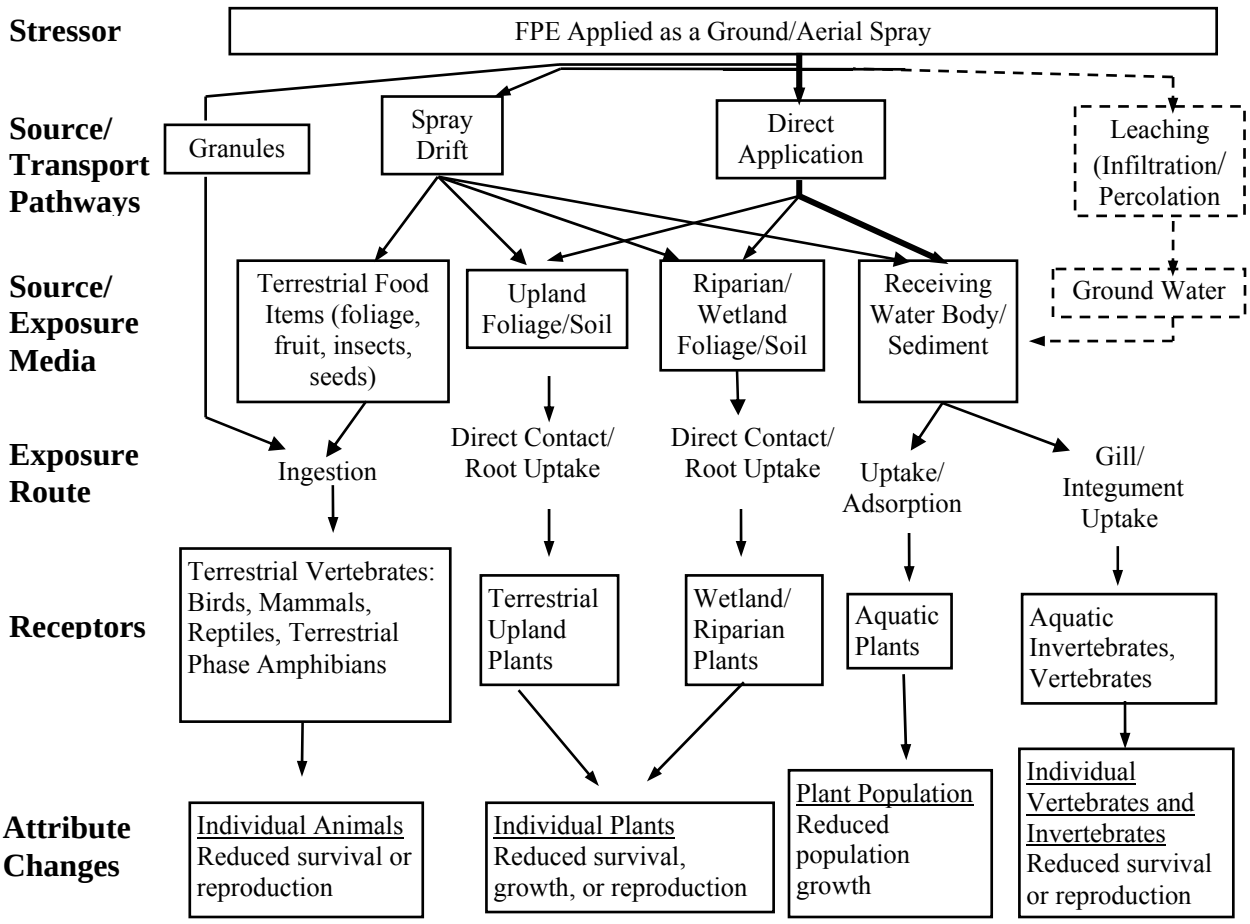


Figure 1. Conceptual model of the transport and effects of FPE in the environment. Dotted lines indicate exposure routes that were considered and not thought to contribute significantly to the fate and transport of FPE.

9. ANALYSIS PLAN OPTIONS

In Registration Review, pesticide ecological risk assessments will follow the Agency's Guidelines for Ecological Risk Assessment, will be in compliance with the paper titled "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency" ("Overview Document"; USEPA, 2004), and will be done in accordance with Section 7 of the Endangered Species Act.

A review of previously completed screening level risk assessments indicate that screening level assessments of acute and chronic risk to non-target organisms has not been completed for all uses. Based on toxicity data and Risk Quotients (RQs) described in the Section 18 assessment for grass grown for seed in Oregon (the most recent ecological assessment available), there are potential effects to mammals and birds from chronic exposures to FPE in terrestrial habitats, when applied at the proposed label rates. The proposed application rate for grass grown for seed

(0.0825 lbs a.i./A/year) is lower than or similar to the maximum application rates on the current labels for all other uses (see **Table 6**). Furthermore, due to a lack of toxicity data, potential risks to aquatic organisms, birds, and beneficial insects have not previously been assessed by the Agency. **Appendix B** shows the current status of risk assessments for registered uses of FPE.

9.1. Discussion of Assumptions and Uncertainties

In addition to conducting screening level assessments (and refined assessments, if necessary) for all FPE uses, other uncertainties and potential paths forward are described below.

- Maximum yearly application rates could not be determined based on information provided on product labels for all uses. In the absence of label clarifications, assumptions will be made in the ecological risk assessments according to the information in **Table 6**.

Table 6. Assumptions related to maximum rates per application, number of applications per year, intervals between applications, and maximum number of seasons per year for FPE.

Use	Max Application Rate per Application (lbs a.i./A)	Max # of Applications Per Season	Min application Interval (days)	Max # of Seasons Per Year
Barley	0.0825	1	NA	1
Conservation Reserve	0.126	NS	NS	26*
Cotton	0.126	1	NA	1
Ornamental	0.092	NS	NS	26*
Peanuts	0.126	1	NA	1
Rice	0.0713	2	14	2
Right-of-Way	0.178	3	14	2
Soybeans	0.128	1	NA	1
Turf	0.178	3	14	2
Wheat	0.084	1	NA	2

NS = not specified
NA = not applicable
* It is assumed that it is possible to apply every 14 days.

- Available product labels identified maximum application rates per season, not per year. **Table 6** also includes assumptions related to the maximum number of seasons per year.
- Since multiple crops to which FPE can be applied can be rotated on the same field within the same year (*e.g.* barley and wheat; peanuts and cotton), it is possible to have multiple season applications of FPE.
- The following amendments are recommended for improving label clarity:

i. All labels should be amended to define the maximum rate per application for each use, as well as the maximum number of applications per year in accordance with CFR 156.10 (i)(2).
ii. Several labels indicate "recommended" application rates. This language should be altered to read "maximum application rates."
iii. On several labels, including 72155-62, 72155-63, 72155-66, 72155-74, 72155-77 and 72155-78, the density of FPE per product (*e.g.* lbs FPE per gallon) should be cited.
iv. See **Appendix A** for label specific details.

- It will be assumed that aerial and ground methods of application can be employed for all uses, excluding residential uses.
- No data are available for assessing the responses of an estuarine/marine fish species to exposures to FPE. In the absence of these data, available data for the exposures of fenoxaprop-ethyl to sheepshead minnow (MRID 00163779) will be used.
- No acute, sub-acute or chronic toxicity data are available for exposures birds to FPE. In the absence of these data, available data for the exposures of fenoxaprop-ethyl to mallards and quail (MRIDs 00130333, 00155305, 00130330, 00130334 and 00155304) will be used.
- No acute or chronic toxicity data are available for exposures of mammals to FPE. In the absence of these data, available data for the exposures of fenoxaprop-ethyl to laboratory rats (MRIDs 00130010, 00130011, 0014847) will be used.
- No data are available for assessing the responses of beneficial terrestrial insects to exposures to FPE. In the absence of these data, available data for fenoxaprop-ethyl exposures to the honey bee (MRID 00130641) will be used.
- Several toxicity studies have been submitted in relation to the effects of FPE to aquatic organisms. At this time, only draft DERs are available. Therefore, there is uncertainty in which data will be used for risk estimation.
- No data are available for assessing the responses of freshwater invertebrates and estuarine/marine fish to chronic exposures of FPE. In the absence of these data, the ACR method will be used to estimate NOEC values for these taxa.

9.2. Preliminary Assessment of Exposure and Risks

Preliminary estimated environmental concentrations (EECs) were calculated for aquatic habitats using the GENEEC2 Model. EECs relevant to terrestrial animals and plants were calculated using T-REX (v. 1.3.1) and TerrPlant (v.1.2.2), respectively (see **APPENDICES F and G** for details).

Based on preliminary aquatic EECs and the assumptions discussed above, acute and chronic risks at the highest labeled application rate are expected for non-listed and listed aquatic animals. Risks are also expected for non-listed and listed birds and terrestrial mammals due to chronic dietary based or dose based exposures to FPE. Risks are expected as well for non-listed and listed species of monocots inhabiting semi-aquatic and dry areas based on exposures of FPE originating from the maximum application rate. Because of the potential risk from direct effects to the listed and non-listed taxa described above, should exposure occur, listed species in all taxa

may potentially be affected indirectly due to alterations in their habitat (*e.g.*, food sources, shelter, and areas to reproduce).

