

CARBARYL IRED FACTS [Revised 10/22/04]

Action and Rationale

EPA has assessed the risks of carbaryl and, on June 30, 2003, reached an Interim Reregistration Eligibility Decision (IRED) for this carbamate pesticide. A revised IRED document is being released for public comment on October 27, 2004. A letter from EPA to registrants dated October 22, 2004 precedes the IRED document and explains the revisions made.

Although all uses may not meet the current safety standard and some uses may pose unreasonable risks to human health and the environment, these effects can be mitigated by the measures identified in the Carbaryl IRED. Provided that these risk mitigation measures are adopted, aggregate risks for carbaryl alone will be within acceptable levels and the pesticide will be eligible for reregistration once EPA considers the cumulative risks of the carbamates.

Carbaryl is one of the most widely used broad-spectrum insecticides in agriculture, professional turf management and ornamental production, and residential pet, lawn, and garden markets. Although dietary (food and drinking water) exposures are not of concern, carbaryl does pose risks of concern from uses in and around the home. With mitigation measures discussed in the IRED document, carbaryl will fit into its own "risk cup" and will not pose significant aggregate risk concerns. Carbaryl also poses risks of concern to occupational handlers who mix, load, and apply the pesticide in agricultural sites, and to workers who may be exposed upon re-entering treated agricultural areas. Carbaryl poses ecological risks, particularly to honey bees and aquatic invertebrates. With mitigation measures, these occupational and ecological risks also will not be of concern for reregistration.

EPA's next step under the Food Quality Protection Act of 1996 (FQPA) is to consider the cumulative effects of the carbamate pesticides, which have a common mechanism of toxicity. The interim decision on carbaryl will not be final until carbamate risks have been considered. The carbamate cumulative assessment may result in further risk mitigation measures for carbaryl.

EPA is reviewing the carbamate pesticides to determine whether they meet current health and safety standards. Older carbamates require decisions about their eligibility for reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Carbamates with food, drinking water, residential, and any other non-occupational exposures must also be reassessed to make sure they meet the Federal Food, Drug, and Cosmetic Act (FFDCA) safety standard brought about by FQPA.

The carbaryl decision was made through EPA's public participation process, which increases transparency and maximizes stakeholder involvement in the Agency's development of risk assessments and risk management decisions. EPA worked extensively with numerous affected parties to reach the decisions presented in the Carbaryl IRED document.

Uses

- The insecticide carbaryl, also known by the trade name Sevin, is registered for use on over 400 sites, including agriculture, professional turf management and ornamental production, and residential settings. Carbaryl also is registered for use as a mosquito adulticide. Washington State also has a Special Local Needs registration to control burrowing shrimp in oyster beds.
- Carbaryl is used on many agricultural sites including fruit and nut tree, fruit and vegetable, and grain crops. More than 140 tolerances are established for carbaryl. Crops with the greatest amount (most pounds) of annual carbaryl use include apples, pecans, grapes, alfalfa, oranges, and corn. Crops with the highest percent of acres treated include asparagus, okra, cranberries, apples, blueberries, sweet cherries, pumpkins, and strawberries.
- Carbaryl is used by homeowners in residential settings for lawn care, gardening (vegetables and ornamentals), and pet care (pet collars, powders, and dips, in kennels, and on pet sleeping quarters).
- Carbaryl also is used by nursery, landscape, and golf course industries on turf, annuals, perennials, and shrubs.
- A total of approximately 3.9 million pounds of carbaryl active ingredient are sold annually in the U.S.; about half is used in agriculture and half in non-agricultural settings (per 1998 data). The amount of carbaryl usage in agriculture has declined from an average of 1.9 million pounds of active ingredient per year from 1992 through 2001, to 1 to 1.5 million pounds of active ingredient in 2001.

Human Health Effects

- A member of the n-methylcarbamate class of pesticides, carbaryl can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at high exposures, respiratory paralysis, and death. Carbaryl is a reversible inhibitor of acetylcholinesterase.
- Carbaryl is classified as a likely human carcinogen based on vascular tumors in mice. However, non-cancer risks are seen as the primary risk driver for almost all use scenarios.

Risks

- Dietary Risks – Both acute and chronic (non-cancer and cancer) risks from food are below EPA's level of concern. Screening-level modeling estimates indicate that acute dietary risks from carbaryl residues in surface water sources of drinking water are above the Agency's level

of concern for children and the general population. Due to uncertainties and limitations of model predictions, and based on results of monitoring data, however, actual concentrations of carbaryl in drinking water derived from surface water are likely to be much lower than estimated. Further, EPA expects conventional drinking water treatment to significantly reduce concentrations of carbaryl in drinking water. Chronic (non-cancer and cancer) dietary risks from surface water sources, based on screening-level modeling estimates, are below the Agency's level of concern. Estimated concentrations of carbaryl in ground water sources of drinking water also are below the Agency's level of concern for acute and chronic (non-cancer and cancer) exposure.

- Residential Risks – EPA is concerned about exposures of homeowners using carbaryl lawn, garden, ornamental plant, and pet flea control products, as well as adults doing yard work and toddlers playing on treated lawns. To address the greatest residential handler risk concerns, the carbaryl registrant is voluntarily canceling all pet uses except flea collars. The registrant also has agreed to measures that will effectively mitigate other residential handler risks, such as changes in the amount of active ingredient, packaging, and size of residential use products. Residential post-application risks of concern also will be mitigated by canceling liquid and dust use on pets (allowing flea collars only), and canceling liquid broadcast use on lawns, pending the results of data being developed to refine these risks (spot treatments with liquid products may continue). **[Note: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of the carbaryl IRED document.]** With these mitigation measures, residential risks will no longer be of concern to the Agency.
- Aggregate Risks – EPA assessed the aggregate risks of exposures to carbaryl through food, drinking water, and residential uses, excluding uses that are being canceled to mitigate risks. The Agency made an interim determination that the human health risks from these combined exposures are within acceptable limits. Although combined exposures appear to “fill” the aggregate risk cup, the drinking water exposure estimate is based on screening-level modeling; actual drinking water exposures are believed to be lower than estimated. Confirmatory data are required to verify the Agency's conclusion that carbaryl does “fit” within the aggregate risk cup.
- Occupational Risks – Carbaryl poses risks of concern to occupational handlers who mix, load, and apply the pesticide in agricultural sites, and to workers who are exposed upon re-entering treated agricultural areas. EPA evaluated 28 major occupational exposure scenarios which resulted in about 140 crop/rate/acreage risk calculations to assess dermal and inhalation exposures to carbaryl handlers. Although several scenarios exceeded the Agency's level of concern, these handler risk concerns can be mitigated by implementing various levels of personal protective equipment and engineering controls, in most cases.

EPA also evaluated post-application (reentry) risks to workers who enter areas previously treated with carbaryl. For workers involved in post-application activities, the Agency assessed risks at various time intervals after application, and then set restricted entry intervals (REIs) to ensure that workers wearing baseline protective clothing could safely reenter treated areas. Because reentry risks are of concern for many crops and scenarios at the currently labeled REI of 12 hours, the REI is being lengthened for many crops.

- Ecological Risks – Carbaryl is very highly toxic on an acute exposure basis to honey bees, estuarine/marine invertebrates, and other aquatic animals, including Atlantic salmon (see next paragraph which addresses endangered species). Based on a screening-level assessment, ecological risks for carbaryl are low and some are of concern. Mitigation measures will help address these risk concerns. In addition, oyster growers in Washington State who use carbaryl to control burrowing shrimp on oyster beds in tidal mudflats have agreed to phase out this use.
- Endangered Species – EPA consulted with the US Fish and Wildlife Service (FWS) in 1989 regarding carbaryl impacts on endangered species. As a result, FWS issued a formal Biological Opinion which identified reasonable and prudent measures and alternatives to mitigate effects of carbaryl use on endangered species. EPA currently is consulting with the National Marine Fisheries Service (NMFS) concerning carbaryl effects on endangered species of salmon and steelhead, and is engaged in a proactive conservation review with FWS and NMFS to determine best processes to assess pesticide impacts on endangered species.

Benefits

- Carbaryl controls a wide spectrum of insect pests across a wide range of use sites, both agricultural and non-agricultural. EPA reviewed carbaryl's use patterns on many sites, and used that information in forming a regulatory position and determining the mitigation measures necessary to address risks of concern. In particular, the Agency considered the benefits associated with the use of carbaryl on citrus, especially in Florida and California, and grapes to evaluate occupational and ecological risks.

Mitigation Measures

Residential

- Residential lawn care liquid broadcast applications will be voluntarily canceled pending the outcome of data that the registrant is voluntarily generating to refine post-application risks. *[See earlier NOTE concerning data submission by Bayer CropScience.]* Liquid broadcast use on sod farms, golf courses, commercial landscape areas, and cemeteries are not being cancelled.

- Home garden/ornamental dust products must be packaged in ready-to-use shaker can containers, with no more than 0.05 lbs. active ingredient per container.
- Certain uses and application methods will be canceled:
 - All pet uses (dusts and liquids) except collars;
 - Aerosol products for various uses;
 - Belly grinder applications of granular and bait products for lawns;
 - Hand applications of granular and bait products for ornamentals and gardens.

Occupational

To address handler risk concerns:

- Certain uses and application methods will be canceled:
 - Wheat use;
 - Pet uses (except pet collars);
 - Applications by hand, spoon, and bellygrinder;
- Maximum application rates are reduced for mosquito control, citrus, and asparagus.
- Aerial applications are prohibited for:
 - Wettable powder formulations;
 - Granular and bait formulations applied to corn (field, pop, and sweet), grain sorghum, alfalfa, rice, and sunflowers.
- Additional personal protective equipment (PPE) and engineering controls are to be used for aerial/chemigation and ground airblast applications, and for use of granular and bait, liquid, and wettable powder formulations.

To address post-application worker risk concerns:

- Current 12-hour restricted entry interval (REI) for carbaryl is being extended for most crop uses;
- Maximum application rates are reduced for citrus (including California citrus and Florida 24(c) registration), asparagus (including both pre-harvest and post-harvest applications), field corn, and stone fruit;
- For brassica crops, leafy vegetables, and table beets and turnips when harvested for greens, use is restricted for applications only within 30 days of crop emergence/ transplanting.

Ecological

- To address toxicity concerns for honey bees, all carbaryl products must carry a bee precaution statement in the Environmental Hazards section of all their labels, as follows:
 “This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are

visiting the treatment area.”

- Several mitigation measures required to address residential and occupational risks, described above, will also address risks to terrestrial and aquatic organisms, including:
 - Reducing maximum application rates for mosquito control, citrus, asparagus, field corn, and stone fruit;
 - Canceling use on wheat;
 - Prohibiting certain aerial applications;
 - Canceling liquid broadcast applications to home lawns pending EPA review of pharmacokinetic data to refine postapplication risk estimates. [*See earlier NOTE concerning data submission by Bayer CropScience.*]
- Oyster growers in Washington State who use carbaryl to control burrowing shrimp on oyster beds in tidal mudflats are phasing out this use per local agreements and independent of EPA.

Next Steps

- EPA is publishing a Federal Register notice announcing a 60-day public comment period on a revised carbaryl IRED. Revisions are explained in a letter to registrants dated October 22, 2004 at the beginning of the revised IRED document.
- Once EPA has considered the cumulative risks of the carbamate pesticides, the Agency will issue its final tolerance reassessment decision for carbaryl and may need to pursue further risk management measures. The Agency will propose revocation of 9 carbaryl tolerances now, will lower 31 tolerances, and will reassign 49 tolerances to conform with changes in commodity definitions. For all carbamates, including carbaryl, tolerances will not be raised and new tolerances will not be established until cumulative risks have been considered.



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 22, 2004

CERTIFIED MAIL

Dear Registrant:

The Interim Reregistration Eligibility Decision (IRED) document for carbaryl was signed on June 30, 2003 and made available on the Internet. Since signing the IRED document, EPA has completed a number of informational IRED appendices, and has also received additional data from one of the carbaryl technical registrants, Bayer CropScience, that the Agency wants to make available for formal public comment. To the extent EPA has found corrections, clarifications, updates or other amendments needed in the IRED document, these are enumerated in this letter and included within the revised IRED document being announced for public comment. The revised IRED document is marked "[Revised: 10/22/04]" on the title page, and supersedes the June 30, 2003 IRED document previously posted on the Internet. Registrants and all parties should use the revised carbaryl IRED document for purposes of implementing and commenting on the Agency's IRED.

The Agency is providing a 60 day public comment period for the IRED. The carbaryl IRED, risk assessments and supporting documents can be found on EPA's online docketing system, EDOCKET, at <http://www.epa.gov/edocket> (OPP-2003-0376). Comments, once submitted, will also be available via EDOCKET. EPA encourages commenters to use the EDOCKET system to submit their comments.

The EDOCKET system includes two previously established dockets covering earlier phases of the public participation process. Docket OPP-2002-0138, which closed for public comment on October 28, 2002, contains preliminary (Phase 3) carbaryl risk assessments. Docket OPP-2003-0101, which closed for public comment on June 2, 2003, contains the carbaryl revised (Phase 5) risk assessments. The current docket, OPP-2003-0376, contains documents generated since the closing of the last docket on June 2, 2003, and includes EPA's response to comments submitted on the revised risk assessments for carbaryl.

The IRED document and supporting documents announced for public comment include the following corrections, clarifications, updates, or other amendments, which unless otherwise noted, were the result of EPA's own review of the IRED document or reflect the status of ongoing issues.

The most significant status update concerns risk estimates associated with application of carbaryl liquid formulations on residential turf. On June 27, 2003, the carbaryl technical

registrants agreed not to produce new technical ingredient labeled for residential lawn broadcast application of carbaryl liquid formulations until EPA could consider data being submitted to refine the Agency's risk assessment for post-application exposures to toddlers. Bayer CropScience has since submitted to the Agency new pharmacokinetic data, and a method for using the data in a deterministic calculation to refine risk estimates. Based on its current review of the documents submitted by Bayer, EPA believes that the submitted data and methodology sufficiently demonstrate that risks from this use are not of concern. EPA is continuing, however, to seek independent scientific review of the information through a FIFRA Scientific Advisory Panel (SAP) meeting on December 2, 2004. For the latest information about that SAP meeting, go to <http://www.epa.gov/scipoly/sap/#december>. The title of the meeting is "Use of Pharmacokinetic Data to Refine Carbaryl Risk Estimates from Oral and Dermal Exposure." The primary document submitted by Bayer, and EPA's review of that document, are also included in docket OPP-2003-0376. To address this issue in the amended IRED, EPA has inserted an editorial note at each point in the text where EPA discusses risk estimates or mitigation for the residential liquid lawn broadcast use. The editorial note refers the reader to this letter so that readers are aware of the Agency's preliminary conclusions about the submission by Bayer CropScience, and can provide comment.

Another ongoing issue concerns labeling carbaryl formulations for hazards to bees, particularly the Sevin XLR Plus formulation. Many commenters have expressed their views and concerns to the Agency. EPA is encouraging all interested parties to submit their comments to docket OPP-2003-0376 through the online EDOCKET system. EPA has not amended the June 30, 2003 IRED with regard to this issue.

Other amendments are as follows. Page numbers refer to the IRED as corrected and made available for formal public comment.

Clarifications include:

- C Punctuation led to confusion about the mitigation status for residential use of granulars and baits. Only applications by bellygrinder or by hand are prohibited. The sentence on page xi., third bullet, has been revised for clarity, to read as follows: "The following uses are to be cancelled: all pet uses (dusts and liquids, except for collars); belly grinder application of granulars and baits for spot treatment; hand application of granular and baits for ornamentals and gardens; and aerosols for various uses."
- C In Table 25, rewording the decision and rationale for mitigation of "Garden/ornamental dust on vegetables/ornamentals." The last sentence concerning cancer risk was difficult to read, and is revised as follows: "The Agency also calculated that exposures would have to exceed 40 days per year over multiple years before the cancer risks to handlers would be of concern (i.e., $> 1 \times 10^{-6}$). Therefore, this use is no longer a risk of concern to the Agency."

- C One example of a minor clarification includes a sentence on page 110 regarding occupational risk mitigation, where EPA completes a phrase by adding the following text (in italics): "EPA must also take into account the economic, societal, and environmental costs and benefits of the pesticide's use *when determining whether the use poses unreasonable adverse effects.*"
- C Even more minor would be certain conforming changes. For example, using the term "risk estimates" instead of "risks" when discussing the high-end results of screening level assessments. We have not enumerated instances of these and other minor changes that are insignificant from the standpoint of public comment, but which improve the clarity of the document.

Corrections include:

- C A typo in the executive summary refers to "0.5 lb ai/container" of residential dust formulation that should read "0.05 lb ai/container (p. xi of the Executive Summary)." The figure appears correctly elsewhere in the IRED document.
- C In Table 2, titled "Estimated Carbaryl Usage by Agricultural Site," we removed the row for avocado. Avocado is no longer a registered carbaryl use.
- C In Table 29, "Occupational Handler Mitigation Measures to be Adopted," under category B., Bayer CropScience noted after signature that the correct maximum application rates for the following crops should be lower than what is reflected in the IRED. Specifically, that *aerial liquid application* rates should be reduced for the following crops: Field corn, from 2 to 1.5 lb ai/acre (the maximum ground application rate remains 2 lb ai/acre); Stone fruit, from 5 to 3 lb ai/acre except for California, where the maximum is 4 lb ai/acre due to pest pressures. The maximum ground application rate for stone fruit remains 5 lb ai/acre for dormant use only. The corrections noted by Bayer correspond with our mitigation notes, and we have made the corrections in the revised IRED.

Addition of Informational Appendices

EPA is also making informational appendices to the IRED available for public comment. EPA would particularly appreciate public comment on the "label table," which describes the changes needed on labels to comply with mitigation specified in the IRED, and Appendix A, which is intended to be a comprehensive list of the carbaryl use patterns eligible for reregistration. Because of the wide array of pesticide formulations, application scenarios, and crops, comments on this information would be helpful to ensure its accuracy.

EPA is also issuing concurrent with this letter the Generic and Product-Specific Data Call Ins (DCIs) for carbaryl. One item not included in the DCI is confirmatory data identified in the IRED for the effects of drinking water treatment on estimated drinking water concentrations. Prior to issuance of the IRED, Bayer CropScience began a study of the effect of water treatment on carbaryl, and EPA expects those data will be submitted soon.

If you have questions on the carbaryl IRED, the Generic DCI, or any of the revisions listed above, please contact the Chemical Review Manager, Anthony (Tony) Britten at (703) 308-8179. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen E. Jones at (703) 308-8047.

Sincerely,

Debra Edwards, Ph.D.
Director
Special Review and Reregistration Division

Attachment

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 30, 2003

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the carbamate pesticide carbaryl. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on April 2, 2003. This concluded Phase 4 of the Public Participation Process developed by the Tolerance Reassessment Advisory Committee (TRAC), and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. The Phase 5 public comment period closed on June 2, 2003.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of carbaryl. EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for carbaryl and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for carbaryl will be finalized once the cumulative risks for all of the carbamate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Carbaryl," which was approved on June 30, 2003, contains the Agency's decision on the individual chemical carbaryl. The Agency is providing a 60-day public comment period on the carbaryl interim risk management decision. If substantive data or comments are received and indicate that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, EPA will make appropriate modifications at that time.

A Notice of Availability for this Interim Reregistration Eligibility Decision (IRED) for carbaryl is being published in the *Federal Register*. To obtain a copy of the IRED document, please contact the OPP Public Regulatory Docket at (703) 305-5805. Electronic copies of the IRED and all supporting documents are available on the Internet at the following address: <http://www.epa.gov/EDOCKETS>.

The IRED is based on the updated technical information found in the carbaryl public

docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes updates to the Agency's revised risk assessments for carbaryl. The docket also includes comments on the revised risk assessment and any risk mitigation proposals submitted during Phase 5.

This document and the process used to develop it are the result of a process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for these pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets on the carbamate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the carbamate pesticides are following this process.

Please note that the carbaryl risk assessment and the attached IRED document concern only this particular carbamate. This IRED presents the Agency's conclusions on the dietary risks posed by exposure to carbaryl alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of carbaryl. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the carbamates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire carbamate class of chemicals after considering the risks for the individual carbamates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each carbamate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of carbaryl. The Agency will issue the final tolerance reassessment decision for carbaryl and finalize decisions on reregistration eligibility once the cumulative risks for all of the carbamates are considered.

This document contains both generic and product-specific Data Call-Ins (DCIs) that outline further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

As part of the IRED, the Agency has determined that carbaryl will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of carbaryl may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk management measures identified in this IRED document. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this

IREED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by carbaryl. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Anthony Britten, at (703) 308-8179. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen E. Jones at (703) 308-8047.

Sincerely,

Richard P. Keigwin, Jr., Acting Director
Special Review and
Reregistration Division

Attachment

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INTERIM REREGISTRATION ELIGIBILITY

DECISION

for

Carbaryl

[REVISED: 10/22/04]

LIST A

CASE 0080

CARBARYL TEAM

Office of Pesticide Programs

Health Effects Risk Assessment

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GLOSSARY OF TERMS AND ABBREVIATIONS

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

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

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA) has completed its review of public comments on the revised human health and environmental risk assessments for carbaryl and is issuing its interim risk management decision. The decisions outlined in this document do not include the final tolerance reassessment decision for carbaryl. Revocations, lowering tolerances, changing definitions, and other actions will occur after the Interim Reregistration Eligibility Decision (IRED) is finalized. Raising or establishing new tolerances will be deferred until cumulative risks have been considered. Nine tolerances will be proposed for revocation now, for commodities that are no longer regulated with tolerances, for commodities with no currently registered uses, or for commodities for which the technical registrant has requested, and the Agency has approved, cancellation of carbaryl use. Thirty one tolerances will be lowered and twenty one tolerances will be increased based on residue data submitted to the Agency. Forty-nine tolerances will be reassigned to conform with changes in commodity definitions, concomitant with establishing new tolerances. The carbaryl IRED also provides that eight tolerances must be established for wet apple pomace, aspirated grain fractions, sugar beet roots, citrus oil, raisins, proso millet hay, rice hulls, and sorghum grain stover. As previously mentioned, the final tolerance reassessment, including establishing the eight new tolerances and increasing the 21 tolerances, will be deferred until after cumulative risks for all of the carbamate pesticides are considered.

Carbaryl is a carbamate insecticide used on a variety of crops. It was first registered in 1959 for use on cotton. Carbaryl is currently registered for use on over 400 sites, and there are more than 140 tolerances for carbaryl in the Code of Federal Regulations. At present, carbaryl is registered for domestic outdoor uses on lawns and gardens, and indoors in kennels and on pet sleeping quarters. It is also currently registered for direct application to cats and dogs (collar, powder, and dip) to control fleas and ticks. Based on available pesticide usage information from 1992 through 2001, approximately 1.9 million pounds of carbaryl active ingredient (lbs ai) are used in agriculture, and approximately 1.3 million acres are treated. In 1998, a total of 3.9 million lbs ai was sold, with about half of this used in nonagricultural settings. The most recent available data shows a decline in agricultural usage; only 1 to 1.5 million lbs ai were used in agriculture in 2001.

Overall Risk Summary

The Agency's human health risk assessment for carbaryl indicates some risk concerns. Both acute and chronic risks from food are below the Agency's level of concern. Drinking water risk estimates based on screening level models, from both ground and surface water exposures, suggest concern for potential surface water exposure. Dietary exposure from ground water sources of drinking water are not of concern. There are also risk concerns for occupational handlers who mix, load, and apply carbaryl; for homeowner users; and for occupational workers who are exposed to carbaryl residues after it is applied to agricultural crops. The screening level ecological risk assessment for carbaryl shows risk quotients (RQs) ranging from 0.01 to 51 for terrestrial organisms and from 0.03 to 55 for aquatic organisms. EPA consulted with the US Fish and Wildlife Service in 1989 regarding impacts carbaryl on endangered species. The Agency is currently consulting with the National Marine Fisheries Service concerning effects of carbaryl on endangered species of salmon.

Dietary Risk

Acute and chronic dietary (food) risks are less than 100% of the aPAD and cPAD for the general U.S. population and all population subgroups. The maximum lifetime dietary cancer risk from carbaryl is 2.14×10^{-8} , which is not of concern. Therefore, no mitigation measures are necessary to reduce dietary risks from food.

Children (1-2 years), the most highly exposed population group, are exposed to carbaryl at a level of 93% of the aPAD at the 99.9th percentile of exposure. When residue data from all commodities in the Carbamate Market Basket survey is used, children age 1-2 are exposed to carbaryl at 86% of the aPAD. Although the market basket survey data contain some uncertainties, the data support the conclusion that acute dietary risk is not of concern. Chronic dietary exposure for all population groups, including children (1-2 years), is less than 1% of the cPAD.

Drinking Water Risk

Estimated exposure concentrations (EECs) of carbaryl in surface water were modeled using PRZM-EXAMS. Based on currently registered uses, the surface water EECs for carbaryl range from 23 to 410 ppb for acute exposure, and from 1.3 to 23 ppb for chronic exposure. Therefore, the modeled EEC values exceed the acute drinking water levels of comparison (DWLOCs) of 7.4 ppb for children age 1-2 and 200 ppb for the general population. However, because the EECs are derived from modeling, they should be considered upper bound estimates of drinking water concentrations. Actual concentrations of carbaryl in drinking water derived from surface water are likely to be much lower than the surface water EECs. This is supported by extensive surface water monitoring data for carbaryl, which show low measured concentrations of carbaryl in surface water, many below the level of detection, and all below the lowest DWLOC of 7.4 ppb. This includes monitoring data from both urban and rural watersheds. Further, EPA expects conventional drinking water treatment to significantly reduce the concentration of carbaryl in drinking water and is requiring confirmatory data to evaluate its effect.

The DWLOC is considered to be a screening level used to measure the maximum concentration of a pesticide that can occur in drinking water without exceeding EPA's concern for aggregate risk. To refine the drinking water assessment, EPA conducted a probabilistic aggregate exposure assessment for exposure to carbaryl residues from food and drinking water. This assessment focused on the following high use scenarios for carbaryl, which were thought to be associated with highest drinking water concentrations: Florida citrus, California citrus, Pennsylvania apples, and Georgia peaches and pecans. The results of the aggregate assessment showed the greatest risk concern for drinking water exposure for carbaryl use on Florida citrus.

Ground water EECs for carbaryl were derived from a Tier I screening-level model (SCI-GROW), which estimates the maximum ground water concentrations from the application of a pesticide to crops. The maximum estimated ground water EEC is 0.08 ppb and does not exceed the DWLOC for acute or chronic exposures.

Residential Risk

Carbaryl is currently registered for residential use on flower and vegetable gardens, lawns, ornamental flowers and shrubs, and pets. Indoor residential use is limited to the use on pets. Carbaryl is also used on golf courses and may be used in other outdoor recreational areas. An aquatic use of carbaryl on oyster beds in Washington State may result in potential postapplication exposure to people swimming in the ocean or walking on the beach.

Handler Risk. MOEs for outdoor residential uses of carbaryl range from 21, for liquid broadcast lawn treatments, to over 1,000,000. MOEs for indoor use on pets range from 4, for dusts, to over 1,000,000 for flea collars. Short-term MOEs for adults range from 4, for application of carbaryl dust to dogs, to greater than 20,000, for use of a backpack sprayer in home gardens, liquid applications to dogs, or pet flea collars. Cancer risks for all scenarios were less than 1×10^{-6} and not of concern.

To address the greatest risk concerns for residential handlers, the registrant is voluntarily canceling uses, including all pet uses except flea collars. For other scenarios with risk concerns, the registrant has agreed to measures that will effectively mitigate risks, such as changes in the amount of active ingredient allowed in residential products, and changes in packaging and size of products for residential use. Therefore, provided that the stipulated mitigation measures are implemented, residential handler risks are not of concern to the Agency.

Postapplication Risk. The Agency conducted a residential, postapplication risk assessment for adults, children 10-12 years old, and toddlers (3-5 years old) exposed to carbaryl. EPA assessed postapplication risk from short- and intermediate-term exposure (less than 1 month and 1-6 months, respectively) for all residential uses except pet collars. Postapplication exposure from the pet collar use is considered to be 6 months or longer. For adults, EPA evaluated postapplication risk from walking on treated lawns, golfing, and gardening. For children, EPA evaluated postapplication risks from walking on treated lawns, gardening, and playing with pets treated with carbaryl. EPA evaluated postapplication exposures to adults and children from swimming or playing on beaches where carbaryl is used to treat oyster beds.

Postapplication MOEs range from less than 1, for toddlers exposed to pets treated with carbaryl dusts, to greater than 30,000, for adults exposed to residential turf after mosquito adulticide treatment. Postapplication risks of concern will be mitigated by discontinuing the liquid broadcast use on lawns and the liquid and dust use on pets. Use of liquid formulations on lawns will be limited to spot treatments pending EPA review of data being developed by Bayer CropScience. **[NOTE: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]** Pet use will be limited to flea collars only, and additional confirmatory exposure data are required for this use.

EPA also estimated postapplication cancer risks for the scenarios described above. Cancer risks for adults only were calculated using a frequency of one exposure per year over a lifetime. Cancer risks are not of concern for any turf uses, with risk estimates in the 10^{-8} range or less on the day of application, when evaluating a single reentry event per year during lawncare

activities. Risks from home gardening, golfing, mosquito control, or oyster bed treatment, are also not of concern; they were in the 10^{-9} to 10^{-12} range when evaluating a single reentry event per year on the day of application.

Aggregate Risk

An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Uses which are being cancelled to mitigate risks of concern are not included in the aggregate assessment. Based on the results of this aggregate assessment, the Agency made an interim determination that the human health risks from these combined exposures to carbaryl are within acceptable limits. Although combined carbaryl exposures from food, residential use, and surface water sources of drinking water appear to “fill” the aggregate risk cup, the drinking water exposure is based on screening-level modeling estimates. The Agency believes actual drinking water exposures are lower than predicted by the model, and has made an interim determination that carbaryl does “fit” within the dietary risk cup. Confirmatory data will be required to verify this conclusion.

Acute aggregate dietary risk, which combines acute food and drinking water exposure, was evaluated using two methods: the conventional DWLOC method for exposure to food and both surface water and ground water, and a probabilistic method for exposure to food and surface water. The acute drinking water level of comparison (DWLOC) for children 1-2 years old, the most highly exposed population subgroup, is 7.4 ppb whereas the DWLOC for the general population is 200 ppb. Modeled acute surface water EECs for carbaryl range from 23 to 410 ppb. The highest EEC is based on the citrus use in Florida. The probabilistic acute aggregate assessment for carbaryl shows exposures exceeding 100% of the aPAD for certain regional use scenarios. However, the Agency believes that the actual risks are much lower and not of risk concern because of uncertainties with specific fate data; conservative inputs to the water model, including the default PCA and assumption of 100% crop treated; the expected effects of water treatment; and the overall results of available monitoring data.

Short-term aggregate risk from food, drinking water, and residential exposure, are not of concern, provided that risk mitigation measures are implemented. The results of a screening level assessment show DWLOCs ranging from 19.4 to 340, which are greater than the highest modeled EECs of 18.6 ppb for surface water and 0.08 ppb for ground water. Because all DWLOCs are greater than the EECs, short-term aggregate risk is not of concern. Intermediate-term aggregate risks are identical to those for short-term exposure, and are not of concern.

Aggregate cancer risks were also not of concern, provided that risk mitigation measures are implemented. The drinking water EECs (for both surface and ground water sources) were less than the DWLOCs, regardless of the source of drinking water. The DWLOC for all scenarios considered ranged from 32.4 to 39.3 ppb, and the highest modeled chronic (average) drinking water EEC, from the Florida citrus use was 18.6 ppb for surface water and 0.08 ppb for ground water. Therefore, the cancer aggregate risks are not of concern for all population subgroups.

Occupational Risk

EPA assessed occupational exposure to carbaryl using data from the Pesticide Handler Exposure Database (PHED); Agricultural Re-entry Task Force (ARTF); Outdoor Residential Exposure Task Force (ORETF); and proprietary data, including chemical-specific data submitted by the technical registrant for carbaryl. Occupational exposure to carbaryl is of concern to the Agency and mitigation measures are necessary both for handlers and postapplication workers. Most scenarios can be mitigated with the addition of personal protective equipment or engineering controls for handlers, or longer reentry intervals for postapplication workers.

Handler Risk. Anticipated use patterns and current labeling for carbaryl indicate 28 major occupational exposure scenarios which can result in handlers receiving dermal and inhalation exposures to carbaryl. These exposure scenarios are based on the chemical formulations, equipment and techniques that handlers can use to make carbaryl applications. Within the 28 major occupational exposure scenarios assessed, about 140 different crop/rate/acreage calculations were made. Most of these risk calculations (about 110) were not of concern with the use of some level of PPE, though generally the level of PPE needed was higher than presently required on the current label, which is a single layer of clothing and gloves, but no respirator. For carbaryl, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern. These handler risk concerns can be mitigated provided that registrants implement the changes described in the summary of mitigation measures.

Postapplication Risk. The Agency evaluated postapplication (reentry) risks to workers who enter areas previously treated with carbaryl. EPA estimated postapplication exposures over time for workers involved in low, medium, and high contact activities, and determined worker MOEs at various time intervals after carbaryl application. The Agency then set restricted entry intervals (REIs) to ensure that workers wearing long-sleeve shirt, long pants, shoes, and socks could safely re-enter treated areas. Because re-entry risks are of concern for many crops and scenarios at the currently labeled REI of 12 hours, the REI is being lengthened for many crops.

Ecological Risk

The Agency conducted a screening level ecological risk assessment to determine potential impact of carbaryl use on nontarget terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for carbaryl. Based on this assessment, ecological risks are also of concern. Mitigation measures will address these risk concerns.

Birds and Mammals. The Agency has some chronic risk concerns for birds for exposure scenarios using the highest application rates for carbaryl (7.5 to 16 lb ai/A). EPA also identified some acute and chronic risk concerns for mammals, with acute RQs ranging from less than 0.01 to 12 and chronic RQs ranging from 0.2 to 51. These risk concerns are mitigated by reducing application rates.

Insects. EPA has concerns for adverse effects of carbaryl on honeybees based on the high toxicity of carbaryl to insects and reports of poisoning incidents. The Agency also received comments from Minnesota bee keepers concerned about the adverse impacts of local carbaryl use on their bee hives. To mitigate the risk to bees, revised bee advisory statements are to be

added to all end-use product labels.

Aquatic Organisms. The Agency has some risk concerns for the impacts of carbaryl on aquatic organisms. Acute, but not chronic, risks are of concern for freshwater fish; at maximum label rates, acute RQs range from 0.09 to 0.19, and chronic RQs range from 0.03 to 0.2. There are no available data to evaluate the impacts of carbaryl on saltwater fish. Both acute and chronic risks are of concern for freshwater aquatic invertebrates, with acute RQs ranging from 5 to 30 and chronic RQs ranging from 9 to 55. Acute risks are also of concern for saltwater invertebrates, with RQs ranging from 1.2 to 18. There are no data available to determine potential chronic impacts of carbaryl on saltwater invertebrates. In addition, EPA has some concerns for the chronic effects of carbaryl on amphibians, based on studies published in the open literature.

In addition, oyster growers in Washington State, who use carbaryl to control burrowing shrimp on oyster beds in tidal mudflats, have agreed to phase out the use of carbaryl on oyster beds.

Endangered Species. EPA consulted with the US Fish and Wildlife Service on the impacts of carbaryl use to endangered species in 1989. As a result of this consultation, the U.S. Fish and Wildlife Service issued a formal Biological Opinion on carbaryl in 1989, which identified reasonable and prudent measures and reasonable and prudent alternatives to mitigate the effects of carbaryl use on endangered species. The Agency is currently consulting with the National Marine Fisheries Service on potential effects of carbaryl on endangered species of salmon. (Freshwater fish were the major impacted species identified by the 1989 US Fish and Wildlife Biological Opinion.) Further, EPA is engaged in a proactive conservation review with US Fish and Wildlife Service and National Marine Fisheries to determine the best process for assessing impacts of pesticides on endangered species.

Regulatory Decision

The Agency is issuing this IRED for carbaryl, as announced in a Notice of Availability published in the *Federal Register*. This IRED document includes guidance and requested time frames for making any necessary label changes for products containing carbaryl. The Agency is providing a final 60-day opportunity for stakeholders to respond to the carbaryl interim risk management decision. If substantive information is received during the comment period, which indicates that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, appropriate modifications will be made at that time.

Note that neither the tolerance reassessment nor the reregistration eligibility decision for carbaryl can be considered final, however, until the cumulative risks for all carbamate pesticides are considered. The cumulative assessment may result in further risk mitigation measures for carbaryl.

Summary of Mitigation Measures

EPA believes that carbaryl is eligible for reregistration provided the following actions are implemented, combined with the general mitigation measures previously described:

Dietary Risk

- No label changes are necessary, however, certain confirmatory data are required.

Residential Risk

- For the garden/ornamental dust on vegetables/ornamentals scenario, all end-use products are to be packaged in ready-to-use (RTU) shaker can containers, with no more than 0.05 lb ai/container.
- For the lawn care hose-end sprayer for liquid lawn broadcast scenario, all liquid formulation end-use products for lawncare are to be packaged in pint-size RTU hose-end sprayers. Because of postapplication risk concerns, the technical registrants, Bayer CropScience and Burlington Scientific, have sent EPA amended labels with this use deleted from their technical products. The technical registrants have also submitted voluntary cancellation letters for this use, effective July 1, 2004. Use of liquid formulation products for turf/lawn applications (except for applications to sod farms, golf courses, commercial landscape areas, and cemeteries) is limited to spot treatments only (less than 1000 square feet), with the use of a RTU sprayer. Voluntary pharmacokinetics data are being generated to refine postapplication risks from broadcast applications to turf lawns with liquid formulations. **[NOTE: Bayer CropScience has submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]**
- The following uses are to be cancelled: all pet uses (dusts and liquids, except for collars); belly grinder application of granulars and baits for spot treatment; hand application of granular and baits for ornamentals and gardens; and aerosols for various uses. Also, confirmatory data on pet collars are required.
- Confirmatory transferable turf residue (TTR) data on granular formulations applied to lawns are required.

Occupational Risk

Handler Risks

- The following uses and application methods are to be cancelled: wheat use; broadcast applications using liquid formulations on residential lawns and turf, except for golf courses **[see NOTE above]**; pet uses (with the exception for pet collars); applications with hand, spoon, and bellygrinder.
- The following maximum application rates are to be reduced: mosquito control - from 1.0 to 0.2 lb ai/A; citrus (entire US except California) - from 7.5 to 5 lb ai/A; California citrus - from 16 to 12 lb ai/A; Florida Special Local Need (FIFRA Sec. 24c) for Diaprepes root weevil control on citrus - from 10 to 8 lb ai/A; and asparagus - preharvest

rate from 2 to 1 lb ai/A, and postharvest rate from 4 to 2 lb ai/A.

- Aerial applications are prohibited for the following: wettable powder formulations; and granular and bait formulations applied to corn (field, pop, and sweet), grain sorghum, alfalfa, rice, and sunflowers.
- PPE and engineering controls for aerial/chemigation applications: closed systems designed to provide dry disconnect/dry break links with the product container for protection of mixers and loaders. Only formulations compatible with these closed systems may be used (e.g., emulsifiable concentrates and soluble concentrates); enclosed cockpits for aerial applicators; and mechanical flaggers or global positioning system (GPS) equipment that negates the need for human flaggers.
- PPE and engineering controls for ground airblast applications (applicators): enclosed cabs for applications to olives; enclosed cabs for applications to citrus trees in California; enclosed cabs for applications to citrus trees in Florida under Section 24(c) Special Local Need at 8 lb ai/A; and for all other ground airblast applications the following PPE must be worn: coveralls over long-sleeved shirt and long pants, chemical resistant gloves, protection factor 10 respirator (half-mask, air purifying), WPS head protection, shoes and socks.
- PPE and engineering controls for granular and bait formulation (loaders and/or applicators): long-sleeved shirts and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise; and Ready-to-Disperse containers are stipulated for Ornamental and Garden uses to administer product without direct contact of the formulation to the applicator.
- PPE for liquid formulation (e.g., emulsifiable concentrates, soluble concentrates) (mixer/loaders and/or applicators): long-sleeved shirt and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise.
- PPE and packaging for wettable powder formulation: water soluble packaging (an engineering control) is stipulated for all wettable powder formulations; long-sleeved shirts and long pants, chemical resistant gloves, shoes and socks.

Postapplication Risks

- For brassica crops: use is restricted to applications only within 30 days of crop emergence/transplanting; REI = 5 days
- For bunch/bundle crops: REI = 8 days
- For cucurbit vegetables: REI = 3 days
- For roses: REI = 7 days
- For stone fruits: for a 3 lb ai/A rate, the REI = 12 hours for all activities; however, workers may not enter treated areas to hand thin until 7 days after application. For 4 lb ai/A rate in California only, the REI = 3 days for all activities; however, workers may not enter treated areas to hand thin until 7 days after application.
- For citrus crops: the maximum application rate is reduced to 5 lb ai/A rate with an REI =

24 hours; for FL §24(c) registration, the maximum rate is reduced to 8 lb ai./A with an REI = 5 days; and maximum application rate for California only is reduced to 12 lb ai/A with an REI = 5 days.

- For eggplant, bell/chili peppers, and tomatoes: REI = 2 days
- For leafy vegetables: use is restricted for applications only within 30 days of crop emergence/transplanting
- For strawberries: REI = 4 days
- For stringbeans, dry beans/peas, chick peas and green peas: REI = 5 days
- For alfalfa, forage, flax, peanuts, rice, and sugarbeets: REI = 2 days
- For almonds, hazelnuts (filberts), macadamia, pistachios, and walnuts: REI = 10 days
- For olives: REI = 14 days
- For table beets and turnips when harvested for greens: use is restricted for applications only within 30 days of crop emergence/transplanting
- For table beets, carrots, potatoes, sweet potato, turnips when harvested for roots: REI = 4 days
- For asparagus: for pre-harvest applications, the maximum application rate is reduced to 1 lb ai/A with a REI = 24 hours; and for post-harvest applications, the maximum application rate is reduced to 2 lb ai/A with an REI = 24 hours
- For corn and sorghum: REI = 4 days
- For seed corn: REI = 4 days for all activities; however, workers may not enter treated areas to hand detassel until 30 days after application
- For sunflowers: REI = 24 hours
- For sweet corn: prohibition of hand harvesting and the REI = 3 days
- For sod farms: REI = 12 hours for all activities; however, workers may not reenter treated areas to harvest sod until 9 days after application
- For blackberries, raspberries, highbush blueberries and pole beans: REI = 2 days
- For grapes: east of the Rocky Mountains the REI = 48 hours; west of the Rocky Mountains the REI = 7 days

Ecological Risk

To address ecological risks, the following mitigation is required:

- To address toxicity concerns for honey bees, a bee protection statement must be added to the Environmental Hazards section of carbaryl product labels, as follows:
“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”
- Several mitigation measures required to address residential and occupational risks, described above, will also address risks to terrestrial and aquatic organisms, including:
 - Reducing maximum application rates for mosquito control, citrus, and asparagus;
 - Canceling use on wheat;
 - Prohibiting certain aerial applications, and
 - Canceling liquid broadcast applications to home lawns. **[NOTE: Bayer CropScience has submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]**

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 (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 hazards 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 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 tolerance reassessment during reregistration. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Carbaryl belongs to a group of pesticides called carbamates, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. Although FQPA significantly affects the Agency’s reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency’s revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the interim reregistration eligibility decision (IREDD) for carbaryl. This action is intended to be only the first phase in the reregistration process for carbaryl. The Agency will eventually proceed with its assessment of the cumulative risk of the carbamate pesticides and issue a final reregistration eligibility decision (RED) for carbaryl.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- C Applying the FQPA 10-Fold Safety Factor
- C Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- C How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- C Refining Dietary (Food) Exposure Estimates

- C Refining Dietary (Drinking Water) Exposure Estimates
- C Assessing Residential Exposure
- C Aggregating Exposure from all Non-Occupational Sources
- C How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- C Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- C Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above.

This 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 resulting from public comments and other information; Section IV presents the Agency's decision on interim reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices include Data Call-In (DCI) and other information. The revised risk assessments and related addenda are not included in this document, but are available in the public docket, the electronic docket at www.epa.gov/edockets, and on Office of Pesticide Programs web page at www.epa.gov/pesticides/reregistration.

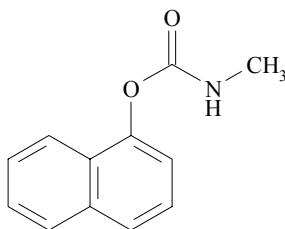
II. Chemical Overview

A. Regulatory History

Carbaryl is a carbamate insecticide and molluscicide that was first registered in 1959 for use on cotton. Carbaryl has many trade names, but is most commonly known as Sevin. In 1980, the Agency published a position document summarizing its conclusions from a Special Review of carbaryl, and concluded that risk concerns, particularly concerning teratogenicity, did not warrant cancellation of the registration for carbaryl. A Registration Standard, issued for carbaryl in 1984 and revised in 1988, described the terms and conditions for continued registration of carbaryl. Carbaryl is currently registered for use on over 400 sites, and there are more than 140 tolerances for carbaryl in the Code of Federal Regulations. At present, carbaryl is registered for domestic outdoor uses on lawns and gardens, and indoors in kennels and on pet sleeping quarters. It is also currently registered for direct application to cats and dogs (collar, powder, and dip) to control fleas and ticks.

B. Chemical Identification

Carbaryl:



- Common Name: Carbaryl
- Chemical Name: 1-naphthyl methylcarbamate
- Chemical Family: Carbamate
- Case Number: 0080
- OPP Chemical Code: 056801
- Empirical Formula: $C_{12}H_{11}NO_2$
- Molecular Weight: 201.2 g/mole
- CAS Registry No.: 63-25-2
- Common Trade Name: SEVIN
- Basic Manufacturer: Bayer CropScience

The physical state of carbaryl is a white to light tan solid with a melting point of 142°C; vapor pressure of 0.000041 mm Hg at 26°C; specific gravity of 1.23 at 20°C; and an octanol/water partition coefficient (K_{ow}) of 217. Its solubility is: water (40 ppm at 25 C), dimethyl formamide (#45 g/100 mL); acetone, cyclohexanone, and isophorone (#25 g/100 mL); methylethyl ketone (#20 g/100 mL); dichloromethane (#15 g/100 mL); ethanol and ethyl acetate (#10 g/100 mL); mixed aromatic solvents and xylene (#3 g/100 mL); and kerosene (#1 g/100 mL).

C. Use Profile

The following information is limited to the currently registered uses of carbaryl. During the reregistration process, Bayer CropScience, the primary technical registrant, voluntarily canceled the direct use on poultry and in poultry houses and deleted it from the carbaryl technical label. Therefore, this use is not considered in this IRED. EPA issued notices in the Federal Register on October 24, 2001 (66 FR 53789) and December 6, 2002 (67 FR 72673).

Type of Pesticide

Insecticide.

Summary of Use Sites

Food and Feed Crops. Alfalfa, almond, apple, apricot, asparagus, beans (dried type), beets, blackberry, blueberry, boysenberry, broccoli, brussels sprouts, cabbage, caneberries, carrot (including tops), cauliflower, celery, cherry, chestnut, Chinese cabbage, Chinese okra, clover, collards, commercial fishery water systems, corn, cotton, cowpea/blackeyed pea, cowpea/sitao, crabapple, cranberry, cucumber, dandelion, dewberry, dill, eggplant, endive (escarole), field corn, field peas, filbert (hazelnut), flax, grapefruit, grapes, grass forage/fodder/hay, hanover salad, horseradish, kale, kohlrabi, lemon, lentils, lettuce (head, crisphead types, leaf types), lime, loganberry, longan, loquats, mango, melons, millet (proso), mustard, nectarine, okra, olive, orange, oriental pears, oyster beds, parsley, parsnip, pastures, peach, peanuts, pear, peas (dried type), peas, pecan, pepper, pistachio, plum, popcorn, proso millet, prune, pumpkin, quince, radish, rangeland, raspberry (black, red), rhubarb, rice, rutabaga, salsify, sorghum, southern pea, soybean, spinach, squash, strawberry, succulent beans (lima and snap), succulent peas, sugar beet, sunflower, sweet corn, sweet potato, Swiss chard, tangerine, tomato, trefoil, turnip, turnip, walnut (english/black), wheat, white/irish potato.

Non-Food Crops - Christmas tree plantations, flax, grasses grown for seed, tobacco, turf (ornamental sod farm).

Residential Use Sites - Fire ant mounds, Lawns and Ornamentals (lawns, house perimeter, shrubs and flowers); Trees (fruits, nuts, and shade/ornamental); Vegetables (beans, berries, broccoli, brussels sprouts, cabbage, carrots, cauliflower, corn, cowpeas, cucumbers, eggplant, herbs, lettuce, melon, okra, onions, peas, peppers, potatoes, summer squash, tomatoes); and Pet uses (dogs, cats, and housing/bedding). Aside from pets, there are no other indoor uses (such as crack and crevice uses). Lawn and

ornamental care includes professional applications. Some residential areas in California are also treated to control the spread of an agricultural pest (glassy winged sharp shooter) which vectors a plant disease (Pierce's disease).

Other Use Sites - Agricultural fallow/idleland and Agricultural rights-of-way/fencerows/hedgerows, Commercial/Industrial/Institutional Premises and Equipment, Commercial/Institutional/Industrial premises/Equipment (Outdoor), Forestry uses, Nonagricultural Uncultivated Areas - Outdoor buildings/structures, rights-of-way/fencerows/hedgerows, uncultivated areas/soils, and recreational areas, Ornamental Lawns and Turf - commercial/industrial lawns, golf course turf, Ornamental sod farm (turf), recreational area lawns, urban areas, wide area/general outdoor treatment (public health use), Ornamentals (non-flowering plants, woody shrubs and vines, ornamental and/or shade trees, and greenhouse uses on certain ornamentals).

Public Health - Carbaryl is registered for use as a mosquito adulticide, but the Centers for Disease Control and Prevention is not aware of any significant use in public health programs.

Target Pests

On Fruit Trees and Nut Trees: apple aphid, apple maggot, apple mealybug, apple rust mite, apple sucker, bagworms, California pearslug, codling moth, eastern tent caterpillar, European apple sawfly, eyespotted bud moth, fruittree leafroller, green fruitworm, Japanese beetle, lesser appleworm, lygusbugs, orange tortrix, pear leaf blister mite, pear psylla, pear rust mite, periodical cicada, plum curculio, redbanded leafroller, scale insects, tarnished plant bug, tentiform leafminers. White apple leafhopper, wooly apple aphid, navel orangeworm, peach twig borer, san Jose scale, European raspberry aphid, omnivorous leafroller, raspberry sawfly, rose chafer, snowy rose tree cricket, blueberry maggot, sherry fruitworm, cranberry fruitworm, European fruit lecanium, chestnut weevil, avocado leafroller, california orangedog, citrus cutworm citrus root weevil, fullers rose beetle, orange tortrix, western tussock moth, west Indian sugarcane borer, filbert aphid, filbert leafroller, filbertworm, eight spotted forester, grape berry moth, grape leafroller, grape leafhopper, June beetles, saltmarsh caterpillar, western grapeleaf skeletonizer, western yello-striped armyworm, olive scale, apple pendemis, cucumber beetles, European earwig, lesser peach tree borer, oriental fruit moth, peach twig borer, tarnished plant bug, tussock moth, black margined aphid, fall webworm, pecan leaf phylloxera, pecan nut casebearer, pecan spittlebug, pecan stem phylloxera, pecan weevil, twig girdler, walnut caterpillar, calico scale.

On Terrestrial Food and Feed Crops: blister beetles, Mexican bean beetles alfalfa caterpillar, beanleaf beetle, cucumber beetle, grasshoppers, green cloverworm, japanese beetle, leafhoppers, three cornered alfalfa hopper, thrips, velvetbean caterpillar, alfalfa weevil larvae, armyworm, cloverhead weevil, cotton fleahopper, cotton leafworm, flea beetle, striped blister beetle, boll weevil, bollworms, cotton leafperforator, plant bugs, saltmarsh caterpillar, corn earworm, corn rootworm adults, southwestern corn borer, japanese beetle, European corn borer, cutworms, Egyptian alfalfa weevil larvae, Essex skipper, European alfalfa beetle, fall armyworm, lygus bugs, webworms, yellowstriped

armyworm, asparagus beetle, apache cicada, stinkbugs, tarnished plant bug, webworm, cowpea curculio, aster leafhoppers, harlequin bug, imported cabbageworm, melonworm, pickleworm, squash bugs, pink bollworm, range caterpillars, thrips, white grubs, white fringed beetle adult, Colorado potato beetle, pea leaf weevil, tomato fruitworm, tomato hornworm, grape colaspis, sweet potato weevil, tortoise beetles, green June beetle grubs, budworms, cereal leaf beetle (except in CA).

On Ornamentals: blister beetle, flea beetle, boxelder bug, japanese beetle, June beetle, lace bug, leafhopper, leafroller, mealybug, plant bug, psyllids, rose aphid thrips, apple aphid, bagworm, birch leafminer, cankerworm, eastern spruce gall aphid, elm leaf aphid, elm leaf beetle, gypsy moth, mimosa webworm, oak leafminer, orange tortrix, periodical cicada, puss caterpillar, rose aphid, rose slug, sawfly, scale, tent caterpillar, thrips, willow leaf beetle.

On Lawns/Turf: ants, bluegrass billbug, chinch bug, cut worm, crane fly, earwig, European chafer, fall armyworm, fleas, green June beetle, leafhopper, millipedes, mosquitoes, sod webworms (lawn moths), *ixoides spp.* (deer tick, bear tick, black legged tick), *amblyomma spp.* (lone star tick).

In and Around Commercial Buildings: ants, crickets, firebrats, silverfish, bees, wasps, brown dog ticks, fleas, carpenter ants, scorpions, centipedes, earwigs, millipedes, cockroaches, spiders.

Outdoors: ants, bees, wasps, brown dog ticks, carpenter ants, centipedes, cockroaches, crickets, earwigs, firebrats, fire ants (mound treatment), silverfish, fleas millipedes, scorpions and spiders.

Dogs and Cats: fleas and ticks, on animal and in bedding/housing.

Formulation Types Registered

Formulation types registered for carbaryl end-use products are listed in Table 1.

