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Amended Reregistration Eligibility Decision (RED) for Carbaryl

Revised August 2008

AMENDED REREGISTRATION ELIGIBILITY

DECISION

for

Carbaryl

Case No. 0080

Revised August 2008

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Date

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I. Introduction

The Environmental Protection Agency (EPA or the Agency) is amending the Reregistration Eligibility Decision (RED) for Carbaryl, signed September 24, 2007, to incorporate the revised occupational exposure and risk assessment. The 2007 RED amended the Interim Reregistration Eligibility Decision (IRED) for carbaryl, which was completed by EPA on June 30, 2003 and previously amended on October 22, 2004. This amendment updates the 2007 Red to reflect the Revised Occupational Exposure and Risk Assessment, dated July 9, 2007. The revised occupational risk assessment incorporates updates to the toxicological points of departure (PoD); considers the mitigation measures required in the 2003 IRED and 2004 amended IRED; and incorporates responses to submitted public comments and data submitted in response to the Generic Data Call-In, issued in March 2005, which are applicable to the occupational risk assessment.

This document summarizes the revised occupational handler and post-application risk assessments, and presents the Agency's revised regulatory decision and risk mitigation for the occupational uses of carbaryl. The document consists of five sections. Section I contains the regulatory framework for reregistration; Section II provides a regulatory history of the chemical and a profile of its use and usage; Section III gives an overview of the revised occupational risk assessment; Section IV presents the Agency's decision on reregistration eligibility and risk management, and compares the new mitigation to that required in the 2004 amended IRED; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. The revised occupational risk assessment for carbaryl and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (<http://www.regulations.gov>.) under docket number EPA-HQ-2007-0941 and are available on the Agency's web page <http://www.epa.gov/pesticides/reregistration/carbaryl/>.

II. Background

A. Regulatory History

Carbaryl is an N-methyl carbamate (NMC) pesticide, which was first registered in 1959 for use on cotton. In 2001, the Agency identified the NMC pesticides as a group which shares a common mechanism of toxicity. Therefore, the Agency was required to consider the cumulative effects on human health resulting from exposure to this group of chemicals when considering whether to establish, modify, or revoke a tolerance for pesticide residues in food, in accordance with the Food Quality Protection Act of 1996 (FQPA).

The Interim Reregistration Eligibility Decision (IRED) for Carbaryl, signed on June 30, 2003, addressed the potential human health and ecological risks from carbaryl. The Agency amended the IRED on October 22, 2004 to incorporate clarifications and corrections, updated the residential risk assessment to reflect the voluntary cancellation of the liquid broadcast use of carbaryl on residential turf to address post-application risk to toddlers identified in the 2003 IRED, and addressed issues regarding labeling of carbaryl formulations for mitigating potential hazards to bees. In addition, the revised occupational risk assessment, which is summarized in Section III of this document, also incorporates the mitigation measures required in the 2004 amended IRED applicable to potential occupational exposures, such as cancellation of certain uses and application methods, reduction of application rates, application prohibitions, personal protective equipment (PPE) and engineering control (EC) requirements, and extension of restricted-entry intervals (REIs) for post-application exposure.

The Agency also issued generic and product-specific data call-ins (DCIs) for carbaryl in March 2005. The carbaryl generic DCI required several studies for the active ingredient carbaryl, including additional toxicology, worker exposure monitoring, and environmental fate data. The product DCI required acute toxicity and product chemistry data for all pesticide products containing carbaryl. EPA has received numerous studies in response to these DCIs, and, where appropriate, these studies were considered in the revised occupational risk assessment for this amendment to the carbaryl RED.

In response to the 2005 DCIs, many carbaryl registrants chose to voluntarily cancel their carbaryl products. Approximately 80% of all of the carbaryl end-use products registered at the time of the 2003 IRED have since been canceled through this process or other voluntary cancellations.

On September 26, 2007, EPA published a revised NMC cumulative risk assessment (docket number EPA-HQ-OPP-2007-0935), which concluded that the cumulative risks associated with the NMC pesticides meet the safety standard set forth in the Federal Food, Drug, and Cosmetic Act (FFDCA). Concurrently, on September 24, 2007, the Reregistration Eligibility Decision (RED) for carbaryl was completed. The 2007 RED presents EPA's revised carbaryl human health risk assessment under FQPA and the Agency's final tolerance reassessment decision for carbaryl. The 2007 Carbaryl RED and its background/support documents were published on October 17, 2007 and can be found at www.regulations.gov docket number EPA-HQ-OPP-2007-0941.

B. Summary of Use Profile

The insecticide carbaryl is used in agriculture to control pests on terrestrial food crops including fruit and nut trees, many types of fruit and vegetables, and grain crops; cut flowers; nursery and ornamentals; turf, including production facilities; greenhouses; golf courses; and in oyster beds. Carbaryl is also registered for use on residential sites (e.g., annuals, perennials, shrubs) by professional pest control operators and by homeowners on gardens, ornamentals and turfgrass.

Carbaryl products are manufactured as granular, liquid, wettable powder, and dust formulations. All dry flowable (water dispersible granule) products have been voluntarily cancelled. Groundboom, airblast, and aerial applications are typical for agricultural uses. Other applications can also be made using handheld equipment, such as low pressure handwand sprayers, turfguns, and various ready-to-use products. Applications by aerosol cans, hand, spoon, shaker can, and front- and back-mounted spreaders are prohibited.

In addition, the use of dust formulation in agriculture and backpack sprayers are not being supported by Bayer CropScience, the carbaryl technical registrant, who is amending their carbaryl registrations to delete these uses. EPA intends to publish a formal *Notice* of this action in the Federal Register in August 2008.

Tables 1 and 2 summarize the best Agency’s estimates of carbaryl usage on agricultural crops and non-agricultural sites, respectively.

Table 1. Summary of Carbaryl Use Data for Agricultural Crops			
Crop	Estimated Pounds Active Ingredient (a.i.) used per year	Percent Crop Treated	
		Estimated Average	Estimated Maximum
Alfalfa	50,000	<1	<2.5
Almonds *	10,000	<1	<2.5
Apples	300,000	40	55
Apricots	1,000	5	15
Asparagus	50,000	35	45
Avocados	3,000	5	5
Beans, Green	10,000	5	5
Beets†	<500	Not Calculated‡	5
Blackberries	3,000	30	35
Blueberries	20,000	20	25
Broccoli	4,000	<1	5
Brussels Sprouts *	<500	Not Calculated‡	Not Calculated‡
Cabbage	3,000	5	10
Caneberries	<500	<1	<2.5
Cantaloupes	10,000	15	25
Carrots	3,000	5	5
Cauliflower	<500	<1	<2.5
Cherries	70,000	20	25
Corn	30,000	<1	<2.5
Cotton	8,000	<1	<2.5

Table 1. Summary of Carbaryl Use Data for Agricultural Crops			
Crop	Estimated Pounds Active Ingredient (a.i.) used per year	Percent Crop Treated	
		Estimated Average	Estimated Maximum
Cranberries †	30,000	Not Calculated‡	20
Cucumbers	10,000	5	10
Cucumbers, Pickles	2,000	<1	<2.5
Dry Beans/Peas	2,000	<1	<2.5
Eggplant	<500	15	15
Grapefruit	30,000	5	10
Grapes	70,000	5	5
Hay, Other†	600,000	Not Calculated‡	<1
Lemons	4,000	<1	<2.5
Lettuce	6,000	<1	<2.5
Nectarines	5,000	5	5
Olives	6,000	<1	<2.5
Onions	<500	<1	<2.5
Oranges	100,000	5	5
Parsley †	<500	Not Calculated‡	5
Peaches	50,000	10	20
Peanuts	20,000	<1	5
Pears	4,000	5	10
Pecans	200,000	10	15
Peppers	7,000	5	5
Pistachios	20,000	5	5
Plums	7,000	5	5
Potatoes	10,000	<1	5
Prunes	6,000	<1	<2.5
Pumpkins	20,000	15	25
Rice	10,000	<1	<2.5
Sod†	2,000	Not Calculated‡	<1
Sorghum	10,000	<1	<2.5
Soybeans	40,000	<1	<2.5
Spinach	<500	<1	<2.5
Squash	10,000	15	20
Strawberries	10,000	10	15
Sugar Beets	2,000	<1	<2.5
Sunflowers	5,000	<1	<2.5
Sweet Corn	20,000	<1	5
Sweet Potatoes†	20,000	Not Calculated‡	15
Tangelos	1,000	5	5
Tangerines	9,000	5	10
Tobacco	2,000	<1	<2.5
Tomatoes	20,000	5	10
Walnuts	3,000	<1	<2.5
Watermelons	20,000	10	15
Wheat	10,000	<1	<2.5

*The only use data available for this crop is from California's Department of Pesticide Regulation, but 95% or more of the U.S. acreage for this crop is in California. † Data from Crop Life America, National Pesticide Use Database 2002, because no other data are available. ‡ Not calculated due to insufficient data.

Table 2. Summary of Carbaryl Nonagricultural Use Data

Use Category	Uses in Category	Annual Average Pounds Applied (active ingredient)
Turf	Turf farms	201,000
	Commercial turf	
	Golf courses	
	Lawn Care Operators	
Landscape and Horticulture	Nurseries	44,000

III. Revised Human Health Risk Assessment

The June 29, 2007 *CARBARYL. HED Chapter of the Reregistration Eligibility Decision Document (RED)*, which revised the February 2003 human health risk assessment, incorporates changes to the hazard assessment, dietary assessment (including the drinking water exposure assessment), residential assessment, and occupational assessment. The occupational exposure portion of the 2003 occupational and residential exposure risk assessment was revised to incorporate new data, relevant public comments, and new toxicological methods. The following section summarizes the July 9, 2007, *Carbaryl: Revisions to Occupational Exposure and Risk Assessment*.

A. Summary of Changes to the Occupational Risk Assessment

Since the Amended Carbaryl IRED (2004 amended IRED) was posted for public comment in October 2004, EPA received numerous comments regarding the occupational and residential exposure assessment portions. Those which are specific to the occupational portion, and have not been addressed in the past, are considered and incorporated in the July 9, 2007, *Revisions to Occupational Exposure and Risk Assessment*. Additionally, the revised occupational assessment includes worker monitoring data required by the IRED through a Generic Data Call-In, as well as additional toxicological studies, which revise the toxicological PoD. Also, as discussed previously in Section II, the revised assessment also incorporates the mitigation measures required in the 2004 amended IRED applicable to potential occupational exposures.

1. New Data

EPA issued a Generic Data Call-In (GDCI) for carbaryl in March 2005 (GDCI-056801-21325). This DCI required several confirmatory studies, including exposure monitoring and toxicology studies. In addition, the Agency received three occupational handler studies from Bayer CropScience in response to the GDCI requirement for applicator exposure data. All of the following studies submitted were conducted by the Agricultural Handler Exposure Task Force (AHETF):

- “Determination of Dermal and Inhalation Exposure to Workers during Application of a Liquid Pesticide Product by Open Cab Airblast Application to Orchard Crops” (MRID 464482-01);

- “Determination of Dermal and Inhalation Exposure to Workers during Closed-System Loading and ULV Application of a Liquid Pesticide Product to Cotton” (MRID 466341-05); and
- “Determination of Dermal and Inhalation Exposure to Workers During Loading or Application of Carbaryl Bait” (MRID 470516-01).

In addition, to the studies submitted in response to the GDCI, two key studies that were incorporated into the revised occupational handler risk assessment include the following:

- *Dermal penetration study for carbaryl.* Bayer CropScience conducted an *in vitro* comparative dermal penetration study using rat skin and human skin (MRID 471519-02). These study data were used to determine the relative dermal absorption for carbaryl in rats and humans and were used to derive the dermal PoD used in the carbaryl risk assessment.
- *Comparative cholinesterase study.* The EPA’s Office of Research and Development conducted a comparative cholinesterase (ChE) study to compare carbaryl-induced ChE inhibition in adult and juvenile rats (MRID 471430-01). These data were used to establish the occupational inhalation (short- and intermediate-term) PoD and the dermal PoD.

A residue dissipation study, “Carbaryl: Dissipation of Dislodgeable Foliar Residues from Chrysanthemums” (MRID 468928-01), was submitted by the Interregional Research Project Number 4 (IR-4) of Rutgers University in support of carbaryl use on chrysanthemums and was considered in the revised post-application risk estimate for cut flowers. Other changes from the February 2003 occupational risk assessment include changes in some transfer coefficients (TCs) applicable to specific crop grouping/activity combinations. Required TC changes are as follows:

- **Cut Flowers:** The 2003 occupational risk assessment indicated that the Agricultural Re-Entry Task Force (ARTF) was in the process of conducting a more definitive study in the cut-flower industry which would likely be a more reliable source of information. Since that time, the study was conducted and submitted to the Agency for review. Results of the ARTF study are a TC of 5100 cm²/hour and 2700 cm²/hour for hand-harvesting activities.
- **Evergreen Tree Fruit:** The TC for pruning of evergreen tree fruit was reduced from 1500 cm²/hour to 1000 cm²/hour. This change was based upon an ARTF pruning study of apple and olive trees. While not specific to the evergreen tree fruit crop grouping, the exposure data is scenario- and chemical-specific.
- **Turf/Sod:** Based upon the results of ARTF studies on sod farm harvesting and golf course maintenance, TCs for these activities have been changed. The TC for the sod farm harvesting activity has been reduced from 16500 to 6800 cm²/hr. The existing TC for golf course maintenance is 500 cm²/hr for mowing. This value has been used in addition to a TC of 3400 cm²/hr from the ARTF study to assess post-application risk from golf course maintenance activities.

