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and Toxic Substances
(7508P)

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March 2007

Reregistration Eligibility Decision for Rotenone

REREGISTRATION ELIGIBILITY

DECISION

for

Rotenone

List A
Case No. 0255

Approved by:

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
PIS	Primary Irritation Score
ppb	Parts Per Billion (µg/L; micrograms per liter)
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions. FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection Agency (EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

The Agency made its reregistration eligibility determination (RED) for rotenone based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered piscicidal (fish-kill) uses of rotenone are eligible for reregistration provided the requirements for reregistration identified in the RED are implemented. In March and April 2006, registrants requested voluntarily cancellation of all livestock, residential and home owner uses, domestic pet uses, and all other uses except for piscicide uses. In July 2006, EPA issued its "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)" in which the Agency indicated its intent to revoke the three tolerance exemptions for rotenone (40 CFR 180.905).

This document consists of six sections: Section I contains the regulatory framework for reregistration reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov in docket number EPA-HQ-OPP-2005-0494.

II. Chemical Overview

Rotenone, or (6R, 6aS, 12aS)-1,2,6,6a,12,12a-hexahydro-2-isopropenyl-8,9-dimethoxychromenyl[3,4- bfuro[2,3-h]chromen-6-one, is a botanical pesticide registered by EPA for piscicidal (fish kill) uses. The chemical is related to isoflavonoid compounds derived from the roots of Derris spp., Lonchocarpus spp., and Tephrosia spp., found primarily in Southeast Asia, South America, and East Africa, respectively. Rotenone has

three chiral centers, and thus has a complex stereochemistry. Other plant flavonoids (rotenoloids) that are similarly structured to rotenone are also contained in the plants from which rotenone is extracted. Formulated end-use products of rotenone may have varying amounts of "cube root extractables" containing rotenoloids. Rotenone products are classified as Restricted Use Pesticides (RUP) due to acute inhalation, acute oral, and aquatic toxicity. Table 1 presents the three chemical groups in case number 0255.

Table 1. Ingredients in Chemical Case 0255

PC Code	Chemical Name	CAS Number
071001	Derris resins other than rotenone	--
071003	Rotenone	83-79-4
071004	Cube resins other than rotenone	--

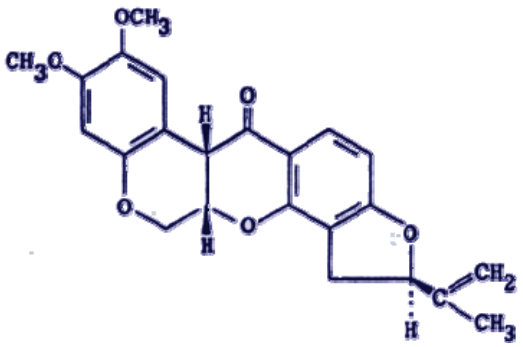
A. Regulatory History

Rotenone was first registered in the U.S. in 1947. The Registration Standard and associated data call-ins (DCI) were issued for rotenone in October 1988. Another DCI was issued in October 1995 requiring a foliar residue dissipation study, and dermal and inhalation passive dosimetry studies. A third DCI was issued in February 2004 requiring a sub-chronic (28-day) inhalation neurotoxicity study. This sub-chronic inhalation study was required to further investigate the results of independent studies in animals at very high doses that led to Parkinson's Disease-like symptoms. At the time the study was required, rotenone had registered uses for dust products in agricultural and residential settings which were of particular concern for inhalation exposure. Because all non-RUP agricultural and residential uses, and all food uses were voluntarily cancelled in 2006, this requirement has been waived. Further, as a result of this RED, additional personal protective equipment (PPE) including respiratory protection will be required for all remaining uses. However, using the existing database, EPA cannot quantitatively asses a potentially critical effect (neurotoxicity) at doses to which rotenone users could be exposed; therefore, an additional 10x database uncertainty factor has been applied.

There are currently three manufacturing-use product registrants: Prentiss Incorporated, Foreign Domestic Chemicals Corporation, and Tifa International LLC. In letters dated March 7, 2006 (Prentiss), March 17, 2006 (Foreign Domestic), and April 5, 2006 (Tifa), registrants requested voluntarily cancellation of all livestock, residential, and home owner uses, domestic pet uses, and all other uses except for piscicide uses in accordance with Section 6(f) of FIFRA. EPA provided a public comment period for the use deletions from June 7, 2006 to July 7, 2006 (EPA–HQ–OPP–2005–0494; FRL–8071–1) and no substantive comment was received; therefore, the associated tolerance exemptions will be revoked. The piscicidal uses are the only uses supported for reregistration and the only uses discussed in this RED.

B. Chemical Identification and Nomenclature

Table 2.

PC Code:	071003
Common name:	Rotenone
Chemical structure:	
Molecular Formula:	C_{23} H_{22} O_6
IUPAC name:	2R,6aS,12aS)-1,2,6,6a,12,12a-hexahydro-2-isopropenyl-8,9-dimethoxychromeno[3,4-b]furo[2,3-h]chromen-6-one
Chemical Class:	Rotenoid
CAS #	83-79-4

C. Use Profile

Type of Pesticide:	Piscicide.
Summary of Use:	Rotenone is applied directly to water to manage fish populations in lakes, ponds, reservoirs, rivers, streams, and in aquaculture. The chemical can be applied to an entire water body to achieve a "complete kill" or to a portion of a water body to achieve a "partial kill." Complete kills are used to eliminate all fish in the treatment area; partial kills are used to reduce or sample fish populations in the treatment area.
Target Organisms:	Undesired fish species.
Mode of Action:	Rotenone acts through uncoupling oxidative phosphorylation within cell mitochondria by blocking electron transport at complex I.
Tolerances:	No tolerance exists for the piscicidal uses of rotenone.

Use Classification:	Rotenone products are classified as Restricted Use Pesticides due to acute inhalation, acute oral, and aquatic toxicity.
Formulations:	Liquid, wettable powder.
Methods of Application:	Applications are made with helicopters and boats in lakes, reservoirs, and ponds; with direct metering into moving water such as streams; and with hand-held equipment such as backpack sprayers in difficult-to-reach aquatic areas.
Use rates:	Labels evaluated in this RED allow rotenone to be applied to achieve treatment concentrations up to 50 parts per billion (ppb) in streams/rivers and up to 250 ppb in lakes/reservoirs/ponds.
Application Timing:	Rotenone may be applied at any time of year. Fish management program applications typically occur during warm months because the compound degrades more rapidly in warm water than cold water. Aquaculture applications typically occur during the spring prior to stocking.
Annual usage:	Annual usage data for piscicidal applications are not available.

III. Summary of Risk Assessments

This section summarizes EPA's human health and ecological risk conclusions for rotenone to help the reader better understand EPA's risk management decisions. The full risk assessments and related supporting documents are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2005-0494. EPA's human health and ecological risk assessments were updated based on comments received during the May 2006 public comment period.

Where possible, EPA relied on maximum labeled application concentrations to estimate exposure in its human health and ecological risk assessments. Although some rotenone labels permit application concentrations up to 250 ppb in lakes/reservoirs/ponds, the solubility limit of rotenone is 200 ppb. That is, in a water body treated to achieve a maximum concentration of 200 ppb, any additional rotenone would not further increase the concentration available for exposure. Therefore, except for occupational exposure, EPA estimated human health and ecological exposure based on rotenone's solubility limit of 200 ppb. Because the maximum labeled concentration could result in higher occupational risk, EPA estimated occupational exposure using both the maximum labeled concentration (250 ppb) and rotenone's solubility limit (200 ppb). As required by this

RED, labels must be updated to reflect rotenone's solubility limit as the maximum application concentration of 200 ppb (see Section IV).

A. Human Health Risk Assessment

EPA conducted a human health risk assessment for rotenone to support the reregistration eligibility decision. EPA evaluated the submitted toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision for the piscicidal use.

1. Toxicity Profile

Toxicity assessments estimate to what degree a pesticide could cause adverse health effects in humans and the level or dose at which such effects could occur. EPA evaluates acute, short and intermediate term, and chronic effects.

a) Acute Toxicity Profile

Rotenone has high acute toxicity via the oral and inhalation routes of exposure (Category I) and low acute toxicity via the dermal route of exposure (Category IV). Rotenone is not an eye or skin irritant nor is it a skin sensitizer. Table 3 presents the acute toxicity profile for rotenone.