Table 1. Carbaryl End-Use Product Formulations

Formulation Type	Number of Products	Range of Percent Active Ingredient
Emulsifiable Concentrates & Flowable Concentrates	57	0.3 - 80
Wettable Powders & Soluble Granules	36	0.5 - 95
Dusts	130	0.3 - 80
Granular	45	1.43 - 15
Bait	55	1.3 - 13
Dips, Shampoos	2	0.5 - 60

Formulation Type	Number of Products	Range of Percent Active Ingredient
Pet collars (treated articles)	2	8.5 - 16
Ready to Use Pump Sprayers & Aerosol Cans	6	0.12 - 1

Methods of Application

Equipment -Typical application methods in agriculture include groundboom, airblast, chemigation, and aerial. Carbaryl can also be applied using handheld equipment such as low and high pressure handwand sprayers, backpack sprayers, compressed air sprayers, and turfguns. Homeowners can apply carbaryl with equipment that includes trigger sprayers, hose end sprayers, ready-to-use (RTU) dust packaging, belly grinders, push-type spreaders, and outdoor foggers.

Label Use Rates

Carbaryl rates vary depending on the crop. The maximum amount of carbaryl that can be used in a *season* varies from of 1 to 20 pounds active ingredient per acre (lb ai/A). The maximum amount of carbaryl that can be used in a *single application* is 16 lb ai/A (California citrus only). Examples of use sites that have relatively high application rates include citrus, tree nut crops and golf courses. Examples of use sites that have low application rates include certain field and row crops. Depending on the crop, the maximum *number* of carbaryl applications per season can range from 1 to 8.

Use Classification

Nonrestricted

D. Estimated Usage of Carbaryl

This section summarizes the best estimates available for many of the pesticide uses of carbaryl, based on available pesticide usage information for 1992 through 2001. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns, as well as the variability in using data from various information sources. Based on available usage information for the years 1992 through 2001, an annual estimate of total carbaryl domestic usage in agriculture averaged approximately 1.9 million pounds of active ingredient for over 1.3 million acres treated. In 1998, Bayer had estimated approximately 3.9 million pounds total active ingredient sold. The most recent data available to EPA reflects a decline in agricultural usage; carbaryl usage for 2001 was between 1 to 1.5 million pounds active ingredient.

The largest agricultural markets for carbaryl (as the percentage of pounds active ingredient used annually) are Apples (13%), Pecans (10%), Grapes (7%), Alfalfa (6%), Oranges (6%), and Corn (6%). Most of this use was in California, Michigan, Indiana, Illinois, Ohio, Texas, Georgia, Oklahoma, Mississippi, and Arkansas. Crops with a high percentage of the total U.S. planted acres treated include Avocados (38%), Asparagus (35%), Okra (33%), Cranberries (32%), Apples (24%), Blueberries (22%), Sweet Cherries (22%), Pumpkins (18%), and Strawberries (17%). Table 2 lists crops for which EPA has survey data on carbaryl usage.

Table 2. Estimated Carbaryl Usage by Agricultural Site

Use Site	Pounds Active Ingredient Applied	Percent of Crop Treated	
	Weighted Average	Weighted Average	Estimated Maximum
Alfalfa	121,000	1	1
Almonds	6,000	1	1
Apples	242,000	24	35
Asparagus	36,000	35	45
Beans, Dry	4,000	1	3
Beans, Lima, Fresh	<500	3	8
Beans, Snap, Fresh	11,000	10	14
Beans, Snap, Proc.	26,000	10	14
Beets	1,000	16	26
Blackberries	2,000	18	30
Blueberries	26,000	22	44
Broccoli	2,000	3	6
Brussels Sprouts	<500	15	38
Cabbage, Chinese	1,000	18	39
Cabbage, Fresh	3,000	2	5
Canola	<500	<1	5
Cantaloupes	11,000	9	13
Carrots	9,000	4	6
Cauliflower	1,000	1	3
Celery	1,000	1	4
Cherries, Sweet	30,000	22	33

Use Site	Pounds Active Ingredient Applied	Percent of Crop Treated	
	Weighted Average	Weighted Average	Estimated Maximum
Cherries, Tart	12,000	10	20
Collards	<500	5	11
Corn	103,000	<1	0
Cotton	28,000	<1	1
Cranberries	21,000	32	68
Cucumbers	12,000	7	22
Cucumbers, Proc.	5,000	3	8
Eggplant	10,000	6	13
Flax	1,000	<1	1
Grapefruit	27,000	6	11
Grapes	134,000	7	10
Hazelnuts (Filberts)	2,000	3	8
Lemons	2,000	1	3
Lettuce, Head	5,000	2	4
Melons, Honeydew	3,000	11	36
Nectarines	7,000	6	13
Oats/Rye	5,000	<1	<1
Okra	2,000	33	53
Olives	11,000	7	13
Onions, Dry	22,000	3	11
Oranges	105,000	2	4
Pasture	27,000	<1	<1
Peaches	62,000	9	12
Peanuts	48,000	3	5
Pears	3,000	3	5
Peas, Dry	3,000	1	5
Peas, Green	3,000	1	1

Use Site	Pounds Active Ingredient Applied	Percent of Crop Treated	
	Weighted Average	Weighted Average	Estimated Maximum
Peas, Green, Processed	3,000	1	2
Pecans	207,000	15	18
Peppers, Bell	4,000	5	12
Peppers, Sweet	8,000	8	14
Pistachios	23,000	13	34
Plums	11,000	5	8
Potatoes	34,000	2	3
Pumpkins	21,000	18	24
Raspberries	1,000	3	7
Rice	25,000	1	1
Safflower	<500	1	5
Sod	<500	<1	3
Sorghum	25,000	<1	<1
Soybeans	74,000	<1	<1
Squash	9,000	13	24
Strawberries	25,000	17	27
Sugar Beets	28,000	1	3
Sugarcane	<500	<1	<1
Sunflower	7,000	<1	1
Sweet Corn, Fresh	23,000	3	7
Sweet Corn, Processed	12,000	1	3
Sweet Potatoes	24,000	17	38
Tobacco	16,000	1	3
Tomatoes, Fresh	15,000	6	10
Tomatoes, Processed	31,000	6	9
Walnuts	2,000	1	2
Watermelons	11,000	8	12

Use Site	Pounds Active Ingredient Applied	Percent of Crop Treated	
	Weighted Average	Weighted Average	Estimated Maximum
Wheat, Spring	14,000	<1	<1
Wheat, Winter	38,000	<1	<1
Woodland	28,000	<1	<1
<i>Approx. Total lbs :</i>	<i>1,919,500</i>		
Source: EPA Quantitative Usage Analysis, December 17, 2002.			

III. Summary of Carbaryl Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of the human health and ecological risk assessments, and to enhance understanding of the conclusions reached in the assessments. The list of EPA's revised human health and ecological risk assessments, and supporting information that were used to formulate the findings and conclusions for the carbamate pesticide carbaryl can be found in the docket and on the Internet at <http://www.epa.gov/edocket/>.

EPA issued its preliminary risk assessments for carbaryl on August 28, 2002 for public comment (67 FR 55233). Based on the comments received and additional information, the Agency revised the risk assessments and released them for public comment on April 2, 2003 (68 FR 16030). The public comment period on the revised risk assessments ended June 2, 2003. In response to comments and studies submitted during the most recent public comment period, as well as corrections identified by the Agency, EPA issued the following documents amending the risk assessments or providing further data on carbaryl usage:

- C *Final Report of Carbaryl EEC's for Drinking Water, Additional Simulations*, dated June 25, 2003.
- C *Carbaryl Acute Dietary Assessment Including Drinking Water*, dated June 25, 2003.
- C *Carbaryl: Risk Mitigation Addendum for Phase 5 Risk Assessment*, dated June 23, 2003.
- C *Biological and Economic Assessment for Carbaryl Use on Grapes: Impacts from Changes in the Re-entry Interval*, dated June 19, 2003.
- C *Benefits Assessment for Carbaryl Use in Citrus: Impact of Extending the Re-entry Interval*, dated June 24, 2003.
- C *BEAD Analysis of Carbaryl Use on Residential Lawns*, dated June 16, 2003.
- C *Summary Tables of Carbaryl Benefit Information on Selected Crops*, dated May 23, 2003.

A. Human Health Risk Assessment

1. Dietary Risk from Food

a. Toxicity and Carcinogenicity

The Agency has reviewed all toxicity studies submitted, and has determined that the toxicity database for carbaryl is substantially complete for all currently registered uses. Carbaryl is a carbamate pesticide, and its primary mode of toxic action is through cholinesterase inhibition (ChEI) after single or multiple exposures. In most of the toxicity studies in which ChEI was measured, it was the endpoint used to set the Lowest Observed Adverse Effect Level (LOAEL) and the No Observed Adverse Effect Level (NOAEL). Carbaryl is a reversible inhibitor of cholinesterase. In an acute time-course study in the rat, following a single gavage dose of carbaryl, brain cholinesterase inhibition had returned to pre-treatment values by 8 hours in the 10 mg/kg group, by 24 hours in the 30 mg/kg group, and by 48 hours in the 90 mg/kg group. No cumulative effects were shown in a subchronic neurotoxicity feeding study; cholinesterase inhibition was similar when determined at week 4, 8, or 13.

The Agency has also considered the toxicity of carbaryl degradates found in the environment, as well as the metabolites of carbaryl found in plants and animals. The major degrade of carbaryl is 1-naphthol, which EPA has determined not to be toxicologically significant relative to the most sensitive endpoint for carbaryl, cholinesterase inhibition. Therefore, EPA has determined that only carbaryl *per se* (parent carbaryl) should now be considered in the tolerance expression for plant commodities. Of the metabolites identified in livestock commodities, five are considered significant and part of the tolerance expression for all endpoints of dietary concern for livestock commodities only: carbaryl; 5,6-dihydro-5,6-dihydroxy carbaryl; and 5-methoxy-6-hydroxy carbaryl and all residues which can be hydrolyzed to carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, or 5-methoxy-6-hydroxy carbaryl under acidic conditions. The Agency included these compounds in the dietary risk assessment for carbaryl, and in the reassessment of carbaryl tolerances for livestock commodities only.

Carbaryl is classified as “likely to be carcinogenic to humans,” based on increased incidence of vascular tumors in mice. Cancer risks are calculated by multiplying dietary exposure by the Q_1^* , or unit risk, which is a quantitative dose response factor, by the lifetime average daily dose. The Q_1^* for carbaryl is $8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$.

For more detail on the toxicity and carcinogenicity of carbaryl beyond what is found in the human health risk assessment for carbaryl, see the *Toxicology Chapter for Carbaryl*, dated May 24, 2002, and the *Hazard Identification Assessment Review Committee (HIARC) Report for Carbaryl* dated May 9, 2002. To examine how these toxicity endpoints relate to dietary risk, see the *Revised Dietary Risk Assessment for Carbaryl*, dated March 18, 2003.

b. FQPA Safety Factor

The special FQPA Safety Factor was removed (reduced to 1x) for carbaryl. Determination of the FQPA safety factor was based on an analysis of all the toxicology data following the approach described in the 2002 guidance document, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, dated February 28, 2002. This analysis entails: (1) a determination of the level of concern for effects in the context of all available toxicity data; (2) identification of any residual concerns after establishing toxicity endpoints and traditional uncertainty factors; and (3) a determination as to whether residual concerns (if any) can be addressed by a special FQPA safety factor.

EPA applied a standard uncertainty factor of 3X to address uncertainty from extrapolating a NOAEL from a LOAEL for chronic exposures based on a 1-year chronic dog feeding study. The HIARC was confident that the 3X factor used to extrapolate the NOAEL was adequate (see *Hazard Identification Assessment Review Committee (HIARC) Report for Carbaryl* dated May 9, 2002). Carbaryl was re-evaluated by the HIARC and FQPA Safety Factor Committees several times as new toxicity studies were submitted (developmental toxicity in rats and rabbits and two-generation reproduction toxicity). Submission of these studies reduced uncertainties originally present in the carbaryl database. Carbaryl was also re-evaluated because new measurements in the developmental neurotoxicity study were made; however, the NOAEL and conclusions of this study did not change.

Based on the foregoing discussion, EPA has determined that the 1X special FQPA factor is adequate to protect infants and children. The toxicology database is complete, the risk assessment had well defined endpoints for the NOAELs (uncertainty for the chronic NOAEL is already addressed by a standard 3x FQPA Safety Factor), and therefore there are no remaining residual uncertainties in the exposure data. In the toxicology database, no quantitative or qualitative evidence of increased susceptibility in rat or rabbit fetuses following *in utero* exposure in the standard developmental studies was observed. There was a low level of concern for evidence of susceptibility seen in the developmental neurotoxicity study.

Despite this low level of concern, the Agency selected the NOAEL from the developmental neurotoxicity study in setting the acute RfD. Lending further support to this conclusion are the results of an EPA/ORD study titled *Neurotoxic Potential of Pesticides: Age-Related Effects of Pesticides Relevant to Youth in Agriculture*, Task # 51595E104. This acute toxicity study in rats found that adult rats were more sensitive to carbaryl toxicity than young rats. There was evidence of increased susceptibility in offspring in the 2-generation reproduction study; however, the Agency believes that the chronic reference dose (RfD) is protective of these effects, principally because the NOAEL used to set the chronic RfD is lower than the NOAEL in the 2-generation rat reproduction study.

The RfD equals the dose used to establish the NOAEL in animal studies, divided by conventional Uncertainty Factors (UF) to account for interspecies extrapolation (10X) and intraspecies variability (10X) for a total uncertainty factor of 100. In the case of the chronic

toxicity endpoint, an added uncertainty factor (3X) is used for extrapolating a NOAEL from a LOAEL, for an uncertainty factor of 300. Thus, the acute dietary RfD for carbaryl is the acute dietary NOAEL of 1 mg/kg/day (from the developmental neurotoxicity study in rat) divided by 100, equal to 0.01 mg/kg/day. The chronic RfD is the chronic dietary LOAEL of 3.1 mg/kg/day (chronic study in dog) divided by 300, which also equals 0.01 mg/kg/day (see Table 3).

c. Population Adjusted Dose (PAD)

The PAD is used to characterize the dietary risk of a chemical, and equals the RfD divided by the special FQPA Safety Factor. In the case of carbaryl, the FQPA Safety Factor is 1X; therefore, the PAD and RfD are identical. Table 3 below summarizes the toxicological dose and endpoints used in the carbaryl dietary risk assessment.

Table 3. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Dietary Assessment

Exposure Scenario	Dose (mg/kg/day) & Total UF	Special FQPA Safety Factor	Study and Endpoint for Risk Assessment
Acute Dietary <u>general population</u> including infants and children	NOAEL = 1 UF = 100	1	Developmental Neurotoxicity - rat LOAEL = 10 mg/kg/day based on increased incidence of changes in the functional observational battery (FOB) on first day of dosing in maternal animals Acute RfD and aPAD = 0.01 mg/kg/day
Chronic Dietary <u>all populations</u>	LOAEL = 3.1 UF = 300	1	Chronic toxicity - dog LOAEL = 3.1 mg/kg/day based on plasma and brain cholinesterase inhibition in females. Chronic RfD and cPAD = 0.01 mg/kg/day [Note: Study failed to identify NOAEL; therefore, additional 3x uncertainty factor was applied to extrapolate a NOAEL from the LOAEL.]
Cancer	Classification: likely to be carcinogenic to humans, based on increased incidence of vascular tumors in mice. The $Q_1^* = 8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$.		

d. Exposure Assumptions

The dietary (food) exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM-FCID™), that uses exposure and consumption data to calculate risk as a percentage of the PAD. The DEEM-FCID™ analysis evaluated individual food consumption as reported by respondents in the USDA 1994-1996 and 1998 Continuing Survey for Food Intake by Individuals (CSFII). For acute dietary (food) risk assessments, the entire distribution of consumption events for individuals is multiplied by a randomly selected distribution of residues (probabilistic analysis, referred to as "Monte Carlo") to obtain a distribution of exposures. For chronic dietary (food) risk assessments, a 3-day average consumption for each subpopulation is

combined with average residues in commodities to determine average exposures.

The anticipated pesticide residues on food have been extensively refined for the acute dietary assessment and were derived from: (1) monitoring data from USDA's Pesticide Data Program (PDP); (2) FDA's Surveillance Monitoring Program; (3) the percentage of the crop treated (estimated maximum percentage); and (4) data from crop field trials where there were insufficient PDP or FDA monitoring data. Field trial data were used for the following commodities: garden beets, turnips, mustards, dried beans, almonds, pecans, walnuts, field corn grain, rice, flax seed, okra, olive, peanuts, pistachio, and sunflower. The Agency also used data for two commodities, oranges and bananas, from the Carbamate Market Basket Survey (CMBS).

The CMBS is an industry-sponsored, year-long, national survey of carbamate residues on selected food commodities purchased at grocery stores. This survey collected up to 400 single-serving samples for 8 different crops (apple, banana, broccoli, grape, lettuce, orange, peach, and tomato). Residue data from a market basket survey are generally considered to provide a close approximation to residues potentially found at the "dinner plate." Survey data are generally considered the most appropriate data source for use in pesticide risk and exposure assessment. The CMBS survey protocol, however, included a step for rubbing while rinsing commodities, whereas the PDP survey calls for rinsing only. The added rubbing protocol introduces a degree of uncertainty in the reported survey results for carbaryl, which is a non-systemic, surface acting pesticide and thus more susceptible to residue loss from the added mechanical action of rubbing. The degree to which rubbing affected residue levels cannot be quantified. Because of this uncertainty, EPA developed its primary acute dietary (food) assessment using only the two CMBS crops that were essentially unaffected by the rubbing step because they are peeled before being eaten: oranges and bananas.

EPA did, however, do a separate analysis which included all the CMBS crop data for carbaryl. The CMBS survey data tend to support PDP monitoring data findings of detectable residues on commodities important to the diets of infants and children. The results of the separate assessment using all the CMBS crops is included in the following discussion.

e. Acute Dietary (Food) Risk

For carbaryl, a dietary risk estimate that is less than 100% of the aPAD is not of concern to the Agency. The Agency conducted a probabilistic (Monte Carlo) analysis which estimated a dietary (food) exposure of 93% of the aPAD at the 99.9th exposure percentile for the most highly exposed subpopulation (children 1 - 2 years). The acute dietary (food) risk for carbaryl is less than 100% of the aPAD for all subpopulations, and is therefore not of concern to the Agency. Results of the Agency's acute dietary risk assessment for food are summarized in Table 4.

Table 4. Acute Dietary (Food) Risk Estimates (included CMBS data for oranges and bananas)

Population Subgroup	99.9 th Percentile of Exposure	
	Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.004294	43
All Infants (< 1 year old)	0.006747	68
Children 1-2 years old	0.009390	93
Children 3-5 years old	0.008084	81
Children 6-12 years old	0.005434	55

In EPA's separate dietary assessment using data for all eight of the crops in the CMBS survey, the dietary risk (% of the aPAD) dropped to 86% of the aPAD for children 1-2 years old. Sensitivity analysis conducted by the Agency found that strawberry residues had the greatest impact on the dietary assessment.

f. Chronic Dietary (Food) Risk

For carbaryl, a dietary (food) risk estimate that is less than 100% of the cPAD is not of concern to the Agency. The chronic dietary exposure is estimated to be less than 1% of the cPAD for the most highly exposed subgroup (children 1-2 years). The chronic dietary (food) risk for carbaryl is therefore not of concern to the Agency. CMBS data are not used in chronic dietary assessment because they reflect single-serving data. Results of the Agency's chronic dietary risk assessment for food are summarized in Table 5 below.

Table 5. Chronic Dietary Risk Estimates

Population Subgroup	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000024	<1
All Infants (< 1 year old)	0.000055	<1
Children 1-2 years old	0.000076	<1
Children 3-5 years old	0.000054	<1
Children 6-12 years old	0.000029	<1

g. Cancer Dietary Risk Assessment

The Agency calculated dietary (food) exposure and cancer risk using the Q_1^* approach for carbaryl (i.e., linear, low dose extrapolation). Results indicate a maximum lifetime risk of 2.14×10^{-8} based on the exposures calculated for the general US population. EPA generally is not concerned about cancer risks lower than 1×10^{-6} , so the risk of cancer from dietary (food) exposure to carbaryl is not of regulatory concern.

2. Dietary Risk from Drinking Water

Exposure to pesticides from drinking water can occur through surface and ground water contamination. The Agency considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available. EPA assessed the potential for carbaryl to reach surface or ground water sources of drinking water based on available ground and surface water monitoring data, laboratory and field studies, and Agency models.

Carbaryl is fairly mobile, but is not likely to persist or accumulate in the environment. As such, it is difficult for monitoring studies to detect peak concentrations that can occur. EPA determined that currently available monitoring studies for carbaryl are limited in this regard, and did not use them to define peak values for carbaryl. Instead, EPA used computer modeling to estimate potential drinking water estimated environmental concentrations (EECs) from ground and surface water that could be expected from normal agricultural use. Modeling is designed to provide a screening-level high-end estimate of exposure. Although there are some limitations to the available monitoring data, these data are useful in characterizing modeled drinking water estimates of carbaryl exposure.

As previously mentioned, 1-naphthol is a primary degradate of carbaryl. However, the Agency is not concerned about levels of 1-naphthol in drinking water for this assessment. Due to the limited persistence of 1-naphthol, it is not expected to be found in significant concentrations resulting from carbaryl applications, and even if found, it is not a cholinesterase inhibitor nor is it expected to be carcinogenic.

The results of the Agency's drinking water analysis are summarized here. Details of this analysis are found in the following supporting technical documents: (1) *Revised EFED Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision*, dated March 18, 2003. (2) *Final Report of Carbaryl EEC's for Drinking Water - Additional Simulations*, dated June 30, 2003.

a. Surface Water

Based on available monitoring data and model estimates of carbaryl in drinking water, higher levels of carbaryl are generally found in surface water than in ground water sources, and are of greater potential risk concern.

Monitoring

Monitoring data for both surface water and groundwater are available, but are of limited utility for quantitative assessment. In surface water, based on the United States Geological Survey (USGS) National Ambient Water Quality Assessment (NAWQA) database, carbaryl is the second most widely detected insecticide, with a significant portion apparently transported to streams. Out of 5220 surface water samples analyzed, about 21% (1082) had detections greater than the minimum detection limit (0.063 ppb). The maximum observed concentration for carbaryl in surface water from the non-targeted USGS NAWQA study is 5.5 ppb. Another finding in the NAWQA data are that streams draining urban areas showed more frequent detections and higher concentrations than streams draining agricultural or mixed land use areas. EPA has limited tools for assessing the effects of pesticide use in urban and suburban settings on surface water and ground water quality; however, the Agency has concluded that the best estimate of exposure to carbaryl in urban areas at the present time is provided by available monitoring data. Nevertheless, these concentrations detected in urban drainages are not high enough to exceed level of concern thresholds for either human health through drinking water or for fish.

The EPA Storage and Retrieval (STORET) water quality database contains 8048 records indicating that analysis was done for carbaryl. Out of these, 432 reported concentrations above the detection limits, and 18 detections were above 1 ppb. Similar to the NAWQA database, the maximum reported detection is 5.5 ppb. The data in the STORET database are of limited usefulness, because of quality assurance/quality control and analytical methodology limitations, and are used to give a general indication of the occurrence pattern only. However, reported detections of carbaryl suggest that the compound is detected infrequently in surface water, at low levels.

Additional carbaryl monitoring data are available from a pilot reservoir monitoring study, which was conducted by the USGS and EPA to better understand pesticide behavior in reservoirs. Twelve reservoirs were sampled across the country with an emphasis on watersheds that were expected to be vulnerable to pesticide contamination, but with no emphasis on any particular pesticide. Samples were collected at the drinking water intake (312 total samples), the reservoir outflow (73 samples) and finished water from the water supply (225 samples). Not all sites had samples collected at the reservoir outflow. Carbaryl was detected at 5 separate sites, of which 4 sites had detections at the water intake, 2 sites had detections at the water outflow, and 2 sites had detections in finished water. These data are consistent with most other data which generally show widespread low-level contamination of carbaryl in surface water.

Furthermore, the registrant conducted a 3-year surface water monitoring study to provide the Agency with data to refine the drinking water exposure estimates for carbaryl. The main study goal is in line with data needed by the Agency to refine the drinking water risk. However, the implementation of the study (i.e., site selection and vulnerability characteristics of watersheds, and sampling frequency) was not consistent with the study goal. Despite these drawbacks, it was one of the better surface-water monitoring studies submitted to the Agency

over the past several years. The analytical methodology and method sensitivity, quality assurance procedures, study duration, and some aspects of the approach to site selection were sound. This study provides useful information on measured concentrations of carbaryl in selected surface waters of the United States. These data were used in conjunction with other monitoring data to characterize surface water modeling estimates of carbaryl exposure from surface water sources of drinking water.

Results of this 3-year monitoring study indicate that carbaryl was found in source drinking water (raw water) at low concentrations in the majority of sites (13 of 16 sites) selected to represent impacts from agricultural uses, despite the relative lack of vulnerability of these sites. Concentrations measured at these sites were low (roughly 0.002 to 0.031 ppb) in raw water and generally lower in treated drinking water; however, the highest concentration detected were in finished drinking water (0.181 ppb). Where residues were detected, frequency of detection in raw water samples ranged from a few percent of total samples (1-6 %) at 9 of the 13 sites, to about 20% of total samples (14 - 21%) at 4 sites. At several agricultural sites, low-level concentrations were measured over 3-4 week periods in weekly samples. Given the environmental fate characteristics of this compound, this is most likely the result of the volume of usage rather than the persistence of the compound.

Carbaryl was reported in the raw water of all four community water systems (CWSs) selected to represent impacts from home and garden uses. Concentrations measured in raw water at these sites were low (roughly 0.002 to 0.044 ppb), and detection frequencies ranged from approximately 1 to 20%. How representative these systems are of the home and garden use of carbaryl cannot be determined from the data provided; however, the lowest detection frequency occurred at the community water system (CWS) with the largest watershed size (exceeding the 70th percentile nationally). At one site, concentrations were reported in sequential weekly samples for a period of several months, likely due to the volume of usage. For all of the sites monitored, the data do not give any indication of the effectiveness of treatment in removing carbaryl, because raw and finished drinking water samples were collected at the same time.

Modeling

Drinking water EECs from surface water sources were derived from computer modeling with the EPA PRZM and EXAMS programs. Index reservoir scenarios corrected for Percent Cropped Area (PCA) for representative crops were also used. Drinking water EECs from modeling vary depending on different scenarios for geographic location, crop, and pesticide application rates. Calculated drinking water EECs are also adjusted for PCA, which represents the percentage of a watershed planted with crops that are treated with carbaryl. For most crops, including apples, citrus, and sugar beets, the default PCA of 87% for all agricultural land was used. Moreover, for Florida citrus and Georgia pecan simulations, an additional set of drinking water EECs were generated to more fully characterize exposure to carbaryl residues in drinking water from these uses using a provisional default regional PCA of 38%, which was used in the organophosphate cumulative assessment. For the field crops, including field and sweet corn, a refined PCA of 46% was applied.

The Agency initially estimated drinking water EECs for surface water using just the following five crop scenarios: (1) Ohio Sweet Corn, (2) Ohio Field Corn, (3) Pennsylvania Apples, (4) Minnesota Sugar Beets, and (5) Florida Citrus. These scenarios were selected to represent the range of crops and use rates likely to result in high-end EECs. After completion of the revised risk assessment for drinking water, the Agency identified a number of corrections which needed to be incorporated, including adjustment of two maximum application rates for the citrus and apple crop scenarios. Specifically, EPA increased the maximum application rates for citrus from 5 lbs ai/A to 7.5 lbs ai/A and for apples from 2 lbs ai/A to 3 lbs ai/A.

In addition, a number of new crop use scenarios have been added to the assessment to evaluate specific use patterns. For instance, EPA included an additional scenario to consider the drinking water impact of a California only use that allows a single, maximum application rate up to 16 lbs ai/A to control scale on citrus trees. Another scenario was added to assess the higher 10 lb ai/A application rate to citrus from a Section 24c (Special Local Need) registration in Florida. Furthermore, because the modeled EECs from carbaryl use on citrus in Florida (the worst-case scenario) were significantly higher than the other crops modeled, the Agency also assessed carbaryl use on peaches and pecans in Georgia to more fully characterize the range of potential EECs for other representative crops in this region. Table 6 presents the EECs for drinking water from surface water sources, which reflect different application rates and methods of application in some cases.

Table 6. Surface Water Modeled Concentrations of Carbaryl Residues

Crop Scenario	Use Rate lb ai/A	No. of Apps	Interval (days)	App Method	PCA	Concentrations (ppb)	
						Acute (peak)	Chronic (average)
Sweet corn - OH	2	8	14	aerial	0.46	57.3	5.5
Field corn - OH	2	4	4	aerial	0.46	51.3	2.7
Sugar beets - MN	1.5	2	14	aerial	0.87	48.2	2.2
Citrus - FL	7.5 5	2 1	3	aerial	0.87	410.4	18.6
Citrus - FL	7.5 5	2 1	14	airblast	0.38	172.8	7.0
Citrus - FL	4	2	14	airblast	0.38	108.7	3.8
Citrus - FL	10	2	14	aerial	0.87	646.8	23.3
Citrus - CA	7.5 5	2 1	14	airblast	0.87	22.7	1.6
Citrus - CA	16	1	--	aerial	0.87	87.9	3.4
Citrus - CA	16	1	--	airblast	0.87	34.6	1.3
Apple -PA	3	5	14	airblast	0.87	86.6	3.2

Crop Scenario	Use Rate lb ai/A	No. of Apps	Interval (days)	App Method	PCA	Concentrations (ppb)	
						Acute (peak)	Chronic (average)
Apple -PA	3	3	14	airblast	0.87	67.0	3.2
Pecan - GA	5	3	7	airblast	0.87	159.9	7.0
Pecan - GA	5	3	7	airblast	0.38	69.8	3.1
Peach - GA	5	3	7	aerial	0.87	44.9	2.0

b. Ground Water

Monitoring

In groundwater, US EPA's Pesticides in Groundwater Database reports carbaryl detections in only 0.4% of wells sampled in several states (i.e., California, Missouri, New York, and Rhode Island) as a result of normal agricultural use. Although the maximum concentration detected was 610 ppb in a well in New York, the typical measured concentrations were orders of magnitude lower. The EPA STORET database contains 9389 records showing analysis for carbaryl. Of these, only four reported concentrations above the detection limits, all from one well in Oklahoma in 1988, with concentrations between 0.8 and 1 ppb. In the USGS NAWQA program, 1.1% of groundwater samples recorded results above the detection limit (0.003 ppb), with a maximum concentration of 0.021 ppb. Detections were mainly from wheat, orchard and vineyard, and urban use areas.

Modeling

The drinking water EEC for ground water (0.8 ppb) was estimated using the Tier 1 SCI-GROW computer model based on the upper-end agricultural application rate for carbaryl use on citrus. SCI-GROW provides a screening value to use in determining exposure and the potential risk to human health from pesticide residues in ground water.

c. Effects of Drinking Water Treatment

There is some evidence which indicates that conventional drinking water treatment (i.e., coagulation, flocculation and settling) is expected to reduce carbaryl concentration by 43% of the concentration prior to treatment. In addition, ozone has been shown to be 99% effective at removing carbaryl from water, although there is also evidence which suggests that chlorine and hypochlorite may be ineffective at removing or degrading carbaryl. At this point in time, ozonation is only infrequently used for disinfection of public drinking water in the United States.

Based on the hydrolysis data, softening would be expected to substantially reduce carbaryl concentrations (via alkaline hydrolysis) as softening raises the pH of the water as high

as 11. Softening is used on ‘hard’ water that is high in calcium and magnesium to decrease the concentrations of these cations. The Agency currently does not have sufficient information to account for locations where water softening processes are utilized at public drinking water treatment facilities, and thus cannot systematically use this information in estimating drinking water concentrations at this time. To provide better quality data for model input parameters, and to confirm the Agency’s understanding that treatment significantly reduces drinking water EECs used to assess drinking water risks, the Agency is requiring drinking water treatment data as part of the IRED for carbaryl.

3. Residential and Occupational Risk

Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Noncancer risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational or residential exposure comes to a NOAEL. Occupational workers, such as individual farmers or custom applicators, can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Risk for all of these potentially exposed populations is also measured by an MOE. For carbaryl, MOEs greater than 100 are not of concern to the Agency for short- and intermediate-term residential and occupational exposure. The only exception is chronic (long term) exposures, which are not of concern if MOEs are 300 or higher. Cancer risks are discussed separately.

The occupational and residential risk assessments are summarized here. For more details, see the following documents: (1) *Carbaryl: Revised HED Risk Assessment – Phase 5*, dated March 14, 2003. (2) *Carbaryl: Revised Phase 5 Occupational and Residential Exposure Assessment*, dated February 20, 2003.

a. Toxicity

All risk calculations are based on the most current toxicity information available for carbaryl. The toxicological endpoints and other factors used in the residential and occupational risk assessments for carbaryl are listed in Table 7.

Table 7. Toxicological Endpoints for Residential and Occupational Risk Assessment

Exposure Scenario	Dose (mg/kg/day) & Total UF	Endpoint for Risk Assessment
Oral: Short-term Incidental Exposure (1 - 30 Days) [Residential Only]	NOAEL= 1 UF = 100	Developmental Neurotoxicity - rat LOAEL = 10 mg/kg/day based on increased incidence of FOB changes & decreases in RBC, whole blood, plasma, and brain cholinesterase
Oral: Intermediate-Term Incidental Exposure (30 days - several months) [Residential Only]	NOAEL= 1 UF = 100	Subchronic Neurotoxicity - rat LOAEL = 10 mg/kg/day based on increased incidence of FOB changes; decrease in RBC, whole blood, plasma & brain cholinesterase.

Exposure Scenario	Dose (mg/kg/day) & Total UF	Endpoint for Risk Assessment
Dermal: Short-Term Exposure (1 - 30 days)	NOAEL= 20 UF = 100	4-week dermal toxicity with technical - rat Systemic LOAEL = 50 mg/kg/day based on stat. sig. decreases in RBC cholinesterase in males & females & brain cholinesterase in males.
Dermal: Intermediate-Term Exposure (30 days - several months)	NOAEL= 20 UF = 100	4-week dermal toxicity with technical - rat Systemic LOAEL = 50 mg/kg/day based on stat. sig. decr. in RBC cholinesterase in males & females & brain cholinesterase in males.
Dermal: Long-Term Exposure (Several months to a lifetime)	LOAEL= 3.1 UF = 300	Chronic oral toxicity - dog LOAEL = 3.1 mg/kg/day based on plasma & brain cholinesterase inhibition in females.
	Note: Study failed to identify NOAEL. Therefore, additional 3x UF was applied to extrapolate a NOAEL from the LOAEL. Also, dermal absorption factor of 12.7 % from rat dermal absorption study used for route to route extrapolation.	
Inhalation: Short-Term Exposure (1 - 30 days)	NOAEL= 1 UF = 100	Developmental Neurotoxicity - rat oral LOAEL = 10 mg/kg/day based on an increased incidence of FOB changes and stat. sig. decreases in RBC, whole blood, plasma and brain cholinesterase
	Note: Absorption factor of 100 % used for route-to-route extrapolation.	
Inhalation: Intermediate-Term Exposure (30 days - several months)	NOAEL= 1 UF = 100	Subchronic Neurotoxicity - rat LOAEL = 10 mg/kg/day based on increased incidence of FOB changes; decrease in RBC, whole blood, plasma & brain cholinesterase.
	Note: Absorption factor of 100 percent was used for route-to-route extrapolation.	
Inhalation: Long-Term Exposure (Several months to a lifetime) [Occupational only]	LOAEL= 3.1 UF = 300	Chronic toxicity - dog LOAEL = 3.1 mg/kg/day based on plasma and brain cholinesterase inhibition in females.
	Note: Study failed to identify NOAEL. Therefore, additional 3x uncertainty factor was applied to extrapolate a NOAEL from the LOAEL. Absorption factor of 100 percent used for route-to-route extrapolation.	
Cancer	Classification: likely to be carcinogenic to humans, based on increased incidence of vascular tumors in mice. $Q_1^* = 8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$.	

Results of acute toxicity studies with carbaryl are listed in Table 8. The acute toxicity studies showed that carbaryl was relatively toxic by the oral route (Toxicity Category II); but the acute dermal and inhalation toxicities were low (Toxicity Categories III and IV, respectively). Carbaryl was not a dermal or eye irritant and was not a dermal sensitizer in animal studies. However, human incidents of dermal irritation and dermal manifestations of an allergic response

have been reported.

Table 8. Acute Toxicity Categories for Carbaryl

Guideline No.	Study	MRID Nos.	Results	Toxicity Category
81-1	Acute Oral - rat (99% a.i.)	00148500	LD ₅₀ for males = 302.6 mg/kg; for females = 311.5 mg/kg; combined = 307.0 mg/kg	II
81-2	Acute Dermal -rabbit (99% a.i.)	00148501	LD ₅₀ > 2000 mg/kg	III
81-3	Acute Inhalation - rat (99% a.i.)	00148502	LC ₅₀ > 3.4 mg/L	IV
81-4	Primary Eye Irritation - rabbit (99% a.i.)	00148503	not a primary eye irritant	IV
81-5	Primary Skin Irritation - rabbit (99% a.i.)	00148504	not a primary skin irritant	IV
81-6	Dermal Sensitization - guinea pig (99% a.i.)	00148505	negative	NA

b. Residential and Non-Agricultural Risk Assessment

Residential and Non-Agricultural Uses of Carbaryl

Carbaryl has a wide variety of residential uses, including lawns, gardens, ornamentals, and pets. Other than pet treatment, there are no registered indoor uses. Carbaryl is used on golf courses, and may be used in outdoor public areas, such as schools or parks. Carbaryl is also labeled as a mosquito adulticide; however, it does not appear to be a public health use in state or local mosquito control programs, according to the Centers for Disease Control and Prevention. Nevertheless, EPA considered this use in the risk assessment. EPA also assessed a special local need registration (FIFRA Section 24(c)) in Washington State to control burrowing shrimp on oyster beds in two estuarine bays. The Agency modeled potential exposures to persons who might come into contact with carbaryl residues on the beach or in the water.

Residential Handler Assessment

For homeowner exposure assessments, the Agency does not consider personal protective equipment (PPE) to be a feasible risk mitigation option. Homeowners often lack access to PPE and do not possess expertise in the proper use of PPE. Also, PPE requirements for homeowners are difficult to enforce. As a result, homeowner assessments are completed using a single scenario based on the use of short-sleeved shirts, short pants, and shoes and socks, which are common homeowner attire during the pesticide application season. In addition, only short-term exposures were assessed, as the Agency does not believe homeowners who apply carbaryl will be exposed for more than 30 consecutive days. The Agency assessed the following scenarios:

- (1) Garden Uses: Ready-to-use Trigger Sprayer;
- (2) Garden Uses: Ornamental Duster;
- (3) Garden Uses: Hose-end Sprayer;
- (4) Garden Uses: Low Pressure Handwand;
- (5) Tree/ornamental Uses: Low Pressure Handwand;
- (6) Tree/ornamental Uses: Hose-end Sprayer;
- (7) Garden Uses: Backpack Sprayer;
- (8) Lawn-care Liquid Uses: Hose-end Sprayer;
- (9) Pet (Dog and Cat) Uses: Dusting;
- (10) Pet (Dog and Cat) Uses: Liquid Application;
- (11) Lawn-care Granular and Bait Uses: Belly Grinder;
- (12) Lawn-care Granular and Bait Uses: Push-type Spreader;
- (13) Ornamental and Garden Uses: Granulars and Baits By Hand;
- (14) Various Pest Uses: Aerosol Cans;
- (15) Pet (Dog and Cat) Uses: Collars;
- (16) Garden and Ornamental Uses: Sprinkler Can; and
- (17) Garden and Ornamental Uses: Paint-on.

The unit exposure values used in this assessment were based on three carbaryl-specific residential handler studies which quantified exposures during pet treatments with a dust; applications to gardens using a ready-to-use trigger sprayer, a dust, a hose-end sprayer, and a low-pressure handwand; and during applications to trees using a low-pressure handwand and a hose-end sprayer. Two other studies completed by the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handlers Exposure Database (Version 1.1 August 1998) (PHED) were also used as sources of surrogate information. Summaries of the five studies are included in the Occupational and Residential Risk Assessment. These studies are all considered to be of high quality. The quality of the data in PHED varies from scenarios that meet study guideline requirements to others where a limited number of data points are available. However, in all cases, the data used represent the best available for the scenario. The PHED unit exposure values range between geometric mean and median of available exposure data. When data from other studies were used, the appropriate statistical measure of central tendency was used. Central tendency values, coupled with other inputs, are thought to result in conservative (i.e., protective), deterministic estimates of risk. For pet collars only, EPA calculated exposures based on a scenario from its standard operating procedures for conducting a residential exposure assessment in the absence of monitoring data. The factors derived from these standard operating procedures are generally thought to be conservative.

Residential, noncancer risk for each scenario is expressed as an MOE, and is summarized in Table 9. For carbaryl, residential risks with MOEs less than 100 are of concern.

Table 9. Residential Handler Short-Term, Noncancer Risks from Carbaryl

No.	Scenario Descriptor	Use Site	Amount of Carbaryl Used (lb ai/event)	Combined Dermal and Inhalation MOEs
1	Garden: Ready-to-Use Trigger Sprayer	Vegetables/Ornamentals	0.012 to 0.00075	2,108 to 33,730
2	Garden/Ornamental Dust	Vegetables/Ornamentals	0.4 to 0.1	21 to 85
			0.079*	107
3	Garden: Hose-End Sprayer	General Use (2% soln)	2	21
		Fire Ants	0.75	55
		Other Uses: Perimeter Nuisance Pests, Vegetables, Vegetables/Ornamentals,	0.26 to 0.012	158 to 3,427
4	Garden: Low Pressure Handwand	General Use (2% soln), Perimeter Nuisance Pests, Vegetables, Ornamentals, Fire Ant	0.19 to 0.012	193 to 3,056
5	Trees/Ornamentals: Low Pressure Handwand	Ornamentals, Pome Fruits, Nuts/Stone Fruits, Citrus	0.176 to 0.023	142 to 1,084
6	Trees/Ornamentals: Hose End Sprayer	Ornamentals, Pome Fruits, Nuts/Stone Fruits, Citrus	0.5*	72
			0.176 to 0.023	204 to 1,559
7	Garden: Backpack Sprayer	General Use (2% soln), Perimeter Nuisance Pests, Vegetables, Vegetables/Ornamentals, Fire Ants	0.19 to 0.012	1,293 to 20,468
8	Lawn Care: Hose End Sprayer	Lawn (broadcast)	5	25
		Lawn (spot)	0.25	495
9	Dogs: Dusting	Dog	0.0026*	142
			0.1	4
			0.05	7
10	Dogs: Liquid Application	Dog	0.001	>1,000,000**
11	Granular & Baits Lawn Care: Belly Grinder	Lawn (spot)	0.21	60
			0.1	126
12	Granular & Baits Lawn Care: Push-Type Spreader	Lawn (broadcast)	4.2 to 2	477 to 1,003
13	Granulars & Baits By Hand	Ornamentals and Gardens	0.21	15
14	Aerosol	Various	0.08	65
15	Collars: Pet	Dog	0.013	>1,000,000**
16	Sprinkler Can (Source: Scenario 6)	Ornamentals (2% solution)	0.1	359
17	Ornamental Paint On	Ornamentals (2% solution)	0.02	297

*Average use rate based on exposure study data.
 ** These scenarios reflect dermal MOEs only, and are based on EPA's *Standard Operating Procedures for Residential Exposure Assessment* as opposed to monitoring data.

Cancer risks for residential handler exposures were assessed based on the Agency's

classification of carbaryl as “likely to be carcinogenic to humans,” based on increased incidence of vascular tumors in mice. Cancer risks are calculated by multiplying the Lifetime Average Daily Dose (LADD), which represents dermal and inhalation exposure amortized over a lifetime, by the Q_1^* or unit risk, for carbaryl of 8.75×10^{-4} (mg/kg/day)⁻¹.

For the 17 handler scenarios considered in EPA’s residential handler assessment, cancer risks are not of concern to the Agency; the risks are equal to or less than 1×10^{-6} (most are in the 10^{-8} or 10^{-10} range) when evaluating a single application per year. EPA also calculated the maximum number of days per year, over a lifetime, that a person could engage in a scenario before incurring cancer risks greater than the 1×10^{-6} level of concern. Usage data indicates that most residential users make 5 or fewer applications per year. All scenarios assessed allow for six or more days of exposure per year over a lifetime, except for the following four scenarios:

- 2. *Garden and Ornamental Dust* if using an entire 4 lb. bottle (5 days);
- 3. *Garden: Hose-End* if spraying 100 gallons of 2% solution (5 days);
- 9. *Dusting Dog* if using 10% or 5% solution and one-half of a 2 lb. container (1 and 4 days respectively); and
- 13. *Granulars and Baits by Hand* if treating 1000 square feet (4 days).

Residential Postapplication Assessment

Several carbaryl-specific studies were used in developing this assessment, including a turf transferable residue study conducted in California, Georgia, and Pennsylvania at approximately 8 lb ai/A. This study was conducted using the standard protocol from the Outdoor Residential Exposure Task Force. Dislodgeable foliar residue studies on olive pruning and cabbage weeding, conducted by the Agricultural Reentry Task Force, were also used in the home garden risk assessments.

EPA assessed the residential risks from postapplication exposure to carbaryl residues for the following populations: adults (homeowners); children (10 to 12 years old); and toddlers (3 to 5 year olds). EPA considered short- (1 to 30 days) and intermediate-term (30 days to several months) exposures. The only long-term postapplication residential exposure considered (greater than 6 months) is for pet collar uses.

Adults. EPA assessed the following 5 scenarios for adult residential postapplication exposures: residential turf for lawn care and after mosquito control; recreational swimming and beach activity (following oyster bed treatments); golfing; home garden exposure to deciduous trees; and home garden exposure to fruiting vegetables. Within each scenario, ranges of exposure were evaluated for different application rates, duration of exposure, and postapplication activities (e.g., weeding, harvesting). Note that although postapplication exposures from golfing were assessed for adults only, the Agency believes that the adult assessment is applicable to children as well, because of similar surface area to body weight ratios, and that younger children are not likely to be as efficient (i.e., play as many holes of golf) as adults.

Children (10 to 12 year-olds). Children of this age can help with garden maintenance, and therefore are considered for postapplication activities related to fruiting vegetables and fruit trees (such as weeding and harvesting).

Toddlers (3 to 5 year-olds). Toddlers were selected as a representative population for turf and companion animal risk assessments to provide the most conservative risk estimates. Exposures from turf were evaluated separately for lawn care uses and after mosquito control. Beach activity following oyster bed treatment was also evaluated. The assessment is based on combined risk estimates for several routes of exposure: dermal, hand-to-mouth, object-to-mouth, and soil ingestion.

Table 10 shows the residential postapplication scenarios assessed. As noted above, the target MOE for residential postapplication risk is 100 for short and intermediate term exposures. The target MOE for long-term exposures (pet collar) is 300.

Table 10. Residential Postapplication Risks

Population Subgroup	Scenario	Descriptor	Results			
			Short-term MOE on Day 0	Day When Short-term MOE\$100	Intermediate-term MOE	Chronic MOE
Adults	Residential Turf (Lawn care)	Max Rate at 4 lb ai/A	88	1	>800	NA
		Max Rate at 8 lb ai/A	43	5	>400	NA
		After Mosquito Adulticide Treatment, Ground or Aerial (up to 1 lb a.i./A)	>3000	0	>30,000	NA
	Golfing	Max rate up to 8 lb ai/A, or Mosquito Adulticide Treatment	>600	0	>6000	NA
	Home Garden (Deciduous Tree or Fruiting Vegetable)	Highest Exposure Activity (Tree thinning)	>500	0	>1000	NA
	Oyster Beds	Harvest or Swimming	>20,000	0	No data	NA
Youth (10 to 12 years)	Home Garden (Deciduous Trees or Fruiting Vegetables)	Highest Exposure Activity (Tree thinning)	>600	0	>1000	NA

Population Subgroup	Scenario	Descriptor	Results			
			Short-term MOE on Day 0	Day When Short-term MOE\$100	Intermediate-term MOE	Chronic MOE
Toddlers (3 to 5 years)	Residential Turf (High Activity)	Max Rate at 4 lb ai/A	11	14	91	NA
		Max Rate at 8 lb ai/A	5	18	45	NA
	Mosquito Aerial Adulticide	Rate of .016 to 1.0 lb ai/A	>400	0	>3000	NA
	Pet Treatments	Liquids	10	+30	19	NA
		Dusts	<1	+30	<1	NA
		Collars	85	+30	85	110 (need 300)
		Collars* (measured transferable residues over whole dog)	>300	0	Not enough data	Not enough data
	Oyster Beds	Beach Play	>20,000	0	>80,000	NA

Inhalation MOE for children mosquito control calculated using a ground concentration of 40 ng/L calculated with AgDrift, a respiration rate for light activity, and a 20 minute duration to allow for dissipation of the spray. The MOE for inhalation is 1609.

* Alternate MOE based on data from submitted studies of marginal quality, displayed to provide a comparison to the Agency's MOEs based on standard assumptions.

Cancer risks for residential postapplication considered the same scenarios used for assessing noncancer risks. Risks were calculated using a frequency of one exposure per year over a lifetime, and therefore were calculated for adults only. For all scenarios on turf, cancer risks are not of concern to the Agency; risks were in the 10^{-8} range or less on the day of application when evaluating a single reentry event per year during lawncare activities. Risks from home gardening, golfing, mosquito control, or oyster bed treatment, are also not of concern; they were in the 10^{-9} to 10^{-12} range when evaluating a single reentry event per year on the day of application. To assess multiple reentry events, the Agency also calculated, for each scenario, the maximum number of days of exposure per year to reach a risk level of 1×10^{-6} (i.e., not of concern). The results range from 20 days for the residential turf (lawncare) use to over 365 days for most other scenarios.

c. Aggregate Risk

Aggregate risk considers the combined dietary exposure (food and drinking water) for both acute and chronic exposures, and residential and other non-occupational pesticide exposures (e.g., golf course turf). Occupational exposure is not considered in any aggregate exposure assessment. For carbaryl, aggregate risk assessments were conducted for acute, chronic, and short- and intermediate-term exposures. The chronic aggregate assessment

considered both cancer and non-cancer risks. Results of the aggregate risk assessment are summarized here, and are discussed more extensively in the document *Carbaryl: Revised HED Risk Assessment* dated March 14, 2003, and *Carbaryl Acute Dietary Assessment Including Drinking Water*, dated June 30, 2003, which are available in the public docket and on the internet.

Acute Aggregate Risk (food + drinking water exposure)

Acute aggregate dietary risk, which combines acute food and drinking water exposure, is presented using two different approaches; i.e., a new probabilistic aggregate assessment, and the conventional drinking water level of concern (DWLOC) calculation.

Probabilistic Assessment

The acute aggregate dietary assessment is groundbreaking from a methodological perspective in that it is the Agency's first undertaking to incorporate distributions of drinking water EECs using PRZM/EXAMS into DEEM-FCID™ to provide a level of refinement to the screening-level DWLOC approach. In essence, in this assessment drinking water was considered like any other commodity in calculations and interpretations of results. The crop scenario with the highest distribution of drinking water concentrations modeled was Florida citrus.

EPA's revised human health risk assessment stated that even this highest distribution did not result in a risk estimate of concern for combined food and drinking water exposure. Subsequent review of this data by the Agency identified an error in the input files for DEEM-FCID™ which caused a significant underestimate of aggregate dietary risk. New DEEM-FCID™ results using corrected input files showed potential aggregate dietary risks of concern for Florida citrus at the maximum application rate, as well as risks of concern for some other use scenarios, depending upon the application rate, method, timing, and other factors. Additional acute aggregate dietary probabilistic assessments, including new scenarios for citrus in California and Florida, and pecans and peaches in Georgia, were conducted to provide more information on the sensitivity of certain model parameters, as well as to better understand the range of potential drinking water risks in the southeastern region of the U.S. Citrus use in Florida, as well as pecan and peaches in Georgia, and apples in Pennsylvania, were identified as regional uses that would result in the highest drinking water concentrations. Hence, an acute aggregate probabilistic risk assessment was not conducted for some of the other use scenarios originally evaluated, including Ohio sweet corn and field corn and Minnesota sugar beets. Table 11 below shows the results of EPA's drinking water analysis and acute aggregate dietary assessment for these scenarios.

Table 11. Results of New Acute Dietary (Food and Drinking Water) Risk Estimates for Maximum Label Rates

Crop Scenario	Use Rate (lb ai/A)	No. of Apps	Interval (days)	App Method	PCA	Most Sensitive	aPAD at 99.9%ile
Citrus - FL	7.5 5	2 1	3	aerial	0.87	All infants Children 1-2	620 303
Citrus - FL	7.5 5	2 1	14	airblast	0.38	All infants Children 1-2	186 119
Citrus - FL	4	2	14	airblast	0.38	All infants Children 1-2	114 99
Citrus - FL	10	2	14	aerial	0.87	All infants Children 1-2	589 270
Citrus - CA	7.5 5	2 1	14	airblast	0.87	All infants Children 1-2	93 81
Citrus - CA	16	1	--	aerial	0.87	All infants Children 1-2	158 108
Citrus - CA	16	1	--	airblast	0.87	Children 1-2 All infants	93 81
Apple -PA	3	5	14	airblast	0.87	All infants Children 1-2	103 98
Apple -PA	3	3	14	airblast	0.87	Children 1-2 All infants	95 90
Pecan - GA	5	3	7	airblast	0.87	All infants Children 1-2	178 115
Pecan - GA	5	3	7	airblast	0.38	All infants Children 1-2	95 95
Peach - GA	5	3	7	aerial	0.87	All infants Children 1-2	107 101

As indicted in Table 11, the acute aggregate dietary risk for a number of scenarios is greater than 100% of the aPAD, depending upon the application rate, method, timing and other factors which were inputs to the drinking water model. The scenario with the highest %aPAD is citrus use in Florida.

DWLOC Calculation

For comparison purposes, the Agency also assessed acute aggregate risks from food and drinking water exposure using the DWLOC approach, the same method used in the Agency's preliminary risk assessment. The DWLOC represents the maximum drinking water concentration which, when considered together with exposure through food, does not exceed EPA's level of concern. If the DWLOC is greater than the drinking water EEC, then the risk is not of concern to the Agency. If, on the other hand, the EEC is greater than the DWLOC, the Agency would need to investigate the potential dietary exposure more closely, and may require

additional data on potential water contamination. The results of the DWLOC calculations for carbaryl are presented below in Table 12.

Table 12. DWLOCs and EECs for Acute Dietary Food and Drinking Water Exposure

Population Subgroup	Acute DWLOC (ppb)	EECs (ppb)	
		Surface Water	Ground Water
All Commodities Using 1994-1998 CFSII Consumption Data			
General Population	200	Citrus in FL - 410.4 Apples in PA - 86.6 Sweet Corn in OH - 57.3 Field Corn in OH - 51.3 Sugar Beets in MN - 48.2 Peaches in GA - 44.9 Pecans in GA - 159.9	0.08
Infants (< 1 yr)	32		
Children (1-2 yrs)	7.4		
Children (3-5 yrs)	19		
Children (6-12 yrs)	45		

For the crop scenarios that resulted in aggregate acute dietary risks of concern, EPA conducted additional acute drinking water model estimates, adjusting for changes in the application rate, number of applications, interval between applications, method of application, and the percent cropped area (PCA) factor. This information provides a more complete picture of the potential range of high-end EECs for specific use patterns.