If the planned ecological risk assessment continues to indicate that FPE may potentially impact, either directly or indirectly, listed species or critical habitat, and therefore does not support a "no effect" determination, further refinements will be made. This will involve determining whether use of FPE is "likely to adversely affect" the species, or in the case of designated critical habitat, whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat, and if so, whether the expected impacts are "likely to adversely affect" the critical habitat. The first step in the process is to improve the exposure estimates based on refining the geographic proximity of FPE's use and the listed species and/or critical habitat. If there is no geographic proximity, this information would support a determination that FPE use will have no effect on the species or critical habitat. If after conducting the first step of this analysis the Agency determines that geographic proximity exists, both potential direct effects and any potential indirect effects of the pesticide use will be examined. This process is consistent with the Agency's Overview Document. The Agency will consult as necessary with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively 'the Services'), consistent with the Services' regulations.

If the screening level risk assessment identifies potential concerns for indirect effects on listed species, the next step for EPA and the Services would be to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether FPE's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by FPE. Then EPA would determine whether the use of FPE overlaps the critical habitat or the occupied range of those listed species.

9.3. Anticipated Data Needs

EFED is awaiting review of the majority of submitted environmental fate studies for FPE before recommending the request of any additional environmental fate data.

As stated above, there is uncertainty associated with the use of toxicity studies involving fenoxaprop-ethyl to represent effects of organisms to FPE. Although there is evidence to suggest that FPE and fenoxaprop-ethyl are of similar acute toxicities to aquatic organisms, there are currently no data to compare effects of FPE and fenoxaprop-ethyl to terrestrial animals. When this assessment is conducted, if there is a lack of data for exposures of mammals and birds FPE, available data for fenoxaprop-ethyl will be used. However, availability of toxicity data for mammals and birds exposed to FPE would decrease uncertainties associated with assuming that the two isomers are of equivalent toxicities to these organisms. EFED recommends requiring acceptable toxicity studies of mammals and birds exposed to FPE. EFED is particularly

interested in data related to chronic exposures (reproductive toxicity studies), since effects were observed in studies where mammals and birds were exposed to fenoxaprop-ethyl (MRIDs 00014847 and 00155304).

The Agency will also conduct a search of the open literature to ensure that the best available science is utilized. The Agency uses the ECOTOX (www.epa.gov/ecotox) database as its mechanism for searching the open literature for ecological effects information. ECOTOX integrates three previously independent databases - AQUIRE, PHYTOTOX, and TERRETOX - into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife, respectively. ECOTOX utilizes specific screening criteria to ensure consistent data quality for OPP risk assessment purposes.

9.4. Other Information Needs

There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is interested in obtaining the following information:

6. confirmation on the following label information
    a. sites of application
    b. formulations
    c. maximum application rates
    d. frequency of application, application intervals, and maximum number of applications per season
    e. geographic limitations on use
7. use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses)
8. use history
9. median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county
10. application timing (date of first application and application intervals) by use – national, state, and county
11. sub-county crop location data
12. usage/use information for non-agricultural uses (*e.g.*, golf courses, athletic fields, ornamentals)
13. directly acquired county-level usage data (not derived from state level data)
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county

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

10. REFERENCES

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APPENDIX A: Current FPE Registrations and Uses, Including Maximum Application Rates and Application Timing.

Use	Label	Application Method	Application timing	Application Interval (days)	Maximum Application Rate/Ap (lbs a.i./A)	Max # aps/year	Comments
Barley	264-666	ground, aerial	from emergence to 5 leaf stage	NA	0.0825	1*	
Conservation Reserve (set aside)	264-647	ground, aerial	Not specified	Not specified	0.07125	Not specified	
Conservation Reserve (set aside)	264-650	ground, aerial	Not specified	Not specified	0.126	Not specified	
Cotton	264-650	ground, aerial	Not specified	NA	0.126	1*	Label states that the user can make 2 applications per season for a maximum of 1.5 pints product per season. The maximum single application rate allowed by the label corresponds to 1.5 pints product per season.
Cotton	100-1059	ground, aerial	"before, during or after planting or after harvest of soybeans or cotton"	NA	0.105	1*	Applications allowed in: AL, AR, FL, GA, LA, MS, MO, NC, NM, OK, SC, TN, TX, VA
Ornamental - residential	432-958	ground***	to young, actively growing weeds	Not specified	0.092	Not specified	
Ornamental	432-957	ground, aerial**	preemergence to 3 tiller	NA	0.09	1*	
Ornamental	432-959	ground, aerial**	to young, actively growing weeds	NA	0.09	1*	
Ornamental	432-950	ground, aerial**	when weeds emerge	14	0.089	6*	
Ornamental - residential	72155-74	ground***	Not specified	Not specified	0.075	Not specified	Application rate determined using product density defined on MSDS.

Use	Label	Application Method	Application timing	Application Interval (days)	Maximum Application Rate/Ap (lbs a.i./A)	Max # aps/year	Comments
Peanuts	264-650	ground, aerial	Not specified	NA	0.126	1*	Label states that the user can make 2 applications per season for a maximum of 1.5 pints product per season. The maximum single application rate allowed by the label corresponds to 1.5 pints product per season.
Rice	264-647	ground, aerial	see label	14	0.07125	2*	
Rice	264-682	ground, aerial	can be applied to rice from 2 leaf stage to late tillering stage	14	0.068	2*	Maximum single application rate is not specified. 2 applications per season are permitted for a total of 0.136 lbs a.i./a.
Right-of Way	432-950	ground, aerial**	when weeds emerge	14	0.178	3*	Label gives recommended single application rates, with a maximum of 39 oz. Maximum single application rate in this table is relevant to 40 oz application. The total application per season is 120 oz (0.534 lbs a.i./A), which could conservatively be the maximum single application rate.
Right-of Way	432-957	ground, aerial**	preemergence to 3 tiller	NA	0.09	1*	
Right-of Way	432-959	ground, aerial**	to young, actively growing weeds	NA	0.09	1*	
Right-of Way	100-1059	ground, aerial	Not specified	Not specified	0.039	Not specified	
Soybeans	264-647	ground, aerial	see label	NA	0.128	1*	

Use	Label	Application Method	Application timing	Application Interval (days)	Maximum Application Rate/Ap (lbs a.i./A)	Max # aps/year	Comments
Soybeans	264-650	ground, aerial	Not specified	NA	0.126	1*	Label states that the user can make 2 applications per season for a maximum of 1.5 pints product per season. The maximum single application rate allowed by the label corresponds to 1.5 pints product per season.
Soybeans	100-1059	ground, aerial	"before, during or after planting or after harvest of soybeans or cotton"	NA	0.105	1*	Applications allowed in: AL, AR, CT,DE, FL, GA,ID, IL, In, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NH, NJ, NY, NC, ND, OH, KO, OR, PA, RI, SC, SD, TN, TX, VT, VA, WA, WV, WI, WY
Turf	432-950	ground, aerial**	when weeds emerge	14	0.178	3*	Label gives recommended single application rates, with a maximum of 39 oz. Maximum single application rate in this table is relevant to 40 oz application. The total application per season is 120 oz (0.534 lbs a.i./A), which could conservatively be the maximum seasonal application rate.
Turf	432-957	ground, aerial**	preemergence to 3 tiller	NA	0.09	1*	
Turf	432-959	ground, aerial**	to young, actively growing weeds	NA	0.09	1*	
Turf - residential	432-958	ground***	to young, actively growing weeds	Not specified	0.092	Not specified	
Turf - residential	72155-74	ground***	Not specified	Not specified	0.075	Not specified	Application rate determined using product density defined on MSDS.
Turf - residential	72155-62	ground***	Not specified	Not specified	Not specified	Not specified	

Use	Label	Application Method	Application timing	Application Interval (days)	Maximum Application Rate/Ap (lbs a.i./A)	Max # aps/year	Comments
Turf - residential	72155-63	ground***	Not specified	Not specified	Not specified	Not specified	
Turf - residential	72155-66	ground***	Not specified	Not specified	Not specified	Not specified	
Turf - residential	72155-77	ground***	Not specified	Not specified	Not specified	Not specified	
Turf - residential	72155-78	ground***	Not specified	Not specified	Not specified	Not specified	
Wheat	264-650	ground, aerial	3 leaf to tillering stage in wheat	NA	0.084	1*	For use in TX and OK only.
Wheat	264-666	ground, aerial	from emergence to 70 days from harvest	NA	0.0825	1*	
Wheat	264-655	ground, aerial	3 leaf to 6 leaf stage in wheat	NA	0.0388	1*	

*Maximum number of applications of maximum application rate per SEASON.

**Application method is not defined.

***It is assumed that since this product is intended for residential uses (including small volume applications), applications will be made by ground methods.

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APPENDIX B: Past Ecological Risk Assessments for FPE.