- Vine and Trellis: Based upon the results of an ARTF study which monitored blackberry harvest, the resulting TC of 1100 cm²/hr was used to assess risks for blackberry hand harvesting in addition to existing TCs.

2. Relevant Public Comments

The occupational assessment was revised to include public comments received since the carbaryl IRED that are specific to the occupational portion and have not been addressed in the past. The Agency received comment from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), the National Grasshopper Management Board, and state-run allied programs, regarding the application of carbaryl bait formulations for suppression of Mormon cricket and rangeland grasshoppers, as well as a comment from Bayer CropScience which addresses a new AHETF open-cab tractor airblast applicator exposure study in orchards (MRID 464482-01). Several other comments received (i.e., clarifications or corrections for REI changes, application methods, or application rates for specific crops) have been incorporated in the revisions in the revised occupational risk assessment.

The USDA APHIS submitted a comment (FDMS Docket # EPA-HQ-OPP-2003-0376-0029) regarding the need to retain a maximum labeled treatment rate of 0.5 lb ai/A for the bait and liquid formulations to be effective for Mormon cricket and grasshopper suppression, which was not considered in the 2004 IRED, and specifying that the risks from carbaryl bait formulations are not necessarily the same as the risks from granular formulations of pesticides. Additionally, in subsequent communication with the Agency, APHIS and program managers from state-run allied programs provided additional information on the application of carbaryl bait formulations for suppression of Mormon cricket and rangeland grasshoppers, including refined use and usage data (i.e. pounds per acre, 2006 and 2007 acres treated, and hours of application per day); specifics and characteristics of aerial and ground application equipment; and additional information on seasonal application practices (i.e. applied once per season by local applicators).

In order to address USDA APHIS' concerns, the Agency assessed all bait and liquid carbaryl aerial applications (mixer/loader and applicator) at the maximum labeled application rate (0.5 lb ai/A). To assess the potential exposure/risk from the use of the aerial bait applications, the Agency used data for granular formulations applied aerially, which is the best data available to the Agency.

3. New Toxicological Methodology

The mode of action of carbaryl, and all NMC insecticides, is carbamylation of acetylcholinesterase. As described above, additional studies in adult and juvenile rats which describe the time-course and dose-response for brain and red blood cell (RBC) ChE inhibition have been received since the 2004 amended IRED. The occupational assessment for carbaryl was updated to reflect the recent ChE data and resulting toxicological PoDs.

Table 3 summarizes the dermal, inhalation, and cancer dose and endpoints used in the revised occupational risk assessment, and Table 4 compares the endpoints used in the 2003 and

2007 carbaryl risk assessments. Further discussion of the changes in the dermal and inhalation exposure scenarios follows.

Exposure Scenario	Point of Departure (mg/kg/day)	Uncertainty Factors (UF)	LOC for Risk Assessment	Study and Toxicological Effects
Dermal (short- and intermediate-term)	86	UF _A = 10X UF _H = 10X	MOE = 100 (adult)	Rat Adult Dermal Study (MRID 45630601), Brain ChE inhibition most sensitive, BMD ₁₀ = 49.35 mg/kg and BMDL ₁₀ = 30.56 mg/kg Adjusted by 2.8X to account for rat skin permeability compared to human skin (MRID 47151902)
Inhalation (short- and intermediate-term)	1.1	UF _A = 10X UF _H = 10X	MOE = 100	Oral Comparative ChE Study- (MRID 47143001) BMD ₁₀ = 1.5 mg/kg and BMDL ₁₀ = 1.1 mg/kg, based on brain ChE inhibition in post-natal day 11 (PND 11) pups
Cancer	Classification: "Likely to be carcinogenic in humans" Q ₁ * = 8.75 x 10 ⁻⁴ (mg/kg/day) ⁻¹			

UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. BMD₁₀ = Bench Mark Dose analysis using a 10% benchmark response for brain ChE inhibition. BMDL₁₀ = lower 95% confidence limit of the benchmark dose.

Exposure Pathway	Toxicology Endpoint for Risk Assessment	
	2003/2004 IREDs	2007 Revision
Dermal - short and intermediate term	Rat 4-week dermal toxicity study NOAEL of 20 mg/kg/day (LOAEL of 50 mg/kg/day for decreased RBC & brain ChE)	Rat 4-week dermal toxicity study BMDL ₁₀ of 30 mg/kg/day adjusted to 86 mg/kg/day using 2.8X dermal penetration factor to account for absorption across human skin
Dermal - long term	Chronic dog study LOAEL of 3.1 mg/kg/day and 3X to account for data deficiency (no NOAEL); dermal absorption factor of 12.7%	Long-term assessment is not appropriate for carbaryl due to rapid recovery of ChE inhibition
Inhalation - short term	Rat DNT study NOAEL of 1 mg/kg/day	Rat CCA Study Pup brain BMDL ₁₀ of 1.1 mg/kg/day
Inhalation - long-term	Chronic dog study LOAEL of 50 mg/kg/day and 3X to account for data deficiency (no NOAEL)	Long-term assessment is not appropriate for carbaryl due to rapid recovery of ChE inhibition
Cancer, all routes of exposure	Q ₁ * of 8.75 x 10 ⁻⁴ (mg/kg/day) ⁻¹ based on incidence of hemangiosarcomas in mice; classified as C carcinogen	

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. BMD₁₀ = Bench Mark Dose analysis using a 10% benchmark response for brain ChE inhibition. BMDL₁₀ = lower 95% confidence limit of the benchmark dose.

For more detail on the revised hazard assessment, refer to the June 29, 2007, *CARBARYL HED Chapter of the Reregistration Eligibility Decision (RED)*.

a. Dose-Response Assessment

EPA has developed a benchmark dose analysis for carbaryl using the same modeling methodology used in the NMC cumulative risk assessment. A benchmark dose analysis models the dose-response relationship with a dose-response curve, which allows selection of doses corresponding to a specified level of response, called a benchmark response. This analysis allows EPA to determine a more appropriate PoD from a toxicology study rather than using the study No Observable Adverse Effect Level (NOAEL) or Lowest Observable Adverse Effect Level (LOAEL). For more information on benchmark dose modeling, please see the EPA draft report, *Benchmark Dose Technical Guidance Document* (USEPA 2000).

b. Dermal Exposure

The 4-week dermal toxicity rat study with a NOAEL of 20 mg/kg/day established the PoD for both the short- and intermediate-term dermal scenarios in the 2003 IRED. The LOAEL of 50 mg/kg/day was based on significant decreases in RBC ChE in males and females and brain ChE in males. The long-term dermal (months to a lifetime) scenario relied on the chronic dog study that did not establish a NOAEL. The LOAEL of 3.1 mg/kg/day was based on plasma and brain ChE inhibition in females. An additional uncertainty factor of 3 was applied to account for the data deficiency.

Since the 2003 IRED, a benchmark dose (BMD) analysis from the same 4-week dermal adult rat study has provided the central estimate (BMD₁₀) and lower limit (BMDL₁₀) of the ChE data. As stated above, this BMD analysis is the same methodology used in the NMC cumulative risk assessment for the dermal exposure scenario. The benchmark dose analysis allows for a more accurate selection of a PoD than the previously used NOAEL approach, which is limited by dose levels selected in a given toxicology study. The BMD₁₀ is 49 mg/kg, which corresponds with the brain and RBC ChE inhibition observed at that LOAEL of 50 mg/kg. As in the NMC cumulative risk assessment, the BMDL₁₀ is used as the PoD. Therefore, the BMDL₁₀ of 30.56 mg/kg is the PoD for adults in the dermal short- and intermediate-term scenarios. The 10X intraspecies and 10X interspecies uncertainty factors are both applicable and an MOE of 100 defines the Agency's level of concern for dermal exposures. The FQPA factor is not applicable to the occupational scenarios.

The long-term dermal exposure duration is not appropriate for carbaryl since peak inhibition occurs rapidly with recovery occurring within hours. In 2003, EPA believed it was appropriate to evaluate long-term (> 6 months) and chronic exposure. However, this revised risk assessment does not include endpoints for long-term exposure because of the rapid recovery of enzyme activity from inhibition by carbaryl. Recent data for carbaryl and the other NMCs show that cholinesterase inhibition is reversible, with recovery in less than 24 hours and, therefore, daily exposure is independent of the previous day's exposure. Thus, for the occupational risk assessment, the daily exposure (short and intermediate-term) to carbaryl is the main duration of concern. An *in vitro* dermal absorption study was also evaluated. The study showed that

carbaryl was slowly absorbed through rat and human skin *in vitro* and that rat skin was about 2.8 times more permeable than the human skin at the low and mid dose. Therefore, the dermal PoD was adjusted by 2.8X to account for the differences in permeability between human and rat skin.

c. Inhalation Exposure

Inhalation studies are not available for carbaryl; instead, PoDs from oral studies were used. For the inhalation scenarios in the 2003 IRED, the NOAEL from a rat developmental neurotoxicity study was used as the PoD for the short-term exposure while the NOAEL from the rat subchronic neurotoxicity study was used for the intermediate-term exposure. The chronic dog study NOAEL was relied on for the long-term inhalation scenario. The updated inhalation PoD was selected from the recently conducted comparative cholinesterase study in which cholinesterase activity was measured in both postnatal day 11 (PND 11) and 17 pups and adult rats. The BMDL₁₀ of 1.1 mg/kg was selected for both children and adults. A 100% absorption factor is appropriate. The 10X FQPA factor is reduced to 1X since cholinesterase data from the most sensitive subpopulation is the basis of the PoD. As discussed previously, due to the rapid recovery of ChE inhibition a long-term inhalation assessment is not appropriate for carbaryl. The 10X intraspecies and 10X interspecies factors are applicable and an MOE of 100 defines the Agency's level of concern.

B. Summary of Revised Risk Assessments

Workers can be exposed to a pesticide through mixing, loading, and/or applying the pesticide, and from entering areas previously treated with the pesticide. For dermal and inhalation exposures, worker risk is estimated by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the benchmark response discussed in Section III.A.3 above. Refer to Table 3 for the toxicological PoDs used in the carbaryl occupational assessment. The risk assessments for all durations (short and intermediate term) of occupational exposures are similar because the toxicity PoDs are numerically the same and the target MOE of 100 is the same for all durations. Since carbaryl is currently classified as a "likely to be carcinogenic to humans," the Agency assessed both cancer and non-cancer risks for occupational handlers and post-application workers.

For carbaryl, MOEs that are greater than 100 and cancer risks within the range of an increased cancer risk of 1×10^{-6} generally do not exceed the Agency's level of concern. The Agency generally considers occupational cancer risks within the range of 1 to 3×10^{-6} (approximately 1-3 in 1 million persons) or less to be negligible. However, when occupational MOEs are less than 100 or occupational cancer risks exceed 3×10^{-6} , EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls.

1. Occupational Handler Exposure and Risk

Exposure of carbaryl to pesticide handlers (mixers, loaders, applicators and flaggers) is likely with the type of equipment and techniques that can potentially be used. Twenty-two occupational exposure scenarios were assessed based on registered labels, equipment, and techniques that could be used for carbaryl applicators. The scenario numbers correspond to the

non-cancer and cancer risk estimate tables presented in the *Carbaryl: Revisions to Occupational Exposure and Risk Assessment*, June 9, 2007. The quantitative exposure/risk assessment developed for occupational handlers is based on the following scenarios:

Mixer/Loader:

- (1a) Dry Flowable (DF) for Aerial/Chemigation in Agriculture;
- (1b) DF for Airblast;
- (1c) DF for Groundboom;
- (1d) DF for Applications;
- (1e) DF for Aerial Wide Area Uses;
- (2a) Granular for Aerial;
- (2b) Granular for Broadcast Spreader;
- (3a) Liquids for Aerial/Chemigation;
- (3b) Liquids for Airblast;
- (3c) Liquids for Groundboom;
- (3d) Liquids for Lawn Care Operators (LCO) Applications;
- (3e) Liquids for Aerial Wide Area Uses;
- (3f) Liquids for Ground Wide Area Uses;
- (4a) Wettable Powder (WP) for Airblast;
- (4b) WP for Groundboom;
- (4c) WP for LCO Applications;

Applicator:

- (5a) Aerial/Liquid Application;
- (5b) Aerial/Liquid Wide Area Application;
- (5c) Aerial/Granular Application;
- (6a) Airblast Application;
- (6b) Wide Area Ground Fogger (Airblast as surrogate);
- (7) Groundboom Application;
- (8) Solid Broadcast Spreader Application;
- (9) Aerosol Can Application;
- (10) Trigger Sprayer Ready-to-Use (RTU) Application;
- (11) High Pressure Handwand Application (Right of Way Sprayer as surrogate) [Occupational and Residential Exposure task Force (ORETF) Data];

Mixer/Loader/Applicator:

- (12) Turfgun Application;
- (13a) WP, Low pressure handwand;
- (13b) Liquid: Low Pressure Handwand;
- (14) Backpack;
- (15) Push-type Granular Spreader;
- (16) Handheld Fogger;
- (17) Powered Backpack;
- (18) Granular Backpack;
- (19) Tree Injection;
- (20) Drenching/Dipping Seedlings for Propagation;
- (21) Sprinkler Can;

Flagger:

- (22a) Flagging for Liquid Sprays; and
(22b) Flagging for Granular Applications.