For ground water sources of drinking water, the acute aggregate risk was also assessed by the DWLOC method. The drinking water EEC for ground water (0.8 ppb) was estimated using a screening-level model, which produced an upper-end estimate of carbaryl exposure and potential risk to human health from pesticide residues in ground water. As indicated in Table 12, the EEC for ground water was less than the DWLOCs for all population subgroups. Therefore, acute aggregate risk from ground water sources of drinking water is not of concern to the Agency.

Chronic (non-cancer) Aggregate Risk (food + drinking water exposure)

Since no chronic residential (non-dietary) exposure scenarios have been identified, the chronic aggregate risk assessment considers exposure only through food and drinking water. To assess aggregate risks from chronic food and drinking water exposure, EPA used the DWLOC approach only. For chronic aggregate dietary risks, the drinking water EECs estimated from the PRZM/EXAMS (surface water) and SCI-GROW (ground water) screening-level models are significantly less than the chronic DWLOCs, and are therefore not of concern to the Agency. The results of this assessment for carbaryl are presented below in Table 13.

Table 13. DWLOCs and EECs for Chronic Dietary Food and Drinking Water Exposure

Population Subgroup	Chronic DWLOC (ppb)	EECs (ppb)	
		Surface Water	Ground Water
All Commodities Using 1994-1998 CFSII Consumption Data			
General Population	350	18.6 (citrus in FL)	0.8
All Infants (<1 yr)	100		
Children (1-2 yrs)	99		
Children (3-5 yrs)	99		
Children (6-12 yrs)	99		

Short-Term Aggregate Risk (food + drinking water + residential exposure)

This section describes the aggregate (combined) risk from food, drinking water and residential sources of exposures. The purpose of the aggregate assessment is to identify risks that become a concern when the exposure pathways are combined. Residential exposure scenarios with estimated risks that were of concern were not included in the aggregate assessment for carbaryl; they were considered and addressed separately (see Section IV of this document). Therefore, EPA assessed representative residential exposure scenarios where risks were not of concern to determine whether, when these exposures were combined with food and drinking water exposures, resulting risks exceeded EPA's level of concern. Section IV of this document presents EPA's short-term aggregate risk conclusions for all scenarios that had risks of concern before mitigation measures and risk refinements were considered.

The residential exposure scenarios considered for the aggregate assessment include postapplication scenarios (adults and children), and handler scenarios (adults). Representative postapplication exposure scenarios for children and adults include mosquito control; swimming/beach activity (after oyster bed treatments); golfing; and garden harvest. The handler (adult) scenarios selected include application of dusts to gardens and to pets; hose-end sprayer applications; liquid spray spot treatments to lawns; and broadcast application of the granular formulation to lawns. For a full description of short-term aggregate risk scenarios, see the document titled *Carbaryl: Revised HED Risk Assessment – Phase 5*, March 14, 2003.

After aggregating the chronic dietary (food) exposures with residential exposures, EPA determined the DWLOC for each scenario. Chronic (average) food exposures and chronic (average) drinking water EECs are used to assess short-term (as well as intermediate-term and chronic) aggregate exposures, because it is not expected that an individual would be simultaneously exposed to acute (peak) food and drinking water residues, and maximum

exposures from residential sources. EPA compared the calculated DWLOCs to the chronic drinking water EEC model estimates for both surface water and ground water. The DWLOCs for all scenarios considered ranged from 19.4 ppb (adult females handling dusts during gardening activities, residential MOE =120) to 350 ppb (adults swimming following oyster bed treatments, residential MOE \$42,000). For children, DWLOCs ranged from 105 ppb (postapplication exposure to pet collars, residential MOE = 340) to 149 ppb (swimming following oyster bed treatments, residential MOE \$11,000). The highest modeled chronic drinking water EEC, from the Florida citrus use, was 18.6 ppb for surface water and 0.08 ppb for ground water sources. For short-term residential exposure scenarios assessed, all DWLOCs are greater than the chronic drinking water EECs; therefore, short-term aggregate risks for these scenarios are not of concern. See Section IV of this document for short-term aggregate risk conclusions for scenarios that had risks of concern prior to residential risk mitigation.

Intermediate-Term Aggregate Risk (food + drinking water + residential exposure)

Aggregate risk results for intermediate-term exposure are identical to the short-term aggregate risk, because the hazard inputs are the same for both short- and intermediate-term exposure; therefore, intermediate-term aggregate risks from these scenarios are not of concern.

Cancer Aggregate Risk (food + drinking water+residential exposure)

Aggregate cancer risks were assessed using a broad range of adult handler and postapplication exposures from carbaryl uses. For all of the scenarios assessed, the drinking water EECs (for both surface and ground water sources) were less than the DWLOCs, regardless to the source of drinking water. The DWLOC for all scenarios considered ranged from 32.4 to 39.3 ppb, and the highest modeled chronic (average) drinking water EEC, from the Florida citrus use was 18.6 ppb for surface water and 0.08 ppb for ground water sources. Therefore, the cancer aggregate risks are not of concern for any population subgroup.

d. Occupational Risk Assessment

The occupational risk assessment addresses on the job risks to workers who may be exposed to carbaryl when mixing, loading, or applying a pesticide (i.e., handlers), and when entering treated sites for routine tasks (postapplication). The occupational assessment calculates noncancer risks using the MOE approach, and the toxicological endpoints (NOAELs and LOAELs) are the same as the residential assessment endpoints. See Table 7 on page 23. Cancer risks are assessed using the Q_1^* approach.

EPA assessed occupational exposure to carbaryl using data from the Pesticide Handler Exposure Database (PHED); Agricultural Re-entry Task Force (ARTF); Outdoor Residential Exposure Task Force (ORETF); and proprietary data, including chemical-specific data submitted by the technical registrant for carbaryl. In addition, standard default assumptions about average body weight, work day, and area treated daily were used to calculate risk estimates. Application rates used in this assessment are derived directly from current carbaryl labels. Worker exposure

and risk estimates are based on the best data currently available to the Agency. Details of the assessment and the data used for each scenario is discussed in the occupational and residential exposure assessment for carbaryl titled: *Carbaryl: Revised Phase 5 Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*, dated February 20, 2003, which is available on the internet and in the public docket.

Handler Risks

Occupational handler exposure assessments are conducted by the Agency using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then adds protective measures in a tiered approach to determine the level of protection necessary to obtain appropriate MOEs. The lowest level (baseline) of personal protective equipment (PPE) includes long sleeve shirts, long pants, shoes, and socks. A single layer of PPE includes the addition of chemical-resistant gloves to the standard attire of long sleeves, long pants, shoes, and socks. A respirator may also be added if there is a concern for inhalation exposure. If MOEs at that level of PPE are less than 100, increasing levels of PPE are applied (i.e., coveralls are added to provide a double layer of protective clothing). If MOEs are still less than 100 with a maximum PPE, then engineering controls are applied. The typical carbaryl label for agricultural products specifies single-layer clothing, chemical-resistant gloves, and no respirator. The types of protection, including PPE and engineering controls, that were used to calculate occupational exposure from carbaryl include the following:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline clothing, plus chemical-resistant gloves, with or without a dust/mist respirator.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, plus chemical-resistant gloves, with and without a dust/mist respirator.
- Engineering Controls: Closed mixing/loading systems for liquids (mechanical closed mixing/loading or transfer systems); Closed loading systems for granulars (Smartbox® or LockNLoad®); Enclosed Cockpits or Enclosed Cabs with or without inhalation protection (air filtration).

Anticipated use patterns and current labeling for carbaryl indicate 28 major occupational exposure scenarios which can result in handlers receiving dermal and inhalation exposures to carbaryl. These exposure scenarios are based on the chemical formulations, equipment and techniques that handlers can use to make carbaryl applications. Exposures are also considered based on their duration. The Agency assessed short- (1 to 30 days) and intermediate-term exposures (30 days to several months) to carbaryl, though the results were essentially the same because the numerical inputs did not differ in carbaryl's case. The Agency also assessed long term exposures (greater than 180 days) for a small number of scenarios for which these exposures are likely, mostly in the greenhouse and floriculture industry. For short and

intermediate-term exposures, MOEs greater than 100 are not of concern to the Agency. For long-term exposures, the target MOE is 300.

Short and intermediate-term risks

Within the 28 major occupational exposure scenarios assessed, about 140 different crop/rate/acreage calculations were made. Most of these risk calculations (about 110) were not of concern at some level of PPE, though generally the level of PPE needed was higher than presently required on the current label, which is single layer clothing, gloves, and no respirator. Table 14 summarizes the results for short-term and intermediate-term occupational handlers. The level of PPE or engineering controls that result in risk estimates that meet or exceed the target MOE of 100 are identified in the last column, titled “PPE at which MOE > 100”. For example, the abbreviation “EC” indicates that engineering controls bring estimated MOEs above 100. The remaining scenarios that failed to meet or exceed the target MOE even at the highest feasible level of PPE or engineering controls are identified by the abbreviation “MOE < 100”. For details about the occupational handler risk assessment, see the Human Health Risk Assessment for Carbaryl, dated March 14, and the Occupational and Residential Exposure Assessment for Carbaryl, dated February 20, 2003.

The following two tables use abbreviations to describe the level of PPE. These abbreviations are defined as follows:

- Baseline = Long pants, long-sleeved shirts, no gloves
- SL = Single layer clothing with or without gloves (GL or NG)
- DL = Double layer clothing (i.e., coveralls over SL) with or without gloves (GL or NG)
- EC = Engineering controls
- NR = No respirator
- PF5 = Protection factor 5 respirator
- PF10 = Protection factor 10 respirator
- Current label = SL/GL/NR

Table 14. Occupational Handler Noncancer Risks: Short and Intermediate-Term Exposure Summary

Scenario	Rate (lb ai/A, unless noted) and Use Site	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	PPE at which MOE > 100
Mixer/Loaders				
1a Dry Flowable: Aerial/Chemigation	1-2 (wheat/corn)	1200	>300	EC
	2-5 (veg., stone fruit, 24C on oysters)	350	>400	EC
1b Dry Flowable: Airblast	7.5-16 (various fruit & nut trees)	40	>1300	EC
	5 (nuts)	40	>100	SL/GL/PF5
	1.1-3 (pome & stone fruit, grapes)	40	>100	Baseline

Scenario	Rate (lb ai/A, unless noted) and Use Site	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	PPE at which MOE > 100
1c Dry Flowable: Groundboom	1.5-2 (wheat/corn) 2 (strawberry/veg) 8 (turf/golf courses) 4 (turf/golf courses)	200 80 40 40	>2100 >100 >2700 >100	EC Baseline EC Baseline
1d Dry Flowable: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	>400	Baseline
1e Dry Flowable: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	>400	Baseline
1f Dry Flowable: Wide area aerial	2 (rangeland/forestry)	7500	58	MOE < 100
2a Granular: Aerial	2 (corn) 2 (corn) 0.03 (APHIS grasshopper)	1200 350 1000-6000	>600 >100 >100	EC SL/GL/PF5 Baseline
2b Granular: Solid broadcast spreader	1.5 (wheat/corn) 2 (wheat/corn) 2 (vegetables) 6 (turf/golf courses) 9 (turf/golf courses)	200 200 80 40 40	>100 >200 >200 >100 >200	Baseline SL/GL/PF5 Baseline Baseline SL/GL/PF5
3a Liquid: Aerial/Chemigation	1.5-2 (wheat, max corn) 1 (avg. corn) 5 (stone fruit) 2 (vegetables)	1200 1200 350 350	57-76 >100 78 >100	All MOEs < 100 EC MOE<100 DL/GL/PF10
3b Liquid: Airblast	16 (Citrus-24C in California) 7.5 (Citrus) 5 (Nuts) 1.1-3 (Grapes, pome & stone fruit)	40 40 40 40	100 >100 >100 >200	DL/GL/PF10 SL/GL/PF5 SL/GL/NR SL/GL/NR
3c Liquid: Groundboom	1.5 (wheat) 2 (corn) 2 (strawberries) 8 (turf/golf courses) 4 (turf/golf courses)	200 200 80 40 40	>100 >100 >100 >100 >100	SL/GL/PF5 SL/GL/PF5 SL/GL/NR SL/GL/PF5 SL/GL/NR
3d Liquid: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	>700	SL/GL/NR
3e Liquid: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	>700	SL/GL/NR
3f Liquid: Wide area aerial	2 (Range/Forestry) 0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide) 0.375-0.5 (APHIS grasshopper) 0.125 (APHIS grasshopper)	7500 7500 7500 7500 6000 6000	9 >200 >100 18 46-61 >100	MOE < 100 SL/GL/NR EC MOE < 100 MOE<100 EC

Scenario	Rate (lb ai/A, unless noted) and Use Site	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	PPE at which MOE > 100
3g Liquid: Wide area ground	0.016 (Mosquito adulticide)	3000	>600	SL/GL/NR
	0.15 (Mosquito adulticide)	3000	>100	SL/GL/PF5
	1 (Mosquito adulticide)	3000	45	MOE < 100
4a Wettable Powders: Aerial	1-2 (Wheat/corn)	1200	40-80	All MOEs < 100
	5 (stone fruit)	350	55	MOE < 100
	2 (vegetables)	350	>100	EC
4b Wettable Powders: Airblast	16 (Citrus-24C in California)	40	>100	EC
	1.1-7.5 (Citrus, nuts, grapes, pome & stone fruit)	40	>300	EC
4c Wettable Powders: Groundboom	1.5-2 (wheat/corn)	200	>200	EC
	2 (strawberries)	80	>500	EC
	4-8 (turf/golf courses)	40	>200	EC
4d Wettable Powders: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	>100	SL/GL/PF5
4e Wettable Powders: Low press./High Vol. Turfgun	4 (LCO on turf)	5	>100	SL/GL/PF5
	8 (LCO on turf)	5	>200	SL/GL/PF5
4f Wettable Powders: Wide area aerial	2 (Range/Forestry)	7500	6	MOE<100
Applicators				
5a Aerial: Agricultural uses, liquid sprays	1-1.5 (wheat/avg. corn)	1200	>100	EC
	2 (max corn)	1200	85	MOE<100
	5 (stone fruit)	350	>100	EC
	2 (vegetables, 24C on oysters)	350	>200	EC
5b Aerial: Wide area uses, liquid sprays	2 (Range/Forestry)	7500	14	MOE<100
	0.016-0.15 (Mosquito adulticide)	7500	>100	EC
	1 (Mosquito adulticide)	7500	27	MOE<100
	0.375-0.5 (APHIS grasshopper)	6000	68-91	MOE<100
	0.125 (APHIS grasshopper)	6000	>200	EC
5c Aerial: Agricultural uses, granular applications	2 (corn)	1200	21	MOE<100
	2 (corn)	350	72	MOE<100
	0.03 (APHIS grasshopper)	1000-6000	>200	EC
6a Airblast: Agricultural uses	16 (Citrus 24C in California)	40	>100	EC
	7.5 (Citrus, nuts, max pome & stone fruit)	40	>200	EC
	5 (Nuts)	40	>300	EC
	3 (Pome & stone fruit)	40	>500	EC
	2 (Grapes)	40	>800	DL/HEAD/GL/PF5
	1.1 (Avg pome & stone fruit)	40	>1500	SL/GL/PF5
6b Airblast: Wide area uses, liquid sprays	0.016 (Mosquito adulticide)	3000	>100	SL/GL/PF5
	0.15 (Mosquito adulticide)	3000	>100	EC
	1 (Mosquito adulticide)	3000	22	MOE<100

Scenario	Rate (lb ai/A, unless noted) and Use Site	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	PPE at which MOE > 100
7 Groundboom	1.5-2 (Wheat, corn) 2 (Strawberries) 4-8 (Turf/golf course)	200 80 40	>100 >300 >100	Baseline Baseline Baseline
8 Solid broadcast spreader (granular)	1.5-2 (Wheat, corn) 2 (Strawberries) 4-8 (Turf/golf course)	200 80 40	>100 >200 >100	Baseline Baseline Baseline
9 Aerosol Can	0.01 lb ai/can	2 cans	>300	Baseline
10 Trigger pump sprayer	0.01 lb ai/can	1 can	>8700	SL/GL/NR
11 Right of way sprayer	1.5 lb ai/100 gallons	1000 gallons	>100	SL/GL/NR
12 High pressure handwand	4 lb ai/100 gallons	1000 gallons	66	MOE<100
13 Animal groomer, liquid application	0.01 lb ai/dog	8 dogs	10	MOE<100
14 Animal groomer, dust application	0.2 lb ai/dog	8 dogs	>8700	Baseline (dermal exp only)
15 Granulars & baits applied by hand	9 (Ornamentals & gardens)	1	4	MOE<100
16 Granulars & baits applied by spoon	9 (Ornamentals & gardens)	1	75	MOE<100
Mixer/Loader/Applicators				
17 Low pressure, high volume turfgun (ORETF Data)	8 (LCO Use on turf) 4 (LCO Use on turf)	5 5	94 >100	MOE<100 SL/GL/PF5
20 Granular, bellygrinder	9 (Turf)	1	27	MOE<100
21 Granular, push-type spreader	9 (Turf)	5	>100	SL/GL/PF5
22 Handheld fogger	No data	No data	No data	No data
23 Power backpack	No data	No data	No data	No data
24 Granular, backpack	9 (Ornamentals)	1	>1500	DL/GL/NR
25 Tree injection	No data	No data	No data	No data
26 Drench/dipping forestry/ornamentals	1.5 lb ai/100 gallons (Ornamental/seedling dip)	100 gallons	>100	SL/GL/NR
27 Sprinkler can	2% solution (Ornamentals)	10 gallons	>200	Baseline
Flaggers				
28a Flagger: liquid sprays	2 (Corn) 2 (Vegetables)	1200 350	>200 >100	EC Baseline
28b Flagger: granular applications	2 (Corn) 2 (Vegetables)	1200 350	>100 >300	Baseline Baseline

Scenario	Rate (lb ai/A, unless noted) and Use Site	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	PPE at which MOE > 100
Uses in poultry houses were also assessed, but are not presented here because these uses have been voluntarily cancelled by the registrant. MOE<100 = Scenario for which the MOE which does not meet or exceed the target MOE of 100 even with the highest feasible level of protection (e.g., engineering controls, in most cases).				

Long-term risks. Only a few occupational uses are expected to result in long-term exposures. Of 5 scenarios assessed, 3 meet or exceed the target MOE of 300 at some level of personal protection. The two scenarios that fail to meet or exceed the target MOE are scenario 15: *Granulars & baits applied by hand*; and scenario 16: *Granulars and baits applied by spoon*. Both were assessed at the maximum application rate of 9 lb ai/A. Table 15 shows the occupational handler noncancer risks from long-term exposure.

Table 15. Occupational Handler Noncancer Risks: Long-Term Exposure Summary

Scenario	Rate and Use Site	Area Treated or Amount Used	Risk Summary	
			MOEs	PPE at which MOE>300
Applicators				
15 Granulars & baits applied by hand	9 lb ai/A (Ornamentals & gardens)	1 acre/day	5	MOE<300*
16 Granulars & baits applied by spoon	9 lb ai/A (Ornamentals & gardens)	1 acre/day	92	MOE<300*
Mixer/Loader/Applicators				
18a Wettable powder, low pressure handwand	2% solution (ornamentals)	40 gallons	>302	DL/GL/PF10
18b Liquids, low pressure handwand	2% solution (ornamentals)	40 gallons	>3200	SL/GL/NR
19 Backpack sprayer	2% solution (ornamentals)	40 gallons	>700	Baseline
*MOE<300 = Scenario for which the MOE does not meet or exceed the target MOE of 300 even with the highest feasible level of protection (e.g., engineering controls, in most cases).				

Cancer risks for handlers. Occupational cancer risks equal to or less than 1×10^{-6} (1 in 1 million) are not of concern to the Agency. The Agency also carefully examines uses with estimated risks in the 10^{-6} to 10^{-4} range to seek cost-effective ways of reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protective equipment (PPE) or engineering controls are added to the extent practical. If occupational cancer risks in the 10^{-6} to 10^{-4} range despite practicable mitigation measures, EPA will consider whether benefits of the use warrant such risks. The Agency considered two distinct

populations for the carbaryl cancer risk assessment: private growers, at 10 applications per year, and commercial applicators at 30 applications per year. Cancer risks for occupational handler exposures are calculated separately for private growers and for commercial applicators.

Cancer risks to private handlers (10 applications/year). Of the 140 scenario combinations considered for private growers, all scenarios have risks less than 1×10^{-6} at some level of PPE or engineering controls, except for 8 scenarios. Of these 8 scenarios, 7 have risks between 1×10^{-4} and 10^{-6} based on existing label PPE, and only 1 scenario needs more than label PPE to have risks in this range.

Cancer risks to commercial applicators (30 applications/year). Of the 140 scenario combinations considered for commercial applicators, all have risks less than 1×10^{-6} at some level of PPE or engineering controls, except for 21 scenarios. Of these 21 scenarios, 20 have risks between 1×10^{-4} and 10^{-6} based on current label PPE, and only 1 scenario needs more than label PPE to have risks in this range.

For both private (10 applications per year) and commercial (30 applications per year), noncancer risks are more of a risk driver than cancer risks. The level of PPE needed to mitigate noncancer risk scenarios are also at least equally protective of cancer risk scenarios. However, some scenarios have risks that are greater than 1×10^{-6} even with maximum personal protection including engineering controls. For commercial growers, these risks range from 1.1×10^{-5} to 1.1×10^{-6} . Risks for private growers are less. Where the Agency has made benefits determinations for noncancer scenarios, these also apply to the corresponding cancer scenarios.

Postapplication Risks

The Agency also assessed postapplication risks to workers who may be exposed to carbaryl when they enter previously treated areas and their skin may contact treated surfaces. Exposures are directly related to the type of tasks performed. EPA estimates the amount of pesticide exposure to postapplication workers over time based on various studies. The Agency evaluates this information to determine the number of days following application that must elapse before the pesticide residues dissipate to a level where worker MOEs equal or exceed 100 while wearing baseline attire. Baseline attire is defined as long-sleeved shirt, long pants, shoes and socks. Based on the results of the postapplication worker assessment, the Agency may establish restricted-entry intervals (REIs) to determine when workers may safely enter treated areas. At present, the Worker Protection Standard designates the carbaryl REI to be 12 hours. Table 16 summarizes the number of days necessary to reach the target MOE following foliar applications of carbaryl.

Table 16. Occupational Postapplication Risks from Foliar Applications of Carbaryl

Exposure Duration	Low Exposure (e.g., irrigation)	Medium Exposure (e.g., scouting)	High to Very High Exposure (e.g., hand harvesting or thinning)
Short-term Exposure Duration (1 to 30 days)	<u>Crop and # of days to reach target MOE of 100</u> Cut Flowers: 7 Evergreen Fruit Trees: 6 Brassica: 6	<u>Crop and # of days to reach target MOE of 100</u> Cut Flowers: 9 Evergreen Fruit Trees: 17 Brassica: 9 Bunch/Bundle Group: 6 Low/Medium Field/Row Crops: 3 Tall Field/Row Crops: 4 Sugarcane: 3 Root vegetables: 4 Curbit Vegetables: 4 Leafy Vegetables: 4 Stem/stalk Vegetables: 1 Vine/Trellis Group: 2	<u>Crop and # of days to reach target MOE of 100</u> Cut Flowers: 12 Decid Fruit Trees: 8 Brassica: 11 Bunch/Bundle Group: 8 Low/Medium Field/Row Crops: 5 Tall Field/Row Crops: 11-30 Sugarcane: 7 Root vegetables: 7 Curbit Vegetables: 7 Leafy Vegetables: 7 Stem/stalk Vegetables: 5 Vine/Trellis Group: 11-14 Low Berry: 4 Fruiting Vegetable: 2 Nut Trees: 11 Turf/Sod: 14
Intermediate-term Exposure Duration (30 days to several months)	None	None	<u>Crop (calculated MOE)</u> Cut Flowers (MOE=57) Evergreen Fruit Trees (MOE=59) Brassica (MOE=79) Turf/Sod (MOE=46) Tall Field Row Crops (MOE range = 97 to 6) Vine/Trellis (MOE range =79 to 40)
Long-Term Exposure Duration (greater than six months)	None	None	<u>Crop (calculated MOE)</u> Cut flower industry (MOE=69)

Cancer risks for occupational postapplication exposures. Occupational cancer risks equal to or less than 1×10^{-6} (1 in 1 million) are not of concern to the Agency. The Agency also carefully examines uses with estimated risks in the 10^{-6} to 10^{-4} range to seek cost-effective ways of reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protective equipment (PPE) or engineering controls are added to the extent practical. If occupational cancer risks in the 10^{-6} to 10^{-4} range despite practicable mitigation measures, EPA will consider whether benefits of the use warrant such risks.

Based on a 1×10^{-6} risk concern threshold, the current 12 hour REI appears adequate to address cancer risks for many crop/activity combinations. But for higher exposure situations, longer REIs are needed so that risks are not of concern. In all cases, though, REIs based on cancer risks are either not as long, or are similar to, REIs based on the noncancer effects of carbaryl. Cancer risks for occupational postapplication exposures are calculated separately for private growers and for commercial farmworkers.

Cancer risks for private growers (10 applications/year). The highest exposure for private growers was in the 10^{-5} range, i.e., very high exposure for tall field/row crops. All other scenarios have risks in the 10^{-6} range. Those risks that are greater than 1×10^{-6} take up to 5 days to fall below 1×10^{-6} . The risk in the 10^{-5} range takes 23 days to fall below 1×10^{-6} .

Cancer risks for commercial farmworkers (30 applications/year). All scenarios had cancer risks in the 10^{-6} range or less on the day of application at the current REI, except for two very high exposure activities (hand harvesting). All risks in the 10^{-6} range take approximately 8 days to fall below 1×10^{-6} . The two very high exposure activities, for tall field/row crops and vine/trellis crop groups, have risks in the 10^{-5} range on the day of application, and take 31 and 13 days, respectively, to fall below 1×10^{-6} .

e. Incident Reports

Human Incident Reports

The Agency evaluated reports of human carbaryl poisonings and adverse reactions associated with its use from the following sources: OPP Incident Data System (IDS); Poison Control Center's Toxic Exposure Surveillance System; California Department of Pesticide Regulation; the National Pesticide Information Center (NPIC, formerly the National Pesticide Telecommunications Network); open literature; and an unpublished study submitted by the registrant.

The data from IDS indicated that a majority of incidents associated with carbaryl exposure involved dermal reactions. A number of other cases involved asthmatics and people who experienced hives and other allergic type reactions. According to California data, about half of the cases involved skin and eye effects in handlers. About a quarter of the skin reactions were due to workers who were exposed to residues on crops. Reports from the literature are very limited but tend to support the finding that carbaryl has irritant properties.

The Poison Control Center cases involving nonoccupational adult exposure and exposures of older children showed an increased risk in five of the six measures used for comparing carbaryl incidents to all other pesticides. The carbaryl cases were almost twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were two and a half times more likely to experience major medical outcome (life-threatening effects or significant residual disability) than other pesticides. This pattern of increased risk was not seen among occupational reports or in young children, which may mean that careless handling

by non-professionals is a particular hazard. In addition, five case report studies suggested that carbaryl may be a cause of chronic neurological or psychological problems.

Another incident was recently reported in April 2003 involving workers who reported feeling ill while working in a citrus grove that had been treated with carbaryl about five days before the workers entered the grove and began harvesting the fruit. Based on the State of Florida investigation of the incident, which included cholinesterase measurements of some workers and residue samples from fruit and foliage, the cause of the reported health effects is inconclusive.

Pet Incident Reports

The incident reports on domestic animals in IDS were evaluated. Based on limited data, there is some evidence that young kittens may be susceptible to adverse reactions to carbaryl.

B. Environmental Risk Assessment

The Agency's environmental risk assessment for carbaryl provides a screening level estimate of potential risks to nontarget organisms from carbaryl use. The potential risk is calculated considering carbaryl exposure and toxicity. The Agency determined the potential for ecological exposure to carbaryl by calculating Estimated Environmental Concentrations (EECs), based on carbaryl's chemical properties, particularly fate and transport, and carbaryl use pattern data. The Agency determined carbaryl's potential ecological toxicity using endpoints from required acute and chronic ecological toxicity studies. Acute toxicity values used were the median lethal concentration, or LC50, and the median lethal dose value, or LD50. The LC50 and LD50 are the concentration or dose that results in death for 50% of the study population. The chronic toxicity endpoint used was the No Observed Adverse Effect Level, or NOAEC, for chronic reproductive and growth effects in study populations. The Agency determined potential risk for carbaryl by calculating a Risk Quotient, or RQ, which is the ratio of potential ecological exposure to toxicity. For an acute RQ the equation is $Acute\ RQ = EEC / LC50\ or\ LD50$. Generally, the higher the RQ, the higher the potential risk.

RQs are also compared to Levels of Concern, or LOCs, established by the Agency for birds, mammals, insects, fish, aquatic invertebrates, and plants. If an RQ value is lower than the LOC, it is considered unlikely to pose a significant risk. If an RQ is higher than the LOC, the Agency may take further action to refine or characterize the risk estimate, or to mitigate the risk potential. A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the document, *Revised Environmental Fate and Ecological Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision*, dated March 18, 2003.

1. Environmental Fate and Transport

Laboratory and field studies provide the basis for determining the fate profile for carbaryl; that is, how rapidly carbaryl breaks down, the likely pathways of degradation, the nature of the degradation products, and the likelihood that it will move to ground or surface water. This fate profile is used in predicting potential pesticide exposure to nontarget organisms. Carbaryl dissipates in the environment by abiotic and microbially mediated degradation. The major degradate for carbaryl is 1-naphthol, which further degrades to CO₂. Under acidic conditions, carbaryl is stable to hydrolysis (i.e., it persists), but it hydrolyzes in neutral (pH 7 half-life=12 days) and alkaline environments (pH 9 half-life=3.2 hours). Under aerobic conditions the compound degrades rapidly by microbial metabolism, with half-lives of 4 to 5 days in both soil and aquatic environments. In anaerobic environments metabolism is much slower, with half-lives on the order of 2 to 3 months. Carbaryl is moderately mobile in the environment. Carbaryl is not expected to bioaccumulate. Open literature information suggests that its major degradate, 1-naphthol, is less persistent and less mobile than carbaryl, and is categorized as moderately to highly toxic to aquatic organisms on an acute exposure basis.

2. Ecological Effects (Toxicity) Assessment

Carbaryl is practically nontoxic to birds, moderately toxic to mammals and fish, and very highly toxic to bees and aquatic invertebrates on an acute exposure basis. Additionally, data indicate that the major carbaryl hydrolysis degradate, 1-naphthol, ranges in toxicity from moderately to highly toxic to aquatic organisms. A more detailed discussion of the ecological toxicity studies that went into this assessment can be found in the *Environmental Fate and Ecological Risk Assessment for the Re-registration of Carbaryl*, dated March 18, 2003, and particularly Appendix D1 of that document. Table 17 provides a summary of the most sensitive ecological toxicity endpoints used in the hazard assessment of terrestrial animals.

Table 17. Carbaryl Acute and Chronic Toxicity Endpoints for Birds and Mammals

Test Species	Acute Toxicity		Chronic Toxicity	
	LD ₅₀ (ppm)	Acute Oral Toxicity	NOAEC/LOAEC (ppm)	Affected Endpoints
Mallard duck <i>Anas platyrhynchos</i>	>2000	practically nontoxic	300 / 600	decreased number of eggs; eggs cracked
Honey bee <i>Apis melliferus</i>	0.0011	very highly toxic	--	--
Laboratory rat <i>Rattus norvegicus</i>	301	moderately toxic	75 / 300	decreased pup survival

The most sensitive endpoints used in the hazard assessment for aquatic animals are summarized in the Table 18.

Table 18. Carbaryl Acute and Chronic Toxicity Endpoints for Aquatic Animals

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC ₅₀ (mg/L)	48-hr EC ₅₀ (mg/L)	Toxicity Category	NOAEC / LOAEC (mg/L)	Affected Endpoints
Atlantic Salmon <i>Salmo salar</i>	0.250	--	very highly toxic	--	--
Fathead Minnow <i>Pimephales promelas</i>	--	--	--	0.21 / 0.68	reduced growth
Stonefly <i>Chloroperla grammatica</i>	0.0051	--	very highly toxic	--	--
Water flea <i>Daphnia magna</i>	--	--	--	0.0015 / 0.0033	reproduction
Sheepshead minnow <i>Cyprinodon variegatus</i>	2.6	--	moderately toxic	--	--
Mysid shrimp <i>Mysidopsis bahia</i>	0.45	0.0057	very highly toxic	--	--

Ecological Incidents

Reports of ecological incidents also play a role in EPA's assessment of ecological toxicity effects. The documented fish and wildlife kills in EPA's Ecological Incident Information Systems are believed to be a small fraction of total mortality caused by pesticides. To be entered in EPA's database, mortality incidents must be seen, reported, investigated and have investigation reports submitted to EPA, and all these necessary steps may not occur for a variety of reasons. For carbaryl, there are relatively few reports of ecological incidents. Discussions of the several incidents involving birds, small mammals, bees, and fish are included in the following sections that describe carbaryl effects on these animals.

3. Ecological Risk Profile

EPA estimated the potential concentrations of carbaryl in *terrestrial* environments using the Kengaga nomograph, as modified by Fletcher, et al. (1994), based on a large set of actual field residue data. To estimate the potential concentrations of carbaryl in aquatic environments, EPA used computer modeling with data on crop usage (such as the application rate and frequency of carbaryl application), carbaryl chemical and fate properties, and site information (such as soils, weather patterns, terrain, etc.). The model, PRZM-EXAMS, provided screening-level EECs for carbaryl.

As stated earlier, the Agency evaluates the potential risk to nontarget organisms from the use of a pesticide by calculating Risk Quotient (RQs), which is the ratio of the EECs to the toxicity endpoint values. These RQ values are compared to the Agency's Levels of Concern

(LOCs) for birds, mammals, insects, fish and aquatic invertebrates. In general, the higher the RQ, the greater the potential risk. The LOCs and the corresponding risk presumptions are presented in Table 19.

Table 19. LOCs and Risk Presumptions

<i>FOR...</i>	<i>IF...</i>	<i>THEN the Agency presumes...</i>
Mammals and Birds,	The acute RQ > LOC of 0.5,	Acute risk.
	The acute RQ >LOC of 0.2,	Risk that may be mitigated through restricted use.
	The acute RQ > LOC of 0.1,	Acute effects may occur in endangered species.
	The chronic RQ > LOC of 1	Chronic risk. Endangered species may also experience chronic effects.
Fish and Aquatic Invertebrates,	The acute RQ > LOC of 0.5	Acute risk.
	The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use.
	The acute RQ >LOC of 0.05	Acute effects may occur in endangered species.
	The chronic RQ > LOC of 1	Chronic risk. Endangered species may also experience chronic effects.
Plants,	The RQ > LOC of 1	Acute risk. Endangered species may also experience acute effects.

A summary of EPA’s assessment of ecological risks for carbaryl based on the RQs and LOCs for terrestrial and aquatic organisms follows. For more detail, see the document titled *Environmental Fate and Ecological Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision*, dated March 18, 2003, particularly Appendix F.

a. Risk to Birds and Mammals

Table 20 shows RQs calculated for birds and mammals for nongranular formulations. Only the highest and lowest RQs are presented to provide a range. Crops associated with the highest RQs appear first in the table. For birds, RQs are based on diet only, with the most sensitive diet being short grass. Other diets assessed, generally in descending order of sensitivity, are tall grasses, broadleaf plants/small insects, and fruit/seeds/large insects. Note that acute risks to birds are not assessed because laboratory studies suggest carbaryl is practically non-toxic to birds.

For mammals, the highest RQs are based on the smallest mammals (15 grams) feeding on the highest exposure diet (short grass). The lowest RQs are based on the largest mammals (1000 grams) feeding on the lowest exposure diet (seeds).

Table 20. Birds and Mammals Highest and Lowest RQs for Nongranular Formulations

Use Sites	Application - Max Label Rate - Frequency - Interval Apart	Bird Chronic Highest RQ* (Lowest RQ)	Mammal Acute Highest RQ (Lowest RQ)	Mammal Chronic Highest RQ (Lowest RQ)
		LOC=1	LOC=0.5	LOC=1
Citrus (California)	16 lb ai/A 1 appl	13 (1)	12 (0.02)	51 (3)
Turfgrass	8 lb ai/A 2 appl 7 days	8 (0.5)	8 (0.02)	31 (2)
Olives	7.5 lb ai/A 2 appl 14 days	6 (0.4)	6 (0.01)	26 (2)
Tree nuts (almond, chestnut, filbert, pecan, pistachios, walnut)	5 lb ai/A 3 appl 7 days	5 (0.3)	5 (0.01)	22 (1)
Citrus (orange, lemon, grapefruit)	5 lb ai/A 4 appl 14 days	4 (0.3)	4 (0.01)	17 (1)
Corn (sweet)	2 lb ai/A 8 appl 3 days	4 (0.2)	3 (0.01)	15 (0.9)
Asparagus	2 lb ai/A 5 appl 3 days	4 (0.2)	3 (0.01)	14 (0.9)
Stone fruits (peaches, apricot, cherry, nectarine, plum/prune)	4 lb ai/A 3 appl 14 days	3 (0.2)	3 (0.01)	14 (7)
Pome fruits (apple, pear)	3 lb ai/A 5 appl 14 days	3 (0.1)	2 (<0.01)	10 (0.7)
Broccoli, Brussels sprouts, cabbage, cauliflower, collards, mustard greens, celery, lettuce, parsley, spinach, beets, potato, carrot, horseradish, parsnip, rutabaga, salsify, sorghum	2 lb ai/A 3 appl 7 days	2 (0.1)	2 (<0.01)	9 (0.5)
Small fruits & berries (grapes, blueberry, caneberry, cranberry, strawberry)	2 lb ai/A 5 appl 7 days	2 (0.1)	2 (<0.01)	8 (0.5)

Use Sites	Application - Max Label Rate - Frequency - Interval Apart	Bird Chronic Highest RQ* (Lowest RQ) LOC=1	Mammal Acute Highest RQ (Lowest RQ) LOC=0.5	Mammal Chronic Highest RQ (Lowest RQ) LOC=1
Solanaceous (tomato, pepper, eggplant), peanuts, tobacco, sweet potato	2 lb ai/A 4 appl 7 days	2 (0.1)	2 (<0.01)	8 (0.5)
Corn (field, pop)	2 lb ai/A 4 appl 14 days	2 (0.1)	2 (<0.01)	7 (0.4)
Rice, sunflower	1.5 lb ai/A 2 appl 7 days	2 (0.1)	1 (<0.01)	6 (0.4)
Legumes (beans, peas, lentils, cowpeas, soybeans)	1.5 lb ai/A 4 appl 7 days	2 (0.1)	2 (<0.01)	6 (0.4)
Alfalfa, clover	1.5 lb ai/A 8 appl 30 days	1 (0.08)	1 (<0.01)	5 (0.3)
Sugar beets, wheat, millet, flax, pasture, grasses, noncropland	1.5 lb ai/A 2 appl 14 days	1 (0.08)	1 (<0.01)	5 (0.3)
Forested areas (non-urban)	1 lb ai/A 2 appl 7 days	1 (0.06)	1 (<0.01)	4 (0.2)
Cucurbits (cucumbers, melons, squash, pumpkin), trees and ornamentals	1 lb ai/A 6 appl 7 days	1 (0.07)	1 (<0.01)	4 (0.3)
Rangeland	1 lb ai/A 1 appl	0.8 (0.05)	0.8 (<0.01)	3 (0.2)
*Acute risks to birds are not assessed because laboratory studies suggest carbaryl is practically nontoxic to birds on an acute basis.				

Since carbaryl is practically nontoxic to birds on both an acute and subacute dietary exposure basis, no acute RQ values have been calculated; they are assumed to be RQ < 0.1 and therefore not of concern to the Agency. Chronic risk quotients are based on a mallard duck NOAEC of 300 mg/kg of diet (ppm) for birds feeding on four categories of food, i.e., short grasses, tall grasses, broadleaf plants/small insects, and fruit/seeds/large insects. Table 20 shows RQs only for crop uses at the maximum application rate for nongranular formulations.

Based on criteria for Table 20, bird RQs exceed the chronic risk LOC of 1 for all, or 100%, of the assessed uses. When assessing average use rates, the percentage of uses that exceed the LOC drops to 50%. For birds feeding on tall grasses and broadleaf plants/small insects, 55% and 60% of the modeled use categories exceed the chronic LOC, respectively, at the maximum label rate. None of the modeled uses exceeded the chronic LOC for birds feeding on fruit/seeds/large insects.

Passerine birds (perching birds) may be more sensitive. Open literature suggests that carbaryl may be moderately toxic to small birds. Additionally, of the two field incidents that could be clearly attributed to carbaryl, both affected smaller-sized birds. In one reported incident, a single morning dove (*Zenaida macroura*) died after a homeowner had applied carbaryl to the lawn in the vicinity of a bird feeder, apparently contaminating feed on the ground. The animal exhibited reduced acetylcholinesterase activity and had 2.4 mg/kg of carbaryl in its stomach contents. In a second incident, five blackbirds were discovered dead. No residue analysis was conducted on the birds, but carbaryl residues were detected in a dead squirrel found in the vicinity; however, acetylcholinesterase activity was not reduced in the squirrel.

Carbaryl is moderately toxic ($LD_{50} = 301$ mg/kg) to mammals on an acute exposure basis. In addition to the risks listed in Table 20 for nongranular formulations, mammals may also experience exposure to granular/bait formulations of carbaryl through ingestion and/or walking on exposed granules. Table 21 shows the risk estimates for granular use.

Table 21. RQs for Mammals for Granular Formulations (broadcast, unincorporated)

Uses	Rate in lb ai/A	Body Weight (g)	Acute RQ (LD_{50}/ft^2)
Asparagus, <i>Brassica</i> crops (broccoli, cabbage, cauliflower, collards, etc.), corn (field, sweet), sorghum, solanaceous crops (tomato, pepper, eggplant), leafy vegetables (celery, lettuce, parsley, spinach, etc.), roots & tubers (beets, carrots, radishes, potatoes, etc.), strawberries	2	15	5
		35	2
		1000	0.07
Cucurbits (cucumber, melon, pumpkin, squash)	1	15	2
		35	1
		1000	0.03
Legumes (beans, peas, lentils, cowpeas, southern peas), Wheat, millet, Sugar beets	1.5	15	3
		35	1
		1000	0.05
Trees and ornamentals, turfgrass, tick control	9.15	15	21
		35	9
		1000	0.32

The acute risk LOC for small and intermediate-sized mammals is exceeded (RQ range: 0.99 - 21) for all 40 registered granular uses. For large-sized mammals, acute restricted use and endangered species LOCs are exceeded following application for trees and ornamentals, turfgrass, and tick control. *Chronic mammalian exposure* to carbaryl resulted in decreased second-generation pup survival in a two-generation rat reproduction study (NOAEC = 75 mg/kg

of diet). For terrestrial animals, the highest RQs were for chronic mammalian exposures to carbaryl, with an RQ range of 3 to 51.

A total of two incidents were reported for mammals, both incidents involving smaller mammals. One involved a gray squirrel (*Sciurus carolinensis*), and a second involved a hairytail mole (*Parascalops breweri*). In neither case was information provided on what use of carbaryl may have resulted in the deaths of these animals.

b. Risk to Insects

Acute contact toxicity studies indicate that technical carbaryl is highly toxic to honey bees (*Apis mellifera*) with an $LD_{50} = 0.0011$ mg ai/bee; however, acute contact toxicity testing of Carbaryl SC, an end-use product, indicates bees are less sensitive to formulations with an $LD_{50} = 0.0040$ mg ai/bee. *Acute oral toxicity studies* with carbaryl reveal that technical grade carbaryl, with an $LC_{50} = 0.0001$ mg ai/bee, is roughly ten times more toxic than the formulated soluble concentrate (Carbaryl SC $LC_{50} = 0.0016$ mg ai/bee). Carbaryl ranged from being moderately to highly toxic to predacious insects, mites and spiders.

In a field study to examine the effects of carbaryl on bees when the chemical is used to thin fruit, carbaryl SC (water miscible concentrate) applications to apple orchards at a rate of 0.8 lbs ai/A did not have a significant effect on bee mortality and/or behavior.

A total of five incidents related to carbaryl are reported in the Ecological Incident Information System . Two of the reports do not contain any data but rather reflect general concerns expressed by the American Beekeeper Federation and the Honey Industry Council on the role pesticides play in bee kills. The remaining three incidents are: a bee mortality incident associated with 0.08 ppm carbaryl residues in North Carolina; another North Carolina bee mortality incident more likely attributable to methyl parathion than carbaryl; and a Washington State bee mortality incident associated with carbaryl use on asparagus. EPA also received comments from Minnesota bee keepers expressing concerns about carbaryl on poplar groves. EPA received these comments after issuing the revised risk assessment.

c. Risk to Aquatic Animals

To assess potential risk to aquatic animals, the Agency used the PRZM-EXAMs computer model to generate EECs of carbaryl in surface water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir and Percent Crop Area factor. The Index Reservoir and Percent Crop Area factor represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EECs used to assess exposure to aquatic animals are not the same, and are generally higher, than the drinking water EEC values used to assess human dietary exposure from drinking water sources. Table 22 shows the RQs for freshwater fish and invertebrates for selected crops.

Table 22. RQs for Freshwater and Invertebrates at Maximum Label Rates

Uses	Application -Max Label Rate - # of Apps. - Interval	Freshwater Fish*		Freshwater Invertebrates*	
		Acute LOC = 0.5	Chronic LOC = 1	Acute LOC = 0.5	Chronic LOC = 1
Citrus (orange, lemon, grapefruit) [Florida scenario]	5 lb ai/A 4 appl 14 days	0.6	0.2	30	55
Corn (sweet), [Ohio scenario]	2 lb ai/A 8 appl 3 days	0.2	0.09	10	20
Sugar beets, wheat, millet, flax, pasture, grasses, non-cropland, [Minnesota scenario]	1.5 lb ai/A 2 appl 14 days	0.09	0.03	5	9
Pome fruits (apple, pear) [Pennsylvania scenario]	3 lb ai/A 5 appl 14 days	0.12	0.03	6	10
Corn (field, pop) [Ohio scenario]	2 lb ai/A 4 appl 14 days	0.19	0.07	9	17
* Acute RQs for <i>estuarine/marine fish and invertebrates</i> , not shown in the table, are within the same range or are less than those listed for freshwater fish and invertebrates in this Table. Guideline data for <i>chronic</i> effects for estuarine/marine organisms are still outstanding.					

Freshwater Fish

Table 22 above shows acute and chronic risk quotients for freshwater fish based on maximum label rates; the acute risk LOC (RQ \$0.5) is exceeded on citrus alone. The endangered species LOC, however, is met or exceeded on all of the crops modeled, even when assessed separately at average use rates. As discussed later, EPA is currently in consultation with the National Marine Fisheries Service about possible effects to endangered salmonids.

Although a total of three fish-kill incidents were reported for carbaryl, only one report could be credibly associated with a specific carbaryl use, i.e., to control gypsy moth in New Jersey.

Amphibians

EPA considered effects on amphibians in the ecological risk assessment for carbaryl because of literature data on potential carbaryl effects on amphibians, including citations submitted to the Agency as part of public comment. Data suggest that carbaryl ranges from

being slightly to moderately toxic to amphibians on an acute exposure basis. Intra and inter-species variability contributed to the range of amphibian responses to carbaryl. While much of the current research focuses on direct acute effects of carbaryl on tadpoles/frogs, the indirect effects of carbaryl on impairing predator avoidance is frequently raised as a concern.

On a chronic exposure basis, carbaryl has been shown to have the potential to adversely affect amphibians. Southern leopard frog tadpoles exposed to carbaryl during development exhibited some type of developmental deformity, including both visceral and limb malformations, compared to less than 1% in control tadpoles (Bridges, 2000). Although the length of the larval period was the same for all experimental groups, tadpoles exposed throughout the egg stage were smaller than their corresponding controls. Appendix D2 of the *Environmental Fate and Ecological Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision*, dated March 18, 2003 includes EPA's review of data related to amphibian effects.

Freshwater Invertebrates

Acute risk quotients (RQ range: 4.5 - 30) and chronic risk quotients (RQ range: 8.7 - 55) for freshwater invertebrates exceed their respective LOCs at maximum label rates. Note that Table 22 shows only the results for maximum label rates. EPA also assessed RQs at average use rates. These also exceeded the respective LOCs for acute risks (RQ range: 1.4 - 20) as well as chronic risks (RQ range: 2 - 34) for freshwater invertebrates.

Estuarine/Marine Fish

Similar to freshwater fish, carbaryl is moderately toxic to estuarine/marine fish; however, none of the estimated RQs exceeded acute risk LOCs. The acute endangered species LOC was minimally exceeded (RQ = 0.06) for citrus. At present there are no data with which to evaluate the chronic toxicity of carbaryl for marine/estuarine fish. These data requirements are still outstanding.

Estuarine/Marine Invertebrates

Carbaryl is very highly toxic to estuarine/marine invertebrates. The acute risk LOC for estuarine/marine invertebrates is exceeded for all five carbaryl uses modeled at maximum label rates. The Agency also separately assessed uses at average rates (RQ range: 1.2 - 18). No data were available to assess the chronic risk of carbaryl to estuarine/marine invertebrates. These data requirements are still outstanding.

Section 24c Use of Carbaryl to Control Burrowing Shrimp

For several decades, carbaryl has been used to control burrowing shrimp on tidal mudflats in Willapa Bay and Grays Harbor, Washington. Although concern has been raised regarding this use and its potential impact to nontarget animals outside of treated areas, very

little data have been provided to substantiate these concerns. The available data indicate that acute mortality will likely be near 100% for animals trapped on mudflats in the immediate application area and that carbaryl will likely drift off-site with the tide. But potential nontarget acute and chronic effects are remote given the relatively small number of acres treated and the rapid degradation of carbaryl from biotic and abiotic factors combined with the dilution from a relatively large influx of water. Additionally, as part of a settlement agreement with the Washington Toxics Coalition, oyster growers on Willapa Bay and Grays Harbor have agreed to a 12-year phase-out of carbaryl use on oyster beds while they look for alternatives for controlling populations of burrowing shrimp. For more details, see the March 18, 2003 *Environmental Fate and Ecological Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision*, particularly Appendices E1 to E3.

d. Risk to Plants

Based on limited data, the likelihood of adverse effects to aquatic and terrestrial plants appears to be low from maximum label use rates. Although toxicity data suggest that carbaryl is relatively innocuous to plants, the greatest number of incidents (11) for carbaryl have involved terrestrial plants. While the majority of these reports have been associated with homeowner use of the product, some agricultural crops, *e.g.*, quince and olive, have reported losses resulting from spotting, low fruit set and malformations in fruit shape.

Only two studies of the filamentous green algae *Pseudokirchneriella subcapitata* were available to assess the toxicity of carbaryl to aquatic plants. With technical grade carbaryl the concentration inhibiting plant growth (in terms of number of algal cells) by 50% was roughly similar to the endpoint for formulated end product. In neither study were abnormalities in cell morphology or signs of phytotoxic effects observed. As reported earlier, carbaryl use has been associated with increases in phytoplankton numbers. Whether this is due to reduced predation by zooplankton as a result of their greater susceptibility to carbaryl and/or a response to 1-naphthol being a plant auxin is unclear.

e. Risks to Endangered Species

Avian

Chronic LOCs are exceeded for birds feeding on short grasses for all uses modeled except rangeland. For birds feeding on tall grasses, the avian chronic LOC is exceeded for 55% of the modeled uses and for birds feeding on broadleaf/forage plants and small insects, the chronic LOC is exceeded for 60% of the uses modeled. When RQs were based on average use rates, 49% of the uses exceeded chronic LOCs.

Mammals

For mammals that are herbivores, all uses modeled exceeded the acute endangered species LOC. For mammals foraging on broadleaf plants and small insects, the endangered species LOC is exceeded for all uses except cucurbits, trees, ornamentals, rangeland and forested areas. For mammals feeding on large insects, roughly 70% and 45% of the use categories modeled exceeded the acute endangered species LOC for small (15 g) and intermediate-sized (35 g) mammals, respectively. Only one use, i.e., California citrus, exceeded the LOC for large-sized animals (1,000 g). For mammals that are granivores, the acute endangered species LOC is exceeded for small-sized animals feeding in citrus and turfgrass areas and for intermediate-sized mammals feeding in citrus areas. Chronic LOCs are exceeded for all modeled uses for mammals feeding on all food items except seeds/fruits and large insects. For granivores, the chronic LOC is exceeded for citrus, olives, stone fruits, tree nuts and turf grass. When RQs were based on average rates, acute and chronic endangered species LOCs are exceeded for all of the modeled uses. Additionally, granular products represented an acute risk to both small and intermediate-sized mammals all on of the uses modeled. Granules were only a risk to large-sized mammals for trees, ornamental, turfgrass and tick control uses.

Aquatic Animals

For freshwater fish the endangered species LOC is exceeded for all of the crops modeled for all use rates, except for sugar beets. For freshwater invertebrates, the acute and chronic endangered species LOCs are exceeded for all of the uses modeled. For estuarine/marine fish, only use on citrus exceeded the acute LOC for all use rates. For estuarine/marine invertebrates, the acute endangered species LOC is exceeded for all of the use and rates modeled; however, there currently are no federally listed estuarine invertebrates. At the current application rates, carbaryl use is likely to result in both acute and chronic risks to endangered/threatened species of animals.

Background on Carbaryl and Endangered Species

In 1989 the U.S. Fish and Wildlife Service (USFWS) issued a Biological Opinion (USFWS 1989) on carbaryl in response to the EPA's request for consultation. In issuing its opinion the USFWS considered the following factors: (1) potential for exposure of the listed species to the pesticide; (2) information on the chemical toxicity relative to EECs; (3) potential for secondary impacts; and (4) special concerns not specifically addressed in the preceding factors or unique to the situation being evaluated. Given the evaluation criteria, a total 127 species (6 amphibians, 77 fish, 32 mussels, 9 crustaceans, 1 insect, and 2 bird species) were considered potentially affected by the use of carbaryl. Of those organisms potentially affected, the USFWS listed 85 aquatic species as jeopardized, of which the majority (51%) were endangered/threatened species of freshwater fish. One terrestrial (avian) species was also classified as being in jeopardy. The remaining potentially affected organisms were listed either as having no potential for exposure or as not being in jeopardy. For all of the species listed as jeopardized the USFWS lists reasonable and prudent alternatives (RPA) to mitigate the effects of

carbaryl use. For some of the species listed as not jeopardized, the USFWS lists reasonable and prudent measures (RPM) and incidental take (IT) to mitigate effects. For details on the RPA and RPM recommendations, the reader is referred to USFWS 1989 publication. Many additional species, especially aquatic species, have been federally listed as endangered/threatened since the Biological Opinion of 1989 was written, and determination of jeopardy to these species has not been assessed for carbaryl.