DATE	COMPOUND	TYPE OF ACTION	USE(S)	POTENTIAL RISK IDENTIFIED	SUMMARIZED ECOLOGICAL CONCLUSIONS
2-14-1996	FPE	S3NU	Wheat, soybeans, cotton, peanuts, conservation reserve	Yes	Potential risk to terrestrial plants, including 10 listed plants.
7-10-1997	FPE	§18	Barley in North Dakota	Yes	Minimal risk to animals; risk to terrestrial plants. Insufficient data on aquatic plants.
10-3-1997	FPE	DWA	All	N/A	N/A
4-28-1998	FPE's safener	§18	Barley in North Dakota	Yes	Low risk to mammals, birds, fish, aquatic invertebrates and aquatic plants from safener. No expected unacceptable risk to listed species.
3-25-1999	FPE	§18	Rice in Arkansas	Yes	Risk only to terrestrial plants. No endangered species concerns.
2-2-2001	FPE & its safener	§18	Rice in Arkansas and Louisiana	Yes	Little risk to non-target animals. Potential risk to terrestrial plants, including 3 listed dicots in AR.
6-25-2007	FPE	§18	Grass for seed in Oregon	Yes	Chronic risk to mammals; no listed mammals identified. Risk to semi-aquatic monocots and listed terrestrial monocots; 1 listed monocot identified.

APPENDIX C: Comparison of available ecotoxicity data for FPE and fenoxaprop-ethyl.

Data are available for 4 aquatic species for comparison of the effects of FPE and fenoxaprop-ethyl exposure to the same species. Acute exposures of aquatic organisms to FPE and fenoxaprop-ethyl result in similar EC_{50} values, generally being on the same order of magnitude (**Table C.1**). When considering all acute exposure toxicity data for aquatic animals (fish and invertebrates), FPE and fenoxaprop-ethyl are classified highly to moderately toxic to these organisms (**Figure C.1**). References for these toxicity data are identified in **Appendix D**.

TABLE C.1. Comparison of available aquatic toxicity data for FPE and fenoxaprop-ethyl. Units in mg a.i./L.

Species (common name)	End-point	Duration (hours)	FPE	Fenoxaprop-ethyl
Lepomis macrochirus (Bluegill Sunfish)	LC_{50}	96	0.58	0.31
Daphnia magna (waterflea)	EC_{50}	48	>1.058	3.18
Mysidopsis bahia (Mysid shrimp)	LC_{50}	96	0.107-0.109	0.098
Selenastrum capricornutum (Green algae)	EC_{50}	120	0.43	0.65

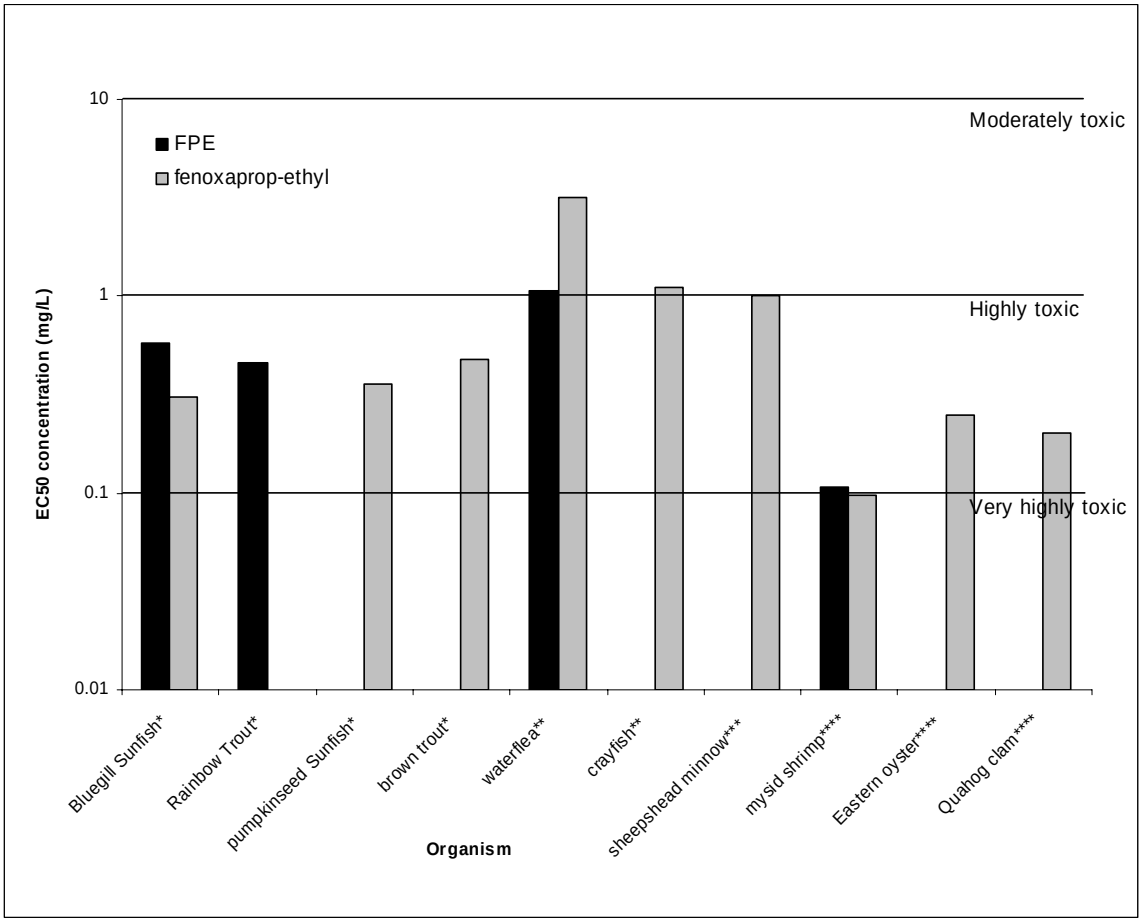


Figure C.1. Acute toxicity data (EC_{50}s) for aquatic animals exposed to FPE or fenoxaprop-ethyl.
***freshwater fish; **freshwater invertebrates; ***estuarine/marine fish; ****estuarine/marine invertebrates**

APPENDIX D: Registrant submitted effects data for TGAI FPE and Fenoxaprop-ethyl.

Available aquatic toxicity data for FPE and fenoxaprop-ethyl are presented in **Tables D.1 and D.3**, respectively. Available terrestrial toxicity data for FPE and fenoxaprop-ethyl are presented in **Tables D.2 and D.4**, respectively.

TABLE D.1. Summary of submitted toxicity studies for aquatic organisms exposed to FPE (PC 129092). Endpoints are based on measured test concentrations, except where noted.

Species (common name)	Measure of Effect	End-point	Duration (hours)	Mean conc, units in mg a.i./L (95% c.i.)	Test substance (% a.i.)	Study Classification	Ref. (MRID)
Freshwater Fish							
Lepomis macrochirus (Bluegill Sunfish)	Mortality	LC_{50}	96	0.58**	95.6	Acceptable	42009603
Oncorhyncus mykiss (Rainbow Trout)	Mortality	LC_{50}	96	0.46**	95.6	Acceptable	42009604
	Mortality	LC_{50}	96	0.58**	95.6	Supplemental	42009605
	Length and wet weight	NOEC	91 (days)	0.022**	88.1	Draft DER	44786801
		LOEC		0.036**			
Freshwater Invertebrates							
Daphnia magna (Water Flea)	Immobility	EC_{50}	48	>1.058	88.1	Supplemental	44664002
	Immobility	EC_{50}	48	2.7**	95.6	Invalid	42009606
Estuarine/Marine Invertebrates							
Mysidopsis bahia (Mysid shrimp)	Mortality	LC_{50}	96	0.107	89.5	Acceptable	42009607
	Dry Weight	NOEC	28 (days)	0.01095	88.1	Draft DER	44786802
		LOEC		0.03265			
Aquatic Plants							
Lemna gibba (duckweed)	Frond number	EC_{50}	14 (days)	>3.00	88.1	Supplemental	44664003
		NOEC		3.00			

TABLE D.1. Summary of submitted toxicity studies for aquatic organisms exposed to FPE (PC 129092). Endpoints are based on measured test concentrations, except where noted.							
Species (common name)	**Measure of Effect**	**End-point**	**Duration (hours)**	**Mean conc, units in mg a.i./L (95% c.i.)**	**Test substance (% a.i.)**	**Study Classification**	**Ref. (MRID)**
Navicula pelliculosa (Freshwater diatom)	% Inhibition	EC_{50}	96	2.5	88.1	Draft DER	44768105
		NOEC		1.6			
Skeletonema costatum (Marine diatom)	% Inhibition	EC_{50}	96	>0.8	88.1	Draft DER	44768104
		NOEC		0.38			
Anabaena flos-aquae (Blue-green algae)	% Inhibition	EC_{50}	96	>0.78	88.1	Draft DER	44768103
		NOEC					
Selenastrum capricornutum (Green algae)	% Inhibition	EC_{50}	120	0.43	97.4	Supplemental	42009609
		NOEC		0.027			
** Based on nominal concentrations.							

