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Interim Reregistration Eligibility Decision

Carbofuran

List [A]

Case No. 0101

Interim Reregistration Eligibility Decision (IRED) Document for Carbofuran

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Table of Contents

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
BMD	Benchmark Dose
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FCID	Food Commodity Intake Database
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD50	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
Φg/g	Micrograms Per Gram
Φg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day

mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TAF	Toxicity Adjustment Factor
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid (nitrapyrin Metabolite)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
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. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (hereafter referred to as 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 risks arising from the currently registered uses of the 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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted by August 2006. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process. FQPA also amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors that include an assessment of cumulative effects of chemicals with a common mechanism of toxicity. The reason for consideration of other substances is that the possibility exists that low-level exposures to multiple chemicals that cause a common toxic effect lead to the same adverse health effect as would a high level of exposure to any one of the other substances individually.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Carbofuran is a member of the N-methyl carbamate (NMC) class of pesticides. This class also includes carbaryl, aldicarb, methomyl, and oxamyl, among others. The NMCs, as a group, have been determined to share a common mechanism of toxicity (July 2001 memo from Office Director Marcia Mulkey). The preliminary cumulative risk assessment (CRA) for the NMC cumulative Assessment Group, which includes carbofuran, was released in July 2005. The revised CRA is currently being developed and will be completed during 2006. The results of this NMC cumulative assessment, as well as the single chemical carbofuran assessment, will be considered during the carbofuran reregistration process in which decisions regarding establishing, modifying, or revoking carbofuran tolerances will be made.

This document presents EPA's revised human health and ecological risk assessments and its progress toward tolerance reassessment, and the interim reregistration eligibility decision for carbofuran. The document consists of six sections: section I contains the regulatory framework for reregistration/tolerance reassessment; section II provides a profile of the use and usage of the chemical; section III gives an overview of the revised

human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments, section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and section VI provides information on how to access related documents. Finally, the Appendices list related and 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 under docket number EPA-HQ-OPP-2005-0162.

II. Chemical Overview

A. Regulatory History

Carbofuran is a broad spectrum N-methyl carbamate insecticide and nematicide registered for control of soil and foliar pests on a variety of field, fruit, and vegetable crops. It was first registered in the United States in 1969. Through an agreement between EPA and the technical registrant in 1991, granular carbofuran has been limited to the sale of 2,500 lbs of active ingredient per year in the U.S. since 1994, for use only on certain crops. Today granular carbofuran is limited to use on spinach grown for seed, pine seedlings, bananas (in Hawaii only), and cucurbits only. Carbofuran is classified as a restricted use pesticide.

In the late 1990s, the technical registrant made a number of changes to labels in order to reduce drinking water and ecological risks of concern. These included reducing application rates and numbers of applications for alfalfa, cotton, corn, potatoes, soybeans, sugarcane, and sunflowers. Numbers of applications were also restricted on some soils to reduce groundwater concentrations.

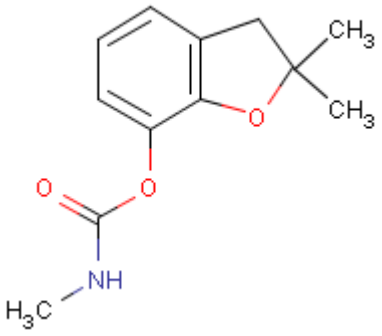
Three human studies have been conducted for carbofuran – one oral and two dermal. Since the 1990s, the Agency has considered the appropriateness of these studies for risk assessment purposes several times. Most recently, these studies were reviewed by the Agency's Human Studies Review Board (HSRB) in May 2006. The HSRB concluded that, while informative, the studies are not appropriate for use by the Agency in either the individual carbofuran or N-methyl carbamate cumulative risk assessment. This decision was based upon the following, for all three studies: small sample size, lack of control subjects, and highly variable results for red blood cell cholinesterase activity. Additionally, the board had concerns regarding inappropriate application methods in the dermal studies and also determined that the conduct of the dermal studies was unethical.

There are currently one technical, two manufacturing-use, and six end-use products registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). There are also 77 active Special Local Need registrations under Section 24(c) of FIFRA. This Interim Reregistration Eligibility Decision document evaluates risks from all currently registered uses.

EPA followed a 6-phase public participation process in developing this interim decision. This means that there were two 60-day public comment periods on the risk assessments. EPA released the revised human health and ecological risk assessments for the second phase of public comment (Phase 5) on March 22, 2006. This IRED document will be posted in the carbofuran reregistration docket, along with any revised risk assessments and responses to public comments received.

B. Chemical Identification

Chemical Structure:



Common Name: Carbofuran

Chemical Name: 2,3-dihydro-2,2-dimethyl-7-benzofuranyl-N-methylcarbamate

Chemical Family: N-methyl Carbamate

Empirical Formula: $C_{12}H_{15}NO_3$

CAS Registry Number: 1563-66-2

Case Number: 0101

OPP Chemical Code: 090601

Molecular weight: 221.3

Trade Names: Furadan

Basic Manufacturers: FMC Corporation

Carbofuran is an odorless, white, crystalline solid with a melting point range of 150-154 ^{o} C. It is slightly soluble in water, and is highly soluble in N-methyl-2-pyrrolidone, dimethylformamide, dimethyl sulfoxide, acetone, acetonitrile, methylene

chloride, cyclohexanone, benzene, and xylene. Carbofuran is stable under neutral and acidic conditions, but decomposes under alkaline conditions.

C. Use Profile

The following is information on the currently registered uses of carbofuran, including an overview of use sites and application methods.

Type of Pesticide: Restricted use systemic insecticide

Summary of Use: Used for control of a variety of insect pests on a variety of field, fruit, and vegetable crops. Carbofuran is not used in residential settings or food-handling establishments.

Food uses: Registered for use on the following crops/sites:

Alfalfa, artichoke, banana, barley, coffee, corn (field, pop, and sweet), cotton, cucurbits (cucumber, melons, and squash), grapes, oats, pepper, plantain, potato, sorghum, soybean, sugar beet, sugarcane, sunflower, and wheat

Non-food uses:

Agricultural fallow land, cotton, ornamental and/or shade trees, ornamental herbaceous plants, ornamental non-flowering plants, ornamental woody shrubs and vines, pine, spinach grown for seed, and tobacco

Target Pests: Alfalfa weevil, aphids, banana root borer, Colorado potato beetle, corn rootworm, cribrate weevil, cucumber beetles, European corn borer, flea beetles, grasshoppers, leafhoppers, nematodes, potato tuberworms, Southwestern corn borer, thrips, wireworms

Formulation Types: Granular and flowable

Method and Rates of Application:

Application Methods: Foliar, soil, seedling dip

Application Equipment: Aerial equipment, chemigation systems, groundboom sprayers, airblast sprayers, tractor-drawn spreaders, and handheld equipment.

Application Rates: Application rates range from 0.19 (agricultural fallow land) to 10 lbs a.i./A (grapes and potatoes), depending on the application scenario.

Application Timing: At plant, post-plant

Use Classification: Restricted

D. Estimated Usage of Pesticide

The estimate for total domestic use (annual average) of carbofuran is nearly 1 million pounds of active ingredient for the liquid formulation, with the majority of use occurring on the following crops: corn, alfalfa, and potatoes. Under the existing terms and conditions of the registration, sale of the granular formulation is limited to 2,500 pounds active ingredient per year, and use is limited to pine seedlings, cucurbits, bananas (in Hawaii only), and spinach grown for seed.

III. Summary of Carbofuran Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessments form the basis of interim regulatory decisions for carbofuran. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2005-0261 and may be accessed on the internet at http://www.regulations.gov.

A. Human Health Risk Assessment

1. Toxicity of Carbofuran

Table 1. Acute Toxicity of Carbofuran

Guideline No./ Study Type	Species	MRID No.	Results	Toxicity Category
870.1100 Acute oral toxicity	Rat	Gronning and Kimmerle, 1974	LD50 = 7.8 mg/kg _ 6.0 mg/kg _	I
870.1200 Acute dermal toxicity	Rabbit	44671601	LD50 = 4403 (2900 - 6685) mg/kg - intact skin	III
870.1300 Acute inhalation toxicity	Rat	Gronning and Kimmerle, 1974	LC_{50} = 0.08 mg/L	I
870.2400 Acute eye irritation	Rabbit	00070347	Minimal irritation	III
870.2500 Primary dermal irritation	Rabbit	00054336	Primary Irritation Score = 0.25	IV
870.2600 Skin sensitization	Guinea pig	44827101	Non sensitizer	N/A

Animal toxicity studies show that, as with other N-methyl carbamate pesticides, the critical effect of carbofuran for various exposure durations is cholinesterase inhibition. Similar to other N-methyl carbamate pesticides, inhibition is followed by rapid recovery of cholinesterase.

The toxicology database is considered to be adequate for selection of endpoints for risk assessment.

EPA considered a human oral study as part of its deliberations; however, due to serious scientific limitations, EPA has not included it in the carbofuran risk assessment that supports the reregistration decision outlined in this document. The results of the rat comparative ChE study are considered to be the most suitable for risk assessment purposes.

Developmental toxicity studies in both the rat and rabbit show no evidence of quantitative or qualitative increased susceptibility of the developing fetuses. There was evidence of qualitative increased susceptibility in the rat multi-generation reproduction study since offspring toxicity was manifested as decreased pup survival between birth and post natal day (PND) 4, whereas parental toxicity was limited to decreased body weight gain.

The rat developmental neurotoxicity study also provided evidence of a qualitative increase in offspring susceptibility. At the lowest observed adverse effects level (LOAEL) of 75 ppm, maternal toxicity was manifested as decreased body weight gain and food consumption, whereas offspring toxicity at this dose was manifested as increased mortality, decreased pup viability, and decreased fetal weight.

Carbofuran is primarily metabolized into three phenolic carbamate metabolites and into 3-hydroxy carbofuran. The trio of phenolic metabolites is not deemed to be of toxicological significance. For risk assessment purposes, 3-hydroxycarbofuran is considered to be of equal toxicity as parent carbofuran.