EPA's current assessment of ecological risks uses more refined methods to define ecological risks of pesticides, as well as new data, such as data for spray drift. Therefore, the RPAs and RPMs in the Biological Opinion may need to be reassessed and modified based on these new approaches.

The Agency sent a consultation package to the National Marine Fisheries Service (NMFS) on April 1, 2003, to address possible effects to listed Pacific salmon and steelhead in Washington, Oregon, Idaho, and California. EPA is committed to look at other species beyond those discussed in this consultation package; additional consultations with both USFWS and NMFS are expected to cover other terrestrial and aquatic species.

The Agency is also engaged in a Proactive Conservation Review with USFWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects on federally listed threatened and endangered species from carbaryl use. At that time the Agency will also consider any regulatory changes recommended in the IRED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets which address carbaryl, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to carbaryl at levels of concern.

C. Benefits and Alternatives

Carbaryl controls a wide spectrum of insect pests across a wide range of use sites, both agricultural and non-agricultural. Carbaryl's use pattern varies substantially across the spectrum of use sites on which it is registered. The Agency reviewed its use patterns on many use sites and utilized that information in forming a regulatory position and for determining the mitigation measures necessary to address risks of concern.

The Agency analyzed the impact of two main mitigation strategies for addressing risks of concern: extending the restricted entry interval (REI) and reducing application rates. Detailed benefits assessments were completed for three specific uses of carbaryl: citrus, grapes and residential lawns. Additionally, 21 individual crop analyses were completed for crops that had an estimate of 5% crop treated or more with carbaryl (*Summary Tables of Carbaryl Benefit Information on Selected Crops*, May 23, 2003). For the individual crop sites presented in this

document, the Agency determined that a full benefits analysis was not needed because the proposed mitigation strategies could be implemented without substantially affecting carbaryl's use on these crops. For several sites, extending the REI will have little to no impact because there are no activities involving hand labor that typically take place at the same time as carbaryl applications. A summary of the benefits findings for carbaryl's use on citrus and grapes are presented below.

Citrus

The largest amount of carbaryl use on citrus crops occurs in California and Florida, which also produce the majority of US citrus, with additional small amounts of use in other states (Texas and Arizona). EPA focused its assessment of carbaryl on use patterns in California and Florida. The preharvest interval following applications of carbaryl is 5 days for citrus.

California Citrus

The main targets of carbaryl use in California are the California red scale, *Aonidiella aurantii*, and the cottony cushion scale, *Icerya purchasi*. Carbaryl is also used to control other sporadic but potentially serious pests, including Fuller rose beetle, black scale, fruittree leafroller, amorbia caterpillars, and the western tussock moth. Of these, the Fuller rose beetle, *Asynonychus godmani*, is arguably the most serious, because Pacific Rim countries require fumigation of citrus shipments if even a single insect is detected, which is expensive and can damage the fruit.

Scale are sedentary insects, and for most of their life, are covered by a thick layer of waxy material as protection. Packing houses often cannot clean infested fruit, in which case they are downgraded from the fresh market to processing (juice). Uncontrolled scale damage to fruit can result in up to 48% of the harvest being downgraded. High populations of both scale can also reduce tree vigor and yield since they feed on the nutrient-rich tree sap. The cottony cushion scale was, until recently, under effective control by the Vedalia beetle, *Rodolia cardinalis*. However, the recent registration of new insect growth regulators (IGRs), buprofezin and pyriproxyfen, has resulted in population outbreaks of this scale. This is because these insecticides, while very effective in controlling scale, are also toxic to the Vedalia beetle.

California red scale can also be controlled by a natural enemy, a parasitic wasp, *Aphytis melinus*. It is mass-reared and released by growers throughout the state. While this natural enemy is not affected by IGRs, it is sensitive to dust that covers leaves and fruit, and so it is not always completely effective. Hence, growers in areas affected by both scale species - virtually all in the San Joaquin Valley region - must also apply insecticides to achieve adequate control. High rates of carbaryl are used in this region (up to 16 lb ai/A) to achieve adequate penetration and coverage of foliage; high rates also appear more effective on adult cushion scale females. However, actual use of the maximum allowed 16 lb ai/A rate appears to be rare. In 2001, California Department of Pesticide Regulation (CDPR) data indicate that the modal (most frequently used) application rate of carbaryl in oranges, the majority of which is grown in the

San Joaquin valley, was 12 lb ai/A.

In addition to the natural control exerted by the Vedalia beetle and *Aphytis* wasps, the organophosphates methidathion and malathion, and the IGRs buprofezin and pyriproxyfen, are currently efficacious against both scale species. However, at least 40% of the citrus acreage in the San Joaquin Valley harbors populations of both scale that are resistant to organophosphates and carbamates, which increases the importance of rotating chemistries to reduce the spread of resistance. In addition, as described earlier, use of the IGRs can increase cushion scale infestations. Thus, in the San Joaquin valley in particular, the importance of carbaryl as a management tool for scale is greatly increased as compared to other areas. About 80% of California oranges are grown in this region.

Carbaryl sprays aimed at red scale are typically timed for May through July when crawlers are the most vulnerable life stage. Carbaryl used for cushion scale is most often applied in early spring (March through April) so as to most affect adult females. Almost all applications are foliar sprays applied by air blast sprayers, though rarely aerial application is also made (approx. 10% of acres treated). Worker activities likely to coincide with these carbaryl applications are irrigation and scouting, which can occur multiple times within a week, and hand harvesting, which occurs according to the mandated 5 day pre-harvest interval (PHI). Pruning also can occur at the time cottony cushion scale treatments are made. Carbaryl was applied once per season, on average, in California on oranges and grapefruit in 2001 (NASS 2002).

Florida Citrus

A complex of eight root feeding beetle species are targets of most carbaryl applications in citrus grown in Florida. Of these, the *Diaprepes* or Apopka root weevil, *Diaprepes abbreviatus*, is considered the most critical pest. Isolated populations also exist in citrus grown in Texas.

All root weevils can seriously damage citrus roots when feeding as larvae, but *Diaprepes* is particularly destructive because its feeding appears to foster the entry of *Phytophthora palmivora*, a fungus which causes “foot rot” in the roots. Although damage by all weevils is most severe in young trees, the combination of feeding damage and foot rot due to this fungus can affect even mature citrus. Adult weevils also feed on citrus foliage, but do not cause economic levels of damage. However, carbaryl application targets the adults feeding on the foliage in an attempt to suppress egg laying.

Insects other than these beetles that are also occasionally targeted by carbaryl applications in Florida include orangedog caterpillars, katydids, grasshoppers, crickets and scale. These insects are relatively rare economic problems, however.

Carbaryl applications targeting *Diaprepes* weevil use rates of between 4 and 8 lb ai/A. Growers rarely, if ever, appear to use the maximal 10 lb ai/A application rate that is allowed by an existing special local needs label for Florida citrus. An average of 1.5 applications was made in Florida citrus in 2001. Florida extension service literature recommends a maximum of two

applications per season for *Diaprepes* weevil. It is also noteworthy that carbaryl use is not recommended at temperatures above 94° F. However, Florida extension literature also advises growers to time foliar insecticide applications to coincide with peak adult emergence. For *Diaprepes* weevil, two peaks occur, one in late August to mid-October, and another from April to mid-June.

From this, EPA infers that carbaryl use intended for weevil control is optimally timed to occur in the usually cooler period of April - June. Carbaryl applications are thus likely to occur when workers need to enter fields to irrigate, scout, or harvest. Harvesting in Florida is most often done mechanically, though some hand harvest does also occur. Harvesting is typically done on a weekly basis, as in California. However, irrigation activities (primarily checking and repairing equipment) and scouting for pests must often be carried out more than once a week throughout the season. As in California, most carbaryl applications are by ground airblast sprayers.

For those insects rarely targeted by carbaryl in Florida, the Agency believes effective alternatives currently exist, including *Bacillus thuringiensis* (*Bt*), chlorpyrifos, and azinphos-methyl. For *Diaprepes* weevil, efficacious alternatives currently registered include fenprothrin, a synthetic pyrethroid, and diflubenzuron, an IGR. Bifenthrin, also a pyrethroid, is also effective but is only available until 2004 under a Section 18 registration and its use is targeted at controlling the larval stage of *Diaprepes* and is directed at the soil. Cultural controls, such as weed control to eliminate alternate hosts, adequate soil drainage and irrigation, along with the use entomophagous nematodes active against weevil larvae, can also provide some control, though EPA believes they are not often adequate without some use of synthetic insecticides targeting the adult weevils.

Grapes

California is by far the largest producer of grapes in the U.S. with about 825,000 bearing acres in 2002, out of about 935,000 acres nationally, with acreage in most states is expanding in recent years. Certain grape varieties are targeted toward specific markets, including table grapes, grapes for raisins, and wine grapes. However, actual utilization is somewhat flexible, particularly within table grape varieties. According to the USDA National Agricultural Statistics Service (USDA/NASS), over half of California production is for wine, including about 15-20% of the table and raisin grapes varieties. About 25% of total production is dried for raisins; in California, almost 70% of raisin varieties and about 4% of table grapes are dried. About 13% of total production goes to the fresh market, including about 80% of the table grapes and 10% of the raisin varieties in California. Arizona and Georgia are the other main states where table grapes are dominant. The production region around the Great Lakes, including New York, Michigan and Pennsylvania, and the Pacific Northwest primarily focus on juice production with some wine. Nationally, about 7% of production is for juice or other uses, but makes up almost 70% of the production outside California.

EPA estimates, based on data covering the period of 1992 to 2001, that carbaryl is used

on approximately 7% of the grapes grown in the US. The most recent USDA/NASS reports (2000, 2002) indicate that about 84,400 lb a.i. are used annually to treat approximately 41,300 acres. Carbaryl is used on only about 4% of current acreage in states surveyed; however, these data are from only selected states and may underestimate total usage. Carbaryl is predominantly applied by ground airblast equipment.

This low national estimate of use masks some important regional differences in carbaryl use patterns. Over 90% of grape bearing acreage is found in California, but the most recent USDA and California Department of Pesticide Regulation data indicate that only 1.2% of the area is treated with carbaryl. Similarly, only 2.2% of the grape acreage in the Pacific Northwest are treated. However, east of the Rocky Mountains, usage is much greater. Grape producers in the Northeast and South treat about 60% of their acreage, often multiple times. The USDA/NASS (2000, 2002) report between 60 and 70% of acreage is treated in Michigan, New York and Pennsylvania. According to available USDA crop profiles, carbaryl is applied to 40% of the acreage in Missouri, 90% of the acreage in Ohio, Virginia, and North Carolina; and up to 100% of the grape acreage in Indiana and Tennessee. Grapes produced east of the Rocky Mountains utilize nearly 85% of the total pounds of carbaryl used in the US on grapes.

Current carbaryl labels for grapes allow a maximum application rate of 2 lb a.i./A and up to five applications per season. Nationwide, carbaryl is applied to this crop, on average, once or twice per year, at a rate of 1 to 2 lb a.i./A/application.

In wine producing states east of the Rockies, carbaryl is used mainly to control the grape berry moth (*Endopiza viteana*) and grape leafhopper (*Erythroneura comes*), both of which are key pests of grapes, capable of inflicting severe damage to the crop if not controlled. Carbaryl is also used to control numerous minor pests, such as the banded grape bug, potato leafhopper, grape flea beetle, grape rootworm, Japanese beetle, green June beetles, rose chaffer, several climbing cutworm species, European corn borer, and yellow jackets and other wasps. The Japanese beetle, a voracious foliage feeder, is of some concern. Although damage to grapes is reported to be mostly cosmetic in growing vines, excessive foliar feeding in newly planted vineyards can result in delayed root and canopy development resulting in a delay of one year or more in terms of full crop production. As a rule, applications intended to control the two primary pests also control secondary pests.

Unlike the eastern states, carbaryl plays a minor role in grape pest management in western states. In California, carbaryl is applied to table and raisin grapes primarily for late season leafhopper control, at a rate of up to 2.0 lb ai/A. Comments submitted by Western Region Pest Management Center Director, Rick Melnicoe, indicate that in 2001 the median application rate was 1.0 lb ai/A on table grapes and 1.6 lb ai/A on wine grapes. Carbaryl has also been used occasionally in California to control the omnivorous leafroller, western grape-leaf skeletonizer, the grape leaf folder, and the false chinch bug. In California carbaryl is considered to be disruptive to mite's natural enemies and newer chemistries, such as fenpropathrin, are preferred.

In the grape-producing states east of the Rockies, carbaryl is generally preferred to its alternatives because it has broad-spectrum activity, being effective against key and secondary grape pests; it does not tend to flare spider mites by killing predatory mites as is the case with methomyl and fenpropathrin; it has long-lasting residual effect; it is not a restricted use pesticide (RUP) while its leading alternatives fenpropathrin, methomyl, and azinphos methyl are RUPs; and its use is economical.

East of the Rockies, carbaryl is applied at bloom time to control first generation grape berry moths, leafhoppers, and the rose chaffer. Later in the season, control of the berry moth coincides with the need to control the Japanese beetle and late-season leafhopper populations. Several key worker activities are often performed on a daily basis during the time when carbaryl is used. This is especially true for grapes grown for wine. Growers and workers need to enter their vineyards for thinning, leaf-pulling, shoot positioning/tucking, and other manual canopy adjustments throughout the season.

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing carbaryl as an active ingredient.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient carbaryl, as well as carbaryl-specific dietary and residential risk assessments. However, the Agency has not considered the cumulative effects of carbamates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient carbaryl, EPA has sufficient information on the human health and ecological effects of carbaryl to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that carbaryl is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures, including the deletion of broadcast applications with the liquid formulations for residential turfgrass and other specified uses from the technical product labels; and (iii) cumulative risks considered for the carbamates support a final reregistration eligibility decision (RED). Label changes as a result of these risk mitigation measures are described in Section V of this document. Moreover, Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of carbaryl, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered cumulative risks for the carbamates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of carbaryl. Based on its current evaluation of carbaryl alone, the Agency has determined that carbaryl products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risks of concern from use of carbaryl.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For carbaryl, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. But, because this is an interim RED (IREDD), the Agency may take further actions, if warranted, to finalize the RED for carbaryl after assessing the cumulative risk of the carbamate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each carbamate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the

carbamates in as timely a manner as possible.

Because the Agency has not yet considered cumulative risks for the carbamates, this IRED does not fully satisfy the reassessment of the existing carbaryl food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has considered cumulative risks, carbaryl tolerances will be reassessed in that light. At that time, the Agency will reassess carbaryl along with the other carbamate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical carbaryl, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the RED, that any of the determinations described in this IRED are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this IRED.

B. Summary of Phase 5 Comments

The Agency considered comments received during Phase 5 of the Public Participation Process for Carbaryl. EPA received comments from a technical registrant for carbaryl, an end-use formulator for carbaryl, grower groups, land grant universities, environmental groups, state and local government, and private citizens. Many stakeholders sent informal comments to EPA via e-mail as a followup to USDA conference call held on May 7, 2003. Other stakeholders submitted formal comments to public docket for carbaryl. All formal comments are available in their entirety in the public docket for carbaryl and on the internet. The Agency's formal response to comments will be finalized after the IRED is completed. Comments are briefly summarized below.

Registrants

Bayer CropScience, a technical registrant for carbaryl, submitted formal comments to the docket. Bayer commented on the restricted entry intervals (REIs) listed in the revised risk assessment and on the current rotational crop restrictions for carbaryl. The registrant believes that the REIs for carbaryl should be based on data submitted by the Agricultural Re-Entry Task Force, rather than default transfer coefficients. The registrant also commented on the existing rotational crop restriction for carbaryl and submitted data to support removing current rotational crop restrictions from carbaryl labels. Bayer has also submitted a probabilistic risk assessment to EPA outside the formal public process.

Another registrant, the Scotts Company, submitted substantive comments on EPA's residential risk assessment outside the formal public process. Scotts submitted extensive

comments on the underlying assumptions used in the revised risk assessment. Scotts also proposed some measures to mitigate residential risks.

Grower Groups

The following grower groups submitted comments to the carbaryl docket: California Cantaloup, Honeydew, and Mixed Melon Industries, California Melon Research Board; Florida Cattlemen's Association, the Lawn Care Association of America, the Cranberry Institute, the Michigan Blueberry Growers Association, the Texas Vegetable Association, Texas Citrus Mutual, Wild Blueberry Commission of Maine, Florida Citrus Mutual, the American Sugarbeet Growers Association, the United States Apple Association, and the Washington Asparagus Commission (on behalf of growers in Washington, California, and Michigan). Although comments from grower groups are far too extensive to list in this document, comments focused on the nature, extent, and importance of carbaryl use; application rates; cultural practices for specific crops; pest pressures; alternatives, if available; REIs; and preharvest intervals. Some grower groups provided information on typical re-entry activities to help EPA refine the risk assessment. A few grower groups also commented on the importance of carbaryl in integrated pest management (IPM) programs.

The informal comments from grower groups focused primarily on the proposed REIs for various crops presented in the revised risk assessment. Some comments discussed the importance of carbaryl to crop production and the lack of alternatives. Other comments provided general information about carbaryl use on various crops. Grower representatives who commented via e-mail (but did not also send comments to the docket) include the Ohio Farm Bureau, the Florida Farm Bureau, the California Strawberry Commission, the National Grape Cooperative, and the consulting firm Schramm, Williams, and Associates.

Land Grant Universities

Cooperative extension offices from the following universities submitted comments to the carbaryl docket: Mississippi State, Michigan State, University of Hawaii, and Washington State (TriCities Campus). Mississippi State commented on carbaryl use on corn, forage, pecans, and sorghum; Michigan State commented on blueberry and sod farm uses; the University of Hawaii commented on carbaryl use on sweet potatoes, golf courses, and cut flowers; and Washington State commented on carbaryl use on numerous commodities grown in the Pacific Northwest. General topics covered in these comments included REIs, exemptions, and re-entry activities, use practices, cultural practices, efficacy of reduced rates, and alternatives (or lack thereof).

Numerous other universities submitted informal comments, including the University of Delaware, Rutgers, University of Georgia, University of Maryland, Penn State, University of Maine, Cornell, South Dakota State University, and Oklahoma State. Most of these comments focused on REIs, but some mentioned the importance of carbaryl use on various commodities, cultural practices, target pests, and pesticide alternatives, where available.

Environmental Groups

The environmental and public advocacy groups Natural Resources Defense Council (NRDC) and Beyond Pesticides submitted comments to the carbaryl docket. Both groups commented on EPA's decision regarding the FQPA safety factor for carbaryl. NRDC commented on various aspects of the revised risk assessment, including the use of percent crop treated to calculate dietary exposure, and use of the registrant's probabilistic risk assessment by EPA. NRDC requested that carbaryl be considered with other N-methyl carbamates and the organophosphates in a cumulative risk assessment. NRDC suggested that EPA consider urban runoff (from residential use of carbaryl) in the water assessment, and that EPA include exposure from food purchased at farm stands or pick your own facilities in the dietary assessment. In addition, NRDC commented on ecological risks from granular products, including risks of concern to honeybees and endangered species. The advocacy group, Beyond Pesticides, commented that EPA doesn't consider the estrogenic potential of carbaryl in the risk assessment, as mandated by FQPA. Beyond Pesticides requested that EPA consider exposure from actual, rather than labeled use rates of carbaryl and that EPA also consider the potential changes in the amount of carbaryl used in residential settings as it replaces other pesticides, such as chlorpyrifos and diazinon. This group requested that EPA consider exposure to children from the golf course use, from aerial spraying, and from drinking water in the risk assessment. Last, Beyond Pesticides stated that EPA must consult with the Fish and Wildlife Service and National Marine Fisheries regarding the impact of carbaryl on endangered species.

State and Local Governments

The California Department of Food and Agriculture, the California Regional Water Quality Control Board (San Francisco Bay Region), the County Sanitation District of Los Angeles, and the California Stormwater Association submitted comments to the carbaryl docket. The California Department of Food and Agriculture commented on the importance of carbaryl in a program to control Peirce's Disease in California vineyards. The California Water Quality Control Board requested that EPA evaluate the impacts of the residential use of carbaryl on surface water to comply with the Clean Water Act, Section 303(d) on water quality criteria. This water board also requested that EPA consider the economic impacts of habitat impairment in the carbaryl regulatory decision. Last, the water board requested that EPA consider the costs to water quality agencies responsible for compliance with the Clean Water Act. The County Sanitation District of Los Angeles expressed concerns about the carbaryl released to water treatment facilities as a result of use in pet shampoos. The California Stormwater Quality Association expressed concern about carbaryl contamination of surface water from runoff associated with urban use and requested that EPA limit carbaryl uses which are most likely to impact surface water and require surveillance monitoring in urban watersheds. This association believes that the revised risk assessment underestimates aquatic impacts from urban runoff and requests that OPP use methodologies available through EPA's Office of Water. The stormwater association also wants EPA to conduct economic impacts of urban uses of carbaryl, including costs to water quality agencies and costs from impaired habitats. Further, they want EPA to promote safer alternatives and limit carbaryl use to situations where those alternatives are not

available. Last, they want EPA to commit to a schedule for post-RED activities, especially those associated with water and endangered species.

Private Citizens

Private citizens who submitted comments included an oyster farmer in Washington State, an environmental educator, two beekeepers from Minnesota, and a law office involved in litigation on behalf of a beekeeper. The oyster farmer and the beekeepers reported substantial business losses from misuse of carbaryl. The environmental educator requested that carbaryl be banned.

Others

A consulting firm, G. Fred Lee and Associates, submitted comments regarding a study on the impacts of carbaryl on aquatic organisms on the Upper Newport Bay/San Diego Creek Watershed in Orange County, California.

C. Regulatory Position

1. FQPA Assessment

a. “Risk Cup” Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this carbamate. The assessment was for this individual carbamate, 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 carbamates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of carbamates once the policy concerning cumulative risks is resolved.

EPA has determined that dietary risk from exposure to carbaryl is within its own “risk cup.” In other words, if carbaryl did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for carbaryl meet the FQPA safety standards, provided the risk mitigation measures outlined in this document are adopted and additional data needs are addressed. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, residential uses, and drinking water. Based on the results of this aggregate assessment, the Agency has determined that the human health risks from these combined exposures are considered to be within acceptable levels. While the screening-level modeling estimates indicate that carbaryl may in fact fill its aggregate risk cup, the Agency has determined that actual drinking water exposures are likely lower than predicted by the model, and has made an interim determination that carbaryl does “fit” within the dietary risk cup. However, EPA will seek

additional data to help refine and confirm this assessment. Except for those tolerances that are to be lowered or revoked, the current carbaryl tolerances will remain in effect and unchanged until a full reassessment of the cumulative risk from all carbamate pesticides is considered.

b. Tolerance Summary

Tolerances for residues of carbaryl in/on plant commodities [40 CFR §180.169] are presently expressed in terms of the combined residues of carbaryl (1-naphthyl *N*-methylcarbamate), including its hydrolysis product 1-naphthol, calculated as 1-naphthyl *N*-methylcarbamate. The tolerance expression for carbaryl in/on plant commodities should be modified to include only the parent compound.

Tolerances for residues of carbaryl in livestock commodities (meat and milk) are presently expressed as the combined residues of carbaryl (1-naphthyl *N*-methylcarbamate) and its metabolites: 1-naphthol (naphthyl sulfate); 5,5-dihydroxycarbaryl; and 5,6-dihydrodihydroxy naphthol, calculated as 1-naphthyl *N*-methylcarbamate. The tolerance expression for livestock commodities should be amended to also include free and conjugated residues of carbaryl: 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl.

The Agency will commence proceedings to revoke and modify the existing tolerances, and correct commodity definitions. The establishment of a new tolerance or raising tolerances will be deferred, pending consideration of cumulative risk for the carbamates. The term “reassessed” does not imply that all of the tolerances for carbaryl have been reassessed as required by FQPA, since these tolerances may only be reassessed once the cumulative risk assessment of all carbamate pesticides is considered, as required by the statute. Rather, this IRED provides reassessed tolerances for carbaryl in/on various commodities, supported by all of the submitted residue data, only for the single carbamate chemical carbaryl.

The Agency’s tolerance summary is provided in Table 23. This table lists several tolerances associated with uses that are no longer registered, as announced in several FIFRA 6(f)(1) Notices of Receipt of Requests from the registrant for cancellation and/or use deletion, which EPA approved. Therefore, the associated tolerances should be revoked. Many existing carbaryl tolerances will be reassigned to crop groups, and these tolerances will be revoked as new tolerances are established for residues in/on various crop groups and subgroups. The recommended changes are also summarized in Table 23. New tolerances need to be established for carbaryl residues in/on the following raw agricultural commodities: aspirated grain fractions, proso millet hay, sorghum stover, and sugar beet roots. At the present time, sufficient data are only available to determine an appropriate tolerance for residues in/on aspirated grain fractions (70 ppm), sugar beet roots (0.5 ppm), and sorghum stover (30.0 ppm). Additional residue data are required before appropriate tolerances can be determined for residues in/on proso millet hay and pineapple. Separate tolerances also need to be established for residues in the following processed food/feed items: wet apple pomace (15.0 ppm), citrus fruit oil (20.0 ppm), raisins (12.0 ppm), and rice hulls (30.0 ppm).

Table 23. Tolerance Reassessment Summary Table for Carbaryl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment ¹ (ppm)	Comments [Correct Commodity Definition]
Tolerance Listed Under 40 CFR §180.169(a)(1) Raw Agricultural Commodities			
Alfalfa	100	50	Residue data indicate that the tolerance should be lowered to 50 ppm. [<i>alfalfa, forage</i>]
Alfalfa, hay	100	75	Residue data indicate that the tolerance should be lowered to 75 ppm.
Almond	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on [<i>nut, tree, group 14, except walnut.</i>]
Almond, hulls	40	50	Residue data indicate that the tolerance should be increased to 50 ppm.
Apricot	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on [<i>fruit, stone, group 12</i>].
Asparagus	10	15	Residue data indicate that the tolerance should be increased to 15 ppm.
Banana	10	5	Residue data indicate that the tolerance should be lowered to 5 ppm.
Bean	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance for [<i>vegetable, legume, edible-podded, subgroup 6A</i>], and a 1.0 ppm tolerance for [<i>pea and bean, dried shelled, except soybean, subgroup 6C</i>].
Bean, forage	100	Revoke	Tolerance should be revoked. Bean forage and hay are no longer considered significant livestock feed items.
Bean, hay	100		
Beet, garden, roots	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [<i>vegetable, root and tuber, group 1, except sugar beet and sweet potato</i>].
Beet, garden, tops	12	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the [<i>vegetable, leaves of root and tuber, group 2, except sugar beet tops</i>].
Beet, sugar, tops	100	25	Residue data indicate that the tolerance should be lowered to 25 ppm.
Blackberry	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [<i>caneberry subgroup 13A</i>].

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Blueberry	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [bushberry subgroup 13B].
Boysenberry	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Broccoli	10	10	[vegetable, brassica, leafy, group 5, except cabbage]
Brussels sprouts	10	10	Residue data on broccoli translates to Brussels sprouts. [vegetable, brassica, leafy, group 5, except cabbage]
Cabbage	10	21	Residue data indicate that tolerance should be increased to 21 ppm.
Cabbage, chinese	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [vegetable, brassica, leafy, group 5, except cabbage].
Carrots	10	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetables, root and tuber, group 1, except sugar beet and sweet potato].
Cauliflower	10	10	Data on broccoli translates to cauliflower. [vegetable, brassica, leafy, group 5, except cabbage]
Celery	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [leaf petioles subgroup 4B].
Cherry	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [fruit, stone, group 12].
Chestnut	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on [nut, tree, group 14, except walnut].
Clover	100	50	Residue data indicate that the tolerance should be lowered to 50 ppm. [clover, forage]
Clover, hay	100	70	Residue data indicate that the tolerance should be lowered to 70 ppm.
Collards	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [vegetable, brassica, leafy, group 5, except cabbage].

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Corn, fresh, (including sweet), kernal plus cobs with husks removed	5	0.1	Residue data indicate that a separate tolerance on sweet corn should be established at 0.1 ppm [corn, sweet, kernel plus cob with husks removed].
		0.02	Residue data indicate that a separate tolerance should be established for corn, grain at 0.02 ppm. [corn, field, grain] and [corn, pop, grain]
Corn, fodder	100	20	Residue data indicate that the tolerance for field and pop corn stover should be lowered to 20 ppm. [corn, field, stover] and [corn, pop, stover]
		215	Residue data indicate that the tolerance for sweet corn stover should be increased. to 215 ppm. [Corn, sweet, stover].
Corn, forage	100	30	Residue data indicate that the tolerance for field corn forage should be lowered to 30 ppm. [Corn, field, forage].
		185	Residue data indicate that the tolerance for field corn forage should be increased to 185 ppm. [Corn, sweet, forage].
Cottonseed	5	Revoke	Use on cotton has been cancelled; therefore, the tolerance is no longer needed.
Cowpea	5	Reassign	Tolerance should be reassigned concomitant with establishing a 1 ppm tolerance for [pea and bean, dried shelled, except soybean group 6C].
Cowpea, forage	100	Reassign	Tolerances should be reassigned concomitant with establishing a 60 ppm tolerance for [vegetable, foliage of legume, group 7].
Cowpea, hay	100		
Cranberry	10	3	Residue data indicate that the tolerance should be lowered to 3 ppm.
Cucumber	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [vegetable, cucurbit, group 9].
Dandelions	12	22	Residue data on spinach translated to dandelion, indicate that tolerance should be increased to 22 ppm. [dandelion, leaves]
Dewberry	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A]
Eggplant	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the [vegetable, fruiting, group 8]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Endive (escarole)	10	10	Residue data on lettuce may be translated to endive. <i>[endive]</i>
Filbert (hazelnuts)	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on the <i>[nut, tree, group 14, except walnut]</i> .
Flax, seed	5	0.5	Residue data indicate that the tolerance should be lowered to 0.5 ppm.
Flax, straw	100	Revoke	No longer considered a raw agricultural commodity of flax.
Fruit, citrus	10	10	<i>[Fruit, citrus, group 10]</i>
Grape	10	10	
Grass	100	100	Residue data on rangeland grass forage harvested at a 0-day PGI support the current tolerance of 100 ppm. <i>[Grass, forage]</i> .
Grass, hay	100	15	Residue data on pasture hay indicate that the tolerance should be lowered to 15 ppm.
Horseradish	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Kale	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[vegetable, brassica, leafy, group 5, except cabbage]</i> .
Kohlrabi	10	10	Residue data on broccoli translates to kohlrabi. <i>[brassica, leafy, group 5, except cabbage]</i>
Lentils	10	Reassign	Tolerance should be reassigned concomitant with establishing a 1 ppm tolerance on the <i>[pea and bean, dried shelled, except soybean group 6C]</i> .
Lettuce	10	10	
Loganberry	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the <i>[caneberry subgroup 13A]</i> .
Melon	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the <i>[vegetable, cucurbit, group 9]</i> .
Millet, proso, grain	3	1	Residue data for wheat grain indicate that the tolerance should be lowered to 1 ppm. Data for wheat grain translates to millet.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Millet, proso, straw	100	20	Residue data on wheat straw indicate that the tolerance should be lowered to 20 ppm. Data for wheat straw translates to millet straw.
Mustard greens	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[vegetable, brassica, leafy, group 5, except cabbage]</i> .
Nectarine	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[fruit, stone, group 12]</i> .
Okra	10	4	The available data indicate that the tolerance should be lowered to 4 ppm.
Olive	10	10	
Oyster	0.25	0.25	
Parsley	12	22	Available residue data on spinach indicate that the tolerance on parsley should be increased to 22 ppm. Spinach data translates to parsley. <i>[Parsley, leaves]</i>
Parsnip	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Peach	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[fruit, stone, group 12]</i> .
Peanut	5	0.05	Residue data indicate that the tolerance should be lowered to 0.05 ppm.
Peanut, hay	100	20	Residue data indicate that the tolerance should be lowered to 20 ppm.
Pea (with pods)	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance for <i>[vegetable, legume, edible podded, subgroup 6A]</i> .
Pea vines	100	Reassign	Tolerance should be reassigned concomitant with establishing a 60 ppm tolerance for the <i>[vegetable, foliage of legume, group 7]</i> .
Pecans	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on the <i>[nut, tree, group 14, except walnut]</i> .
Pepper	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the <i>[vegetable, fruiting, group 8]</i> .

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Pistachio nut	1	0.1	Residue data indicate that the pistachio tolerance should be lowered to 0.1 ppm. <i>[pistachio]</i>
Plum, prune, fresh	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[fruit, stone, group 12]</i> .
Poultry, fat	5	Revoke	Poultry tolerances are no longer needed because there is no reasonable expectation of finite residues. Also, the direct use on poultry and in poultry houses has been cancelled.
Poultry, meat	5	Revoke	
Potato	0.2(N)	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Prickly pear cactus, fruit	12	5	Residue data indicate that the tolerance should be lowered to 5 ppm. <i>[cactus, fruit]</i>
Prickly pear cactus, pads	12	12	<i>[cactus, pads]</i>
Pumpkin	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the <i>[vegetable, cucurbit, group 9]</i> .
Radish	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Raspberry	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the <i>[caneberry subgroup 13A]</i> .
Rice	5	15	Residue data indicate that the tolerance should be increased to 15 ppm. <i>[Rice, grain]</i>
Rice, straw	100	60	Residue data indicate that the tolerance should be lowered to 60 ppm.
Rutabagas	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Salsify (roots)	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Salsify, tops	10	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the [vegetable, leaves of root and tuber, group 2, except beet, sugar, tops].
Sorghum, forage	100	30	Residue data indicate that tolerance should be lowered to 30 ppm [sorghum, grain, forage]
Sorghum, grain	10	10	[Sorghum, grain, grain]
Soybean	5	0.5	Residue data indicate that the tolerance should be lowered to 0.5 ppm. [Soybean, seed]
Soybean, forage	100	15	Residue data indicate that the tolerance should be lowered to 15 ppm.
Soybean, hay	100	15	Residue data indicate that the tolerance should be lowered to 15 ppm.
Spinach	12	22	Residue data on spinach indicate that the tolerance should be increased to 22 ppm.
Squash, summer	10	Reassign	Tolerances should be reassigned concomitant with establishing a 3 ppm tolerance on the [vegetable, cucurbit, group 9].
Squash, winter	10		
Strawberry	10	4	Residue data indicate that the tolerance should be lowered to 4 ppm.
Sunflower, seed	1	0.5	Residue data indicate that tolerance should be lowered to 0.5 ppm.
Sweet potato	0.2	0.2	[Sweet potato, roots]
Swiss chard	12	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [leaf petioles subgroup 4B].
Tomato	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the [vegetable, fruiting, group 8].
Trefoil, birdsfoot, forage	100	15	Residue data on alfalfa forage translates to [trefoil, forage] and indicates that the tolerance should be lowered to 15 ppm.
Trefoil, birdsfoot, hay	100	25	Residue data on alfalfa hay translates to [trefoil, hay] and indicates that the tolerance should be lowered to 25 ppm.
Turnip, roots	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].

Commodity	Current Tolerance (ppm)	Tolerance Reassessment¹ (ppm)	Comments [Correct Commodity Definition]
Turnip, tops	12	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the [vegetable, leaves of root and tuber, group 2, except sugar beet tops].
Walnut	1	1	
Wheat, grain	3	1	Residue data indicate that the tolerance should be lowered to 1 ppm. Import only.
Tolerances Listed Under 40 CFR §180.169(a)(2) Livestock Commodities			
Cattle, fat	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Cattle, kidney	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [cattle, meat byproducts].
Cattle, liver	1		
Cattle, meat	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Cattle, meat byproducts	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Goat, fat	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Goat, kidney	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [goat, meat byproducts].
Goat, liver	1		
Goat, meat	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Goat, meat byproducts	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Horse, fat	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Horse, kidney	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [horse, meat byproducts].
Horse, liver	1	Reassign	
Horse, meat	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Horse, meat byproducts	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Sheep, fat	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment ¹ (ppm)	Comments [Correct Commodity Definition]
Sheep, kidney	1	Reassign	Residue data indicate that the tolerance should be increased to 3 ppm and reassigned to <i>[sheep, meat byproducts]</i> .
Sheep, liver	1		
Sheep, meat	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Sheep, meat byproducts	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Swine, fat	0.1	0.05	Residue data indicate that the tolerance should be lowered to 0.05 ppm. <i>[hog, fat]</i>
Swine, kidney	1	Reassign	Tolerance should be lowered to 0.5 ppm and reassigned to <i>[hog, meat byproducts]</i> .
Swine, liver	1		
Swine, meat	0.1	0.1	<i>[hog, meat]</i>
Swine, meat byproducts	0.1	0.5	Reassessed tolerance should include kidney and liver. <i>[hog, meat byproducts]</i>
Tolerance Listed Under 40 CFR §180.169(a)(3) Milk and Eggs			
Milk	0.3	1.0	Tolerance should be moved to 40 CFR §180.169(a)(2).
Tolerance Listed Under 40 CFR §180.169(a)(4)			
Fruit, pome	10	12	Residue data indicate that the tolerance should be increased to 12 ppm. Tolerance should be moved to 40 CFR §180.169(a)(1). <i>[fruit, pome, group 11]</i>
Pineapple bran (wet and dry)	20	Revoke	No longer a regulated commodity.
Pineapple	2	TBD ²	Residue data are required. Tolerance should be moved to 40 CFR §180.169(a)(1).
Tolerance Listed Under 40 CFR §180.169(c) Regional Registrations			
Dill (fresh)	0.2	0.2	<i>[dillweed, fresh leaves]</i>
Interim Tolerance Listed Under 40 CFR §180.319			
Eggs	0.5	Revoke	Tolerance no longer needed because there is no reasonable expectation of finite residues.
Tolerance Listed Under 40 CFR §186.550			
Pineapple, bran, wet and dry	20	Revoke	No longer considered a significant processed commodity (40 CFR §186.550).

Commodity	Current Tolerance (ppm)	Tolerance Reassessment ¹ (ppm)	Comments [Correct Commodity Definition]
Tolerances to be Established Under 40 CFR §180.169(a)(1) Raw Agricultural Commodities			
Apple, wet pomace	None	15	Residue data support establishing a 15 ppm tolerance on wet apple pomace. [<i>apple, wet pomace</i>]
Grain, aspirated fractions	None	70	Residue data indicate that a tolerance of 70 ppm should be established for residues in/on aspirated grain fractions. [<i>grain, aspirated fractions</i>]
Beet, sugar, roots	None	0.5	The available data indicate that a tolerance of 0.5 ppm should be established for residues in/on sugar beet roots. [<i>beets, sugar, roots</i>]
Citrus, oil	None	20	Residue data support establishing a 20 ppm tolerance on citrus fruit oil. [<i>citrus, oil</i>]
Grape, raisin	None	12	Residue data support establishing a 12 ppm tolerance on raisin. [<i>grape, raisin</i>]
Millet, proso, hay	None	TBD ²	Residue data are required.
Rice, hulls	None	30	Residue data support establishing a 30 ppm tolerance for residues in/on rice hulls.
Sorghum, grain, stover	None	30	Residue data support establishing a 30 ppm on [<i>sorghum grain, stover</i>].
¹ "Reassessed" does not imply that the tolerances have been reassessed as required by FQPA; tolerances may only be reassessed once the cumulative risk assessment of all carbamate pesticides is considered. ² TBD, to be determined pending completion of outstanding residue studies. Pineapple tolerance will be determined pending submission of 5 crop field trials, three from Costa Rica and two from Mexico (OPPTS Guideline 860.1500). Pineapple field trials must be conducted at maximum application rate and minimum PHI. Proso millet hay tolerance will be determined pending receipt of field trials (OPPTS Guideline 860.1500).			

Codex Harmonization

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for carbaryl residues in/on various plant and livestock commodities (*Guide to Codex Maximum Limits For Pesticide Residues, Part A.1*, 1995). Current U.S. tolerances are not compatible with the Codex MRLs because the U.S. and Codex tolerance expressions are different. The U.S. tolerance expression for plant commodities includes parent carbaryl and its metabolite 1-naphthol for most raw agricultural commodities [40 CFR §180.169(a)]. The tolerance expression for livestock commodities includes carbaryl and its metabolites 1-naphthol, 5,6-dihydrodihydroxy carbaryl, and 5,6-dihydrodihydroxy naphthol [40 CFR §180.169(b)]. The Codex MRL is for carbaryl *per se*.

At present, only the established tolerances for residues in/on pineapples, pome fruits,

avocados, and fresh dill are expressed in terms of carbaryl *per se*. For plant commodities, the U.S. tolerance expression will be amended to carbaryl *per se* so that it is compatible with the Codex MRLs. However, for livestock commodities, Codex MRLs and U.S. tolerances cannot be made compatible. The U.S. tolerance expression for livestock commodities will be amended to include the free and conjugated forms of carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl. In summary,

- Reassessed U.S. tolerances and Codex MRLs will be compatible for the following commodities: apricot, beetroot, carrot, cherries, cowpea (dry), cucumber, eggplant, hay or fodder (dry) of grasses, leafy vegetables, melons (except watermelon), nectarine, olives, parsnip, peppers, plums (including prunes), pumpkins, radish, tomato, and winter squash.
- U.S. tolerances and Codex MRLs can not be harmonized for some commodities, including alfalfa forage; apple; asparagus; blackberries; cabbage; milk; meat of cattle, goats, and sheep; citrus fruits; clover; common bean; cranberry; dewberries (including boysenberry and loganberry); grapes; maize forage; okra; pea vines; peanut (whole and fodder); pear; peas (podded and succulent); potato; raspberries; sorghum forage; soya bean (dry); soya bean forage; strawberry; sugar beet; sugar beet tops; sweet corn (kernels); and tree nuts. The use pattern registered in the United States and the available residue data support U.S. tolerances that are different from the Codex MRLs.
- U.S. tolerances and Codex MRLs can not be harmonized for livestock commodities because the tolerance definitions are different, as previously described.

A comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 24, below.

Table 24. Codex Maximum Residue Limits (MRLs) and Corresponding U.S. Tolerances for Carbaryl.

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Alfalfa forage (green)	100	CXL ²	15	U.S. residue data support a tolerance of 15 ppm.
Apple	5	CXL	12	U.S. residue data support a tolerance of 12 ppm. U.S. tolerance for <i>[fruit, pome, group 11]</i> to be listed under 40 CFR § 169(a)(1).
Apricot	10	CXL	10	U.S. tolerance to be reassigned to the <i>[fruit, stone, group 12]</i> .
Asparagus	10	CXL	15	U.S. residue data support a tolerance of 15 ppm.
Banana	5	CXL	5	

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Barley	5 (Po)	CXL	None	Not registered for use in the U.S.
Bean forage (green)	100	CXL	None	U.S. tolerance to be revoked because bean forage is no longer considered a significant livestock feed item.
Beetroot	2	CXL	2	U.S. tolerance to be reassigned to <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Blackberries	10	CXL	12	U.S. residue data support a tolerance of 12 ppm. U.S. tolerance to be reassigned to <i>[caneberry subgroup 13A]</i> .
Blueberries	7	CXL	3	U.S. residue data support a tolerance of 3 ppm. Tolerance to be reassigned to <i>[bushberry subgroup 13B]</i> .
Cabbages, head	5	CXL	21	U.S. residue data support a tolerance of 21 ppm.
Carrot	2	CXL	2	U.S. tolerance to be reassigned to <i>[vegetables, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Cattle meat	0.2	CXL	1	U.S. tolerance expression includes metabolites not included in Codex MRL expression.
Cherries	10	CXL	10	U.S. tolerance to be reassigned to <i>[fruit, stone, group 12]</i> .
Citrus fruits	7	CXL	10	U.S. residue data support a tolerance of 10 ppm. <i>[fruit, citrus, group 10]</i>
Clover	100 fresh wt	CXL	70	U.S. residue data support a tolerance of 70 ppm.
Common bean (pods and or immature seeds)	5	CXL	10 succulent	U.S. residue data support a tolerance of 10 ppm. Tolerance to be reassigned to <i>[vegetable, legume, edible podded, subgroup 6A]</i> .
			1 dry	U.S. residue data support a tolerance of 1 ppm. Tolerance to be reassigned to <i>[pea and bean, dried shelled, except soybean, subgroup 6C]</i> .
Cotton seed	1	CXL	Revoke	No longer registered for use in the U.S.
Cowpea (dry)	1	CXL	1	U.S. tolerance to be reassigned to <i>[pea and bean, dried shelled, except soybean group 6C]</i> .
Cranberry	7	CXL	3	U.S residue data support a tolerance of 3 ppm.
Cucumber	3	CXL	3	U.S. tolerance to be reassigned to <i>[vegetable, cucurbit, group 9]</i> .

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Dewberries (including boysenberry and loganberry)	10	CXL	12	U.S. residue data support a tolerance of 12 ppm. Tolerance to be reassigned to <i>[caneberry subgroup 13A]</i>
Eggplant	5	CXL	5	U.S. tolerance to be reassigned to <i>[vegetable, fruiting, group 8]</i>
Eggs	0.5	CXL	None	No longer registered for direct use on poultry in the U.S. No reasonable expectation of finite residues.
Goat meat	0.2	CXL	1	U.S tolerance expression includes metabolites not included in Codex MRL expression.
Grapes	5	CXL	10	U.S residue data support a tolerance of 10 ppm.
Hay or fodder (dry) of grasses	100	CXL	15	U.S. residue data support a tolerance of 15 ppm.
Kiwifruit	10	CXL	None	Not registered for use in the U.S.
Leafy vegetables	10	CXL	3	U.S. residue data support tolerance of 3 ppm. Tolerance to be reassigned to <i>[leaf petioles subgroup 4B]</i> .
			10	U.S. tolerance to be reassigned to <i>[vegetable, brassica, leafy, group 5, except cabbage]</i> .
			22 spinach	U.S. residue data for spinach support a tolerance of 22 ppm.
Maize forage (fresh wt)	100	CXL	30 field corn	U.S. residue data support a tolerance of 30 ppm for <i>[corn, field, forage]</i> .
			185 sweet corn	U.S residue data support a tolerance of 185 ppm for <i>[corn, sweet, forage]</i> .
Melons, except watermelon	3	CXL	3	U.S. tolerance to be reassigned to <i>[vegetable, cucurbit, group 9]</i> .
Milk products	0.1*	CXL	1.0	U.S. tolerance to be moved to 40 CFR §180.160(1)(a). U.S tolerance expression includes metabolites not included in Codex MRL expression.
Milks	0.1*	CXL	1	
Nectarine	10	CXL	10	U.S. tolerance to be reassigned to <i>[fruit, stone, group 12]</i> .
Nuts (whole in shell) except peanut, whole and tree nuts	10	CXL	0.1	U.S. residue data support a tolerance of 0.1 ppm. Tolerance to be reassigned to <i>[nut, tree, group 14, except walnut]</i> .
Oats	5 (Po)	CXL	None	Not registered for use in the U.S.
Okra	10	CXL	4	U.S residue data support a tolerance of 4 ppm.
Olives	10	CXL	10	

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Olives, processed	1	CXL	None	U.S. residue data do not support a separate tolerance for processed olives.
Parsnip	2	CXL	2	U.S. tolerance to be reassigned to <i>[vegetables, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Pea vines (green) (Fresh wt)	100	CXL	60	U.S. residue data support tolerance of 60 ppm. Tolerance to be reassigned to <i>[vegetable, foliage of legume, group 7]</i> .
Peanut fodder	100	CXL	20	U.S. residue data support tolerance of 20 ppm. <i>[Peanut, hay]</i>
Peanut, whole	2	CXL	0.05	U.S. residue data support tolerance of 0.05 ppm.
Pear	5	CXL	12	U.S. residue data support tolerance of 12 ppm. U.S. tolerance for <i>[fruit, pome, group 11]</i> to be listed under 40 CFR § 169(a)(1).
Peas (pods and succulent = immature seeds)	5	CXL	10	U.S. residue data support tolerance of 10 ppm. Tolerance to be reassigned to <i>[vegetable, legume, edible podded, subgroup 6A]</i> .
			TBD ³	No U.S. residue data available for succulent, shelled pea and beans.
Peppers	5	CXL	5	U.S. tolerance to be reassigned to <i>[vegetable, fruiting, group 8]</i> .
Plums (including prunes)	10	CXL	10	U.S. tolerance to be reassigned to <i>[fruit, stone, group 12]</i> .
Potato	0.2	CXL	2	U.S. residue data support a tolerance of 2 ppm. Tolerance to be reassigned to <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Poultry meat	0.5 (V)	CXL	None	No longer registered for use on poultry in the U.S. No reasonable expectation of finite residues.
Poultry skin	5	CXL	None	
Pumpkins	3	CXL	3	U.S. tolerance to be reassigned to <i>[vegetable, cucurbit, group 9]</i> .
Radish	2	CXL	2	U.S. tolerance to be reassigned to <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Raspberries, red and black	10	CXL	12	U.S. residue data support a tolerance of 12 ppm. Tolerance to be reassigned to <i>[caneberry subgroup 13A]</i> .
Rice	5 (PoP)	CXL	15	Not registered for postharvest use on rice or rye in the U.S.

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Rice, husked	5 (Po)	CXL	None	
Rye	5 (Po)	CXL	None	
Sheep meat	0.2	CXL	1	U.S tolerance expression includes metabolites not included in Codex MRL expression.
Sorghum	10 (Po)	CXL	None	Not registered for this use in the U.S.
Sorghum forage (green) (fresh wt)	100	CXL	30	U.S residue data support a tolerance of 30 ppm.
Soya bean (dry)	1	CXL	0.5	U.S residue data support a tolerance of 0. 5 ppm.
Soya bean forage (green) (fresh wt)	100	CXL	15	U.S residue data support a tolerance of 15 ppm.
Squash, summer	3	CXL	3	U.S. tolerance to be reassigned to <i>[vegetable, cucurbit, group 9]</i> .
Strawberry	7	CXL	4	U.S residue data support a tolerance of 4 ppm.
Sugar beet	0.2	CXL	0.5	U.S residue data support a tolerance of 0.5 ppm
Sugar beet leaves or tops	100	CXL	25	U.S residue data support a tolerance of 25 ppm
Swede	2	CXL	2	U.S. tolerance to be reassigned to <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Sweet corn (kernels)	1	CXL	0.1	U.S residue data support a tolerance of 0.1 ppm on sweet corn. <i>[corn, sweet, kernel plus cob with husks removed]</i>
Tomato	5	CXL	5	U.S. tolerance to be reassigned to <i>[vegetable, fruiting, group 8]</i> .
Tree nuts	1	CXL	0.1	U.S residue data support a tolerance of 0.1 ppm. Tolerance to be reassigned to <i>[nut, tree, group 14, except walnut]</i> .
			1	U.S. residue data support a separate tolerance of 1 ppm for walnuts.
Wheat	5 (Po)	CXL	1	Not registered for postharvest use on wheat in the U.S. U.S. residue data support a 1 ppm tolerance for wheat grain (import only) but do not support a separate tolerance on processed wheat.
Wheat bran, unprocessed	20 (PoP)	CXL	None	
Wheat flour	0.2(PoP)	CXL	None	
Wheat wholemeal	2	CXL	None	U.S. residue data do not support a separate tolerance on processed wheat. Carbaryl use on wheat to be cancelled.

Codex Maximum Residue Limit (MRL)			Reassessed U.S. Tolerance (ppm)	Comments
Commodity, As Defined	MRL ¹ (mg/kg)	Step		
Winter squash	3	CXL	3	U.S. tolerance to be reassigned to [vegetable, cucurbit, group 9].
¹ MRL was established at or about the limit of detection. The designation “Po” or “PoP” indicates that the MRL was established based on postharvest uses. ² “CXL” indicates that the Codex Alimentarius Commission accepted this as the final MRL for this commodity. ³ TBD, to be determined pending submission of residue data.				

Residue Analytical Methods

The available methods for tolerance enforcement (*Pesticide Analytical Methods*, Volume II, Methods I through IV, A, and B) measure total combined residues of carbaryl and 1-naphthol, calculated as carbaryl. The requirement for acceptable enforcement methods, which determine residues of carbaryl *per se* in plant and livestock commodities, remains outstanding. Although some analytical methods determine the combined residue of carbaryl and 1-naphthol, 1-naphthol is a very minor part of the residue; therefore, the plant commodity tolerances, which are based on carbaryl only, are not greatly exaggerated.

The registrant has proposed High Performance Liquid Chromatography (HPLC) Method CACR-0194 as an enforcement method. This method quantifies carbaryl *per se* in plant matrices and has undergone successful independent laboratory validation using samples of representative plant commodities (oily and non-oily matrices). This method has been successfully radiovalidated using samples from plant metabolism studies. The method should be submitted to the Agency for method validation.

Residue data on most crop plants and processed commodities have been collected using the above HPLC method with only minor modifications involving changes in solvents and cleanup procedures. Method CACR-1212, a modification of CACR-0194, has also been used to generate data on residues of carbaryl *per se* in some of the recent residue studies. The two methods are identical, except that with method CACR-1212 residues are extracted with ethyl acetate instead of DCM, and cleanup procedures use deactivated rather than activated Florisil. The carbaryl-HPLC-alfalfa method, described in the *Final Registration Standard and Tolerance Reassessment*, was used to generate data for earlier residue studies. This method does not distinguish between carbaryl and 1-naphthol; however, the EPA concluded that the contribution of residues of 1-naphthol is insignificant relative to residues of carbaryl *per se*.

The registrant must also propose an enforcement method for determining residues of free and conjugated forms of carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl in livestock commodities. An adequate HPLC data collection method (Aventis File No. 45186) used to determine residues of carbaryl (free and conjugated) and its metabolites in livestock commodities is available, and has undergone a successful independent laboratory

validation. The method is similar to method CARDC-1286. When the modified method is submitted, the Agency will initiate a method validation.

The Food and Drug (FDA) PESTDATA database indicates that residues of carbaryl *per se* are completely recovered using FDA Multiresidue Protocols A and D (*Pesticide Analytical Methods*, Volume I, Sections 242.2 and 232.4). No data are available concerning the recovery of carbaryl by Protocol E (PAM I Section 211.1 and 211.2). These methods are not expected to recover conjugated carbaryl residues.

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

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, carbaryl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. Cumulative Risks

The FQPA stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Carbaryl is a member of the carbamate class of pesticides. This class also includes aldicarb, methomyl and oxamyl among others. The N-methyl carbamates, as a group, have been determined to share a common mechanism of toxicity. However, a cumulative risk assessment has not yet been performed as part of this review because the Agency is currently examining approaches for completing this type of assessment for the carbamates.