Table 3. Acute Toxicity Profile

Guideline Number	Study Title	MRID	Results	Toxicity Category
870.1100	Acute oral [rat]	00145496	LD_{50} = 102 mg/kg (M) LD_{50} = 39.5 mg/kg (F)	I
870.1200	Acute dermal [rabbit]	43907501	LD_{50} > 5000 mg/kg	IV
870.1300	Acute inhalation [rat]	42153701	LC_{50} = 0.0212 mg/L (combined) LC_{50} = 0.0235 mg/L (M) LC_{50} = 0.0194 mg/L (F)	I
870.2400	Acute eye irritation [rabbit]	42076203	PIS = 3.3 at 1 hr, cleared less than 24 hrs.	IV
870.2500	Acute dermal irritation [rabbit]	42076204	PIS = 0.08 at 1 hr which decreased to 0 at 72 hours	IV
870.2600	Skin sensitization [guinea pig]	42153702	Not a dermal sensitizer	NA

LD_{50} = Median Lethal Dose; PIS = primary irritation score

b) Completeness of Database

The toxicological database for rotenone is adequate to support a reregistration eligibility decision. However, using the existing database, EPA cannot quantitatively asses a potentially critical effect (neurotoxicity) at doses to which rotenone users could be exposed. Therefore, an additional 10x database uncertainty factor – in addition to the inter-species (10x) uncertainty factor and intra-species (10x) uncertainty factor – has been applied to protect against potential human health effects and the target margin of exposure (MOE) is 1000.

c) Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for rotenone are presented in Table 4. Dermal absorption was estimated using a fluazifop-butyl dermal absorption study. Fluazifop-butyl has a dermal absorption factor of 9% and is a structurally related analog based on molecular weight. Based on a structure activity relationship and human dermal information, the estimated dermal absorption of rotenone is 10%. For inhalation absorption, a default factor of 100% was used.

Table 4. Summary of Rotenone Toxicological Endpoints

Exposure Scenario	**Dose Used in Risk Assessment, Uncertainty Factor (UF)**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (females 13-49)	NOAEL = 15 mg/kg/day UF = 1000 aRfD = 15 mg/kg/day / 1000 = 0.015 mg/kg/day	Acute PAD = 0.015 mg/kg/day	Developmental toxicity study in mouse (MRID 00141707, 00145049) LOAEL = 24 mg/kg/day based on increased resorptions
Acute Dietary (all populations)	An appropriate endpoint attributable to a single dose was not identified in the available studies, including the developmental toxicity studies.		
Chronic Dietary (all populations)	NOAEL = 0.375 mg/kg/day UF = 1000 cRfD = 0.375 mg/kg/day / 1000 = 0.0004 mg/kg/day	Chronic PAD = 0.0004 mg/kg/day	Chronic/oncogenicity study in rat (MRID 00156739, 41657101) LOAEL = 1.9 mg/kg/day based on decreased body weight and food consumption in both males and females
Incidental Oral Short-term (1-30 days) Intermediate-term (1-6 months)	NOAEL = 0.5 mg/kg/day	Residential MOE = 1000	Reproductive toxicity study in rat (MRID 00141408) LOAEL = 2.4/3.0 mg/kg/day [M/F] based on decreased parental (male and female) body weight and body weight gain
Dermal Short-, Intermediate-, and Long-Term	NOAEL = 0.5 mg/kg/day 10% dermal absorption factor	Residential MOE = 1000 Worker MOE = 1000	Reproductive toxicity study in rat (MRID 00141408) LOAEL = 2.4/3.0 mg/kg/day

Exposure Scenario	Dose Used in Risk Assessment, Uncertainty Factor (UF)	Level of Concern for Risk Assessment	Study and Toxicological Effects
Inhalation Short-term (1-30 days) Intermediate-term (1-6 months)	NOAEL = 0.5 mg/kg/day 100% inhalation absorption factor	Residential MOE = 1000 Worker MOE = 1000	[M/F] based on decreased parental (male and female) body weight and body weight gain
Cancer (oral, dermal, inhalation)	Classification: No evidence of carcinogenicity		

UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, aPAD = acute population adjusted dose, cPAD = chronic population adjusted does, RfD = reference dose, MOE = margin of exposure, NA = Not Applicable

2. Metabolites and Degradates

EPA reviewed the metabolism of rotenone and concluded that there are degradation products including rotenoloids which occur in plants from which rotenone is obtained and in varying amounts in end-use rotenone products. Based on structural similarities, EPA believes that degradation products are no more toxic than rotenone.

3. Dietary Risk

EPA estimated acute dietary exposure through food and water from the piscicidal uses of rotenone. The acute dietary risk assessment considered only the population subgroup "females 13-49 years old" because an appropriate endpoint for this subgroup was available from a developmental toxicity study in rat. No acute dietary endpoint could be identified for the general population because other effects attributable to a single dose were not observed in the available toxicity studies. The chronic dietary risk assessment considered drinking water for the general population and various population subgroups. The chronic assessment only considered drinking water because chronic exposure from food (consumption of treated fish) is not expected based on rotenone's generally rapid degradation and low propensity to bioaccumulate in fish.

a) Acute Dietary Risk (Food and Drinking Water)

An acute dietary exposure assessment was performed for rotenone in food and drinking water.

Acute exposure estimates considered residues in fish from the piscicidal use in fish management applications only. EPA did not consider exposure to rotenone from aquaculture uses because the chemical is applied to ponds prior to stocking to eliminate undesirable fish species that would otherwise compete with the fingerlings. These applications typically occur in the spring prior to stocking of a new "crop" of food fish. Because the Agency is requiring rotenone levels to be below the level of detection prior to fingerling stocking, residues in fish are not expected as a result of aquaculture uses (see Section IV).

When rotenone is used in fish management applications, food exposure may occur when individuals catch and eat fish that either survived the treatment or were added to the water body (restocked) prior to complete degradation. Although exposure from this route is unlikely for the general U.S. population, some people might consume fish following a rotenone application. EPA used maximum residue values from a bioaccumulation study to estimate acute risk from consuming fish from treated water bodies. This estimate is considered conservative because the bioaccumulation study measured total residues in edible portions of fish including certain non-edible portions (skin, scales, and fins) where concentrations may be higher than edible portions (tissue) and the Agency assumed that 100% of fish consumption could come from rotenone exposed fish. In addition, fish are able to detect rotenone's presence in water and, when possible, attempt to avoid the chemical by moving from the treatment area. Thus, for partial kill uses, surviving fish are likely those that have intentionally minimized exposure.

Acute exposure estimates for drinking water considered surface water only because rotenone is only applied directly to surface water and is not expected to reach groundwater. The estimated drinking water concentration (EDWC) used in dietary exposure estimates was 200 ppb, the solubility limit of rotenone. The drinking water risk assessment is conservative because it assumes water is consumed immediately after treatment with no degradation and no water treatment prior to consumption.

Acute dietary exposure estimates result in dietary risk below the Agency's level of concern. Generally, EPA is concerned when risk estimates exceed 100% of the acute population adjusted dose (aPAD). The exposure for the "females 13-49 years old" subgroup (0.1117 mg/kg/day) utilized 74% of the aPAD (0.015 mg/kg/day) at the 95th percentile (see Table 5). It is appropriate to consider the 95th percentile because the analysis is deterministic and unrefined. Measures implemented as a result of this RED will further minimize potential dietary exposure (see Section IV).

Table 5. Acute Dietary (Food + Drinking Water) Exposure and Risk

Population Subgroup	**Food + Drinking Water Exposure (mg/kg/day)**	**% aPAD**
Females 13-49 years old	0.01117	74
General U.S. population	N/A[1]	

[1] N/A = not applicable; no acute dietary endpoint could be selected for the general population because effects attributable to a single dose were not seen in the available toxicity studies.

b) Chronic Dietary Risk (Drinking Water Only)

A chronic dietary exposure assessment was performed for rotenone in drinking water only. The chronic assessment only considered drinking water because chronic exposure from food is not expected based on rotenone's generally rapid degradation and low propensity to bioaccumulate in fish. The degradation of rotenone can vary greatly depending on environmental conditions (e.g., rotenone degrades more rapidly in warm water and less rapidly in cold water). When estimating chronic dietary exposure, EPA assumed that rotenone could reach drinking water intakes. Based on the chronic toxicity endpoint, EPA estimated the drinking water level of concern (DWLOC) to be 40 ppb for the most sensitive population subgroups (infants and children).