FQPA Safety Factor

The FQPA Safety Factor (as mandated by the Food Quality Protection Act of 1996) is intended to provide up to an additional 10-fold safety factor (10X), to account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure (food, water, and non-occupational) and toxicity to infants and children. In the case of carbofuran, there was no evidence of either quantitative or qualitative increased susceptibility of fetus/pups in the rat or rabbit developmental toxicity studies. There was evidence of qualitative increased susceptibility in the rat multi-generation reproduction study and the rat developmental neurotoxicity study. BMD (benchmark dose) analyses of the comparative ChE rat study revealed that the BMD values for the PND11 pups were lower (i.e., more sensitive) than those of adult rats. The Agency has retained a FQPA factor (for database uncertainties) in the derivation of the carbofuran acute PAD, which is based on brain ChE inhibition in rat pups. The magnitude of this factor is 5X. This

factor was based on the following rationale: the comparative ChE rat study measured only brain ChE inhibition, red blood cell (RBC) ChE inhibition in adult rats is the more sensitive endpoint; there is an observed 5-fold difference between brain ChE inhibition and RBC ChE inhibition in adult rats; and the assumption is made that for rat pups, there will be a similar 5-fold difference in RBC vs. brain ChE inhibition. See also the discussion below under "Endpoints selected for risk assessment."

Cancer Classification

Carbofuran does not appear to possess mutagenic activity and was negative in both rat and mouse oncogenicity assays. Carbofuran is classified as a "Not likely" human carcinogen based on the lack of evidence of carcinogenicity in mice or rats.

Endpoints selected for risk assessment

There are several studies available which measured acute ChE inhibition at or near the peak time of inhibition (15 to 45 minutes), and which the Agency was able to use to determine the derivation of the acute RfD and acute PAD. These include two studies performed by the registrant: 1) a time course study in which male and female rats were dosed at 0.5 and 1.0 mg/kg, and 2) a comparative ChE study where adult and juvenile (PND11) rats were dosed at 0.3, 0.6, and 1.0 mg/kg. A third ChE study was performed in support of the Agency's cumulative risk assessment for the N-methyl carbamates. In this study, scientists from the USEPA National Health and Environmental Effects Research Laboratory (NHEERL) performed dose-response studies in male rats, where brain and RBC ChE inhibition, along with motor activity, were measured. This study included doses of carbofuran ranging from 0.1 mg/kg to 1.5 mg/kg.

The risk assessment for carbofuran is based on BMD values, rather than No Observed Adverse Effect Level (NOAEL) or LOAEL values. The Agency used this method because NOAELs and LOAELs do not necessarily offer the best characterization between dose and response for a given chemical, and are often limited by dose selection. In order to evaluate the appropriate point of departure (PoD) for ChE inhibition, EPA performed a BMD analysis using the available comparative cholinesterase study in rats (the most sensitive species).

The dose at which 10% ChE inhibition is observed (BMD_{10}) and the lower 95% confidence intervals ($BMDL_{10}$) were estimated from the comparative cholinesterase study. The BMD_{10} was selected because it is generally at or near the limit of sensitivity for discerning a statistically significant decrease in ChE activity across the blood and brain compartments, and is a response level close to the background ChE. Moreover, the Agency believes that 10% is likely to be protective to other toxicities, such as clinical signs and/or behavioral endpoints.

The $BMDL_{10}$ of 0.03 mg/kg/day for inhibition of ChE in the brain of PND11 male pups was selected for derivation of the acute RfD. The following uncertainty factors were applied: 5X FQPA safety factor based on database uncertainties, 10X for variability

among individuals, and 10X for interspecies extrapolation. The resulting aPAD for the general population and all population subgroups is 0.00006 mg/kg/day.

The Agency's analysis of the brain ChE inhibition data from the comparative ChE study suggests that PND 11 pups are 2.5X more sensitive than adults (0.11 mg/kg and 0.12 mg/kg for male and female adult rats, respectively, as compared to 0.04 mg/kg and 0.05 mg/kg for male and female PND11 rats, respectively). In addition, the following uncertainties exist: 1) RBC ChE inhibition may be a more sensitive endpoint compared to brain ChE; 2) pups appear to be more sensitive than adult rats; and 3) due to the lack of reliable RBC data in pups, there is residual uncertainty in the available toxicology database. Given these uncertainties, the Agency has retained a 5X FQPA safety factor in the derivation of the carbofuran acute RfD. Due to the fact that the RfD is based on a $BMDL_{10}$ in rat pups, there is no need to account for the 2.5X sensitivity observed in pups vs. adults.

A chronic RfD was not selected because the acute RfD is considered protective of chronic exposures, given that carbofuran-induced inhibition of ChE activity is reversible (within 24 hours). The longer-term exposures could be considered a series of acute exposures.

Table 2. Toxicity Endpoints for Human Health Risk Assessment for Carbofuran

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary All Populations	$BMDL_{10}$ = 0.03 mg/kg/day UF = 500 Acute RfD = 0.00006 mg/kg/day	FQPA SF = 5X aPAD = 0.00006 mg/kg/day	Comparative ChE Study $BMDL_{10}$ = 0.03 mg/kg/day, based on cholinesterase inhibition in the brain of postnatal day 11 (PND11) male pups.
Short, Intermediate and Long-Term Dermal (Occupational)	$BMDL_{10}$ = 0.01 mg/kg/day UF=100 Dermal absorption rate (rat dermal study) = 6%	MOE $\geq$ 100 does not exceed level of concern	Special ChE Study (USEPA 2005) $BMDL_{10}$ = 0.01 mg/kg/day, based on RBC cholinesterase inhibition in adult rat
Short, Intermediate and Long-Term Inhalation (Occupational)	$BMDL_{10}$ = 0.01 mg/kg/day UF=100 Inhalation absorption rate = 100%	MOE $\geq$ 100 does not exceed level of concern	Special ChE Study (USEPA 2005) $BMDL_{10}$ = 0.01 mg/kg/day, based on RBC cholinesterase inhibition in adult rat
Cancer (oral, dermal, inhalation)	"Not likely"		Risk assessment not required

2. Dietary Exposure and Risk from Food and Water

A refined (Tier 3) acute probabilistic dietary risk assessment was conducted using DEEM-FCID™, Version 2.02, which incorporates consumption data from USDA's CSFII, 1994-1996 and 1998, as well as monitoring data from PDP and the FDA Surveillance Monitoring Program, estimated percent crop treated information, and processing/cooking factors, where applicable. EPA has determined that, because of the rapid reversibility of cholinesterase inhibition related to carbofuran, the acute dietary assessment would be protective of any chronic exposures in the diet. Therefore, a separate chronic dietary exposure assessment was not conducted. Exposure estimates are reported in milligrams per kilogram of body weight per day, and risk is expressed as a percent of the aPAD. Exposure estimates that are less than 100% of the PAD are below the EPA's level of concern.

Combined anticipated residues of carbofuran and 3-hydroxycarbofuran on food were included in the acute assessment. Acute anticipated residues for many foods (artichoke, cucumber, melons, milk, peppers, potatoes, pumpkin, squash, strawberry and sweet corn) were derived using USDA Pesticide Data Program (PDP) monitoring data from recent years (through 2003 for all commodities except milk, for which recently available 2004 data were used). For artichokes, PDP data for peppers were used as surrogate data. Anticipated residues for bananas and grapes were derived using monitoring data from the 2000 Carbamate Market Basket Survey. Most of the samples analyzed by the PDP and the Carbamate Market Basket Survey Task Force contained no detectable residues of carbofuran or its 3-hydroxy metabolite.

A value equal to ½ the combined limits of detection (LODs) of carbofuran and 3-hydroxycarbofuran was assumed for samples with non-detectable residues, with zeros incorporated to account for the percent of the crop not treated with carbofuran. For commodities with no monitoring data available (cranberries, coffee, sugar beets, sugarcane and sunflowers) and for field crops that are typically blended prior to marketing (barley, field corn, oats, rice, soybean, and wheat), anticipated residues were based on field trial data. Although PDP data are generally assumed to provide more refined estimates of exposure than field trial data, they may sometimes overestimate exposure, particularly for blended commodities, such as those listed above, with low percent crop treated estimates, no detections in the PDP data and relatively high ½ LOD values. Therefore, field trial data were used, with adjustments for percent crop treated, to provide more refined exposure estimates for these commodities. Exposure estimates are reported in milligrams per kilogram of body weight per day, and risk is expressed as a percent of the aPAD. Exposure estimates that are less than 100% of the aPAD are below the EPA's level of concern.

The estimated acute dietary (food only) exposure exceeds the Agency's level of concern for the U.S. population and all reported population subgroups at the 99.9th percentile of exposure. Carbofuran dietary exposure at the 99.9th percentile was estimated at 0.000154 mg/kg/day for the U.S. population **(260% of the aPAD)** and

0.000292 mg/kg/day **(490% of the aPAD)** for children 1-2 years old, the population subgroup with the highest estimated dietary exposure. See Table 3 below.

Table 3. Summary of Acute Dietary Exposure and Risk for Carbofuran for Food Alone (aPAD = 0.00006 mg/kg/day) at 99.9th Percentile of Exposure

Population Subgroup	Dietary Exposure (mg/kg/day)	% aPAD
General US Population	0.000154	260
Infants < 1 year	0.000182	300
Children 1-2 years old	0.000292	490
Children 3-5 years old	0.000290	480

Surface Water Estimated Drinking Water Concentrations

For surface water, estimated environmental drinking water concentrations (EDWCs) were calculated using the PRZM/EXAMS model. If appropriate, regional percent cropped area factors (PCA) were considered. EDWCs represent the range of concentrations that are expected to result from the annual use of carbofuran over a 30-year period at lowest and maximum application rates in different growing areas nationally, and vary over several orders of magnitude across use areas. Only acute values are presented here since the Agency did not assess chronic or cancer dietary risks for carbofuran. For an in-depth discussion of modeling and the range of values, please see the carbofuran drinking water assessment.

Table 4. Acute EDWCs (ppb) for Carbofuran on Selected Agricultural Crops. (Ranges of acute concentrations based on a distribution of default PCAs.)

Location/Crop	Using Lowest Label Rate[1]	Using Highest Label Rate[1]
Potato	0.25-3.1	1.6-20
CA Grape	0.4	4.3
Alfalfa	0.13-1.5	1.1-12
Alfalfa	0.11-1.2	0.86-10
ID Potato	--	10
Tobacco	8-17	12-26
Cotton	14-18	57-72
Corn	19-36	26-49
Sorghum	2.4-7.8	23-75

1. One-in-ten-year annual peak concentration

3-Hydroxycarbofuran has not been shown to form in the majority of environmental fate studies, with the exception of one study in which it was detected in low amounts as a result of soil photolysis. Therefore, 3-hydroxycarbofuran was not included in the Agency's human drinking water exposure assessment. While estimation of potential exposure to 3-hydroxycarbofuran remains an uncertainty in the human drinking water assessment, it is not expected to significantly add to exposure estimates (maximum concentrations in monitoring were approximately 6% of carbofuran concentrations).

Groundwater Estimated Drinking Water Concentrations

Estimation of carbofuran in groundwater was based on a study conducted by the registrant. Following detection of carbofuran in ground water in Long Island, NY, FMC voluntarily conducted a prospective groundwater (PGW) monitoring study during 1981-1983 near Salisbury, Maryland to assess impacts from the labeled use of carbofuran. Soils at the study site are sandy and promote leaching to groundwater. A corn plot had one application of Furadan 10G (totaling 3.0 lbs a.i./A; the labeled rate has since been reduced to 1 lbs a.i./A on corn for these soils).

Because this prospective ground water study was conducted over only one growing season, the reported ground water concentrations do not represent impacts from carbofuran use in multiple years. Thus, EPA used superpositioning techniques to provide estimates of concentrations following long-term (25 years) use of carbofuran at current label rates. These estimation techniques assumed chemical transformation processes and transport and interaction mechanisms are linear with respect to concentration. Based on these assumptions, the carbofuran concentrations in groundwater for various application rates were estimated (Table 5). EDWCs for ground water, estimated from PGW monitoring data, range from 1.4 ppb (low application to alfalfa) to 110 ppb (high application to grapes).

Table 5. Estimated 90-day Average Concentrations of Carbofuran in Shallow Groundwater for a Range of Application Rates

Crop	Application Rate (lbs a.i./A)	Groundwater EDWCs (ppb)
Alfalfa	0.125	1.4
Cotton	0.25	2.8
Corn	1.0	11
Corn	2.0	22
Tobacco	4.0	44
Grapes	10.0	110

Water Monitoring Data

Available groundwater monitoring studies conducted in the 1980s at locations associated with carbofuran uses report peak carbofuran concentrations ranging from 1.4-176 ppb. Several studies reported peak concentrations in the 50 ppb range resulting from application rates comparable to currently used application rates. Non-targeted monitoring tends to show detections at lower concentrations, rarely exceeding 1 ppb, although higher concentrations have been reported. Over the last decade, non-targeted ground water monitoring reports indicate fewer locations with detections. Consistent with its environmental fate properties, carbofuran has been detected more frequently and at higher concentrations in acidic environments. The most vulnerable drinking water sites appear to be shallow private wells near carbofuran use areas, where the ground water has a lower pH.

Only non-targeted monitoring data are available for surface water; consequently, detections cannot be directly associated with specific use sites or locations that are most vulnerable to contamination. Few detections exceeding 1 ppb have been found since the mid-1990s.

Detectable residues of carbofuran (no 3-hydroxycarbofuran found) were found in 14 out of 1418 PDP water samples (data from 2001-2003). Carbofuran residues ranged from 0.001 ppb to 0.079 ppb. These data were not deemed appropriate for use in risk assessment as the data may not be reflective of areas with significant carbofuran use and the community water systems sampled by PDP are generally deep ground water or surface water systems and do not include private wells. Since the highest carbofuran concentrations are likely to occur in shallow, private wells in areas where carbofuran is used, use of the PDP data would not be protective of people whose drinking water comes from such wells.

The Agency evaluated data from state, USGS and registrant monitoring programs. The EPA Office of Water collected monitoring data for compliance with the Safe Drinking Water Act and in a 2002 report described levels of carbofuran found in 16 states in finished drinking water. No system exceeded the carbofuran MCL of 40 ppb; however, several systems exceeded concentrations of 7 and 4 ppb. Because these data were collected for compliance purposes (i.e., not to determine acute exposures) they are not included directly into the risk calculations. Some forms of drinking water treatment such as softening may reduce concentrations of carbofuran in finished water, but other water treatment methods do not affect concentrations.

3. Residential and Other Non-occupational Risk

Carbofuran is a restricted use pesticide and is not registered for residential or other non-occupational uses. Therefore, no residential exposure and risk assessment was conducted for carbofuran.

4. Aggregate Exposure and Risk

The Food Quality Protection Act (FQPA) amendments to the Federal Food, Drug and Cosmetic Act (FFDCA, Section 408(b)(2)(A) (iii) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures for which there is reliable information." Aggregate exposure will typically include dietary exposures (food plus drinking water), residential uses of a pesticide, and other non-occupational sources of exposure.

There are no residential uses of carbofuran. Therefore, when evaluating aggregate exposures, only the dietary pathways of food and drinking water would be relevant.

Acute dietary exposure and risk from food alone exceeds the Agency's level of concern (i.e., >100% aPAD). For the most highly exposed subpopulation (children 1-2 years old), the acute dietary (food only) risk estimate is 490% of the aPAD. For the general U.S. population, the acute dietary (food only) risk estimate is 260% of the aPAD.

Using the PRZM/EXAMS model, the acute EDWCs in surface water range from 0.11 ppb (low application rate to alfalfa) to 75 ppb (maximum label application rate to sorghum) for nine crop location scenarios. EDWCs for ground water, based on prospective ground water monitoring data, range from 1.4 ppb (low application to alfalfa) to 110 ppb (maximum application to grapes).

If one assumes that there are no acute dietary food exposures to carbofuran and all of the allowable exposure occurred through water sources (i.e., assuming the aPAD of 0.00006 mg/kg/day is completely allocated to exposure to residues in water), the drinking water level of concern (DWLOC) would be 2.1 ppb for the general U.S. population and 0.6 ppb for infants and children. These values are based on daily water consumption estimates of two liters for adults and one liter for infants and children. DWLOCs based on consumption of a single 8 ounce serving of water would be 2.6 ppb for infants and children and 18 ppb for adults. Therefore, even if all of the allowable dietary exposure (i.e., the entire aPAD or "risk cup") occurred through a single serving of drinking water, the Agency would have concerns for acute exposure to carbofuran, particularly for individuals (both adults and children) who may derive their water from vulnerable watersheds that are highly cropped and where carbofuran applications may be made up to the maximum label rates. Exposure to individuals (adults) whose drinking water comes from sources where crop/location scenarios result in lower EDWCs (scenarios with lower applications) may not be of concern if the entire risk cup were available for water exposures.

5. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk is measured by a Margin of Exposure (MOE), which describes how close the occupational exposure comes to a point of departure (e.g., BMD or NOAEL). The target MOE for carbofuran is 100, meaning that MOEs that fall below 100 indicate a possible need for mitigation.

Occupational handler scenarios were assessed using the short-term endpoint for dermal and inhalation exposures. The short-term dermal and inhalation endpoint is a $BMDL_{10}$ of 0.01 mg/kg/day, based on red blood cell ChE inhibition in adult male rats. Additionally, a dermal absorption factor of 6% has been used, based on a 24-hour exposure duration from a dermal penetration study. The UF for both dermal and inhalation endpoints is 100 (10X for intraspecies variability and 10X for interspecies extrapolation). Dermal and inhalation exposures were combined to assess handler risk.

Occupational handler risk estimates have been assessed for short-term exposures. Intermediate-term and long-term exposures were not assessed, as ChE inhibition does not

increase with continued exposure to carbofuran and because of the rapid reversibility of ChE inhibition.

No chemical-specific data for assessing human exposures during pesticide handling activities were submitted, so short-term dermal and inhalation exposures for handlers were developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1.

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle carbofuran during the usual use patterns associated with the pesticide. Thirteen major occupational exposure scenarios were identified based on the type of equipment that potentially can be used to make carbofuran applications. These scenarios are listed in Table 6 below.

The calculations of short-term total risks indicate that most occupational handler risks are above the Agency's level of concern (i.e., MOEs less than 100), even at the maximum mitigation level (engineering controls) for all handler scenarios except mixing/loading granulars for tractor-drawn spreader application (cucurbits, spinach) and flagging for spray application (corn, sugarcane). Additionally, total MOEs for mixing/loading/applying liquids for application to any crop via backpack sprayer were greater than 100 with baseline protection. Total MOEs for mixing/loading/applying liquids for low-pressure handwand application were greater than 100 with PPE2 protection (single layer protection, gloves, and PF5 respirator). Table 6 below shows MOEs for the remaining handler scenarios, which do not reach 100, even with engineering controls.

Table 6. Summary of Handler Scenarios Total (Dermal and Inhalation) MOEs with Engineering Controls (i.e., Maximum MOEs)

Exposure Scenario	Crop	Application Rate (lbs a.i./A)	Daily Area Treated (Acres/day)	Total MOE
MIXER/LOADER				
Mixing/Loading Liquids for Aerial application	Alfalfa, Corn (field and pop), Cotton	1 lb	1200	0.96
	Potatoes	2 lb	350	1.7
	Sorghum	0.50	1200	2.0
	Small grains (wheat, barley, oat), Soybeans	0.25	1200	3.9
	Ag Fallow/Idle land	0.19	350	18
	Corn (sweet), Sunflowers	0.50	350	6.8
	Sugarcane	0.75	350	4.4
Mixing/Loading Liquids for Chemigation application	Grapes	6	350	0.56
Mixing/Loading Liquids for Groundboom application	Grapes	10	80	1.5
	Ornamentals	10	40	2.9
	Coffee (seedbeds)	6.90	80	2.1
	Tobacco	6	80	2.4

Exposure Scenario	Crop	Application Rate (lbs a.i./A)	Daily Area Treated (Acres/day)	Total MOE
	Peppers	3	80	4.8
	Sugar Beets	2	200	3.0
	Sunflowers	1.40	80	10
	Alfalfa, Corn (field and pop), Cotton	1	200	6.0
	Potatoes	3	80	4.8
	Sugarcane	0.75	80	20
	Sorghum	0.50	200	12
	Corn (sweet)	1	80	15
	Artichoke	1	80	15
	Small grains (wheat, barley, oat), Soybeans	0.25	200	23
APPLICATOR				
Aerial application	Alfalfa, Corn (field and pop), Cotton	1	1200	1.6
	Potatoes	2	350	2.7
	Sorghum	0.50	1200	3.2
	Small grains (wheat, barley, oat), Soybeans	0.25	1200	6.4
	Corn (sweet), Sunflowers	0.50	350	11
	Ag Fallow/Idle land	0.19	350	29
	Sugarcane	0.75	350	7.2
Groundboom application	Grapes	10	80	2.6
	Ornamentals	10	40	5.2
	Coffee (seed beds)	6.90	80	3.2
	Tobacco	6	80	4.4
	Peppers	3	80	8.4
	Sugar Beets	2	200	5.2
	Sunflowers	1.40	80	18
	Alfalfa, Corn (field and pop), Cotton	1	200	10
	Potatoes	3	80	8.4
	Sugarcane	0.75	80	34
	Sorghum	0.50	200	20
	Corn (sweet)	1	80	26
	Small grains (wheat, barley, oat), Soybeans	0.25	200	40
	Artichoke	1	80	26
Applying Granulars for Tractor-drawn Spreaders application	Cucurbits, spinach	0.50	80	52
FLAGGER				
Flagging for Spray application	Potatoes	2	350	48
	Sorghum	2	1200	14
	Small grains (wheat, barley, oat), Soybeans	2	1200	14

The Agency did not assess risks to workers mixing, loading or applying flowable carbofuran to pine seedlings as a slurry dip because there are no appropriate exposure data to evaluate the risks at this time. In the absence of appropriate data, the exposure for dipping pine seedlings is considered to be less than or similar to exposures from handwand applications to ornamentals with regards to amount of product which could be handled. Total MOEs for mixing/loading/applying liquids for low-pressure handwand application were greater than 100 with single layer clothing, gloves, and a PF5 respirator. As a conservative measure, this level of protective clothing will be required for flowable carbofuran use on pine seedlings.

Postapplication Occupational Risk

For workers entering a treated site, restricted entry intervals (REIs) are calculated to determine the minimum length of time required before workers can safely reenter (i.e., MOEs ≥ 100). Many of the registered uses of carbofuran involve applications to the soil only and do not result in treatment of plant foliage. Therefore, these scenarios were not included in the postapplication risk assessment. However, multiple applications of sprays to foliage may occur for a number of crops. EPA expects harvesting for all these particular crops to be fully mechanized.

For those crops for which postapplication exposures are expected to occur, exposure was estimated using dislodgeable foliar residue (DFR) data for carbofuran applied to corn, cotton, and potatoes. MOEs failed to reach 100 within the currently prescribed REIs for most of these crops.

Short-term exposures may occur for several crops requiring reentry by crop advisors. Such exposures also may occur for field workers involved in irrigation activities, early season hoeing and thinning, and de-tasseling corn grown for seed.

A 14-day restricted entry interval is specified on current carbofuran labeling for foliar application to corn, sunflowers, and sorghum. A 48-hour REI is specified on product labels for all other crops, based on the acute toxicity of carbofuran (per EPA's Worker Protection Standard).

Most crops with postapplication activities failed to reach MOEs of 100 within the currently prescribed REIs. Only sunflower and sorghum had postapplication MOEs of 100 within the label REI of 14 days.

Table 7. Crop Groupings, Selected Transfer Coefficients, Treated Crops, Rates, Proposed REIs, Current REIs

Transfer Coefficient Group	Crop	Max Foliar Rate (lb ai/acre)	DFR Data Used	Transfer Coefficient (cm2/hr)			# of days until MOE reaches 100		
				Low	Med	High	Low	Med	High
Field/row crops, Low/medium	Soybeans	0.25	Cotton	100	1500		6	12	
	Small Grains	0.25	Cotton	100	1500		6	12	
	Alfalfa	1	Potatoes	100	1500		4	>14*	
	Sugar Beets	2	Potatoes	100	1500		8	>14*	
Field/row crops, Tall	Corn (field and pop)	1	Corn (MN site)	100	1000		7	10	
			Corn (CA site)	100	1000		25	>32*	
	Corn (sweet)	0.5	Corn (MN site)	100	1000	17000	2	10	>11*
			Corn (CA site)	100	1000	17000	18	32	>32*
	Sunflowers	0.5	Potatoes	100	1000		0	13	
	Sorghum	0.5	Potatoes	100	1000		0	13	
Sugarcane	Sugarcane	0.75	Potatoes	100	1000	2000	2	>14*	
Vegetable, root	Potatoes	1	Potatoes	300	1500		4	>14*	

* Studies ended at the number of days indicated, and MOEs still had not reached 100.

Drench applications made to container grown nursery stock may result in dermal exposure to workers performing postapplication reentry tasks and for workers handling treated soil while moving containers. However, the Agency has no exposure data to estimate these exposures.

6. Smoker Assessment

A short-term inhalation risk assessment for adult smokers has been completed, since carbofuran is registered for use on tobacco. Based on the short-term inhalation BMDL10 of 0.01 mg/kg/day (based on red blood cell ChE inhibition in adult male rats), the short-term MOE for carbofuran exposure from the use of tobacco is 12. This conservative risk estimate is above HED's level of concern for inhalation exposure to carbofuran.

7. Human Incident Data

For a review of the pesticide poisoning incident data for carbofuran, EPA consulted the following data bases: (1) OPP Incident Data System (IDS); (2) Poison Control Centers (PCC); (3) California Department of Pesticide Regulation; (4) National Pesticide Telecommunications Network (NPTN), and (5) National Institute of Occupational Safety and Health's Sentinel Even Notification System for Occupational Risks (NIOSH SENSOR). In all, more than 700 possible carbofuran poisoning incidents were reported.

In the IDS, from 1996 through 2003, there have been 42 reported incidents from carbofuran exposure. Common among these reports is evidence that carbofuran is a

prevalent cause of eye problems, which was reported in about one quarter of all the cases. Although data were often limited, most cases involved failure to wear proper protective equipment, or they occurred when workers were cleaning or repairing spray equipment.

PCC results for the years 1993 through 2001 for occupational and non-occupational incidents involving adults and older children and for children under age six were compared between carbofuran and all other reported pesticides. The PCC data indicate that carbofuran exposure is likely to result in more serious medical outcomes and serious medical care than exposure to other pesticides. Most of the reported symptoms for carbofuran incidents were specific to cholinergic poisoning and most resulted from dermal and inhalation exposure, rather than oral exposure. While approximately four percent of the non-occupational incidents could be attributed to misuse, or misreading of the label, it was not possible to determine what percentage of occupational incidents were attributable to misuse.

On the list of the top 200 chemicals for which NPTN received calls from 1984 to 1991 inclusively, carbofuran was ranked 37th, with 103 incidents in humans reported.

In the NIOSH/SENSOR data (surveillance in seven states) there were 19 reports due to carbofuran alone, out of 4,221 reports.

A 1997 EPA incident review stated that, overall, carbofuran was judged second among 28 pesticides on measures of hazard derived from California and PCC data. Most of the risk from this pesticide is due to use by pesticide handlers, especially mixer/loaders who handle the concentrated material. Less often, groups of people have been poisoned from spray drift of from exposure to field residue. A 1998 case in California illustrates the effects from field residues when workers reentered treated cotton fields within two hours, instead of the required 48 hours, after application. Such residues are capable of causing moderate to relatively serious effects which require medical treatment.

Detailed descriptions of incidents reported to the California Pesticide Illness Surveillance Program from 1982 through 2002 identified a total of 88 cases in which carbofuran was either used alone or in combination with other chemicals, but was judged to be responsible for the reported health effects. The majority of illnesses were of a systemic type. The majority of incidents occur among handlers who mix, load, and apply carbofuran in agricultural fields.

The number and rate of poisoning cases due to carbofuran exposure is sufficient to warrant priority attention to risk reduction measures for this pesticide.

B. Environmental Risk Assessment

The ecological risk assessment for carbofuran primarily focused on the liquid (flowable) formulation because it makes up the greatest portion (≥ 99%) of carbofuran's uses. However, since some granular product uses remain, a summary of the associated

ecological risk of these uses is presented separately in the ecological risk assessment (see section 4.0 of Appendix 1 of the ecological risk assessment).

Terrestrial and aquatic plants were not a part of this risk assessment. Since the mode of action of carbofuran is cholinesterase inhibition and both terrestrial and aquatic plant studies show no phytotoxic effects, the Agency does not have concerns for plants as a result of use of carbofuran.

Three lines of evidence were examined to evaluate the risk of the use of flowable carbofuran products to non-target animal species. They include a screening level risk assessment (deterministic), a refined assessment (probabilistic) for aquatic risks and acute risks to birds, and the consideration of field data for carbofuran.

First, standard screening level quotient models were used for estimating the acute and chronic risk to non-target aquatic and terrestrial organisms associated with the major uses of flowable carbofuran. This screening level ecological risk assessment compared toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of carbofuran products, the Agency calculated risk quotients (RQ), which are the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD50) for terrestrial organisms or the median lethal concentration (LC_{50}) for aquatic organisms. These RQ values are then compared to the Agency's levels of concern (LOCs), given in Table 8, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects on non-target organisms. When the RQ exceeds the LOC for a particular category, (e.g., endangered species), the Agency presumes a risk of concern to that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the relative degree of uncertainty in the assessment.

Table 8. EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	**LOC terrestrial animals**	**LOC aquatic animals**
Acute Risk - there is potential for acute risk	0.5	0.5
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05
Chronic Risk - there is potential for chronic risk	1	1

Secondly, to help understand the ecological risk estimates derived from the screening level (deterministic) assessment, probabilistic methods were employed to provide more refined risk estimates that move away from the protective assumptions of the quotient model by using less conservative exposure scenarios and biological information on wildlife species likely to be associated with carbofuran use. The refined probabilistic assessment models estimate the magnitude and probability of acute effects

to non-target species occurring from pesticides by integrating distributions of carbofuran exposure with distributions of toxicity. The refined risk assessment addresses bird mortality (acute), as well as survival and reproductive (chronic) effects to fish and aquatic invertebrates following application of carbofuran. The probabilistic models and methods were subjected to external peer review by the FIFRA Science Advisory Panel.

Lastly, available field data, including field studies, monitoring programs, and well-documented wildlife kill incident reports attributed to the normal agricultural use of flowable carbofuran were examined.

All three lines of evidence support the conclusion that there are risk concerns to both aquatic and terrestrial species from acute and chronic exposure following the use of flowable carbofuran: risk concerns are particularly high for avian species.

For a more detailed explanation of the ecological risks posed by the use of carbofuran, refer to "Revised Ecological Carbofuran RED Chapter," dated March 8, 2006.

1. Environmental Fate and Transport

Carbofuran is highly mobile in soils and can therefore leach into groundwater and enter surface water as runoff. Carbofuran breaks down into several degradates though hydrolysis, photodegradation and moderate bacterial degradation at rates that depend on environmental conditions. Hydrolysis is faster in water with a pH $\geq$ 7 (basic conditions), with a half-life ranging from a few hours to 28 days. Carbofuran is stable to hydrolysis in acidic water. Photodegradation is fast in a thin water layer, with a half-life of 6 days. In the top few millimeters of a sandy loam soil, carbofuran degrades in 78 days.
There is low potential for bioconcentration of carbofuran and its metabolites/degradates.

2. Ecological Risk Estimation

a. Terrestrial Organisms

In its screening level (deterministic) assessment, the Agency assessed exposure to terrestrial organisms by first predicting the amount of carbofuran residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items is based on the Fletcher nomogram and the current maximum and minimum application rates, maximum numbers of applications, and potential for residue dissipation between applications. The Fletcher nomogram is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994).

i) Birds

Carbofuran is characterized as "very highly toxic" to birds on an acute oral basis and "highly toxic" on a sub-acute basis. Chronic toxicity testing in birds showed dose-

related parental mortality at all test concentrations, so a NOAEL and LOAEL could not be established. A LOAEL of <2.0 mg/kg-diet was chosen as the toxicological risk assessment for chronic risk assessment, since 2.0 mg/kg-diet was the lowest dose tested.

Table 9. Summary of Avian Toxicity Data Used for Risk Assessment

Test Type	Species (Citation)	Endpoint	Toxicity Category	Affected Endpoints
Avian acute effects (oral)	Fulvous whistling duck (*Dendrocygna bicolor*) (Hudson *et al*., 1984)	LD_{50} = 0.238 mg/kg	Very highly toxic	NA
Avian chronic effects (reproduction)	Mallard duck (*Anal platyrhynchos*) (Roberts *et al*./1982b)	NOAEC: not determined LOAEC = 2 ppm	NA	Dose-related parental mortality at all test concentrations

Acute RQs exceed the LOC for all uses of flowable and granular carbofuran. Table 10 presents the RQs for flowable carbofuran as they relate to the minimum and maximum use rates on various crops. The lower end of the range represents RQ values associated with large birds whose body weight is equivalent to 1,000 g, while the higher end of the RQ range is associated with small birds of 20 g. For RQs calculated for use of granular carbofuran, see the Granular Carbofuran Risk Assessment.

Table 10. Avian (Herbivore) Acute RQs for Flowable Carbofuran Based on Filvous Whistling Duck LD_{50} of 0.238 mg/kg (Level of Concern = 0.5)

Crop	RQ Values at Minimum Application Rates		RQ Values at Maximum Application Rates	
	Large Birds	Small Birds	Large Birds	Small Birds
Alfalfa	17	144	134	1,150
Corn (all)	67	575	804	6,898
Cotton	28	241	63	538
Grapes	201	1,724	268	2,299
Potatoes	67	575	157	1,345
Small grains (wheat, oats, barley)	17	144	63	538
Sorghum	20	5,633	27	6,553
Soybeans	17	144	63	538
Sugarcane	67	575	188	1,613
Sunflowers	17	241	125	1,075
Tobacco	80	690	121	1,035

The chronic risk LOC is also exceeded for all avian species in all application scenarios. All scenarios compared four different feeding groups: short grass, tall grass, broadleaf plants/insects and seeds. The lower RQ values are associated with granivores (seedeaters) and the higher values are associated with herbivores (short grass eaters). The NOAEC was <2.0 mg/kg; the Lowest Observed Adverse Effect Concentration (LOAEC) was 2.0 mg/kg; and at all other concentrations tested, the test birds died.

Table 11. Avian Chronic RQs for Flowable Carbofuran Based on a Mallard NOAEC of <2.0 mg/kg (Level of Concern = 1.0)

Crop	RQ Values at Minimum Application Rates		RQ Values at Maximum Application Rates	
	Granivores (Seed)	Herbivores (Short Grass)	Granivores (Seed)	Herbivores (Short Grass)
Alfalfa	1	15	8	120
Corn (all)	4	90	2	720
Cotton	1	30	2	56
Grapes	15	135	11	473
Potatoes	4	60	4	224
Small grains (wheat, oats, barley)	1	15	4	56
Sorghum	1	30	7	690
Soybeans	1	15	4	56
Sugarcane	4	60	11	168
Sunflowers	1	50	2	112
Tobacco	5	72	5	108

The refined probabilistic assessment (second line of evidence), which assessed acute avian risk associated with use on corn and alfalfa only, predicted high mortality in at least some species, regardless of the application rate and method. The analysis took into consideration both foliar and soil applications at use rates that span the majority of application rates for which carbofuran is registered (0.125 to 1.0 lbs a.i./A). Based on the sensitivity distribution, the more sensitive the species, the higher the mortality predicted from exposure. It is possible that crops with a higher application rate of carbofuran would result in greater avian morality. Results of the refined assessment show that from 55 to 95% of the bird species modeled will experience at least some mortality as a result of the application of flowable carbofuran. At the highest application rate, if exposed, 62% of bird species will experience 10 % mortality on average, and 23% of bird species will have 70% mortality or greater, with a predicted maximum mortality rate of 93%.

ii) Mammals

Carbofuran is considered to be highly toxic to mammals on an acute basis. Chronic toxicity testing on laboratory rats showed reduced offspring survival and body weight reductions.

Table 12. Summary of Mammalian Toxicity Data for Terrestrial Animals Exposed to Dimethoate

Test Type	Species (Citation)	Endpoint	Toxicity Category	Affected Endpoints
Mammalian acute effects (oral)	Laboratory mouse (*Mus musculus*) (Fahmy *et al*. 1970)	LD_{50} = 2.0 mg/kg (males)	Very highly toxic	NA
Mammalian chronic effects (3-generation reproduction)	Laboratory rat (*Rattus morvegicus*) (Goldenthal and Rapp/1979, MRIDs 00030514, 00030570, and 00079810)	NOAEC = 20 ppm LOAEL = 100 ppm	NA	Decreased pup survival and pup body weight decrease

A refined assessment was not conducted for mammalian species. Few studies exist on wild mammalian species; therefore, the laboratory mouse LD_{50} of 2.0 mg/kg/day was used to calculate RQs. The deterministic assessment showed that the acute and chronic LOCs are exceeded for herbivorous, insectivorous, and granivorous mammals. RQs at the lower end of the range are associated with 1,000 g mammals, while the high end of the range is associated with 15 g mammals.

Table 13. Acute RQs for all Mammal Groups LD_{50} 2.0 mg/kg/day

Crop	Herbivores and Insectivores		Granivores	
	Large Mammal	Small Mammal	Large Mammal	Small Mammal
Alfalfa	8	114	0.2	2
Corn	50	684	1	9
Potatoes	15	213	0.4	3
Sorghum	47	650	1	9
Cotton	4	53	0.1	1

LOC = 0.5

The chronic mammal LOC is exceeded for most uses. The lower RQ value is associated with seedeaters (granivores) and the higher RQ is associated with short grass eaters (herbivores). This is usually the case because short grass contains the highest pesticide residues.

Table 14. Mammalian Chronic RQs for Applications LD_{50} 2.0 mg/kg/day

Crop	Herbivores and Insectivores		Granivores	
	Large Mammal	Small Mammal	Large Mammal	Small Mammal
Alfalfa	0.1	2	0.8	12
Corn	0.2	3	5	72
Cotton	0.2	3	0.3	6
Grapes	1	13	5	47
Potatoes	0.4	6	1	22
Sorghum	0.1	2	4	69

LOC = 1.0

iii) Non-target insects

Carbofuran is characterized as highly toxic to honey bees, based on a honey bee acute contact study (LD_{50} = 0.16 µg/bee).

Terrestrial Field Data and Incidents

The field studies and incident data available for flowable carbofuran (third line of evidence) support the conclusions of the deterministic and probabilistic risk assessments; that is, acute risk from the use of flowable carbofuran to non-target terrestrial species is high.

The majority of controlled field studies conducted by the registrant support the deterministic and probabilistic models. These studies demonstrated that bird mortality occurs at typical to low-end application rates. Of the five studies submitted to the Agency, four had study designs that were adequate to meet the Agency guideline

requirement for detecting significant mortality events. In the acceptably designed studies, bird mortality in and around treated fields relative to untreated fields was great enough to reasonably conclude that carbofuran treatment-related mortality was the cause of death.

From 1972 to 2000, 31 bird kill incidents have been reported following the use of flowable carbofuran on five of the major crops where it is registered, and these are almost exclusively bird kills as a result of direct exposure. A majority (27) of the kills were reported following carbofuran use on corn and alfalfa, the two major crops where carbofuran is used. Thirty-seven species with a total of 7,300 carcasses were reported found in twelve different states, with both primary and secondary poisonings suspected.

In the late 1990s, the technical registrant made a number of label changes in order to reduce drinking water and ecological risks of concern. These included reducing application rates and numbers of applications for alfalfa, cotton, corn, potatoes, soybeans, sugarcane, and sunflowers. EPA therefore evaluated incidents that have occurred since 1998. Since 1998, there have been 47 carbofuran incidents reported in EPA's Ecological Incident Information System (EIIS). Four of these incidents were from registered uses:

1) 1998 in PA, use on corn (flowable), 2 grackles
2) 1998 in PA, use on corn (flowable), 12 grackles
3) 2000 in NM, use on alfalfa (flowable), 800-1200 snow geese and ducks, and
4) 2000 in CA, use on alfalfa (flowable), 4 bee hives.

The remaining incidents were from intentional misuse (28) or the legality of use was undetermined (14). Of the 47 incidents, 13 were attributed to flowable carbofuran, two were attributed to granular carbofuran, and for the remaining incidents (32) the formulation was not reported.

Additionally, three incidents since 2000 (two in 2000 and one in 2004) were reported aggregately by the registrant, and are not in the EIIS. Details are not available on these incidents.

b. Aquatic Organisms

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in groundwater. Surface water models are used to estimate exposure to freshwater aquatic animals, since monitoring data are generally not from studies targeted on small water bodies and primary streams within agroecosystems where the pesticide is used and where many aquatic animals are found. The modeling results used in risk calculations for carbofuran are detailed in "Revised Ecological Carbofuran RED Chapter," dated March 8, 2006.

Carbofuran concentrations in surface water bodies were estimated using PRZM and EXAMS and several crop/location scenarios and application rates which were chosen to ensure that: (1) the greatest acreage treated with flowable carbofuran was assessed; (2)

application rates covered all label use rates; and (3) PRZM/EXAMS scenario site vulnerability was at the high-end for the crop and carbofuran use combination. These crop scenarios are outlined in Table 15 below.

Table 15. Estimated Environmental Concentrations (µg ai/L)* of Carbofuran in Surface Water for Selected Use Patterns

Crop/Location	Using Minimum Rate			Using Maximum Rate		
	Acute	21-day Avg	60-day Avg	Acute	21-day Avg	60-day Avg
Alfalfa, California	0.7	0.6	0.4	5.2	4.5	3.0
Alfalfa, Pennsylvania	0.7	0.6	0.4	5.7	4.6	3.0
Corn, Illinois	17	14	9.4	25	20	17
Cotton, Mississippi	10	7.9	5.5	11	8.2	5.7
Grape, California	0.31	0.24	0.15	7.0	5.4	3.5
Potato, Maine	3.6	2.9	2.0	26	21	14
Potato, Idaho	4.5	3.4	2.2	6.7	5.1	3.3
Sorghum, Texas	36	27	18	36	27	19
Tobacco, North Carolina	--	--	--	10	7.7	5.0

* EEC values represent the 1-in-10 year maximum concentration for the designated time interval.

i) Freshwater and Estuarine/Marine Fish

Carbofuran is very highly toxic to freshwater and estuarine/marine fish on an acute basis. Chronic toxicity testing with freshwater fish revealed larval survival as the most sensitive endpoint (NOAEC = 24.8 ppb a.i., LOAEC = 56.7 ppb a.i.). The available chronic test showed estuarine/marine fish were more sensitive than fresh water fish with embryo hatching as the most sensitive endpoint (NOAEC = 2.6 ppb a.i., LOAEC = 6.0 ppb a.i.). Table 16 summarizes the data that support the toxicity endpoints used in assessing the risks to fish.

Table 16. Summary of Measurement Endpoint Values Used to Calculate Screening Level RQs for Fish

Assessment Endpoint	Test Species (Citation)	Endpoint	Toxicity Category	Affected Endpoints
Freshwater fish acute effects	Bluegill sunfish (*Lepomis macrochirus*) (MRID 400980-01)	LC_{50} = 88	Very highly toxic	NA
Freshwater fish chronic effects	Rainbow trout (*Oncorhynchus mykiss*) (Acc. GEOCAR08)	NOAEC = 5.7 ppb a.i.	NC[a]	Larval survival, scoliosis
Estuarine/marine fish acute effects	Atlantic silverside (*Menidia menidia*) (Acc. 260899)	LC_{50} = 33	Very highly toxic	NA
Estuarine/marine fish chronic effects	Sheepshead minnow (*Cyprindodon varigatus*) (MRID 432505-01)	NOAEC = 2.6 ppb a.i.	NC[a]	Embryo hatching

[a] Not characterized

According to the deterministic assessment, carbofuran is not expected to reach surface water concentrations high enough to exceed the acute risk LOC for any crop

application for freshwater fish. The chronic risk LOC is exceeded; however, for use on corn, sorghum, and potatoes. For estuarine/marine fish, there were acute and chronic LOC exceedences resulting from all uses.

Table 17. Acute and Chronic RQ Ranges for Fish at Maximum and Minimum Application Rates

Crop	Freshwater		Estuarine/Marine	
	Acute	Chronic	Acute	Chronic
Alfalfa	0.01-0.06	0.07-0.53	0.02-0.17	0.15-1.2
Corn	0.19-0.28	1.6-3.0	0.52-0.76	3.6-6.5
Cotton	0.11-0.13	0.96-1.0	0.3-0.33	2.1-2.2
Grapes	0.01-0.08	0.03-0.61	0.01-2.1	0.06-1.3
Potatoes	0.04-0.3	0.35-2.5	0.11-0.79	0.77-5.4
Sorghum	0.41	3.2-3.3	1.1	6.9-7.3
Tobacco	0.11	0.88	0.3	1.9

Results of the refined probabilistic assessment show that for all uses of carbofuran modeled for surface water, at least 95% of exposed freshwater fish species will experience less than 0.5% mortality for any given use. Reproductive effect levels for the most sensitive freshwater species, bluegill sunfish, are exceeded in at least 4% (approximately 1 out of 25 years) of application years for all crops and up to 89% of application years (approximately 9 out of 10 years) for use on corn.

For exposed Atlantic silverside fish (estuarine), use on corn and sorghum is estimated in modeled surface waters to, on average, result in greater than 18% mortality. However, for the other crop uses modeled, the results indicated no demonstrable mortality (<1 case of mortality in a million) for the minimum application rate on cotton to 9% mortality for the maximum application to potatoes.

ii) Freshwater and Estuarine/Marine Invertebrates

Carbofuran is considered to be very highly toxic to freshwater and estuarine/marine invertebrates on an acute basis. Table 18 summarizes the data that support the toxicity endpoints used in assessing the risks to invertebrates.

Table 18. Summary of Measurement Endpoint Values Used to Calculate Screening Level RQs for Aquatic Invertebrates

Study Type	Test Species (Citation)	Endpoint	Toxicity Category	Affected Endpoints
Freshwater invertebrate acute effects	Water flea (Ceriodaphnia dubia) (Bailey et al., 1996)	EC_{50} = 2.23	Very highly toxic	Mortality
Freshwater invertebrate chronic effects	(*Daphnia magna* and *Ceriodaphnia dubia*) (Acc. 262093, GEOCAR10)	ENEC 0.75	Not classified	Reproduction

Study Type	Test Species (Citation)	Endpoint	Toxicity Category	Affected Endpoints
Estuarine/marine invertebrate acute effects	Pink shrimp (*Penaeus duorarum*) (MRID 40228401)	LC_{50} = 4.6	Very highly toxic	Mortality
Estuarine/marine invertebrate chronic effects	Mysid shrimp (*Americanysis bahia*) (MRID 40536001)	NOAEC = 0.4	Not classified	Reproduction

ENEC = Estimated No Effect Concentration

According to the deterministic assessment, carbofuran is not expected to reach surface water concentrations high enough to exceed the acute risk LOC or chronic risk LOC for freshwater invertebrates at minimum label rates for alfalfa and grapes. All other uses exceed the acute and chronic risk LOCs. For estuarine/marine invertebrates, the acute LOC was exceeded for saltwater fish for corn, potatoes, and sorghum uses, with the chronic LOC exceeded for all uses except at minimum application rates to alfalfa and grapes.

Table 19. Acute and Chronic RQ Ranges for Invertebrates at Maximum and Minimum Application Rates

Crop	Freshwater		Estuarine/Marine	
	Acute	Chronic	Acute	Chronic
Alfalfa	0.31-2.6	0.8-6.1	0.15-1.2	1.5-12
Corn	7.6-11	19-27	3.7-5.4	35-50
Cotton	4.5-4.9	11	2.2-2.4	20-21
Grapes	0.14-3.1	0.32-7.2	0.07-1.5	0.6-14
Potatoes	1.6-12	3.9-28	0.78-5.7	7.2-53
Sorghum	16	36	7.8	68
Tobacco	4.5	11	2.2	19

In the refined probabilistic assessment, for modeled surface water, on average at least 5% of exposed freshwater invertebrate species were estimated to experience greater than 80% mortality and 25% of exposed freshwater species were estimated to have up to 28% mortality for most uses of carbofuran, except for the Idaho and Washington Special Local Need (SLN) labeled rate on potatoes. Reproductive effect levels for *C. dubia*, the most sensitive freshwater invertebrate tested, were exceeded for nearly all uses, except cotton and the Idaho and Washington SLN labeled rate for potatoes, in all application years. The frequency of exceedences of the reproductive level was in the range of 70% for cotton and 43% for the Idaho and Washington SLN labeled rates.

For exposed pink shrimp, results of the refined assessment show essentially 100% mortality in modeled surface waters for use on corn and sorghum and greater than 83% mortality for use on potatoes. For the other application rates, methods and crops, the median percent mortality estimate for exposed pink shrimp populations ranges from 0.6% for the minimum application rate for cotton to 69% for the maximum application rate on grapes.

Aquatic Field Data and Incidents

In comparison to birds, relatively few incidents with fish and shellfish have been reported, and only limited monitoring has been conducted in association with the use of liquid carbofuran in aquatic habitats. In California, elevated levels of carbofuran in the Colusa Basin resulted in the listing of that area for Total Maximum Daily Load (TMDL) development. Eight incidents have been attributed to carbofuran use according to the label directions. Two of these incidents were associated with flowable carbofuran formulations, two with granular, and for the remainder, the formulation was not reported. More than 600 fish were killed in two ponds following use of liquid carbofuran spray on alfalfa in Clark County, Missouri, following a rain event in May 1981. Another incident, involving liquid carbofuran chemigation to grapes, occurred in San Joaquin County, California. In that incident (November 1991), more than 3,000 fish, 4,000 crayfish and frogs, and 5,000 other large aquatic invertebrates were killed in a creek near a vineyard.

3. Risk Characterization

The Agency has taken action in the past for avian risks from the granular formulation of carbofuran. To arrive at the current decision, the Agency used multiple lines of evidence, including refined probabilistic risk estimates, to conclude that the flowable formulation of carbofuran also poses significant acute risks to birds. In addition, based on the previously conducted risk assessments, and extrapolating from the assessments on the flowable formulation, EPA continues to believe that the granular formulation poses significant acute risks to birds.

The terrestrial risk assessments also show acute and chronic risks to mammals and chronic risks to birds. The aquatic assessments show some risks to fish and significant risks to aquatic invertebrates. There is lower confidence in the estuarine/marine aquatic risk conclusions relative to the other non-target organism assessments.

Carbofuran has often been misused to poison predators, including foxes, coyotes, wolves, and bears. The technical registrant has conducted an educational/stewardship program to deter misuse, but intentional baiting continues to be a concern with carbofuran.

Many carbofuran incidents which have been classified as “misuse” or “off-label” appear to be the result of mistakes in application, rather than deliberate misuse. Given the high toxicity of carbofuran, the margin of error is small so that a minor mistake can have serious consequences.

There is high confidence in these risk assessment findings since the deterministic and probabilistic risk assessments, as well as controlled field studies and incident reviews, all support the same conclusion: that carbofuran use poses potentially serious risks to non-target organisms.

4. Endangered Species Considerations

The Agency's preliminary risk assessment for endangered species indicates that RQs exceed the endangered species LOC for terrestrial and aquatic animals, indicating the potential for direct effects. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of carbofuran can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and, because they do not take into account such factors as whether the species would be expected to be exposed to carbofuran, do not constitute "may affect" findings under the Endangered Species Act.

EPA is currently engaging in informal consultations with the Fish and Wildlife Service and the National Marine Fisheries Service, which is a part of the National Oceanic and Atmospheric Administration. This means that the Agencies are working together to conduct a full endangered species assessment for carbofuran, which is separate from this IRED. The likelihood of potential impacts to endangered species will need to be assessed for all counties in which: 1) crops registered for carbofuran use are grown; and 2) contain habitat for at least one listed species.

IV. Interim Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical or manufacturing-use grade) data required to support reregistration of products containing carbofuran as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the ecological, occupational, and dietary risks associated with the use of pesticide products containing the active ingredient carbofuran. Based on these data, the Agency has sufficient information on the human health and ecological effects of carbofuran to make its interim decisions as part of the tolerance reassessment process under FFDCA, as amended by FQPA, and the reregistration process under FIFRA, pending completion of the cumulative assessment of the N-methyl carbamate class of pesticides, of which carbofuran is a member. Additional mitigation may be necessary after this cumulative assessment is completed.

The Agency has determined that all products containing carbofuran are not eligible for reregistration. Some uses have been identified as providing moderate benefits to growers, and those will be subject to a phase-out.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for carbofuran. During the most recent public comment period on the risk assessments, which closed on May 22, 2006, the Agency received many sets of comments from stakeholders. These included comments from the technical registrant, growers, the Fish and Wildlife Service, the National Agricultural Aviation Association, the Natural Resource Defense Council, and others. The comments included some urging the Agency to regulate carbofuran more stringently, as well as some requesting that the Agency retain certain uses. These comments, in their entirety, are available in the public docket (docket # OPP-2005-0162) at http://www.regulations.gov. EPA has prepared responses to these comments and they are posted in the docket, along with this IRED. The Agency also received comments after the comment period closed, including 23 additional grower comments in support of carbofuran and several thousand comments from private citizens requesting that the Agency cancel use of carbofuran.

In addition, EPA worked with USDA to solicit input from the grower community on the importance of carbofuran use for those crops with < 1% of cropped area treated with carbofuran. EPA received many comments from growers through this process. EPA has considered these comments, and will be responding to them through a formal response to comments memo, which will be placed in the public docket, along with this document.

The IRED and technical supporting documents for carbofuran are also available to the public through EPA's electronic public docket and comment system, the Federal Docket Management System (FDMS), under [legacy] docket identification (ID) number EPA-HQ-OPP-2005-0162. In addition, the carbofuran IRED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position Under FIFRA and FFDCA

The following is a summary of the rationale for managing risks associated with the use of carbofuran. Under FIFRA, the Agency is proposing to cancel all uses of carbofuran, due to ecological and occupational risks of concern (See the ecological and human health risk assessments for carbofuran). In addition, there are dietary risks of concern from some crops. See the first listing of crops under Mitigation Summary below. Benefits are low to moderate for all of these uses, and do not outweigh the risks.

There are several uses for which residues do not pose dietary risks of concern *and* which have moderate benefits to growers [artichokes, chile peppers in the Southwestern U.S., cucurbits (granular formulation only), spinach grown for seed, sunflowers, and pine seedlings in the Southeastern U.S.]. For these uses, EPA is allowing a 4-year phase-out in order to allow time for new alternatives to become available to growers. In addition, import tolerances will be maintained for bananas, coffee, rice, and sugarcane. Dietary

risks from the imported foods are below the level of concern for these crops when considered together. For bananas, sugarcane, and coffee, however, benefits to U.S. growers are low when compared to ecological and occupational risks from domestic uses of these crops. Carbofuran is no longer registered for use on rice in the U.S. Dietary risks of phase-out crops plus these imported foods are below the Agency's level of concern.

1. Mitigation Summary

- **Cancellation based on high ecological and worker risks and low economic benefits for growers**

Sorghum	Alfalfa	Sweet corn
Cotton	Grapes	Field corn and popcorn
Wheat	Potatoes	Bananas/plantains
Cucurbits (flowable)	Oats	Soybeans
Barley	Tobacco	Fallow/idle land
Sugarcane	Ornamentals	Sugar beets
Peppers (except chile)		

- **4-year Phase-out for the crops which have moderate benefits to growers.**

  Artichokes, chile peppers in the Southwestern U.S., cucurbits (granular formulation only), sunflowers, spinach grown for seed, and pine seedlings in the Southeastern U.S.

2. Regulatory Rationale

The Agency evaluated the relationship of risks and benefits for all carbofuran uses on a use-by-use basis. These analyses show high ecological and occupational risks for all carbofuran uses. In addition, as discussed below, the benefits associated with most crops are low, although some uses have moderate benefits. Based on the assessment of ecological and human health risks associated with carbofuran uses, the Agency has determined that all uses of carbofuran do not meet the standard for continued registration under FIFRA.

The Agency has identified a few niche uses, however, for which there are moderate benefits to growers. In the short term, at least, these moderate benefits would justify retaining uses for a limited time. The Agency believes that there are not enough affordable alternatives to provide effective pest control for artichokes, chile peppers grown in the Southwestern U.S., cucurbits (granular formulation only), spinach grown for seed, pine seedlings grown in the Southeastern U.S., and sunflowers. EPA believes, however, that with the development of newer chemistries and other alternative pest control practices, the benefits of these uses will decrease. Therefore, a phase-out period of four years, with some additional restrictions to ensure the risks are reduced to

acceptable levels, is appropriate, given the current risk/benefit analyses. Cancellation of all but the phase-out crops reduces 98% of the total annual carbofuran use.

Additionally, some uses of carbofuran result in dietary risks above the Agency's level of concern under FFDCA. Therefore, EPA has determined that, in addition to significant occupational and ecological risks, these uses would not be eligible for reregistration because the Agency cannot determine that the tolerances for such crops meet the FQPA safety standard, based on the contribution of these uses to the aggregate risks for carbofuran. The uses which do not fit within the dietary risk cup based on food residues alone from the individual commodity are: sweet corn, potatoes, and flowable carbofuran on the following cucurbits: pumpkins, squash (summer and winter), casaba melons, cucumbers, honeydew, and watermelon. Additionally, the dietary contribution of carbofuran in milk exceeds the Agency's level of concern for infants and children with corn and alfalfa being cattle feed items which are assumed to be the primary sources of residues in milk. The risk estimates for cucurbits are based on both granular and flowable carbofuran treatments at current usage levels. Estimated dietary risks based on the granular use only, with the current production cap of 2,500 pounds per year, are below the level of concern.

The Agency also has dietary risk concerns posed by exposure from drinking water sources. Since food alone completely fills the risk cup (i.e. exposure is greater than 100% of the aPAD), any level of carbofuran residues in drinking water would result in additional risks of concern. Modeling estimates of residues in surface and ground water from all uses result in residue values above EPA's level of concern. In addition, recent USGS NAWQA monitoring data show multiple detections at low concentrations. The Agency recognizes that shallow, slightly acidic groundwater sources are the most vulnerable to carbofuran contamination. Such groundwater sources are located primarily in portions of the Southeast and the east coast of the United States. The uses for which EPA is not proposing immediate cancellation are those that are not expected to significantly contribute to groundwater contamination since they are limited in spatial extent of production (artichokes, chile peppers), applied in arid regions or in areas where pH is higher (chile peppers, sunflowers), or limited due to method of treatment (pine seedling dip). Cancellation of all other uses will reduce the amount of carbofuran applied from approximately 1 million pounds annually to approximately 19,500 pounds of use remaining for four years.

Additionally, because dietary risks from use of flowable carbofuran on cucurbits alone exceed the risk cup based on PDP food residue monitoring data and a high percent crop treated, the four year phase-out for cucurbits applies only to granular carbofuran.

The Agency will maintain import tolerances for bananas, coffee, rice, and sugarcane. Dietary risks from the import tolerances are below the Agency's level of concern when considered together with the food residues from the phase-out crops (56 % of the aPAD). There are currently domestic uses for bananas, sugarcane, and coffee, but they are ineligible for reregistration based on low benefits and ecological and occupational risks of concern.

3. Significance of Use

Carbofuran is a systemic insecticide which is used to control pests on a variety of fruit, vegetable, and field crops. Use has been declining in recent years and is now mostly limited to niche uses. Adequate alternatives exist for all crops except artichokes, chile peppers in the Southwestern U.S., cucurbits, spinach grown for seed, sunflowers, and pine seedlings in the Southeastern U.S. Use on cucurbits will be limited to the granular formulation based on dietary risks.

During the two public comment periods on the carbofuran risk assessments, the Agency received many grower comments in support of retaining carbofuran use for various crops.

EPA divided uses into two groups based on percent crop treated. If a low percentage of a crop is treated, the Agency makes the preliminary assumption that the significance of use on that crop is also low. For these crops, the Agency consulted with the USDA Office of Pest Management Policy (OPMP) to determine whether there were niche uses which should be considered in any mitigation plan. The nineteen use sites in this category are: bananas, barley, coffee, cotton, cranberry, flax, grapes, oats, ornamentals, pine forests, plantains, sorghum, soybeans, spinach grown for seed, sugar beets, sugarcane, sunflowers, tobacco, and wheat. OPMP received comments from the Integrated Pest Management Centers on carbofuran use on these crops. In general, these comments supported the conclusion that minimal impacts would be expected if carbofuran were no longer available for those crops with less than one percent crop treated.

For those use sites with either greater than 1% crop treated or at least 100,000 lbs carbofuran applied each year, the Agency assumed that the higher use frequency implied significance of use. For these sites, the Agency examined carbofuran use patterns, available alternatives, and the impacts of cancellation to growers. Analyses were conducted for artichokes, potatoes, field corn, alfalfa, cucurbits, and peppers. Through conducting these in-depth benefits analyses, the Agency was able to determine that, with the exception of artichokes, certain cucurbits, and chile peppers, minimal impacts would also be expected if carbofuran were no longer available for use on those crops with greater than 1% crop treated or 100,000 lbs applied annually. The Agency's benefits assessments will be posted to the carbofuran docket, along with this IRED.

In addition, after the most recent public comment period closed, the Agency received some new information from corn growers regarding the use of carbofuran as a rescue treatment for corn rootworm damage. The Agency therefore took particular care to examine potential benefits from this use. Corn rootworm pressure has been increasing for a variety of reasons, including rotation resistance (i.e., rootworms have become resistant to the control offered by rotating soybeans with corn) and the uncertain performance of seed treatments under high rootworm pressure. In addition, increasingly higher production of corn and continuous corn production are being practiced due to

increasing demand for ethanol. When high rootworm pressure is likely, most growers will use at-plant insecticides, such as tefluthrin, or plant genetically modified Bt corn. When low to moderate rootworm pressure is likely, growers will typically rely on seed treatments and survey for root damage instead of rootworm larvae. Clothianidin acts as a feeding depressant, and thus growers sampling soil in corn fields for larvae may misinterpret the presence of moribund (inactive) larvae as a control failure. Extension entomologists have recommended that growers look for root pruning and damage (rather than rootworm larvae) to assess the success of seed treatments. In limited circumstances, some growers may experience yield losses as a result of rootworm damage and have used carbofuran as a rescue treatment over the corn canopy. However, based on information from a variety of state extension publications and experts and the general lack of supporting data, the Agency believes that rescue treatments of carbofuran applied over the canopy to control corn rootworm damage perform erratically and are not a sound investment for growers.

There are several crops for which the Agency believes there are moderate benefits to growers: artichokes, chile peppers in the Southwestern U.S., cucurbits, spinach grown for seed, sunflowers, and pine seedlings. Some moderate benefits have also been identified for sweet corn for control of the wheat curl mite, which transmits High Plains disease. However, the Agency is not planning to allow a phase-out of this use due to the fact that there are dietary risks of concern.

Flowable formulation

- Growers apply carbofuran to artichokes for control of cribrate weevils, proba bugs, and artichoke aphids. Effective alternatives exist for aphids; however, the alternatives for cribrate weevil and proba bugs are not as effective (see Alternatives Assessment for Carbofuran on Artichoke, D. Brassard and S. Smearman, July 14, 2006).

- Carbofuran is used on chile peppers for control of flea beetles, thrips, and leafhoppers, as well as the green peach aphid in Arizona and Texas. There are adequate alternatives available; however, EPA acknowledges that some growers would face higher production costs without the availability of carbofuran. In addition, use of carbofuran on chile peppers is limited to Arizona, New Mexico, and Texas (see Impact Assessment for Carbofuran on Peppers, N. Zinn and E. Rim, June 28, 2006).

- Carbofuran is used on sunflowers to control stem weevils. Alternatives are available for the post plant foliar use, but not for the soil at-plant use. There are also a number of natural enemies available; however, it is unclear whether they can achieve adequate control of stem weevils (see Carbofuran Response to Comments and Alternatives Analysis for Crops with Low Usage, D. Brassard et al, July 7, 2006).

- Only limited alternatives are available for control of pales and pitch weevil in pine seedlings (see Carbofuran Response to Comments and Alternatives Analysis for Crops with Low Usage, D. Brassard et al, July 7, 2006).

Granular formulation

The Agency and the technical registrant reached an agreement in 1991 that sales of granular carbofuran would be limited to 2,500 lbs a year. This agreement was based on the ecological risks of concern posed by use of carbofuran, and phase-out use is limited to cucurbits, spinach for seed, and pine seedlings only.

- Only limited alternatives are available for control of pales and pitch weevil in pine seedlings (see Carbofuran Response to Comments and Alternatives Analysis for Crops with Low Usage, D. Brassard et al, July 7, 2006).

- In spinach grown for seed, springtails and European craneflies can cause yield losses of 100%, and carbofuran is the only pesticide available for control of these pests (see Carbofuran Response to Comments and Alternatives Analysis for Crops with Low Usage, D. Brassard et al, July 7, 2006).

- There are adequate alternatives available for cucurbits; however, EPA acknowledges that some growers would face higher production costs without the availability of carbofuran. [see Impact Assessment for Carbofuran on Cucurbits (Cucumbers, Pumpkins, Squash, and Watermelon), N. Zinn and E. Rim, June 14, 2006.]

D. Endangered Species Considerations

Endangered species acute and chronic LOCs are exceeded for all groups of terrestrial animals (birds, mammals, and invertebrates) for all uses and for all rates of flowable and granular formulations of carbofuran, indicating a potential for direct effects on listed species. Endangered species acute and chronic LOC are also exceeded for all groups of aquatic organisms for most uses of flowable and the limited remaining granular formulations of carbofuran. Exceedences of the LOCs indicate a potential for effects to listed species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs/IREDs and considers these data in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral

aspects of the particular species, as part of a refined species-specific analysis. Carbofuran is one of the first chemicals for which the Agency has begun a full, species-specific endangered species analysis. The Agency is currently participating in informal consultations with the Fish and Wildlife Service and the National Marine Fisheries Service within the National Oceanic and Atmospheric Administration. The Agencies hold monthly meetings to exchange information. This species-specific analysis is being completed separately from this IRED, and will take into consideration any regulatory changes recommended in this IRED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of carbofuran, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of carbofuran "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this IRED will reduce the likelihood that endangered and threatened species may be exposed to carbofuran at levels of concern. EPA is not requiring specific carbofuran label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

E. Food Quality Protection Act Findings and Tolerance Summary

1. FQPA

a. Risk Cup Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this N-methyl carbamate (NMC). The assessment is for this individual NMC, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the NMCs through a common biochemical interaction with the cholinesterase enzyme. The preliminary cumulative risk assessment for the NMC Cumulative Assessment Group, which includes carbofuran, was released in July 2005. The revised cumulative risk assessment is currently being developed and will be completed during 2006. The results of this NMC cumulative assessment, as well as the single chemical carbofuran assessment, will be considered in the final tolerance reassessment decision for carbofuran.

EPA has determined that risk from food (dietary sources only) exposure to carbofuran exceeds its own "risk cup" (490% of the aPAD for children). Therefore, residues in drinking water will be of concern. Exposure from the crops allowed for four-year phase-out plus the four crops maintained as import tolerances is estimated at 56% of

the aPAD for infants, the population subgroup with the highest exposure. Residues in water are expected to decline when use ceases.

b. Endocrine Disruptor Effects

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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

2. Interim Tolerance Summary

The Agency is proposing to cancel all uses of carbofuran based on ecological, occupational, and dietary risks of concern, and to revoke all tolerances, with the exception of bananas, rice, sugarcane, and coffee. These tolerances will be maintained for import purposes only. Several uses were identified as having moderate benefits to growers, and the Agency is proposing to implement a 4-year phase-out for those crops. Therefore EPA is proposing to delay the effective date of revocation of the tolerances for artichokes, corn, peppers, and sunflowers until 2010. All other tolerances will be proposed for revocation following completion of this IRED.

A summary of the dietary aggregate assessment for food and drinking water that supports the finding that the (1) time-limited retention of the uses to be phased out and (2) retention of the import tolerances meets the FQPA safety standard is presented in the Regulatory Rationale section of this document, and in the carbofuran reregistration docket (EPA-HQ-OPP-2005-0162).

Table 20. Interim Tolerance Summary for Carbofuran

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.254 (a)			
Alfalfa , fresh; alfalfa, hay; barley, grain; barley, straw; beet, sugar; beet, sugar, tops; corn, forage; corn, fresh (including sweet corn) (K+CWHR); corn, grain (including popcorn); corn, stover; cotton, undelinted seed; cranberry; grape; grape, raisin; milk; oat, grain; oat, straw; potato, raisins, waste; sorghum, fodder; sorghum, forage; sorghum, grain; soybean; soybean, forage; soybean, hay; strawberry; wheat, grain; wheat, straw	10 (5)	Revoke	
Banana	0.1	0.1	Maintained for import purposes.
Coffee bean	0.1	0.1	*[Coffee, green bean]* Maintained for import purposes.
Cucumber	0.4 (0.2)	Revoke (Maintain at current level until expiration in 2010.)	Revoke individual tolerances and establish a crop group tolerance for *Cucurbit Vegetables Group* 9. Tolerance will expire in 2010.
Melons	0.4 (0.2)		
Pumpkin	0.8 (0.6)		
Squash	0.8 (0.6)		
Pepper	1 (0.2)	Revoke (Maintain at current level until expiration in 2010.)	*[pepper, nonbell]* Tolerance will expire in 2010.
Rice, grain	0.2	0.2	No Section 3 registrations. Maintained for import purposes.
Sugarcane, cane	0.1	0.2	Maintained for import purposes.
Sunflower, seed	1.0 (0.5)	Revoke (Maintain at current level until expiration in 2010.)	Tolerance will expire in 2010.
Tolerances Listed Under 40 CFR §180.254 (c)			
Artichoke, globe	0.4 (0.2)	Revoke (Maintain at current level until expiration in 2010.)	Tolerance will expire in 2010.

(Number in parentheses reflects the ppm level that residues of carbamates may not exceed.)