The Agency also does not believe that calculation of cumulative risks for the organophosphorus (OP) pesticides and N-methyl carbamates (including carbaryl) is appropriate. Both classes of compounds inhibit acetylcholinesterase (ChEI), but there are differences in pharmacokinetics and pharmacodynamics between the two groups that raise significant uncertainty regarding the potential for cumulative toxicity. Thus, these two classes of anticholinesterase inhibiting compounds have a very different time course of events including: time to peak effect, compound half-life in the body, duration of action, and recovery time after exposure. EPA's Office of Research and Development is currently investigating the pharmacokinetics and pharmacodynamics of N-methyl carbamates, which will provide a more solid scientific foundation for the cumulative assessment of these pesticides.

EPA has developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance reflects recent revisions based on review and comment from earlier guidance issued on June 30, 2000 (65 FR 40644-40650) that is available from the OPP Website at: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-30/6049.pdf>. The recently revised guidance is entitled *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have A Common Mechanism Of Toxicity*, January 14, 2002. In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

D. Regulatory Rationale

EPA has determined that risk mitigation measures and label amendments are necessary for carbaryl products to be eligible for reregistration. The regulatory rationale for each of the mitigation measures for managing risks associated with the current use of carbaryl is discussed below. Where labeling revisions are warranted, specific language will be set forth in a label changes summary table.

1. Human Health Risk Mitigation

a. Dietary Mitigation

Dietary risk from food sources alone are not of concern. Screening-level water modeling estimates indicate that aggregate carbaryl exposure from food and drinking water may fill the risk cup; however, the Agency has determined that actual drinking water exposures will be lower than predicted by modeling. Therefore, the Agency has made an interim determination that no

additional dietary mitigation is necessary at this time. EPA will require additional data to refine the drinking water modeling estimates and confirm this interim decision.

Acute (Food)

The acute dietary (food) risk estimate is below EPA's level of concern; that is, it is less than 100% of the aPAD for the general population and all population subgroups. Children (1-2 years), the most highly exposed population group, are exposed to carbaryl at a level of 93% of the aPAD (0.01 mg/kg/day) at the 99.9th exposure percentile; therefore, no mitigation measures are necessary to reduce food risk.

Acute risk estimates decrease further in EPA's separate assessment using residue data for all eight commodities that were sampled in the industry-sponsored Carbamate Market Basket Survey. Dietary risk declined to 86% of the aPAD for children 1-2 years old. These estimates were conducted separately, however, because of uncertainty about the effect of a rubbing protocol on residues, as described in the acute dietary discussion under Section III. However, they support the conclusion that no additional food risk reduction is necessary at this time.

Chronic (Food)

The non-cancer chronic dietary (food) risk estimate is significantly less than 100% of the cPAD for the general population and all population subgroups. Because all population subgroups are less than 1% of the cPAD, the Agency did not identify a most highly exposed population subgroup for chronic dietary exposure. The non-cancer chronic dietary (food) risk estimate is not of concern; therefore, no mitigation measures are necessary to reduce these risks.

Cancer (Food)

The maximum estimated lifetime cancer dietary (food) risk estimate of 2×10^{-8} for the US general population is significantly less than 1×10^{-6} (1 in 1 million) level of concern; therefore, no mitigation measures are necessary to reduce these risks.

Drinking Water (Surface)

As presented in Table 24, the Agency assessed a number of crop/region drinking water scenarios with different combinations of application rates, methods, timing and other factors to gain a more full understanding of the risks, as well as to consider the mitigation measures that are to be implemented to address occupational risk concerns (which are described later in this section of the document).

Drinking water EECs from surface water sources were derived from the screening-level PRZM/EXAMS model and utilizing the index reservoir scenario and percent cropped area (PCA) factors for representative crops. Drinking water EECs from modeling are upper-bound and vary depending on different scenarios for geographic location, crop, and pesticide

application rates. To produce a more refined probabilistic aggregate dietary (food and drinking water) assessment, the distribution of drinking water residue values from the PRZM/EXAMS model was added to DEEM-FCID™ for each of the crop scenarios modeled. As stated above, the model results are upper-bound estimates of potential drinking water concentrations. The Agency believes that actual concentrations of carbaryl in drinking water are far lower than modeled EECs for the reasons outlined below.

Drinking Water Model Parameter Uncertainties

Drinking water EECs were calculated and then adjusted for PCA. For most crops, including apples, citrus, peaches, and pecans, the default PCA for all agricultural land of 87%, or 0.87, was used. The full distribution of EECs were used in the dietary exposure estimation. These values are greater than those that would be expected to be found in the environment primarily for three reasons.

First, the default PCA of 0.87 was used for citrus in Florida and other crop scenarios. The 0.87 PCA is based on data showing that this is the maximum proportion of agricultural land in any watershed basin in the U.S. Use of the 0.87 PCA value is therefore an upper-bound estimate of the potential area within a watershed that could be treated with carbaryl. EPA believes that the actual PCA for citrus in Florida is closer to one-third the 0.87 value, though a precise number is not available at this time. As presented in Table 24, adjustments to the PCA have a major impact on calculated EECs. For instance, for the pecan drinking water scenario in Georgia, the reduction of the PCA input to the model from 0.87 to 0.38, resulted in the reduction of the peak drinking water from 160 ppb to 70 ppb. Similar comparisons can be made with other use scenarios, including citrus use in Florida.

Second, modeling assumes that 100% of the cropped land within the watershed is treated with carbaryl at the maximum rate and frequency permitted, and with the shortest retreatment interval allowed by product labeling. While theoretically possible, EPA believes that this is highly unlikely given usage data showing that percent crop treated for citrus, for example, ranges from 1.5% to 6%, and that typical application rates and frequencies are considerably lower than the maximum allowed on labels, and retreatment is seldom done at the shortest possible interval. These factors result in higher modeled EECs.

Third, although in general the environmental fate database for carbaryl is good, the soil and aquatic metabolism data are limited. Due to the limitations in metabolism data, for modeling EPA used the upper 90th percent confidence limit of the mean values from the available data to provide a conservative estimate of potential EECs. Additional metabolism data would greatly increase the Agency's confidence, and likely reduce the modeled EECs. Because the Agency believes that the quantity and quality of the metabolism data can substantially effect the estimates, additional metabolism data are required to be submitted to the Agency to confirm the conclusions reached in the IRED for carbaryl.

Monitoring Data

As discussed in the previous section, a significant volume of monitoring data are available to assess concentrations of carbaryl in surface waters, including the USGS NAWQA program; EPA STORET database; joint USGS and EPA pilot reservoir monitoring study; and a drinking water monitoring study voluntarily conducted by Bayer. These data show that while carbaryl is widely detected in water sources, measured concentrations tend to be very low with half falling below the minimum detection limits and ninety five percent of samples showing concentrations below 0.065 ppb. Carbaryl is not very persistent in most surface water conditions, suggesting that the frequent occurrence is a result of its extensive use in a variety of applications. Although EPA believes it is unlikely that non-targeted monitoring will routinely detect peak concentrations, the large volume of data show much lower concentrations than those reflected in modeling. Of the thousands of surface water samples collected and analyzed, none had detections greater than the lowest DWLOC (7.4 ppb) for the most highly exposed population subgroup. While EPA did not use monitoring specifically to define peak EEC values, the data are useful to characterize drinking water model estimates.

Water Treatment Effects

Also as stated in the previous section, study evidence indicates that conventional drinking water treatment (i.e., coagulation, flocculation and settling) is expected to reduce carbaryl concentration by 43% of the concentration prior to treatment. This method of treatment is an industry standard and is expected to have a substantial effect on reducing carbaryl concentrations in finished drinking water. Other types of treatment, including ozone and softening, are also expected to reduce carbaryl residues in finished drinking water. Hence, the Agency is requiring confirmatory drinking water treatment data to provide better quality model inputs, and to confirm the Agency's understanding that treatment would significantly reduce drinking water EECs used to assess potential drinking water risks.

Surface Water Effects from Residential and Urban Uses

Use information indicates that as much as 50% of carbaryl is used on residential and urban sites. At this time, the Agency does not have the capability to model the hydrology for urban watersheds and consequently cannot generate concentration estimates of carbaryl or other urban-use pesticides, as it can for agricultural pesticide uses. As a result, the best estimate of exposure to carbaryl through water in urban areas at the present time is provided by available monitoring data. These data indicate that carbaryl has been found in urban watersheds at concentrations up to 3.2 ppb, and more frequently than in agricultural watersheds, with detection in approximately 45% of the samples. However, these concentrations detected in urban drainages are not high enough to exceed level of concern thresholds for human health through drinking water.

As discussed above, the Agency expects that conventional drinking water treatment, as well as other treatment methods, significantly reduce carbaryl residues in finished drinking

water. It is presumed that treatment facilities near residential and urban areas have effective treatment capabilities, because it is likely that some of the source of their intake is from urban drainage. Thus, it is expected that concentrations of carbaryl in finished drinking water from these treatment facilities are likely lower than the monitored detections described above.

Drinking Water (Ground)

Drinking water EECs used to assess ground water sources of drinking water, which were based on conservative, screening-level model predictions, are low (0.8 ppb). Moreover, the available ground water monitoring data for carbaryl do not indicate that the model estimate is not a high-end estimate. This information is used to assess both acute and chronic (cancer and non-cancer) aggregate dietary risks; therefore, any mitigation measures for this type of exposure is discussed in the following appropriate section of this document.

b. Residential Risk Mitigation

Handler Risks

Table 25 includes residential handler scenarios where risks are of concern, because one or more use sites and/or application rates result in MOEs below the target MOE of 100. The table also shows mitigation considered by EPA, and the Agency's regulatory decision.

Table 25. Residential Handler Risks of Concern, Mitigation Considered, and Regulatory Decision

Scen. #	Scenario Descriptor and Use Site		Amount of Carbaryl Used (lb ai/event)	Combined MOEs for Dermal and Inhalation Exposures
2	Garden/Ornamental Dust on Vegetables/Ornamentals	<p><i>Risks Assessed</i></p> <p><i>Mitigation Considered</i></p> <p><i>Decision/Rationale</i></p>	<p>0.4 to 0.1</p> <p>0.05 to 0.0125</p> <p>To mitigate the risks associated with this use, the packaging for this product is to be only in a ready-to-use shaker can container, and the container (shaker can) must contain no more than 0.05 lb ai. With the implementation of these risk mitigation measures, the Agency has calculated MOEs for this scenario ranging from 169 if using a whole container to over 600 if using only 1/4 of a container. The Agency also calculated that exposures would have to exceed 40 days per year over multiple years before the cancer risks to handlers would be of concern (i.e., > 1 x 10⁻⁶). Therefore, this use is no longer a risk of concern to the Agency.</p>	<p>21 to 85</p> <p>169 to >600</p>
3	Garden Hose-End Sprayer as a General Use Solution	<p><i>Risks Assessed</i></p> <p><i>Mitigation Considered</i></p> <p><i>Decision/Rationale</i></p>	<p>2</p> <p>None needed – 2 lb rate is not a label rate</p> <p>This 2 lb rate is a default value used by EPA for screening-level assessments, and is not appropriate for regulating this use, since it would require nearly a gallon of formulation. Using that rate would be roughly equivalent to treating a one acre garden using a hose-end sprayer. The other assessed rates of 0.26 to 0.012 lb ai result in MOEs of 158 to 3427, respectively, and better reflect a home garden application. Therefore, no mitigation measures are warranted for this use.</p>	<p>21</p> <p>None needed – 2 lb rate is not a label rate</p>

Scen. #	Scenario Descriptor and Use Site		Amount of Carbaryl Used (lb ai/event)	Combined MOEs for Dermal and Inhalation Exposures
3 cont.	Garden Hose-End Sprayer on Fire Ants	<i>Risks Assessed</i>	0.75	55
		<i>Mitigation Considered</i>	0.26 to 0.012 (garden) and 0.25 (lawn spot treatment)	158 to >3,000 (garden) and 495 (lawn spot treatment)
		<i>Decision/Rationale</i>	The use scenario assessed at 0.75 lb ai/event is for the liquid spray control of fire ants on lawns and in garden (not drench treatment of an ant mound). Moreover, the 0.75 lb ai/ event rate is based on the use of three full pint containers of concentrated formulation in a single 100 gallon application, which the Agency believes is an unlikely amount to be used for this type of treatment. The scenarios assessed for gardens (scenario 4) or spot lawn treatment (scenario 8) are more appropriate to assess risks from fire ant control on these sites. The risks from these scenarios are shown in Table 9 and indicate that the MOEs are above the target MOE of 100 and therefore are not of concern.	
6	Trees/Ornamentals Hose-End Sprayer on Ornamentals, Pome Fruits, Nuts/Stone Fruits, Citrus	<i>Risks Assessed</i>	0.5	72
		<i>Mitigation Considered</i>	0.176 to 0.023	204 to >1,500
		<i>Decision/Rationale</i>	The 0.5 lb ai/event rate is based on the use of a quart of concentrate applied with 100 gals of water, which is an amount that is highly unlikely to be used. The Agency believes that the other assessed rates of 0.176 to 0.023 lb ai/event are more appropriate to calculate risks associated with this scenario of treating a 1000 square feet area. Considering these rates, the corresponding MOEs are greater than the target MOE of 100 and therefore are not of concern.	

Scen. #	Scenario Descriptor and Use Site		Amount of Carbaryl Used (lb ai/event)	Combined MOEs for Dermal and Inhalation Exposures
8	Lawn Care Hose-End Sprayer for Liquid Lawn Broadcast	<i>Risks Assessed</i>	5	25
		<i>Mitigation Considered</i>	2.75	181
		<i>Decision/Rationale</i>	The mitigation option above is based on a “ready to use” or RTU hose-end sprayer, which reduces the potential exposure to the homeowner from filling “dial type” sprayers, and also limits the amount of area that can be treated with a single pint-size RTU container. The MOE of 181 represents a treatment area of 10-11,000 square feet, or approximately 0.25 acre. A homeowner would have to use a number of pint size containers to treat a quarter-acre, or 10-11,000 square feet of lawn, which is highly unlikely for homeowner use. To mitigate risks for this handler scenario, all liquid formulation end-use products for lawncare are to be packaged only in pint-sized RTU hose-end sprayers. Although handler risks are not of concern based on this mitigation option, current data shows postapplication risks of concern to adults and toddlers from carbaryl use in liquid lawn broadcast applications, as discussed in Table 26. Pending the outcome of pharmacokinetics data that Bayer CropScience is generating to refine postapplication risks associated with this use scenario, the use of liquid formulation products for turf/lawn applications (except for applications to sod farms, golf courses, commercial landscape areas, and cemeteries) is limited to spot treatments only (less than 1000 square feet), with the use of a RTU sprayer. [NOTE: Bayer CropScience has submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]	
9	Dog Dusting	0.1 to 0.05 4 to 7		
11	Granular & Baits Lawn Care: Belly Grinder for Spot Treatment		0.21	60 The registrant is voluntarily cancelling this use.
13	Granulars & Baits By Hand for Ornamentals and Gardens		0.21	15 The registrant is voluntarily cancelling this use.
14	Aerosol for Various Uses		0.08	65 The registrant is voluntarily cancelling this use.

Cancer Risks for Residential Handlers

For the 17 handler scenarios considered in EPA’s residential handler assessment, cancer risks are not of concern to the Agency; the risks are equal to or less than 1×10^{-6} (most are in the 10^{-8} or 10^{-10} range) when evaluating a single application per year. EPA also calculated the maximum number of days per year, over a 70 year lifetime, that a person could engage in a scenario before incurring cancer risks greater than the 1×10^{-6} level of concern. Usage data indicates that most residential users make 5 or fewer applications per year. All scenarios allow for six or more days (some are greater than 365 days) of exposure per year over a lifetime before cancer risks reach the threshold of concern (1×10^{-6}), except for the following four scenarios:

- 2. *Garden and Ornamental Dust* if using an entire 4 lb. bottle with 0.4 lb ai (5 days);
- 3. *Garden: Hose-End* if spraying 100 gallons of 2% solution (5 days);
- 9. *Dusting Dog* if using 10% or 5% solution and ½ of a 2 lb container (1 and 4 days respectively); and
- 13. *Granulars and Baits by hand* if treating 1000 square feet (4 days).

None of these use scenarios will remain registered as a result of mitigation for noncancer handler risks, except for 2. *Garden and Ornamental Dust*. For this scenario, EPA has concluded that the cancer risks would reduce substantially and are not of concern provided the measures to mitigate short-term risks are implemented, which include the repackaging to a ready-to-use shaker can and limiting the amount of active ingredient in the container from a maximum of 0.4 lb ai to a maximum of 0.05 lb ai per use.

Postapplication Risk

Table 26 includes all residential postapplication risk scenarios, which had assessed risks below the target MOE of 100 and are therefore of concern. The table also shows EPA’s regulatory decision for each of these scenarios.

Table 26. Residential Postapplication Risks of Concern

Population Subgroup and Scenario	Descriptor	Results			
		Short-term MOE on Day 0	Days For Short-term MOE\$100	Intermediate-term MOE	Chronic MOE
Adults: Residential Turf High Activity	<i>Risks Assessed</i> Max Rate at 4 lb ai/A Max Rate at 8 lb ai/A	88	1	842	NA
		43	5	412	NA
Following Liquid Broadcast Lawncare	<i>Mitigation Considered</i> --	--	--	--	--

Population Subgroup and Scenario	Descriptor	Results				
		Short-term MOE on Day 0	Days For Short-term MOE\$100	Intermediate-term MOE	Chronic MOE	
	<i>Regulatory Rationale</i>	The registrants are deleting the liquid lawn broadcast treatment from the technical labels as described below for toddlers 3-5. [NOTE: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]				
Toddlers 3 to 5 years:	<i>Risks Assessed</i>	Max Rate at 4 lb ai/A	11	14	91	NA
		Max Rate at 8 lb ai/A	5	18	45	NA
Residential Turf High Activity Following Liquid Broadcast Lawn care	<i>Mitigation Considered</i>	--	--	--	--	--
	<i>Regulatory Rationale</i>	There are significant postapplication risks of concern to toddlers from <i>liquid</i> lawn broadcast treatment. Although the registrant has submitted a carbaryl lawn biological monitoring study, the Agency's assessment of this and other information, including a probabilistic aggregate assessment using the CARES model, still concludes that this use is of risk concern and warrants mitigation. The technical registrants, Bayer CropScience and Burlington Scientific, have sent EPA amended labels with this use deleted from their technical products. The technical registrants have also submitted voluntary cancellation letters for this use, effective July 1, 2004. Pending the outcome of pharmacokinetics data that Bayer CropScience is voluntarily generating to refine postapplication risks associated with this use scenario, the use of liquid formulation products for turf/lawn applications (except for applications to sod farms, golf courses, commercial landscape areas, and cemeteries) is limited to spot treatments only (less than 1000 square feet), with the use of a RTU sprayer. [See NOTE above on residential lawn liquid broadcast applications.]				

Population Subgroup and Scenario	Descriptor	Results				
		Short-term MOE on Day 0	Days For Short-term MOE\$100	Intermediate-term MOE	Chronic MOE	
Toddlers 3 to 5 years: Pet Uses High Activity	<i>Risks Assessed</i>	Liquids	10	60	19	NA
		Dusts	<1	+30	<1	NA
		Collars	85	+30	85	110 (need 300)
	<i>Mitigation Considered</i>	For Collars only; based on preliminary data on measured transferable residues over whole dog	>300	0	Not enough data	Not enough data
	<i>Regulatory Rationale</i>	The registrant is voluntarily cancelling pet uses with liquid and dust formulations. The Agency has received preliminary data on measured transferable residues, which indicate that short-term risks for pet collars are lower than assessed based on standard assumptions. Confirmatory data are required both for quality assurance and to support the Agency's determination for pet collars that intermediate-term and chronic risks also exceed the target MOE and thus are not of concern.				

Granular Formulations Used for Broadcast Treatment of Lawns

The Agency assessed postapplication risks from lawn activity based on lawns treated with a liquid formulation. Based on data from ORETF and from other sources, EPA fully anticipates substantially lower Turf Transferable Residues (TTRs) from the use of granular formulations of carbaryl and thus substantially lower postapplication risks from exposures, including exposures to toddlers from both the dermal and hand-to-mouth routes of exposure from lawn activity. EPA is requiring a biomonitoring similar to the biomonitoring study submitted by Bayer for the liquid formulation. EPA is also requiring several other studies, including a study to confirm the TTR for the carbaryl granular formulation. For more information, see the memo titled *Carbaryl: Risk Mitigation Addendum for Phase 5 Risk Assessment*, dated June 23, 2003.

Cancer Risks

The Agency also calculated postapplication cancer risks for the same scenarios, but for adults only. For all scenarios on turf, cancer risks are in the 10⁻⁸ range or less on the day of application. For home gardening, golfing or from mosquito control, the cancer risks are even

lower in the 10^{-9} to 10^{-12} range. The Agency also calculated the number of days needed to reach a risk level of 10^{-6} for each scenario, and the results range from 20 to over 356 days per year. Hence, the residential postapplication cancer risk are not of concern to the Agency, and do not warrant mitigation.

c. Aggregate Risk Mitigation

Acute Dietary Aggregate Risks

Acute aggregate dietary risk, which combines acute food and drinking water exposure, was evaluated using a new probabilistic aggregate method assessment (for surface water concentrations only) and the conventional DWLOC calculation for (both surface water and ground water concentrations).

Ground Water

For ground water sources of drinking water, the acute aggregate risk was assessed by the DWLOC method. The drinking water EEC for ground water (0.8 ppb) was estimated using a screening-level model, which produced an upper-end estimate of carbaryl exposure and potential risk to human health from pesticide residues in ground water. As indicated in Table 12 the EEC for ground water was less than the DWLOCs for all population subgroups. Therefore, acute aggregate risk from ground water sources of drinking water are not of concern to the Agency and no mitigation measures are warranted for these risks.

Surface Water

The probabilistic approach aggregates the distribution of screening-level estimated drinking water residue values (surface water only) derived from PRZM/EXAMS models with the DEEM-FCID™ for each of the crop scenarios modeled to estimate the combined %aPAD. The results from this analysis are also compared to the DEEM-FCID™ results without water in order to determine how much water contributes to overall risk.

As indicted in Table 27, there are also several use scenarios which result in acute aggregate dietary risk estimates greater than 100% of the aPAD. However, based on the reasons discussed below, the Agency believes the actual risks are below the Agency’s level of concern.

Table 27. Acute Aggregate Dietary (Food and Drinking Water) Risk Estimates

Crop Scenario	Use Rate (lb ai/A)	No. of Apps	Interval (days)	App Method	PCA	Most Sensitive	aPAD at 99.9%ile
Citrus - FL	7.5	2	3 days	aerial	0.87	All infants	620
	5	1				Children 1-2	303
Citrus - FL	7.5	2	14 days	airblast	0.38	All infants	186
	5	1				Children 1-2	119
Citrus - FL	4 lb/A	2	14 days	airblast	0.38	All infants	114
						Children 1-2	99

Crop Scenario	Use Rate (lb ai/A)	No. of Apps	Interval (days)	App Method	PCA	Most Sensitive	aPAD at 99.9%ile
Citrus - CA	7.5	2	14	airblast	0.87	Children 1-2	93
	5	1				Children 3-5	81
Citrus - CA	16	1	--	aerial	0.87	All infants Children 1-2	158 108
Citrus - CA	16	1	--	airblast	0.87	Children 1-2 All infants	93 81
Apple -PA	3	5	14 days	airblast	0.87	All infants Children 1-2	103 98
Apple -PA	3	3	14 days	airblast	0.87	Children 1-2 All infants	95 90
Pecan - GA	5	3	7 days	airblast	0.87	All infants Children 1-2	178 115
Pecan - GA	5	3	7 days	airblast	0.38	All infants Children 1-2	95 95
Peach - GA	5	3	7 days	aerial	0.87	All infants	107
						Children 1-2	101

Crop-Specific Rationale

For citrus use in Florida, the acute aggregate dietary risk estimate is 620% of the aPAD for the most highly exposed population subgroup, based on a 7.5 lb ai/A maximum application rate and a PCA of 87%. These risks fall to 186% of the aPAD with a more realistic PCA of 38%, which more accurately reflects actual acreage planted in the region. To address occupational risk concerns for this use, which is discussed in detail later in this document, the maximum application rate for carbaryl use on citrus will be reduced to 5 lb ai/A (except for a FIFRA 24(c) registration in Florida to control root weevil at 8 lb ai/A). Moreover, use information indicates that nearly all citrus growers in Florida apply carbaryl at a much lower rate than at the maximum 7.5 lb ai/A. Data from the National Agricultural and Statistical Service (NASS) show that the average application rates for citrus in Florida ranged from 1.5 lb ai/A to 3 lb ai/A. Based on 4 lb ai/A, a rate higher than the highest reported average rate, and a provisional default PCA of 38%, the acute aggregate risk is 114% of the aPAD, which is only slightly greater than the Agency's level of concern. Accordingly, acute aggregate dietary risks based on the high-end average rate of 3 lb ai/A are expected to be less than 100% of the aPAD.

For citrus use in California, the acute aggregate dietary risk is 93% of the aPAD, based on a 7.5 lb ai/A maximum multiple application rate, which as noted above will be reduced to 5 lb ai/A, and a PCA of 87%, and is therefore not a risk concern even without considering a refinement to the PCA. However, there is also a single maximum application rate of 16 lb ai/A on the label for California use only. Even at the 16 lb ai/A rate with the unrefined 87% PCA, the aggregate risk is 93% of the aPAD, based on airblast application method. California Department of Pesticide Regulation use data for the year 2000, indicates that about 90% of all carbaryl applications to citrus were by ground methods. Although the calculated %aPAD increases to

158% when modeled with an aerial application method, the Agency believes that with refinements to the default PCA, which has a significant effect on reducing the model estimates, the risk results are below the Agency's level of concern. Also, to address occupational risk concerns for this use, which is discussed in detail later in this document, the maximum application rate for carbaryl use on citrus in California is to be reduced from 16 lb ai/A to 12 lb ai/A, which would also reduce the aggregate dietary risk for this scenario accordingly.

For apple use in Pennsylvania, the acute aggregate dietary risk is 103% of the aPAD, based on the labeled maximum 5 applications with the unrefined PCA of 87%. However, use information indicates that apples are predominately treated with 3 applications per season. Considering 3 applications per season, again with the unrefined PCA of 87%, the risk reduces to 95% of the aPAD, and is therefore not of concern. The Agency believes that the actual PCA is likely much lower, and would thus reduce the calculated risk further and not be of concern even for the labeled maximum number of applications.

For pecan use in Georgia, the acute aggregate dietary risk is 178% of the aPAD, based on an unrefined PCA of 87%. Considering a refined PCA of 38%, which again more accurately reflects actual acreage planted in the region, the aggregate dietary risk reduces to 95% of the aPAD, and is therefore not of concern. Although the calculated %aPAD would increase slightly if modeled with an aerial application method, the Agency believes that this estimated increase is marginal, based on similar comparisons with some of the other use scenarios, and would not result in risks of concern.

For peach use in Georgia, the acute aggregate dietary risk slightly exceeds the level of concern at 107% of the aPAD, based on the unrefined PCA of 87%. Further, the Agency believes that with possible refinements to the default PCA, which have a significant effect on reducing the model estimates, the risk results are expected to be much lower and not of concern.

Monitoring Data

As previously discussed, there is a significant volume of monitoring data available to assess concentrations of carbaryl in surface waters and to characterize drinking water model estimates. These data show that while carbaryl is widely detected in water sources, measured concentrations tend to be very low. Of the thousands of surface water samples collected and analyzed, the maximum observed concentration of carbaryl in surface water was 5.5 ppb, which is approximately 75x lower than the peak drinking water EEC (410.4 ppb from Florida citrus) derived from screening-level models to assess acute dietary risks from drinking water sources. Moreover, none of the samples had detections greater than the lowest DWLOC (7.4 ppb) for the most highly exposed population subgroup.

Carbamate Market Basket Survey

Furthermore, as discussed above in Section III, the anticipated pesticide residues on food, which were used for the acute dietary assessment and were derived from a number of sources, including only a subset of the Carbamate Market Basket Survey (CMBS). Data for oranges and bananas from the CMBS were included in the acute dietary assessment; however, the remaining six commodities (i.e., apple, broccoli, grape, lettuce, peach and tomato) were not included because the survey protocol called for rubbing while washing the commodities. This procedure in the study introduced a degree of uncertainty in the reported survey results for carbaryl, which is a non-systemic, surface acting pesticide and thus more susceptible to residue loss from the added mechanical action of rubbing. The degree to which rubbing affected residue levels cannot be quantified; however, it is reasonable to assume that actual residues for these six remaining commodities may be lower than the values used in the acute dietary risk assessment. The acute dietary risk (% of the aPAD) when all CMBS data (not only apples and oranges) are used in the dietary assessment is 86% of the aPAD, for the most highly exposed population subgroup (children 1-2 yrs). It may not be appropriate to assume that the actual residues on the commodities that were sampled for the CMBS would reduce the acute dietary risk to 86% of the aPAD; however, it is reasonable to expect that the actual risk is likely between 93% and 86% of the aPAD.

This factor is important to consider because it impacts the amount of room available in the acute dietary “risk cup” for the drinking water contribution. As stated earlier, the acute DWLOC is 7.4 ppb for the most highly exposed population subgroup, based on food exposure occupying 93% of the aPAD. For comparison purposes, the acute DWLOC is 14.1 ppb for the same population subgroup when all CMBS commodities are included in the dietary assessment, resulting in food occupying 86% of the aPAD. Therefore, it is reasonable to expect that the actual acute DWLOC is between 7.4 ppb and 14.1 ppb.

Data Refinements

This dietary assessment is highly refined; very little field trial data were used and processing, cooking and washing factors were incorporated to the greatest extent possible. Nonetheless, further refinement could be carried out with the submission of additional washing, cooking, canning, and other processing studies and with monitoring data for commodities where field trial data were found to be the best source of residue data.

Regulatory Rationale and Conclusion

Given these considerations, and the other factors discussed as part of the Agency’s understanding of drinking water EECs from model predictions, such as:

- the uncertainties with specific fate data,
- certain conservative inputs to the model, including the default PCA and assumption of 100% crop treated,
- the expected effects of water treatment, and
- the overall results of available monitoring data, which indicate that while carbaryl

is widely detected in water sources, measured concentrations tend to be very low; the Agency believes that for the use site scenarios assessed with acute aggregate dietary risks greater than 100% of the aPAD, the actual risks are much lower and not of risk concern to the Agency. Therefore, EPA concludes that no additional risk mitigation is necessary to address acute aggregate dietary risks. As previously discussed, the Agency is requiring certain drinking water treatment and environmental fate data to help confirm this conclusion.

Chronic Dietary Aggregate Risks

To assess aggregate risks from chronic food and drinking water exposure, EPA used the DWLOC approach only. For chronic aggregate dietary risks, the drinking water EECs estimated from the PRZM/EXAMS screening-level model for both surface and ground water sources are significantly less than the chronic DWLOCs for all population subgroups (see Table 12). Therefore, aggregate chronic dietary risks are not of concern to the Agency, and no mitigation measures are warranted for these risks.

Short-Term Aggregate Risk

This section describes the aggregate (combined) risk from food, drinking water, and short-term residential exposures, as well as risk refinements and the mitigation measures that need to be implemented to manage risks of concern. As noted above in Section III of this document, short-term aggregate risks for all scenarios assessed are below EPA’s level of concern and no additional risk reduction is needed. However, because certain residential scenarios had risks that were of concern they were not included in the short-term aggregate assessment for carbaryl. For those scenarios, various measures have been identified to mitigate risks that were of concern and refinements have been made to risk estimates. These measures include repackaging to ready-to-use containers and sprayers, limiting the amount of active ingredient in the product container and, in some cases, voluntary cancellation of the use. These are discussed in detail above under the section on residential risk mitigation. These scenarios have now been evaluated to determine whether any would pose short-term aggregate risks of concern when residential, food, and water sources of exposure are combined. Table 28 summarizes the residential scenarios that previously were of concern and the new risk results based on mitigation measures detailed above.

Table 28. Reassessed Residential Scenarios

Residential Exposure Scenario	Pre-mitigation MOEs	New MOEs
Handler Scenarios		
2 Garden: dust handling, high rate	21 to 85	169 to >600
3 Garden: hose-end sprayer handling, high rates	21 to 55	158 to 3,400
6 Trees/ornamentals: hose-end sprayer, high rate	72	200 to >1,500
8 Lawn care: hose end sprayer, broadcast treatment	25	181
9 Dogs: Dusting	4 to 7	Canceled

11 Granular and baits lawn care: belly grinder	60	Canceled
13 Granular and baits by hand	15	Canceled
14 Aerosol	65	Canceled
Postapplication Scenarios		
Adults on turf following liquid broadcast applications	43 to 88	Canceled
Toddlers on turf following liquid broadcast applications	5 to 11	Canceled
Toddlers, liquid and dust pet uses	<1 to 10	Canceled
Toddlers, pet collars	85 to >300	>300

For residential scenarios that were previously included in the short-term aggregate assessment, the residential scenario that posed the highest estimated risk was adult females handling dusts during gardening activities with a residential MOE of 120. Since all post-mitigation residential MOEs are well above 120, and given the considerations detailed above regarding the conservative nature of drinking water risk estimates, EPA has determined that short-term aggregate exposures to carbaryl will not pose risks of concern and that no additional risk mitigation is necessary at this time, provided the risk mitigation measures outlined in the section on residential risk mitigation are implemented.

Intermediate-Term Aggregate Risk

Aggregate risk results for intermediate-term exposure are identical to the short-term aggregate risks since hazard inputs are the same for both short- and intermediate-term exposures. Therefore, no further risk mitigation beyond the measures discussed above to reduce residential risks of concern are needed to address intermediate-term aggregate risks.

Cancer Aggregate Risk

Aggregate cancer risks, which include exposures from food, drinking water, and residential sources, were assessed using a broad range of adult handler and postapplication exposures from carbaryl uses. As discussed in Section III of this document, for all of the scenarios assessed, the drinking water EECs (for both surface and ground water sources) were less than the DWLOCs, including the high-end surface water EECs for Florida citrus. Therefore, EPA has determined that the cancer aggregate risks are not of concern for any population subgroup, and no additional mitigation measures are needed to address these risks.

d. Occupational Risk Mitigation

It is the Agency's policy to mitigate occupational risks to the greatest extent necessary and feasible with PPE and engineering controls. EPA considers a wide range of factors in making risk management decisions for worker risks. EPA must take into account the economic, societal, and environmental costs and benefits of the pesticide's use when determining whether the use poses unreasonable adverse effects. The Agency also considers incident data, the nature

and severity of adverse effects, uncertainties in the risk assessment, availability and relative risk of alternatives, importance of the chemical in integrated pest management (IPM) programs, and other similar factors when evaluating occupational risk mitigation measures.

1) Agricultural Uses

Handler Risk

As summarized in Table 14, most of the risk calculations for occupational handlers were not of concern at some level of PPE, though generally the level of PPE needed was higher than currently required on the label (long-sleeved shirt, long pants, and chemical resistant gloves). Therefore, there are specific mitigation measures and additional data needs which are necessary to address these risk concerns. When considering the occupational handler risks for users of carbaryl as presented in this document, the Agency also evaluated whether the mitigation measures being considered would negatively impact a grower's ability to use carbaryl. The mitigation measures listed below are necessary to address risks of concern for occupational handlers, and they were determined to not considerably impact users. In summary, for carbaryl to be eligible for reregistration, the mitigation measures in Table 29 must be implemented for the protection of agricultural occupational handlers. Following the implementation of these risk mitigation measures, handler risks will no longer be of concern to the Agency.

Table 29. Occupational Handler Mitigation Measures to be Adopted

Category	Specific Mitigation Measures and Affected Uses	Regulatory Rationale
A. Voluntarily Cancelled Uses and Application Methods	<ul style="list-style-type: none"> Wheat (scenarios 1a, 1c, 2b, 3a, 3c, 4a 4c, 7, 8). 	<ul style="list-style-type: none"> Aerial applicator risk of concern even with engineering controls (MOEs 40-80); very limited use and low benefits.
	<ul style="list-style-type: none"> Broadcast applications using liquid formulations on residential lawns and turf (home lawns, sports fields, schools, parks, and campsites) played on by children; except for golf courses, where high contact activity is not expected for children. Occupational handlers may continue to use the liquid formulation for broadcast applications to golf courses, sod farms commercial landscape areas and cemetery turf. 	<ul style="list-style-type: none"> Postapplication risks to adults and toddlers are of concern for liquid broadcast applications to turf; voluntary cancellation pending results of proposed pharmacokinetics data.
	<ul style="list-style-type: none"> Pet uses (with the exception for pet collars) (scenarios 13 and 14). 	<ul style="list-style-type: none"> Risks of concern for applicators and to children for postapplication exposures; voluntary cancellation.
	<ul style="list-style-type: none"> Hand, spoon, and bellygrinder applications are canceled (scenarios 15, 16, and 20). 	<ul style="list-style-type: none"> Risks of concern for applicators (MOEs from 4-75).

Category	Specific Mitigation Measures and Affected Uses	Regulatory Rationale
B. Reduced Maximum Application Rates	<ul style="list-style-type: none"> Asparagus - preharvest rate from 2 lb ai/A to 1 lb ai/A; postharvest rate from 4 lb ai/A to 2 lb ai/A. 	<ul style="list-style-type: none"> Lower application rate reflects use pattern in asparagus for target pests and to address postapplication worker exposure issues.
	<ul style="list-style-type: none"> Citrus (entire US except CA) - from 7.5 lb ai/A to 5 lb ai/A. 	<ul style="list-style-type: none"> Lower application rate reflects use pattern in citrus for target pests and results in greater protection for mixers, loaders and applicators (see airblast application mitigation below). Also impacts postapplication worker exposures.
	<ul style="list-style-type: none"> California citrus - from 16 lb ai/A to 12 lb ai/A. 	<ul style="list-style-type: none"> Lower application rate reflects use pattern in citrus for target pests in CA and results in greater protection for mixers, loaders and applicators (see airblast application mitigation below). Also impacts postapplication worker exposures.
	<p>CFlorida Special Local Need (FIFRA Sec. 24c) for Diaprepes root weevil control on citrus use rate of 10 lbs ai/A to 8 lb ai/A.</p>	<ul style="list-style-type: none"> Lower application rate reflects use pattern in citrus for Diaprepes root weevils in Florida and results in greater protection for mixers, loaders and applicators (see airblast application mitigation below). Also impacts postapplication worker exposures.
	<ul style="list-style-type: none"> Mosquito control - from 1.0 lb ai/A to 0.2 lb ai/A. EPA approached the Centers for Disease Control (CDC) about carbaryl use as a mosquito adulticide in public health programs. CDC responded that carbaryl does not represent a significant public health use as an adulticide (scenario 3f, 3g, 5b, 6b). 	<p>C</p> <ul style="list-style-type: none"> Risks of concern at 1 lb ai/A rate (MOEs 18-45) for mixers, loaders and applicators; review of efficacy data indicated that 0.2 lb ai/A is effective for target mosquito species. Risks are not a concern with rate reduced to 0.2 lb ai/A (MOEs 91-136).
	<p>C</p> <ul style="list-style-type: none"> Rangeland application - from 1.0 lb ai/acre to 0.5 lb ai/acre for the APHIS grasshopper / mormon cricket control program. Forestry (which EPA assessed using assumptions for rangeland use) remains at a rate of 1 lb ai/acre. 	<p>C</p> <ul style="list-style-type: none"> Rangeland: based on information from APHIS, a 0.5 lb ai/acre rate is sufficient, and it substantially reduces risk concerns for handlers. Also, the actual amount of chemical applied is equivalent to half of the rate. Only half of the total acreage is treated in "swaths." Based on data from the U.S. Forest Service indicating that forestry acreage treated per day would be well less than 1000 acres, significantly lowering the volume of chemical handled.
	<p>C</p> <ul style="list-style-type: none"> Stone fruit - <i>maximum aerial liquid application rate</i> reduced from 5 lbs ai/acre to 3 lbs ai/acre, except for California, which has a 4 lb ai/acre rate due to unique pest pressures. The maximum allowable ground rate remains 5 lbs ai/acre. 	<p>C</p> <ul style="list-style-type: none"> Data available to EPA suggests 3 lbs ai/acre liquid aerial applicaiton is generally the maximum rate used, except for California. Reducing the rate to 3 lbs ai./acre reduces risk to mixers and loaders, and reduces ecological risk and water contamination from runoff and drift.

Category	Specific Mitigation Measures and Affected Uses	Regulatory Rationale
	<p>C Field Corn - <i>maximum aerial liquid application rate</i> reduced from 2 lbs ai/acre to 1.5 lbs ai/acre. The maximum allowable ground rate remains 2 lbs ai/acre.</p>	<p>Data available to EPA suggests 1.5 lbs ai/acre liquid aerial applicaiton is generally the maximum rate used. Reducing the rate to 3 lbs ai./acre reduces risk to mixers and loaders, and reduces ecological risk and water contamination from runoff and drift.</p>
<p>C. Prohibited Aerial Applications</p>	<ul style="list-style-type: none"> • Wettable powder formulations (scenarios 4a and 4f). • Granular and bait formulations applied to corn (field, pop, and sweet), grain sorghum, alfalfa, rice, and sunflowers (scenarios 2a and 5c). 	<ul style="list-style-type: none"> • All wettable powder formulations will only be available in water soluble packets which are generally incompatible with aerial application because of the high number of acres treated and the number of packets needed. No impacts to growers expected. • Formulations are not compatible with dry disconnect/dry link closed mixing and loading systems (see below) and applicator MOEs are low (21).
<p>D. Aerial/Chemigation Application Engineering Controls</p>	<ul style="list-style-type: none"> • Closed systems designed to provide dry disconnect/dry break links with the product container for protection of mixers and loaders. Only formulations compatible with these closed systems may be used (e.g., emulsifiable concentrates and soluble concentrates) (scenario 3a, 3f). An exception is the USDA/APHIS grasshopper/Mormon cricket control program, where applications at a rate out of the plane of 0.06 lb ai/acre is acceptable. The USDA program treats the rangeland in swaths, so that only half of the total acreage is treated, resulting in actual deposition on land of 0.03 lbs ai/acre. • Enclosed cockpits for aerial applicators (scenario 5a, 5b). • Mechanical flaggers or global positioning system (GPS) equipment that negates the need for human flaggers (scenario 28a, 28b). 	<ul style="list-style-type: none"> • Exposure data in PHED are based on older closed system technologies; closed system technologies available today offer more protection than indicated by PHED. EPA is requiring confirmatory data to better evaluate the protection value of these newer systems. Adoption of these systems are not expected to impact users because the Agency believes they are commonly in use today. • EPA believes that enclosed cockpits are the industry standard and no impacts would associated with this mitigation measure. • Although these scenarios did not have risks of concern, EPA believes that these systems are the industry standard and no impacts would associated with this mitigation measure.

Category	Specific Mitigation Measures and Affected Uses	Regulatory Rationale
<p>E. Ground Airblast Application Engineering Controls and PPE (Applicators)</p>	<ul style="list-style-type: none"> • Enclosed cabs for applications to olives (scenario 6a). • Enclosed cabs for applications to citrus trees in California (scenario 6a). • Enclosed cabs for applications to citrus trees in Florida under Section 24(c) Special Local Need at 8 lb ai/A (scenario 6a). • For all other ground airblast applications the following PPE must be worn: coveralls over long-sleeved shirt and long pants, chemical resistant gloves, protection factor 10 respirator (half-mask, air purifying), WPS head protection, shoes and socks (scenario 6a). 	<ul style="list-style-type: none"> • Enclosed cabs are necessary to alleviate risks of concern for applicators with a max. rate of 7.5 lb ai/A. Minimal impact expected from this mitigation measure. • Enclosed cabs are necessary to alleviate risks of concern for applicators with a max. rate of 12 lb ai/A. Minimal impact expected from this mitigation measure. • Enclosed cabs are necessary to alleviate risks of concern for applicators with a max. rate of 8 lb ai/A. Minimal impact expected from this mitigation measure. • Although MOEs for applicators for some ground airblast uses in this category will still be below the target MOE with the prescribed PPE (50-126), the Agency weighed several factors regarding these uses. All these uses generally have orchard or field designs that make it very difficult for tractors with enclosed cabs to navigate without damaging the crop. Maximum use rates for these uses are all 5 lb ai/A and less, and a review of available usage data indicate that average application rates are all below 3 lb ai/A where the MOEs are all greater than 84. EPA is satisfied that the benefits outweigh the risks in this case.
<p>F. Granular and Bait Formulation PPE and Packaging (Loaders and/or Applicators)</p>	<ul style="list-style-type: none"> • Long-sleeved shirts and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise (scenario 2a, 2b, 8, 21). • Ready-to-Disperse containers are stipulated for Ornamental and Garden uses to administer product without direct contact of the formulation to the applicator. 	<ul style="list-style-type: none"> • PPE level necessary to alleviate risks of concern for granular and bait formulations. • Necessary to protect applicator from risks of concern and because direct applications by hand, spoon and bellygrinder are no longer allowed.

Category	Specific Mitigation Measures and Affected Uses	Regulatory Rationale
G. Liquid Formulation (e.g., emulsifiable concentrates, soluble concentrates) PPE (Mixer/Loaders and/or Applicators)	<ul style="list-style-type: none"> • Long-sleeved shirt and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise (scenario 3a, 3b, 3c, 3d, 3e, 3g, 7). 	<ul style="list-style-type: none"> • PPE level necessary to alleviate risks of concern for liquid formulations.
H. Wettable Powder Formulation Packaging and PPE	<ul style="list-style-type: none"> • Water soluble packaging (an engineering control) is stipulated for all wettable powder formulations (scenario 4b, 4c, 4e). • Long-sleeved shirts and long pants, chemical resistant gloves, shoes and socks (scenario 4b, 4c). 	<ul style="list-style-type: none"> • Engineering control necessary to alleviate risks of concern for wettable powder formulations to mixers and loaders. • PPE level necessary to alleviate risks of concern for wettable powder formulations.
I. Dry Flowable Formulation and Engineering Controls (Mixer/Loaders)	<p>CEngineering controls to be used for all mixer/loader activities (scenarios 1a, 1b, 1c, 1e, and 1f).</p>	<p>CEngineering controls necessary to alleviate risks of concern for dry flowable formulations.</p>

In the revised risk assessment for carbaryl, EPA identified a number of scenarios that had risks of concern even with the highest feasible level of PPE or engineering controls. Table 30 summarizes the mitigation measures discussed above that apply to these scenarios.

Table 30. Occupational Handler Mitigation as Applied to Specific Scenarios of Concern

Crop/Use (Scenario #)	Form.	Application method (acres trt./day) (unless noted)	Application Rate Assessed (lb ai/acre) (unless noted)	MOE Short/Interm-Term Combined (w/ Max. Feasible PPE and/or EC)			Mitigation Category From Table 29 and Scenario Specific Comments [Refer to Table 29 for details]
				M/L	Applicator	M/L/A	
Animal Groomer - Dog (13)	liquid	liquid application (8 dogs)	0.01 lb ai/dog	N/A	9.7 (SL/GL/PF10)	NA	A. Voluntarily Cancelled Use All pet uses to be cancelled except for collars. Collar manufacturer to submit confirmatory data as a condition of reregistration.
APHIS Grasshopper (3f, 5b)	liquid	aerial (6,000)	1	30	45	NA	D. Aerial/Chemigation Engineering Controls. EPA believes MOEs improve considerably with this mitigation. USDA/APHIS have in place other measures to help assess and mitigate handler risks.
			0.375 - 0.5	46 - 61	68 - 91		
			0.125	182	272		
Corn, field (3a, 4a, 5a, 5c)	liquid	aerial (1,200)	1.5	76	113	NA	D. Aerial/Chemigation Engineering Controls and PPE
	granular	aerial (1,200)	2	688	21	NA	C. Prohibited Aerial Applications
		aerial (350)	2	146 (SL/GL/P5)	72		
WP	aerial (1,200)	aerial (1,200)	2	40	85	NA	C. Prohibited Aerial Applications
			1	80	170		

Crop/Use (Scenario #)	Form.	Application method (acres trt./day) (unless noted)	Application Rate (lb ai/acre) (unless noted)	MOE Short/Interm-Term Combined (w/ Max. Feasible PPE and/or EC)			Mitigation Category From Table 29 and Scenario Specific Comments [Refer to Table 29 for details]
				M/L	Applicator	M/L/A	
Mosquito Adulticide (3f, 3g, 5b, 6b)	liquid	aerial (7,500)	1 0.15	18 121	27 181	NA	B. Reduced Maximum Application Rates Reduce maximum use rate to 0.2 lb ai/A. D. Aerial/Chemigation Application Engineering Controls and PPE G. Liquid Formulation PPE (Mixer/Loaders and/or Applicators)
		ground (3,000)	1 0.15	45 112 (SL/GL/PF5)	22 150	NA	B. Reduced Maximum Application Rates Reduce maximum use rate to 0.2 lb ai/A. E. Ground Airblast Application Engineering Controls and PPE (Applicators) G. Liquid Formulation PPE (Mixer/Loaders and/or Applicators)
Ornamentals and Gardens (15, 16)	Granular and Baits	by Hand (1)	9	N/A	3.8 (DL/GL/PF10)	NA	A. Voluntarily Cancelled Use
		by Spoon (1)	9	N/A	72 (SL/GL/PF5)		

Crop/Use (Scenario #)	Form.	Application method (acres trt./day) (unless noted)	Application Rate Assessed (lb ai/acre) (unless noted)	MOE Short/Interm-Term Combined (w/ Max. Feasible PPE and/or EC)			Mitigation Category From Table 29 and Scenario Specific Comments [Refer to Table 29 for details]
				M/L	Applicator	M/L/A	
Rangeland/ Forestry (3f, 4f, 5b)	liquid	aerial (7,500)	1	18	27	NA	B. Reduced Maximum Application Rates D. Aerial/Chemigation Application Engineering Controls and PPE G. Liquid Formulation PPE (Mixer/Loaders and/or Applicators) The only high acreage rangeland use is the USDA/APHIS use on grasshoppers. Any other rangeland or pastureland use is expected to be far less acreage, and likewise for forestry.
	WP	aerial (7,500)	1	13	27		C. Prohibited Aerial Applications
Stone Fruit (3a, 4a)	liquid	aerial (350)	3 4	130 98	194 146	NA	D. Aerial/Chemigation Application Engineering Controls and PPE G. Liquid Formulation PPE (Mixer/Loaders and/or Applicators)
	WP	aerial (350)	3 4	91 69	194 146		C. Prohibited Aerial Applications
Turf (17, 20)	liquid	low pressure, high vol. turfgun (5)	8 4	NA	NA	94 (DL/GL/PF10) 104 (SL/GL/PF5)	G. Liquid Formulation (e.g., emulsifiable concentrates, soluble concentrates) PPE (Mixer/Loaders and/or Applicators)
	granular	bellygrinder (1)	9	NA	NA	27 (DL/GL/PF10)	A. Voluntarily Cancelled Use

Crop/Use (Scenario #)	Form.	Application method (acres trt./day) (unless noted)	Application Rate Assessed (lb ai/acre) (unless noted)	MOE Short/Interm-Term Combined (w/ Max. Feasible PPE and/or EC)			Mitigation Category From Table 29 and Scenario Specific Comments [Refer to Table 29 for details]
				M/L	Applicator	M/L/A	
Wheat (3a)	liquid	aerial/ chemigation (1,200)	1.5	76	113	NA	A. Voluntarily Cancelled Use

Occupational Handler Cancer Risk

Occupational cancer risks equal to or less than 1×10^{-6} (1 in 1 million) are not of concern to the Agency. The Agency also carefully examines uses with estimated risks in the 10^{-6} to 10^{-4} range to seek cost-effective ways of reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protective equipment (PPE) or engineering controls are added to the extent practical. If occupational cancer risks in the 10^{-6} to 10^{-4} range despite practicable mitigation measures, EPA will consider whether benefits of the use warrant such risks.

As stated previously, noncancer risks are the risk driver relative to cancer risks. For all scenarios, provided handler mitigation measures are implemented, resultant cancer risks for nearly all scenarios are less than 1 in 1 million (1×10^{-6}) and therefore are not of concern. For those scenarios that have cancer risks greater than 1×10^{-6} , mitigation for short-term risks also had the effect of bringing cancer risks into the 10^{-6} range. Considering the benefits associated with some uses, in particular orchard crops, and the importance of having consistent and concise label directions, the Agency believes the cancer risks associated with these uses are not of concern, and that no further mitigation measures are necessary.

Postapplication Risk

Postapplication (reentry) risks are of concern for workers performing tasks in areas that have received applications of carbaryl (see Table 31). Exposure activities which result in significant worker exposure to treated fruit and foliage, such as hand harvesting, hand fruit thinning, and leaf pulling, result in estimates of risk that are of concern to the Agency. Based on the postapplication scenarios assessed, the number of days calculated to reach the target MOE following applications of carbaryl exceed the current label REI of 12 hours for some uses. Based on these calculations, EPA has determined that changes to the REIs are needed. FIFRA provides for the Agency to consider the economic, societal, and environmental costs and benefits of pesticidal use when weighing the risks associated with occupational postapplication exposures. The following mitigation for specific crops is based on EPA's review of comments received; direct consultation with knowledgeable experts and growers; evaluation of carbaryl's use pattern, pest management needs and benefits to users; refinements to the risk assessment where appropriate; and other information available to the Agency. Table 31 below details the mitigation considered, if any, and the Agency's rationale for addressing occupational postapplication risks of concern.