Under typical piscicidal use conditions, rotenone is relatively short-lived. Based on aquatic field dissipation studies, rotenone dissipates under cold water and warm water conditions with half-lives of 20 and 1.5 days, respectively. The dissipation appears due to a combination of both abiotic (aqueous photolysis and hydrolysis) and biotic (microbial degradation) factors. Additionally, there is evidence that rotenone is readily deactivated through the use of oxidizing agents, such as potassium permanganate. It is also likely that drinking water treatment through chlorination, ozonation or charcoal filtering will deactivate rotenone similar to potassium permanganate. Thus, the Agency expects no chronic exposures to rotenone in situations where water is either treated with potassium permanganate for deactivation purposes or is subject to an oxidative drinking water treatment regimen. To confirm these assumptions in the risk assessment, confirmatory laboratory studies will be required using protocols similar to the Tier I drinking water protocols developed by the EPA Office of Research and Development (ORD).

The Agency believes that under certain limited circumstances – e.g., drinking water intakes near lentic (standing) cold water treatment areas with no oxidative raw or finished water treatment – residues of rotenone in drinking water could exceed the DWLOC (40 ppb) for up to several weeks. Thus, to ensure that chronic or sub-chronic exposures above 40 ppb through drinking water will not occur, as a result of this RED, registrants will be required to submit proposed labeling or a monitoring plan to preclude such exposures. Options which could be considered include label restrictions to prohibit use in standing waters with drinking water intakes, development of a set of use parameters that would preclude any potential for exposures above 40 ppb (e.g., based in dilution factors/distance of water intakes from treatment area, water temperature at time of treatment, pH, etc.), and/or a monitoring (e.g., analytical chemistry or sentinel bioassay) requirement at water intakes.

4. Residential and Recreational Risk

Rotenone is permitted for sale only to Certified Applicators and can be applied in private and public water bodies. The public is prohibited from entering the treatment area during treatment but may be exposed to rotenone by swimming, wading, fishing, or performing other recreational activities in treated water. The Agency uses the term "post-

application" to describe exposures to individuals in an environment that has been previously treated with a pesticide.

The Agency only estimated post-application recreational exposure and risk from swimming (dermal and incidental ingestion) because other recreational scenarios would likely result in significantly less exposure. EPA estimated recreational risks by calculating margins of exposure (MOE). MOEs compare estimated exposure to the no observed adverse effect level (NOAEL) in a toxicity study. For rotenone recreational exposures, MOEs $\geq$1000 indicate that risks will not exceed EPA's LOC for inhalation, dermal, and incidental oral residential risk. The target MOE includes a 10x uncertainty factor for interspecies extrapolation, a 10x uncertainty factor for intraspecies variation, and a 10x database uncertainty factor because a potentially critical effect (neurotoxicity) cannot be assessed quantitatively with the existing database.

a) Adult Post-Application Recreational Risk

For all adult post-application scenarios, short-term risks for swimmers on the day of application do not exceed the Agency's level of concern (see Table 6).

Table 6. Adult Post-Application Recreational Risk

Exposure Scenario		Margin of Exposure	Days Until Concentrations are below EPA's LOC
Swimming (200 ppb application scenario)	Dermal	1,600	N/A[1]
	Incidental Ingestion	7,000	

[1] NA = Not Applicable; adult post-application exposure to rotenone does not exceed EPA's LOC on the day of application.

b) Toddler Post-Application Recreational Risk

For all toddler post-application scenarios, short-term risks for swimming on the day of application exceed the Agency's level of concern. EPA estimated the number of days required to reach rotenone concentrations below the LOC (MOE = 1000, rotenone concentration = 90 ppb). Table 7 presents estimated post-application risk from rotenone applications made at 200 ppb in water 25^{o}C. Generally, swimming in water colder than 25^{o}C is not expected.

MOEs for swimming in treated areas exceed EPA's LOC for 3 days after treatment. As a result of this RED, EPA will require that swimmers do not enter treated areas until exposures are below the LOC (see Section IV).

Table 7. Toddler Post-Application Recreational Risk

Exposure Scenario		Margin of Exposure		Days Until Concentrations are below EPA's LOC[1]
		Non-Dietary Risk (Short-Term Oral)	Combined Non-Dietary Risk	
Swimming (200 ppb application scenario)	Dermal	970	450	3
	Incidental Ingestion	850		

[1] Level of concern = 90 ppb; mitigated maximum application rate = 200 ppb

5. Aggregate Risk

An aggregate risk assessment considers the combined risk from dietary exposure (food, drinking water) as well as exposure from non-occupational sources (residential, recreational). Dietary and non-occupational exposure sources for rotenone include food, drinking water, and recreational activities.

EPA aggregated acute exposure from food (consumption of treated fish) and drinking water and concluded that risk does not exceed the Agency's level of concern (74% of the aPAD). This estimate is conservative because food exposure is based on conservative residue values from a bioaccumulation study and the assumption that 100% of a person's fish intake would come from treated fish, and drinking water exposure is based on the maximum treatment concentration of rotenone (200 ppb).

EPA did not aggregate dietary risk with recreational risk because the dietary assessment is considered conservative and the recreational exposure is expected to be intermittent and would not occur for the general population. In addition, measures implemented as a result of this RED will minimize recreational exposure (see Section IV).

6. Occupational Risk

Workers can be exposed to rotenone while performing mixing, loading, or application activities or when re-entering treated sites. EPA estimated occupational risks by calculating margins of exposure (MOE). MOEs compare estimated exposure to the no observed adverse effect level (NOAEL) in a toxicity study. For rotenone occupational/handler exposures, MOEs $\geq$1000 indicate that risks will not exceed EPA's LOC for short-term (1 to 30 days) and intermediate-term (1 to 6 months) exposure and risk. The target MOE includes a 10x uncertainty factor for interspecies extrapolation, a 10x uncertainty factor for intraspecies variation, and a 10x data base uncertainty factor because a potentially critical effect (neurotoxicity) cannot be assessed quantitatively with the existing database.

a) Occupational Handler Exposure Scenarios

The Agency initially estimates handler risks using baseline work clothing (i.e., long sleeve shirt, long pants, shoes and socks), no gloves, and no respirator. If these estimates exceed EPA's LOC, the Agency estimates the extent to which the use of additional protective measures (e.g., personal protective equipment and engineering controls) would lower the exposure. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, and a respirator. Common examples of engineering controls include enclosed cabs, closed mixing/loading systems, and water-soluble packaging. Table 8 presents the occupational handler scenarios that were assessed for rotenone.

Table 8. Occupational Handler Exposure Scenarios

Handler(s)	Scenario Number	Scenario Description
Mixer/Loader	1a	Liquid Formulations for Helicopter Applications
	1b	Liquid Formulations for Boat Applications (boom and underwater weighted hose applications)
	2a	Wettable Powder Formulations for Boat Applications (boom and underwater weighted hose applications)
Applicator	3	Helicopter Spray Applications (using PHED fixed wing aerial spray application data)
	4	Boat Boom Spray Applications (using PHED groundboom spray application data)
Mixer/Loader/ Applicator	5	Liquid Formulations: Backpack Sprayer (using PHED liquid low pressure handwand data)
	6	Liquid Formulations: Closed System Aspirators (using PHED closed system mixing/loading liquids) – no contact should occur once liquid rotenone is loaded
	7	Liquid Formulations: Drip Bars (using PHED mixing/loading liquids) – no contact should occur once liquid rotenone is loaded
	8	Wettable Powder: Backpack Sprayer (using PHED wettable powder low pressure handwand data)
	9	Wettable Powder Formulations: Closed System Aspirators (using PHED closed system mixing/loading wettable powders) - no contact should occur once wettable powder rotenone is loaded
	10	Wettable Powder Formulations: Drip Bars (using PHED mixing/loading wettable powders) - no contact should occur once wettable powder rotenone is loaded
	11	Wettable Powder Formulations: Powder/Sand/Gelatin Pastes

b) Occupational Handler Risk

Risks for occupational handlers addressed the following scenarios for short- and intermediate-term exposure: mixer/loader, applicator, and mixer/loader/applicator. These scenarios were used to estimate exposures based on application of wettable powders and liquids, via helicopter, boat, backpack, and drip bars.