TABLE D.2. Summary of submitted toxicity studies for terrestrial plants exposed to FPE (PC 129092).						
Species (common name)	**Measure of effect**	**End-point**	**Mean Concentration (C.I.)**	**Test Substance (% a.i.)**	**Study Classification**	**Reference (MRID)**
Carrot, soybean, cabbage, lettuce, tomato, cucumber	Seedling Emergence (Tier 1)	EC_{25}	>0.1 lb a.i./A	7.2 (D-isomer)	Acceptable	41276904
Corn, oat, ryegrass, onion	Seedling Emergence (Tier 1)	EC_{25}	<0.1 lb a.i./A	7.2 (D-isomer)	Acceptable	41276904
Corn	Seedling Emergence (Tier 2)	EC_{25}	0.002 lbs a.i./A	7.2 (D-isomer)	Acceptable	41276905
		NOEC	<0.0006 lbs a.i./A			
Oat	Seedling Emergence (Tier 2)	EC_{25}	0.0096 lbs a.i./A	7.2 (D-isomer)	Acceptable	41276905
		NOEC	<0.0006 lbs a.i./A			
Ryegrass	Seedling Emergence (Tier 2)	EC_{25}	0.0578 lbs a.i./A	7.2 (D-isomer)	Acceptable	41276905
		NOEC	<0.0240 lbs a.i./A			
Onion	Seedling Emergence (Tier 2)	EC_{25}	N/A	7.2 (D-isomer)	Acceptable	41276905
		NOEC	>0.0960 lbs a.i./A			
Corn	Vegetative vigor (Tier 2)	EC_{25}	0.0025 lbs a.i./A	7.2	Acceptable	41276907
		NOEC	<0.0006 lbs a.i./A			
Oat	Vegetative vigor (Tier 2)	EC_{25}	0.0779 lbs a.i./A	7.2	Acceptable	41276907
		NOEC	N/A			
Ryegrass	Vegetative vigor (Tier 2)	EC_{25}	0.0817 lbs a.i./A	7.2	Acceptable	41276907
		NOEC	<0.0480 lbs a.i./A			

TABLE D.3. Summary of submitted toxicity studies for aquatic organisms exposed to fenoxaprop-ethyl (PC 128701).

Species (common name)	Measure of Effect	End-point	Duration (hours)	Mean conc, units in mg a.i./L (95% c.i.)	% a.i.	Study Classification	Ref. (MRID)
Freshwater Fish							
Lepomis macrochirus (Bluegill Sunfish)	Mortality	LC_{50}	96	0.31 (0.26-0.35)	95.8	Acceptable	00130337
Lepomis gibbosus (pumpkinseed Sunfish)	Mortality	LC_{50}	96	0.36 (0.32-0.41)	96.0	Acceptable	00130338
Salmo trutta (brown trout)	Mortality	LC_{50}	96	0.48 (0.45-0.52)	96.0	Acceptable	00130335
Idus melanotus (golden orfe)	Mortality	LC_{50}	96	>0.8	Technical	Invalid	00130340
Freshwater Invertebrates							
Daphnia magna (Water Flea)	Immobility	EC_{50}	48	3.18 (1.79-7.36)	96.0	Acceptable	00130342
Procambarus simulans (crayfish)	Mortality	LC_{50}	96	1.1 (0.74-1.5)	96.5	Supplemental	00154343
Estuarine/Marine Fish							
Cyprinodon variegatus (Sheepshead minnow)	Mortality	LC_{50}	96	>1.0	96.5	Supplemental	00163779
Estuarine/Marine Invertebrates							
Mysidopsis bahia (Mysid shrimp)	Mortality	LC_{50}	96	0.098 (0.068-0.15)	96.5	Acceptable	00163777
Mysidopsis bahia (Mysid shrimp)	Mortality	LC_{50}	96	0.107	96.8	Acceptable	42009608
Crassostrea virginica (Eastern oyster)	Immobility	EC_{50}	48	0.25 (0.15-0.38)	96.5	Supplemental	00163775

TABLE D.3. Summary of submitted toxicity studies for aquatic organisms exposed to fenoxaprop-ethyl (PC 128701).

Species (common name)	Measure of Effect	End-point	Duration (hours)	Mean conc, units in mg a.i./L (95% c.i.)	% a.i.	Study Classification	Ref. (MRID)
Mercenaria mercenaria (Quahog clam)	Immobility	EC_{50}	48	0.20 (0.11-0.35)	96.5	Acceptable	ACC: 40404702
Aquatic Plants							
Selenastrum capricornutum (Green algae)	% Inhibition	EC_{50}	7 (days)	731.9 (227.7-6093.2)	96.5	Acceptable	Acc: 40404704
	% Inhibition	EC_{50}	5 (days)	0.65	96.8	Acceptable	42009610
		NOEC		0.104			

* Draft DER available.
** Based on nominal concentrations.
*** Not listed in OPPIN under this PC code.

TABLE D.4. Summary of submitted toxicity studies for terrestrial organisms exposed to fenoxaprop-ethyl (PC 128701).

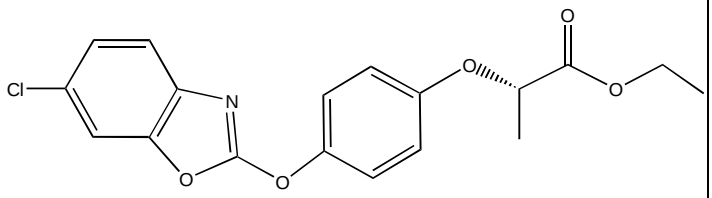
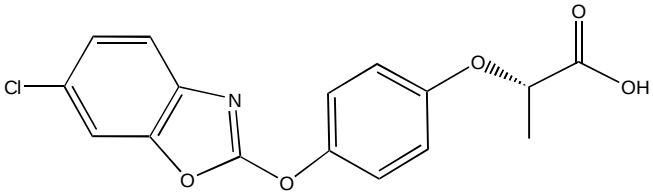
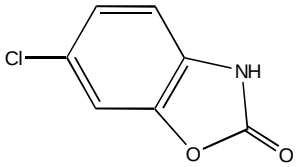
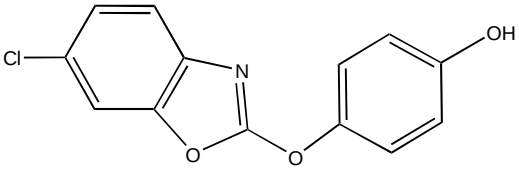
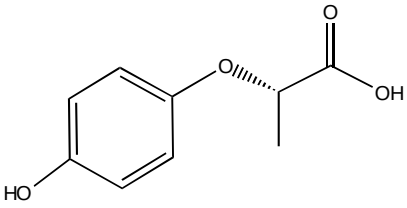
Species (common name)	Measure of effect	End-point	Mean Concentration (C.I.)	Test Substance (% a.i.)	Study Classification	Reference (MRID)
Mammals						
Rattus norvegicus (laboratory rat)	Mortality	LD_{50}	2357 mg/kg (males) 2500 mg/kg (females)	Technical	Acceptable	00130010 00130011
	Reproduction	NOAEL	5 ppm (0.25 mg/kg/day)	97.2	Acceptable	0014847
		LOAEL	30 ppm (1.5 mg/kg/day)			
Birds						
Anas platyrhynchos (Mallard Duck)	Mortality	LD_{50}	>2510 mg/kg	96.6±0.9	Invalid	00130329
	Mortality	LC_{50}	>5620 ppm	96.6±0.9	Acceptable	00130333
	Reproduction	NOAEC	180 ppm (highest test conc.)	95.5	Acceptable	00155305
		LOAEC	>180 ppm			
Japanese Quail (male)	Mortality	LD_{50}	>5000 mg/kg	Technical	Supplemental	00130331
Japanese Quail (female)	Mortality	LD_{50}	>5000 mg/kg	Technical	Supplemental	00130332
Colinus virginianus (Northern Bobwhite Quail)	Mortality	LD_{50}	>2510 mg/kg	96.6±0.9	Acceptable	00130330
	Mortality	LC_{50}	>5620	96.6±0.9	Acceptable	00130334
	hatching	NOEC	30 ppm	95.5	Acceptable	00155304
		LOEC	180 ppm			
Terrestrial Invertebrates						
Apis mellifera (Honey Bee)	Mortality	LD_{50}	>100 µg/bee	Technical	Acceptable	00130641

APPENDIX E: Chemical Names, Structures, and Maximum Reported Amounts of Fenoxaprop-p-ethyl and its Degradates.

Table E.1. Maximum Reported Amounts of Fenoxaprop-p-ethyl Degradation Products.