Table 31. Occupational Postapplication Risk Management Decision Matrix

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Brassica - bok choy - broccoli - brussel sprouts - cabbage (including Chinese) - cauliflower - collards - kale - kohlrabi - mustard greens - napa	Risks Assessed	2	(5) 95 Exposure Activities - irrigation, scouting, thinning, weeding immature plants	(9) >100 Exposure Activities - scouting mature plants	(10) 100 Exposure Activities - hand harvesting, irrigation, pruning, topping, tying mature plants	NA
	Mitigation Considered	2	(5) 95	Carbaryl use does not coincide with these activities after label revisions	Carbaryl use does not coincide with these activities after label revisions	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: Carbaryl is used early in the season and generally only within 30 days of planting. As such, carbaryl applications only coincide with low exposure activities such as weeding and irrigation. Use is predominantly targeted at flea beetles, armyworm species, corn earworm and imported cabbageworm.</p> <p>CHANGES TO USE PATTERN: Use restricted to applications only within 30 days of crop emergence/transplanting REI = 5 days</p> <p>The MOE at day 5 is 95 for low exposure activities, close to the target MOE, and not of concern to the Agency.</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Bunch/Bundle - hops * - tobacco	Risks Assessed	2	(0) 411 Exposure Activities - irrigating, hand weeding and scouting immature, low foliage plants	(6) >100 Exposure Activities - irrigating and scouting mature plants	(8) >100 Exposure Activities - harvesting, stripping, training, thinning, topping, mechanical harvesting of hops	NA
	Mitigation Considered	2	Activities covered with revised REI based on High exposure activities	Activities covered with revised REI based on High exposure activities	(8) >100	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: High exposure worker activities appropriate for tobacco include harvesting, stripping, thinning and topping. Very little use of carbaryl occurs on tobacco. Several alternative insecticides are available for the main target pests (tobacco hornworm and flea beetle) for which carbaryl is recommended.</p> <p>CHANGES TO USE PATTERN: REI = 8 days</p>				

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low	Medium	High	Very High	
		(Reentry Day) MOE	(Reentry Day) MOE	(Reentry Day) MOE	(Reentry Day) MOE	
Cucurbit Vegetables - cantaloupe - cucumber - gourds - pumpkins - squash - watermelon - zucchini	Risks Assessed	2	(0) 147 Exposure Activities - irrigation, scouting, thinning, weeding immature plants	(4) >100 Exposure Activities - irrigation, scouting, hand weeding mature plants	(7) >100 Exposure Activities - hand harvesting, pulling, leaf thinning, thinning, turning	NA
	Mitigation Considered	1	(0) 295	(0) 98	(3) 104	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency erroneously assessed a maximum application rate of 2 lb ai/A when the current label only allows a maximum use rate of 1 lb ai/A. The recalculated REI and corresponding MOEs based on the correct maximum use rate are presented above. The high exposure activities listed above are commonly practiced in these crops, particularly hand harvesting. According to comments submitted to the Agency, carbaryl is predominantly used in the early part of the growing season (within 30 days of planting) to control cucumber beetles and squash bugs. Carbaryl has a pre-harvest interval (PHI) of 3-days for the cucurbit vegetables.</p> <p>CHANGES TO USE PATTERN: REI = 3 days</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Cut Flowers (floriculture crops including roses)	Risks Assessed	2	(7) >100 Exposure Activities - irrigation, scouting, thinning, weeding immature/low foliage plants	(9) >100 Exposure Activities - irrigation, scouting mature/high foliage plants	(12) >100 Exposure Activities - hand harvesting, pruning, thinning, pinching	NA
	Mitigation Considered	2	(0) 147 Exposure Activities - flower harvesting, except roses.	(7) 107 Exposure Activities - rose harvesting	NA	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency reviewed a recently available exposure study conducted by the California Department of Pesticide Regulation (HS-1835; Pesticide Exposure of Workers in Greenhouses, November 19, 2002) appropriate to this crop grouping and calculated new MOEs based on revised transfer coefficients (Carbaryl: Risk Mitigation Addendum for Phase 5 Risk Assessment; DP Barcode: D327509; PC Code 056801. Memo from J. Dawson, 06/17/03). The Agency decided that this study is a more appropriate source of information for calculating risks for greenhouse workers than the previously used data. The MOEs and REIs listed in the row titled Mitigation Considered incorporate these changes. Data from the new study indicate higher transfer of residues from rose harvesting compared to other flower types, and therefore the Agency has treated roses separately. Confirmatory data are needed for this exposure activity (e.g., ARTF cut flower study).</p> <p>CHANGES TO USE PATTERN: Cut Flowers (except roses): REI = 12 hours</p> <p>Roses: REI = 7 days</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Pome Fruit - apples - pears	Risks Assessed	3	(0) 146 Exposure Activities - irrigation, scouting, weeding	NA	(0) 97 Exposure Activities - hand harvesting, training, pruning, tying.	(7) 97 Exposure Activities - hand thinning
	Mitigation Considered	3	(0) 146	NA	(0) 97	(0) 49
	Regulatory Decision	<p>COMMENTS ABOUT USE: Carbaryl use on pome fruit is unique when compared to its other uses as an insecticide; its use on pome fruit is almost entirely as a chemical fruit thinning agent and rarely as an insecticide. Under most conditions, apple trees will set more fruit than needed for a full crop. Most apple cultivars will retain this heavy set of fruit throughout the growing season resulting in small, poorly colored, low quality fruit. Fruit thinning is the removal of a portion of the crop before it matures on the tree to increase the marketability of the remaining fruit and to reduce the biennial bearing tendency of the tree. When carbaryl is applied to developing fruitlets (usually in the late Spring) it causes a percentage of them to be aborted resulting in the desired fruit thinning affect. Hand thinning is the activity that has the most worker exposure under current Agency policy. Since carbaryl is applied as a chemical thinning agent, workers conducting hand thinning activities would not enter treated areas until at least 7 days following applications in order to take advantage of the chemical thinning treatment. The MOE at day 7 is 97 for hand thinning, close to the target MOE, and not of concern to the Agency. For this reason, the REI remains unchanged at 12 hours.</p> <p>CHANGES TO USE PATTERN: REI = 12 hours</p>				

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Stone Fruit - apricots - cherries(sweet/tart) - nectarines - peaches - plums/prunes - pomegranates* - figs*	Risks Assessed	3	(0) 146	NA	(0) 97	(7) 97
		4 (CA only)	(0) 109 Exposure Activities - irrigation, scouting, weeding.		(3) 98 Exposure Activities - hand harvesting, training, pruning, tying.	(10) 98 Exposure Activities - hand thinning
	Mitigation Considered	3 4 (CA only)	Activities covered with revised REI based on High exposure activities	NA	(0) 97 (3) 98	(7) 97 (7) 73
	Regulatory Decision	<p>COMMENTS ABOUT USE: Carbaryl is generally not used during the period when hand thinning activities occur on these crops. Carbaryl is predominantly used late season near harvest time to control fruit damaging pests which can significantly impact fruit quality and marketability. Use rates are higher (up to 4 lb ai/A) in California because of more difficult to control pests. Carbaryl can also be applied at up to 5 lb ai/A as a dormant application throughout the U.S.; pruning is generally the only worker reentry activity occurring during this timing, however, since no foliage is present exposures would be expected to be minimal. The preharvest interval following applications of carbaryl is 3 days except in CA, where it is 1 day.</p> <p>CHANGES TO USE PATTERN: 3 lb ai/A: REI = 12 hours for all activities; however, workers may not enter treated areas to hand thin until 7 days after application.</p> <p>4 lb ai/A - CA only: REI = 3 days for all activities; however, workers may not enter treated areas to hand thin until 7 days after application. Provided the mitigation measures are adopted, the calculated MOE is near the target and not a risk of concern to the Agency.</p>				

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Citrus Crop Group - grapefruit - lemons - oranges - papaya* - avocados* - dates* - mangoes*	Risks Assessed	7.5	(5) 95	(9) 94	(16) 94	NA
		10 (FL only)	(8) 96	(12) 95	(19) 95	
		16 (CA only)	(13) 99	(17) 97	(24) 97	
	Mitigation Considered	5	Exposure Activities - irrigation, scouting, pruning	Exposure Activities - hand harvesting	Exposure Activities - hand thinning	
		8 (FL only)	(1) 96	(5) 95	NA	NA
		12 (CA only)	(5) 89	(5) 60		
		(5) 60	(5) 40			

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories												
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE									
	Regulatory Decision	<p>BENEFITS OF USE: The Agency originally classified hand pruning in the medium exposure category; however, based on a review of several activity-based exposure studies on hand pruning, the Agency has determined that hand pruning should be moved from the medium exposure category to the low exposure category (Carbaryl: Risk Mitigation Addendum for Phase 5 Risk Assessment; DP Barcode: D327509; PC Code 056801. Memo from J. Dawson, 06/17/03). Hand thinning is only rarely used in citrus production, therefore, the Agency is basing its decision on REIs on the medium exposure worker activity of hand harvesting. Carbaryl has distinct use patterns in citrus depending on the target pests and the geographic region of use. For example, FL has a Special Local Needs (FIFRA §24c) registration that currently allows applications of 10 lb ai/A to control the <i>Diaprepes</i> root weevil. For control of scale insects in CA, the label allows a single application of up to 16 lb ai/A.</p> <p>Based on a review of current use patterns and extensive discussions with growers and university researchers in CA and FL, a reduction in the maximum use rate to 12 lb ai/A in CA for scale insect control and to 5 lb ai/A in FL is necessary. The FIFRA §24(c) label in FL for control of <i>Diaprepes</i> root weevil adults will be modified with a rate reduction to 8 lb ai/A from 10 lb ai/A. The application of carbaryl does coincide with the harvest period of citrus crops, which depending on the type of citrus crop, can occur weekly for more than 6 months out of the year. If the REI for carbaryl was extended to the day(s) when MOEs reach the target for the applicable application rates (8 lb ai/A and above), further use of carbaryl would not be feasible. An assessment conducted by the Agency of the impacts to growers if carbaryl were not available indicates that current users would face increased costs from having to utilize alternative pest control measures and reduced gross revenues (up to 46% in CA) due to fruit quality losses from insect damage. Therefore, the Agency believes that the critical need for the use of carbaryl on citrus during the period when harvest activities occur outweigh the risks associated with postapplication exposure. Given that the preharvest interval for carbaryl is 5 days, the longest practical REI is 5 days for use rates of 8 lb ai/A and above because of the co-occurrence of carbaryl applications and hand harvesting. However, with the reduction of the use rate to 5 lb ai/A, the REI calculates to 24 hours with a MOE of 96 for low exposure activities, which is not of concern to the Agency.</p> <p>CHANGES TO USE PATTERN:</p> <table> <tr> <td>5 lb ai/A:</td> <td></td> <td>REI = 24 hours</td> </tr> <tr> <td>FL §24(c):</td> <td>Max. Rate = 8 lb ai/A</td> <td>REI = 5 days</td> </tr> <tr> <td>CA only rate:</td> <td>Max. Rate = 12 lb ai/A</td> <td>REI = 5 days</td> </tr> </table>				5 lb ai/A:		REI = 24 hours	FL §24(c):	Max. Rate = 8 lb ai/A	REI = 5 days	CA only rate:	Max. Rate = 12 lb ai/A	REI = 5 days
5 lb ai/A:		REI = 24 hours												
FL §24(c):	Max. Rate = 8 lb ai/A	REI = 5 days												
CA only rate:	Max. Rate = 12 lb ai/A	REI = 5 days												

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Evergreen Tree Crop Group - conifers	Risks Assessed	7.5	(6) 105 Exposure Activities - irrigation, scouting, hand weeding, thinning Christmas trees	(10) >100 Exposure Activities - harvesting, pollination, bagging, tying, misc. hand labor, staking, topping, training, pruning, cone pruning	(17) >100 Exposure Activities - hand thinning	NA
	Revised Risk Assessed	1	(0) 437	(0) 291	(0) 146	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency erroneously assessed a maximum application rate of 7.5 lb ai/A when the current label only allows a maximum use rate of 1 lb ai/A. The recalculated REI and corresponding MOEs based on the correct maximum use rate are presented above.</p> <p>CHANGES TO USE PATTERN: REI = 12 hours</p>				

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Fruiting Vegetables - eggplant - okra - bell/chili peppers - tomatoes	Risks Assessed	2	(0) 147 Exposure Activities - irrigating, scouting, thinning, weeding immature plants	(0) 105 Exposure Activities - irrigating and scouting mature plants	(2) 108 Exposure Activities - hand harvesting, pruning, staking, tying	NA
	Mitigation Considered	2 1.5 (okra only)	Activities covered with revised REI based on High exposure activities	Activities covered with revised REI based on High exposure activities	(2) 108 (0) 98	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency erroneously assessed a maximum rate for okra of 2 lb ai/A when the maximum rate currently allowed is 1.5 lb ai/A. With this change in the assessed use pattern of carbaryl on okra, there is no need to modify the existing 12 hour REI for okra. The current preharvest interval for all fruiting vegetable crops is 3 days. Therefore, a 2 day REI for eggplant, bell/chili peppers and tomatoes is not expected to negatively impact users.</p> <p>CHANGES TO USE PATTERN: Eggplant, Bell/chili Peppers, Tomatoes: REI = 2 days</p> <p>Okra: REI = 12 hours (the MOE of 98 at day 0 is close to the target MOE and is not of concern to the Agency)</p>				

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Leafy Vegetables - celery - dandelion - endive - lettuce/romaine - parsley - swiss chard - spinach - watercress*	Risks Assessed	2	(0) 147 Exposure Activities - scouting, thinning, weeding immature plants	(4) >100 Exposure Activities - irrigation and scouting mature plants	(7) >100 Exposure Activities - hand harvesting, pruning and thinning mature plants	NA
	Mitigation Considered	2	(0) 147	Carbaryl use does not coincide with these activities after label revisions	Carbaryl use does not coincide with these activities after label revisions	NA
	Regulatory Decision	COMMENTS ABOUT USE: Carbaryl is used early in the season and generally only within 30 days of planting. As such, carbaryl applications only coincide with low exposure activities such as weeding and irrigation. Use is predominantly targeted at flea beetles, armyworm species, corn earworm and imported cabbageworm. CHANGES TO USE PATTERN: Use restricted for applications only within 30 days of crop emergence/transplanting. REI = 12 hours				

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Low Berry - lowbush blueberries - cranberries - strawberries	Risks Assessed	2	(0) 184 Exposure Activities - irrigation, scouting, weeding, pruning, thinning, rake harvesting cranberries, mulching	NA	(4) >100 Exposure Activities - hand harvesting, hand pruning, pinching, training (strawberries only)	NA
	Mitigation Considered	2	(0) 184	NA	(4) >100	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: High exposure activities are only appropriate for strawberries. Given that the current preharvest interval for strawberries is 7 days, the Agency believes that growers will have little or no impact from increasing the REI to 4 days. Based on the low exposure worker activities practiced in cranberries and lowbush blueberries and the calculated MOE, the REI will remain at 12 hours for those crops.</p> <p>CHANGES TO USE PATTERN: Strawberries: REI = 4 days</p> <p>Cranberries and Lowbush Blueberries: REI = 12 hours</p>				

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Low/Med Field/Row Crops - stringbeans - dry beans / peas - chick peas - green peas - alfalfa - forage - flax - peanuts - rice - wheat* - sugarbeets - barley** - canola** - cotton** - mint** - safflower **	Risks Assessed	1.5	(0) 982 Exposure Activities - irrigating, scouting, thinning, weeding immature/low foliage plants	(2) 96 Exposure Activities - irrigating, scouting, weeding mature/high foliage plants	(5) >100 Exposure Activities - Hand harvesting	NA
	Mitigation Considered	1.5	(0) 982	(2) 96	(5) >100	NA
	Regulatory Decision	COMMENTS ABOUT USE: Comments submitted to the Agency indicate that for stringbeans, dry beans/peas, chick peas and green peas a 5 day REI is acceptable based on hand harvesting activities. However, hand harvesting is not a practice utilized for alfalfa, forage, flax, peanuts, rice, and sugarbeets, therefore, a 2 day REI is appropriate for these crops, based on medium exposure activities. Impacts to growers are not expected based on these changes. CHANGES TO USE PATTERN: Stringbeans, Dry Beans/peas, Chick Peas and Green Peas: REI = 5 days Alfalfa, Forage, Flax, Peanuts, Rice, and Sugarbeets: REI = 2 days (the MOE of 96 at day 2 is close to the target MOE and is not of concern to the Agency)				

* The registrant is dropping the use on wheat.

** Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Nursery/Ornamentals - various species (balled & burlapped, containerized, plugs, etc.)	Risks Assessed	2	(0) 669 Exposure Activities - hand pruning	(0) 421 Exposure Activities - hand pinching	(0) 184 Exposure Activities - hand harvesting	NA
	Mitigation Considered	2	(0) 669	(0) 421	(0) 184	
	Regulatory Decision	<p>COMMENTS ABOUT USE: Carbaryl use on nursery and ornamental crops does not need to be changed because the assessed MOE is greater than the target MOE for workers engaged in high exposure activities.</p> <p>CHANGES TO USE PATTERN: REI = 12 hours</p>				

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Nut Trees - almonds - hazelnuts - macadamia - olives - pistachios - pecans - walnuts	Risks Assessed	5 7.5 (olives only)	(0) 175 (0) 116 Exposure Activities - scouting, thinning, weeding	NA	(10) 94 (14) 93 Exposure Activities - harvesting/poling, pruning, thinning	NA
	Mitigation Considered	5 7.5 (olives only)	(0) 175 NA	NA NA	(10) 94 (14) 93	NA NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: Use of carbaryl on these crops can occasionally coincide with harvest activities. Use of carbaryl on olives is highly variable. It targets the crawler stage of black scales, which is the primary insect pest of olive. Carbaryl is the only registered chemical for in-season use and it is generally applied with oil to enhance efficacy against the target pests. Extending the REI for olives to 14 days and to 10 days for almonds, hazelnuts, macadamia and walnuts is not expected to cause adverse impacts to growers based on comments received from growers and university specialists and because the preharvest interval for carbaryl is 14 days for these crops.</p> <p>Carbaryl is applied to pecans to control pecan weevil through late summer to early fall (or just prior to harvest). Most pecans are harvested mechanically, therefore low level of exposure would result from this activity. The minimal hand harvesting that does occur involves knocking the pecans out of the tree with a pole and then hand picking the nuts off the orchard floor, however, often some machinery is used when hand harvesting. Orchard floor preparation, which generally involves mowing and some minor pruning of low hanging limbs must be completed before harvest. The pruning that occurs would generally only be for a short period of time (< 2 hours) on any given day. The risk assessment assumes that workers spend 8 hours/day doing the various activities. If that assumption is adjusted to 2 hours/day for pruning activities on pecans the MOE is 140 at 12 hours after application. Given that the PHI is 14 days, no hand harvesting activities would occur until that period has passed following applications of carbaryl.</p> <p>CHANGES TO USE PATTERN: Pecans: REI = 12 hours</p> <p>Almonds, Hazelnuts (Filberts), Macadamia, Pistachios, Walnuts: REI = 10 days (the MOE of 94 at day 10 is close to the target MOE and is not of concern to the Agency)</p> <p>Olives: REI = 14 days (the MOE of 93 at day 14 is close to the target MOE and is not of concern to the Agency)</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Root Vegetables - table beets - carrots - dry/green onions* - potatoes - sweet potatoes - turnips	Risks Assessed	2	(0) 245 Exposure Activities - irrigation, scouting, thinning and weeding immature plants	(4) 105 Exposure Activities - irrigation and scouting mature plants	(7) >100 Exposure Activities - hand harvesting	NA
	Mitigation Considered	2	(0) 245	(4) 105	NA	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: Table beets and turnips are often hand harvested for their tops (similar to greens in leafy vegetable crop grouping) in certain regions of the country. Carbaryl is used early in the season and generally only within 30 days of planting when table beets and turnips are harvested for their tops. When the crops in this grouping are harvested for their roots, hand harvesting is not a common practice. Therefore, based on medium exposure activities, an MOE of 4 days is not expected to impact growers.</p> <p>CHANGES TO USE PATTERN: Table beets and Turnips when harvested for Greens: Use restricted for applications only within 30 days of crop emergence/transplanting REI = 12 hours</p> <p>Table beets, Carrots, Potatoes, Sweet Potato, Turnips when harvested for Roots: REI = 4 days</p>				

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)	Application Rate (lb ai/A)	Exposure Potential Categories				
		Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE	
Stem/Stalk Vegetables - artichoke* - asparagus - pineapple**	Risks Assessed	2	(0) 137	(1) 101	(5) >100	NA
		4	(2) 103 Exposure Activities - irrigating, scouting, thinning and weeding immature plants	(4) 93 Exposure Activities - irrigation and scouting mature plants	(8) 106 Exposure Activities - hand harvesting	
	Mitigation Considered	1	(0) 274	(0) 164	(1) 101	NA
		2	(0) 137	(1) 101	NA	
	Regulatory Decision	<p>BENEFITS OF USE: Carbaryl is labeled at a rate of 2 lb ai/A for preharvest applications and up to 4 lb ai/A for post harvest application to asparagus ferns; it currently has a one day preharvest interval. Asparagus grows very quickly and must be harvested frequently. Harvesting generally begins in mid-January in the western US and in early Spring in the mid-west and east coast growing areas, and continues through June. Virtually all harvesting is done by hand, on a repetitive basis, every one to five days throughout the growing season. Depending on growing conditions, harvesting can occur every day. Carbaryl is used during the harvest period to control asparagus beetle adults to prevent them from laying eggs on the developing spears; there is a zero tolerance for asparagus beetle eggs on asparagus spears. Maintaining the use rate at 2 lb ai/A during the harvest period would calculate to an REI of 5 days before hand harvesting could occur. According to growers, this would essentially eliminate carbaryl from use during this critical period. Following discussions with growers and University researchers, it has been determined that carbaryl is efficacious for the target pests at 1 lb ai/A during the harvest period. Reducing the rate to 1 lb ai/A allows for workers to reenter treated areas 24 hours after application (MOE = 101) to conduct harvest activities; this period coincides with the existing preharvest interval.</p> <p>Higher carbaryl use rates are used during the fern stage (post harvest) of asparagus growth. Few worker activities occur in the field during this time period. Again, following discussions and comments received from growers and researchers, it has been determined that the use rate can be reduced for use during the post harvest period to 2 lb ai/A with no loss of efficacy. With the reduced rate of 2 lb ai/A, and the fact that few worker activities require reentry during this growth period, a 24 hour REI is appropriate.</p> <p>CHANGES TO USE PATTERN: Asparagus: Pre-Harvest Applications: Max. Rate = 1 lb ai/A REI = 24 hours Post-Harvest Applications: Max. Rate = 2 lb ai/A REI = 24 hours</p> <p>Max. amount of active ingredient that can be applied preharvest is reduced to 3 lb ai/A.</p>				

* Carbaryl is not currently registered for use on these crops.

** Carbaryl is not currently registered on pineapples in the US, but an import tolerance on pineapples is established.

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Sugarcane*	Risks Assessed	1.5	NA	(3) 101 Exposure Activities - scouting, weeding immature plants	(7) >100 Exposure Activities - scouting, irrigating, weeding mature plants	NA
	Mitigation Considered	NA	NA	NA	NA	NA
	Regulatory Decision	COMMENTS ABOUT USE: NA NEW USE PATTERN: NA				

* Carbaryl is not currently registered for use on these crops.

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Tall Field/Row Crops - field corn (including seed corn) - sunflowers - sorghum - sweet corn	Risks Assessed	2	(0) 245 Exposure Activities - scouting, weeding immature/foilage plants	(4) 105 Exposure Activities - scouting, weeding more mature/foilage plants	(11) >100 Exposure Activities - scouting, irrigation, weeding mature/full foliage plants	(30) 80 Exposure Activities - sweet corn hand harvest, detasseling
	Mitigation Considered	2 1.5 (sunflowers only)	(0) 245 NA	(3) 92 (1) 94	NA NA	(30) 80 NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency erroneously assessed a maximum rate for sunflowers of 2 lb ai/A when the maximum rate currently allowed is 1.5 lb ai/A. The Agency believes that the worker activities modeled in the high exposure potential category do not normally occur in these crops. Based on the medium exposure category REIs of 4 days (2 lb ai/A for corn, sorghum and sweet corn) and 1 day (1.5 lb ai/A for sunflowers) result in MOEs >100.</p> <p>Sweet corn hand harvest and detasseling are in the very high worker exposure category. Detasseling is the process of removing the tassel from the corn plant so the plant cannot pollinate itself. This is only practiced on corn hybrids being developed for seed production. A REI of 30 days is required to protect workers from exposure levels of concern. Carbaryl is sometimes applied to sweet corn grown for fresh market consumption and during the period when harvesting occurs. The preharvest interval for ear harvest is 2 days, therefore, a 30 day or more REI for hand harvesting is impractical and a defacto cancellation. Approximately 3% of the US sweet corn acreage grown for fresh markets was treated with carbaryl with 2-3 applications made per year. Several alternative insecticides (lambda cyhalothrin, methomyl, esfenvalerate, and thiodicarb) are available and are more routinely used than carbaryl. Because the MOEs are so low for hand harvesters and there is interest in maintaining the use of carbaryl for possible resistance management purposes, the mitigation measure to be adopted is to prohibit hand harvesting and allow for a 3 day REI based on medium exposure activities.</p> <p>CHANGES TO USE PATTERN:</p> <p>Corn and Sorghum. REI = 4 days.</p> <p>Seed Corn. REI = 4 days for all activities; however, workers may not enter treated areas to hand detassel until 30 days after application.</p> <p>Sunflowers: REI = 24 hours</p> <p>Sweet Corn: Prohibition of hand harvesting REI = 3 days</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories			
			Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Turf/Sod - golf course - sodfarm turf	Risks Assessed	8.17	(0) 312 Exposure Activity - mowing	NA	(14) >100 Exposure Activities - transplanting, hand weeding	NA
	Revised Risks Assessed	8.17	(0) 312 Exposure Activity - mowing	(4) 90 Exposure Activities - golf course maintenance	(9) 104 Exposure Activities - sod farm harvesting	NA
	Regulatory Decision	<p>COMMENTS ABOUT USE: The Agency recently reviewed two studies conducted by the Agricultural Reentry Task Force on worker exposure levels from golf course maintenance activities and sod farm harvesting. The data from these studies indicate that a change in transfer coefficients is appropriate to more accurately estimate exposure levels. Based on the new transfer coefficients, the Agency recalculated the MOEs as presented above. Even with this activity specific data, the REI calculates to 9 days. Since applications to control grubs are generally made well before harvest, the 9 day REI is not expected to impact growers. Golf courses are not covered by the WPS and do not require REIs as established for crop uses.</p> <p>CHANGES TO USE PATTERN: Sod Farms: REI = 12 hours for all activities; however, workers may not reenter treated areas to harvest sod until 9 days after application.</p> <p>Golf Courses: None needed</p>				

Crop Grouping (crops considered)		Application Rate (lb ai/A)	Exposure Potential Categories				
			Very Low (Reentry Day) MOE	Low (Reentry Day) MOE	Medium (Reentry Day) MOE	High (Reentry Day) MOE	Very High (Reentry Day) MOE
Vine/Trellis - pole beans - blackberries - highbush blueberries - grapes - kiwi* - raspberries * Carbaryl is not currently registered for use on kiwi.	Risks Assessed	2	NA	(0) 147 Exposure Activities irrigating, scouting, hand weeding, training/tying blueberry plants	(2) 108 Exposure Activities scouting, training, tying	(10) 100 Exposure Activities hand harvest, leaf pulling, thinning, pruning, training/tying grapes	(14) 106 Exposure Activities grape girdling and cane turning
	Mitigation Considered	2	(0) 147 irrigating, scouting, hand weeding, training/tying blueberry plants	(2) 108 scouting, training, tying	(2) 98 caneberry and highbush blueberry harvest	(2) 22 (7) 56 hand harvest grapes, leaf pulling, thinning, pruning, training/tying grapes	(2) 11 (7) 28 grape girdling and cane turning
	Regulatory Decision	<p>BENEFITS OF USE: The Agency recently reviewed a study conducted by the Agricultural Reentry Task Force on worker exposure levels from caneberry (blackberries and raspberries) harvest activities. The data from this study indicate that a change in transfer coefficients is appropriate to more accurately estimate exposure levels, namely a new medium exposure category for caneberry harvest. The Agency believes that highbush blueberry and pole bean harvest is substantially similar to caneberry harvest techniques so these crops will be considered together. Carbaryl has a 7 day preharvest interval for all crops in the vine/trellis group, therefore, a 2 day REI is not expected to impact growers.</p> <p>The exposure activities in the high and very high exposure categories are common only in grape production, specifically wine and table grape production. These cultural practices are particularly important to meet the exacting demands of the wine and table grape markets. Carbaryl use in grapes varies significantly by region of production. In the west (CA, WA, OR and AZ), which represents over 90% of US grape production and acres grown, carbaryl was applied to less than 2% of the grape acreage. However, east of the Rocky Mountains carbaryl is used on approximately 60% of the acreage grown, and they often treat several times. Based on differences in carbaryl use patterns and the need to conduct various worker activities on a frequent basis on wine and table grapes, the Agency determined that significant economic impacts to growers would occur if the REI were extended beyond 48 hours for grapes grown east of the Rocky Mountains. However, for grapes grown west of the Rocky Mountains, significant impacts to growers are not expected if the REI is extended beyond 7 days. See EPA's benefits assessment for grapes in Section 3 of this document. After weighing the benefits associated with use of carbaryl on grapes against the postapplication risks, the Agency no longer has concerns with this use pattern.</p> <p>CHANGES TO USE PATTERN: Blackberries, Raspberries, Highbush Blueberries and Pole Beans: REI = 2 days</p> <p>Grapes: East of the Rocky Mountains: REI = 48 hours West of the Rocky Mountains: REI = 7 days</p>					

Occupational Postapplication Cancer Risks

Cancer risks for occupational postapplication exposures. Occupational cancer risks equal to or less than 1×10^{-6} (1 in 1 million) are not of concern to the Agency. The Agency also carefully examines uses with estimated risks in the 10^{-6} to 10^{-4} range to seek cost-effective ways of reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protective equipment (PPE) or engineering controls are added to the extent practical. If occupational cancer risks in the 10^{-6} to 10^{-4} range despite practicable mitigation measures, EPA will consider whether benefits of the use warrant such risks.

Based on a 1×10^{-6} risk concern threshold, the current 12 hour REI appears adequate to address cancer risks for many crop/activity combinations. But for higher exposure situations, longer REIs are needed so that risks are not of concern. In all cases, though, REIs based on cancer risks are either not as long, or are similar to, REIs based on the noncancer effects of carbaryl. Therefore, REIs that are protective for noncancer risk will be as protective or more protective for cancer risks. EPA's risk management determination is that the mitigation or benefits decisions made for noncancer risks of concern adequately mitigate the cancer risks of concern. Cancer risks for occupational postapplication exposures are calculated separately for private growers and for commercial farmworkers.

2. Environmental Risk Mitigation

The Agency's assessment suggests that the use of carbaryl can result in adverse effects to terrestrial land aquatic organisms. Acute RQs for terrestrial animals, based on applications with nongranular formulations, range from <0.01 to 12, and chronic RQs range from 0.05 to 51. The highest RQs are based on applications to citrus in California at the 16 lb ai/A rate. For granular formulations, the RQs range from 0.05 to 21. Acute RQs to freshwater fish and invertebrates range from 0.09 to 30, and chronic RQs range from 0.07 to 55. The highest calculated RQs are also based on applications to citrus in Florida.

To mitigate residential and occupational risk of concern, a number of measures are to be implemented as part of this IRED which will also have a significant affect on reducing ecological risks as well. For instance, maximum application rates for some uses are to be reduced, including rates for citrus in California only from 16 lb ai/A to 12 lb ai/A, and from 7.5 lb ai/A to 5 lb ai/A for the rest of the country, except for Florida where the Section 24(c) registration rate will be reduced from 10 lb ai/A to 8 lb ai/A. Since the highest acute terrestrial RQ with nongranular formulations was assessed based on applications to citrus, reducing the maximum rate for this use will also reduce these risk concerns. Likewise, the reductions of maximum application rates to citrus in Florida will also reduce the corresponding RQs for freshwater fish and invertebrates. Reducing maximum application rates for mosquito control and asparagus, cancelling carbaryl use on wheat, and prohibiting certain aerial applications will also reduce potential ecological risks.

In addition, due to postapplication risk concerns for broadcast applications with liquid formulations to home lawns and recreational areas, except golf courses, the technical registrants

have voluntarily requested that this use be cancelled, pending the results of data that is being generated to potentially refine these risks. In the meantime, the technical registrants have also voluntarily deleted this use from their technical label. Discontinuing this use, especially to residential and urban areas, is also expected to reduce risk to terrestrial and aquatic organisms.

To address toxicity concerns to honey bees and potential risk concerns, and to respond to comments expressing concern about carbaryl applications and the effects to honey bees, the following Environmental Hazard language is to be added to carbaryl end-use products:

“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”

In addition, the Agency has been in consultation with the technical registrant and other concerned parties about conducting a study on the chronic toxicity effects of carbaryl on bees.

Although risks are expected to exist for birds, mammals, aquatic fish and invertebrates, and nontarget insects, no additional mitigation measures are recommended at this time.

E. Labeling

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing carbaryl. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

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 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 to affect any particular species, EPA puts basic toxicity and exposure data developed for interim REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will include consideration of the regulatory changes recommended in this interim RED. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

The Endangered Species Protection Program as described in a *Federal Register* notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate

many of the specific measures outlined in the Biological Opinions issued to date. The pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp.

2. Spray Drift Management

The Agency is currently working with stakeholders to develop appropriate generic label statements to address spray drift risk. Once this process is completed, carbaryl product labels will need to be revised to include this additional language.

F. Carbaryl Risk Mitigation Summary

Based on the rationale for the interim regulatory decisions associated with the use of carbaryl, the following risk mitigation measures are necessary to be incorporated in their entirety into labels for carbaryl-containing products. Specific language of these revisions is set forth in the summary tables of Section V of this document. Likewise, the data required to be provided to the Agency to confirm these regulatory decisions are also listed in Section V.

Dietary Risk

- No label changes are necessary for these risks; however, confirmatory data listed in Section V of this document is required.

Residential Risk

- For the garden/ornamental dust on vegetables/ornamentals scenario, all end-use products are to be packaged in ready-to-use (RTU) shaker can containers, with no more than 0.5 lb ai/container.
- For the lawn care hose-end sprayer for liquid lawn broadcast scenario, all liquid formulation end-use products for lawncare are to be packaged in pint-size RTU hose-end sprayers. Because of postapplication risk concerns, the technical registrants, Bayer CropScience and Burlington Scientific, have sent EPA amended labels with this use deleted from their technical products. The technical registrants have also submitted voluntary cancellation letters for this use, effective July 1, 2004. Pending the outcome of pharmacokinetics data that Bayer CropScience is voluntarily generating to refine postapplication risks associated with this use scenario, the use of liquid formulation products for turf/lawn applications (except for applications to sod farms, golf courses, commercial landscape areas, and cemeteries) is limited to spot treatments only (less than 1000 square feet), with the use of a RTU sprayer. [NOTE: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of this IRED document.]
- The following uses are to be cancelled: all pet uses (dusts and liquids, except for collars); granular and baits lawn care: belly grinder for spot treatment; granular and baits by hand

for ornamentals and gardens; and aerosol for various uses. Also, confirmatory data on pet collars are stipulated in Section V of this document.

- Confirmatory transferable turf residue (TTR) data on granular formulations applied to lawns are required and listed in Section V. of this document.

Occupational Risk

Handler Risks

- The following uses and application methods are to be cancelled: wheat use; broadcast applications using liquid formulations on residential lawns and turf, except for sod farms, golf courses, commercial landscape areas, and cemeteries; pet uses (with the exception for pet collars); applications with hand, spoon, and bellygrinder;
- The following maximum application rates are to be reduced: mosquito control - from 1.0 lb ai/A to 0.2 lb ai/A; citrus (entire US except CA) - from 7.5 lb ai/A to 5 lb ai/A; California citrus - from 16 lb ai/A to 12 lb ai/A; Florida Special Local Need (FIFRA Sec. 24c) for Diaprepes root weevil control on citrus use rate of 10 lbs ai/A to 8 lb ai/A; and aAsparagus - preharvest rate from 2 lb ai/A to 1 lb ai/A; postharvest rate from 4 lb ai/A to 2 lb ai/A.
- Aerial applications are prohibited for the following: wettable powder formulations; and granular and bait formulations applied to corn (field, pop, and sweet), grain sorghum, alfalfa, rice, and sunflowers.
- PPE and engineering controls for aerial/chemigation applications: closed systems designed to provide dry disconnect/dry break links with the product container for protection of mixers and loaders. Only formulations compatible with these closed systems may be used (e.g., emulsifiable concentrates and soluble concentrates); enclosed cockpits for aerial applicators; and mechanical flaggers or global positioning system (GPS) equipment that negates the need for human flaggers.
- PPE and engineering controls for ground airblast applications (applicators): enclosed cabs for applications to olives; enclosed cabs for applications to citrus trees in California; enclosed cabs for applications to citrus trees in Florida under Section 24(c) Special Local Need at 8 lb ai/A; and for all other ground airblast applications the following PPE must be worn: coveralls over long-sleeved shirt and long pants, chemical resistant gloves, protection factor 10 respirator (half-mask, air purifying), WPS head protection, shoes and socks.
- PPE and engineering controls for granular and bait formulation (loaders and/or applicators): long-sleeved shirts and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise; and Ready-to-Disperse containers are stipulated for Ornamental and Garden uses to administer product without direct

contact of the formulation to the applicator.

- PPE for liquid formulation (e.g., emulsifiable concentrates, soluble concentrates) (mixer/loaders and/or applicators): long-sleeved shirt and long pants, chemical resistant gloves, dust/mist respirator, shoes and socks, unless specified otherwise.
- PPE and packaging for wettable powder formulation: water soluble packaging (an engineering control) is stipulated for all wettable powder formulations; long-sleeved shirts and long pants, chemical resistant gloves, shoes and socks.

Postapplication Risks

- For brassica crops: use is restricted to applications only within 30 days of crop emergence/transplanting; REI = 5 days
- For bunch/bundle crops: REI = 8 days
- For cucurbit vegetables: REI = 3 days
- For roses: REI = 7 days
- For stone fruits: for a 3 lb ai/A rate, the REI = 12 hours for all activities; however, workers may not enter treated areas to hand thin until 7 days after application. For 4 lb ai/A rate in CA only, the REI = 3 days for all activities; however, workers may not enter treated areas to hand thin until 7 days after application.
- For citrus crops: the maximum application rate is reduced to 5 lb ai/A rate with an REI = 24 hours; for FL §24(c) registration, the maximum rate is reduced to 8 lb ai./A with an REI = 5 days; and maximum application rate for CA only is reduced to 12 lb ai/A with an REI = 5 days.
- For eggplant, bell/chili peppers, and tomatoes: REI = 2 days
- For leafy vegetables: use is restricted for applications only within 30 days of crop emergence/transplanting
- For strawberries: REI = 4 days
- For stringbeans, dry beans/peas, chick peas and green peas: REI = 5 days
- For alfalfa, forage, flax, peanuts, rice, and sugarbeets: REI = 2 days
- For almonds, hazelnuts (filberts), macadamia, pistachios, and walnuts: REI = 10 days
- For olives: REI = 14 days
- For table beets and turnips when harvested for greens: use is restricted for applications only within 30 days of crop emergence/transplanting
- For table beets, carrots, potatoes, sweet potato, turnips when harvested for roots: REI = 4 days
- For asparagus: for pre-harvest applications, the maximum application rate is reduced to 1 lb ai/A with a REI = 24 hours; and for post-harvest applications, the maximum application rate is reduced to 2 lb ai/A with a REI = 24 hours
- For corn and sorghum: REI = 4 days
- For seed corn: REI = 4 days for all activities; however, workers may not enter treated areas to hand detassel until 30 days after application
- For sunflowers: REI = 24 hours
- For sweet corn: prohibition of hand harvesting and the REI = 3 days

- For sod farms: REI = 12 hours for all activities; however, workers may not reenter treated areas to harvest sod until 9 days after application
- For blackberries, raspberries, highbush blueberries and pole beans: REI = 2 days
- For grapes: east of the Rocky Mountains the REI = 48 hours; west of the Rocky Mountains the REI = 7 days

Ecological Risk

To address ecological risks, the following mitigation is required:

- To address toxicity concerns for honey bees, a bee protection statement must be added to the Environmental Hazards section of carbaryl product labels, as follows:
“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”
- Several mitigation measures required to address residential and occupational risks, described above, will also address risks to terrestrial and aquatic organisms, including:
 - Reducing maximum application rates for mosquito control, citrus, and asparagus;
 - Canceling use on wheat;
 - Canceling liquid broadcast applications to home lawns; and
 - Prohibiting certain aerial applications.

V. What Registrants Need to Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV and V, which include, among other things, submission of the following:

A. Data Call-In Responses

For carbaryl technical grade active ingredient products, registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI): (1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant’s response form); and (2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI: cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Anthony Britten at (703) 308-8179 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:

Document Processing Desk (DCI/SRRD)
Anthony Britten
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)
Anthony Britten
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

For products containing the active ingredient carbaryl, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI): (1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and (2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI: (1) two copies of the confidential statement of formula (EPA Form 8570-4); (2) a completed original application for reregistration (EPA Form 8570-1) (Indicate on the form that it is an "application for reregistration"); (3) five copies of the draft label incorporating all label amendments outlined in Table 32 of this document; (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); (6) and the product-specific data responding to the PDCI.

Please contact Karen Jones at (703) 308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:

Document Processing Desk (PDCI/PRB)
Karen Jones
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)
Karen Jones
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of carbaryl for the above eligible uses has been reviewed and determined to be substantially complete. Data gaps for which EPA has not previously issued a DCI are listed in Appendix E, which is a sample of the Generic Data Call In being sent to technical registrants. Data gaps previously identified by the Agency which

remain unfulfilled and which are deemed necessary by the Agency, are related to product residue chemistry. A list of these data gaps is included in Chapter 9.0 of HED's Phase 5 human health risk assessment, dated March 14, 2003 (D287532). An electronic copy is available in EDOCKET. See docket OPP-2003-0101, document -0002.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 32 at the end of this section.

C. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 32 at the end of this section.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this IRED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this IRED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy;" *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell carbaryl products bearing old labels/labeling for 26 months from the date of issuance of this IRED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this IRED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products

they sell or distribute.

E. Label Changes Summary Table

In order to be eligible for reregistration, all product labels are to be amended to incorporate the risk mitigation measures outlined in Section IV. Table 32 describes how language on the labels should be amended.

Table 32. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
<p>One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group</p>	<p>“Only for formulation into an <i>insecticide</i> for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”</p> <p>The following uses are cancelled: wheat, pets (except for pet collars) and all pet-related uses. Revise technical and end-use product labels to delete all references to and use-directions for these cancelled use patterns.</p> <p>Dust, bait, and granular formulations with directions for use on commercial ornamentals or nursery plants must be packaged in a ready-to-dispense container. Bait and granular formulations with directions for use on home gardens and ornamentals must be packaged in a ready-to-dispense container. Dust formulations with directions for use on home gardens and ornamentals must be packaged in a ready-to-use shaker can containing no more than 0.05 pounds active ingredient per container.</p> <p>Dry flowable and wettable powder formulations must be packaged in water-soluble packets.</p> <p>Liquid, wettable powder, and dry flowable formulations labeled for homeowner use on home lawns must be packaged in ready-to-use pint-sized containers for use in hose-end sprayers. Such formulations must limit applications to spot treatments of less than 1,000 square feet. [NOTE: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to the registrant, dated 10/22/04, at the front of this IRED document.]</p> <p>Packaging this product into aerosol can formulations is prohibited.</p> <p>After December 31, 2009, the Special Local Needs Registration in Washington State (SLN WA-900013) that permits use on oyster beds expires. Registrants should immediately contact the issuing states about changing their SLN labels to reflect the upcoming expiration and should send a copy of the letter to Product Manager 13, Insecticide Branch, Registration Division (7505C) in EPA’s Office of Pesticide Programs.</p>	<p>Directions for Use</p>

Description	Amended Labeling Language	Placement on Label
	“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”	Directions for Use
Environmental Hazards Statements Required by the IRED and/or Agency Label Policies	" Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Directions for Use
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
Determining PPE labeling requirements for end-use products containing this active ingredient	<p>The PPE, if any, that would be established on the basis of the acute toxicity category of each end-use product must be compared to the active-ingredient specific personal protective equipment specified below. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p> <p>PPE Requirements for sole-active-ingredient end-use products that contain carbaryl: The product labeling must be revised to adopt the handler personal protective equipment and/or engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.</p> <p>PPE Requirements for multiple-active-ingredient end-use products that contain carbaryl: The handler personal protective equipment and/or engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.</p>	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the IRED¹ for Liquid products</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.</p> <p>Handlers using airblast equipment, handheld or backmounted fogging equipment, or high pressure handwand equipment must wear:</p> <ul style="list-style-type: none"> - Coveralls over long-sleeved shirt and long pants, - Chemical-resistant gloves, - Chemical-resistant footwear plus socks, - Chemical-resistant headgear, and - NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter. <p>All other mixers, loaders, applicators, and handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Shoes plus socks, - Chemical-resistant gloves, and - NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter, plus - Chemical-resistant apron, if mixing, loading, chemigating, drenching, dipping, or cleaning equipment or spills. <p>See engineering controls for additional requirements and exceptions.</p> <p>Human flagging is prohibited.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the IRED¹ for Wettable Powder and Dry Flowable Formulations</p> <p>(Note: these formulations must be sold in water-soluble packaging)</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.</p> <p>Handlers using airblast equipment or high pressure handwand equipment must wear:</p> <ul style="list-style-type: none"> - Coveralls over long-sleeved shirt and long pants, - Chemical-resistant gloves, - Chemical-resistant footwear plus socks, - Chemical-resistant headgear, and - NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter.” <p>“All other mixers, loaders, applicators, and handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Shoes plus socks, - Chemical-resistant gloves, - Chemical-resistant apron, if mixing, loading, drenching, dipping, or cleaning equipment or spills; plus - NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter for all handlers, except mixers and loaders. <p>Application by air or through irrigation systems is prohibited.</p> <p>See engineering controls for additional requirements and exceptions.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the IRED¹ for Granular and Bait Formulations with Directions for Use for Broadcast Applications</p> <p>(Note: this does not include granular and bait formulations sold in ready-to-dispense packaging)</p> <p>(Note also: if the granular/bait formulation does NOT have directions for use for rangeland applications, then the prohibition on aerial application should be added to the other prohibited equipment and the APHIS exception should be eliminated.)</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>Loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Chemical-resistant gloves, and - Shoes plus socks. <p><i>In addition</i>, handlers loading into or applying with motorized ground equipment, such as a tractor-drawn spreader <i>or</i> loading into airplanes (see APHIS exception below), must wear a NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH- approved respirator with any N, R, P or HE filter.</p> <p>Application by hand, spoon, shaker can, or back- or front-mounted spreader is prohibited.</p> <p>Aerial application is prohibited, except for aerial applications through the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program at a maximum application rate of 0.03 pounds active ingredient per acre.</p> <p>See engineering controls for additional requirements and exceptions.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements Established by the IRED¹ For Granular, Bait, or Dust Formulations Sold in Ready-To-Use Packaging</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.</p> <p>Loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Shoes plus socks, and - Chemical-resistant gloves.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the IRED¹ for the EPA SLN FL-890037 label for control of citrus weevil adults in Florida</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.</p> <p>Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Shoes plus socks, - a NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter, - Chemical-resistant gloves, and - Chemical-resistant apron, if mixing/loading or cleaning equipment or spills. <p>See engineering controls for additional requirements.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the IRED for Tree Injection Applicators</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are (<i>registrant inserts correct chemical-resistant material</i>). If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.</p> <p>Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - Long-sleeved shirt and long pants, - Shoes plus socks, and - Chemical-resistant gloves. 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
User Safety Requirements	<p><i>If coveralls are not listed as a PPE requirement for handlers, use the following statement:</i></p> <p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p><i>If coveralls are listed as a PPE requirement for handlers, use the following in addition to the above statement:</i></p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for Liquids</p> <p>(Note: this does not include the EPA SLN FL-890037 for control of citrus weevil adults in Florida)</p>	<p>Mixers and loaders supporting aerial or chemigation applications must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)]. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to no more than 2 ml per disconnect. In addition, mixers and loaders must:</p> <ul style="list-style-type: none"> -- wear the personal protective equipment required on this labeling for mixers/loaders, except that no respirator is required; -- wear protective eyewear, if the system operates under pressure; and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and the respirator specified on this labeling for handlers. <p>Applicators using airblast equipment for application to <i>citrus in California</i> or to <i>olives in any state</i> must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> -- wear long-sleeve shirt, long pants, shoes, and socks; -- <i>either</i> wear the respirator specified for handlers on this label <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers; -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear (if overhead exposure) plus – if not already using one – the respirator specified on this labeling for handlers; -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab. <p>Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(6)].</p> <p>Human flagging is prohibited, <i>except</i> for flagging to support aerial applications through the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program using ultra low volume applications. Flagging to support aerial application for all other use patterns is limited to use of the Global Positioning System (GPS) or mechanical flaggers.</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Controls for Liquids - continued</p> <p>(Note: this does not include the EPA SLN FL-890037 for control of citrus weevil adults in Florida)</p>	<p>For APHIS Rangeland Grasshopper and Mormon Cricket Suppression Program only: Flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, flaggers must:</p> <ul style="list-style-type: none"> -- wear long-sleeve shirt, long pants, shoes, and socks, -- <i>either</i> wear the type of respirator specified in the PPE section of this labeling* <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling, -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: chemical-resistant gloves and chemical-resistant headgear, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” 	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)</p>
<p>Engineering Controls for Wettable Powders and Dry Flowable Formulations</p> <p>Water-Soluble Packaging is required for all Wettable Powder and Dry Flowable formulations</p>	<p>“Water-soluble packaging when used correctly qualifies as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water soluble packets must:</p> <ul style="list-style-type: none"> -wear the personal protective equipment on this labeling for mixers/loaders, <i>however</i>, they do NOT need to wear a respirator, and -be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and a NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter. <p>Applicators using airblast equipment for application to <i>citrus in California</i> or to <i>olives in any state</i> must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> -- wear long-sleeve shirt, long pants, shoes, and socks; -- <i>either</i> wear the respirator specified for handlers on this label <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers; -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area coveralls, chemical-resistant gloves, and chemical-resistant footwear and – if not already using one – the respirator specified for handlers; -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” 	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Control Requirements Established by the IRED¹ for the EPA SLN FL-890037 for control of citrus weevil adults in Florida</p>	<p>Mixers and loaders supporting aerial applications must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)]. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to no more than 2 ml per disconnect. In addition, mixers and loaders must:</p> <ul style="list-style-type: none"> -- wear long-sleeved shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron; -- wear protective eyewear, if the system operates under pressure; and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant footwear and the respirator specified on this labeling for handlers. <p>Applicators must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must:</p> <ul style="list-style-type: none"> -- wear long-sleeve shirt, long pants, shoes, and socks; -- <i>either</i> wear the respirator specified for handlers on this label <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the respirator specified for handlers; -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area coveralls, chemical-resistant gloves, and chemical-resistant footwear and – if not already using one – the respirator specified for handlers; -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab. <p>Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(6)].</p> <p>Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.</p> <p>When applicators use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
<p>Engineering Control Requirements Established by the IRED¹</p> <p>Granular/Bait Formulation Labelled for Use for Rangeland Grasshopper or Mormon Cricket Control</p> <p>(Note also: if the granular/bait formulation does NOT have directions for use for rangeland applications, then these statements are not needed.</p>	<p>“Aerial application is permitted only through the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program at a maximum application rate of 0.03 pounds active ingredient per acre.</p> <p>Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(6)].</p> <p>Flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, flaggers must:</p> <ul style="list-style-type: none"> -- wear long-sleeve shirt, long pants, shoes, and socks, -- <i>either</i> wear a NIOSH-approved dust/mist filtering respirator with NIOSH/MSHA approval number prefix TC-21C or a NIOSH- approved respirator with any N, R, P or HE filter OR use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as this type of respirator, -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: chemical-resistant gloves and chemical-resistant headgear and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified above, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” 	
<p>Additional Engineering Controls Statement for all liquid, wettable powder, dry flowable formulations and for granular and bait formulations with directions for broadcast application. (Note: this statement is not needed for the 0.03% granular/ bait formulation or the EPA SLN FL-890037 for control of citrus weevil adults in Florida</p>	<p>“When applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5), the handler PPE requirements may be reduced or modified as specified in the WPS.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following any other engineering control requirements.)</p>

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Placed in a box in the Precautionary Statements under Hazards to Humans and Domestic Animals immediately following Engineering Controls.
Environmental Hazards	<p>“This product is extremely toxic to aquatic and estuarine invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Discharge from rice fields may kill aquatic and estuarine invertebrates. Do not apply when weather conditions favor drift from area treated. Do not contaminate water by cleaning equipment or disposal of wastes. Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.”</p>	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval	<p>“Do not enter or allow worker entry into treated areas during the “Restricted-entry interval (REI). The REI for each crop is listed in the directions for use associated with each crop.”</p>	Directions for Use, Inside the Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the IRED	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> - Coveralls, - Shoes plus socks, and - Chemical-resistant gloves made of any waterproof material” 	Directions for Use, Inside the Agricultural Use Requirements Box
Notification Requirements	<p>“When the Restricted-Entry Interval for a crop is 7 days or longer, you must notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.”</p>	Directions for Use, inside the Agricultural Use Requirements Box

Description	Amended Labeling Language	Placement on Label
NonWPS Entry Restrictions for applications applied as a spray	“Do not enter or allow others to enter the treated area until sprays have dried.”	If no WPS uses are on the label - Place the NON -WPS entry restrictions in the Directions for Use, under the heading “Entry Restrictions.”
NonWPS Entry Restrictions for dust applications.	“Do not enter or allow others to enter the treated area until dusts have settled. ”	If WPS uses are also on the label - Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate Non-WPS entry restrictions in that box.
NonWPS Entry Restrictions for granular applications	“Do not enter or allow others to enter the treated area until dusts have settled. In addition, if directions for use require watering-in, do not enter or allow others to enter the treated area (except those involved in the watering-in) until the watering-in is completed and the area has dried.”	
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation.”	For WPS products and products with both WPS and NonWPS uses, place directly above the Agricultural Use Requirements box. For Non-WPS products, place in the Direction for Use under General Precautions and Restrictions.
Application Restrictions for Dry Flowable and Wettable Powder Products	Aerial application is prohibited.	Directions for Use in a prominent place near the beginning

Description	Amended Labeling Language	Placement on Label
Application Restrictions for Liquid, Wettable Powder, and Dry Flowable Products containing instructions for application to turfgrass or lawns	"Broadcast applications to turfgrass are permitted only on golf courses, sod farms, cemeteries, and commercial landscapes. Applications to all other turfgrass or lawns are limited to spot treatments of less than 1000 square feet."	Directions for Use associated with the lawn/turfgrass directions