Because chemical-specific and equipment-specific data for assessing occupational exposure to rotenone were not available, EPA estimated handler exposure using the Pesticide Handlers Exposure Database (PHED) Version 1.1 (August 1998). Occupational risks may be conservative because the best available data used to estimate exposure are surrogate data meant for assessing agricultural pesticide applications. EPA's agricultural exposure calculations assume daily exposure of up to 30 consecutive days, whereas rotenone applications are likely sporadic and of only a few days duration. Also the calculations in Table 9 include only the maximum application rates and rotenone applications may be made at lower rates. Furthermore, estimated occupational risks may be conservative because the toxicity endpoints used in the assessment were based on a rat developmental toxicity study in which the effect of concern was decreased body weight gain seen at a LOAEL approximately 6-fold higher than the NOAEL used in the assessment. Actual reproductive toxicity (decreased numbers of live pups) was seen at doses 8- to 10-fold higher than the NOAEL.

Although EPA generally estimated human health and ecological exposure based on rotenone's solubility limit of 200 ppb, because the maximum labeled concentration of 250 ppb could result in higher occupational risk, EPA estimated occupational exposure using both the maximum labeled concentration and rotenone's solubility limit. Table 10 presents handler exposure estimates based on 250 ppb (0.68 lb. ai/A-ft) and 200 ppb (0.54 lb. ai/A-ft) for lakes, ponds, and streams. Because many occupational handler risks exceed EPA's level of concern, EPA will require the maximum labeled treatment concentration to be reduced from 250 ppb to 200 ppb, additional PPE, and other measures to reduce occupational exposure (see Section IV).

Table 9. Summary of Handler Risks at 250 ppb and 200 ppb Application Rates

Exposure Scenario	Crop or Target	Application Rate[1]	Area Treated Daily	Combined MOEs[2]							
				Baseline	G + NR	G, DL + NR	G + 80% R	G, DL + 80% R	G + 90% R	G, DL + 90% R	Eng Cont
Mixing/Loading Liquid Concentrates for Helicopter Applications (1a)	Lakes	0.68	10 acres	3.5	290	350	410	530	430	570	1100
	Lakes	0.68	5 acres	7.1	590	710	810	1100	850	1100	2200
	Lakes	0.54	10 acres	4.5	370	450	510	670	540	710	1400
	Lakes	0.54	5 acres	8.9	740	890	1000	1300	1100	1400	2700
Mixing/Loading Liquid Concentrates for Boat Applications (1b)	Lakes	0.68	100 acres	0.35	29	35	41	53	43	57	110
	Lakes	0.68	50 acres	0.71	59	71	81	110	85	110	220
	Lakes	0.54	100 acres	0.45	37	45	51	67	54	71	140
	Lakes	0.54	50 acres	0.89	74	89	100	130	110	140	270
Mixing/Loading Wettable Powders for Boat Applications (2a)	Lakes	0.68	100 acres	0.25	1.7	1.8	4	4.8	4.8	6	84
	Lakes	0.68	50 acres	0.5	3.4	3.7	8	9.5	9.7	12	170
	Lakes	0.54	100 acres	0.31	2.2	2.3	5.1	6	6.1	7.5	110
	Lakes	0.54	50 acres	0.63	4.3	4.6	10	12	12	15	210
Applying Sprays via Helicopter (3)	Lakes	0.68	10 acres	ND	ND	ND	ND	ND	ND	ND	1800
	Lakes	0.68	5 acres	ND	ND	ND	ND	ND	ND	ND	3600
	Lakes	0.54	10 acres	ND	ND	ND	ND	ND	ND	ND	2300
	Lakes	0.54	5 acres	ND	ND	ND	ND	ND	ND	ND	4600
Applying Sprays via Boat Over-surface Boom Equipment (4)	Lakes	0.68	100 acres	48	48	56	66	82	70	88	190
	Lakes	0.68	50 acres	96	96	110	130	160	140	180	380
	Lakes	0.54	100 acres	61	61	70	84	100	88	110	240
	Lakes	0.54	50 acres	120	120	140	170	210	180	220	480

Exposure Scenario	Crop or Target	Application Rate[1]	Area Treated Daily	Combined MOEs[2]							
				Baseline	G + NR	G, DL + NR	G + 80% R	G, DL + 80% R	G + 90% R	G, DL + 90% R	Eng Cont
Mixing/Loading/ Applying Liquids with a Backpack Sprayer (using PHED liquid low pressure handwand data) (5)	Lakes	0.68	2 acres	0.51	71	77	110	120	110	130	NF
	Lakes	0.54	2 acres	0.51	71	77	110	120	110	130	NF
	Streams	0.000016 lb ai/ft3	10,560 ft long	10	1400	1500	2100	2400	2300	2600	NF
	Streams	0.000013 lb ai/ft3	10,560 ft long	13	1700	1900	2600	3000	2800	3200	NF
Mixing/Loading/ Applying Liquids with Closed System Aspirators (PHED: mixing/loading liquid - closed system) (6)	Lakes	0.68	10 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	110
	Lakes	0.68	5 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	220
	Lakes	0.54	10 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	140
	Lakes	0.54	5 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	270
Mixing/Loading/ Applying Liquids with Drip Bars (PHED: mixing/loading liquid) (7)	Streams	0.000016 lb ai/ft3	10,560 ft long	360	30000	36000	41000	53000	43000	57000	110000
	Streams	0.000013 lb ai/ft3	10,560 ft long	440	36000	44000	50000	66000	53000	70000	140000
Mixing/Loading/ Applying Wettable Powders with a Backpack Sprayer (using PHED wettable powder low pressure handwand data) (8)	Lakes	0.68	2 acres	ND	2.6	3	4.8	6.1	5.3	7.1	NF
	Lakes	0.54	2 acres	ND	2.6	3	4.8	6.1	5.3	7.1	NF
	Streams	0.000016 lb ai/ft3	10,560 ft long	ND	53	60	96	120	110	140	NF
	Streams	0.000013 lb ai/ft3	10,560 ft long	ND	65	74	120	150	130	170	NF
Mixing/Loading/ Applying Wettable Powders with Closed System Aspirators (PHED: mixing/loading liquid - closed system) (9)	Lakes	0.68	10 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	84
	Lakes	0.68	5 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	170
	Lakes	0.54	10 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	110
	Lakes	0.54	5 acres	N/A	N/A	N/A	N/A	N/A	N/A	N/A	210
Mixing/Loading/ Applying Wettable Powders with Drip Bars (PHED: mixing/loading liquid) (10)	Streams	0.000016 lb ai/ft3	10,560 ft long	250	1700	1800	4000	4800	4900	6000	85000
	Streams	0.000013 lb ai/ft3	10,560 ft long	310	2100	2300	5000	5900	6000	7400	100000
Mixing/Loading/ Applying Wettable Powders via Powder/Sand/ Gelatin Paste (11)	Seeps and Springs	There are currently no data to assess this scenario. EPA believes this scenario will result in minimal exposure due to the amount of rotenone used and the fact that this paste is typically mixed in either a lab under a fume hood or by an individual wearing a respirator.									

[1] Lb ai/A-ft unless otherwise noted

[2] G = Gloves; DL = Double Layer (baseline clothing + gloves); NR = No Respirator; R = Respirator; Eng Cont = Engineering Controls; ND = No Data; N/A = Not Applicable; NF = Not Feasible

c) Post-Application Occupational Risk

Occupational post-application scenarios were not assessed for rotenone because both dermal exposure from collecting dead fish and inhalation exposure from volatilization are expected to be minimal and no other post-application exposure is expected.

7. Human Incident Data

EPA reviewed reported incidents from piscicide applications and the now cancelled agricultural and residential uses. Incident data for rotenone were available from five sources including the OPP Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), National Pesticide Information Center (NPIC), and National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR).

The most common symptom reported was eye irritation, which was four times more prevalent that any other symptoms. Other symptoms reported included dermal irritation, throat irritation, nausea, and cough/choke. Most incidents appeared to be caused by rotenone's irritant properties. Few neurological symptoms other than headache and dizziness were reported, though there were several reports of peripheral neuropathy, numbness, or tremor. No fatalities or systemic poisonings were reported in relation to ordinary use.

B. Ecological Risk Assessment

EPA conducted an ecological risk assessment for rotenone to support the reregistration eligibility decision. EPA evaluated the submitted environmental fate and ecological studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision.

1. Environmental Fate and Transport

Rotenone is mobile to moderately mobile in soil and sediment (K_d = 4 – 426 mL g_{oc}^{-1}) and has a relatively low potential for bioconcentrating in aquatic organisms (BCF < 30X). Rotenone is not persistent in the environment and its low vapor pressure ($6.9x10^{-10}$ torr) and Henry's Law constant ($1.1x10^{-13}$ atm-m^3 mol^{-1}) limit its volatility. If released to water, rotenone generally degrades quickly through abiotic (hydrolytic and photolytic) mechanisms, with half-lives of a few days to several weeks or longer depending on water temperature. The extent of degradation through biotic mechanisms is unknown since no data were available to assess this potential route of degradation.

2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient (RQ) method. RQs are calculated by dividing

acute and chronic estimated environmental concentrations (EEC) by ecotoxicity values for various wildlife and plant species. RQs are then compared to the levels of concern (LOC) presented in Table 10.

Table 10. EPA's Levels of Concern for Risk Quotients

Risk Presumption	**Level of Concern**		
	Terrestrial Animals	**Aquatic Animals**	**Plants**
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

[1] RQs that exceed EPA's level of concern for endangered species do not constitute a "may affect finding" under the Endangered Species Act.

When the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern. In general, the higher the RQ, the greater the potential risk. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed.

a) Aquatic Organisms

EPA estimated toxicity, exposure, and risk to freshwater fish and invertebrates. Data were not available to evaluate the risk of rotenone exposure to non-target aquatic plants.

As a registered piscicide, rotenone is expected to kill fish and aquatic invertebrates at the concentrations at which it is applied. To estimate risks to aquatic animals, the Agency considered estimated environmental concentrations (EECs) in surface water bodies based on labeled application rates (concentrations): 250 ppb for lakes/reservoirs/ponds and 50 ppb for streams/rivers. The maximum solubility concentration for rotenone is 200 ppb. Although applicators may apply up to 250 ppb rotenone in lakes/reservoirs/ponds for difficult-to-control species, only 200 ppb will be available in the water for exposure. Therefore, the ecological risk assessment considers 200 ppb and 50 ppb to be the maximum potential exposure for exposed aquatic organisms in lakes/reservoirs/ponds and streams/rivers, respectively (see Table 11).

Table 11. EECs for Aquatic Organisms

Use Sites	**Peak EEC**
Lakes/Reservoirs/Ponds	200 ppb
Streams/Rivers	50 ppb

Aquatic organism acute and chronic toxicity values are presented in Table 12 and Table 13, respectively. No guideline studies were required to assess either acute or

chronic toxicity of rotenone to estuarine/marine fish or invertebrates; however, rotenone is not used in estuarine/marine environments and labels will be updated to make this clarification (see Section IV). Chronic effects to aquatic organisms may occur when aquatic fish and invertebrates are not eliminated during acute exposure.

Table 12. Rotenone Acute Toxicity Values for Freshwater Fish and Invertebrates

Species	**Toxicity Value (ppb)**	**Effects Endpoint**	**Exposure Duration**	**Toxicity Classification**	**Reference**
Freshwater Fish Rainbow Trout *Oncorhynchus mykiss*	LC50 = 1.94	Survival	96 hour	Very highly toxic	MRID 43975102
Freshwater Invertebrates Daphnid	EC50 = 3.7	Survival	96 hour	Very highly toxic	MRID 40063303

Table 13. Rotenone Chronic Toxicity Values for Freshwater Fish and Invertebrates

Species	**Toxicity Value (ppb)**	**Effects Endpoint**	**Exposure Duration**	**Reference**
Freshwater Fish Rainbow Trout *Oncorhynchus mykiss*	NOAEC = 1.01	Growth	32 day	MRID 40063302
Freshwater Invertebrates Daphnid	NOAEC = 1.25	Reproduction	21 day	MRID 40063303

Acute Risk

At maximum treatment concentrations, acute EECs of rotenone are expected to be equivalent to the solubility limit of 200 ppb. At this exposure concentration, risk quotient values (RQ = EEC/LC50) for fish and invertebrates are 103 (200/1.94) and 54 (200/3.7), respectively. Both RQs exceed the acute risk level of concern (RQ = 0.5). When used at the maximum treatment concentrations, rotenone is likely to cause the intended effect of acute mortality for many aquatic species in the treatment area.

Chronic Risk

Based on the dissipation rates, and the highest application rates in each type of site, effects might be expected on sensitive species for less than two weeks in warm water environments. However, rotenone can be quite persistent in cold environments where it might remain at levels causing effects for approximately 160 days at maximum labeled treatment concentrations. Chronic risk quotients (RQs) exceed the Agency's LOC.

b) Terrestrial Organisms

EPA estimated toxicity, exposure, and risk to avian and mammalian terrestrial organisms.

Birds

Since rotenone is applied directly to water, there is little likelihood that terrestrial forage items for birds will contain rotenone residues from this use. While it is possible that some piscivorous birds may feed opportunistically on dead or dying fish located on the surface of treated waters, protocols for piscicidal use typically recommend that dead fish be collected and buried, rendering the fish less available for consumption (see Section IV). In addition, many of the dead fish will sink and not be available for consumption by birds.

However, whole body residues in fish killed with rotenone ranged from 0.22 µg/g in yellow perch (*Perca flavescens*) to 1.08 µg/g in common carp (*Cyprinus carpio*) (Jarvinen and Ankley 1998). For a 68 g yellow perch and an 88 g carp, this represents totals of 15 µg and 95 µg rotenone per fish, respectively. Based on the avian subacute dietary LC_{50} of 4110 mg/kg, a 1000-g bird would have to consume 274,000 perch or 43,000 small carp. Thus, it is unlikely that piscivorous birds will consume enough fish to result in a lethal dose.

Mammals

The application of rotenone directly to water is not likely to present significant exposure to wild mammals because dead fish tend to bloat and sink below the surface of the water where they disintegrate and are not available for terrestrial animal consumption. Based on the remote chance, however, that different-sized mammals could forage on dead or dying fish, it is possible to estimate the potential amount of rotenone in their diet. When estimating daily food intake, an intermediate-sized 350 g mammal will consume about 18.8 g of food. Using data previously cited from the common carp with a body weight of 88 grams, a small mammal would only consume 21% (18.8/88) of the total carp body mass. According to the data for common carp, total body residues of rotenone in carp amounted to 1.08 µg/g. A 350-g mammal consuming 18.8 grams represents an equivalent dose of 20.3 µg of rotenone; this value is well below the median lethal dose of rotenone (39.5 mg/kg * 0.350 kg = 13.8 mg = 13,800 µg) for similarly sized mammals.

When assessing a large mammal, 1000 g is considered to be a default body weight. A 1000 g mammal will consume about 34 g of food. If the animal fed exclusively on carp killed by rotenone, the equivalent dose would be 34 g *1.08 µg/g or 37 µg of rotenone. This value is below the estimated median lethal equivalent concentration adjusted for body weight (30.4 mg/kg * 1 kg = 30.4 mg = 30,400 µg).

Although fish are often collected and buried to the extent possible following a rotenone treatment, even if fish were available for consumption by mammals scavenging

along the shoreline for dead or dying fish, it is unlikely that piscivorous mammals will consume enough fish to result in observable acute toxicity.

Non-Target Insects

Currently, EPA does not estimate RQs for terrestrial non-target insects. However, based on a single contact study in honey bees, technical grade rotenone is classified as practically non-toxic on an acute exposure basis to non-target terrestrial insects ($LD_{50} \geq$ >60 ug/ai per bee).

Non-Target Terrestrial Plants

No data were submitted to evaluate the risk of rotenone exposure to non-target terrestrial plants; however, exposure to non-target terrestrial plants is unlikely given the manner in which rotenone is applied (see Section IV).

3. Ecological Incidents

EPA conducted a review of the Ecological Incident Information System (EIIS) database for ecological incidents involving rotenone. Six of the reported incidents were a result of direct rotenone applications to water, and one was the result of a terrestrial rotenone application.

Two incidents involved rotenone applied to ponds. One incident occurred in South Carolina where 300 sunfish and tadpoles were reported killed. The second pond incident occurred in Missouri and resulted in thousands of fish killed. The Missouri incident occurred in a bait pond that had been treated with rotenone to remove carp and the treated water from the pond was released into an adjoining creek. Dead fish were observed up to 2.4 miles downstream.

A river incident occurred in Illinois. Rotenone was intentionally misused and killed over 11,000 fish of different species. The majority of the fish killed were minnows.

Another incident occurred in Lake Davis, California. Rotenone was intentionally applied to control northern pike (*Esox lusius*) and resulted in thousands of fish being killed. The California Department of Fish and Game applied the rotenone according to its defined operating procedures. Although potassium permanganate was used to detoxify rotenone and prevent its movement downstream, an insufficient amount of permanganate was used and thousands of fish were reported killed outside of the intended treatment area.

There was a report of hundreds of fish being killed in South Carolina following a terrestrial insecticide application of rotenone; however, so few details were reported that it is difficult to gauge causality.

One incident report is associated with mortality of terrestrial animals in New York. A swan and a duck were killed following the treatment of a pond with synergized rotenone containing piperonyl butoxide. Two Canadian geese and one mute swan were found dead several days after the treatment; however it is uncertain whether the mortalities could be clearly associated with the rotenone treatment.

4. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in the RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of rotenone "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment would refine the screening-level assessment to take into account such things as the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for rotenone result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

IV. Risk Management and Reregistration Eligibility Decisions

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for

reregistration. Based on available data, EPA has completed its assessment of the risks associated with the use of pesticides containing the active ingredient rotenone and has concluded that it has sufficient information to make a decision as part of the reregistration process under FIFRA, as amended by the Food Quality Protection Act (FQPA).

EPA has determined that currently registered uses of rotenone will not pose unreasonable risks or adverse effects to humans or the environment if the requirements for reregistration outlined in this document are implemented. Unless labeled and used as specified in this document, rotenone would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the requirements for reregistration identified in this document, the Agency may take regulatory action to address the risk concerns from the use of rotenone.

B. Requirements for Reregistration

Piscicidal uses for rotenone are eligible for reregistration provided that registrants comply with the requirements outlined in this document including the following: (1) submit required data; (2) implement risk mitigation measures; (3) update product labels; and (4) submit an up-to-date confidential statement of formula (CSF) for each product.

1. Required Data

Piscicidal uses for rotenone are eligible for reregistration provided that registrants submit data as required by the generic and product-specific data call-ins that EPA intends to issue as a result of this RED (see Section V).

The generic database supporting the reregistration of rotenone for piscicidal uses has been reviewed and determined to be adequate to support a reregistration eligibility decision; however, as a result of this RED, generic data will be required to confirm that standard water treatment processes are effective at breaking down rotenone. Using the existing database, EPA cannot quantitatively asses a potentially critical effect (neurotoxicity) at doses to which rotenone users could be exposed; therefore, an additional 10x database uncertainty factor has been applied in addition to the inter-species (10x) uncertainty factor and intra-species (10x) uncertainty factor. Product-specific data for each product will also be required as appropriate.

2. Risk Mitigation Measures

Products containing rotenone are eligible for reregistration provided that registrants implement the risk mitigation measures presented in Table 14. Specific labeling requirements to implement these measures are presented in Table 15 and Table 16 (see Section V).

Table 14. Risk Mitigation Measures for Rotenone

Risk of Concern	Mitigation Measures
Chronic dietary exposure from drinking water exceeds OPP's level of concern	• For lentic (standing) water treatment areas with drinking water intakes within the treatment area or downstream/downlake of the treatment area with no oxidative raw or finished water treatment, registrants must submit proposed labeling or a monitoring plan to preclude sub-chronic or chronic exposure to rotenone concentrations above 40 ppb. Options which could be considered include label restrictions to prohibit use in standing waters with drinking water intakes and no oxidative raw or finished water treatment, development of a set of use parameters that would preclude any potential for sub-chronic or chronic exposures above 40 ppb (e.g., based on dilution factors/distance of water intakes from treatment area, water temperature at time of treatment, pH, etc.), and/or a monitoring (e.g., analytical chemistry or sentinel bioassay) requirement at water intakes.
Exposure from swimming in treated areas exceeds OPP's LOC	• Through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit recreational access (e.g., wading, swimming, boating and fishing) to treated areas during treatment. • Through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit swimming in treated areas during treatment and for 3 days thereafter (or until monitoring samples confirm rotenone concentrations in swimming areas are below 90 ppb for 3 consecutive samples taken no less than 4 hours apart).
Exposure from consuming treated fish may exceed OPP's LOC	• Through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit consumption of dead fish taken from treatment areas. • For treated water bodies used for food production (aquaculture), the Certified Applicator or designee under his/her direct supervision must prohibit restocking of fish until monitoring samples confirm rotenone concentrations are below the level of detection for 3 consecutive samples taken no less than 4 hours apart.

Risk of Concern	Mitigation Measures
Occupational exposure exceeds OPP's LOC	• Registrants must update labels to specify maximum treatment concentrations of 50 parts per billion (ppb) in streams/rivers and 200 ppb in lakes/reservoirs/ponds. • Registrants must update labels to require rotenone applications to be supervised by an on-site Certified Applicator. The on-site Certified Applicator should attend a certification program for piscicide applications. • Registrants must update labels to allow the use of backpack sprayers only with products formulated as liquids. • Registrants must package all rotenone products to accommodate closed mixing/loading systems. • The Certified Applicator or designee under his/her direct supervision must ensure that rotenone products are mixed/loaded in closed mixing/loading systems (except backpack sprayers for liquid formulations). • The Certified Applicator or designee under his/her direct supervision must ensure that all rotenone products are mixed/loaded in closed systems (except backpack sprayers for liquid formulations). • The Certified Applicator or designee under his/her direct supervision must ensure that all applications are made beneath the water's surface (except backpack sprayers for liquid formulations and aerial applications). • Registrants must update labels to require all handlers (except aerial applicators) and other individuals directly participating in the treatment to wear the following PPE in addition to baseline protection (long-sleeve shirt, long pants, socks and shoes): chemical resistant gloves, coveralls, and footwear; protective eyewear; and a full-face respirator that also provides eye protection. Aerial applicators must use an enclosed cockpit and wear long-sleeve shirt, long pants, shoes, and socks.
Ecological risk quotients (RQ) for non-target species exceed OPP's LOC	• Registrants must update labels to prohibit rotenone use in estuarine/marine environments. • Through deactivation with potassium permanganate, the Certified Applicator or designee under his/her direct supervision must ensure that rotenone will not affect areas beyond the treatment area. • The Certified Applicator or designee under his/her direct supervision should collect and bury dead fish.

3. Product Label Updates

Manufacturing-Use Products and End-Use Products must be updated to reflect the mitigation measures presented in Table 14 above and the label changes presented in Table 15 and Table 16 (see Section V). As a result of this RED, registrants will also be required to develop and submit a standard operating procedures manual.

EPA believes that a detailed standard operating procedures (SOP) manual is necessary for rotenone because the ways in which it is applied are significantly more complex than typical agricultural pesticides. Because so many detailed instructions and procedures must be followed to conduct a safe, effective, and lawful piscicide application, the product label may not be a practical medium for capturing all of the necessary SOPs.

In addition to other topics and information, the rotenone SOP manual must contain detailed procedures/instructions for completing potentially complex activities including, but not limited to, the following topics: planning a rotenone application; applying rotenone as a complete and partial kill treatment; deactivating rotenone with potassium permanganate; minimizing human (handler and bystander) exposure; minimizing ecological exposure; precluding chronic or sub-chronic exposure to rotenone through drinking water; keeping treatment records; posting and preventing access to treated areas; and facilitating compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Clean Water Act (CWA), the National Environmental Policy Act (NEPA), and the Endangered Species Act (ESA).

It is EPA's expectation that the technical registrants will seek input from EPA for developing a draft SOP manual that will be released for public and stakeholder comment prior to finalization. The registrants will be responsible for updating the manual as necessary and also for making it available to rotenone users.

4. Confidential Statement of Formula

For certain formulations, emulsifiers and solvents are used to extract the active ingredient rotenone from the derris root. The use of these compounds may result in inert ingredients and impurities that have strong chemical odors and may pose risks to human health and the environment. As part of the product-specific data call-in, registrants must submit an updated confidential statement of formula (CSF) for each rotenone product. CSFs must quantify all inert ingredients and impurities >0.1%. If appropriate, EPA will take additional steps to address risks of concern from inert ingredients and impurities (see 40 CFR 158.155).

C. Regulatory Rationale

The Agency has determined that rotenone is eligible for reregistration provided that the requirements for reregistration outlined in this document are implemented. Provided that registrants comply with the requirements of this RED, EPA believes that rotenone will not present risks inconsistent with FIFRA and that rotenone's benefits to society, including enhanced recreational areas and control of non-native and invasive species, outweigh the remaining risks. A summary of EPA's rationale for reregistering and managing risks associated with rotenone is presented below.

1. Benefits and Alternatives

Rotenone and antimycin A (CAS Number 1397-94-0, EPA PC Code 006314) are the only two broad spectrum piscicides registered in the United States. Rotenone and antimycin A each appear to have niche uses, although both can be applied in a variety of situations. In general, antimycin A is used to repopulate native, threatened, or endangered trout species in streams by eliminating nonnative fish species, particularly in high-altitude alpine lakes and streams because it is effective in cold alpine waters and where pH is low. In addition, this piscicide may be used at low concentrations, which makes it easy to transport to isolated or hard to reach mountainous streams. Rotenone is most often used in standing water, such as large lakes and reservoirs. It is typically applied to maintain sport fisheries, to sample fish populations, and to eliminate unwanted species in rearing ponds. The costs of rotenone and antimycin A are similar. For sampling fish populations, alternatives such as electrofishing are available. Electrofishing requires the use of specialized equipment that runs a low-voltage current through the water to temporarily stun fish for easy collection. However, for water bodies requiring partial or complete kill of certain fish species, rotenone and antimycin A are more effective. Dewatering is an effective alternative for complete kill in a water body. In select cases, gill netting, which generally only reduces fish populations, has been used to remove all fish from certain mountain lakes in California.

Although some uses of rotenone and antimycin A coincide, they are not direct replacements for each other. Because there are no other broad spectrum piscicides available, the only possible alternatives are non-chemical fish control methods, and none are applicable for all uses of rotenone or antimycin A. In situations where dewatering or electrofishing are potential replacements, it is not clear if these are more cost effective or less detrimental to the environment.

Rotenone is formulated as a liquid and a wettable powder. In general, liquid formulations are slightly more expensive than wettable powder formulations and, based on the Agency's risk estimates, result in lower occupational exposure and are more compatible with existing closed system technologies. The wettable powder formulations, however, appear to contain fewer potentially toxic impurities and inert ingredients. Through the requirements of this RED and associated product reregistration, EPA intends to minimize the potential adverse effects to human health and the environment from both formulations.

Because there are niche uses and no direct replacements available for all piscicidal uses of rotenone, EPA concludes that continued registration of both liquid and wettable powder rotenone products, subject to the requirements of this RED, would provide benefit to society in controlling invasive or unwanted fish species.

2. Human Health and Ecological Risk

EPA has conducted human health and ecological risk assessments for rotenone to support the reregistration eligibility decision. In its assessments, EPA concluded that most risks are below the Agency's level of concern but also identified potential risks that, if left unmitigated, may pose unreasonable risks or adverse effects to humans or the environment.

As a result of this RED, EPA is requiring registrants to implement risk mitigation measures to address ecological risks from unintended exposure and human health risks from swimming in treated areas, consuming treated fish, and handling rotenone. To mitigate ecological risk, the Agency is requiring deactivation with potassium permanganate to ensure that rotenone will not affect areas beyond the treatment area; encouraging users to collect and bury dead fish; prohibiting rotenone from being applied to estuarine/marine environments; and requiring the maximum application rate to be reduced from 250 ppb to rotenone's solubility limit of 200 ppb. To mitigate human health risk, the Agency is requiring that the Certified Applicator or designee under his/her direct supervision ensures concentrations of rotenone at drinking water intakes are below EPA's LOC (40 ppb); where appropriate, deactivate effluent with potassium permanganate; placard the treatment area to prohibit recreational access during treatment, swimming for at least 3 days following treatment, and consumption of dead fish taken from treatment area; and apply rotenone below the water's surface (except for aerial and backpack sprayer applications). Registrants will update labels to require these measures along with reducing the maximum labeled treatment concentration, limiting the use of backpack sprayers to only liquid formulations, and requiring additional personal protective equipment.

3. Endocrine Screening

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *"may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted,

rotenone may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

V. What Registrants Need to Do

The Agency has determined that rotenone is eligible for reregistration provided that the requirements for reregistration identified in this RED are implemented (see Section IV). Registrants will also need to submit required data, amend product labeling, and submit an updated confidential statement of formula for each product.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic database supporting the reregistration of rotenone for currently registered uses has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, to confirm that no chronic exposures to rotenone (above 40 ppb) will occur in situations where water is either treated with potassium permanganate for deactivation purposes or is subject to an oxidative drinking water treatment regimen, confirmatory laboratory studies will be required through a generic data call-in (GDCI) using protocols similar to the Tier I drinking water protocols developed by the EPA Office of Research and Development (ORD).

Generally, registrants will have 90 days from receipt of a GDCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. Timeframes for submitting generic data will be presented in the GDCI.

2. Confidential Statement of Formula

As part of product reregistration, registrants must submit an updated confidential statement of formula (CSF) for each rotenone Manufacturing-Use Product. Each CSF must list all components present at a concentration of 0.1% or more by weight. These components fall into three general categories: active ingredients, inert ingredients, and impurities. Active ingredients are those that have some active role in controlling the pest. Inert ingredients are intentionally added to the product to achieve effects not directly related to controlling the pest (such as water, emulsifiers, preservatives, carriers). Impurities (also known as contaminants) are compounds not intentionally added to the product. Impurities that do not have toxic properties can be lumped together on the CSF as “Other Ingredients” only if each is below 0.1% by weight.

3. Labeling for Technical Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 15. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved.

However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

B. End-Use Products

1. Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

Generally, registrants will have 90 days from receipt of a PDCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. Registrants will have eight months to submit product-specific data.

2. Confidential Statement of Formula

As part of product reregistration, registrants must submit an updated confidential statement of formula (CSF) for each rotenone End-Use product. Each CSF must list all components present at a concentration of 0.1% or more by weight. These components fall into three general categories: active ingredients, inert ingredients, and impurities. Active ingredients are those that have some active role in controlling the pest. Inert ingredients are intentionally added to the product to achieve effects not directly related to controlling the pest (such as water, emulsifiers, preservatives, carriers). Impurities (also known as contaminants) are compounds not intentionally added to the product. Impurities that do not have toxic properties can be lumped together on the CSF as “Other ingredients” only if each is below 0.1% by weight.

3. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 16. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Table 15. Label Changes Summary Table for Rotenone Manufacturing-Use Products

Description	Amended Labeling Language for Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	"Only for formulation into a piscicide (fish kill) for the following use(s) [*MUP registrant, insert those uses that are being supported by the RED*]." "Only for formulation into products packaged in a manner that is compatible with a closed mixing/loading system." "Only for formulation into products that are classified as Restricted Use."	Directions for Use
For Wettable Powder Manufacturing Use Products	"Only for formulation into products that prohibit the use of a backpack sprayer."	Directions for Use
Additional Uses	"This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is extremely toxic to fish and other aquatic organisms." "Do not contaminate water, food, or feed by storage or disposal." "Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).	Precautionary Statements

Table 16. Label Changes Summary Table for Rotenone End-Use Products Intended for Occupational and Residential Use

Description	Amended Labeling Language for End-Use Products	Placement on Label
RUP	"Restricted Use Pesticide" "Due to acute inhalation and acute oral toxicity and due to toxicity to fish and other aquatic organisms." "For retail sale to and use by only Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."	This statement must appear at the very top of the label's front panel [see 40 CFR 156.10(j)(2)(i) for more information]. No other wording or symbols may appear above the RUP statement.
SOP Manual	"THIS PRODUCT MUST BE ACCOMPANIED BY AN EPA-APPROVED PRODUCT LABEL AND THE EPA-APPROVED 'ROTENONE STANDARD OPERATING PROCEDURES MANUAL.' THE ROTENONE STANDARD OPERATING PROCEDURES (SOP) MANUAL IS LABELING. READ AND UNDERSTAND THE ENTIRE LABELING AND SOP MANUAL PRIOR TO USE. ALL PARTS OF THE LABELING AND SOP MANUAL ARE EQUALLY IMPORTANT FOR SAFE AND EFFECTIVE USE OF THIS PRODUCT."	Immediately below the RUP statement on the label and on the cover page of the Rotenone SOP Manual.

Description	Amended Labeling Language for End-Use Products	Placement on Label
PPE Requirements Established by the RED[1] for all Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" [*EUP registrant, insert correct chemical-resistant material*]. "If you want more options, follow the instructions for category" [*EUP registrant, insert A, B, C, D, E, F, G, or H*] "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators (except pilots), and other handlers must wear, at a minimum, the following PPE: * coveralls over long-sleeved shirt and long pants, * chemical-resistant gloves, * chemical resistant footwear plus socks, and * a NIOSH-approved tight-fitting full-face cartridge or canister respirator with any N, R, P, or HE filter; or a NIOSH-approved helmet or hood-style respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C." "In addition, mixers, loaders, and others exposed to the concentrate, through cleaning equipment or spills must wear: * chemical-resistant apron." [*EUP registrant, drop the "N" type prefilter from the respirator statement if the pesticide product contains or is used with oil.*] "See Engineering Controls for additional requirements and exceptions."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the PPE requirements

Description	Amended Labeling Language for End-Use Products	Placement on Label
Engineering Controls for Mixing/Loading Liquid Formulations	"Engineering Controls for Mixing and Loading" "Mixers and loaders (except mixing/loading to support backpack sprayers) must use a closed system that is designed by the manufacturer to remove the product from the shipping container and transfer the product into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that will limit drippage to no more than 2 ml per disconnect. The closed mixing/loading system must function properly and be used and maintained in accordance with the manufacturer's written operating instructions. Mixers and loaders must wear the personal protective equipment required on this labeling for mixers/loaders."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.
Engineering Controls for Applying Liquid Formulations	"Applications using a boom or other mechanized equipment must release this product below the water's surface. Applications made with aircraft or with a backpack sprayer or other hand-held nozzle or equipment may release this product above the water's surface."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.
Engineering Controls for Mixing/Loading Wettable Powder Formulations	"Engineering Controls for Mixing and Loading" "Mixers and loaders must use a closed system. The system must be capable of removing the product from the shipping container, transferring the product into mixing tanks and/or application equipment, and applying the product below the water's surface. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that will limit drippage to no more than 2 ml per disconnect. In addition, mixers and loaders must wear the personal protective equipment required on this labeling for mixers/loaders."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.
Engineering Controls for Applying Wettable Powder Formulations	"Applications using a boom or other mechanized equipment must release this product below the water's surface. Applications with a backpack sprayer are prohibited. Applications made with other hand-held nozzles or equipment or with aircraft may release this product above the water's surface."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.

Description	Amended Labeling Language for End-Use Products	Placement on Label
Engineering Controls for Aerial Applicators	"Engineering Controls for Aerial Applications" "Open cockpits are prohibited. Pilots must use a cockpit that has a nonporous barrier that totally surrounds the cockpit occupants and prevents contact with pesticides outside the enclosed area. Pilots in enclosed cockpits may wear a long-sleeve shirt, long pants, shoes, and socks, instead of the PPE required for applicators in the PPE section of this labeling."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.
Engineering Controls Exception for Boat Applications	"Engineering Controls for Boat Applications" "When boat pilots or others on the application boat are located within an enclosed area that has a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the enclosed area, they: * may wear a long-sleeve shirt, long pants, shoes, and socks, instead of the PPE required for applicators in the PPE section of this labeling. * must be provided and have immediately available for use in an emergency when they must exit the enclosed area while application is taking place, the PPE required for applicators in the PPE section of this labeling; * must take off any PPE that was worn while outside the enclosed area before reentering the enclosed area, and * store all such used PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the enclosed area."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the User Safety Requirements.

Description	Amended Labeling Language for End-Use Products	Placement on Label
User Safety Recommendations	"User Safety Recommendations" "Certified Applicators applying or supervising the application of this product should attend a training program for piscicide applications." "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below the Engineering Controls. (These statements must be placed in a box.)
Environmental Hazards	"Environmental Hazards" "This product is extremely toxic to fish and other aquatic organisms." "Do not contaminate water by cleaning of equipment or disposal of equipment wash waters." "Do not contaminate water, food, or feed by storage or disposal." "Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW)."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals" immediately following/below User Safety Recommendations
Personal Protective Equipment When Re-entering Treated Areas	"Re-entering the Treatment Area" "For the first 72 hours after treatment, handlers re-entering the treatment area, including shorelines, must wear, at a minimum, the following PPE: * Coveralls over long-sleeved shirt and long pants, * Chemical-resistant gloves, * Chemical resistant footwear plus socks, and * Chemical-resistant apron."	Direction for Use under the heading "Re-Entering the Treatment Area"

Description	Amended Labeling Language for End-Use Products	Placement on Label
Complete and Partial kills	"Complete and Partial Kills" "This product may be used to achieve a 'complete kill' or a 'partial kill.' Complete kills are intended to eliminate all fish in the treatment area whereas partial kills are intended eliminate or reduce the number of only certain (more vulnerable) species or to sample fish populations. Detailed instructions for conducting complete and partial kills are presented in the Rotenone SOP Manual."	Directions for Use under the heading "Complete and Partial kills"
General Application Restrictions for all Formulations	"The Certified Applicator supervising the treatment must remain on-site for the duration of the application." "Do not allow recreational access (e.g., wading, swimming, boating, fishing) within the treatment area while rotenone is being applied." "In lakes/reservoirs/ponds, do not apply this product in a way that will result in treatment concentrations greater than 200 parts per billion." "In streams/rivers, do not apply this product in a way that will result in treatment concentrations greater than 50 parts per billion." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "This product must not be applied to estuarine or marine environments." "Where practical, users should collect and bury dead fish on the surface of the treatment area."	Directions for Use
General Application Restrictions for Liquid Formulations	"Applications using a boom or other mechanized equipment must release this product below the water's surface. Applications made with aircraft or with a backpack sprayer or other hand-held nozzle or equipment may release this product above the water's surface."	Directions for Use

Description	Amended Labeling Language for End-Use Products	Placement on Label
General Application Restrictions for Wettable Powder Formulations	"Applications using a boom or other mechanized equipment must release this product below the water's surface. Applications with a backpack sprayer are prohibited. Applications made with other hand-held nozzles or equipment or with aircraft may release this product above the water's surface."	Directions for Use
Monitoring Requirements for Use in Aquaculture	"For treated water bodies used for food production (aquaculture), the Certified Applicator or designee under his/her direct supervision must prohibit restocking of fish until monitoring samples confirm rotenone concentrations are below the level of detection for 3 consecutive samples taken no less than 4 hours apart." "Detailed instructions for monitoring levels of rotenone in water are presented in the Rotenone SOP Manual."	Directions for Use under the heading "Monitoring Samples"
Drinking Water Notification Requirements	"Drinking Water Notification" If drinking water intakes are present within the treatment area, prior to application, the Certified Applicator must provide notification to the party responsible for the public water supply or to individual private water users. "Detailed instructions for notifications are presented in the Rotenone SOP Manual."	Directions for Use under the heading "Drinking Water Notification"

Description	Amended Labeling Language for End-Use Products	Placement on Label
Notification Requirements for all applications	"Placarding of Treatment Areas" "The Certified Applicator in charge of the application (or someone under his/her supervision) must placard all access areas to the treatment area. Detailed instructions for placarding are presented in the Rotenone SOP Manual. At a minimum, placards must be placed every 250 feet (including the shoreline of the treated area and up to 250 feet of shoreline past the application site to include immediate public access points) and contain the following information:" "NOTICE: AREA CLOSURE" * Skull and crossbones symbol * "DANGER/PELIGRO" * "DO NOT ENTER/NO ENTRE: Pesticide Application" * The name of the product applied * The agency or entity performing the application * The purpose of the application * The start date and time of application * The end date and time of application * The duration of the area closure * "Recreational access (e.g., wading, swimming, boating, fishing) within the treatment area is prohibited while rotenone is being applied." * "Do not swim or wade in treated water for a minimum of 72 hours after the last application." * "Do not consume dead fish from treated water." * The name, address, and telephone number of the Certified Applicator in charge of the application "Signs must remain legible during the entire posting period and must be removed no earlier than 3 days after treatment and no later than 14 days after treatment."	Directions for Use under the heading "Placarding of Treatment Areas"

Description	Amended Labeling Language for End-Use Products	Placement on Label
Deactivation with Potassium Permanganate	"Deactivation with Potassium Permanganate" "Effluent water must be deactivated with potassium permanganate to prevent exposure beyond the defined treatment area. Detailed instructions for deactivation with potassium permanganate are presented in the Rotenone SOP Manual."	Directions for Use under the heading "Deactivation with Potassium Permanganate ($KMnO_4$)"
Spray Drift Label Language for Products Applied as an Aerial Spray	RELEASE HEIGHT: "Do not release spray at a height greater than 10 feet above the water." BOOM LENGTH: "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." SWATH ADJUSTMENT: "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Leave at least one swath unsprayed at the downwind edge of the treated area." DROPLET SIZE: "Apply as a medium or coarser spray (ASAE standard 572)." WIND SPEE: "Do not apply when wind speeds are greater than 12 miles per hour."	Directions for Use under the heading "General Precautions and Restrictions"

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.