Degradate	Maximum % of Applied	Study Type	MRID
AE F088406	**63.6** (14 d) **65.8** (3 d) **100.8** (2 d)	Hydrolysis Aerobic soil metabolism Anaerobic aquatic metabolism	MRID 44659602 MRID 43400602 MRID 45081601
AE F054014[1]	**35.8** (21 d) 8.2 (168 d) 2.8 (27 d)	Hydrolysis Aqueous photolysis Anaerobic aquatic metabolism	MRID 44659602 MRID 44676401 MRID 45081601
AE F040356	4.9 (168 d) 6.8 (14 d) 5.5 (97 d)	Aqueous photolysis Aerobic soil metabolism Anaerobic aquatic metabolism	MRID 44676401 MRID 43400602 MRID 45081601
AE F096918	**42.0** (64 d)	Anaerobic aquatic metabolism	MRID 45081601
M1 (multiple compounds)	**12.4** (168 d)	Aqueous photolysis	MRID 44676401
M2 (unidentified)	6.4 (168 d)	Aqueous photolysis	MRID 44676401
M3 (unidentified)	**10.2** (59 d)	Aerobic soil metabolism	MRID 43400602
M4 (unidentified)	3.3 (7 d)	Aerobic soil metabolism	MRID 43400602
M5 (unidentified)	4.9 (168 d)	Aqueous photolysis	MRID 44676401
CO_2	**14.5** (98 d) **29.9** (238 d)	Aerobic soil metabolism Anaerobic aquatic metabolism	MRID 43400602 MRID 45081601
Unextracted residues	**60.3** (98 d) **58.5** (163 d)	Aerobic soil metabolism Anaerobic aquatic metabolism	MRID 43400602 MRID 45081601

[1] AE F054014 accounted for up to **20.7%** of the applied in unextracted residues during the aerobic soil metabolism study (MRID 43400602).

Table E.2. Chemical Names and Structures of Fenoxaprop-p-ethyl and its Degradates.	
Chemical Name	**Structure**
AE F046360 (D+)-ethyl-2-[4-(6-chloro-2-benzoxazolyloxy)phenoxy]propanoate Fenoxaprop-p-ethyl	
AE F088406 (D+)-2-[4-(6-chloro-2-benzoxazolyloxy)phenoxy]propanoate Fenoxaprop-p	
AE F054014 6-chloro-2,3-dihydro-benzoxazol-2-one	
AE F040356 4-(6-chloro-2-benzoxazolyloxy)phenol	
AE F096918 2-(4-hydroxyphenoxy)propanoate	

APPENDIX F: Preliminary EECs for aquatic habitats and RQs for aquatic organisms.

Table F.1. Agency Levels of Concern (LOCs).

Risk Presumption	Taxa	LOC
Acute Risk	Birds, mammals, aquatic animals	0.5
	Plants	1
Acute Restricted Use	Birds, mammals	0.2
	Aquatic animals	0.1
Acute Endangered Species	Birds, mammals	0.1
	Aquatic animals	0.05
	Plants	1
Chronic Risk	Birds, mammals, aquatic animals	1

Input parameters, justifications, and source references for the GENEEC2 (Mar. 9, 2006) model appear in **Table F.2** for the maximum use patterns of FPE listed in **Table F.3**.

Table F.2. GENEEC2 Input Parameters for Maximum Use Patterns of FPE.

Input Parameter	Value	Justification	Source
K_d (mL/g)	4.10	Represents the lowest total residue K_d for a non-sand soil.	MRID 42915001 (provisional)
Aerobic soil metabolism half-life (days)	564	Represents 3 times a single total residue half-life.	MRID 43400602 (provisional)
Wetted in?	No	Label directions	Current labels
Application method	Aerial	Label directions	Current labels
Solubility in water (ppm)	0.7	Represents the measured water solubility value for FPE.	MRID 44676401 (provisional)
Aerobic aquatic metabolism half-life (days)	1128	Represents 2 times the aerobic soil metabolism half-life input value in the absence of data and with near stability of total residues to hydrolysis.	N/A
Aqueous photolysis half-life (days)	Stable	Represents the single environmental phototransformation half-life for total residues.	MRID 44676401 (provisional)

Table F.3. Preliminary Tier I Aquatic Estimated Environmental Concentrations (EEC) of FPE Residues of Concern, Reported in µg/L (Calculated using GENEEC2).

Use pattern	Max. Annual App. Rate (lbs a.i./acre)	Peak EEC	Max. 4-day Mean EEC	Max. 21-day Mean EEC	Max. 60-day Mean EEC	Max. 90-day Mean EEC
Barley	0.0825	3.33	3.32	3.28	3.18	3.11
Conservation Reserve	3.276 (assuming 26 app/yr)	111	110	109	106	103
Conservation Reserve	0.378 (assuming 3 app/yr)	15.2	15.2	15.0	14.5	14.2
Cotton, Peanuts	0.126	5.08	5.07	5.00	4.86	4.75
Ornamental	2.392 (assuming	80.7	80.5	79.5	77.2	75.5

Table F.3. Preliminary Tier I Aquatic Estimated Environmental Concentrations (EEC) of FPE Residues of Concern, Reported in µg/L (Calculated using GENEEC2).

Use pattern	Max. Annual App. Rate (lbs a.i./acre)	Peak EEC	Max. 4-day Mean EEC	Max. 21-day Mean EEC	Max. 60-day Mean EEC	Max. 90-day Mean EEC
	26 app/yr)					
Rice	0.1426 (assuming 2 app/yr)	83.9	83.9	83.9	83.9	83.9
Right-of-Way	1.068 (assuming 6 app/yr)	41.5	41.4	40.9	39.7	38.8
Soybeans	0.128	5.16	5.15	5.08	4.93	4.83
Turf	1.068 (assuming 6 app/yr)	39.8	39.8	39.2	38.1	37.2
Wheat	0.168 (assuming 2 app/yr)	6.47	6.45	6.37	6.18	6.04

At the Tier I screening level, preliminary acute RQs exceed the listed LOC for freshwater fish from use on conservation reserves, ornamentals, rice, rights-of-way, and turf; for freshwater invertebrates and estuarine/marine fish from use on conservation reserves, ornamentals, and rice; and for listed estuarine/marine invertebrates from all labeled uses other than barley (**Table F.4**).

Table F.4. Preliminary RQs for acute exposures of aquatic organisms to FPE (exceedances in bold).[1]

Use pattern	FW Fish	FW Invertebrates	EM Fish	EM Invertebrates
Barley	0.0107	0.00315	0.00333	0.0340
Conservation Reserve (26 app)	**0.358**	**0.105**	**0.111**	**1.13**
Conservation Reserve (3 app)	0.0490	0.0144	0.0152	**0.155**
Cotton	0.0164	0.00480	0.00508	**0.0518**
Ornamental	**0.260**	**0.0763**	**0.0807**	**0.823**
Peanuts	0.0164	0.00480	0.00508	**0.0518**
Rice	**0.271**	**0.0793**	**0.0839**	**0.856**
Right-of-Way	**0.134**	0.0392	0.0415	**0.423**
Soybeans	0.0166	0.00488	0.00516	**0.0526**
Turf	**0.128**	0.0376	0.0398	**0.406**
Wheat	0.0209	0.00612	0.00647	**0.0660**

[1] EECs were based on peak values reported in **Table F.3**; toxicity values were reported in **Table 2**.

At the Tier I screening level, preliminary chronic RQs exceed the LOC for all aquatic animals at the highest labeled annual application rate of FPE (0.126 lbs a.i./A @ 26 applications per year on conservation reserves) (**Table F.5**). Preliminary chronic RQs exceed the LOC for freshwater fish and estuarine/marine invertebrates from use on conservation reserves, ornamentals, rice,

rights-of-way, and turf; for freshwater invertebrates from use on conservation reserves; and for estuarine/marine fish from use on conservation reserves, ornamentals, and rice.

Table F.5. Preliminary RQs for chronic exposures of aquatic organisms to FPE (exceedances in bold).[1]

Use pattern	FW Fish	FW Invertebrates	EM Fish	EM Invertebrates
Barley	0.145	0.0304	0.0665	0.300
Conservation Reserve (26 app)	**4.82**	**1.01**	**2.22**	**9.95**
Conservation Reserve (3 app)	0.659	0.139	0.303	**1.37**
Cotton	0.221	0.0463	0.102	0.457
Ornamental	**3.51**	0.736	**1.62**	**7.26**
Peanuts	0.221	0.0463	0.102	0.457
Rice	**3.81**	0.777	**1.76**	**7.66**
Right-of-Way	**1.80**	0.379	0.831	**3.74**
Soybeans	0.224	0.0470	0.103	0.464
Turf	**1.73**	0.363	0.797	**3.58**
Wheat	0.281	0.0590	0.129	0.582

[1] For fish, EECs were based on 60-day values reported in **Table F.3**. For invertebrates, EECs were based on 21-day values reported in **Table F.3**. Toxicity values were reported in **Table 2**. As discussed in the effects section, the ACR method was used to derive toxicity value.

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APPENDIX G: Preliminary EECs for terrestrial habitats and RQs for terrestrial organisms.