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Labels must be amended to reflect the following application restrictions which supercede or are in addition to restrictions currently on labels.</p> <p>Alfalfa “Restricted-entry interval (REI) = 2 days”</p> <p>Almonds “Restricted-entry interval (REI) = 10 days”</p> <p>Apples “Restricted-entry interval (REI) = 12 hours”</p> <p>Apricots <u>In California only:</u> “Restricted-entry interval (REI) = 3 days. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 4 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval (REI) = 12 hours. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 3 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p>Asparagus “Restricted-entry interval (REI) = 24 hours Apply a maximum of 3 pounds active ingredient per acre per year (registrant state this in amount of formulation per acre). For preharvest application, apply a maximum of 1 pound active ingredient per acre (registrant state this in amount of formulation per acre). For postharvest application to the plants remaining in the field, apply a maximum of 2 pounds active ingredient per acre (registrant state this in amount of formulation per acre).”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Beans <u>Stringbeans and Dry Beans</u> “Restricted-entry interval (REI) = 5 days”</p> <p><u>Pole Beans</u> “Restricted-entry interval (REI) = 2 days”</p> <p>Blackberries “Restricted-entry interval (REI) = 2 days”</p> <p>Blueberries (Lowbush) “Restricted-entry interval (REI) = 12 hours”</p> <p>Blueberries (Highbush) “Restricted-entry interval (REI) = 2 days”</p> <p>Boysenberry “Restricted-entry interval (REI) = 2 days”</p> <p>Brassica (bok choy, broccoli, Brussel sprouts, cabbage [including Chinese], cauliflower, collards, Hanover salad, kale, kohlrabi, mustard greens, napa) “Restricted-entry interval (REI) = 5 days Application is permitted only within 30 days from the date of crop emergence or the date of transplanting.”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Carrots <u>Harvested for Greens (Tops)</u> “Restricted-entry interval (REI) = 12 hours Application is permitted only within 30 days from the date of crop emergence or the date of transplanting.”</p> <p><u>Harvested for Roots</u> “Restricted-entry interval (REI) = 4 days”</p> <p>Chestnuts “Restricted-entry interval (REI) = 10 days”</p> <p>Cherries <u>In California only:</u> “Restricted-entry interval (REI) = 3 days. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 4 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval (REI) = 12 hours. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 3 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p>Citrus (citron, grapefruit, kumquats, lemons, limes, oranges, tangelos, tangerines, and hybrids) <u>California only:</u> “Restricted-entry interval = 5 days Do not apply more than 12 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval = 12 hours Do not apply more than 5 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>Florida SLN FL-890037 only:</u> “Restricted-entry interval = 5 days Do not apply more than 8 pounds active ingredient per acre per application (registrant state this in amount of</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Corn (field, sweet, seed, and pop) “Restricted-entry interval = 4 days. Prohibition: Do not enter or allow workers to enter treated areas to perform hand detasselling tasks until 30 days after application. You must notify workers of this prohibition. Hand harvesting is prohibited. You must notify workers of this prohibition.”</p> <p>Crabapples “Restricted-entry interval (REI) = 12 hours”</p> <p>Caneberries (blackberry and raspberry) “Restricted-entry interval = 2 days”</p> <p>Cranberries “Restricted-entry interval = 12 hours</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Cucurbits (cantaloupe, cucumber, gourds, pumpkins, squash, watermelon, zucchini, Chinese okra) “Restricted-entry interval (REI) = 3 days”</p> <p>Dewberry “Restricted-entry interval (REI) = 2 days”</p> <p>Dill “Restricted-entry interval (REI) = 12 hours”</p> <p>Eggplant “Restricted-entry interval (REI) = 2 days”</p> <p>Flax “Restricted-entry interval (REI) = 2 days”</p> <p>Forest Trees, Conifers, and Christmas Trees “Restricted-entry interval (REI) = 12 hours</p> <p>Grapes <u>East of the Rocky Mountains:</u> “Restricted-entry interval (REI) = 48 hours”</p> <p><u>West of the Rock Mountains:</u> “Restricted-entry interval (REI) = 7 days”</p> <p>Grass grown for Seed Production “Restricted-entry interval = 2 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Hazelnuts (Filberts) “Restricted-entry interval (REI) = 10 days”</p> <p>Horseradish “Restricted-entry interval = 4 days”</p> <p>Lentils “Restricted-entry interval (REI) = 5 days”</p> <p>Leafy vegetables (celery, dandelion, endive, escarole, lettuce, romaine, parsley, Swiss chard, spinach, carrot tops) “Restricted-entry interval (REI) = 12 hours Application is permitted only within 30 days from the date of crop emergence or the date of transplanting.”</p> <p>Loganberry “Restricted-entry interval (REI) = 2 days”</p> <p>Longan “Restricted-entry interval (REI) = 24 hours”</p> <p>Loquat “Restricted-entry interval (REI) = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Macadamia “Restricted-entry interval (REI) = 10 days”</p> <p>Nectarines <u>In California only:</u> “Restricted-entry interval (REI) = 3 days. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 4 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval (REI) = 12 hours. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 3 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p>Okra “Restricted-entry interval (REI) = 12 hours”</p> <p>Olives “Restricted-entry interval (REI) = 14 days”</p> <p>Ornamentals and Nursery Plants “Restricted-entry interval (REI) = 12 hours”</p> <p>Parsnip “Restricted-entry interval (REI) = 4 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Peas (dry peas, field peas, southern peas, succulent peas, blackeyed peas, chick peas, green peas, cowpeas, sitao, and oriental peas) “Restricted-entry interval (REI) = 5 days”</p> <p>Peaches <u>In California only:</u> “Restricted-entry interval (REI) = 3 days. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 4 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval (REI) = 12 hours. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 3 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p>Peanuts “Restricted-entry interval (REI) = 2 days”</p> <p>Pears (including Oriental Pears) “Restricted-entry interval (REI) = 12 hours”</p> <p>Pecans “Restricted-entry interval (REI) = 12 hours”</p> <p>Peppers (bell/chili) “Restricted-entry interval (REI) = 2 days”</p> <p>Pistachio “Restricted-entry interval (REI) = 10 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Plums/Prunes <u>In California only:</u> “Restricted-entry interval (REI) = 3 days. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 4 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p><u>All States other than California:</u> “Restricted-entry interval (REI) = 12 hours. Prohibition: do not allow workers to enter treated areas to hand thin until 7 days after application. You must notify workers of this prohibition. Do not apply more than 3 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application).”</p> <p>Potatoes (White and Irish) “Restricted-entry interval (REI) = 4 days”</p> <p>Proso millet “Restricted-entry interval (REI) = 2 days”</p> <p>Quince “Restricted-entry interval (REI) = 12 hours</p> <p>Radish “Restricted-entry interval (REI) = 4 days”</p> <p>Raspberries (Black and Red) “Restricted-entry interval (REI) = 2 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Rice “Restricted-entry interval (REI) = 2 days”</p> <p>Rutabaga “Restricted-entry interval (REI) = 4 days”</p> <p>Roses Grown for Cutting “Restricted-entry interval (REI) = 7 days”</p> <p>Salsify “Restricted-entry interval (REI) = 4 days”</p> <p>Strawberries “Restricted-entry interval (REI) = 4 days”</p> <p>Sorghum “Restricted-entry interval (REI) = 4 days”</p> <p>Soybeans “Restricted-entry interval (REI) = 2 days”</p> <p>Sugarbeets “Restricted-entry interval (REI) = 2 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Sunflower “Restricted-entry interval (REI) = 24 hours”</p> <p>Sweet Potatoes “Restricted-entry interval (REI) = 4 days”</p> <p>Table Beets <u>Harvested for Greens:</u> “Restricted-entry interval (REI) = 12 hours Application is permitted only within 30 days from the date of crop emergence or the date of transplanting.”</p> <p><u>Harvested for Roots:</u> “Restricted-entry interval (REI) = 4 days”</p> <p>Tobacco “Restricted-entry interval (REI) = 8 days”</p> <p>Tomatoes “Restricted-entry interval (REI) = 2 days”</p> <p>Trefoil “Restricted-entry interval (REI) = 2 days”</p> <p>Turf Grown for Sod Production “Restricted-entry interval (REI) = 12 hours</p> <p>Turnips <u>Harvested for Greens:</u> “Restricted-entry interval (REI) = 12 hours Application is permitted only within 30 days from the date of crop emergence or the date of transplanting.”</p> <p><u>Harvested for Roots:</u> “Restricted-entry interval (REI) = 4 days”</p> <p>Walnuts (English and Black) “Restricted-entry interval (REI) = 10 days”</p>	Directions for Use, Under Application Instructions for Each Crop

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p><u>Mosquito control</u> "Do not apply more than 0.2 pounds active ingredient per acre per application (registrant state this in amount of formulation per acre per application). Not for use in public health programs."</p> <p>NOTE: At this time, neither EPA nor CDC are aware of any uses of carbaryl in public health programs. Current labels for ultra-low volume application are labeled solely for non-urban forested areas, non cropland, and rangeland uses.</p>	Directions for Use Associated with the Use Pattern
End Use Products Intended Primarily for Use by Homeowners		
Application Restrictions	"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	<p>Liquids: "Do not allow people or pets to enter the treated area until sprays have dried."</p> <p>Dust Formulations: "Do not allow people or pets to enter the treated area until dusts have settled."</p> <p>Granular Formulations: "Do not allow people or pets to enter the treated area until dusts have settled. In addition, if directions for use require watering-in, do not allow people (except those involved in the watering-in) or pets to enter the treated area until the watering-in is completed and the area has dried."</p>	Directions for Use under General Precautions and Restrictions
Environmental Hazard Statement	"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."	Precautionary Statements under Environmental Hazards heading
Application Restrictions for Liquid, Wettable Powder, and Dry Flowable Formulations with Directions for Use on Home Lawns	"Broadcast application to lawns is prohibited. Application is limited to spot treatments of 1000 square feet or less."	Directions for Use under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Application Restrictions for Impregnated Pet Collars with Directions for Use on Cats	Registrants: modify labeling to be consistent PR Notice 96-6.	Directions for Use under General Precautions and Restrictions

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

² If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped. Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label. Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Appendices

Appendix A-1. Food and Feed Use Patterns Subject to Reregistration for Carbaryl (Case 056801)

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Food/Feed Crop Uses						
Alfalfa						
Broadcast foliar Ground	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	Aerial application prohibited.
Broadcast foliar Ground or aerial	4 lb/gal F/C	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	
Almond, chestnut, filbert, pecan, walnut, pistachios						
Foliar, dormant/delayed dormant Ground	50% WP 80% WP 85% WP	5.0 lb/A	4	15.0 lb/A	14	Aerial application prohibited. Other use directions and limitations same as below.
Foliar, dormant/delayed dormant Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	5.0 lb/A	4	15.0 lb/A	14	7-day minimum retreatment interval. For almonds only, dormant/delayed dormant applications may be made in combination with dormant oil.
Foliar application Ground only	50% WP [CA830007] 80% WP [CA830007]	1.0 lb/100 gal	NS	NS	1 (for nut crops)	Aerial application prohibited. Other use directions and limitations same as below. Use limited to CA for nut crops. Applications may be made at 7-day retreatment intervals or as needed.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Apricot, cherry, nectarine, peach, plum/prune						
Foliar and dormant/delayed dormant Ground only	50% WP 80% WP 85% WP	3.0 lb/A 4.0 lb/A (CA only) 5.0 lb/A (dormant/delayed only)	3 (foliar) and 1 (dormant/ delayed dormant)	14.0 lb/A	3 (except CA) 1 (CA only)	Aerial application prohibited. Minimum 7-day retreatment interval (14 days in CA). A maximum seasonal rate of 14.0 lb ai/A (5.0 lb ai/A during dormant/delayed dormant period and 9.0 lb ai/A during production season) has been established.
Foliar and dormant/delayed dormant Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	3.0 lb/A 4.0 lb/A (CA only) 5.0 lb/A (dormant/delayed only)	3 (foliar) and 1 (dormant/ delayed dormant)	14.0 lb/A	3 (except CA) 1 (CA only)	Minimum 7-day retreatment interval (14 days in CA). A maximum seasonal rate of 14.0 lb ai/A (5.0 lb ai/A during dormant/delayed dormant period and 9.0 lb ai/A during production season) has been established.
Foliar application Ground only	50% WP [CA830007] 80% WP [CA830007]	1.0 lb/100 gal	NS	NS	3	Aerial application prohibited. Use limited to CA. Applications may be made at 7-day retreatment intervals or as needed.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Asparagus						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.0 lb/A	3 (before harvest)	6.0 lb/A 3.0 lb/A for 5% P/T only	1	Aerial application prohibited. Minimum 3-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	1.0 lb/A	3 (before harvest)	6.0 lb/A 3.0 lb/A for 5% P/T only	1	Minimum 3-day retreatment interval.
Postharvest Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	2 (after harvest)	10.0 lb/A	NA	Aerial application prohibited. Minimum 3-day retreatment interval.
Postharvest Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	2 (after harvest)	10.0 lb/A	NA	Minimum 3-day retreatment interval.
Asparagus (continued)						
Postharvest (to fern or brush growth) Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	NA	Aerial application prohibited. Minimum 7-day retreatment interval.
Postharvest (to fern or brush growth) Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	NA	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground only	7% G	2.2 lb/A	4	NS	1	Aerial application prohibited. Use prohibited in CA. Minimum 7-day retreatment interval.
Bean, cowpea, pea						
Broadcast foliar Ground or aerial	5% P/T 10.04% P/T	1.5 lb/A	4	6.0 lb/A	3	A maximum of four applications may be made with a minimum 7-day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Bean, fresh and dried (<i>Phaseolus</i> species including snap, navy, and kidney), cowpea, lentil, pea, fresh and dried (<i>pisum</i> species), soybean						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	4	6.0 lb/A	3 (fresh beans) 14 (forage) 21 (dried beans, or hay)	Aerial application prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	1.5 lb/A	4	6.0 lb/A	3 (fresh beans) 14 (forage) 21 (dried beans, or hay)	Minimum 7-day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Beet, garden, roots, carrot, horseradish, radish, parsnip, rutabaga, salsify						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	6	6.0 lb/A	7	Aerial application prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	6	6.0 lb/A	7	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Beet, garden, tops						
Broadcast foliar Ground only	5% P/T 10.04% P/T	2.0 lb/A	5	6.0 lb/A	14	Aerial application prohibited. Minimum 7-day retreatment interval. Table beets and turnips when harvested for greens: use is restricted for applications only within 30 days of crop emergence/transplanting

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Beet, sugar						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	28 (roots and forage)	Aerial application prohibited. Minimum 14-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC 1	1.5 lb/A	2	3.0 lb/A	28 (roots and forage)	Minimum 14-day retreatment interval.
Blueberry						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	7	Aerial application prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	7	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	0.05 lb/1,000 sq. ft	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Broccoli, Brussels sprouts, cabbage, cauliflower, Chinese cabbage, collards, kale, kohlrabi, mustard greens						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	4	6.0 lb/A	3 14 (Chinese Cabbage, collards, kale and mustard greens)	Aerial application prohibited. Minimum 7-day retreatment interval. Use restricted to applications only within 30 days of crop emergence/transplanting
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	4	6.0 lb/A	3 14 (Chinese Cabbage, collards, kale and mustard greens)	Minimum 7-day retreatment interval. Use restricted to applications only within 30 days of crop emergence/transplanting
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	3 14 (Chinese Cabbage, collards, kale and mustard greens)	Use prohibited in CA. Minimum 7- day retreatment interval.
Brussels sprouts (see broccoli)						
Cabbage (see broccoli)						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Caneberry [Blackberry, Boysenberry, Dewberry, Loganberry, Raspberry]						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	7	Aerial application prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	7	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Carrot (see beet, garden)						
Cauliflower (see broccoli)						
Celery, dandelion						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	6.0 lb/A	14	Aerial application prohibited. Minimum 7-day retreatment interval. Use restricted for applications only within 30 days of crop emergence/transplanting.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	6.0 lb/A	14	Minimum 7-day retreatment interval. Use restricted for applications only within 30 days of crop emergence/transplanting.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	Use prohibited in CA. Minimum 7- day retreatment interval.
Cherry (see apricot)						
Chestnut (see almond)						
Chinese cabbage (see broccoli)						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Citrus fruits						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	7.5 lb/A	8	16.0 lb/A	5	Aerial application prohibited. Minimum 14-day retreatment interval.
		16.0 lb/A	1	16.0 lb/A	5	Aerial application prohibited. Use limited to CA for control of California red scale and yellow scale.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	7.5 lb/A	8	16.0 lb/A	5	A maximum of eight applications may be made with a minimum 14- day retreatment interval.
		16.0 lb/A	1	16.0 lb/A	5	Use limited to CA for control of California red scale and yellow scale.
Foliar application Ground only	50% WP [CA83007] 80% WP [CA83007]	1.0 lb/100 gal	NS	NS	5	Aerial application prohibited. Use limited to CA. Applications may be made at 7-day retreatment intervals or as needed.
Citrus fruits (continued)						
Foliar application Ground only	80% WP [FL890036]	10.0 lb/A	NS	NS	5	Aerial application prohibited. Use limited to FL. Applications may be made as a dilute or concentrate spray using ground equipment or in a minimum of 10 gal/A by air. Applications may be made as needed.
Foliar application Ground or aerial	4 lb/gal FIC [FL890037]	10.0 lb/A	NS	NS	5	Use limited to FL. Applications may be made as a dilute or concentrate spray using ground equipment or in a minimum of 10 gal/A by air. Applications may be made as needed.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Clover						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	Aerial application prohibited.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	
Collards						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	4	6.0 lb/A	14	Aerial application prohibited. See "Broccoli."
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	4	6.1 lb/A for the 2 and 4 lb/gal FIC (EPA Reg. Nos. 264-334 and 264-335)	14	See "Broccoli."
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	Use prohibited in CA. Minimum 7- day retreatment interval.
Corn, field and pop						
Broadcast foliar, banded Ground	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	4	8.0 lb/A	14 (forage and silage) 48 (grain and fodder)	Aerial application prohibited. Minimum 14-day retreatment interval.
Broadcast foliar, banded Ground or aerial	4 lb/gal FIC	2.0 lb/A	4	8.0 lb/A	14 (forage and silage) 48 (grain and fodder)	Minimum 14-day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Corn, sweet						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	8	16.0 lb/A	2 (ears) 14 (forage) 48 (fodder)	Aerial application prohibited. Minimum 14 day retreatment interval]. Note:Prohibition of hand harvesting.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	8	16.0 lb/A	2 (ears) 14 (forage) 48 (fodder)	Minimum 3-day retreatment interval. Note:Prohibition of hand harvesting.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	2	Use prohibited in CA. Minimum 7- day retreatment interval. Note:Prohibition of hand harvesting.
Cowpea (see bean)						
Cranberry						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	7	Aerial application prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	7	Minimum 7-day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Cucumber, melon, pumpkin, squash						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.0 lb/A	6	6.0 lb/A	3	Aerial application prohibited. Minimum 7-day retreatment interval. P/T formulations not used on pumpkins
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	1.0 lb/A	6	6.0 lb/A	3	Minimum 7-day retreatment interval. P/T formulations not used on pumpkins
Dandelion (see celery)						
Eggplant (see tomato)						
Endive (see lettuce)						
Filbert (see almond)						
Flax						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	42 (seed and straw)	Aerial application prohibited. Use prohibited in CA. Minimum 14-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	3.0 lb/A	42 (seed and straw)	Use prohibited in CA. Minimum 14-day retreatment interval.
Grape						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	7	Aerial application prohibited. See "Blueberry."
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	7	See "Blueberry."
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	See "Blueberry."

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Grasses (grown for seed)						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	14	Aerial application prohibited. Mnimum 14-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	3.0 lb/A	14	Mnimum 14-day retreatment interval.
Horseradish (see beet, garden)						
Kale (see broccoli)						
Kohlrabi (see broccoli)						
Lentil (see bean)						
Lettuce, head and leaf; endive						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	5	6.0 lb/A	14	Aerial application prohibited. Use restricted for applications only within 30 days of crop emergence/transplanting. Minimum 7-day retreatment See "Beet, garden, top" or "Celery."
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	6.0 lb/A	14	Use restricted for applications only within 30 days of crop emergence/transplanting. Minimum 7-day retreatment See "Beet, garden, top" or "Celery."
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	Use prohibited in CA. Minimum 7- day retreatment See "Celery."
Melon (see cucumber)						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Millet, proso						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	7 (forage) 21 (grain and straw)	Aerial application prohibited. Minimum 14-day retreatment interval. Use of the 50%, 80%, and 85% WP (EPA Reg. Nos. 264-314, 264-315, 264-316, and 264-526) and the 4 lb/gal FIC (EPA Reg. Nos. 264-321, 264-333, 264-335, and 264-349) formulations is prohibited in CA.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	3.0 lb/A	7 (forage) 21 (grain and straw)	Minimum 14-day retreatment interval. Use of the 50%, 80%, and 85% WP (EPA Reg. Nos. 264-314, 264-315, 264-316, and 264-526) and the 4 lb/gal FIC (EPA Reg. Nos. 264-321, 264-333, 264-335, and 264-349) formulations is prohibited in CA.
Mustard greens						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	4	6.0 lb/A	14	Aerial application prohibited. Minimum 7-day retreatment interval. Use restricted to applications only within 30 days of crop emergence/transplanting
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	4	6.1 lb/A for the 2 and 4 lb/gal FIC (EPA Reg. Nos. 264-334 and 264-335)	14	Minimum 7-day retreatment interval. Use restricted to applications only within 30 days of crop emergence/transplanting
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	Minimum 7-day retreatment interval.
Nectarine (see apricot)						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Olive						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	7.5 lb/A	2	15.0 lb/A	14	Aerial application prohibited. Minimum 14-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	7.5 lb/A	2	15.0 lb/A	14	Minimum 14-day retreatment interval.
Parsley (see lettuce)						
Parsnip (see beet, garden)						
Pastures						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	14	Aerial applications prohibited. Minimum 14-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	3.0 lb/A	14	Minimum 14-day retreatment interval.
Cereal grain bait application Ground or aerial	4 lb/gal FIC [264-333]	0.5 lb/A	1	NS	0	
Peach (see apricot)						
Peanut						
Broadcast foliar, banded Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	1.0 lb/A 2.0 lb/A	5 5	8.0 lb/A 8.0 lb/A	14 14	Aerial applications prohibited. Minimum 7-day retreatment interval. Aerial applications prohibited. Minimum 7-day retreatment interval.
Broadcast foliar, banded Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	8.0 lb/A	14	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	Use prohibited in CA. Minimum 7- day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Pea (see bean)						
Pea, fresh and dried (<i>Pisum</i> species) and Southern pea (see bean)						
Pecan (see almond)						
Pepper (see tomato)						
Pistachio						
Dormant/delayed dormant and foliar Ground only	50% WP 80% WP 85% WP	5.0 lb/A	4	15.0 lb/A	14	Aerial applications prohibited. Minimum 7-day retreatment interval. Dormant/delayed dormant applications may be made in combination with dormant oil.
Dormant/delayed dormant and foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	5.0 lb/A	4	15.0 lb/A	14	Minimum 7-day retreatment interval. Dormant/delayed dormant applications may be made in combination with dormant oil.
Foliar application Aerial	80% WP [CA810059]	6.0 lb/A	1	NS	14	Use limited to CA. Application may be made in a minimum of 20 gal/A.
Plum/Prune (see apricot)						
Pome fruits (including apples, pears, loquats, crabapples, oriental pears, and quince)						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	3.0 lb/A	8	15.0 lb/A	3	Minimum 14-day retreatment interval. Application of the 80% WP (EPA Reg. Nos. 264-316 and 264-526) and 4 lb/gal FIC (EPA Reg. Nos. 264-333, 264-335, and 264-349) formulations to quince are prohibited.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	3.0 lb/A	8	15.0 lb/A	3	Minimum 14-day retreatment interval. Application of the 80% WP (EPA Reg. Nos. 264-316 and 264-526) and 4 lb/gal FIC (EPA Reg. Nos. 264-333, 264-335, and 264-349) formulations to quince are prohibited.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Pome fruits (including apples, pears, loquats, crabapples, oriental pears, and quince)(continued)						
Postbloom (for fruit thinning) Ground only	50% WP 80% WP 85% WP	3.0 lb/A	8	15.0 lb/A	3	Aerial applications prohibited. Use limited to apples. Minimum 14-day retreatment interval.
Postbloom (for fruit thinning) Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	3.0 lb/A	8	15.0 lb/A	3	Use limited to apples. Minimum 14-day retreatment interval.
Postbloom (for fruit thinning) Ground	4 lb/gal FIC [NC960003] [OH960003] [OR950006] [PA960002] [VA950001] [WA940021]	3.0 lb/A	NS	6.0 lb/A for NC960003	NS	Use limited to NC, OH, OR, PA, VA, and WA. Applications may be made after 80 to 100% petal fall and 9 mm fruit size.
Postbloom (for fruit thinning) Ground	50% WP [NC820007]	1.0 lb/100 gal (dilute) [250-600 gal finished spray/A]	NS	NS	NS	Tank mix use with plant regulator ethephon limited to NC.
Pome fruits (including apples, pears, loquats, crabapples, oriental pears, and quince)(continued)						
Foliar application Ground	50% WP [CA83007] 80% WP [CA83007]	1.0 lb/100 gal	5 (for loquats)	NS	1 (for apples and pears) 5 (for loquats)	Use limited to CA. Applications may be made at 7-day retreatment intervals or as needed.
Potato						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	6	6.0 lb/A	7	Aerial applications prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	6	6.0 lb/A	7	Minimum 7-day retreatment interval.

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Potato (continued)						
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Pumpkin (see cucumber)						
Radish (see beet, garden)						
Rangeland						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	0.5 lb/A	1	1.0 lb/A	0	Aerial application is only allowed for liquid formulations, except for aerial applications through the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program. Note that Forestry uses are addressed in Appendix A-2.
Broadcast foliar Ground or aerial	4 lb/gal FIC 3.2 lb/gal RTU 4 lb/gal RTU	0.5 lb/A	1	1.0 lb/A	0	
Cereal grain bait application Ground or aerial	4 lb/gal FIC [264-333] 4 lb/gal RTU	0.06 lb/A	1	NS	0	
Rhubarb						
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	14	See "Celery."

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Rice						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	2	4.0 lb/A	14 (grain and straw)	Aerial applications prohibited. Minimum 7-day retreatment interval. CA only: for control of tadpole shrimp; max number applications and RTI not specified.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	4.0 lb/A	14 (grain and straw)	Minimum 7-day retreatment interval. CA only: for control of tadpole shrimp; max number applications and RTI not specified.
Rutabaga (see beet, garden)						
Salsify (see beet, garden)						
Sorghum, grain						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	4	6.0 lb/A	21 (grain and fodder) 14 (forage and silage)	A maximum of four applications may be made with a minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC	2.0 lb/A	4	6.0 lb/A	21 (grain and fodder) 14 (forage and silage)	A maximum of four applications may be made with a minimum 7-day retreatment interval.
Soybean (see bean)						
Spinach (see lettuce)						
Squash (see cucumber)						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Strawberry						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	5	10.0 lb/A	7	Aerial applications prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	5	10.0 lb/A	7	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Sunflower						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	2	3.0 lb/A	30 (forage) 60 (seed)	Use in CA is prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	2	3.0 lb/A	30 (forage) 60 (seed)	Use in CA is prohibited. Minimum 7-day retreatment interval.
Sweet potato						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	2.0 lb/A	8	8.0 lb/A	7	Aerial applications prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	8	8.0 lb/A	7	Minimum 7-day retreatment interval.
Sweet potato (continued)						
Soil broadcast Before, during, or after the growing season Ground	7% G	2.3 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Swiss chard (see lettuce)						
Tobacco						

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Broadcast foliar (plant bed and field) Ground only	50% WP 80% WP 85% WP	2.0 lb/A	4	8.0 lb/A	0	Aerial applications prohibited. Water soluble packaging required. Minimum 7-day retreatment interval. Applications may be made in a minimum of 10 gal of finished spray/A.
Broadcast foliar (plant bed and field) Ground or aerial	4 lb/gal FIC	2.0 lb/A	4	8.0 lb/A	0	Minimum 7-day retreatment interval. Applications may be made in a minimum of 10 gal of finished spray/A.
Tomato, pepper, eggplant						
Broadcast foliar Ground only	5% P/T 10.04% P/T 50% WP 80% WP 85% WP	2.0 lb/A	7	8.0 lb/A	3	Aerial applications prohibited. Minimum 7-day retreatment interval.
Broadcast foliar Ground or aerial	2 lb/gal FIC 4 lb/gal FIC	2.0 lb/A	7	8.0 lb/A	3	Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	3	Use prohibited in CA. A maximum of 4 applications may be made per year with a minimum 7-day RTI.
Trefoil, birdsfoot						
Broadcast foliar Ground only	50% WP 80% WP 85% WP	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	Aerial applications prohibited.
Broadcast foliar Ground or aerial	4 lb/gal FIC	1.5 lb/A	1 per cutting	1.5 lb/A per cutting	7	

Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations
Turnip, roots						
Broadcast foliar Ground only	5% P/T 10.04% P/T	2.0 lb/A	6	6.0 lb/A	7	Aerial application prohibited. Minimum 7-day retreatment interval.
Soil broadcast Before, during, or after the growing season Ground	7% G	2.2 lb/A	4	NS	7	Use prohibited in CA. Minimum 7- day retreatment interval.
Turnip, tops						
Broadcast foliar Ground only	5% P/T 10.04% P/T	2.0 lb/A	5	6.0 lb/A	14	Aerial application prohibited. Minimum 7-day retreatment interval. Table beets and turnips when harvested for greens: use is restricted for applications only within 30 days of crop emergence/transplanting
Walnut (see almond)						
Fish and Shellfish Uses						
Oyster beds						
Application to dewatered oyster beds Ground only	80% WP [WA900013]	10.0 lb/A	NS	NS	365	Aerial application prohibited. Application is for control of ghost shrimp and mud shrimp. Application must be made and completed within 30 minutes after low tide to prevent direct contamination of water. Use is limited to areas greater than 200 feet from channels and sloughs. For aerial application, a 200-foot buffer zone is required between the treatment area and the nearest shellfish to be harvested. A 50-foot buffer zone is required if treatment is by hand spray. Treatment is allowed only on ground with no oysters within one year of harvest are present.

Formulations and Example Registrations:

5% P/T [264-320]

7% G [264-429] [264-430]

10.04% P/T [264-312]

50% WP [264-314] [CA830007] [NC820007]

80% WP [264-316] [264-526][WA900013][FL890036][CA810059][CA83007]

85% WP [264-315]

2 lb/gal FIC [264-334]

3.2 lb/gal RTU [264-427] ³

4 lb/gal FI/C [264-321] [264-333] [264-335] [264-349]

[FL890037]

[NC960003]

[OH960003]

[OR950006]

[PA960002]

[VA950001]

[WA940021]

4 lb/gal RTU [264-422]

Appendix A-2. Maximum Carbaryl Use Rates for Non-Food / Non-Feed Uses
 (Generalized Screening Level Portrayal Of Current Label Uses)

Form	Use Site	Max. Rate per App	Max. Rate Unit/Area	Max.# Apps / cc & yr.	Max. App Rate/ cc & yr	Min. App Interval (days)	Comments, Application Equipment //Type
Pet Collar	Pets (Dogs, Cats)	1	collar	NA	NA	NA	All other pet uses (e.g., dusts and shampoos) are cancelled.
Dusts (D)	Residential ornamental and/or shade trees and the following ornamentals: herbaceous plants, nonflowering plants, woody shrubs and vines	0.05	lb ai/ container	NS	NS	7AN	RTU Shaker can
	household/domestic dwellings outdoor premises	0.05	lb ai / container	NS	NS	10	RTU Shaker can //Perimeter treatment
Emulsifiable Concentrate (EC)	agricultural fallow/idleland	1	lb ai/A	1/cc	1 lb/yr	NS	Aircraft/ Center pivot irrigation/ Ground //Chemigation/ Spray
	drainage systems	1	lb ai/A	1/cc	1 lb/yr	NS	Aircraft/ Center pivot irrigation/ Ground //Chemigation/ Spray
	nonagricultural rights-of-way/fencerows/hedgerows	1.5	lb ai/A	2/cc	3 lb/yr	14	Aircraft/ Ground //Spray
	nonagricultural uncultivated areas/soils	1.5	lb ai/A	2/cc	3 lb/yr	14	Aircraft/ Ground //Spray
	ornamental lawns and turf , including sod farms	8	lb ai/A	2/cc	NS	7	For Sod Farms: center pivot irrigation, chemigation. For residential: RTU hose-end ground spray only.
	recreational areas	8	lb ai/A	2/cc	NS	7	Ground //Spray
Granular (G) (Mound Treatments)	residential lawns	.0131	lb mound	NS	NS	NS	Spreader //Mound treatment
	household/domestic dwellings outdoor premises	.0131	lb mound	4/cc	NS	7	[AMEND LABEL TO SPECIFY] No hand, spoon or belly grinder applications forMound treatment
	agricultural uncultivated areas	""	""	""	""	""	""

Form	Use Site	Max. Rate per App	Max. Rate Unit/Area	Max.# Apps / cc & yr.	Max. App Rate/ cc & yr	Min. App Interval (days)	Comments, Application Equipment //Type
	ornamental woody shrubs and vines	""	""	""	""	""	""
	ornamental and/or shade trees	""	""	""	""	""	""
	recreation area lawns	""	""	""	""	""	""
	ornamental herbaceous plants	""	""	""	""	""	""
Granular (G) (other)	household/domestic dwellings outdoor premises	.2100	lb 1K sq.ft	4/cc	NS	7	[AMEND LABEL TO SPECIFY] No hand, spoon or belly grinder applications for Broadcast/ Perimeter treatment Push spreader acceptable.
	ornamentals: nonflowering plants, herbaceous plants, woody shrubs and vines	.2100	lb 1K sq.ft	4/cc	NS	7	""
	recreation area lawns	.2100	lb 1K sq.ft	4/cc	NS	7	""
	ornamental nonflowering plants	.2100	lb 1K sq.ft	NS	NS	7	""
	household/domestic dwellings outdoor premises	.2100	lb 1K sq.ft	NS	NS	7	Spreader //Band treatment/ Broadcast
	ornamental and/or shade trees	.2100	lb 1K sq.ft	NS	NS	7	""
	ornamental woody shrubs and vines	.2100	lb 1K sq.ft	NS	NS	7	""
	residential lawns	.2100	lb 1K sq.ft	4/cc	NS	7	""
	Ornamentals: nonflowering plants, herbaceous plants, woody shrubs and vines	.1000	lb 1K sq.ft	3/cc	NS	7	""
Ready to Use Sprayer (RTU)	agricultural/farm structures/buildings and equipment	See Note	See Note	NS	NS	7	Follow maximum acceptable application scenarios for Ready to Use hose-end

Form	Use Site	Max. Rate per App	Max. Rate Unit/Area	Max.# Apps / cc & yr.	Max. App Rate/ cc & yr	Min. App Interval (days)	Comments, Application Equipment //Type
							sprayers as specified in the carbaryl IRED for residential and commercial use on equivalent area as perimeter/spot treatments.
	christmas tree plantations	""	""	""	""	""	""
	commercial/institutional/industrial premises/equipment (outdoor)	""	""	""	""	""	""
	household/domestic dwellings outdoor premises	""	""	""	""	""	""
	ornamental and/or shade trees; ornamentals: nonflowering plants, herbaceous plants, woody shrubs and vines	""	""	""	""	""	""
	shelterbelt plantings	""	""	""	""	""	""
	urban areas	""	""	""	""	""	""
Wettable Powder (WP)	ornamental and/or shade trees; ornamentals: nonflowering plants, herbaceous plants, woody shrubs and vines	1	lb ai/A	6/cc	NS	7	All wettable powders must be packaged in water soluble packaging. Ground spray of tank mixture acceptable. Water soluble packaging is generally not compatible with the dry-disconnect, closed system engineering controls required for wettable powders. Thus aerial and chemigation methods are prohibited. Ground spray application of tank solution is acceptable.
	ornamental woody shrubs and vines	1	lb/100 gal	5/cc	NS	AN	""
	forest trees (all or unspecified)	1	lb/100 gal	5/cc	NS	AN	""
	nonagricultural uncultivated areas/soils	1	lb mound	NS	NS	7	""
	ornamental and/or	1	lb/100	5/cc	NS	AN	""

Form	Use Site	Max. Rate per App	Max. Rate Unit/Area	Max.# Apps / cc & yr.	Max. App Rate/cc & yr	Min. App Interval (days)	Comments, Application Equipment //Type
	shade trees		gal				
	nonagricultural rights-of-way/fencerows/hedgerows	2	lb ai/A	NS	NS	AN	""
	residential lawns	8	lb ai/A	4/cc	NS	7	""
	golf course turf	8	lb ai/A	4/cc	NS	7	""
	commercial/industrial lawns	8	lb ai/A	4/cc	NS	7	""
	recreation area lawns	8	lb ai/A	4/cc	NS	7	""
	recreational areas	8	lb ai/A	4/cc	NS	7	""
	ornamental sod farm (turf)	8	gal A	4/cc	NS	7	""

LEGEND

HEADER ABBREVIATIONS

Use Site: The use site refers to the entity (crop, building, surface or article) where a pesticide is applied and/or which is being protected.

Max. Rate per App: Maximum dose for a single application to a single site. System calculated. Max. Rate Unit/Area: Units and Area associated with the maximum dose.

Form: The physical form of the end use product found in the container. Max. # Apps cc & yr : The maximum number of applications.

Max. App Rate/cc & yr: The maximum amount of pesticide product that can be applied to a site in one growing season (/cc) or during the span of one year (/yr).

Min. App Interval (days): The minimum retreatment interval between applications in days (aggregated). Application Equipment : The equipment used to apply pesticide (aggregated).

Application Type: The type of pesticide application (aggregated).

ABBREVIATIONS AN - As Needed. NA - Not Applicable. NS - Not Specified (on label).

Appendix B. Data Supporting Guideline Requirements for Reregistration of Carbaryl

REQUIREMENT		CITATION(S) - MRID number	
PRODUCT CHEMISTRY			
New Guideline Number	Old Guideline Number		
830.1550	61-1	Product Identity and Composition	00151776, 42583901
830.1600	61-2A	Start. Mat. & Mnfg. Process	00151776, 42583901
830.1620		Description of Production	00151776, 42583901
830.1670	61-2B	Formation of Impurities	00151776, 42583901
830.1700	62-1	Preliminary Analysis	00151776, 42318501, 42583902
830.1750	62-2	Certification of limits	00151776, 42583901
830.1800	62-3	Analytical Method	00151776, 43075801
830.6302	63-2	Color	00151776
830.6303	63-3	Physical State	00151776
830.6304	63-4	Odor	00151776
830.7050	None	UV/Visible Absorption	
830.7200	63-5	Melting Point	00151776
830.7220	63-6	Boiling Point	
830.7300	63-7	Density	00151776
830.7840 830.7860	63-8	Solubility	00151776
830.7950	63-9	Vapor Pressure	00151776, 41982601
830.7370	63-10	Dissociation Constant	42832401
830.7550	63-11	Octanol/Water Partition Coefficient	00151776
830.7000	63-12	pH	42832401
830.6313	63-13	Stability	00151776, 42318501
830.6314	63-14	Oxidizing/Reducing Action	00151776
830.6315	63-15	Flammability	
830.6316	63-16	Explodability	00151776
830.6317	63-17	Storage Stability	00151776
830.7100	63-18	Viscosity	
830.6319	63-19	Miscibility	00151776
830.6320	63-20	Corrosion characteristics	

REQUIREMENT			CITATION(S) - MRID number
<u>ECOLOGICAL EFFECTS</u>			
850.2100	71-1	Avian Acute Oral Toxicity	42820601, 00160000, 45820601
850.2200	71-2A	Avian Dietary Toxicity - Quail	00022923, 00028757
850.2200	71-2B	Avian Dietary Toxicity - Duck	00022923, 00028757
850.2400	71-3	Wild Mammal Toxicity	00148500, 44732901
850.2300	71-4A	Avian Reproduction - Quail	00160044
850.2300	71-4B	Avian Reproduction - Duck	ACC263701
850.1075	72-1A	Fish Toxicity Bluegill	00043115
850.1075	72-1B	Fish Acute toxicity test-Bluegill Sunfish	00059202, 00042381, 00151519, 00124391
850.1075	72-1C	Fish Toxicity Rainbow Trout	40098001
850.1075	72-1D	Fish Acute toxicity test-Rainbow Trout	00151417, 42397901, 00124383
850.1010	72-2A	Invertebrate Toxicity	45820602, 00150901, 42397903, 42397902, 40098001
850.1010	72-2B	Invertebrate Toxicity - TEP	00150538, 00150540, 42432401, 42397902, 42397903
None	72-3A	Estuarine/Marine Toxicity - Fish	00150539, 40098001, 42372801
None	72-3B	Estuarine/Marine Toxicity - Mollusk	00148221
None	72-3C	Estuarine/Marine Toxicity - Shrimp	42343401
	72-3E	Estuarine/Marine Acute Toxicity- Shrimp	42397904, 42565601, 42343402
	72-3F	Estuarine/Marine Acute Toxicity- Mollusk	42597301
None	72-4A	Fish- Early Life Stage	45784804
None	72-4B	Estuarine/Marine Invertebrate Life Cycle	TOUCAROS, 00150901, 45784802
850.1500	72-5	Life Cycle Fish	
	122-2	Aquatic Plant Growth	
	123-1	Non-target Terrestrial Plant Phytotoxicity	
850.4400	123-2	Aquatic Plant Growth	
	141-1	Honey Bee Acute Contact	05004151, 05001991, 00036935, 45785403, 45785406, 45785407
<u>TOXICOLOGY</u>			
870.1100	81-1	Acute Oral Toxicity-Rat	00148500
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	00148501
870.1300	81-3	Acute Inhalation Toxicity-Rat	00148502
870.1500		Bacterial Reverse Mutation Test	41370303

REQUIREMENT			CITATION(S) - MRID number
870.2400	81-4	Primary Eye Irritation-Rabbit	00148503
870.2500	81-5	Primary Skin Irritation	00148504
870.2600	81-6	Dermal Sensitization	00148505
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	
870.6200	81-8A	Acute Neurotoxicity Screening Battery-Rat	43845201, 43845202, 43845203, 43845204
870.6200	81-8B	Subchronic Neurotoxicity Screening Battery-Rat	44122601
870.6300		Developmental Neurotoxicity-Rat	44393701
870.7600		Dermal Penetration-Rat	43339701, 43552901
870.3100	82-1A	90-Day Feeding - Rodent	
870.3150	82-1B	90-Day Feeding - Non-rodent	
870.3200	82-2	21-Day Dermal - Rabbit/Rat	45630601, 45630602, 45630603
870.3465	82-4	90-Day Inhalation-Rat	
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	40166701, 42022801
870.4200	83-2A	Oncogenicity - Rat	42786901
870.4200	83-2B	Oncogenicity - Mouse	44732901
870.3700	83-3A	Developmental Toxicity - Rat	44904202
870.3700	83-3B	Developmental Toxicity - Rabbit	45448101
870.3800	83-4	2-Generation Reproduction - Rat	42918801
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	
870.5140	84-2A	Gene Mutation (Ames Test)	
870.5375	84-2B	Structural Chromosomal Aberration	
870.5385		In-Vitro Mammalian Chromosome Aberration test (Chinese Hamster)	41370304, 41370302, 41420201
870.5395		Mammalian erythrocyte Micronucleus test	44069301
870.5550		Unscheduled DNA Synthesis	41370301, 41810601
None	84-4	Other Genotoxic Effects	
870.7485	85-1	General Metabolism	43332101, 44402501
	Special Studies-Mice		43282201, 43832601, 45281801, 45236603

REQUIREMENT		CITATION(S) - MRID number	
<u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u>			
875.2100	132-1A	Foliar Residue Dissipation	
875.2200	132-1B	Soil Residue Dissipation	
875.2400	133-3	Dermal Passive Dosimetry Exposure	
875.2500	133-4	Inhalation Passive Dosimetry Exposure	
None	231	Estimation of Dermal Exposure at Outdoor Sites	
None	232	Estimation of Inhalation Exposure at Outdoor Sites	

ENVIRONMENTAL FATE

None	160-5	Chemical Identity	
835.2120	161-1	Hydrolysis	00163847, 44759301
835.2240	161-2	Photodegradation - Water	41982603
835.2410	161-3	Photodegradation - Soil	
835.2370	161-4	Photodegradation - Air	
835.4100	162-1	Aerobic Soil Metabolism	42785101
835.4200	162-2	Anaerobic Soil Metabolism	
835.4400	162-3	Anaerobic Aquatic Metabolism	42785102
835.4300	162-4	Aerobic Aquatic Metabolism	43143401
835.1240	163-1	Leaching/Adsorption/Desorption	43259301, 43320701
835.1410	163-2	Laboratory Volatilization	
835.6100	164-1	Terrestrial Field Dissipation	41982605, 43439801
	164-2	Aquatic Sediment Dissipation	43263001
None	165-4	Bioaccumulation in Fish	
		Field Bird Studies	
		Field Mesocosm Special Studies	
		Special Studies	

RESIDUE CHEMISTRY

None	171-2	Chemical Identity	
860.1300	171-4A	Nature of Residue - Plants	00049135, 00053897, 00116083, 00118342, 00124353, 00124968, 00125170, 43249101, 43249102, 43249103

REQUIREMENT			CITATION(S) - MRID number
860.1300	171-4B	Nature of Residue - Livestock	00015669, 00053897, 00080417, 00080679, 00080680, 00080681, 00080689, 00080690, 00091952, 00095927, 00118346, 00118347, 00118365, 00118368, 00118371, 00118375, 00118376, 0018377, 00139664, 43324601
860.1340	171-4C	Residue Analytical Method - Plants	00080417, 00080680, 00098504, 00107017, 001183421, 00118346, 00118366, 00118367, 00118368, 00118370, 00118372, 0018373, 00118377, 00124334, 00124361, 00145884, 00147760, 00154626, 00156736, 00159326, 05001852, 05004154, 05004934, 05008728, 05010424, 05014156, 05014889, 05016141, 0501884, 05019959, 40255702, 40408601, 43672701, 43672702, 43786805, 44155401
860.1340	171-4D	Residue Analytical Method - Animals	00061103, 00080417, 00080680, 00118346, 00118366, 00118367, 00118368, 00118370, 00118372, 00118373, 00118375, 00118376, 05001852, 05004154, 05008728, 05010424, 05014156, 05014889, 05016141, 05018884, 05019959, 44286901, 44286902, 44286903
860.1380	171-4E	Storage Stability	
860.1380		Storage Stability-Plant Commodities	00163007, 00163009, 00163014, 40408601, 43850902, 44068401, 44123101, 44250301, 44412501
860.1380		Storage Stability- Livestock Commodities	44250901, 44381901
860.1400		Water, Fish and Irrigated crops (oysters)	PP#1E2554
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg	00015669, 00061106, 00080417, 00080419, 00080420, 00089380, 00089836, 00089837, 00118342, 0018346, 00118367, 00118368, 00118370, 00118372, 00118373, 00118374, 00118378, 40881302, 40881312, 40881313, 40881314, 44250901, 44381901
860.1480		Magnitude of Residues- Fat, Meat, Byproducts o of Poultry	00061103, 00080420, 00080680, 00118375, 00118376, 00124367, 00125571, 00135678, 00135680, 40881308, 40881309
860.1500	171-4K	Crop Field Trials (Beet, garden, roots)	00089868, 43813601

REQUIREMENT			CITATION(S) - MRID number
860.1500	171-4K	Crop Field Trials (Beet, sugar, roots)	0089868, 00163007, 40376001, 40376002
860.1500	171-4K	Crop Field Trials (Carrot)	00090325, 43813601
860.1500	171-4K	Crop Field Trials (Horseradish)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Parsnips)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Potato)	00107017, 00134421, 40512501
860.1500	171-4K	Crop Field Trials (Radishes)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Salsify, root)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Turnip, root)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Sweet potato)	00107017, 43702002
860.1500	171-4K	Crop Field Trials (Beet, garden, tops)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Beet, sugar, tops)	00089868
860.1500	171-4K	Crop Field Trials (Salsify, tops)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Turnip, tops)	00089868, 43813601
860.1500	171-4K	Crop Field Trials (Celery)	00124337, 43677401
860.1500	171-4K	Crop Field Trials (Dandelions)	00089868, 43677401
860.1500	171-4K	Crop Field Trials (Endive)	00089868, 43677401
860.1500	171-4K	Crop Field Trials (Lettuce)	00089868, 00090162, 43677401
860.1500	171-4K	Crop Field Trials (Parsley)	00089868, 43677401
860.1500	171-4K	Crop Field Trials (Spinach)	00089868, 43677401
860.1500	171-4K	Crop Field Trials (Swiss chard)	00089868, 43677401
860.1500	171-4K	Crop Field Trials (Broccoli)	00090325, 43721001, 44019701
860.1500	171-4K	Crop Field Trials (Brussels sprouts)	00090325, 43721001
860.1500	171-4K	Crop Field Trials (Cabbage)	00090325, 43786806)
860.1500	171-4K	Crop Field Trials (Cauliflower)	00090325, 43721001
860.1500	171-4K	Crop Field Trials (Chinese cabbage)	00089868, 43794903
860.1500	171-4K	Crop Field Trials (Collards)	00089868, 43794903
860.1500	171-4K	Crop Field Trials (Kale)	00089868, 43794903
860.1500	171-4K	Crop Field Trials (Kohlrabi)	00090325, 43721001
860.1500	171-4K	Crop Field Trials (Mustard greens)	00089868, 43794903
860.1500	171-4K	Crop Field Trials (Beans, fresh, and dried)	00089679, 00089680, 00089681, 00082424, 00089837, 00090113, 00163014, 000124334, 43786804, 43984701
860.1500	171-4K	Crop Field Trials (cowpeas)	00089837, 43694103
860.1500	171-4K	Crop Field Trials (Lentils)	00089837, 00124334, 43694103

REQUIREMENT			CITATION(S) - MRID number
860.1500	171-4K	Crop Field Trials (Peas(with pods)	00090113, 00124334, 43703102
860.1500	171-4k	Crop Field Trials (Soybeans)	00089837, 43694102
860.1500	171-4K	Crop Field Trials (Bean, forage, hay)	00082424, 00089679, 00089680, 00089681, 00089837, 00125090
860.1500	171-4K	Crop Field Trials (Cowpea, forage and hay)	00089837, 43786804
860.1500	171-4K	Crop Field Trials (Pea, vines)	00089837, 00124334, 43786804
860.1500	171-4K	Crop Field Trials (Soybean, forage, and hay)	00089837, 43694102
860.1500	171-4K	Crop Field Trials (Eggplant)	00089600, 43686701, 43996101
860.1500	171-4K	Crop Field Trials (Pepper)	00089600, 43686701
860.1500	171-4K	Crop Field Trials (Tomato)	00089600, 00159326, 43996101
860.1500	171-4K	Crop Field Trials (Cucumber)	00089376, 43786802
860.1500	171-4K	Crop Field Trials (Melon)	00090325, 43786802
860.1500	171-4K	Crop Field Trials (Pumpkin)	00090325, 43786802
860.1500	171-4K	Crop Field Trials (Squash, summer)	00089376, 43786802
860.1500	171-4K	Crop Field Trials (Squash, winter)	00090325, 43786802
860.1500	171-4K	Crop Field Trials (Citrus)	00090204, 00090320, 00163008, 43802101, 44211801
860.1500	171-4K	Crop Field Trials (Pome Fruits)	00080419, 00082420, 00082423, 00083311, 00083312, 00089455, 00089679, 00089680, 00159327, 44072901
860.1500	171-4K	Crop Field Trials (Apricot)	00090160, 43793202, 44284701
860.1500	171-4K	Crop Field Trials (Cherry)	00089348, 00124345, 43793202, 44284701
860.1500	171-4K	Crop Field Trials (Nectarine)	00090160, 43793202, 44284701
860.1500	171-4K	Crop Field Trials (Peach)	00082422, 43793202, 44284701
860.1500	171-4K	Crop Field Trials (Plum fresh prune)	00089348, 00124345, 43793202, 44284701
860.1500	171-4K	Crop Field Trials (Blackberry)	00089868
860.1500	171-4K	Crop Field Trials (Blueberry)	00090161, 43694101
860.1500	171-4K	Crop Field Trials (Boysenberry)	00089868, 43698201
860.1500	171-4K	Crop Field Trials (Dewberry)	00089868, 43698201
860.1500	171-4K	Crop Field Trials (Loganberry)	00089868, 43698201
860.1500	171-4K	Crop Field Trials (Raspberry)	00089868, 43698201
860.1500	171-4K	Crop Field Trials (Almond)	00108985, 00140447, 43786801
860.1500	171-4K	Crop Field Trials (Chestnut)	43786801, 43802102

REQUIREMENT			CITATION(S) - MRID number
860.1500	171-4K	Crop Field Trials (Filbert)	00090156, 43786801, 43802102
860.1500	171-4K	Crop Field Trials (Pecan)	00123219, 43802102
860.1500	171-4K	Crop Field Trials (Walnut)	00108985, 00140447, 43818901
860.1500	171-4K	Crop Field Trials (Barley, grain)	
860.1500	171-4K	Crop Field Trials (Corn, filed, pop)	00089420, 00125090, 00125107, 00163009, 44058001
860.1500	171-4K	Crop Field Trials (Corn, sweet)	00089378, 00089420, 00125090, 00125107, 44058101
860.1500	171-4K	Crop Field Trials (Millet, proso, grain)	00074368, 43975601
860.1500	171-4K	Crop Field Trials (Oats, grain)	
860.1500	171-4K	Crop Field Trials (Rice, grain)	00089837, 00125138, 43802103
860.1500	171-4K	Crop Field Trials (Rye, grain)	
860.1500	171-4K	Crop Field Trials (Sorghum, grain)	43794901
860.1500	171-4K	Crop Field Trials (Wheat, grain)	00015669, 00115284, 00136415, 41594301, 43975601
860.1500	171-4K	Crop Field Trials (Barley, forge, and straw)	
860.1500	171-4K	Crop Field Trials (Corn, fodder, and forge)	00089378, 00089420, 00125090, 00125107, 44058001, 44058101
860.1500	171-4K	Crop Field Trials (Millet, proso, straw)	00074368, 43975601
860.1500	171-4K	Crop Field Trials (Oats, Forge and straw)	
860.1500	171-4K	Crop Field Trials (Rice, straw)	00089837, 00125138, 43802103
860.1500	171-4K	Crop Field Trials (Rye, forge)	
860.1500	171-4K	Crop Field Trials (Sorghum, forge)	00159329, 43794901
860.1500	171-4K	Crop Field Trials (Wheat, forge and straw)	00015669, 00115284, 00136415
860.1500	171-4K	Crop Field Trials (Pastures)	00089837, 00125121, 00125123, 00125555, 00163006, 43716601
860.1500	171-4K	Crop Field Trials (Rangeland)	00089837, 00125121, 00125123, 00125555, 00163006, 44065901
860.1500	171-4K	Crop Field Trials (Alfalfa, forge, and hay)	00089837, 00125121, 00125123, 00159325
860.1500	171-4K	Crop Field Trials (Birdfoot, trefoil, forge and hay)	00089837, 00125121, 00125123, 00159325
860.1500	171-4K	Crop Field Trials (Clover, forage, hay)	00089837, 00125121, 00125123, 43694105
860.1500	171-4K	Crop Field Trials (Dill, fresh)	PP#7E3543
860.1500	171-4K	Crop Field Trials (Aspirated grain fractions)	43794902, 43813602

REQUIREMENT			CITATION(S) - MRID number
860.1500	171-4K	Crop Field Trials (Asparagus)	00083527, 00140449, 43654201
860.1500	171-4K	Crop Field Trials (Avocado)	
860.1500	171-4K	Crop Field Trials (Banana)	44798401
860.1500	171-4K	Crop Field Trials (Cranberry)	00090161, 43697604
860.1500	171-4K	Crop Field Trials (Cotton, seed and forage)	00089837, 00124343, 00125099, 40881307
860.1500	171-4K	Crop Field Trials (Flax, seed and straw)	00074366, 00074367, 43982801
860.1500	171-4K	Crop Field Trials (Grapes)	00089418, 00089458, 00125084, 43793201
860.1500	171-4K	Crop Field Trials (Maple sap)	
860.1500	171-4K	Crop Field Trials (Okra)	00090229, 44123101
860.1500	171-4K	Crop Field Trials (Olives)	00090281, 43702001, 44321301
860.1500	171-4K	Crop Field Trials (Peanuts, nut, and hay)	00089837, 43703101
860.1500	171-4K	Crop Field Trials (Pineapple)	PP#5F3208
860.1500	171-4K	Crop Field Trials (Pistachio nuts)	00124335, 43703103
860.1500	171-4K	Crop Field Trials (Prickly pear cactus)	00103288, 44145201
860.1500	171-4K	Crop Field Trials (Strawberry)	00089348, 43698202
860.1500	171-4K	Crop Field Trials (Sunflower)	00058927, 00058928, 43786803
860.1500	171-4K	Crop Field Trials (Tobacco)	44114301
860.1520	171-4L	Processed Food (Beet, sugar)	00163017
860.1520	171-4L	Processed Food (Citrus fruits)	43694104
860.1520	171-4L	Processed Food (Corn, field)	00163018, 43915201
860.1520	171-4L	Processed Food (Cottonseed)	43850901
860.1520	171-4L	Processed Food (Flaxseed)	00074366, 00074367
860.1500	171-4K	Crop Field Trials (Grapes)	00163010, 00163011, 43697601, 43697602
860.1520	171-4L	Processed Food (Olives)	43698203
860.1520	171-4L	Processed Food (Peanut)	00163012, 44046101
860.1520	171-4L	Processed Food (Pineapple)	PP#5F3208
860.1520	171-4L	Processed Food (Plum)	00159328
860.1520	171-4L	Processed Food (Pome fruits)	43702003
860.1520	171-4L	Processed Food (Potato)	00159324, 43697603
860.1520	171-4L	Processed Food (Rice)	00163013, 43813603
860.1520	171-4L	Processed Food (Sorghum)	00163015, 43813604
860.1520	171-4L	Processed Food (Soybean)	00163016, 43794902

REQUIREMENT			CITATION(S) - MRID number
860.1520	171-4L	Processed Food (Sunflower)	43845205
860.1520	171-4L	Processed Food (Tomato)	43686702
860.1520	171-4L	Processed Food (Wheat)	43813602

OTHER

830.7050	None	UV/Visible Absorption	
850.4400	122-2	Aquatic Plant Growth	
860.1360	171-4M	Multiresidue Method	
810.1000	90-1	Use/Usage Data	
850.3020	141-1	Honey Bee Acute Contact	
860.1850		Confined Rotational Crops	43651701

Appendix C. Technical Support Documents that Contributed to the IRED for Carbaryl

Documents in support of this IRED are maintained in the OPP docket, located in Room 119, Crystal Mall 2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 A.M. to 4:00 P.M.