As stated above, the 2004 amended IRED required various levels of PPE and EC for handler activities. In conducting its revised occupational non-cancer and cancer handler risk assessment, the Agency considered the following levels of PPE or EC:

- Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator (Baseline).
- Baseline plus chemical-resistant gloves, and no respirator (SL/G/NR).
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator (DL/GL/NR).
- Baseline plus chemical-resistant gloves and a protection level 5 respirator (SL/GL/PF5) or a protection level 10 respirator (SL/GL/PF10).
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and an a protection level 5 respirator (DL/GL/PF5) or a protection level 10 respirator (DL/GL/PF10).
- Engineering controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit (EC).

For each of the 22 handler scenarios above, the Agency considered numerous crops or target use sites with various application rates and area treated daily to reflect the way in which carbaryl can be applied (approximately 98 various use patterns were assessed). In addition, as discussed above, Bayer CropScience requested that the Agency consider a new AHETF open-cab tractor airblast applicator exposure study (MRID 464482-01) for the assessment of carbaryl airblast applications. The study considered two additional types of clothing/personal protective equipment (wide brimmed “Sou’Wester” hat and hooded Tyvek® jacket) that are not currently available in the PHED database. These additional 12 exposure scenarios are presented in the non-cancer and cancer (private and commercial farm worker) risk estimate tables 5, 8, and 9, respectively, in the *Carbaryl: Revisions to Occupational Exposure and Risk Assessment*, June 9, 2007.

a. Non-cancer Risk Summary

The non-cancer risk assessment considers all durations (both short- and intermediate-term) exposure to carbaryl, and dermal and inhalation exposures are combined. The Agency did not identify any new or additional risks of concern; non-cancer risks to workers are generally lower than those assessed in the 2004 amended IRED.

All but one use pattern either meet or are below the level of concern ($MOE \geq 100$) at some level of personal protection, and three use patterns did not have adequate data to quantify the risk estimates. Over half of the non-cancer risk estimates (50 of the 98 use patterns) were below the Agency’s level of concern, MOEs ranged from 100 to 26,000, when baseline PPE and chemical-resistant gloves were applied. Forty-four use patterns require additional PPE or engineering controls before the risk estimates are below the Agency’s LOC. These 94 use

patterns are not tabulated in this document; however, a detailed discussion of the required risk mitigation for all handler scenarios is in Section IV of this document. Additionally, all of the occupational handler non-cancer risk calculations are included in Appendix A of the July 9, 2007 *Revisions to Occupational Exposure and Risk Assessment*.

Table 5 presents the four handler use patterns with no data or that result in an MOE < 100 at the maximum level of protection (engineering controls).

Table 5. Summary of Occupational Handler Scenarios with Non-cancer Risks of Concern Or No Data				
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/ day) [unless noted]	Risk Summary	
			MOE (Baseline PPE)	PPE at which MOE > 100
Applicators				
5c Aerial: Agricultural Uses, Granular Applications	0.5 (APHIS grasshopper)	3,300	36 (with EC)	MOE = 36 with EC
Mixer/Loader/Applicators				
16 Handheld Fogger	1 (ornamentals) 0.15 (mosquito adulticide)	No Data	No Data	No Data
17 Power Backpack	2% solution (ornamentals)	No Data	No Data	No Data
19 Tree Injection	No Data	No Data	No Data	No Data
EC = Engineering Controls is the closed cab aircraft				

As noted in Table 5 above, EPA did not have data to evaluate worker exposure from use of a handheld fogger, power backpack sprayer, or tree injection. The Agency required worker exposure monitoring studies for these scenarios, as well as for dust formulations used in agriculture, in the March 2005 generic data call in for carbaryl. The sole technical registrant for carbaryl, Bayer CropScience, decided not to develop the necessary data to support these use scenarios and application methods for carbaryl. Bayer CropScience has requested that their carbaryl registrations be amended to remove these uses and application methods. (EPA is currently processing this request through the FIFRA 6(f) Process.) In addition, Bayer CropScience has informed the Agency that they will not be supporting any agricultural dust formulations of carbaryl, although Bayer CropScience does not have any such products. Bayer CropScience is not conducting the necessary worker exposure monitoring study to support carbaryl dust formulations used in agriculture.

Therefore, all carbaryl product registrants must also remove these uses and application methods from their carbaryl product reregistrations for the products to be eligible for reregistration. This will be addressed further in EPA's response to a petition from NRDC, which will be finalized by September 30, 2008.

Based on a comment to the IRED from the technical registrant, Bayer CropScience, EPA considered a new AHETF open-cab tractor airblast applicator exposure study for the assessment

of carbaryl airblast applications. The study considered two additional clothing/personal protective equipment scenarios (wide brimmed “Sou’Wester” hat and hooded Tyvek® jacket) that are not currently available in the PHED database. Table 6 summarizes the non-cancer risk estimates of the aerial airblast applicator exposure scenario using PHED data, as well as, from the additional PPE (wide brim Southwester Hat and hooded tyvek jacket). The PPE worn during the study included double layer, gloves, but no respirator. In comparison to estimates using the PHED data, some of the crops assessed resulted in reduced risk (i.e., less levels of PPE required); these MOEs are italicized in Table 6. The non-cancer risk calculations for airblast application using PHED data and AHETF open-cab tractor airblast applicator exposure study results are included in Appendix B of the July 9, 2007 *Revisions to Occupational Exposure and Risk Assessment*.

Table 6. Summary of Non-cancer Risks For Carbaryl Airblast Applicators Based on AHETF and PHED data				
Scenario	Rate (lb ai/acre)	Acres/day	Risk Summary	
			MOEs with PPE in AHETF study	PPE at which MOE > 100 using PHED
Open Cab Airblast (Double Layer, Gloves, No Respirator, Wide Brimmed "Sou'Wester" Hat)				
6a Airblast: Agricultural Uses	12 (citrus trees, CA 24C)	40	40	EC
	8 (citrus trees, FL 24C)		60	DL/GL/PF10
	7.5 (stone fruit (olives))		64	DLHD/GL/PF5
	5 (citrus and nut trees)		97	DLHD/GL/PF5
	3 (pome and stone fruit)		160	SL/GL/PF5
	2 (grapes)		240	Baseline
Open Cab Airblast (Double Layer, Gloves, No Respirator, Hooded Tyvek® Jacket)				
6a Airblast: Agricultural Uses	12 (citrus trees, CA 24C)	40	84	EC
	8 (citrus trees, FL 24C)		130	DL/GL/PF10
	7.5 (stone fruit (olives))		130	DLHD/GL/PF5
	5 (citrus and nut trees)		200	DLHD/GL/PF5
	3 (pome and stone fruit)		340	SL/GL/PF5
	2 (grapes)		500	Baseline

Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator. (Baseline).

Baseline plus chemical-resistant gloves, and no respirator (SL/G/NR).

Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator (DL/GL/NR).

Baseline plus chemical-resistant gloves and a protection level 5 respirator (SL/GL/PF5) or a protection level 10 respirator (SL/GL/PF10).

Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and a protection level 5 respirator (DL/GL/PF5) or a protection level 10 respirator (DL/GL/PF10).

Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit (EC).

b. Cancer Risk Summary

Occupational handler cancer exposure and risk calculations and results are presented in this section. Cancer risks were calculated using a linear low-dose extrapolation approach in which a Lifetime Average Daily Dose (LADD) is first calculated and then compared with a Q_1^* that has been calculated for carbaryl based on dose response data from the appropriate toxicology study ($Q_1^* = 8.75 \times 10^{-4} \text{ (mg/kg/day)}^{-1}$). Absorbed average daily dose (ADD) levels were used as the basis for calculating the LADD values.

In order to calculate cancer risk, ADD values are amortized over the lifetime of occupational handlers resulting in LADD values. Product labels limit use to every 7 to 10 days or a seasonal "lb ai per acre" limit. Also, according to available use/usage data, on average, carbaryl is applied more than once per year for most crops. Based on this information and due to the number and variety of target insects and crops registered for carbaryl applications, the Agency considered two distinct populations in the cancer risk assessment including private growers at 10 use events per year and commercial farm workers that would have a more frequent use pattern of 30 days per year. Therefore, cancer risks for occupational handler exposures are calculated separately for private growers and for commercial applicators. A 35 year career and a 70 year lifespan were used to complete the calculations.

Occupational cancer risks equal to or less than 1×10^{-6} (1 in 1 million) are not of concern to the Agency. However, the Agency generally considers occupational cancer risks within the range of 1 to 3×10^{-6} (approximately 1-3 in 1 million persons) or less to be negligible. Since the Q_1^* was not altered since the IRED, many of the reassessed exposure scenarios are the same; however, those scenarios which have changes in application rate, acreage, or unit exposure required revision.

The Agency did not identify any new or additional risks of concern; cancer risks for private growers and commercial farm workers are generally lower than those assessed in the 2004 amended IRED. Of the 98 use pattern combinations considered for private growers and commercial applicators, all have risks less than or within the range of 1 to 3×10^{-6} with various amounts of PPE or with engineering controls. Therefore, these 98 use patterns are not tabulated in this document; however, as stated previously, a detailed discussion of the required risk mitigation for all handler scenarios is in Section IV of this document. For the complete occupational handler cancer (private growers and commercial farm worker) risk calculations, refer to Appendix A of the July 9, 2007 *Revisions to Occupational Exposure and Risk Assessment*.

Further, as discussed previously, Bayer CropScience requested that EPA consider a new AHETF open-cab tractor airblast applicator exposure study for the assessment of carbaryl airblast applications. Table 7 summarize the cancer risk estimate results of the aerial airblast applicator exposure scenario using PHED data, as well as cancer risk estimates resulting from the additional equipment (wide brim Southwester Hats and hooded tyvek jackets) for commercial growers. PPE worn during the study included double layer, gloves, and no respirator. In comparison to estimates using PHED data, all of the crops assessed resulted in reduced risk (i.e., less levels of personal protection required); these risk estimates are italicized in Table 7. The citrus tree, Florida (FL) 24C (8 lbs ai/acre) and stone fruit, olive (7.5 lbs ai/acre) crops resulted in a reduction of the level of personal protection required for commercial growers for the hooded jacket protective equipment scenario only.

Table 7. Summary of Cancer Risks For Commercial Applicator Carbaryl Airblast Applicators Based on PHED and AHETF study				
Scenario	Rate (lb ai/acre) [unless noted]	Acres/ Day	Risk Summary	
			Commercial Growers	
			Risk with PPE in AHETF study	Min. Req. PPE using PHED for risk estimate $\leq 3 \times 10^{-6}$
Open Cab Airblast (Double Layer, Gloves, No Respirator, Wide Brimmed "Sou'Wester" Hat)				
6a Airblast: Agricultural Uses	12 (citrus trees, CA 24C) 8 (citrus trees, FL 24C) 7.5 (stone fruit (olives)) 5 (citrus and nut trees) 3 (pome and stone fruit) 2 (grapes)	40	3×10^{-6} 2×10^{-6} 2×10^{-6} 1×10^{-6} 7×10^{-7} 5×10^{-7}	EC DL/GL/PF5 DL/GL/PF5 DL/GL/NR Baseline Baseline
Open Cab Airblast (Double Layer, Gloves, No Respirator, Hooded Tyvek® Jacket)				
6a Airblast: Agricultural Uses	12 (citrus trees, CA 24C) 8 (citrus trees, FL 24C) 7.5 (stone fruit (olives)) 5 (citrus and nut trees) 3 (pome and stone fruit) 2 (grapes)	40	2×10^{-6} 1×10^{-6} 1×10^{-6} 8×10^{-7} 5×10^{-7} 3×10^{-7}	EC DL/GL/PF5 DL/GL/PF5 DL/GL/NR Baseline Baseline

Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator (Baseline).

Baseline plus chemical-resistant gloves, and no respirator (SL/G/NR).

Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator (DL/GL/NR).

Baseline plus chemical-resistant gloves and a protection level 5 respirator (SL/GL/PF5) or a protection level 10 respirator (SL/GL/PF10).

Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and a protection level 5 respirator (DL/GL/PF5) or a protection level 10 respirator (DL/GL/PF10).

Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit (EC).

2. Occupational Post-application Risks and Exposure

The Agency uses the term “post-application” to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). To assess post-application exposures and risks, the Agency estimates the amount of contact with a treated surface a worker likely would have while doing a specific post-application task or activity, such as hand harvesting, conducting scouting activities, crop maintenance tasks (e.g., irrigating, hoeing, and weeding), and turf maintenance. To determine the amount of post-application exposure for each crop and post-application activity, the EPA used dislodgeable foliar residue (DFR) and turf transferable residue (TTR) data in the post-application risk assessment. The Agency’s standard TCs were also used to assess worker reentry exposures. As discussed in Section III.A.1 above, the occupational post-application risk assessment was revised to incorporate a DFR study from chrysanthemums, and changes in the TCs to the crop/activity groupings.

Post-application exposures are calculated by multiplying the DFR or TTR concentrations and TC factors by an 8 hour work day. Exposures are then normalized by body weight and adjusted for dermal absorption (if necessary) to calculate absorbed doses. Risk estimates were then calculated. Post-application risks diminish over time because carbaryl residues eventually dissipate in the environment. As a result risk values were calculated over time based on changing residue levels. Further, the durations of exposure anticipated for re-entry workers exposed to carbaryl based upon use criteria are short- and intermediate-term. Inhalation exposures are thought to be negligible in outdoor post-application scenarios because of the low vapor pressure and due to the infinite dilution expected outdoors. Therefore, only dermal post-application exposures are considered in this assessment.

Similar to the occupational handler risk assessment, the Agency considered both non-cancer and cancer risks to post-application exposure to carbaryl. Post-application risk levels are generally calculated in the risk assessment process on a chemical-, crop-, and activity-specific basis. 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 and cancer risk estimates are less than or within the range of 1 to 3×10^{-6} while wearing baseline attire. Increasing levels of PPE is not considered a viable approach for mitigating post-application risks, so PPE is not used when calculating MOEs or cancer risk estimates; instead, an administrative approach is used to reduce the risks, referred to as the restricted entry interval (REI). The REI is a measure of the amount of time required to pass after application of a pesticide before engaging in a task or activity in a treated field. To establish REIs, the Agency considers post-application risks on varying days after application. In the IRED, the carbaryl REIs were largely extended beyond the current Worker Protection Standard of 12 hours.

a. Occupational Postapplication Exposure and Non-cancer Risk Estimates

All but one of the short-/intermediate-term post-application worker risk estimates resulted in MOEs that either meet or reduce REIs established by the carbaryl IRED. The cut flower crop groupings assessed using exposure data from the state of Washington resulted in MOEs which increase previously established REI. The majority of the post-application scenarios assessed do not exceed the Agency's non-cancer level of concern ($\text{MOEs} \geq 100$) on the day of application approximately 12 hours following application. The MOEs range from 100 to 6,200 and are, therefore, not tabulated in this document. A summary of the results for each post-application crop/activity combination considered is detailed in the Appendix C of the *Carbaryl: Revisions to Occupational Exposure and Risk Assessment*, dated July 9, 2007.

There are, however, ten use-sites and/or certain activities for some use sites that exceed the Agency's non-cancer level of concern, and require an REI longer than 12 hours before the MOE of ≥ 100 is reached. Table 8 presents these post-application scenarios. A detailed discussion of the required risk mitigation for all post-application scenarios is in Section IV of this document.

Table 8. Carbaryl Post-Application Non-Cancer Risk Estimates Where the MOE < 100 on Day of Application (REI 12 hours)

TC Group [Crops] (lbs ai/A)	Post-Application Activity	Non-Cancer Risk Estimate (MOE when REI=12 hours)
Bunch/Bundle [Hops & Tobacco] (2 lb ai/A)	Hand harvesting, stripping, training, thinning, topping, mechanical hop harvest	88
Cut Flowers (2 lb ai/A)	Irrigation, scouting, thinning, weeding immature/low foliage plants	48
	Irrigation, scouting mature/high foliage plants	30
	Hand harvesting, pruning, thinning, pinching	23
Field/row crop, tall [Corn] (2 lb ai/A)	Hand harvesting or detasselling	6
Turf/grass seed production [Golf course & sod farm] (8.2 lb ai/A)	Harvesting	98
Vine/Trellis [Grapes] (2 lb ai/A)	Hand harvest, leaf pulling, thinning, pruning, training/tying grapes	63
	Cane turning and girdling	31

b. Occupational Postapplication Exposure and Cancer Risk Estimates

EPA assessed the post-application exposure to carbaryl to both hired hand and migrant agricultural workers. The Agency assumed private growers and hired hands would perform post-application activities 10 days per year and migrant workers would perform post-application activities 30 days per year. As stated in the section above, the Agency generally considers occupational cancer risks within the range of 1 to 3 x 10⁻⁶ (approximately 1-3 in 1 million persons) or less to be negligible.

The use of dissipation data and the manner in which daily post-application dermal exposure values were calculated are inherently different than with handler exposures. Lifetime Average Daily Dose (LADD) levels were calculated by amortizing single day re-entry exposures over a lifetime. For carbaryl, the Agency used the same values used in the short- and intermediate-term assessment referred to above for private growers (10 days per year) and migrant workers (30 days per year) to calculate the LADD.

Since the *QI** has not changed since the carbaryl IRED, the cancer risk for many of the reassessed exposure scenarios remain the same. However, some scenarios have been revised because of changes in application rate or revised TCs as discussed in Section III.A.1. Cancer risks estimated for private growers (10 days/year) are generally in the 10⁻⁸ to 10⁻⁶ range. The highest exposures for private growers are in the 10⁻⁶ range. Cancer risks estimated for commercial farm workers (30 days/year) generally fall in the 10⁻⁷ to 10⁻⁶ range. The highest exposures for commercial growers are in the 10⁻⁵ range. The post-application scenarios with cancer risk estimates less than 1x10⁻⁶ are not tabulated in this document. A summary of the

results for each post-application crop/activity combination considered is detailed in the Appendix C of the *Carbaryl: Revisions to Occupational Exposure and Risk Assessment*, dated July 9, 2007.

There are, however, eleven use-sites and/or certain activities for some use sites that exceed the Agency's cancer level of concern, and require an REI longer than 12 hours before the cancer risk estimates are within the range of 1 to 3×10^{-6} . Table 9 presents the worst case cancer risk estimates since the Agency assumed migratory workers are exposed to post-application residues of carbaryl for 30 days per year for 35 years. A detailed discussion of the required risk mitigation for all post-application scenarios is in Section IV of this document.

TC Group [Crops] (lbs ai/A)	Post-Application Activity	Cancer Risk Estimate (30 days/yr for 35 years)
Bunch/Bundle [Hops & Tobacco] (2 lb ai/A)	Hand harvesting, stripping, training, thinning, topping, mechanical hop harvest	4×10^{-6}
Cut Flowers (2 lb ai/A)	Irrigation, scouting, thinning, weeding immature/low foliage plants	5×10^{-6}
	Irrigation, scouting mature/high foliage plants	8×10^{-6}
	Hand harvesting, pruning, thinning, pinching	1×10^{-5}
Evergreen Fruit Trees [Avocados, conifers, dates, grapefruit, lemons, mangoes, oranges, papaya] (CA only- 12 lb ai/A)	Harvesting, pollination, bagging, tying, misc. hand labor, staking, topping, training	4×10^{-6}
Field/row crop, tall [Corn, sunflowers, sorghum, sweet corn] (2 lb ai/A)	Scouting, irrigation, weeding mature/full foliage plants	4×10^{-6}
	Hand harvesting or detasselling ¹	6×10^{-5}
Nuts Trees [Olives] (7.5 lb ai/A)	Harvesting/poling, pruning, thinning	4×10^{-6}
Vine/Trellis [Grapes] (2 lb ai/A)	Hand harvest, leaf pulling, thinning, pruning, training/tying grapes	6×10^{-6}
	Cane turning and girdling	1×10^{-5}

¹Handharvesting of sweet corn is prohibited per the 2004 amended IRED; the REI for hand detasseling is 30 days.

3. Poisoning Incident Data for Carbaryl

The Agency reviewed available sources of human incident data for incidents relevant to carbaryl. The following sources were used: 1) The OPP's Incident Data System (IDS), comprised of reports of adverse effects submitted by registrants, other federal and state health and environmental agencies and the public through FIFRA 6(a)2 since 1992; 2) California Department of Pesticide Regulation's pesticide poisoning surveillance program, comprised of

reports from physicians of illness suspected of being related to pesticide exposure since 1982; 3) National Institutes of Occupational Safety and Health (NIOSH) Sentinal Event Notification System for Occupational Risks (SENSOR), which provides surveillance in seven states from 1998 through 2003; and 4) Poison Control Center (PCC) data covering the years 1993 through 2005 for all pesticides. Symptoms captured in these reports ranged from nervous/sensory (headache, confusion, and dizziness), gastrointestinal (nausea), respiratory (pain/irritation, shortness of breath, irritation), ocular symptoms (eye pain/irritation/ inflammation, and lacrimation), dermal symptoms (erythema, rash, and pruritis), and miscellaneous (alkalosis). EPA's review of the human incident data for carbaryl can be found in the September 21, 2007, *Review of Carbaryl Incident Reports*.

The IDS reported 160 incident cases for carbaryl between the years 2000 and 2006. Of these, 19 cases were the result of misuse (15) or suicide attempts (4). The California Pesticide Illness Surveillance Program (PISP, 2000-2005) reported 11 cases for carbaryl. In 6 of these cases, carbaryl was used alone or was judged to be responsible for the health effects. The NIOSH SENSOR database reports 75 cases involving carbaryl alone (of 5,899 reported cases of pesticide poisonings from 1998 to 2003). Most of the incidents involved residential uses of carbaryl, which are not addressed in this document.

EPA investigated one reported incident in particular. At issue was an incident where twenty-one farmer workers in Florida were taken to emergency rooms on April 9, 2003 after a number of harvesters (fourteen) complained of difficulty breathing, headaches, dizziness, and nausea. EPA conducted a comprehensive investigation of the incident and in particular the role carbaryl may have played. The information available to the Agency does not appear to support a conclusion that the severity of symptoms reported by Florida citrus harvesters in April 2003 can be attributed to carbaryl exposure resulting from contact with foliar residues. During the summer of 2005, EPA met with non-profit advocacy groups that were particularly concerned with this incident to discuss these findings.

IV. Risk Management

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (technical or manufacturing-use grade) data required to support reregistration of products containing carbaryl as an active ingredient. EPA has completed its review of submitted data and its assessment of occupational risks associated with the use of pesticide products containing the active ingredient carbaryl.

Based on the evaluation of the occupational uses of carbaryl described in this document, the September 24, 2007 RED, and in the October 2004 carbaryl IRED amendment, the Agency has determined it has sufficient information on the human health effects to make decisions as part of the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that carbaryl-containing products are eligible for reregistration provided that: (i) the

worker risk mitigation measures outlined in this document are adopted and (ii) label amendments are made to reflect these measures. Label changes are described in Section V of this document.

Further, based on its evaluation of occupational uses of the active ingredient carbaryl, 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 risk concerns from the use of carbaryl. If all changes outlined in this document are incorporated into the product labels, then all current occupational handler and post-application risks for carbaryl will be adequately mitigated for the purposes of this determination under FIFRA.

B. Occupational Risk Mitigation and Regulatory Rationale

It is the Agency's policy to mitigate occupational risk to the greatest extent practical and feasible. Occupational exposure assessments are completed by the Agency considering the use of baseline PPE, and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for carbaryl is 100, based on information provided in Section III of this document. For occupational cancer risks, estimates within the negligible risk range of up to 3×10^{-6} do not exceed the Agency's level of concern. When occupational MOEs are estimated to be less than 100 or occupational cancer risk estimates greater than the general range of 3×10^{-6} , EPA strives to reduce worker risks through the use of PPE and engineering controls or other mitigation measures.

In addition, a wide range of factors are considered in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs and cancer risk estimates, incident data, the nature and severity of adverse effects observed in the animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other factors.

1. Handler Risk Mitigation

As stated in Section III, over half of the non-cancer and cancer risk estimates for occupational handlers were mitigated through the use of baseline PPE and gloves, and almost all could be mitigated with additional PPE or engineering controls. However, as summarized in Table 5, some handler scenarios either did not have data to quantify the risk or could not be mitigated with PPE or engineering controls. Therefore, additional discussion and consideration of the risks and benefits of the use pattern is necessary. Following the implementation of the formulation specific and activity specific risk mitigation measures for the scenarios, handler risks will no longer be of concern to the Agency (see Table 11). The registrants have agreed to the following mitigation:

Mixing, Loading, and Applying Liquid Formulations of Carbaryl

All handler scenarios of the liquid formulation of carbaryl (scenarios 3b, 3c, 3d, 3f, 7, 10, 11, 12, 13a, 13b, 14, 17, 20, and 21) except for those which utilize airblast equipment (6a, 6b) and handheld foggers (16), and mixers and loaders supporting aerial or chemigation applications

(3a, 3e), are below the Agency's non-cancer ($\text{MOEs} \geq 129$) and cancer LOCs ($\leq 2.6 \times 10^{-6}$) with baseline PPE and chemical-resistant gloves.

Additional risk mitigation specific to handlers utilizing airblast (6a, 6b) and handheld foggers (16) and mixers and loaders supporting aerial and chemigation applications are discussed below.

Airblast and Handheld Foggers Handler Scenarios

For applicators of the liquid formulation utilizing airblast equipment (6a), applying a rate < 5 lb ai/A (pome and stone fruit, and grapes) the non-cancer ($\text{MOEs} \geq 161$) and cancer ($\leq 5.3 \times 10^{-7}$) risk estimates are below the Agency's LOC with baseline PPE, chemical-resistant gloves, and a protection level 5 respirator (SL/GL/PF5). For applications ≥ 5 lb ai/A (citrus, nut trees, and olives) the non-cancer ($\text{MOEs} \geq 100$) and cancer ($\leq 1 \times 10^{-6}$) risk estimates are below the Agency's level of concern with coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and a protection level 5 respirator (DL/GL/PF5). One airblast scenario (applying carbaryl via airblast equipment to citrus trees in Florida), however, resulted in an MOE of 94¹ with this level of PPE. Since additional PPE (full face PF 10 respirator) will only marginally reduce the non-cancer risk estimate ($\text{MOE} = 113$), and instead may cause additional heat related stress to workers, the Agency has determined additional PPE will be an undo burden and cost and is not required for this scenario.

However, engineering controls are required for handlers applying the liquid formulation with airblast equipment on citrus in California (6a) and for wide area mosquito adulticide programs (6b). With PPE of DL/GL/PF5, the MOE for handlers applying carbaryl via airblast equipment to citrus in California (24c registration at 12 lb ai/A) was only 62, and applying the maximum amount of PPE (i.e. DL/GL/PF10) only slightly increased the MOE to 76. Additionally, with DL/GL/PF5, the cancer risk estimate for handlers applying carbaryl via airblast for wide area mosquito adulticide applications was 4×10^{-6} , and the risk estimate stayed the same at the maximum level of PPE. However, with engineering controls, the risk estimates for these two scenarios were below the Agency's LOCs, $\text{MOE} > 481$ and $< 6 \times 10^{-7}$, respectively.

The PPE and EC requirements for the airblast scenarios (6a) discussed above are generally reduced compared to those required in the IRED (see Table 11 below). The Agency did consider the exposure study submitted by the AHETF "Determination of Dermal and Inhalation Exposure to Workers during Application of a Liquid Pesticide Product by Open Cab Airblast Application to Orchard Crops" (MRID 464482-01) in Section III.B.1 (Tables 6 and 7) above. However, the Agency determined since it was able to achieve acceptable MOEs with the standard suite of PPE or ECs, it did not need to require the additional burden to occupational handlers of wearing wide brimmed Southwester Hats and hooded tyvek suits (with additional headgear).

As previously mentioned, EPA does not have the necessary data to evaluate worker exposure from use of a handheld fogger, power backpack sprayer, or tree injection, and therefore cannot make a reregistration eligibility decision for these scenarios. Although worker exposure

¹ For Carbaryl, the Agency believes an MOE in the mid-90s is not significantly different from an MOE of 100.

monitoring studies were required for these scenarios in the March 2005 generic DCI for carbaryl, the carbaryl registrant, Bayer CropScience, decided to delete these use scenarios from their registered carbaryl products rather than develop these data. Therefore, all carbaryl product registrants must remove the uses and application methods associated with these scenarios from their carbaryl product reregistrations for the products to be eligible.

Aerial and Chemigation Handler Scenarios

Additional PPE is required for mixers and loaders supporting aerial or chemigation applications (3a, 3e). In addition to baseline PPE and chemical resistant gloves, these handlers must also wear a protection 5 level respirator (SL/GL/PF5). With this additional PPE, all scenarios, except for one, are below the Agency's non-cancer ($MOEs \geq 120$) and cancer ($\leq 2.9 \times 10^{-6}$) LOCs. The MOE for scenario 3a, mixing and loading activities to support aerial or chemigation applications at a rate of 1.5 lb ai/A and 1,200 acres a day, is 80 with this level of PPE. However, the Agency believes that the assumptions used for this scenario are highly conservative. The rate assessed, 1.5 lb ai/A, is the maximum application rate, where as the average application rate of 1 lb ai/A was also assessed and resulted in an MOE of 120 with PPE of SL/GL/PF5. Additionally, the assumption of 1,200 acres treated a day is believed to be an overestimation according to carbaryl use estimates. Based on Agency data (see Table 1), approximately 30,000 lb ai of carbaryl is estimated to be applied to less than 1% of all corn acreage in the US². Therefore, the Agency believes the area treated per day would actually be a much smaller area than 1,200 acres and, therefore, a handler would not be mixing and loading the amount of ai necessary for an application to an area of this size. Considering all of these factors, and the fact that increasing the PPE to a full face respirator with a protection level of 10 would only slightly increase the MOE above 100 (MOE=103), the Agency does not feel the additional PPE is warranted, and that PPE consisting of SL/GL/PF5 is protective for this scenario.

For aerial applications (5a, 5b, 5c), pilots must be in an enclosed cockpit. Moreover, human flagging (22a) is prohibited, except for flagging to support state sponsored aerial applications and the USDA APHIS Rangeland Grasshopper and Mormon Cricket Suppression Program. In these instances, human flaggers must wear the following PPE: baseline, chemical resistant gloves, and a protection level 5 respirator (SL/GL/PF5) (MOE=144).

Loading and Applying Granular and Bait Formulations of Carbaryl

All handler scenarios assessed for the granular and bait formulations of carbaryl (2b, 8, and 15) except for scenarios involving aerial applications, are below the Agency's non-cancer ($MOEs \geq 109$) and cancer ($\leq 8 \times 10^{-6}$) LOCs with baseline PPE.

Applications by hand, spoon, shaker can, and backpack spreaders (front and back mounted) are prohibited per the 2004 Amended RED. Additionally, all aerial applications of the granular or bait formulations of carbaryl are prohibited, except for aerial applications through the

² An average of approximately 75 million acres of field corn were grown in the US between 2003 and 2007 (USDA National Agricultural Statistics Service).

USDA APHIS Rangeland Grasshopper and Mormon Cricket Suppression Program (2a), and state-run allied programs.

Aerial Applications

The Agency assessed the maximum application rate of 0.5 lb ai/A for handlers loading bait formulations into aircraft for use in Rangeland Grasshopper and Mormon Cricket Suppression Programs (2a), and the following PPE is required: baseline PPE, chemical resistant gloves, and a protection level 5 respirator (SL/GL/PF5).

In addition, as presented in Table 5 previously, the non-cancer risk estimate for applicators applying the bait formulation aerially (5c) is the only handler scenario that cannot be mitigated to an $MOE \geq 100$ through PPE or engineering controls ($MOE=36$). Alternative mitigation measures, such as reduction in application rate or daily treated area are also not an option for this use scenario. The application rate and area treated daily are specific to the success and effectiveness of these suppression programs.

As stated in the Agency's response to comments, *BEAD's Response to Comments Submitted by Stakeholders on EPA's Impact Assessments for Carbaryl*, dated December 15, 2006, a review of available literature and recent FIFRA Section 18 Emergency Exemptions indicates that the most effective baits for controlling both immature and adult populations of grasshoppers and Mormon crickets are based on carbaryl as the active ingredient. Therefore, the Agency recognizes the need for the continued use of carbaryl, and has not prohibited this activity for APHIS and related state programs. In addition, there are several factors the Agency believes reduces the actual applicator exposure, and thus decreases the subsequent risk estimate (i.e. $MOE > 36$).

First, the Agency anticipates the actual handler exposure to be less than assessed due to the nature of the bait formulation used in these Programs. A carbaryl pelletized bait product is used, which is expected to produce much less dust than typical granular formulations. In granular formulations, the active ingredient is applied to the surface of a carrier (the granule) and bound to the surface of that carrier with a binder or sticking agent that will keep most of the active ingredient on the carrier in transit, but will allow the active ingredient to release when the granular is applied. However, unlike a granular in which the active ingredient is applied to the surface of the carrier, pellet formulations are homogenous blends (the active ingredient is incorporated throughout the pellet) of the active ingredient carrier. The materials are tightly compressed, and are typically extremely dense. Therefore, the active ingredient is not anticipated to separate from the pellet during application and, thus, the product is less dusty. However, the Agency does not have specific exposure information for baits to include in its assessment. Instead, the Agency relied upon exposure data in PHED for typical granular formulations for use in its risk assessment. While the exposure information in the PHED is considered to be the best available, the Agency recognizes that both the inhalation and dermal exposure to carbaryl from the bait is most likely less than what is currently available in PHED.

A flaky bran wheat bait formulation has also been applied by APHIS and state Agencies in the Rangeland Grasshopper and Mormon Cricket Suppression Programs. However, all flaky wheat registrations have been voluntarily canceled per the registrant during the product

reregistration process following the 2004 Amended RED. The Agency does not have the same level of confidence that the flaky bran wheat formulation would produce less dust than a traditional granular formulation. Therefore, if this formulation were to be registered in the future, the Agency would require a perceived dust study to support its use.

Further, the aircraft used and application practices associated with this Program are likely to result in reduced exposure as well. According to APHIS³, cockpits are enclosed with air intake into the cockpit from above the bait release point, and the bait bin is completely separate from the cockpit. Finally, according to APHIS, workers employed in the APHIS and state-run allied programs are highly trained, making inadvertent exposure due to mishandling of the products during loading and application activities less likely as well.

Although the current MOE for this use scenario is above the Agency's non-cancer LOC, EPA believes that this is an overestimation of risk. EPA expects actual worker exposure, and risk, to be much lower, due to the formulation type, aircraft features, and extensive training of handlers, although this cannot be quantified. Therefore, the Agency has determined that carbaryl bait products that are applied aerially are eligible for reregistration given the following engineering control requirements:

“Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. In addition, the air intake into the cockpit must be located above the bait release point and the bait bin must be completely separate from the cockpit.”

Loading and Applying Wettable Powder and Dry Flowable Formulations of Carbaryl

Based on the risk mitigation established in the 2004 amended IRED, all wettable powder and dry flowable products must be formulated in water-soluble packaging. The use of water-soluble packaging was considered in the risk assessment, and as such resulted in a reduction in PPE for occupational handlers. For all use scenarios assessed, the non-cancer and cancer risk estimates were below the Agency's LOCs with baseline PPE and chemical resistant gloves (MOE ≥ 100 and $\leq 2 \times 10^{-6}$).

All dry flowable (water dispersible granule) products have been voluntarily canceled by the registrant, and a prohibition statement has been added to the Manufacturing Use Product label (see table 13).

Applying Ready-to-Use Dust Formulations of Carbaryl

In response to the 2004 data call-in, the registrants voluntarily canceled dust formulations with agricultural use. Residential use dust formulations were assessed in the 2007 RED. However, there are ready-to-use dust formulations that can be applied by both pest control operators and homeowners. The Agency referred to the risk assessment completed for the 2007 RED, and revised the scenario to assume 2 dust containers applied (versus 1 container used for residential applications). The combined dermal and inhalation MOE was 278 and the cancer risk

³ USDA APHIS comments to the amended carbaryl IRED; see docket EPA-HQ-OPP-2005-0077-029 for details.

estimate was in the 10^{-8} range with baseline PPE and, therefore, below the Agency's level of concern.

2. Post-Application Risk Mitigation

For all post-application risk scenarios assessed, with one exception for cut flowers, the short-/intermediate-term post-application worker risk estimates result in higher MOEs than those reported in the 2004 amended IRED. As a result, EPA has reduced most REIs to the minimum 12 hours established by the worker protection standard. However, as summarized in Tables 8 and 9 previously, eleven crop/post-application activities were above the Agency's non-cancer and cancer LOCs, respectively, with an REI of 12 hours. These scenarios require extended REIs, ranging from 24 hours to 23 days. Table 10 summarizes the REI needed for both the non-cancer and cancer risk estimates to be below the Agency's LOCs. In most cases, both the non-cancer and cancer risk estimates required an extended REI; however, to be protective, the longer REI (bolded below) will be established to ensure the REI is protective of both non-cancer and cancer risks. In addition, the REI established for the highest exposure scenario for each crop, or crop grouping, will also be selected in order to be protective of all post-application activities for that group.

TC Group [Crops] (lbs ai/A)	Post-Application Activity	REI for MOE ≥ 100	REI for cancer risk estimate ≤ 3x10⁻⁶
Bunch/Bundle [Hops & Tobacco] (2 lb ai/A)	Hand harvesting, stripping, training, thinning, topping, mechanical hop harvest	24 hours	2 days
Cut Flowers (2 lb ai/A)	Hand harvesting, pruning, thinning, pinching	18 days	15 days
Evergreen Fruit Trees [Avocados, conifers, dates, grapefruit, lemons, mangoes, oranges, papaya] (CA only- 12 lb ai/A)	Harvesting, pollination, bagging, tying, misc. hand labor, staking, topping, training	12 hours	3 days
Field/row crop, tall [Corn] (2 lb ai/A)	Scouting, irrigation, weeding mature/full foliage plants	12 hours	24 hours
	Detasselling	21 days	9 days
	Hand harvesting ¹	Prohibited	
Nut Trees [Olives] (7.5 lb ai/A)	Harvesting/poling, pruning, thinning	12 hours	3 days

Table 10. Carbaryl Post-Application Non-Cancer Risk Estimates MOE < 100 on Day of Application (REI 12 hours)

TC Group [Crops] (lbs ai/A)	Post-Application Activity	REI for MOE ≥ 100	REI for cancer risk estimate ≤ 3x10 ⁻⁶
Turf/grass seed production [Golf course & sod farm] (8.2 lb ai/A)	Harvesting	24 hours	12 hours
Vine/Trellis [Grapes ²] (2 lb ai/A)	Hand harvest, leaf pulling, thinning, pruning, training/tying grapes	East³ - 2 days West³ - 6 days	East³ - 2 days West³ - 6 days
	Cane turning and grape girdling	East³ - 6 days West³ - 6 days	East³ - 6 days West³ - 6 days

¹Hand harvesting of sweet and field corn is prohibited per the 2004 amended IRED.
²With REIs of 2 and 6 days, the cancer risk estimates are 8x10⁻⁶ and 6x10⁻⁶, respectively.
³East and West of the Rocky Mountains.

Hand harvesting of sweet and field corn is prohibited per the 2004 amended IRED, and the REI for detasseling is 30 days. 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 developed for seed production. Per the revised risk assessment, an REI of 21 days is required to protect workers for both hand harvesting and detasseling. Carbaryl is sometimes applied to sweet corn grown for fresh market consumption and during periods when harvesting occurs. The preharvest interval for ear harvest is 2 days; therefore, a 21 day REI for hand harvesting is impractical. Therefore, this activity will continue to be prohibited.

In addition, for brassica crops, leafy vegetables, table beets, and turnips when harvested for greens, use was restricted to applications only within 30 days of crop emergence/transplanting in the 2004 amended IRED. This was due in part to the extended REIs associated with higher exposure activities such as scouting and hand harvesting. In addition, as stated in the IRED, carbaryl is used early in the season and generally only within 30 days of planting and, therefore, carbaryl applications only coincide with low-exposure activities such as weeding and irrigation. However, the revised risk assessment resulted in a reduced REI for these activities. Therefore, the Agency is removing the use restriction of application only within 30 days of crop emergence/transplanting for leafy vegetables, table beets, and turnips, but not for Brassica crops. The registrants elected to maintain the use restriction for Brassica crops to ensure that high exposure activities, where MOE exceedences still occurred, were not feasible. Therefore, for Brassica crops, the application restriction of use of carbaryl only within 30 days of crop emergence/transplanting will remain and a 12 hour REI will apply for all activities.

The Agency is maintaining an REI of 2 days for grape production east of the Rocky Mountains and prohibiting very high contact activities, such as grape girdling and cane turning until 6 days after application of carbaryl. With a 2 day REI for all re-entry activities except for grape girdling and cane turning, which will require a 6 day REI, both the MOE and cancer risk estimates for all re-entry activities in grapes will be below the Agency's level of concern. The Agency does not anticipate the extended REI for very high contact activities will impact grape growers east of the Rocky Mountains since these post-application activities are not commonly

practiced. In addition, based on the revised post-application risk assessment, the Agency is decreasing the REI for grape production west of the Rocky Mountains from 7 days to 6 days. For more detail on the benefits of carbaryl on grapes, refer to the *Amended Carbaryl IRED*, dated October, 22, 2004.

3. Summary of Occupational Risk Mitigation and Comparison to 2004 Amended IRED Mitigation

Table 11 summarizes the occupational risk mitigation for mixer, loaders, and handlers of carbaryl formulations, and compares the current risk mitigation to that outlined in the 2004 amended IRED. The risk mitigation for all handler scenarios assessed, except for scenario 6b Airblast: Wide Area Uses, Ground Fogger, either remain the same as the mitigation in the 2004 amended IRED, or are reduced. The PPE for scenario 6b was increased due to an increase in the application rate assessed from 0.016 lb ai/A to 0.15 lb ai/A. The last column in Table 11 specifies if the mitigation is the same, increased, or decreased. An explanation of the PPE abbreviations is at the end of the table.

Table 11. Occupational Handler Risk Mitigation Summary			
Handler Scenario	2004 Amended IRED Risk Mitigation	Current Risk Mitigation	No Change, Increase, or Decrease
Mixer/Loaders			
1a Dry Flowables (DF): Aerial/Chemigation	Prohibited	Voluntarily Canceled	N/A
1b DF: Airblast	EC		
1c DF: Groundboom	EC		
1d DF: Turfgun (LCO)	EC		
1e DF: Wide Area Aerial	Prohibited		
2a Granular: Aerial Application	Prohibited (except APHIS) SL/GL/PF5	Prohibited (except APHIS and state programs) SL/GL/PF5	No Change
2b Granular: Broadcast Spreader	SL/GL/PF5	Baseline	PPE Reduction
3a Liquid: Aerial/Chemigation	EC	SL/GL/PF5	PPE Reduction
3b Liquid: Airblast Application	SL/GL/PF5	SL/GL/NR	PPE Reduction
3c Liquid: Groundboom	SL/GL/PF5	SL/GL/NR	PPE Reduction
3d Liquid: LCO Applications	SL/GL/PF5	SL/GL/NR	PPE Reduction
3e Liquid: Wide Area Aerial	EC	SL/GL/PF5	PPE Reduction
3e Liquid: Wide Area Aerial (MRID 46634105)	EC	SL/GL/PF5	PPE Reduction
3f Liquid:	SL/GL/PF5	SL/GL/NR	PPE Reduction

Table 11. Occupational Handler Risk Mitigation Summary			
Handler Scenario	2004 Amended IRED Risk Mitigation	Current Risk Mitigation	No Change, Increase, or Decrease
Wide Area Ground			
4a Wettable Powder (WP): Airblast	EC	EC	No Change
4b WP: Groundboom	EC	EC	No Change
4c WP: Turfgun (LCO)	EC	EC	No Change
Applicators			
5a Aerial: Agricultural Uses, Liquid Sprays	EC	EC	No Change
5b Aerial: Wide Area Uses, Liquid Sprays	EC	EC	No Change
5b Aerial: Wide Area Uses, Liquid Sprays (MRID 46634105)	EC	EC	No Change
5c Aerial: Agricultural Uses, Granular Applications	EC	EC with additional aircraft requirements	Increase engineering control requirements
6a Airblast: Agricultural Uses	EC –Citrus (CA) & Olives	EC- Citrus (CA)	PPE Reduction
	DL/GL/PF5	DL/GL/PF5 (>5 lb ai/A) SL/GL/PF5 (<5 lb ai/A)	No Change for >5 lb ai/A
6b Airblast: Wide Area Uses, Ground Fogger	DL/GL/PF5	EC	Increase
7 Groundboom	SL/GL/PF5	SL/GL/NR	PPE Reduction
8 Solid Broadcast Spreader (Granular)	SL/GL/PF5	Baseline	PPE Reduction
9 Aerosol Can	Prohibited	Prohibited	No Change
10 Trigger Pump Spray	SL/GL/PF5	SL/GL/NR	PPE Reduction
11 High Pressure Handwand (ROW) (ORETF Data)	DL/GL/PF5	SL/GL/NR	PPE Reduction
Mixer/Loader/Applicators			
12 Turfgun (LCO)	SL/GL/PF5	SL/GL/NR	PPE Reduction
13a WP: Low Pressure Handwand	SL/GL/PF5	SL/GL/NR	PPE Reduction
13b Liquids, Low Pressure Handwand	SL/GL/PF5	SL/GL/NR	PPE Reduction
14 Backpack Sprayer	SL/GL/PF5	SL/GL/NR	PPE Reduction
15 Granular, Push-Type Spreader	SL/GL/NR	Baseline	PPE Reduction
16 Handheld Fogger	DL/GL/PF5	DL/GL/PF5	No Change
17 Power Backpack	SL/GL/NR	SL/GL/NR	No Change
18 Granular, Backpack	Prohibited	Prohibited	No Change
19 Tree Injection	SL/GL/NR	SL/GL/NR, plus protective eye wear	No Change
20 Drench/Dripping/ Forestry/Ornamentals	SL/GL/PF5	SL/GL/NR	PPE Reduction
21 Sprinkler Can	SL/GL/PF5	SL/GL/NR	PPE Reduction
Flaggers			
22a Flagger: Liquid Sprays	SL/GL/PF5	SL/GL/PF5	No Change

Handler Scenario	2004 Amended IRED Risk Mitigation	Current Risk Mitigation	No Change, Increase, or Decrease
22b Flagger: Granulars	Baseline	Baseline	No Change
SL- Baseline PPE (long sleeves, long pants, shoes plus socks) DL- Coveralls worn over baseline PPE GL- Chemical resistant gloves NR- No respirator PF5- Respirator with a protection level of 5 PF10- Respirator with a protection level of 10 EC- Engineering Control			

Table 12 summarizes the occupational risk mitigation for post-application activities in areas treated with carbaryl, and compares the new REIs established in this document to those established in the 2004 amended IRED. The REIs for all post-application scenarios assessed, except for Cut Flowers, either remains the same as the mitigation in the 2004 amended IRED, or are reduced. The last column in Table 12 specifies if the REIs remained the same, increased, or decreased.

TC Group (lbs ai/A)	2004 Amended IRED-REI	Current REI	No Change, Increase, or Decrease
Brassica (2 lb ai/A)	Application Restriction – use only within 30 days of planting/transplanting Low exposure activities- 5 days	Application Restriction – use only within 30 days of planting/transplanting Low exposure activities- 12 hours	Decrease for low exposure activities
Bunch/Bundle (2 lb ai/A)	8 days	2 days	Decrease
Cucurbit Vegetables (1 lb ai/A)	3 days	12 hours	Decrease
Cut Flowers (2 lb ai/A)	Cut flowers (except roses) – 12 hours Roses- 7 days	12 hours (including roses) EXCEPTION: 18 days for ornamentals grown for cuttings (cut flowers or cut foliage) where production is in outdoor areas where annual rainfall average is less than 25 inches a year.	Decrease for roses Increase for cut flowers/foilage in arid areas (<25 inches of rain/year)
Pome Fruit/Deciduous Fruit Tree	12 hours	12 hours	No change
Stone Fruit/Deciduous Fruit Tree (3 lb ai/A)	12 hours 7 days for hand thinning	12 hours (all activities and states)	Decrease
(CA only- 4 lb ai/A)	CA only- 3 days 7 days for hand thinning		

Table 12. Occupational Post-Application Risk Mitigation Summary			
TC Group (lbs ai/A)	2004 Amended IRED- REI	Current REI	No Change, Increase, or Decrease
Citrus Crop Grouping/Evergreen Fruit Trees (5 lb ai/A)	24 hours	12 hours	Decrease
	(FL- 8 lb ai/A)		
	(CA- 12 lb ai/A)	CA- 5 days	
Evergreen Crop Grouping/Evergreen Fruiting Trees [Conifers] (5 lb ai/A)	12 hours	12 hours	No change
Field/row crop, tall (2 lb ai/A)	Corn and Sorghum- 4 days	24 hours	Decrease REI
	Seed Corn- 4 days		
	Sweet Corn- 3 days		
	Hand detasseling- 30 days	Hand detasseling- 21 days	Decrease REI
	Prohibition on hand harvesting		Same
Field/row crop, tall [Sunflower] (1.5 lb ai/A)	24 hours	12 hours	Decrease
Fruiting Vegetables (2 lb ai/A)	Eggplant, Bell/chili Peppers, Tomatoes- 2 days	12 hours	Decrease
	Okra- 12 hours		
Leafy Vegetables (2 lb ai/A)	Application Restriction – use only within 30 days of planting/transplanting	12 hours (all activities)	No change, but elimination of use restriction
	Low exposure activities- 12 hours		
Low Berry (2 lb ai/A)	12 hours	12 hours (for all crops)	Decrease
	Strawberries- 4 days		
Low/Medium Field/Row Crops (1.5 lb ai/A)	String Beans, Dry Beans/peas, Chick Peas and Green Peas- 5 days	12 hours (for all crops)	Decrease
	Alfalfa, Forage, Flax,		

Table 12. Occupational Post-Application Risk Mitigation Summary			
TC Group (lbs ai/A)	2004 Amended IRED- REI	Current REI	No Change, Increase, or Decrease
	Peanuts, Rice, and Sugar beets- 2 days		
Nursery/Ornamentals (2 lb ai/A)	12 hours	12 hours	No Change
Nut Trees (5 lb ai/A) (Olives- 7.5 lb ai/A)	Pecans- 12 hours Almonds, Hazelnuts (Filberts), Macadamia, Pistachios, Walnuts- 10 days Olives- 14 days	12 hours Olives- 3 days	Decrease
Root Vegetables (2 lb ai/A)	Application Restriction – use only within 30 days of planting/transplanting Table Beets and Turnips (harvested for greens)- 12 hours Table Beets, Carrots, Potatoes, Sweet Potatoes, Turnips (harvested for roots)- 4 days	12 hours (all crops and activities)	Over all decrease and elimination of use restriction
Stem/Stalk Vegetables (asparagus preharvest application- 1 lb ai/A) (2 lb ai/A)	24 hours	12 hours	Decrease
Sugarcane (1.5 lb ai/A)	N/A- not a registered use	12 hours	REI established
Turf/grass seed production [Golf course & Sod farm] (8.2 lb ai/A)	12 hours Sod farm harvesting- 9 days	12 hours Sod farm harvesting- 24 hours	Decrease
Vine/Trellis (2 lb ai/A)	2 days	12 hours	Decrease
Vine/Trellis [Grapes] (2 lb ai/A)	Rocky Mountains East- 2 days West- 7 days	Rocky Mountains East- 2 days *Very high contact activities (grape girdling and cane turning)- 6 days West- 6 days	East of Rocky Mountains- Increase REI for very high contact activities only West of Rocky Mountains- Decrease

V. What Registrants Need to Do

The Agency has determined that products containing carbaryl are eligible for reregistration provided that the required label amendments are made. Below are the label amendments that the Agency intends to require for carbaryl to be eligible for reregistration.

A. Label Changes Summary Table

In order to continue to be eligible for reregistration, all products labels are to be amended to incorporate the risk mitigation measures outlined in label table that follows. Table 13 describes how language on the labels should be amended.

Summary of Labeling Changes for Carbaryl

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.

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	<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: seedling drench/dipping use, 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>“Carbaryl cannot be formulated into end-use products labeled for seedling drench/dipping use, wheat, pets (except for pet collars) and all pet-related uses.”</p> <p>The following formulations are canceled: dust (for use on agriculture) and dry flowables.</p> <p>“Carbaryl cannot be formulated into any dry flowable end-use products, or dust end-use products for use on agricultural sites. “</p> <p>The following application methods are prohibited: hand, spoon, backpack spreaders (front and back mounted), power backpacks, tree injection, and power handheld foggers.</p> <p>“Carbaryl cannot be formulated into any end use products unless the following application methods are prohibited: hand, spoon, backpack spreaders (front and back mounted), power backpack sprayers, tree injection, and power handheld foggers.”</p> <p>“All carbaryl end use product wettable powder formulations must be packaged in water-soluble packets.”</p> <p>“All carbaryl end use products packaged into aerosol can formulations is prohibited.”</p>	Directions for Use

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	Liquid and wettable powder formulations labeled for use on turfgrass must limit broadcast applications to turfgrass on golf courses, sod farms, cemeteries, and commercial landscapes. Applications to all other turfgrass or lawns must be limited to spot treatments of less than 1000 square feet.	
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
PPE Requirements for Liquid Products that do NOT contain direction for use for the federal (APHIS) or affiliated state Rangeland Grasshopper and Mormon Cricket Suppression Program	<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><i>Note to registrant: if the label does not contain directions for use for airblast applications at ≥ 5 lb ai/A, the following sections may be eliminated and drop the “other” in the section below starting “All other mixers, loaders”, etc.)</i></p> <p>Handlers applying with open cab airblast equipment at application rates equal to or greater than (registrant insert the application rate in terms of pints, quarts, or gallons of end-use product formulation per acre that is equivalent to 5 pounds active ingredient) 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 	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>NIOSH- approved respirator with any N, R, P or HE filter</p> <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, and - Chemical-resistant gloves. <p>In addition, mixers and loaders supporting aerial or chemigation applications must wear</p> <ul style="list-style-type: none"> > 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>“Human flagging is prohibited. Flagging to support aerial application is limited to use of the Global Positioning System (GPS) or mechanical flaggers.”</p> <p>See engineering controls for additional requirements and exceptions.</p>	
<p>PPE Requirements for Liquid Products that contain direction for use for the federal (APHIS) or affiliated state Rangeland Grasshopper and Mormon Cricket Suppression Program</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><i>Note to registrant: if the label does not contain directions for use for airblast applications at ≥ 5 lb ai/A, the following sections may be eliminated and drop the “other” in the section below starting “All other mixers, loaders”, etc.)</i></p> <p>Handlers applying with open cab airblast equipment at application rates equal to or greater than (registrant insert the application rate in terms of pints, quarts, or gallons of end-use product formulation per acre that is equivalent to 5 pounds active ingredient) 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 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, 	

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<ul style="list-style-type: none"> - Shoes plus socks, and - Chemical-resistant gloves. <p>In addition, mixers and loaders supporting aerial or chemigation applications must wear</p> <ul style="list-style-type: none"> > 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>See engineering controls for additional requirements and exceptions.</p>	
<p>PPE Requirements for Wettable Powder Products</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><i>Note to registrant: if the label does not contain directions for use for airblast applications at ≥ 5 lb ai/A, the following sections may be eliminated and drop the “other” in the section below starting “All other mixers, loaders”, etc.)</i></p> <p>Handlers applying with open cab airblast equipment at application rates equal to or greater than (registrant insert the application rate in terms of pints, quarts, or gallons of end-use product formulation per acre that is equivalent to 5 pounds active ingredient) 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 - 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>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 - Chemical-resistant apron when mixing, loading, or cleaning up spills or equipment. <p>In addition, mixers and loaders supporting aerial or chemigation applications must wear</p> <ul style="list-style-type: none"> > 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>(Aerial and chemigation applications are prohibited.)</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	See engineering controls for additional requirements and exceptions.”	
PPE Requirements for Granular and Bait Formulations with Directions for Use for Broadcast Applications that do NOT contain direction for use for the federal (APHIS) or affiliated state Rangeland Grasshopper and Mormon Cricket Suppression Program	<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>Aerial application is prohibited.</p> <p>See engineering controls for additional exceptions.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Granular and Bait Formulations that contain direction for use for the federal (APHIS) or affiliated state Rangeland Grasshopper and Mormon Cricket Suppression Program	<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>In addition, handlers loading bait formulations into airplanes under the auspices of the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program, and allied state programs 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>Aerial application is prohibited, except for aerial applications under the auspices of the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program, and allied state programs.</p> <p>See engineering controls for additional requirements and exceptions.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements for RTU Dust Formulations for Use in Commercial and Residential Areas.</p> <p>(Note: Dust end use products for use on agricultural sites are prohibited)</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Loaders, applicators, and other handlers must wear: - Long-sleeved shirt and long pants, and - Shoes plus socks. “</p> <p>Aerial application is prohibited.</p>	
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
Engineering Controls for Liquid Formulations that permit aerial application	<p>“Engineering Controls:</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>	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)
Engineering Controls for Liquid or Wettable Powder formulations with directions for use to <i>citrus in California</i> and <i>for wide area mosquito adulticide</i> applications,	<p>“Engineering Controls:</p> <p>Applicators using airblast equipment for application to <i>citrus in California</i> and <i>for wide area mosquito adulticide</i> 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, such applicators 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 	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>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;</p> <p>-- be provided, have immediately available for use, and wear 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 above-- take off any PPE that was worn in the treated area before reentering the cab, and</p> <p>-- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.</p>	
<p>Engineering Controls for Liquids that contain direction for use for the federal (APHIS) or affiliated state Rangeland Grasshopper and Mormon Cricket Suppression Program</p>	<p>“Engineering Controls: Human flagging is prohibited, except for flagging to support ultra low volume aerial applications for Rangeland Grasshopper and Mormon Cricket Suppression through the Animal and Plant Health Inspection Service (APHIS) Program or affiliated state programs. 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>Flaggers supporting ultra low volume aerial applications for Rangeland Grasshopper and Mormon Cricket Suppression through the Animal and Plant Health Inspection Service (APHIS) Program or affiliated state programs 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> <p>-- 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 <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 this type of respirator,; -- be provided, have immediately available for use, and wear 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>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)</p>
<p>Engineering Controls for Wettable Powders Formulations</p> <p>Water-Soluble Packaging is required for all</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> <p>-wear the personal protective equipment on this labeling for mixers/loaders, and -be provided, have immediately available, and 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</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following User Safety Requirements.)</p>

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
Wettable Powder Formulations	NIOSH/MSHA approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter.	
Engineering Control Requirements for Granular/Bait Formulation Labeled for Use for Rangeland Grasshopper or Mormon Cricket Control	<p>“Engineering Controls:</p> <p>Pilots applying applications under the auspices of the Animal and Plant Health Inspection Service (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program or related state programs 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 permitted above 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.” 	
Additional Engineering Controls Statement for all liquid, wettable powder, and for granular and bait formulations with directions for broadcast application. (Note: this statement is not needed for the 0.03% granular/bait formulation)	“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.”	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following any other engineering control requirements.)
User Safety	“User Safety Recommendations	Placed in a box in the

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
Recommendations	<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>	Precautionary Statements under Hazards to Humans and Domestic Animals immediately following Engineering Controls.
Restricted-Entry Interval	“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.”	Directions for Use, Inside the Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	<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 over short-sleeve shirt and short-pants, - Chemical-resistant footwear plus socks, - Chemical-resistant gloves made of any waterproof material, and - Chemical-resistant headgear if overhead exposure.” 	Directions for Use, Inside the Agricultural Use Requirements Box
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,
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.”	<p>under the heading “Entry Restrictions.”</p> <p>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</p>

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
		Non-WPS entry restrictions in that box.
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 all Products	“ The following application methods are prohibited: hand, spoon, shaker can, backpack spreaders (front and back mounted), power backpack sprayers, tree injection, and ALL handheld foggers.”	
Application Restrictions for Wettable Powder Products	“Aerial application is prohibited.”	Directions for Use in a prominent place near the beginning
Application Restrictions for Liquid and Wettable Powder 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.”	Directions for Use associated with the lawn/turfgrass directions
Application Restrictions	Labels must be amended to reflect the following application restrictions which supersede or are in addition to restrictions currently on labels.	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>Alfalfa “Restricted-entry interval (REI) = 12 hours”</p> <p>Almonds “Restricted-entry interval (REI) = 12 hours”</p> <p>Apples “Restricted-entry interval (REI) = 12 hours”</p> <p>Apricots “Restricted-entry interval (REI) = 12 hours”</p> <p>Asparagus “Restricted-entry interval (REI) = 12 hours” 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>	
Application Restrictions	<p>Beans <u>String beans and Dry Beans</u> “Restricted-entry interval (REI) = 12 hours”</p> <p>Blueberries (Lowbush) “Restricted-entry interval (REI) = 12 hours”</p> <p>Blueberries (Highbush) “Restricted-entry interval (REI) = 12 hours”</p> <p>Boysenberry “Restricted-entry interval (REI) = 12 hours”</p> <p>Brassica (bok choy, broccoli, Brussel sprouts, cabbage [including Chinese], cauliflower, collards, Hanover salad, kale, kohlrabi, mustard greens, napa) “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>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl

Description	Amended Labeling Language	Placement on Label
Application Restrictions	<p>Carrots “Restricted-entry interval (REI) = 12 hours”</p> <p>Chestnuts “Restricted-entry interval (REI) = 12 hours”</p> <p>Cherries “Restricted-entry interval (REI) = 12 hours</p> <p>Citrus (citron, grapefruit, kumquats, lemons, limes, oranges, tangelos, tangerines, and hybrids) <u>California only:</u> “Restricted-entry interval = 3 days Do not apply more than 12 pounds active ingredient per acre per application (registrant states 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 states this in amount of formulation per acre per application.”</p> <p><u>Florida SLN FL-890037 only:</u> “Restricted-entry interval = 12 hours Do not apply more than 8 pounds active ingredient per acre per application (registrant states this in amount of formulation per acre per application.”</p>	Directions for Use, Under Application Instructions for Each Crop
Application Restrictions	<p>Corn (field, sweet, seed, and pop) “Restricted-entry interval = 24 hours.</p> <p>Prohibition: Do not enter or allow workers to enter treated areas to perform hand detasselling tasks until 21 days after application. You must notify workers of this prohibition. Hand harvesting is prohibited. Notify workers of the hand harvesting prohibition.”</p> <p>Crabapples “Restricted-entry interval (REI) = 12 hours”</p> <p>Caneberries (blackberry and raspberry) “Restricted-entry interval = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>Cranberries “Restricted-entry interval = 12 hours”</p>	
Application Restrictions	<p>Cucurbits (cantaloupe, cucumber, gourds, melon, pumpkins, squash, watermelon, zucchini, Chinese okra) “Restricted-entry interval (REI) = 12 hours”</p> <p>Dewberry “Restricted-entry interval (REI) = 12 hours”</p> <p>Eggplant “Restricted-entry interval (REI) = 12 hours”</p> <p>Flax “Restricted-entry interval (REI) = 12 hours”</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) = 2 days for all activities except for grape girdling and cane turning which requires 6 days”</p> <p><u>West of the Rocky Mountains:</u> “Restricted-entry interval (REI) = 6 days”</p> <p>Grass grown for Seed Production “Restricted-entry interval = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop
Application Restrictions	<p>Hazelnuts (Filberts) “Restricted-entry interval (REI) = 12 hours”</p> <p>Horseradish “Restricted-entry interval = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>Lentils “Restricted-entry interval (REI) = 12 hours”</p> <p>Leafy vegetables (celery, dandelion, endive, escarole, lettuce, romaine, parsley, Swiss chard, spinach, carrot tops) “Restricted-entry interval (REI) = 12 hours”</p> <p>Loganberry “Restricted-entry interval (REI) = 12 hours”</p> <p>Longan “Restricted-entry interval (REI) = 12 hours”</p> <p>Loquat “Restricted-entry interval (REI) = 12 hours”</p>	
Application Restrictions	<p>Macadamia “Restricted-entry interval (REI) = 12 hours”</p> <p>Nectarines “Restricted-entry interval (REI) = 12 hours”</p> <p>Okra “Restricted-entry interval (REI) = 12 hours”</p> <p>Olives “Restricted-entry interval (REI) = 3 days”</p> <p>Ornamentals and Nursery Plants “Restricted-entry interval (REI) = 12 hours” “EXCEPTION: the restricted-entry interval is 18 days for ornamentals grown for cuttings (cut flowers or cut foliage) where production is in outdoor areas where average annual rainfall is less than 25 inches a year. Notify workers of the application and restricted-entry interval by warning them orally and by posting warning signs at entrances to treated area. <i>Note: information on average annual rainfall for your area is available from any nearby weather bureau, such as one located at a local airport or one affiliated with the National Oceanographic and Atmospheric Administration.</i> ”.</p>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>Parsnip “Restricted-entry interval (REI) = 12 hours”</p>	
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) = 12 hours”</p> <p>Peaches “Restricted-entry interval (REI) = 12 hours”</p> <p>Peanuts “Restricted-entry interval (REI) = 12 hours”</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) = 12 hours”</p> <p>Pistachio “Restricted-entry interval (REI) = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop
Application Restrictions	<p>Plums/Prunes “Restricted-entry interval (REI) = 12 hours”</p> <p>Potatoes (White and Irish) “Restricted-entry interval (REI) = 12 hours”</p> <p>Proso millet</p>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>“Restricted-entry interval (REI) = 24 hours”</p> <p>Quince “Restricted-entry interval (REI) = 12 hours”</p> <p>Radish “Restricted-entry interval (REI) = 12 hours”</p> <p>Raspberries (Black and Red) “Restricted-entry interval (REI) = 12 hours”</p>	
Application Restrictions	<p>Rice “Restricted-entry interval (REI) = 12 hours”</p> <p>Rutabaga “Restricted-entry interval (REI) = 12 hours”</p> <p>Salsify “Restricted-entry interval (REI) = 12 hours”</p> <p>Strawberries “Restricted-entry interval (REI) = 12 hours”</p> <p>Sorghum “Restricted-entry interval (REI) = 12 hours.”</p> <p>Soybeans “Restricted-entry interval (REI) = 12 hours”</p> <p>Sugarbeets “Restricted-entry interval (REI) = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop
Application Restrictions	<p>Sugarcane “Restricted-entry interval (REI) = 12 hours”</p> <p>Sunflower “Restricted-entry interval (REI) = 12 hours”</p>	Directions for Use, Under Application Instructions for Each Crop

Table 13. Summary of Label Changes for Carbaryl		
Description	Amended Labeling Language	Placement on Label
	<p>Sweet Potatoes “Restricted-entry interval (REI) = 12 hours”</p> <p>Table Beets “Restricted-entry interval (REI) = 12 hours”</p> <p>Tobacco “Restricted-entry interval (REI) = 48 hours”</p> <p>Tomatoes “Restricted-entry interval (REI) = 12 hours”</p> <p>Trefoil “Restricted-entry interval (REI) = 12 hours”</p> <p>Turf Grown for Sod Production “Restricted-entry interval (REI) = 12 hours Restricted-entry interval (REI) for harvesting = 24 hours”</p> <p>Turnips “Restricted-entry interval (REI) = 12 hours”</p> <p>Walnuts (English and Black) “Restricted-entry interval (REI) = 12 hours”</p>	
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

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 registration

APPENDICES

- I. SUMMARY of CARBARYL DATA REQUIREMENTS FROM 2005 Generic DCI
- II. Bibliography of Studies used in Amended RED

**Appendix I:
Status of Guideline Studies**

OPPTS Guideline Number	Study Title/Description	Required Scenerios	MRID Number
WORKER EXPOSURE MONITORING STUDY			
875.1100	Dermal Exposure – Outdoor	Airblast, open cab, hat & full PPE	46448201
		Aerial mixer/loader for large acreage (i.e., grasshopper use)	47051601 46634105
		Aerial applicator (pilot) for large acreage (i.e., grasshopper use)	47051601 46634105
		Dust application in agriculture	n/a
		Power handheld fogger	
		Power backpack application	
		Tree injection	
Drenching/dipping seedlings			
875.1300	Inhalation Exposure – Outdoor	Airblast, open cab, hat & full PPE	46448201
		Aerial mixer/loader for large acreage (i.e., grasshopper use)	47051601 46634105
		Aerial applicator (pilot) for large acreage (i.e., grasshopper use)	47051601 46634105
		Dust application in agriculture	n/a
		Power handheld fogger	
		Power backpack application	
		Tree injection	
Drenching/dipping seedlings			
POST APPLICATION EXPOSURE DATA REQUIREMENTS			
875.2100	Foliar Dislogeable Residue	Cut flower greenhouse study	46892801

OPPTS Guideline Number	Study Title/Description	Required Scenerios	MRID Number
	Dissipation	Dog collar transferable residues	Study underway, submission pending (6/2009)
		Turf transferable residues	46673901
		Hand press turf transferable residues	46673901
875.2400	Dermal Exposure	Cut flower greenhouse study	46892801
		Dog collar transferable residues	Study underway, submission pending (6/2009)
ENVIRONMENTAL FATE DATA REQUIREMENTS			
835.4100	Aerobic Soil Metabolism	Additional studies required on a range of soil types	46580700
835.4300	Aerobic Aquatic Metabolism	Additional studies required on a range of aquatic environments	46580701 46580702
PRODUCT CHEMISTRY DATA REQUIREMENTS			
830.1800	Enforcement Analytical Method	Analytical Method	46699101
RESIDUE CHEMISTRY DATA REQUIREMENTS			
860.1380	Storage Stability	Oilseed and processed commodities of oily crop.	Submission Pending (10/2008)
		Sugarbeets. Previous study upgraded with data on sampling intervals.	46936301
		Dried fruit stored up to 10 months.	Submission

OPPTS Guideline Number	Study Title/Description	Required Scenerios	MRID Number
			Pending (12/2008)
		Alfalfa commodities - 18 month storage interval.	Submission Pending (12/2008)
		Potatoes - 15 month storage interval.	Submission Pending
		Cottonseed - 17 month storage interval	n/a
		Wheat commodities - 22 month storage interval.	n/a
		Rangeland grass- 33 month storage interval.	Submission Pending
860.1500	Crop Field Trials	Wheat, hay	n/a
		Pea and bean, succulent	n/a
		Pineapple (3 trials in Costa Rica, 2 in Mexico)	47087901
		Vegetable, leafy, except Brassica	n/a
ECOLOGICAL EFFECTS DATA REQUIREMENTS			
850.3040	Field Testing for Pollinators	Sevin XLR, Hybrid Poplars in Minnesota	Study waived; labeling required
TOXICOLOGICAL DATA REQUIREMENTS			
870.3465	Inhalation Study	Two short term inhalation studies	Submission Pending

n/a- Not applicable because the use pattern/scenario is not being supported by the registrant. Cancellation is in progress.

Appendix II:
Bibliography

MRID Number	Study Name
45732201	Emlay, D.; Rudolph, R. (1977) Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars: Lab Project Number: TR-506. Unpublished study prepared by Zoecon Industries, Inc. 14 p. {OPPTS 875.1500}
46015001	Rudolph, R.; Moorman, R. (2003) Determination of the Quantity of Carbaryl Removed by Petting Dogs Wearing 16% Carbaryl Dog Collars. Project Number: TR/506. Unpublished study prepared by Wellmark International. 23 p.
46075601	Wayne, R. (1974) Rate of Release Evaluation of a Four Mouth Carbaryl Dog Collar (F-68-118-1). Project Number: TR/337. Unpublished study prepared by Thuron Industries Research & Development. 14 p.
46448201	Smith, L. (2004) Determination of Dermal and Inhalation Exposure to Workers During Application of a Liquid Pesticide Product by Open Cab Airblast Application to Orchard Crops. Project Number: AHE07. Unpublished study prepared by Stewart Agricultural Research Services. 448 p.
46580700	LaRochelle D. (2005) Carbaryl; 90 Day Response to the Interim Reregistration Eligibility Decision and Generic Data Call-In.
46580701	Oddy, A.; Dobie, M. (2003) [Carbon-14] - Carbaryl: Degradation and Retention in Two Water/Sediment Systems. Project Number: CX/02/047, C031658. Unpublished study prepared by Battelle Agrifood, Ltd. 131 p.
46580702	Doble, M.; Oddy, A. (2004) [Carbon-14] - Carbaryl: Characterisation/Identification of Unknowns from a Water/Sediment Study. Project Number: CX/03/068, C/043396. Unpublished study prepared by Battelle Agrifood, Ltd. 52 p.
46634105	Klonne, D. (2005) Determination of Dermal and Inhalation Exposure to Workers During Closed-System Loading and ULV Application of a Liquid Pesticide Product to Cotton: Malathion. Project Number: AHE13, GR04/487, 040165. Unpublished study prepared by Agricultural Handlers Exposure Task Force, Grayson Research, Ltd. and Golden Pacific Laboratories, LLC (GPL). 460 p.
46673901	Krolski, M. (2005) Sevin 2G - Determination of Transferable Residues from Turf. Project Number: RACAX015, CA25TF01, CA001/03D. Unpublished study prepared by Bayer Corp., Analytical Bio-Chemistry Labs., Inc. and Bayer CropScience. 268 p.
46699101	Forntain, L. (2005) Product Chemistry of Sevin Brand Technical Carbaryl Insecticide. Project Number: PA01/061, ANR/19505, PA01/051. Unpublished study prepared by Bayer Corp. 43 p.
46892801	Barney, W. (2006) Carbaryl: Dissipation of Dislodgeable Foliar Residues From Chrysanthemums. Project Number: 08636,

MRID Number	Study Name
	08636/DF/BER05, 08636/DF/WA/52. Unpublished study prepared by Interregional Research Project No. 4 and U.S. Dept. of Agriculture. 242 p.
46936301	Larochelle, D. (2006) "SEVIN Brand Carbaryl Insecticide Sugar Beet Processing Study". Project Number: 801R11. Unpublished study prepared by Bayer Crop Science LP. 22 p.
47007001	Moser, G. (2006) Report on Cholinesterase Comparative Sensitivity Study of Carbaryl. Unpublished study prepared by U.S. Environmental Protection Agency, ORD, NHEERL. 35 p.
47051601	Collier, K.; Honeycutt, R. (2007) Occupational and Residential Exposure: Determination of Dermal and Inhalation Exposure to Workers During Loading or Application of Carbaryl Bait. Project Number: AHE25. Unpublished study prepared by Agricultural Handlers Exposure Task Force and U.S. Department of Agriculture. 222 p.
47087901	Hoag, R.; Seymour, B. (2007) Sevin XLR 48 SC (Sevin XLR Plus) - Magnitude of the Residue in/on Pineapple. Project Number: RACAS001. Unpublished study prepared by Bayer Corp. and Morse Laboratories, Inc. 110 p.
47151902	Dick, I. (2001) [Carbon-14]-Carbaryl: Comparative in Vitro Dermal Penetration Study Using Human and Rat Skin. Project Number: AES/033/012804, AES/033, C/016768. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 118 p.