G.1. Terrestrial animals

T-REX is used to calculate dietary and dose-based EECs of FPE for mammals and birds. Input values for T-REX are located in **Table G.1**. Upper-bound Kenega nomogram values are utilized to derive EECs for triticonazole exposures to terrestrial mammals and birds based on dietary- and dose-based exposures (**Table G.2**). **The maximum exposure scenario allowed by the labels, which applies to uses on turf, is used to characterize exposures to mammals and birds.** A 1-year time period is simulated. Because label rates indicate a maximum use scenario (i.e. 3 applications of 0.178 lbs a.i./A) per season, not per year, only one season is modeled. Because multiple seasons of turf are possible, EECs and RQs resulting from this modeling approach would result in an underestimation of exposure of terrestrial mammals and birds to FPE. Consideration is given to different types of feeding strategies for mammals and birds, including herbivores, insectivores and granivores. For dose-based exposures, three weight classes of mammals (15, 35 and 1000 g) and birds (20, 100, and 1000 g) are considered. Toxicity values used to define effects to mammals and birds from acute and chronic exposures are described in the effects characterization section of this document. Due to a lack of data specific to FPE, effects data for fenoxaprop-ethyl are used for derivation of RQs.

Table G.1. Input parameters for deriving terrestrial EECs for FPE using T-REX.

Parameter Description	Value
FPE maximum Application Rate (lbs a.i./A)	0.178
Half-life (days)	35[1]
Application Interval (days)	14
Number of Applications	3[2]

[1] default value
[2]Only one season is modeled.

Table G.2. T-REX calculated EECs of FPE on food residues.

Food Type	Dietary Based (ppm) (mammals and birds)	Dose Based (mg/kg-bw) (mammals)			Dose Based (mg/kg-bw) (birds)		
	All Size Classes	Small (15 g)	Medium (35 g)	Large (1000 g)	Small (15 g)	Medium (35 g)	Large (1000 g)
Short Grass	99.6	95.0	65.7	15.2	113	64.7	29.0
Tall Grass	45.7	43.5	30.1	6.98	52.0	29.7	13.3
Broadleaf plants/sm insects	56.0	53.4	36.9	8.56	63.8	36.4	16.3
Fruits/pods/lg insects	6.23	5.94	4.10	0.95	7.09	4.04	1.81

Seeds (granivore)	6.23	1.32	0.91	0.21	7.09	4.04	1.81

Acute dose-based RQs are derived using the reported LD_{50} 2357 mg/kg. The LOC is not exceeded for acute, dose-based exposures of mammals to FPE (**Table G.3**). Chronic dietary-based RQs are derived using the reported NOAEC of 5 ppm (mg/kg-diet). Chronic dose-based RQs are calculated using the NOAEL of 0.25 mg/kg-bw/day. For chronic dietary-based and dose-based exposures, the LOC for non-listed and listed species is exceeded for all mammal size classes and all mammal feeding categories (**Table G.4**).

Table G.3. Acute RQs for mammals of different size and feeding classes.

Food Type	Dose Based		
	Small (15 g)	Medium (35 g)	Large (1000 g)
Short Grass	0.02	0.02	0.01
Tall Grass	0.01	0.01	<0.01
Broadleaf plants/sm insects	0.01	0.01	<0.01
Fruits/pods/lg insects	<0.01	<0.01	<0.01
Seeds (granivore)	<0.01	<0.01	<0.01

Table G.4. Chronic RQs for mammals of different size and feeding classes.

Food Type	Dietary Based	Dose Based		
	All Size Classes	Small (15 g)	Medium (35 g)	Large (1000 g)
Short Grass	**19.9**[1]	**173**[1]	**148**[1]	**79.2**[1]
Tall Grass	**9.13**[1]	**79.2**[1]	**67.7**[1]	**36.3**[1]
Broadleaf plants/sm insects	**11.2**[1]	**97.3**[1]	**83.1**[1]	**44.5**[1]
Fruits/pods/lg insects	**1.25**[1]	**10.8**[1]	**9.23**[1]	**4.95**[1]
Seeds (granivore)	**1.25**[1]	**2.40**[1]	**2.05**[1]	**1.10**[1]

[1] Exceeds LOC (1) for chronic exposures to non-listed and listed terrestrial mammals.

Acute dose-based RQ values are calculated using the value available for the bobwhite quail (LD_{50}>2510 mg a.i./kg-bw). The acute risk listed species LOC is not exceeded for non-listed birds. The acute risk LOC for non-listed species is potentially exceeded only for listed, small birds consuming short grass (**Table G.5**).

Table G.5. Dose-based RQ values for acute exposures to birds.

Food Type	20 g	100 g	1000 g
Short Grass	**<0.06**	**<0.03**	**<0.01**
Tall Grass	**<0.03**	**<0.01**	**<0.01**
Broadleaf plants/sm insects	**<0.04**	**<0.02**	**<0.01**
Fruits/pods/seeds/lg insects	**<0.01**	**<0.01**	**<0.01**

[1]Potentially exceeds the acute LOC for birds (0.5).
[2]Potentially exceeds the acute listed species LOC for birds (0.1).

Acute dietary-based RQ values are calculated using the $LC_{50}$for bobwhite quail (>5620 mg/kg-diet). The acute risk LOC is not exceeded for birds. Chronic dietary-based RQ values are calculated using the bobwhite quail NOAEC (30 mg/kg-diet). The chronic risk LOC is exceeded for birds feeding on short grasses, tall grasses, broadleaf plants and small insects (**Table G.6**).

Table G.6. Acute and chronic, dietary-based RQ s for birds by food type.

Food Type	Acute RQ	Chronic RQ
Short Grass	<0.02	**3.32**[1]
Tall Grass	<0.01	**1.52**[1]
Broadleaf plants/small insects	<0.01	**1.87**[1]
Fruits/pods/seeds/large insects	<0.01	0.21

[1]LOC (1) exceeded for chronic exposures to non-listed and listed birds.

Based on the information above, chronic exposures are potentially of significant concern. If the lowest annual maximum use is modeled in T-REX, LOCs for non-listed and listed mammals are still exceeded (**Table G.7**). This use rate, 0.0825 lb a.i./A per year, applies to barley (**Table 6**).

Table G.7. Chronic RQs for mammals and birds exposed to FPE due to use on barley.

Food Type	Dietary Based (mammals)	Dietary Based (birds)	Dose Based (mammals)		
	All Size Classes	All Size Classes	Small (15 g)	Medium (35 g)	Large (1000 g)
Short Grass	**3.96**[1]	0.66	**34.4**[1]	**29.4**[1]	**15.7**[1]
Tall Grass	**1.82**[1]	0.30	**15.8**[1]	**13.5**[1]	**7.21**[1]
Broadleaf plants/sm insects	**2.23**[1]	0.37	**19.3**[1]	**16.5**[1]	**8.85**[1]
Fruits/pods/lg insects	0.25	0.04	**2.15**[1]	**1.83**[1]	0.98
Seeds (granivore)	0.25	0.04	0.48	0.41	0.22

[1]LOC (1) exceeded for chronic exposures to non-listed and listed mammals or birds.

G.2. Terrestrial Plants

TerrPlant is used to calculate EECs for non-target plant species inhabiting dry and semi-aquatic areas (**Table G.8**). Selected model parameters include: an application rate of 0.178 lbs a.i./A to represent the maximum single application rate of FPE (**Table 6**); and a runoff value of 0.01 (selected based on FPE solubility, which is classified by TerrPlant as <10 mg/L). EECs for these crops correspond to aerial application methods categorized as which assumes 5 % spray drift. EECs relevant to terrestrial plants consider pesticide concentrations in drift and in runoff. Since EECs do not consider multiple applications, exposures could be underestimated in cases where plants are exposed through multiple applications of FPE. Based on the single maximum application rate of FPE applied by air, the LOC is exceeded for non-listed and listed species of monocots inhabiting dry and semi-aquatic areas. The LOC for non-listed and listed dicots is not exceeded (**Table G.9**).

Table G.8. EECs (lbs a.i./A) generated by TERRPLANT (v. 1.2.2) for evaluation of exposure of dry and semi-aquatic area plants to FPE.

Use Pattern	Loading to adjacent areas	Loading to semi-aquatic areas	Drift
Turf	0.00178	0.0178	0.0089

Table G.9. RQ values for plants in dry and semi-aquatic areas exposed to FPE through runoff and/or spray drift.*

Plant Type	Listed Status	Dry	Semi-Aquatic	Spray Drift
Monocot	non-listed	**5.34**	**13.35**	**4.45**
Monocot	listed	**17.8**	**44.5**	**14.8**
Dicot	non-listed	0.11	0.27	<0.1
Dicot	listed	0.11	0.27	<0.1

*If RQ > 1.0, the LOC is exceeded, resulting in potential for risk to that plant group.

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IV. HUMAN HEALTH EFFECTS SCOPING DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

7/19/07

MEMORANDUM

SUBJECT: Fenoxaprop-P-ethyl. Registration Review Scoping Document for Human Health Assessments.