Documents are also available in EPA's on-line docket, EDOCKET. There are three dockets for carbaryl, which correspond to the public comment phases in EPA's Public Participation Process for pesticide reregistration.

Docket OPP-2002-0138, which closed for public comment on October 28, 2002, contains preliminary (Phase 3) carbaryl risk assessments. Docket OPP-2003-0101, which closed for public comment on June 2, 2003, contains the carbaryl revised (Phase 5) risk assessments. The current docket, OPP-2003-0376, contains documents generated since the closing of the last docket on June 2, 2003. It includes EPA's response to comments submitted on the revised risk assessments for carbaryl, and the full IRED document (Phase 6). The current docket will be open for at least 60 days after the document is posted in the EDOCKET system. You can access EDOCKET at <http://www.epa.gov/edockets>.

The documents below are organized beginning with the latest docket, then by the division that produced the documents, and finally by the date of the document.

PHASE 6 - Docket OPP-2003-0376

(Open for comment at time of writing)

Health Effects Division

1. HED: Carbaryl: Risk Mitigation Addendum for Phase 5 Risk Assessment. (Jeffrey Dawson, June 23, 2003)
2. HED: Carbaryl Acute Dietary Assessment Including Drinking Water. (Felicia Fort, June 30, 2003)
3. HED: Carbaryl Acute Mammalian Toxicity Batching Appendix for Carbaryl RED Document. (Marianne Lewis, August 6, 2003)
4. HED: Carbaryl: Response to Phase 5 Comments. (Jeffrey Dawson, October 22, 2004)

Environmental Fate and Effects Division

1. EFED: Final Report of Carbaryl EECs for Drinking Water; Additional Simulations. (David R. Jones, June 30, 2003)
2. EFED: Review of Minnesota Department of Agriculture and Minnesota District Court Information Materials Related to bee Kill Incidents and Carbaryl Use on Hybrid Poplar

Plantations. (Thomas Steeger, July 1, 2003)

3. EFED: Response to Phase 5 Comments on the Interim Reregistration Eligibility Decision (IRED) Document for Carbaryl. (David R. Jones, July 14, 2003)

Biological and Economic Analysis Documents

1. Benefits Information for Carbaryl: Three Documents
 - Citrus (Nikhil Mallampalli, et al., June 24, 2003)
 - Grapes (TJ Wyatt, et al., June 19, 2003)
 - Selected Crops (Donald Atwood, May 23, 2003)

PHASE 5 - Docket OPP-2003-0101

(Public comment closed June 2, 2003)

Health Effects Division

1. Carbaryl: Chemical Number 56801; EPA Reg. No. 264-324; Refinement of Residential Exposure and Risk Assessment for the Reregistration of Carbaryl. (A) Measurement of Pesticide Exposure of Suburban Residents Associated with the Residential Use of Carbaryl. (B) Carbaryl Mammalian Metabolism and Pharmacokinetics.) (D. LaRochelle, F. Rice, J. Grant, J. Ross, and J. Driver, October 10, 2002)
2. Evaluation of Potential Aggregate Human Health Risks Associated with Agricultural and Consumer Uses of Carbaryl. (J. Driver, M. Pandian, J. Ross, and C. Lunchick, February 14, 2003)
3. HED Occupational and Residential Exposure Assessment for Carbaryl. (Jeff Dawon, February 20, 2003)
4. HED Response to Comments on Preliminary Risk Assessment for Carbaryl. (Jeff Dawson, Felicia Fort, and Kit Farwell, March 11, 2003)
5. HED Revised Risk Assessment for Carbaryl. (Jeff Dawson, March 14, 2003)
6. HED Dietary Exposure Assessment for Carbaryl. (Felicia Fort, March 20, 2003)

Environmental Fate and Effects Division

1. EFED Revised Ecological Fate and Effects Risk Assessment for Carbaryl. (Thomas Steeger, March 18, 2003)
2. EFED Response to Comments on Preliminary Risk Assessment for Carbaryl. (Thomas Steeger, David Jones, March 21, 2003)

Biological and Economic Analysis Documents

1. Revised Quantitative Usage Analysis. (Frank Hernandez, December 17, 2002)

PHASE 3 - OPP-2002-0138

(Public comment closed October 28, 2002)

Health Effects Division

1. Carbaryl - 5th Report of the Hazard Identification Assessment Review Committee. (Virginia Dobozy, March 5, 2002)
2. Carbaryl - 3rd Reassessment Report of the FQPA Safety Factor Committee. (Carol Christensen and Brenda Tarplee, April 3, 2002.)
3. Carbaryl - 6th Report of the Hazard Identification Assessment Review Committee. (Virginia Dobozy, April 9, 2002)
4. Carbaryl. Revised Dietary Exposure Analysis for the HED Revised Human Health Risk Assessment. (Felicia Fort, April 28, 2002)
5. Carbaryl: Updated Toxicology Chapter for RED PC Code 056801. (Virginia Dobozy, May 24, 2002)
6. Carbaryl: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document, PC Code 056801. (Jeff Dawson, May 29, 2002)
7. Carbaryl: Revised Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision. (Felicia Fort, May 30, 2002)
8. Registrant Letter to EPA dated July 18, 2002: Carbaryl; Error Correction of Carbaryl Risk Assessments [Review of Draft Human Health Risk Assessment] (July 18, 2002)
9. Carbaryl: Revised HED Risk Assessment - Public Comment Period, Error Correction Comments Incorporated PC Code 056801. (Jeff Dawson, July 30, 2002)
10. Carbaryl: Agency Response to Aventis Crop Science Error Correction Comments on Revised HED Risk Assessment and Supporting Documents. (Jeffrey Dawson, August 6, 2002)

Environmental Fate and Effects Division

1. EFED Review of Documents relative to Section 24c Special Local Needs Registration of Carbaryl for Use on Oyster Beds. (Thomas Steeger, April 8, 2002)
2. EFED Review of Relyea Paper Entitled "Predator-induced Stress makes the pesticide carbaryl more deadly to gray treefrog tadpoles (*Hyla versicolor*)" (Thomas Steeger, May

17, 2002)

3. Revised EFED Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision (RED). (Thomas Steeger, August 17, 2002)
4. Registrant Letter to EPA dated July 18, 2002: Carbaryl; Error Correction of Carbaryl Risk Assessments [Review of Draft Environmental Fate and Ecological Effects Assessment for the Reregistration of Carbaryl] (July 18, 2002)
5. EFED Response to Registrant's 30-day Error Correction Comments on the EFED Risk Assessment Chapter in Support of the Reregistration Eligibility Decision (RED) on Carbaryl (E. Laurence Libelo and Thomas Steeger, August 17, 2002)

Appendix D. Citations considered to be part of the data base supporting the interim reregistration decision (bibliography)

GUIDE TO APPENDIX D

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date

from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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- 44412501 Citation: Ely, C. (1997) Sevin XLR Plus: Magnitude of Carbaryl Residues in/on Wheat Grain: Amended Report: Lab Project Number: US95S10R: 45031: 95-0126. Unpublished study prepared by Colorado Analytical Research & Development Corp. and Agvise Labs. 359 p. {OPPTS 860.1500}
- 44732901 Citation: Repetto-Larsay, M. (1998) Carbaryl: Developmental Toxicology Study in the Rat by Gavage: Lab Project Number: 98070. Unpublished study prepared by Rhone-Poulenc Agro. 243 p.
- 44759301 Citation: Carpenter, M. (1990) Hydrolysis of (carbon 14)-Carbaryl in Aqueous Solutions Buffered at pH 5, 7, and 9: Carbaryl Insecticide: Lab Project Number: 38380. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 83 p.
- 44798401 Citation: Davis, C.; Myers, W.; Thornburg, W. (1985) Magnitude of Residue Data for Carbaryl on Pineapples: Lab Project Number: DAL CAR-2-99: 262-84. Unpublished study prepared by Union Carbide and Del Monte Research Center. 79 p. {OPPTS 860.1500}
- 44904202 Citation: Tyl, R.; Marr, M.; Myers, C. (1999) Developmental Toxicity Evaluation (with Cholinesterase Assessment) of Carbaryl Administered by Gavage to New Zealand White Rabbits: Final Report: Lab Project Number: 65C-7297-200/100: RTI-692. Unpublished study prepared by Research Triangle Institute. 244 p.
- 45236603 Citation: Dange, M. (1998) Carbaryl: Preliminary 28-day Toxicity Study in the Male TSG p53 Wild Type Mouse By Dietary Administration: Lab Project Number: SA 97499: SA97538. Unpublished study prepared by Rhone-Poulenc Agro. 200 p.
- 45281801 Citation: Chuzel, F. (1999) Carbaryl: 6-month Carcinogenicity Study in p53 Knockout Mice by Dietary Administration: Lab Project Number: 604134. Unpublished study prepared by Rhone-Poulenc Agro. 334 p.
- 45448101 Citation: Tyl, R.; Myers, C.; Marr, M. (2001) Two-Generation Reproductive Toxicity Evaluation of Carbaryl (RPA007744) Administered in the Feed to CD: Final Report: Lab Project Number: 65C-07407-400. Unpublished study prepared by Research Triangle Institute. 906 p.
- 45630601 Citation: Austin, E. (2002) 4 Week Repeated-Dose Dermal Toxicity Study with Carbaryl Technical in Rats: Final Report: Lab Project Number: COVANCE 6224-268. Unpublished study prepared by Covance Laboratories Inc. 161 p.
- 45630602 Citation: Austin, E. (2002) 4 Week Repeated-Dose Dermal Toxicity Study with

- Sevin XLR Plus in Rats: Final Report: Lab Project Number: COVANCE 6224-267. Unpublished study prepared by Covance Laboratories Inc. 155 p.
- 45630603 Citation: Austin, E. (2002) 4 Week Repeated-Dose Dermal Toxicity Study with Sevin 80S in Rats: Final Report: Lab Project Number: COVANCE 6224-266. Unpublished study prepared by Covance Laboratories Inc. 149 p.
- 45784802 Citation: Ebeling, M.; Radix, P. (2002) Chronic Toxicity to the Sediment Dwelling Chironomid Larvae: *Chironomus riparius*: Carbaryl; Substance, Technical: Lab Project Number: CE01/043: C017112. Unpublished study prepared by Aventis CropScience GmbH. 50 p.
- 45785403 Citation: Waltersdorfer, A. (2002) Oral Toxicity (LD50) to Honey Bees (*Apis mellifera* L.): Carbaryl Technical: Lab Project Number: CW01/033: C018470. Unpublished study prepared by Aventis CropScience GmbH. 19 p.
- 45785406 Citation: Waltersdorfer, A. (2002) Oral Toxicity (LD50) to Honey Bees (*Apis mellifera* L.) Carbaryl Water Miscible Suspension Concentrate 479 g/l: Lab Project Number: CW01/049: C018472. Unpublished study prepared by Aventis CropScience GmbH. 17 p.
- 45785407 Citation: Waltersdorfer, A. (2001) Contact Toxicity (LD50) to Honey Bees (*Apis mellifera* L.) Carbaryl Water Miscible Suspension Concentrate 479 g/l: Lab Project Number: CW01/036: C017199. Unpublished study prepared by Aventis CropScience GmbH. 17 p.
- 45820601 Citation: Ensenbach, U. (2001) Mallard Duck Acute Oral Toxicity Study: Carbaryl; Substance, Technical: Lab Project Number: C 016989: PT01-0171: NG 28551. Unpublished study prepared by Aventis Pharma Deutschland GmbH. 24 p.
- 45820602 Citation: Schafers, C. (2002) *Chloroperla grammatica*, Acute Toxicity Test, 96 h Exposure: Carbaryl; Substance, Technical: Lab Project Number: C018556: ACS-001/4-26/N. Unpublished study prepared by Fraunhofer-Institute for Molecular Biology and Applied Ecology. 31 p. {OPPTS 850.1020}
- 457848043 Citation: Sousa, J. (2002) 1-Naphthol--Early Life-Stage Toxicity Test to Fathead Minnow (*Pimephales promelas*) Under Dynamic Conditions: Lab Project Number: 13726.6164: 32953: B003688. Unpublished study prepared by Springborn Laboratories, Inc. 77 p. {OPPTS 850.1400}

Appendix E. Generic Data Call-in

See attached table for a list of generic data requirements complete DCI, with all pertinent instructions, will be sent to registrants under separate cover after the DCI is approved by the Office of Management and Budget. The generic data requirements are also listed in the body of the RED.

United States Environmental Protection Agency
 Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
 OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
 Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl Chemical # and Name 056801 Carbaryl	3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-056801-NNNNN
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4. EPA Product Registration NNNNNN-NNNNN	5. I wish to cancel this product registration voluntarily	6. Generic Data <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; vertical-align: top;"> 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below. </td> <td style="width:50%; vertical-align: top;"> 6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." </td> </tr> </table>		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7. Product Specific Data <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; vertical-align: top;"> 7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response." </td> <td style="width:50%; vertical-align: top;"> 7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response." </td> </tr> </table>		7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."								
7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."								
				N.A.	N.A.				

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8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative _____	9. Date
---	---------

10. Name of Company	11. Phone Number
---------------------	------------------

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl Chemical # and Name 056801 Carbaryl	3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-056801-NNNNN
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<u>Applicator Exposure Data Requirements (Conventional Chemical)</u>								
875.1100	Dermal exposure--outdoor	(25 ,26 ,27 ,28 ,29)				A, B, C, D, K, Q, U	TEP	0	
875.1300	Inhalation exposure--outdoor	(30 ,31 ,32 ,33 ,34)				A, B, C, D, K, Q, U	TEP	0	
	<u>Environmental Fate Data Requirements (Conventional Chemical)</u>								
835.4100	Aerobic soil metabolism	(2)				A, B, C, D, K, Q, U	TGAI or PAIRA	24	
835.4300	Aerobic aquatic metabolism					A, B, C, D, K, Q, U	TGAI or PAIRA	24	
	<u>Post-Application Exposure Data Requirements (Conventional Chemical)</u>								
875.2100	Foliar dislodgeable residue dissipation	(35 ,36 ,37 ,38 ,39 ,40)				A, B, C, D, K, Q, U	TEP		
875.2400	Dermal exposure	(41 ,42 ,43 ,44 ,45 ,46)				A, B, C, D, K, Q, U	TEP	24	
875.2500	Inhalation exposure	(47 ,48 ,49 ,50 ,51)				A, B, C, D, K, Q, U	TEP	24	
875.2600	Biological monitoring	(52 ,53 ,54 ,55)				A, B, C, D, K, Q, U	TEP		
	<u>Product Chemistry Data Requirements (Conventional Chemical)</u>								

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law Signature and Title of Company's Authorized Representative _____	11. Date <div style="border: 1px solid black; width: 100px; height: 30px; margin: 0 auto; text-align: center;">Page 248</div>
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12. Name of Company	13. Phone Number
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United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

<p>1. Company Name and Address</p> <p>SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000</p>	<p>2. Case # and Name</p> <p>0080 Carbaryl Chemical # and Name 056801 Carbaryl</p>	<p>3. Date and Type of DCI and Number</p> <p>DD-MMM-YYYY GENERIC ID # GDCI-056801-NNNNN</p>
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.1800	Enforcement analytical method (1)					A, B, C, D, K, Q, U	MP	8	
	<u>Residue Chemistry Data Requirements for Food Uses (Conventional Chemical)</u>								
860.1380	Storage stability data (3 ,4 ,5 ,6)					A, B, C, D, K, Q, U	TEP or res of concern	24	
860.1500	Crop field trials(MILLET, PROSO, HAY) (7 ,19 ,20 ,22)					A, B, C, D, K, Q, U	TEP	24	
860.1500	Crop field trials(PEA AND BEAN, SUCCULENT SHELLED, SUBGROUP 6B) (11 ,12 ,13 ,14)					A, B, C, D, K, Q, U	TEP	24	
860.1500	Crop field trials(PINEAPPLE) (9 ,10 ,15 ,16)					A, B, C, D, K, Q, U	TEP	24	
860.1500	Crop field trials(VEGETABLE, LEAFY, EXCEPT BRASSICA, GROUP 4) (8 ,17 ,18 ,21)					A, B, C, D, K, Q, U	TEP	24	
	<u>Toxicology Data Requirements (Conventional Chemical)</u>								
870.3465	90-day inhalation toxicity (23 ,24)					A, B, C, D, K, Q, U	TGAI	24	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: GDCI-056801-NNNNN

Key: MP = Manufacture
[TGAI]; TGAI or PAIRA = Technical Grade of the Active Ingredient or Active Ingredient, Radio-Labelled

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	U - Residential and public access pi
B - Terrestrial feed crop	K - Residential	
C - Terrestrial nonfood crop	Q - Residential outdoor use	

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 1 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)
- 2 Required for aquatic food and nonfood crop uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to cranberry bogs and rice paddies.
- 3 Data are required for an
- 4 A residue method, storage stability c
tobacco, additional data may be required on cured/dried tobacco and pyrolysis products (guideline 860.1000).
- 5 Required for residential outdoor use on food crops if home gardens:
- 6 Required if indoor use could result in pesticide residues in or on food or feed.
- 7 Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).
- 8 A residue method, storage stability c
tobacco, additional data may be required on cured/dried tobacco and pyrolysis products (guideline 860.1000).
- 9 Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).
- 10 A residue method, storage stability c
tobacco, additional data may be required on cured/dried tobacco and pyrolysis products (guideline 860.1000).
- 11 Required for residential outdoor use on food crops if home gardens:
- 12 A residue method, storage stability c
tobacco, additional data may be required on cured/dried tobacco and pyrolysis products (guideline 860.1000).
- 13 Studies using single serving s;
statistical design accepted by the Agency.
- 14 Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).
- 15 Required for residential outdoor use on food crops if home gardens:

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: GDCI-056801-NNNNN

Key: MP = Manufacture
[TGAI]; TGAI or PAIRA = Technical Grade of the Active Ingredient or Active Ingredient, Radio-Labelled

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	U - Residential and public access pi
B - Terrestrial feed crop	K - Residential	
C - Terrestrial nonfood crop	Q - Residential outdoor use	

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 16 Studies using single serving s:
statistical design accepted by the Agency.
- 17 Required for residential outdoor use on food crops if home gardens
- 18 Studies using single serving s:
statistical design accepted by the Agency.
- 19 A residue method, storage stability c
tobacco, additional data may be required on cured/dried tobacco and pyrolysis products (guideline 860.1000).
- 20 Required for residential outdoor use on food crops if home gardens
- 21 Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).
- 22 Studies using single serving s:
statistical design accepted by the Agency.
- 23 Based on estimates of the magnitude and duration of human
with the Agency to determine whether studies of shorter duration would meet this requirement.
- 24 Required if there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.
- 25 Data are required for residential use sites if the product is applied outdoors.
- 26 Data are required for outdoor occupational site if the product is applied outdoors.
- 27 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.
- 28 EPA needs derma
handheld fogging for mosquito and other pest treatments; power backpack application; tree injection; and drenching/dipping seedlings.
- 29 Biological monitoring data may be submitte
compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.
- 30 Data are required for residential use sites if the product is applied outdoors.

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: GDCI-056801-NNNNN

Key: MP = Manufacture
[TGAI]; TGAI or PAIRA = Technical Grade of the Active Ingredient or Active Ingredient, Radio-Labelled

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	U - Residential and public access pi
B - Terrestrial feed crop	K - Residential	
C - Terrestrial nonfood crop	Q - Residential outdoor use	

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 31 Data are required for outdoor occupational site if the product is applied outdoors.
- 32 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.
- 33 EPA needs inhalation exposure confirmat
handheld fogging for mosquito and other pest treatments; power backpack application; tree injection; and drenching/dipping seedlings.
- 34 Biological monitoring data may be submit
compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.
- 35 Data are required for residential sites if there are uses on turf grass or other plant foliage.
- 36 Bridging applicable residue dissipation data to dermal exposure is required.
- 37 Turf grass transferable residue dissipation data are required when pestic
the foliage of plants other than turf grass.
- 38 Data are required for occupational sites, if (1) there are uses on turf grass or other plant foliage, a
contact with treated foliage while participating in typical activities.
- 39 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.
- 40 Cut flower ARTF greenhouse study ;
transferable residues for granular formulations to assess toddler mouthing behaviors; and a biological monitoring study for granulars.
- 41 Data are required for occupational sites if the human activity data indicate that workers are likely to have post-application exposures while participating in typical activities.
- 42 Data are required for residential sites if post-application exposures are likely.
- 43 Bridging applicable residue dissipation data to dermal exposure is required.
- 44 Cut flower ARTF greenhouse study and DI
to assess toddler mouthing behaviors; and a biological monitoring study for granulars.
- 45 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: GDCI-056801-NNNNN

Key: MP = Manufacture
[TGAI]; TGAI or PAIRA = Technical Grade of the Active Ingredient or Active Ingredient, Radio-Labelled

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	U - Residential and public access pi
B - Terrestrial feed crop	K - Residential	
C - Terrestrial nonfood crop	Q - Residential outdoor use	

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 46 Biological monitoring data may be used for some compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.
- 47 Data are required for occupational sites if the human activity data indicate that workers are likely to have post-application exposures while participating in typical activities.
- 48 Data are required for residential sites if post-application exposures are likely.
- 49 Cut flower ARTF greenhouse study and DFR data needed for confirmatory data. Cut flower ARTF greenhouse study and DFR data needed for confirmatory data. Study also needed for dog collar transferable residue; hand press transferable residue for granular formulations to assess toddler mouthing behaviors; and a biological monitoring study for granulars.
- 50 Biological monitoring data may be used for some compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.
- 51 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.
- 52 Data are required when passive dosimetry techniques are not applicable for a particular exposure scenario, such as a swimmer exposure to pesticides.
- 53 Biological monitoring data may be used for some compounds (i.e., whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.
- 54 Cut flower ARTF greenhouse study and DFR data needed for confirmatory data. Cut flower ARTF greenhouse study and DFR data needed for confirmatory data. Study also needed for dog collar transferable residue; hand press transferable residue for granular formulations to assess toddler mouthing behaviors; and a biological monitoring study for granulars.
- 55 Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

United States Environmental Protection Agency
Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0080,Carbaryl

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE NC PARK	27709
45735	BURLINGTON SCIENTIFIC CORPORATION		71 CAROLYN BLVD.	FARMINGDALE	NY 11735

Appendix F. Product Specific Data Call-in

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In, with all pertinent instructions, is being sent to registrants under separate cover.

United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl Chemical # and Name 056801 Carbaryl	3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-056801-NNNN
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4. EPA Product Registration NNNNNN-NNNNN	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
		N.A.	N.A.		

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8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative _____	9. Date
10. Name of Company	11. Phone Number

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl EPA Reg. No. NNNNNN-NNNNN	3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-056801-NNNN
---	--	--

4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Product Chemistry Data Requirements (Conventional Chemical)								
830.1550	Product Identity and composition (1)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.1600	Description of materials used to produce the product (2)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.1620	Description of production process (3)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8		
830.1650	Description of formulation process (4)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8		
830.1670	Discussion of formation of impurities (5)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.1700	Preliminary analysis (6,7,8)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8		
830.1750	Certified limits (9,10)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.1800	Enforcement analytical method (11)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.6302	Color (12)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.6303	Physical state (13)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		
830.6304	Odor (14)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8		

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law Signature and Title of Company's Authorized Representative _____	11. Date <div style="border: 1px solid black; padding: 5px; display: inline-block;">Page 257</div>
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12. Name of Company	13. Phone Number
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United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl EPA Reg. No. NNNNNN-NNNNN	3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-056801-NNNN
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions (15)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.6314	Oxidizing or reducing action (16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6315	Flammability (17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6316	Explosibility (18)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6317	Storage stability of product (19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6319	Miscibility (20)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6320	Corrosion characteristics (21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.6321	Dielectric breakdown voltage (22)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.7000	pH of water solutions or suspensions (23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & PAI	8	
830.7100	Viscosity (24)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP or EP	8	
830.7200	Melting point/melting range (25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	

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United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl EPA Reg. No. NNNNNN-NNNNN	3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-056801-NNNN
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7220	Boiling point/boiling range (26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	
830.7300	Density/relative density (27)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
830.7370	Dissociation constant in water (28)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method (29)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7840	Water solubility: Column elution method, shake flask method					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7860	Water solubility, generator column method					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
830.7950	Vapor pressure (31)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	
<u>Toxicology Data Requirements (Conventional Chemical)</u>									
870.1100	Acute Oral Toxicity (32)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
870.1200	Acute dermal toxicity (33 ,34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
870.1300	Acute inhalation toxicity (35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	

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Date

United States Environmental Protection
Agency Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2. Case # and Name 0080 Carbaryl EPA Reg. No. NNNNNN-NNNNN	3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-056801-NNNN
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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
870.2400	Acute eye irritation (36)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
870.2500	Acute dermal irritation (37 ,38)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
870.2600	Skin sensitization (39 ,40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP; MP; TGAI	8	
810.3000	General Considerations for efficacy of invertebrate control agents (41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	
810.3100	Soil treatments for imported fire ants (42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	
810.3300	Treatments to control pests of humans and pets (43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	
810.3400	Mosquito, black fly, and biting midge (sand fly) treatments (44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	
810.3500	Premises treatments (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	EP	8	

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: PDCI-056801-NNNN

Key: EP = End Use Prc
Technical Grade Active Ingredient [TGAI]; TGAI & PAI = Technical Ingredient

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	G - Aquatic non-food residential	J - Forestry use	M - Indoor nonfood use
B - Terrestrial feed crop	E - Aquatic nonfood outdoor use	H - Greenhouse food crop	K - Residential	N - Indoor medical use
C - Terrestrial nonfood crop	F - Aquatic nonfood industrial use	I - Greenhouse nonfood crop	L - Indoor food use	O - Residential Indoor use

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 1 Data must be provided in accordance with the "Product Composition" Section.(158.155)
- 2 Data must be provided in accordance with the "Description of Materials used to Produce the Product" Section.(158.160)
- 3 Data must be provided in accordance with the "Description of Production Process" Section.(158.162)
- 4 Data must be provided in accordance with the "Description of Formulation Process" Section.(158.165)
- 5 Data must be provided in accordance with the "Description of Formation of Impurities" Section(158.167)
- 6 Data must be provided in accordance with the "Preliminary Analysis" Section.(158.170)
- 7 Required for TGAIs and products produced by an integrated system.
- 8 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 9 Data must be provided in accordance with the "Certified Limits" Section(158.175)
- 10 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 11 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)
- 12 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 13 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 14 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 15 Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

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Use Categories Key:

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C - Terrestrial nonfood crop	F - Aquatic nonfood industrial use	I - Greenhouse nonfood crop	L - Indoor food use	O - Residential Indoor use

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 16 Required if the product contains an oxidizing or reducing agent
- 17 Required when the product contains combustible liquids.
- 18 Required when the product is potentially explosive.
- 19 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IREDD) Documents."
- 20 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- 21 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IREDD) Documents."
- 22
- 23 Required if the product is dispersible with water.
- 24 Required if the product is a liquid.
- 25 Required when the TGAI is solid at room temperature.
- 26 Required if the TGAI is liquid at room temperature.
- 27 True density or specific density are required for all test substances. Data on bulk density is required for MPs that are solid at room temperature.
- 28 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).
- 29 Required if the TGAI or PAI is organic and non-polar.
- 30 Required if the TGAI or PAI is organic and non-polar.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl
DCI Number: PDCI-056801-NNNN

Key: EP = End Use Prc
Technical Grade Active Ingredient [TGAI]; TGAI & PAI = Technical Ingredient

Use Categories Key:

A - Terrestrial food crop	D - Aquatic food crop	G - Aquatic non-food residential	J - Forestry use	M - Indoor nonfood use
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C - Terrestrial nonfood crop	F - Aquatic nonfood industrial use	I - Greenhouse nonfood crop	L - Indoor food use	O - Residential Indoor use

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 31 Not required for salts.
- 32 Not required if test material is a gas or a highly volatile liquid.
- 33 Not required if test material is a gas or a highly volatile liquid.
- 34 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 35 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).
- 36 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 37 Not required if test material is a gas or a highly volatile liquid.
- 38 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 39 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 40 Required if repeated dermal exposure is likely to occur under conditions of use.
- 41 The Agency has waived all requirements to submit efficacy data fo are efficacious when used in accordance with label directions and commonly accepted pest control practices. The registrant must develop and maintain the relevant data upon which the determination of efficacy is based. The Agency efficacy data for any pesticide product, registered or proposed for registration when necessary.
- 42 Required For fire ant treatments.
- 43 Required for fleas and ticks on animals (dogs and cats).
- 44 Efficacy dat

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0080 Carbaryl

DCI Number: PDCI-056801-NNNN

Key: EP = End Use Prc
Technical Grade Active Ingredient [TGAI]; TGAI & PAI = Technical
Ingredient

Use Categories Key:

- | | | | | |
|------------------------------|------------------------------------|----------------------------------|---------------------|----------------------------|
| A - Terrestrial food crop | D - Aquatic food crop | G - Aquatic non-food residential | J - Forestry use | M - Indoor nonfood use |
| B - Terrestrial feed crop | E - Aquatic nonfood outdoor use | H - Greenhouse food crop | K - Residential | N - Indoor medical use |
| C - Terrestrial nonfood crop | F - Aquatic nonfood industrial use | I - Greenhouse nonfood crop | L - Indoor food use | O - Residential Indoor use |

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

45 Required for carbaryl use agai

Appendix G. EPA's Batching of Carbaryl Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Carbaryl** as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or

Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Two hundred ninety products were found which contain **Carbaryl** as the active ingredient. These products have been placed into thirty seven batches and a "No Batch" category in accordance with the active and inert ingredients and type of formulation. Furthermore, the following bridging strategies are deemed acceptable for this chemical:

- Batch 1: The products in this batch may not cite data generated with EPA Reg. No. 9779-294 (90.0% product).
- Batch 7: The products in this batch may not cite data generated with EPA Reg. No. 5905-251 (40.38% product).
- Batch 15: EPA Reg. No. 16-177 may not cite data generated with EPA Reg. No. 8660-21.
- Batch 26: The three 2.0% products may not cite data generated with EPA Reg. No. 432-1244 (1% product).
- Batch 31: The three 5.0% products may not cite data generated with EPA Reg. No. 5481-95 (4.0% product).
- Batch 32: EPA Reg. No. 5481-323 may not cite data generated with EPA Reg. No. 5481-283.
- No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	% Active Ingredient
	264-324	99.0
	264-325	97.5
	432-982	97.5
	9779-294	90.0
	19713-75	99.0
	19713-84	95.0
	34704-707	99.0
	45735-24	99.0

Batch 2	EPA Reg. No.	% Active Ingredient
	264-315	85.0
	19713-363	85.0

Batch 3	EPA Reg. No.	% Active Ingredient
	264-328	80.0
	769-971	80.0
	19713-244	80.0

Batch 4	EPA Reg. No.	% Active Ingredient
	432-1226	80.0
	5905-517	80.0
	10163-133	80.0
	10163-134	80.0
	19713-50	80.0
	34704-619	80.0
	51036-151	80.0

Batch 5	EPA Reg. No.	% Active Ingredient
	16-176	80.0
	264-316	80.0
	264-526	80.0

Batch 6	EPA Reg. No.	% Active Ingredient
	4-387	50.0
	16-99	50.0
	70-285	50.0

Batch 6	EPA Reg. No.	% Active Ingredient
	264-314	50.0
	769-834	50.0
	769-868	50.0
	769-920	50.0
	769-972	50.0
	829-142	50.0
	5887-86	50.0
	19713-52	50.0
	19713-369	50.0
	34704-350	50.0

Batch 7	EPA Reg. No.	% Active Ingredient
	4-415	42.60
	264-335	43.00
	264-349	43.00
	432-1227	43.00
	5905-251	40.38
	9779-260	43.40
	10163-60	43.70
	11715-207	42.60
	11715-209	42.60
	11715-229	42.60
	34704-447	43.00
	45735-25	42.85
	51036-66	43.30

Batch 8	EPA Reg. No.	% Active Ingredient
	192-174	21.3
	769-648	21.3
	769-865	21.3
	769-883	21.3
	769-919	21.3
	5887-102	21.3
	28293-222	21.3
	46515-36	21.3

Batch 9	EPA Reg. No.	% Active Ingredient
	4-237	22.5
	264-334	22.5
	19713-89	22.5

Batch 10	EPA Reg. No.	% Active Ingredient
	51036-185	13.0
	51036-210	13.0

Batch 11	EPA Reg. No.	% Active Ingredient
	655-789	10.0
	829-200	10.0
	7401-154	10.0
	53883-41	10.0
	71949-11	10.0

Batch 12	EPA Reg. No.	% Active Ingredient
	7401-166	10.0
	8660-241	10.0
	28293-18	10.0

Batch 13	EPA Reg. No.	% Active Ingredient
	264-312	10.04
	61282-04	10.04
	61282-21	10.04

Batch 14	EPA Reg. No.	% Active Ingredient
	16-98	10.0
	70-165	10.0
	239-1513	10.0
	432-1210	10.0
	432-1237	10.0
	769-229	10.0
	769-612	10.0
	769-665	10.0
	869-180	10.0
	2935-320	10.0
	5481-108	10.0
	5481-294	10.0
	9779-81	10.0
	10163-124	10.0
	11715-292	10.0
	19713-53	10.0

Batch 14	EPA Reg. No.	% Active Ingredient
	19713-212	10.0
	49585-26	10.0
	51036-13	10.0
	67517-32	10.0

Batch 15	EPA Reg. No.	% Active Ingredient
	16-177	7.0
	8660-21	6.3

Batch 16	EPA Reg. No.	% Active Ingredient
	264-429	7.0
	432-885	7.0
	28293-233	7.0

Batch 17	EPA Reg. No.	% Active Ingredient
	70-244	5.0
	2935-366	5.0
	8660-111	5.0

Batch 18	EPA Reg. No.	% Active Ingredient
	59639-52	5.0
	59639-60	5.0

Batch 19	EPA Reg. No.	% Active Ingredient
	264-320	5.0
	61282-16	5.0
	61282-22	5.0

Batch 20	EPA Reg. No.	% Active Ingredient
	769-729	5.0
	769-730	5.0

Batch 21	EPA Reg. No.	% Active Ingredient
	10163-32	5.0
	28293-235	5.0

Batch 22	EPA Reg. No.	% Active Ingredient
	192-70	5.0
	769-559	5.0
	8660-234	5.0
	9779-74	5.0
	10159-02	5.0
	28293-06	5.0
	28293-237	5.0

Batch 23	EPA Reg. No.	% Active Ingredient
	4-143	5.0
	228-251	5.0
	655-788	5.0
	829-128	5.0
	869-118	5.0
	34911-6	5.0
	49585-4	5.0
	53883-42	5.0
	53883-43	5.0
	71949-10	5.0

Batch 24	EPA Reg. No.	% Active Ingredient
	4-413	5.0
	16-27	5.0
	70-166	5.0
	239-1349	5.0
	239-2181	5.0
	432-1209	5.0
	432-1239	5.0
	769-611	5.0
	769-642	5.0
	769-647	5.0
	769-906	5.0
	1386-451	5.0
	1386-655	5.0
	2781-25	5.0
	2935-193	5.0
	4758-07	5.0
	5481-58	5.0
	5481-98	5.0
	5481-253	5.0
	5887-43	5.0
	8660-72	5.0
	11715-294	5.0
	19713-213	5.0
	36272-14	5.0
	51036-48	5.0
	67517-31	5.0

Batch 25	EPA Reg. No.	% Active Ingredient
	16-12	2.0
	769-835	1.75
	5481-282	2.0
	7401-291	1.75

Batch 26	EPA Reg. No.	% Active Ingredient
	192-199	2.0
	432-1212	2.0
	432-1244	1.0
	769-976	2.0

Batch 27	EPA Reg. No.	% Active Ingredient
	51036-204	Carbaryl: 1.3 Volatile Floral Attractants: 0.7
	51036-227	Carbaryl: 1.3 Volatile Floral Attractants: 0.7

Batch 28	EPA Reg. No.	% Active Ingredient
	16-127	Carbaryl: 2.0 Copper Sulfate: 7.0
	5481-321	Carbaryl: 2.0 Copper Sulfate: 6.5

Batch 29	EPA Reg. No.	% Active Ingredient
	4-443	Carbaryl: 5.00 Metaldehyde: 0.13
	4-450	Carbaryl: 5.00 Metaldehyde: 0.13

Batch 30	EPA Reg. No.	% Active Ingredient
	4-333	Carbaryl: 5.0 Metaldehyde: 2.0
	4-449	Carbaryl: 5.0 Metaldehyde: 2.0

Batch 31	EPA Reg. No.	% Active Ingredient
	5481-95	Carbaryl: 4.0 Metaldehyde: 3.0
	5481-97	Carbaryl: 5.0 Metaldehyde: 3.0
	5481-451	Carbaryl: 5.0 Metaldehyde: 3.0
	8278-03	Carbaryl: 5.0 Metaldehyde: 3.5

Batch 32	EPA Reg. No.	% Active Ingredient
	5481-283	Carbaryl: 5.0 Maneb: 4.0
	5481-323	Carbaryl: 7.5 Maneb: 6.4

Batch 33	EPA Reg. No.	% Active Ingredient
	769-613	Carbaryl: 5.0 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1
	11715-255	Carbaryl: 5.0 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1
	28293-10	Carbaryl: 5.0 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1

Batch 34	EPA Reg. No.	% Active Ingredient
	11715-250	Carbaryl: 12.5 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1
	37425-13	Carbaryl: 12.5 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1

Batch 35	EPA Reg. No.	% Active Ingredient
	4758-32	Carbaryl: 5.0 Butoxypolypropylene glycol: 4.0 Piperonyl butoxide: 0.5 Pyrethrins: 0.1
	4758-34	Carbaryl: 5.0 Butoxypolypropylene glycol: 4.0 Piperonyl butoxide: 0.5 Pyrethrins: 0.1

Batch 36	EPA Reg. No.	% Active Ingredient
	432-1211	0.126
	432-1238	0.126

Batch 37	EPA Reg. No.	% Active Ingredient
	7401-72	Carbaryl: 4.0 Metaldehyde: 1.0
	7401-265	Carbaryl: 4.0 Metaldehyde: 1.0
	34911-8	Carbaryl: 4.0 Metaldehyde: 1.0

No Batch	EPA Reg. No.	% Active Ingredient
	4-29	Carbaryl: 1.25 Copper: 7.0 Cube Resins: 1.0 Rotenone: 0.5
	4-59	Carbaryl: 0.5 Malathion: 3.0 Captan: 6.0
	4-122	Carbaryl: 0.30 Malathion: 6.0 Captan: 12.0
	4-142	4.6
	4-157	Carbaryl: 13.5 Malathion: 13.5
	16-76	21.3
	16-179	22.5
	228-249	Carbaryl: 5.0 Copper Sulfate: 7.0
	239-2514	Carbaryl: 5.0 Metaldehyde: 2.0
	239-2628	21.3
	264-321	40.0
	264-333	44.1
	264-422	48.0
	264-427	39.7
	432-1213	1.0
	769-573	23.0
	769-574	80.0
	769-614	Carbaryl: 12.5 Piperonyl butoxide: 1.0 Pyrethins: 0.1
	769-728	5.0

No Batch	EPA Reg. No.	% Active Ingredient
	769-970	3.5
	769-977	0.126
	802-351	Carbaryl: 5.0 Metaldehyde: 2.0
	802-493	5.0
	829-131	1.75
	829-182	Carbaryl: 4.25 Metaldehyde: 3.25
	829-285	5.0
	869-119	Carbaryl: 5.0 Methaldehyde: 1.0
	909-83	Carbaryl: 5.0 Methaldehyde: 3.0
	1386-630	Carbaryl: 5.000 Bacillus thuringiensis: 0.048
	2097-08	0.5
	2393-209	5.0
	2393-375	5.0
	2724-75	5.25
	2724-272	9.5
	2724-273	17.0
	5481-65	50.0
	5481-89	10.0
	5481-90	5.0
	5481-100	Carbaryl: 5.0 Metaldehyde: 2.5
	5481-190	46.0
	5481-242	Carbaryl: 0.5 Malathion: 2.5

No Batch	EPA Reg. No.	% Active Ingredient
	5481-271	50.0
	5481-275	Carbaryl: 2.0 Malathion: 2.0
	5481-312	7.5
	5481-316	Carbaryl: 5.0 Endosulfan: 1.5
	5887-77	Carbaryl: 0.3 Malathion: 6.0 Methoxychlor: 12.0
	5887-170	Carbaryl: 5.0 Metaldehyde: 2.5
	5905-169	10.0
	5905-180	15.0
	6973-10	Carbaryl: 4.0 Metaldehyde: 1.0
	7401-38	23.7
	7401-43	3.34
	7401-69	5.0
	7401-81	Carbaryl: 10.0 Sulfur: 40.0
	7401-83	25.0
	7401-148	2.0
	7401-210	25.0
	7401-310	Carbaryl: 5.000 Bacillus thuringiensis: 0.048
	7401-334	Carbaryl: 2.0 Sulfur: 2.0
	7401-386	13.5
	8119-03	Carbaryl: 5.0 Metaldehyde: 2.0

No Batch	EPA Reg. No.	% Active Ingredient
	8119-05	Carbaryl: 5.0 Metaldehyde: 2.0
	8378-31	4.3
	8378-36	1.43
	8660-28	1.0
	8660-60	50.0
	8660-70	24.4
	8660-133	11.7
	8660-188	4.55
	9198-106	6.2
	9198-146	8.0
	9444-98	Carbaryl: 0.500 Piperonyl Butoxide: 0.188 Pyrethrins: 0.075
	9444-190	Carbaryl: 0.500 Piperonyl Butoxide: 0.190 Pyrethrins: 0.076
	10404-61	6.3
	10404-62	4.0
	11656-20	Carbaryl: 4.0 Metaldehyde: 2.0
	11656-21	5.0
	11715-346	23.0
	19713-49	43.4
	19713-131	49.0
	19713-334	10.0
	19713-494	5.0
	28293-08	60.0
	33955-462	5.0

No Batch	EPA Reg. No.	% Active Ingredient
	33955-533	23.4
	34704-23	5.0
	34704-289	10.0
	34704-373	5.0
	34704-483	5.0
	35512-49	2.0
	42057-39	Carbaryl: 4.0 Metaldehyde: 1.0
	43576-03	Carbaryl: 5.0 Piperonyl Butoxide: 1.0 Pyrethrins: 0.1
	49585-24	Carbaryl: 5.00 Piperonyl butoxide: 0.45 Pyrethrins: 0.03 Sulfur: 30.00
	49784-03	Carbaryl: 12.5 Methoxychlor: 0.25
	51036-61	5.0
	51036-123	22.5
	51036-286	10.0
	54705-04	41.2
	60063-15	Carbaryl: 5.0 Chlorthalonil: 3.75
	67650-02	2.0
	67650-03	5.0
	71949-12	5.0
	73049-238	Carbaryl: 1.000 Piperonyl Butoxide: 0.376 Pyrethrins: 0.150

Appendix H. List of Registrants Sent the Product Specific Data Call-In

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0080, Carbaryl

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
4	BONIDE PRODUCTS, INC.		6301 SUTLIFF ROAD	ORISKANY	NY 13424
16	DRAGON CHEMICAL CORPORATION		71 CAROLYN BLVD	FARMINGDALE	NY 11735
70	VALUE GARDENS SUPPLY, LLC		PO Box 585	ST. JOSEPH	MO 64502
192	VALUE GARDENS SUPPLY, LLC		PO Box 585	ST. JOSEPH	MO 64502
228	NUFARM AMERICAS INC.		1333 BURR RIDGE PARKWAY, SUITE 125A	BURR RIDGE	IL 605270866
239	THE ORTHO BUSINESS GROUP		PO Box 190	MARYSVILLE	OH 43040
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709
432	BAYER ENVIRONMENTAL SCIENCE		95 CHESTNUT RIDGE ROAD	MONTVALE	NJ 07645
769	VALUE GARDENS SUPPLY, LLC		PO Box 585	ST. JOSEPH	MO 64502
802	CENTRAL GARDEN & PET D/B/A LILLY MILLER BRANDS/EXCEL GARDEN		PO Box 2289 16201 SE 98TH AVENUE	CLACKAMAS	OR 97015
829	SOUTHERN AGRICULTURAL INSECTICIDES, INC.		PO Box 218	PALMETTO	FL 34220
869	GREEN LIGHT COMPANY		PO Box 17985	SAN ANTONIO	TX 78217
909	CENTRAL GARDEN & PET D/B/A LILLY MILLER BRANDS/EXCEL GARDEN		PO Box 2289 16201 SE 98TH AVENUE	CLACKAMAS	OR 97015
1386	UNIVERSAL COOPERATIVES INC		1300 CORPORATE CENTER CURVE	EAGAN	MN 55121
2097	PET CHEMICALS		PO Box 18993	MEMPHIS	TN 381810993
2393	HACO, INC		PO Box 7190	MADISON	WI 53707
2724	WELLMARK INTERNATIONAL		1100 EAST WOODFIELD ROAD, SUITE 500	SCHAUMBURG	IL 60173
2781	HAPPY JACK INC		PO Box 475	SNOW HILL	NC 28580
2935	WILBUR ELLIS CO.		PO Box 1286	FRESNO	CA 93715
4758	PET CHEMICALS		PO Box 18993 4242 BF GOODRICH BLVD	MEMPHIS	TN 381810993
5481	AMVAC CHEMICAL CORP		4695 MACARTHUR COURT, SUITE 1250	NEWPORT BEACH	CA 926601706
5887	VALUE GARDENS SUPPLY, LLC		PO Box 585	ST. JOSEPH	MO 64502
5905	HELENA CHEMICAL CO		225 SCHILLING BOULEVARD, SUITE 300	COLLIERVILLE	TN 38017
6973	SOILSERV INC		PO Box 1286	FRESNO	CA 93715
7401	VOLUNTARY PURCHASING GROUP INC	BRAZOS ASSOCIATES, INC.	1806 AUBURN DRIVE	CARROLLTON	TX 750071451
8119	MATSON, LLC		PO Box 1820	NORTH BEND	WA 98045

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0080, Carbaryl

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
8278	METRO BIOLOGICAL LABORATORY	ROBINSON ASSOCIATES	102 GREENFIELD PLACE	LOS GATOS	CA 95032
8378	KNOX FERTILIZER CO INC		PO Box 248 W. CULVER ROAD	KNOX	IN 46534
8660	SYLORR PLANT CORP.		PO Box 142642	ST. LOUIS	MO 631140642
9198	THE ANDERSONS LAWN FERTILIZER DIVISION, INC.		PO Box 119	MAUMEE	OH 43537
9444	WATERBURY COMPANIES INC		PO Box 640 129 CALHOUN STREET	INDEPENDENCE	LA 70443
9779	AGRILIANCE, LLC	D. O'SHAUGHNESSY CONSULTING INC.	21 BIRCH PARKWAY	SPARTA	NJ 07871
10159	VOLUNTARY PURCHASING GROUP INC	BRAZOS ASSOCIATES, INC.	1806 AUBURN DRIVE	CARROLLTON	TX 750071451
10163	GOWAN CO		PO Box 5569	YUMA	AZ 853665569
10404	LESCO INC		15885 SPRAGUE ROAD	STRONGSVILLE	OH 44136
11656	WESTERN FARM SERVICE, INC		PO Box 1168	FRESNO	CA 937151168
11715	SPEER PRODUCTS INC		4242 B.F. GOODRICH BOULEVARD	MEMPHIS	TN 381810993
19713	DREXEL CHEMICAL CO		PO Box 13327 1700 CHANNEL AVENUE	MEMPHIS	TN 381130327
28293	UNICORN LABORATORIES		12385 AUTOMOBILE BLVD.	CLEARWATER	FL 33762
33955	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
34704	LOVELAND PRODUCTS, INC.		PO Box 1286	GREELEY	CO 80632
34911	HI-YIELD CHEMICAL COMPANY	BRAZOS ASSOCIATES, INC.	1806 AUBURN DRIVE	CARROLLTON	TX 750071451
35512	HOWARD FERTILIZER & CHEMICAL CO., INC	REGISTRATIONS BY DESIGN INC.	118 1/2 E MAIN STREET, SUITE 1	SALEM	VA 24153
36272	MYSTIC CHEMICAL PRODUCTS CO		3561 WEST 105TH ST	CLEVELAND	OH 44111
37425	PET CHEMICALS		PO Box 18993	MEMPHIS	TN 381810993
42057	MORGRO CHEMICAL CO		145 WEST CENTRAL AVE	SALT LAKE CITY	UT 84107
43576	GIMBORN PET SPECIALTIES, LLC	REGWEST COMPANY, LLC	30856 ROCKY ROAD	GREELEY	CO 806319375
45735	BURLINGTON SCIENTIFIC CORPORATION		71 CAROLYN BLVD.	FARMINGDALE	NY 11735
46515	CELEX, DIVISION OF UNITED INDUSTRIES CORP		PO Box 142642	ST LOUIS	MO 631140642
47000	CHEM-TECH LTD	STEVEN E. ROGOSHESKE	1479 WEST POND ROAD	EGAN	MN 55122
49585	ALLJACK, DIVISION OF UNITED INDUSTRIES CORP		PO Box 142642	ST LOUIS	MO 631140642
49784	RESEARCH LABORATORIES, INC.		PO Box 801854	HOUSTON	TX 772801854
51036	MICRO-FLO COMPANY LLC		530 OAK COURT DRIVE	MEMPHIS	TN 38117

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0080, Carbaryl

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
53883	CONTROL SOLUTIONS, INC.		5903 GENOA-RED BLUFF	PASADENA	TX 775071041
54705	LAWN AND GARDEN PRODUCTS, INC.	LYNNE ZAHIGIAN REGULATORY CONSULTING	PO Box 1566	FALLON	NV 89407
59623	CALIFORNIA DEPT OF FOOD AND AGRICULTURE		1220 N STREET	SACRAMENTO	CA 95814
59639	VALENT U.S.A. CORPORATION		PO Box 8025 1600 RIVIERA AVENUE, SUITE 200	WALNUT CREEK	CA 94596
60063	SIPCAM AGRO USA, INC.		300 COLONIAL PARKWAY, SUITE 230	ROSWELL	GA 30076
67517	PM RESOURCES INC		13001 ST. CHARLES ROCK RD	BRIDGETON	MO 63044
67650	PEACOCK INDUSTRIES (US) INC.	STANLEY GOODWIN - ATTORNEY AT LAW	116 WEST C STREET	MCCOOK	NE 69001
71949	OMS INVESTMENTS, INC.		1105 N. MARKET STREET	WILMINGTON	DE 19899
73049	VALENT BIOSCIENCES CORPORATION		870 TECHNOLOGY WAY, SUITE 100	LIBERTYVILLE	IL 600486316

Appendix I. List of Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

<http://www.epa.gov/opprd001/forms/>

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf

8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit: www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
 - a. 83-3 Label Improvement Program--Storage and Disposal Statements
 - b. 84-1 Clarification of Label Improvement Program
 - c. 86-5 Standard Format for Data Submitted under FIFRA
 - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
 - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
 - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
 - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
 - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/oppmsd1/PR_Notices

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
 - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
 - b. EPA Form No. 8570-4, Confidential Statement of Formula
 - c. EPA Form No. 8570-27, Formulator's Exemption Statement
 - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
 - e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
 - a. Registration Division Personnel Contact List
 - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
 - c. Antimicrobials Division Organizational Structure/Contact List
 - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
 - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by

telephone at (800) 858-7378 or through their website: <http://npic.orst.edu>..

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.