PC Code: 129092
CFR: 40 CFR 180.430
DP Barcode: D338172
Registrant: Bayer CropScience

FROM: Richard Griffin, Risk Assessor
Shanna Recore, Occupational/Residential Assessor
Elissa Reaves, Ph.D., Toxicologist
Donald Wilbur, Chemist
Reregistration Branch 2
Health Effects Division (7509P)

THROUGH: Alan Nielsen, Branch Senior Scientist
William Hazel, Ph.D., Branch Chief
Reregistration Branch 2
Health Effects Division (7509P)

TO: Kylie Rothwell, Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division (7508P)

Docket Number: EPA-HQ-OPP-2007-0437
www.regulations.gov

This is the Registration Review scoping document for the human health assessments of the herbicide fenoxaprop-P-ethyl. HED has considered the available fenoxaprop-P-ethyl risk assessments, updates to toxicity and exposure databases, changes in use directions, changes in manufacturing process, open literature data, and current science policy in the preparation of this scoping document. The primary purposes of this scoping document are to determine the:

- adequacy of previous assessments and their applicability to current standards, policies, registered use patterns, etc.;
- need for additional or revised human health risk assessments;
- need for additional data to support the continued registration of pesticide products containing fenoxaprop-P-ethyl.

This scoping document and other documents will be made available to the public via an electronic docket to which relevant information and data may be submitted during a public comment period. The "public" includes all stakeholders such as government agencies, grower groups, pesticide producers or registrants, private citizens, etc. Upon consideration of any public input, a final determination of needed data and risk assessments will be made by the Agency.

Overview

Fenoxaprop-P-ethyl is a postemergent herbicide of the aryloxyphenoxy propionate group (formerly the oxyphenoxy acid ester group). Other herbicides in this group are fluazifop-butyl, diclofop methyl, quizalofop-ethyl, and haloxyfop-methyl. This group is known for high herbicidal activity against grasses and can be sprayed over the top of broadleaf crops, including cotton and soybean, without significant injury to the crop. Fenoxaprop-P-ethyl is also registered for use in the culture of small grains and peanut as well as on turf and around ornamentals, including golf courses, sod farms, and residential lawns.

In 1987, fenoxaprop-ethyl (P.C. Code 128701) was first registered. It was a racemic mixture (i.e., a 50:50 blend) of the d- and l-isomers; this document refers to this active ingredient as the racemic mixture, or simply FE. The manufacturing-use product (MP) was first registered under FIFRA to Hoechst Celanese Corp. (EPA Reg. No. 8340-43).

An application to amend the registration of the Hoechst MP by enriching it for the herbicidally-active isomer was received 9/18/91; an upper case "P" was introduced in the chemical name denoting "positive," i.e., the direction the enantiomer rotates polarized light. Fenoxaprop-P-ethyl (P.C. Code 129092) was synthesized using a new manufacturing process to produce a new "formulation" of 8340-43 containing the active enantiomer at 89% which was registered on 2/10/94.

A new registrant, Aventis Crop Sciences, USA, LP, under EPA Reg. No. 264-653, further enriched the composition of the former Hoechst MP in 2002 by increasing the concentration of the active or d-isomer from 89% to 95%. All end-use products are currently formulated using this MP (label accepted 5/15/02).

The active ingredient, Fenoxaprop-P-ethyl or FPE, is the subject of the Registration Review being initiated by this document. However, although no longer a registered active ingredient in the U.S., most available toxicology and exposure data involved testing of the racemic mixture. It has recently come to the Agency's attention that certain studies testing FPE have been conducted for the purposes of "bridging" from the FE database to FPE. There are 23 studies that have been conducted with FPE. The Agency has performed a preliminary review of these studies and intends to conduct a full evaluation of the relevant studies during the public comment period to determine whether the available combined FE and FPE toxicology and residue chemistry data are adequate to provide confidence that the existing and/or forthcoming risk assessments are/will be protective of human health. The Agency will also ascertain whether the laboratory-generated test substances used in the bridging toxicity studies (88-99% FPE) are appropriate to represent the currently-marketed 95%. This will necessitate, at a minimum, a comparison of isomer percentages and ratio and the impurity profiles associated with the FPE toxicity study test substances and the current 95% MP.

Tolerances are established under 40 CFR §180.430(a) for the combined residues of the parent compound, fenoxaprop-ethyl [(±)-ethyl-2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoate], and its metabolites 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid (the free acid) and 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl equivalents, in or on barley grain, cottonseed, peanuts, peanut hulls, rice grain, soybeans, and wheat grain at 0.05 ppm; barley straw at 0.1 ppm; and wheat straw at 0.5 ppm. Tolerances for the same residues in livestock commodities have also been established as follows: 0.02 ppm in milk and 0.05 ppm in the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. The tolerances are currently expressed in terms of combined residues of both the active and inactive isomers. If the hazard bridging assessment determines that FE and FPE are toxicologically equivalent, the tolerance expression need not change.

FPE is available as an emulsifiable concentrate (EC), a liquid ready-to-use (RTU), and as a soluble concentrate/liquid (SC/L). Methods of application include band treatment, broadcast, high/low volume spray, and spot treatment. These treatments can be made by aircraft, backpack/hose-end/tank-type sprayers, band sprayers, and boom sprayers.

A Screening-level Usage Analysis (SLUA) was performed by the Biological and Economic Analysis Division (10/17/06) indicating that less than 1 million pounds of FPE are used annually in the U.S. Approximately 5% of the U.S. soybean crop and 25% of the U.S. wheat crop are

treated. There is minimal usage of FPE on barley, cotton, peanut, and rice (<1% crop treated). Usage estimates for turf and ornamentals are not available.

Human Incident Data

Human incidents resulting from exposure to FPE (FE before 1994) have been summarized for this Registration Review by M. Hawkins and H. Allender (4/10/07, D338156). Incident data covering the 13-year period from 1993 to 2005 are stored in the Toxic Exposure Surveillance System (TESS) maintained by the Association of Poison Control Centers. Of five occupationally exposed adults, three had minor symptoms and two had none. Of 14 nonoccupationally exposed adults, four displayed symptoms; of these four showing symptoms, two were moderate and one was major in severity. Of four exposed children reported to PCCs from 1993 to 2005, none were symptomatic or were taken to a Health Care Facility (HCF).

Three cases of potential adult exposure were reported in OPP's Incident Data System from 1999 to present. One was shown to be unrelated to FPE exposure and there was insufficient follow-up of the other two to determine if symptoms resulted.

Of 5,899 cases reported to the National Institute of Occupational Safety and Health/Sentinel Event Notification System for Occupational Risks (NIOSH/SENSOR) from 1998 to 2003, none involved exposure to FPE.

Based on the available human incident data, OPP suggests that no mitigation action be taken on FPE at this time.

Toxicology Data/Endpoints

The hazard database of FE was peer reviewed by HED's Hazard Identification Assessment Review Committee (HIARC) on 9/18/97 and by HED's Risk Assessment Review Committee (RARC) on 10/16/97. The toxicity database for FE was judged at that time to be adequate for all aspects of FQPA-based risk assessment including selection of endpoints for the conduct of acute and chronic aggregate risk assessments and endpoints for occupational risk assessment.

Acute RfD = 0.32 mg/kg/day. The hazard component of acute risk was based on a rat developmental toxicity study (MRID 00152156) in which fetal malformations (diaphragmatic and umbilical hernia, split sternum, scoliosis, and innominate artery), decreased fetal weight and increased total visceral and skeletal anomalies occurred at the LOAEL of 100 mg/kg/day. The NOAEL and dose level for acute risk assessment was 32 mg/kg/day, the interspecies x intraspecies (10 x 10) Uncertainty Factor was 100, and the FQPA Safety Factor was 1. The FQPA Safety Factor was reduced to 1 since the fetal effects only occurred at maternally toxic doses. The population of concern was women of childbearing age. Maternal effects seen at the

LOAEL were increased incidence of salivation, increased water consumption, decreased body weight gain and increased liver weights.

Chronic RfD = 0.0025 mg/kg/day. The hazard component of chronic risk was the NOAEL of 0.25 mg/kg/day based on decreased total blood lipids/cholesterol at the LOAEL of 1.5 mg/kg/day in a rat reproductive toxicity study (MRID 00263030). Furthermore, the highest dose of 9 mg/kg/day also produced increased absolute and relative brain and kidney weights with increased incidence of nephrocalcinosis reported in a previous study. The reproductive LOAEL of 1.5 mg/kg/day was based on reduced pup body weights (F1a). The interspecies x intraspecies (10 x 10) Uncertainty Factor was 100, and the FQPA Safety Factor was 1. The FQPA Safety Factor was reduced to 1 since developmental toxicity studies showed no increased sensitivity; fetal malformations in the rat developmental study were only at maternally toxic doses; and a multi-generation reproduction rat study showed no increased sensitivity to pups as compared to adults.

Short-/Intermediate-/Long-Term Dermal. FE was found not to be toxic via the dermal route as neither dermal nor systemic toxicity was seen at the limit dose (1,000 mg/kg/day) in a rat dermal developmental toxicity study. Also, no dermal or systemic toxicity was observed at the highest dose tested (20 mg/kg/day) in a 21-day dermal toxicity study in rats. Therefore, dermal exposure and risk assessments for pesticide workers as well as adults and children in residential settings were *not required* based on these studies.

Short-/Intermediate-/Long-Term Inhalation. Inhalation risk estimates (for any time interval) were based on a 6-week rat inhalation toxicity study that demonstrated decreased total lipid and adverse kidney/liver effects at the study LOAEL of 0.075 mg/kg/day. The NOAEL and dose level for risk assessment was 0.015 mg/L with a standard MOE requirement of 100.

Carcinogenic Risk. A second mouse cancer study required as a condition of registration was received in 1996. At the 9/18/97 HIARC meeting, it was recommended that, until a Cancer Assessment Review Committee (CARC) meeting could take place, an interim, protective risk assessment should be carried out using the linear low dose extrapolation method (Q_1*) based on the increases in adrenal tumors in male mice. The Q_1* of 9.1 x 10^{-2} was calculated for adrenal tumors and was recommended to calculate lifetime carcinogenic risk. The Agency intends to hold this CARC meeting to determine the cancer classification and potency before final decisions are made as to data and risk assessment needs.

Adequacy of the Toxicity Database

The hazard database is considered to be complete and adequate for the racemic mixture as a food use pesticide including the relatively recently submitted second mouse carcinogenicity study. Note that, upon comparison with FPE bridging studies and detailed evaluation by the CARC to

occur in the near future, it is possible that some shortcomings may be discovered in the existing studies.

At the time of the proposed change in composition of the MP from the racemic mixture to an 85:15 d/l enrichment (9/18/91), it was considered to be registration of an alternate formulation of the same registered product (EPA Reg. No. 8340-43). Apparently typical in such situations at that time was that only the battery of six acute mammalian toxicity studies would be required; these, testing FPE, were submitted in 1991. The Agency did not require additional toxicity studies for the purpose of bridging FE to FPE. Note that, although the 85:15 ratio form of FPE was used for limited toxicity testing, it was apparently never marketed in a registered pesticide product. Instead, by 2/10/94, Hoechst was capable of achieving 89% FPE on a commercial scale.

HED typically considers more than acute toxicity studies necessary to bridge from one toxicity database to another. Generally, the same studies (listed below) necessary to support registration of a nonfood pesticide are needed to permit bridging from an enriched isomer to a racemic mixture of two enantiomers of a pesticide:

- acute toxicity battery
- 90-day repeated dose study (oral or dermal-rat)
- one developmental toxicity study (rat)
- mutagenicity test battery

The Agency became aware that a number of such studies had been conducted on FPE for submission to the European Union. At the Agency's request, Bayer CropScience has recently submitted (4/23/07) 23 toxicology studies conducted with FPE that had not been previously submitted to the Agency. These included acute (all routes), subchronic (all routes), metabolism, developmental (rodent and non-rodent) studies and a mutagenicity battery. The Agency is currently conducting detailed reviews (DERs) of relevant FPE toxicity data. Final conclusions regarding the adequacy of the combined FE and FPE hazard databases for human health risk assessment purposes will be made upon the completion of DERs of FPE studies, the bridging decision, the endpoint selection, and the cancer classification.

Adequacy of Dietary Exposure Data/Risk Estimates

Residue chemistry data are adequate to support the registered food uses and tolerances for FE/FPE tolerances including plant, ruminant, and poultry metabolism, analytical methods, storage stability, processing, and field trials. Tolerances for FE/FPE residues are below the level of detection in the grain/seed portion of each crop (barley, wheat, rice, cottonseed, and soybean), as reflected in the tolerances of 0.05 ppm (the method Limit of Quantification, or LOQ). Both

acute and chronic dietary risk assessments are conservative, being based on tolerance-level residue for all foods although livestock feed items were corrected by percent crop treated.

Adequacy of Drinking Water Exposure Data/Risk Estimates

In the 2/3/98 human health assessment, EFED used the "GENEEC" drinking water model which generates upper-bound (or Tier 1) estimates of surface water runoff. Since dietary and drinking water risk estimates (as seen in the DWLOCs) were negligible based on upper-bound assumptions, an updated drinking water assessment would not likely be useful unless EFED is aware of some significant policy or use pattern change expected to affect estimated drinking water concentrations.

Adequacy of Residential Exposure Data/Risk Estimates

According to the registrant, in 1998, all residential treatments were done by professional applicators. Appropriately, a homeowner "handler" risk assessment was never conducted. However, there are currently several registered homeowner products containing FPE. To assess risks to homeowners, a short-term residential handler inhalation assessment should be done for lawn and ornamental use based on inhalation exposure *only*; dermal exposure would not be assessed because the dermal route of exposure is not of concern for risk assessment.

Also, by current standards, children's "incidental" oral exposure (to treated turf) would be assessed based on an existing (to-be-determined) oral toxicity study of the appropriate exposure duration.

Adequacy of Occupational Exposure Data/Risk Estimates

Occupational handler risk assessment was completed for the 1997 and 1998 barley and wheat tolerance petitions based on inhalation exposure, only. Dermal exposure was not assessed based on the negative results of the dermal toxicity studies. Carcinogenic risk estimates were completed for workers based on their specific function (aerial applicator, ground applicator, etc.). The highest carcinogenic risk estimated was 10^{-6} and was based on the mixer/loader function for aerial applications.

Postapplication dermal exposure does not need to be assessed for FPE since no systemic dermal effects of concern were identified in toxicity studies involving dosing via the dermal route. Postapplication inhalation exposure is not a concern. Restricted Entry Intervals (REIs) are determined according to the Worker Protection Standard (WPS) where applicable.

It does not appear that occupational handler inhalation assessments have been done for cotton, soybeans, rice, or peanuts, or for various turf uses (sod farms, commercial and residential turf), ornamentals, and rights-of-way.

Available Risk Assessment/Risk Estimates

A quantitative human health risk assessment has not been conducted on FPE. The most complete human health risk assessment was conducted on FE (S. Knizner, et al., 2/3/98, D242374). Aggregate acute and chronic exposure estimates were found not to exceed HED's level of concern**.** More specifically, the *acute* dietary risk estimate for women (<13 yr) was well below (<1%) the acute RfD of 0.32 mg/kg/day. C*hronic* dietary risk estimates for all population groups were less than 1% of the chronic RfD. At that time, the drinking water component of aggregate exposure was addressed by using the "Drinking Water Level of Concern" (DWLOC) approach. Potential FE residues in drinking water were found not to be greater than HED's level of concern for acute aggregate (women <13 yr) or for chronic aggregate risk. Use of DWLOCs in aggregate risk has now been replaced by direct incorporation of drinking water consumption and contamination estimates into the DEEM (or other) exposure model. Based on the estimated U.S. population's chronic dietary (food-only) exposure and an "interim" Q_1* of 9.1 x 10^{-2}, the upper-bound (food-only) *carcinogenic* risk estimate was 9.1 x 10^{-7}. Since the carcinogenic risk DWLOC exceeded the average lifetime contamination estimate, there is negligible cancer risk from chronic exposures to FE in drinking water and food.

The 2/3/98 human health risk assessment quantified *occupational* risks associated with inhalation exposure during mixing, loading, and applying FE (Tiller EC Herbicide) to barley. Exposure via the dermal route is not of concern as neither dermal nor systemic effects were observed at the limit dose in a dermal developmental toxicity study in rats and rabbits or in a 21-day rat dermal toxicity study. The Margins of Exposure (MOEs) were 4,500 for aerial mixer/loaders to 80,000 for aerial applicators (well above the level of concern of 100). Carcinogenic risk estimates for pesticide workers did not exceed HED's level of concern.

The 2/3/98 risk assessment did not quantify risks to residential applicators (homeowners) because the registrant attested that, at that time, only professional applicators treated residential turf and ornamentals with FE. In terms of postapplication exposure, dermal toxicity was not considered of concern and neither adults nor children were considered to have significant inhalation exposure.

Recommendations

Agency Action Items

1) Conduct full reviews (DERs) on the newly received FPE developmental toxicity studies

and any other studies deemed relevant. Compare these studies to the analogous studies conducted on FE. Make a decision as to whether the entire FE database, notably the chronic, cancer, and reproductive toxicity studies, may be bridged to FPE. If complete bridging is agreed upon, then no FPE toxicity data are likely to be required. If partial or no bridging is permitted, identify the FPE toxicity studies that must be required.

2) Schedule an evaluation of the carcinogenic potential of FE/FPE by the HED Cancer Assessment Review Committee. Quantified carcinogenic risk estimates may not be appropriate.
3) Prepare an updated human health risk assessment including
   c) Risk estimates for oral exposure to children on treated turf.
   d) Inhalation risk estimates for adult homeowners applying FPE to residential turf.
   e) Estimates of FPE concentrations in drinking water directly input to the "DEEM" or other aggregate exposure model.

V. GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area

PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard