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Agency

Prevention, Pesticides
and Toxic Substances
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Reregistration Eligibility Decision (RED) for Carbaryl

REREGISTRATION ELIGIBILITY

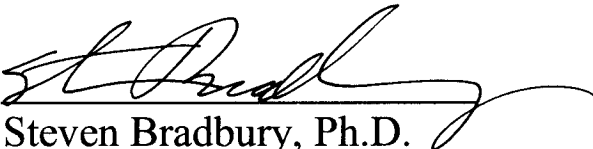
DECISION

for

Carbaryl

Case No. 0080

Approved by:



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

9/29/07
Date

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Office of Pesticide Programs

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I. Introduction

The Environmental Protection Agency (EPA or the Agency) has completed the reregistration eligibility decision (RED) for the currently registered uses of the N-methyl carbamate pesticide carbaryl. This document presents EPA's revised carbaryl human health risk assessment under the Food Quality Protection Act (FQPA) and the Agency's final tolerance reassessment decision for carbaryl. This RED amends the Interim Reregistration Eligibility Decision (IRED) for carbaryl, which was completed by EPA on June 30, 2003 and previously amended on October 22, 2004, and completes the reregistration process for carbaryl. The Agency is currently revisiting the revised occupational risk assessment, which does not identify any additional risk concerns, and will amend this RED to incorporate any resulting changes in the regulatory decision. In addition, as a separate action, EPA is preparing a response to petitions to cancel all uses of carbaryl and revoke all carbaryl tolerances. The Agency's response to these petitions will be released at a later date.

Carbaryl belongs to the N-methyl carbamate group of pesticides, which share a common mechanism of toxicity. The FQPA requires EPA to consider cumulative risk for pesticides that share a common mechanism of action before completing tolerance reassessment for individual chemicals in the common mechanism group, hence the interim decision. The carbaryl tolerance reassessment is now complete with the cumulative risk assessment for the N-methyl carbamate group of pesticides so that all of the remaining carbaryl tolerances, not previously reassessed, can be considered reassessed in accordance with the FQPA.

A. Regulatory History

EPA completed an IRED for carbaryl on June 30, 2003, in accordance with a Consent Decree with the Natural Resources Defense Council (NRDC). The completed IRED was posted on the EPA internet for public viewing in early July 2003. The Agency amended the IRED on October 22, 2004, and published a formal Notice of Availability for the document, which provided for a 60-day public comment period. EPA received numerous comments on the carbaryl IRED, including two petitions. Both the NRDC and the Washington Toxics Coalition submitted petitions requesting that EPA cancel all uses of carbaryl and revoke all tolerances. The Agency published a Notice of Receipt for each of these petitions in the *Federal Register*, which provided for a public comment period on the petitions (see FR of March 30, 2005 and October 13, 2006). The Agency is currently preparing a response to public comments, including these petitions. The response to comments will be released at a later date.

On March 10, 2005, EPA issued a cancellation order for the liquid broadcast use of carbaryl on residential turf to address post-application risk to toddlers. EPA took this action because pharmacokinetic data developed by the carbaryl registrant, Bayer CropScience, were not sufficient to address the risk concerns for toddlers identified in the IRED. The FIFRA Science Advisory Panel (SAP) reviewed these data in December 2004 and concluded that the data were not sufficient to address the risk concern for toddlers.

In March 2005, EPA also issued generic and product-specific data call-ins (DCIs) for carbaryl. 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; these data will be used for product labeling. EPA has received numerous studies in response to these DCIs, and, where appropriate, these studies have been considered in the revised risk assessment for this tolerance reassessment.

In response to the DCIs, many carbaryl registrants chose to voluntarily cancel their carbaryl products, rather than revise their labels or conduct studies to support these products. One technical registrant, Burlington Scientific, chose to cancel their technical product, leaving Bayer CropScience as the sole technical registrant for carbaryl. Approximately two-thirds of all of the carbaryl products registered at the time of the carbaryl IRED (June 2003) have been canceled through this process.

In June 2006, EPA determined that the uses associated with 120 of the existing carbaryl tolerances are not significant contributors to the overall N-methyl carbamate cumulative risk and as a result these tolerances will have no effect on the retention or revocation of other N-methyl carbamate tolerances. Therefore, EPA considered these 120 tolerances for carbaryl as reassessed on June 29, 2006, and posted this decision on the internet site, http://www.epa.gov/pesticides/cumulative/carbamates_commodity.pdf.

In late November 2006, EPA received data from a carbaryl comparative cholinesterase study, conducted to determine the comparative sensitivity of adults and offspring to cholinesterase inhibition by carbaryl. These data were used to revise the FQPA safety factor for carbaryl for the N-methyl carbamate cumulative risk assessment. The Agency determined that it was appropriate to use this new FQPA safety factor in both the N-methyl carbamate cumulative risk assessment and the carbaryl-specific human health risk assessment. Because incorporating a revised FQPA safety factor would result in a revision of the carbaryl human health aggregate risk assessment, EPA decided to also incorporate new data generated in response to the DCI, new methodologies, and other new information to bring the carbaryl-specific risk assessment up to date.

B. N-Methyl Carbamate Cumulative Risk Assessment

FFDCA Section 408(b)(2)(D)(v) requires that the Agency consider “available information” concerning cumulative effects of a particular pesticides residues and “other substances that have a common mechanism of toxicity” when considering whether to establish, modify, or revoke a tolerance for pesticide residues in food. EPA considers cumulative effects from pesticides and other substances because low-level exposures to multiple chemical substances causing a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance.

Carbaryl is a member of the N-methyl carbamate class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures resulting from registered uses of N-methyl carbamate pesticides, including carbaryl. EPA has concluded that the cumulative risks associated with the N-methyl carbamate pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCA. EPA is thereby terminating the tolerance reassessment process under 408(q) of the FFDCA. For additional information, refer to the document, *Revised N-methyl Carbamate Cumulative Risk Assessment*, which is available in the EPA docket EPA-HQ-OPP-2007-0935 and on the website, <http://www.epa.gov/pesticides/cumulative/>.

II Revised Human Health Risk Assessment for Carbaryl

A. What's New

The carbaryl human health risk assessment has been revised to incorporate new data, new methodologies, updated use information, and recent residue data, and other new information obtained from public comments to the IRED.

1. New Data

EPA issued a generic data call-in (DCI) for carbaryl in March 2005. This DCI required several confirmatory studies, including exposure monitoring and toxicology studies. Key studies that were incorporated into the revised human health risk assessment include the following:

Environmental Fate

- *Aerobic Aquatic Metabolism.* This study measures how quickly carbaryl degrades in an aerobic aquatic environment. The half-life value from this study was used in the drinking water modeling for carbaryl.

Drinking Water

- EPA has conducted a comprehensive review of recent surface water monitoring data for carbaryl and investigated the high carbaryl detection in groundwater monitoring reported in the 2003 IRED.

Residential Exposure Monitoring Studies

- *Turf transferable residue study and addendum.* This study measures the amount of carbaryl residues from a granular product applied to turf that are available for post-application exposure. The data from this study were used to calculate post-application exposure and risk in the carbaryl residential risk assessment.

Toxicology Studies

- *Dermal penetration study for carbaryl.* Bayer CropScience conducted an *in vitro* comparative dermal penetration study using rat skin and human skin. These study data were used to determine the relative dermal absorption for carbaryl in rats and humans. The data were used to adjust the dermal point of departure used in the carbaryl risk assessment.
- *Comparative cholinesterase study.* EPA's Office of Research and Development conducted a comparative cholinesterase study to compare carbaryl-induced cholinesterase inhibition in adult and juvenile rats. These data were used to calculate a revised FQPA safety factor for carbaryl and to derive the toxicology points of departure for risk assessment.

2. New Methodologies

Benchmark Dose Modeling

- EPA has developed a benchmark dose analysis for carbaryl using the same modeling methodology used in the N-methyl carbamate 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 point of departure 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).

3. Other New Information

The mitigation measures required in the carbaryl IRED were incorporated into the revised risk assessment, resulting in significant changes to the residential risk assessment. EPA also incorporated the most recent available US Department of Agriculture (USDA) Pesticide Data Program (PDP) residue data (sampling years 2003-2006) and the most recent available data on percent of food crops treated with carbaryl into the dietary risk assessment for food. The drinking water exposure assessment was revised to incorporate information on percent cropped area in various regions of the country and recent surface water monitoring data. EPA also incorporated new information provided in the public comments on the IRED into the revised risk assessment.

Updated Use Information

As part of EPA's re-evaluation of carbaryl, the Agency reviewed all currently available information on use and usage of this pesticide. A summary of the readily available use

data for agricultural crops is given in Table 1. The Agency used the percent crop treated data from this table in the revised dietary risk assessment for carbaryl. For the few commodities where percent crop treated was not calculated due to insufficient data, EPA used the percent crop treated values from the 2002 Quantitative Use Analysis for Carbaryl.

Table 1. Summary of Carbaryl Use Data for Agricultural Crops

Crop	Pounds Active Ingredient (a.i.) used per year	Percent Crop Treated	
		Average	Maximum
Alfalfa	50,000	<1	<2.5
Almonds *	4,000	<1	<2.5
Apples	2,000	5	15
Asparagus	60,000	35	45
Avocados	2,000	<1	5
Beans, Green	10,000	5	5
Beets†	<500	5	Not Calculated‡
Blackberries	3,000	30	35
Blueberries	20,000	20	25
Broccoli	4,000	<1	5
Brussels Sprouts *	<500	Not Calculated	Not Calculated
Cabbage	2,000	<1	5
Canola/Rapeseed	<500	<1	
Cantaloupes	10,000	15	25
Carrots	4,000	5	5
Cauliflower	<500	<1	<2.5
Celery	1,000	<1	<2.5
Cherries	70,000	15	25
Collards	2,000	5	5
Corn	20,000	<1	<2.5
Cotton	5,000	<1	<2.5
Cranberries †	30,000	20	Not Calculated
Cucumbers	20,000	5	10
Dry Beans/Peas	2,000	<1	<2.5
Eggplant	<500	5	5
Grapefruit	40,000	10	20
Grapes	80,000	5	5
Greens, Mustard	1,000	5	5
Greens, Turnip	3,000	20	20
Honeydew	2,000	35	35
Kale	<5000	5	5
Lemons	4,000	<1	<2.5
Lettuce	6,000	<1	<2.5
Nectarines *	4,000	5	5
Okra	6,000	30	30
Olives *	7,000	<1	<2.5
Onions	<500	<1	<2.5
Oranges	100,000	5	5
Parsley †	<500	5	Not Calculated
Peaches	60,000	10	20
Peanuts	20,000	<1	5
Pears	3,000	<1	5

Crop	Pounds Active Ingredient (a.i.) used per year	Percent Crop Treated	
		Average	Maximum
Peas, Green	<500	<1	<2.5
Pecans	200,000	10	15
Peppers	9,000	5	5
Pistachios *	10,000	5	5
Potatoes	20,000	<1	5
Prunes & Plums *	5,000	<1	5
Pumpkins	20,000	15	25
Rice	30,000	<1	<2.5
Sod†	2,000	<1	Not Calculated
Sorghum	10,000	<1	<2.5
Soybeans	30,000	<1	<2.5
Spinach	<500	<1	<2.5
Squash	10,000	15	20
Strawberries	20,000	15	25
Sugar Beets	4,000	<1	<2.5
Sunflowers	6,000	<1	<2.5
Sweet Corn	20,000	<1	5
Sweet Potatoes†	20,000	15	Not Calculated
Tangelos	1,000	5	5
Tangerines	9,000	5	10
Tobacco	2,000	<1	<2.5
Tomatoes	20,000	5	10
Walnuts	2,000	<1	<2.5
Watermelons	20,000	10	15
Wheat	20,000	<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.

EPA also evaluated nonagricultural use of carbaryl, including golf courses, lawn care operators, horticultural nurseries and greenhouses, commercial turf, sod farms, landscape contractors, flea control, fire ant control, and homeowner outdoor use. The Agency obtained information about these uses from proprietary sources. A summary of nonagricultural use data for carbaryl from 1999 to 2005 is given in Table 2.

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
	Greenhouses	

Because carbaryl is also used extensively by homeowners, primarily for lawn care, EPA has reviewed the available data on carbaryl use/usage on residential lawns as

well as potential alternative pesticides. Details of this review may be found in the July 13, 2007, document, *Alternative Assessment for Carbaryl Use on Residential Lawns*.

4. Revised Toxicology Endpoints

New Toxicology Data

Comparative Cholinesterase Study. This study was conducted to determine whether young animals are more susceptible to the effects of carbaryl than adults. This study showed that juvenile 11-day-old (post natal day 11, or PND11) pups were more sensitive to inhibition of brain cholinesterase from carbaryl than adult rats. The results of this study were used to revise the FQPA safety factor for carbaryl. EPA also used this study to determine the point of departure for calculating risks to infants and children.

EPA conducted a benchmark dose analysis for the carbaryl comparative cholinesterase study, using the same modeling methodology used in the N-methyl carbamate cumulative risk assessment. The Agency estimated the 10% benchmark dose response (BMD₁₀) and the BMDL₁₀, or lower 95% confidence limit of the benchmark dose, for this study. The Agency also conducted a full benchmark dose analysis of all rat oral toxicity studies for adults; this analysis showed that the BMDL₁₀ for pups is also protective for adults. Because the brain is the target tissue for the N-methyl carbamates, and the brain BMDL₁₀ of 1.1 mg/kg is also protective of cholinesterase inhibition in blood, then the brain BMDL₁₀ is the appropriate point of departure for both children and adults in the revised carbaryl risk assessment. For additional details regarding the comparative cholinesterase study, see the May 7, 2007 document, *Report on Comparative Cholinesterase Study of Carbaryl* and the June 29, 2007 document, *Carbaryl: Updated Endpoint Selection for Single Chemical Risk Assessment*.

Dermal Penetration Study. An *in vitro* dermal penetration study was conducted using both rat and human skin (MRID 47151902). This study showed that rat skin was 2.8 times more permeable to carbaryl than human skin. Therefore, the dermal point of departure was changed from 49 to 86 mg/kg/day. Additional information about this study may be found in the June 28, 2007 document, *Carbaryl: Review of in vitro Dermal Absorption Study*.

FQPA Safety Factor

To complete the carbaryl IRED in 2003, EPA evaluated the potential for special sensitivity of infants and children to carbaryl and the need for an additional FQPA safety factor. After evaluating the entire toxicity database available for carbaryl at that time, the FQPA safety factor, to account for special susceptibility of infants and children, was reduced from 10x to 1x for all scenarios, except for the chronic dietary endpoint where a 3x uncertainty factor was used to account for the lack of a NOAEL. This decision and rationale is described in detail in the technical support documents for the carbaryl IRED.

The comparative cholinesterase study data was used to derive a new FQPA safety factor by comparing the BMD₁₀ for brain cholinesterase inhibition between adults and pups at postnatal day 11. Because these pups were 1.8x more sensitive to brain cholinesterase inhibition than the adults, the FQPA safety factor was revised to 1.8x, and applied to both the N-methyl carbamate cumulative and the carbaryl-specific risk assessments. This safety factor is applied to the dermal endpoint because the endpoint was selected from a dermal toxicity study, because there are no comparative cholinesterase data in offspring from dermal exposure, and because juvenile rats are 1.8x more sensitive than adults based on the oral comparative cholinesterase study in rats. However, the FQPA safety factor is reduced to 1x for oral and inhalation endpoints because these endpoints are selected from the comparative cholinesterase data for the most sensitive population (postnatal day 11 pups).

Revised Toxicology Endpoints for Carbaryl Risk Assessment

As a result of the new toxicology and dermal penetration data for carbaryl, as well as the incorporation of the benchmark dose methodology into EPA's toxicology assessments, the Agency revisited the toxicology endpoints or points of departure for the carbaryl risk assessment. For a comparison of the toxicology endpoints used in the 2003 risk assessment with those used in this revised risk assessment, see Table 3.

The previous carbaryl risk assessment used endpoints from plasma, red blood cell, and brain cholinesterase inhibition and related effects (tremors, abnormal gait, pinpoint pupils). The revised risk assessment uses the more sensitive endpoint of brain cholinesterase inhibition from the carbaryl comparative cholinesterase study for both the revised carbaryl and the N-methyl carbamate cumulative risk assessments. Brain cholinesterase inhibition was selected as an endpoint, because this is an actual measure of toxicity to the target tissue and the most sensitive endpoint. Red blood cell and plasma cholinesterase inhibition are surrogate indicators of toxicity. A comparison of the oral rat studies showed that brain cholinesterase inhibition is a more sensitive endpoint than is red blood cell cholinesterase inhibition.

EPA used a benchmark dose analysis of the comparative cholinesterase study to select points of departure for use in the revised risk assessment using the BMDL₁₀ for postnatal day 11 pups. More details on the benchmark dose analysis for this study may be found in the May 7, 2007, document, *Report on Comparative Sensitivity Study of Carbaryl*. The BMDL₁₀ doses selected for points of departure were very similar to the doses used for points of departure in the previous 2003 risk assessment. An exception was the BMDL₁₀ for dermal toxicity, which was higher than the NOAEL used in the previous risk assessment (30 vs. 20 mg/kg/day). The benchmark dose analysis allows for a more accurate selection of a point of departure than the previously used NOAEL approach, which is limited by dose levels selected in a given toxicology study.

Table 3. Toxicological Endpoints for 2003 and 2007 Carbaryl Risk Assessments

Exposure Pathway	Toxicology Endpoint for Risk Assessment	
	2003/2004 IRED	2007 Revision
Acute Dietary	Rat Developmental Neurotoxicity (DNT) Study Maternal NOAEL of 1 mg/kg/day (LOAEL is 10 mg/kg/day, FOB changes)	Rat comparative cholinesterase (CCA) study Brain BMDL ₁₀ for pups at postnatal day 11 (PND11) is 1.1 mg/kg/day*
Chronic Dietary	Chronic dog study LOAEL of 3.1 mg/kg/day and 3X to account for data deficiency (no NOAEL)	Not appropriate due to rapid recovery of cholinesterase inhibition
Incidental Oral - short term	Rat DNT study maternal NOAEL of 1 mg/kg/day	Rat CCA Study Pup brain BMDL ₁₀ of 1.1 mg/kg/day
Incidental Oral – Intermediate term	Rat subchronic neurotoxicity study NOAEL of 1 mg/kg/day	Rat CCA Study Pup brain BMDL ₁₀ of 1.1 mg/kg/day
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%	Not appropriate due to rapid recovery of cholinesterase 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 study LOAEL of 50 mg/kg/day and 3X to account for data deficiency (no NOAEL)	Not appropriate due to rapid recovery of cholinesterase 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	

*Brain BMDL₁₀ for pups is protective for both adults and children according to a full BMD analysis of all carbaryl oral toxicity data in adults.

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 N-methyl carbamates show that cholinesterase inhibition is reversible, with recovery in less than 24 hours. Both the previous and present risk assessments evaluate potential cancer risk, but the cancer risk assessment is not included in this tolerance reassessment document because the cancer endpoints remain unchanged and were addressed in the carbaryl IRED. Current cancer risk estimates for carbaryl are below the Agency's level of concern.

Dermal exposure scenarios were adjusted using a dermal penetration factor of 2.8x. A comparative *in vitro* dermal penetration study showed that rat skin was 2.8x more permeable to carbaryl than human skin (MRID 47151902). Therefore, for dermal exposure scenarios, the BMDL₁₀ of 30 mg/kg/day was multiplied by 2.8 to derive the point of departure (86 mg/kg/day) for risk assessment for dermal exposure scenarios. In the 2003 carbaryl risk assessment, EPA used a 12.7% dermal absorption factor derived from a rat dermal absorption study to convert dermal exposures to the equivalent oral dose.

Table 4. Summary of Toxicology Endpoints, Uncertainty Factors, and Levels of Concern for Revised Carbaryl Risk Assessment

Exposure Scenario	Point of Departure (mg/kg/day)	Uncertainty/FQ PA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary <i>All populations</i>	1.1	UF _A =10x UF _H =10x FQPA SF=1x	Acute RfD=0.01 aPAD=0.01	Comparative Cholinesterase Rat 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
Chronic Dietary	Due to the rapid recovery of ChE activity, the acute exposure from carbaryl is the main duration of concern and therefore a chronic assessment is not appropriate for carbaryl.			
Incidental Oral (All durations)	1.1	UF _A =10x UF _H =10x FQPA SF=1x	MOE = 100	Comparative Cholinesterase Study- (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
Dermal (All durations)	86	UF _A =10x UF _H =10x FQPA SF=1.8x (children only)	MOE = 100 (adult) MOE= 180 (children)	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 (All durations)	1.1	UF _A =10x UF _H =10x FQPA SF=1	MOE = 100	Comparative Cholinesterase 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 4 ⁻⁴ (mg/kg/day) ⁻¹ based on incidence of hemangiosarcomas in mice			

Notes: NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A is for interspecies extrapolation from animal to human. UF_H is for potential intraspecies variation in sensitivity among members of the human population. MOE = margin of exposure.

B. Summary of Revised Dietary and Residential Risk Assessments

The Agency revised the dietary and residential risk assessments for carbaryl to incorporate the revised FQPA safety factor, new residues data, and recent information on percent crop treated. The revised human health risk assessment may be found in the June

29, 2007 document, *CARBARYL. HED Chapter of the Reregistration Eligibility Decision Document*. Details of the dietary risk assessment for food and water may be found in the June 27, 2007, document: *Carbaryl Acute Probabilistic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Reregistration Eligibility Decision*. Details of the residential risk assessment may be found in the June 29, 2007 document, *Carbaryl: Revisions to Residential Exposure and Risk Assessment* and in the September 21, 2007 document, *Carbaryl: Addendum to the “HED Chapter of the Reregistration Eligibility Decision Document (RED).”*

1. Dietary Risk from Food and Drinking Water

Food

For the revised carbaryl dietary risk assessment, EPA evaluated dietary exposure to residues in food using the same dietary exposure model and food consumption data used in the 2003 IRED [Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCIDTM)]. The dietary risk assessment was updated to incorporate the most recent residue data from USDA’s PDP program, as well as the most current information on percent of crop treated with carbaryl for various food commodities.

EPA’s revised dietary risk assessment for food shows that acute dietary exposure and risk are below the Agency’s level of concern for the general U.S. population and all population subgroups; exposure to carbaryl residues in food comprises <100% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure. Estimated dietary exposure for the general U.S. population is 29% of the aPAD; exposure to children age 1-2 years, the most highly exposed population subgroup, comprises 60% of the aPAD. Table 6 below summarizes acute dietary risks from food to other population subgroups. As previously mentioned, EPA did not evaluate dietary risk for chronic exposure to carbaryl due to the rapid reversibility of cholinesterase inhibition, the toxicological endpoint of concern.

Table 5. Summary of Acute Carbaryl Dietary Risk from Food.

Population Subgroup	% Acute Population Adjusted Dose (aPAD) at the 99.9th Percentile
General U.S. Population	29
All Infants (< 1 year old)	40
Children 1-2 years old	60
Children 3-5 years old	54
Females 13-49 years old	23

EPA conducted a sensitivity analysis on the carbaryl dietary assessment to determine how using data from various sources (i.e., PDP vs. FDA monitoring data) impacted dietary risk estimates. The Agency did this analysis for carbaryl because PDP data are considered to be the best available residue data for dietary risk assessment and because the N-methyl carbamate cumulative risk assessment uses only PDP residue data

for food. When only commodities with PDP data were included in the dietary assessment, the estimated dietary exposure for the general U.S. population was reduced to 17% of the aPAD and the dietary exposure for children age 1-2 years was reduced to 50% of the aPAD.

The Agency also conducted a critical commodity contribution analysis for carbaryl to determine the commodities contributing the most to dietary exposure, especially to children. From this analysis, EPA determined that carbaryl residues on strawberries are the most significant source of dietary exposure to children age 1-2. Carbaryl residues on strawberries were also identified as the main contributor to dietary risk to young children in the 2003 dietary assessment.

Drinking Water

For the revised carbaryl risk assessment, EPA incorporated estimated pesticide residues in drinking water directly into the exposure component of the dietary assessment, using the DEEM-FDICTM model. Drinking water consumption data and reported body weights from the Combined Survey of Food Intake by Individuals (CSFII) are incorporated into the exposure assessment. A 30-year distribution of drinking water residue values, estimated by modeling carbaryl concentrations in surface water over time (time series values), is incorporated into a probabilistic dietary assessment. The 2003 IRED presented both this methodology and the old methodology, using drinking water levels of comparison (DWLOCs).

The Agency also incorporated new half-life data from an aerobic aquatic metabolism study, regional percent cropped area factors, and the mitigation required in the carbaryl IRED into modeled estimates. Representative carbaryl use scenarios chosen for drinking modeling are summarized in Table 6. The Agency used the PRZM-EXAMS model to generate a distribution of approximately 11,000 values, representing daily peak values over 30 years. This data set was used to create water residue data files for use in DEEM-FCID. The range of annual peak water values was 13-108 ppb over 30 years. One in ten year peak values are summarized in Table 6 below; other modeled values are not presented because they are not relevant to the risk assessment. Details of EPA's refined drinking water modeling may be found in the March 13, 2007, document, *Carbaryl Refined Drinking Water Time Series Simulations Using Regional PCAs*.

Table 6. Surface Water Modeling for Representative Carbaryl Use Scenarios.

Modeling Scenario	Relevance	Regional PCA	Application type	Application Dates	Peak 1-in-10 yr Surface Water Concentration
Georgia Peaches with optional Dormant Spray	Entire US	0.38	Aerial application; 3 applications in season at 3 lb ai/A and; single dormant application at 3 lb ai/A	July 1, 8, 15; October 15	21
Georgia Peaches without	Entire US	0.38	Aerial application; 3 in season applications at 3 lb ai/A	July 1, 8, 15	21

Modeling Scenario	Relevance	Regional PCA	Application type	Application Dates	Peak 1-in-10 yr Surface Water Concentration
optional dormant Spray					
California Peaches with optional dormant spray	CA only	0.56	ground spray; 3 in season at 3 lb and 1 dormant at 3 lb (Note that due to model implementation difficulties, the last application is 1 lb in excess of max seasonal)	July 1, 8, 15; October 15	21
California Peaches without optional dormant spray	CA only	0.56	3 in season at 3 lb, 7 day interval, aerial	July 1, 8, 15	21
Florida Citrus	FL only	0.38	three 5-lb applications, 14 day interval aerial	January 4, 18, February 1	66
California Citrus	CA only	0.56	three 5-lb applications, 7 day interval, aerial	January 4, 18, February 1	35
California Citrus SLN	CA SLN only	0.56	single 12-lb application, aerial	January 4	44
California Grapes	CA only	0.56	five 2 lb applications, aerial	June 1, 8, 17, 24, July 1	30
PA Apple	Mid Atlantic	0.46	five 3-lb applications, 14 days interval, aerial	June 1, 15, 29, July 12, 26	108
Apple Oregon	Western Apples	0.63	five 3-lb applications, 14 days interval	April 15, 29, May 11, 25, June 4	27
FL Strawberry	Entire US	0.38	five 2-lb applications, ground spray	January 3, 10, 17, 24, February 1	64
CA strawberry	CA only	0.56	five 2-lb applications, ground spray	March 3, 10, 17, 24, 31	58

EPA also conducted a review of all readily available surface water monitoring data for carbaryl to evaluate any changes in surface water concentrations of carbaryl in urban and suburban streams with the phase out of residential uses of the pesticides chlorpyrifos and diazinon. The results of this review are summarized below. Details of EPA's updated drinking water assessment may be found in the May 2, 2007 document, *Revised Carbaryl Drinking Water Assessment Including Time Series Simulations* and a March 13, 2007 document, *Carbaryl Refined Drinking Water Time-series Simulations Using Regional PCAs*.

Surface Water Monitoring

The Agency has reviewed surface water monitoring data for carbaryl that has become available since the completion of the IRED in 2003. New information on available surface watering data for carbaryl is summarized below. EPA has focused on data sources providing information on residues of carbaryl in surface water as a result of

urban and suburban use. These data show that carbaryl is commonly found in surface water of both agricultural and urban watersheds. It is found more often in urban watersheds. Higher concentrations are reported for agricultural watersheds than for urban watersheds. Three sources of water monitoring data that were considered in the carbaryl IRED and are still relevant are the Pilot Reservoir Monitoring Study, a Bayer Drinking Water Monitoring Study for Carbaryl, and a joint USGS-EPA Mini-pilot Monitoring Program. Additional details may be found in the May 2, 2007 document, *Revised Carbaryl Drinking Water Assessment Including Time Series Simulations*.

EPA has also considered the impact of the recent phase out of residential uses of chlorpyrifos and diazinon, two widely used home and garden pesticides. There has been some speculation that carbaryl use would increase with the phase out of diazinon and chlorpyrifos, resulting in higher levels of carbaryl in urban and suburban watersheds. Although the long term impact of the phase out on carbaryl surface water concentrations is unclear, EPA has not observed a steady trend toward increased levels of carbaryl in surface water.

National Water Quality Assessment (NAWQA) Monitoring Program. For the 2003 carbaryl IRED, the Agency reviewed the available data from the US Geological Survey (USGS) NAWQA program, sampled between 1991 and 1998. In 2006, USGS published a NAWQA report summarizing results from 1992-2001. Carbaryl was listed in this 2006 report as one of the 14 most frequently detected pesticides in surface water (one of the three most frequently detected insecticides). This report also noted that carbaryl was detected in 50% of urban samples; with roughly 35% of urban samples reporting carbaryl levels < 0.1 µg/L. For this tolerance reassessment, EPA also reviewed NAWQA monitoring data collected between 1999 and 2005. For the more recent data, 29% of samples showed detections; the mean concentration of detections was 0.058 µg/L, with a lower detection frequency associated with agricultural uses than with urban uses. During this time period, samples collected from an agricultural region showed roughly 19% detects while samples representing urban and suburban uses showed roughly 50% detects. The maximum concentration reported was 33.5 µg/L, which was associated with agricultural use of carbaryl. The highest concentration reported in an urban stream was 16 µg/L in Denver, CO. The Agency believes that the frequency of carbaryl detections in urban streams is consistent both with EPA's 2003 drinking water assessment and with earlier data.

USGS-EPA Mini-pilot Monitoring Program. In September 2000, an Intergovernmental Steering Committee and workgroups were formed to design and implement monitoring programs in support of regression model development efforts. The purpose of the monitoring was to resolve technical and logistical issues for development of a larger monitoring program. Phase I of the project sampled water-supply intakes for five community water systems (CWS) that withdraw from free-flowing surface-water bodies. Sampling was scheduled approximately 90 times over the course of a year, occurring most frequently during the primary pesticide application and pesticide runoff periods. Sites were selected to represent a variety of cropping regions and pesticide usage in areas dependent on precipitation-based agriculture. Samples were

shipped overnight in iced coolers to the USGS National Water-Quality Laboratory in Denver Co. for analysis. Low levels of carbaryl were found at several of the monitoring locations, with no sample measuring greater than 1 µg/L.

Surface Water Monitoring Program for Pesticides in Salmonid-bearing Streams. The Washington State Departments of Agriculture and Ecology monitored selected salmonid bearing streams for pesticides during the typical pesticide use season (Burke et al. 2006). This study evaluated watersheds collecting potential surface water runoff from both urban and agricultural regions. Urban regions were represented by Thornton Creek in the Cedar-Sammanish Watershed, a 12.1 square mile area with 75,000 to 100,000 residents, encompassing single family homes, apartment complexes, and schools. Paved impervious surfaces cover 50% of this watershed. Agricultural regions were represented by the Lower Yakima Watershed, which drains an agricultural basin where numerous crops, including grapes, apples and other fruit trees, wheat, asparagus, hops, mint, and potatoes are grown. Agricultural crops cover 47% of this watershed of 216,168 acres. Water from Yakima River systems is managed by US Bureau of Reclamation; while local irrigation districts manage water distribution to farms via canals. Three water bodies were monitored in the Lower Yakima Watershed: Marion Drain, Sulphur Creek Wasteway, and Spring Creek.

From 2003-2005, 78 sampling events occurred in the urban Thornton Creek watershed. Carbaryl was not detected in any sample above the mean lower practical quantitation limit, which varied over this time from 0.19 µg/L (2003) to 0.13 µg/L (2004) to 0.11 µg/L (2005). Carbaryl was detected in samples collected in the agricultural Lower Yakima watershed (which includes the Marion Drain, the Sulfur Creek Wasteway, and Spring Creek). In 2003 carbaryl was detected in the Marion drain at 0.14 µg/L (in 1 of 18 samples); carbaryl was not detected in 2004 or 2005 at this location. Carbaryl was detected in 2004 in the Sulfur Creek Wasteway at 0.16 µg/L g/L (in 1 of 31 samples); carbaryl was not detected in 2003 or 2005 at this location. On June 18, 2003, carbaryl was detected at a concentration of 10 µg/L in the upper Spring Creek station, and 1.7 µg/L at the mid-Spring Creek station.

The Washington State Departments of Agriculture and Ecology also reviewed the USGS NAWQA data for the Cedar-Sammanish and Lower Yakima Watersheds, dating back to 1996. USGS monitoring for these watersheds captured changes in pesticide use, including the phase out of residential uses of diazinon in December 2004. Washington State Departments of Agriculture and Ecology reviewers concluded that carbaryl detection rates have increased slightly over time.

Environmental Monitoring of Carbaryl in Urban Areas in California. The Environmental Monitoring Branch of California's Department of Pesticide Regulation (DPR) measured environmental concentrations of carbaryl and other pesticides in selected media following ground applications of pesticides to control the glassy winged sharpshooter, an insect causing severe damage to California grapes. After spraying carbaryl in five urban areas to control this pest, California's DPR monitored carbaryl residues in pesticide tank mixtures and in air, surface water, foliage, and backyard fruits

and vegetables. DPR found only three detections of carbaryl in surface water¹, and concluded that carbaryl spraying in urban areas to control the glassy winged sharpshooter did not result in significant human or environmental exposure.

Groundwater Monitoring

The carbaryl IRED reported a 1987 groundwater monitoring value of 610 µg/L from Suffolk County New York. Because this value was significantly higher than any other monitoring values from ground or surface water, EPA contacted the Suffolk County government for more information about this particular groundwater sample. The sample associated with that concentration (the actual concentration was 61,000 µg/L) was taken from a sump at a pesticide mixer/loader site as part of a pesticide spill investigation, not from a groundwater monitoring well. Therefore, this value should not have been reported in the Suffolk County water quality database (SCDH, 2007, personal communication); EPA has removed it from the carbaryl drinking water assessment. There were a small number of detections of carbaryl reported to OPP as a result of a quality control check of the Suffolk County database, ranging from 0.1 to 13 µg/L. These values are more in line with other monitoring data for carbaryl reported in the EPA assessment.

2. Risk from Residential Uses of Carbaryl

The Agency revised the residential risk assessment for carbaryl to incorporate the revised toxicology endpoints and FQPA safety factor, the mitigation specified in the IRED, and confirmatory data received as a result of the generic DCI for carbaryl. EPA received turf transferable residue (TTR) data for granular formulations of carbaryl, as well as additional data to support the use of carbaryl in pet collars. The granular TTR data were incorporated into the revised risk assessment; however, the pet collar data were considered but not incorporated because of data quality issues. In addition, the Agency incorporated data from several studies for pesticides applied to turf to estimate the percent of carbaryl transferred from turf to a person's hand. Details of the revised carbaryl residential risk assessment may be found in the June 29, 2007 document, *Carbaryl: Revisions to Residential Exposure and Risk Assessment* and in the September 21, 2007 document, *Carbaryl: Addendum to the "HED Chapter of the Reregistration Eligibility Decision Document (RED)."*

Mitigation Specified in IRED

At the time of the 2003 carbaryl IRED, EPA had risk concerns for several residential uses of carbaryl. To address these risk concerns, the IRED specified the following mitigation measures, which are now being implemented through revised product labeling:

- Cancellation of all pet uses except flea collars, all aerosol products, application of granular and bait products to lawns either by hand or using a belly grinder;

¹ DPR found a high detect in 1 sample, from a furrow in a field adjacent to a treated area. This is attributed to rainfall runoff and is not believed to be significant.

- Special packaging for all carbaryl dust products for use in home gardens (ready to use shaker can, containing no more than 0.05 lb a.i. carbaryl per container); and
- Requirement that all carbaryl liquid products be packaged in pint size containers for use with hose-end sprayers; use on lawns limited to spot treatment.

In addition, EPA required confirmatory data for the granular turf use and the pet collar use. These data requirements are described below.

Confirmatory Data from 2005 Generic DCI

EPA received post-application exposure studies as a result of the March 2005 generic DCI for carbaryl: a new turf transferable residue (TTR) and handpress study for granular carbaryl (MRID 46673901), submitted by Bayer CropScience, and a dog petting and rate of release transferable residue study for dog collars impregnated with carbaryl (MRIDs 45792201, 46075601 and 46015001), submitted by Wellmark International. (Some of the Wellmark data have been previously submitted.) The data from the TTR study, which is described below, was incorporated into the revised residential risk assessment for carbaryl. However, the data from the pet collar studies could not be used in the revised risk assessment due to issues with quality assurance, quality control, and documentation of data. (See the December 5, 2006 document, *[Review of] Transferable residues from dogs treated with 16% carbaryl collar, MRIDS 45792201, 46015001, and 46075601*, for details.) Therefore, these pet collar studies are considered unacceptable, do not meet the DCI requirement, and are not used for quantitative risk assessment purposes.

In the turf transferable residue (TTR) study, data were collected from three sites (Molino, FL; Stilwell, KS; and Fresno, CA) by means of a modified California roller and handpress on turf after the application of 8 lb ai/A of Sevin 2G (2% granular carbaryl). TTR data were collected for both irrigated and nonirrigated turf, and handpress data were collected using both moist and dry hands. Data were collected immediately after application and at 4, 12, and 24 hours and 2, 3, 5, and 7 days after application. The registrant submitted additional data collected for 24 hours at 30 minute increments at the Molino, FL, site as a study addendum.

Residential Exposure Scenarios

There are far fewer potential residential exposure scenarios today than at the time of the carbaryl IRED because of numerous product cancellations and the mitigation described above. As previously mentioned, two-thirds of all carbaryl products registered at the time of the IRED (June 2003) have been voluntarily cancelled. At the present time, 95 carbaryl products are registered.

For the 2007 carbaryl revised residential risk assessment, EPA evaluated the following residential handler scenarios:

- Home gardens, application with ready-to-use trigger sprayer, hose-end sprayer, ornamental duster, or low-pressure handwand;
- Trees and ornamentals, application with hose-end sprayer or low-pressure handwand;
- Lawn care, application of liquid product with hose-end sprayer;
- Lawn care, application of granular and bait products with push-type spreader;
- Pet collars impregnated with carbaryl for dogs and cats; and
- Garden and ornamentals, paint on or sprinkler can application.

The Agency evaluated potential exposure and risk to residential handlers, who would be applying carbaryl products and post-application risk to adults, children, and toddlers who could be reentering a carbaryl treated lawn or garden, playing with pets wearing carbaryl pet collars, or harvesting fruit and vegetables from home gardens. Because the carbaryl technical registrant, Bayer CropScience, has recently requested that EPA allow a larger package size for garden dust products, the Agency has also evaluated potential risks from such a scenario.

Risk to Residential Handlers

EPA's revised risk estimates for residential handlers were not of concern for carbaryl for any use scenario; i.e., MOEs were all greater than 100. MOEs for residential handlers ranged from 280 to 34,000 for combined inhalation and dermal exposure. The lowest combined MOE (highest risk estimate) is 280 for application of 10% carbaryl dust to vegetable gardens and/or ornamentals. Therefore, EPA does not have a risk concern for residential handlers.

Residential Post-application Risk

Exposure Scenarios

EPA evaluated potential risks from the following post-application exposure scenarios in the revised residential risk assessment for carbaryl:

Adults

- Incidental dermal contact with carbaryl residues on turf (lawns and golf courses) from mosquito adulticide use;
- Dermal contact with carbaryl residues on treated deciduous trees;
- Dermal contact with carbaryl residues on treated vegetable gardens;
- Dermal contact with carbaryl residues from Washington state oyster bed use (oyster harvesting and swimming);
- Dermal contact with carbaryl residues from doing heavy yard work on turf treated with granular formulations; and
- Dermal contact with carbaryl residues from golfing on turf treated with liquid or granular formulations;

Children (Age 10-12 years)

- Dermal contact with carbaryl residues on treated deciduous trees; and
- Dermal contact with carbaryl residues on treated vegetable gardens;

Toddlers (Age 3 years)

- Dermal contact and incidental oral ingestion of residues from hugging a pet wearing a carbaryl-impregnated flea collar;
- Dermal contact with residues on turf from mosquito adulticide use;
- Dermal contact with carbaryl residues from Washington state oyster bed use while playing on beach; and
- Dermal and incidental oral ingestion of carbaryl residues from treated residential turf.

The Agency assumed that post-application exposure to adults and older children would be limited to the dermal route, but that toddlers could receive both dermal and incidental oral exposure. EPA assumes that toddlers could be mouthing grass from treated lawns, eating soil from treated lawns, mouthing their hands after touching a treated lawn, or hugging a pet wearing a carbaryl-impregnated flea collar. Although EPA could combine incidental oral exposure from all three potential incidental oral exposure pathways for screening purposes, the Agency does not believe that such a scenario is likely to occur and combining high-end exposure estimates from already conservative exposure scenarios would result in risk estimates associated with toddler behaviors that are unrealistic. For example, the Agency considers it unreasonable to assume a toddler, presumably under some degree of supervision and care, would be playing on a lawn immediately after the lawn was treated with carbaryl (at the maximum rate after watering in) and the toddler would be putting both hands on the ground and then in his or her mouth, eating a handful of grass, and eating soil, all within the same 2 hour time period. In addition, each of these activities is assumed to occur multiple times, over the 2 hour time period, with the same amount of pesticide residue picked up and ingested each time. For example, EPA assumes that a toddler would have 20 hand-to-mouth events per hour, which reflects the high-end (90th percentile) of exposure from observational data on children's activities. For each of these incidental oral scenarios, EPA assumes a high amount of residues would be transferred to a child's hand or be found in the grass or soil that is eaten. EPA believes that these assumptions, especially when taken together, would significantly overestimate children's exposure to carbaryl. Therefore, EPA assessed a number of reasonably realistic, and representative, toddler post-application scenarios.

The major assumptions underlying each of the toddler exposure scenarios are listed below:

Dermal Exposure

From Lawn

- Child playing on a wet lawn *immediately* after carbaryl is applied and watered- in
- Child plays on lawn for 2 hours

- Child places both hands on grass (area of 20 cm² contacts grass) and picks up significant residues from blades of grass (5200 cm²/hour)

From Pet Collar

- Child hugs a medium size (30 lb) dog and residues are transferred from fur to hands and forearms
- 20% of available carbaryl in pet collar is evenly distributed over dog's fur and residues are available for transfer to child for each event
- Child plays with dog for 2 hours

Incidental Oral Exposure

Hand- to-Mouth Pathway

- Child puts hand in mouth 20 times/hour
- Child ingests all pesticide residues on his hand
- Child picks up the same amount of residues each time and ingests them all

Object-to-Mouth Pathway (Eating Grass)

- Child mouths all of the grass from 4 square inches of lawn per day
- Residue levels on grass equal 3-5% of maximum application rate for carbaryl

Soil Ingestion Pathway

- Soil residues in top layer of soil equal 100% of maximum application rate for carbaryl
- Child ingests 100 mg of soil per day

Risk Estimates

Risk estimates for a single route of exposure to adults, children, and toddlers are expressed as MOEs. EPA has a risk concern for dermal MOEs < 180 and for oral MOEs < 100, as shown in Table 4. Risk estimates for toddlers exposed by multiple routes of exposure are expressed as an Aggregate Risk Index (ARI) because EPA has different levels of concern for oral and dermal exposure to toddlers. For toddlers, EPA calculated ARIs for scenarios combining risk from dermal exposure with risks from certain oral exposure pathways, such as eating grass or mouthing their hands after touching a treated lawn. The Agency generally has a risk concern for ARIs < 1.

Adults. Dermal MOEs for adults from post-application exposure to granular carbaryl on turf range from 720 to 63,000 when the pesticide is watered in after application; and from 380 to 38,000 when the pesticide is not watered in. Dermal MOEs for adults range from 930 to 27,000,000 for all other scenarios. Therefore, EPA does not have a risk concern for adults for any post-application exposure scenario.

Children age 10-12 years. Children (age 10-12 years) working in home vegetable gardens treated with carbaryl have post-application dermal MOEs ranging from 4,200 to 8,400. Children working in home orchards treated with carbaryl have post-application

dermal MOEs ranging from 1,000 to 31,000. Because all of these MOEs exceed 180, EPA’s level of concern for this age group, the Agency does not have a risk concern for post-application exposure to children age 10-12.

Toddlers. EPA has calculated separate dermal and incidental oral MOEs for toddlers exposed to carbaryl residues from the potential scenarios described above. In addition, EPA has calculated risk to toddlers from combined dermal and incidental oral exposure (hand-to-mouth or object-to-mouth pathways) to account for the possibility that toddlers could be exposed to pesticide residues from both oral and dermal routes on the same day, potentially at the same time, from use of a single carbaryl product.

EPA has calculated separate dermal and incidental oral MOEs for toddlers exposed to carbaryl residues on turf as a result of the carbaryl lawn care use. As shown in Table 7 below, dermal MOEs for toddlers playing on treated turf range from 230 to 3,100, and are not of concern. These risk estimates were derived from the new TTR study (MRID 46673901) which measured carbaryl residues on turf following the application of Sevin 2G at a rate of 8 lb ai/A with a drop spreader. EPA also assumed 2 hours of exposure/day, and a transfer coefficient of 5,200 cm²/hour. Transferable residues were measured using both the California roller and handpress methods. The handpress data, collected only at the Kansas site, were used to assess children’s hand-to-mouth exposure.

Table 7. Post-application Dermal Risks to Toddlers from Use of Sevin 2G on Turf

Turf Transferable Residue Study Site	Short-term Post-application Dermal MOEs for Toddlers*	
	Non-Irrigated	Irrigated
Florida	230	430
Florida Study Addendum	1,600	Not Applicable, No Irrigation or Rainfall
California	270	3,100
Kansas (rain during study)	760	2,600

* Dermal MOEs > 180 are not of concern.

Toddler risks from the three potential pathways of incidental oral exposure to carbaryl are summarized in Table 8 below. Oral MOEs for hand-to-mouth exposure to toddlers range from 71 to 720; MOEs for object-to-mouth exposure range from 150 to 250; and the MOE for soil ingestion is 2,800.

Table 8. Post-application Incidental Oral Risks for Toddlers Playing on Turf

Exposure Pathway	Range of Short Term Incidental Oral MOEs	Residue Available for Transfer	Data Source/ Methodology
Hand-to-Mouth	71-720	100%	Carbaryl TTR Study, Kansas data (MRID 46673901)
Object-to-Mouth	150-250	3-5%	Residue data from multiple turfgrass studies, Residential SOPs
Soil Ingestion	2,800	100%	Residential SOPs

Handpress data from the Kansas site were used to calculate hand-to-mouth incidental oral exposure and risk. These were the only handpress data available. Handpress data were collected with both dry and moist hands to simulate a toddler’s mouthing behavior. These data were also collected for irrigated and nonirrigated test plots to allow the Agency to evaluate risk from a variety of potential scenarios. EPA calculated MOEs for each of these possible scenarios, as shown in Table 9.

Table 9. Toddler Hand-to-Mouth Risks based on TTR Data from Kansas site.

Type of Handpress	Short-Term Oral MOE	
	Non-irrigated	Irrigated
Dry	170	720
Moist	71	500

MOEs calculated for dry and wet hands contacting irrigated turf are 720 and 500, respectively, and therefore not of risk concern. Likewise, the MOE for dry hands contacting non-irrigated turf is 170 and not of risk concern. The MOE for wet hands contacting non-irrigated turf is 71, and is below 100, EPA’s level of concern. At present, labels for all granular residential use products specify that people or pets contain the following language:

“Do not allow people or pets to enter the treated area until dusts have settled. In addition, if directions for use require watering-in, do not allow people (except those involved in the watering-in) or pets to enter the treated area until the watering-in is completed and the area has dried.”

Most carbaryl granular products for homeowner use recommend watering in so that the product can effectively control soil-borne insect pests, such as mole crickets and white grubs. As part of this RED, EPA will be requiring that all labels for granular turf products for residential use require watering-in.

Moreover, EPA believes that the MOE of 71 is conservative and likely overstates actual risk for several reasons. The Agency’s current screening-level methodology² to estimate hand-to-mouth exposure to toddlers incorporates several conservative assumptions. EPA assumes that a toddler is exposed to residues immediately following

² EPA used methodology from the Residential Standard Operating Procedures (SOPs)

application of carbaryl at the maximum rate, 8 lbs ai/A, which represent a worst case exposure scenario. The Agency assumes that a toddler is playing on a lawn that has just been treated with carbaryl and that the child remains on the lawn for 2 hours. EPA also assumes that an area of 20 cm² (palms of both hands) comes into contact with the treated lawn and that the child ingests all of the pesticide residues on his hand. The Agency further assumes that 100% of the residues picked up and ingested the first time are replenished each subsequent time the child contacts the treated lawn, and ingested each subsequent time the child puts his hand in his mouth. In addition, EPA assumes that the child puts his hand in his mouth 20 times per hour, for 2 hours per day, for a total of 40 hand-to-mouth events per day. The number of hand-to-mouth events represents the 90th percentile of observational data on mouthing behavior by young children³.

Moreover, because most labels for granular carbaryl lawn care products recommend watering-in after application, EPA believes that the residue values and exposure estimates for irrigated turf are more representative of actual use than values from non-irrigated turf. Furthermore, as previously mentioned, the Agency will be requiring that all labels for carbaryl granular turf products be modified to require irrigation, or watering-in after product application to turf.

In summary, EPA believes that the label requirement to water in granular carbaryl residential turf products after application reduces the potential risk concern for toddlers. Given the conservativeness of this screening-level exposure scenario (complete removal/ingestion of residues on the hand, full replenishment of residues, and 40 hand-to-mouth activities per day) and considering the label requirement for watering-in, which would result in lower exposures and acceptable MOEs, the Agency does not have a risk concern for children's hand-to-mouth exposure resulting from the use of carbaryl granular turf products.

EPA has combined incidental oral (hand-to-mouth and/or object-to-mouth pathway) and dermal risk estimates for toddler post-application exposure scenarios associated with playing on turf following aerial or ground spraying of carbaryl as a mosquito adulticide; playing on a beach following use of carbaryl to treat oyster beds; playing with (hugging) a pet wearing a carbaryl flea collar; and playing on treated lawns.

Toddler post-application risk estimates are presented as ARIs; EPA typically has a risk concern for ARIs < 1. Post-application ARIs for toddlers exposed by both incidental oral and dermal routes range from 0.92 to 420, and are not of concern. Although the ARI for combined dermal and object-to-mouth exposure for a child playing on a treated lawn is 0.92, this value is based on object-to-mouth exposure derived from use of liquid rather than granular products on turf because these are the only available data. Granular turf products are expected to fall to the underlying thatch or soil, reducing the amount of foliar residue available; whereas liquid products are expected to remain on turf and be more available for transfer. Also, this value does not reflect watering-in,

³ Data from observational studies on young children show a mean of 6 hand-to-mouth events per hour; 20 hand-to-mouth events per hour represents the 90th percentile of the data and should therefore be considered a high-end value (Xue et al, 2007).

when granulars/residues are less likely to be available. Post application risks to toddlers are summarized in Table 10.

Table 10. Post-application Risks to Toddlers from Oral and Dermal Exposure

Use Scenario	Exposure Scenario	Co-occurring Exposure Pathways	Aggregate Risk Index (ARI)
Mosquito Adulticide (ground application)	Incidental residues from residential lawn	Dermal + Hand-to-Mouth	6.7
Mosquito Adulticide (aerial application)		Dermal + Hand-to-Mouth	13
Oyster Beds (Washington SLN)	Beach Play	Dermal + Hand-to-Mouth	420
Pet Collar Use	Child Hugging Pet	Dermal + Hand-to-Mouth	1.6
Lawn Care Use	Child Playing on Lawn	Dermal + Hand-to-Mouth	1.6
Lawn Care Use	Child Playing on Lawn	Dermal + Object-to-Mouth	0.92

The Agency did not consider it reasonable or realistic to combine toddler risks from post-application scenarios, such as the pet flea collar with lawn care products. The ARIs for the lawn care and pet collar exposure scenarios are essentially equivalent, given the precision of the underlying data and assumptions used in the risk estimates, and indicate that the combined dermal and oral exposure risks are comparable for both use scenarios. Therefore, if a toddler were playing on a lawn for 2 hours immediately after it was treated with carbaryl (at the maximum rate and after the product was watered-in) and at the same time playing with a dog that has a carbaryl pet collar, the potential screening-level risk is no greater than the independent estimates associated with the lawn or pet collar scenarios, assuming a toddler can not have both of its hands on the grass and the dog at the same time or have its mouth on the grass and the dog at the same time.

An example of another possible scenario would entail a toddler playing for two uninterrupted hours with a pet that has a carbaryl pet collar and immediately thereafter playing for two uninterrupted hours on a lawn that was just treated with carbaryl at the maximum rate. In this hypothetical scenario a toddler, presumably under some degree of care and supervision, would spend an uninterrupted four hour period playing with a pet wearing a carbaryl pet collar and subsequently playing for two hours on a lawn freshly treated with carbaryl, without engaging in any other activity for the entire period of time. The Agency concludes that assuming such a pattern of behavior unrealistic and an unreasonable conceptual model from which to formulate screening-level risk estimates. To the extent that the activities of playing with a dog wearing a carbaryl collar and playing on a lawn just treated with carbaryl are separated by an activity not associated with carbaryl exposure, recovery to any adverse effect would occur, because carbaryl, like the other N-methyl carbamates, causes a reversible effect (cholinesterase inhibition). Thus, carbaryl exposure events separated by any other activity are essentially independent.

In addition, because carbaryl pet collars and granular lawn products comprise a fairly small market share, EPA does not expect that co-exposure or sequential exposure to these products is likely to occur. The Residential Exposure Joint Venture (REJV)

database estimates that 1.2% of all households apply carbaryl as a lawn treatment⁴, and 0.1% of households apply granular carbaryl. EPA's 1990 National Home and Garden Pesticide Use Survey estimates that 1% of all households apply carbaryl to lawns. Details of this analysis may be found in the July 13, 2007 document, *Alternative[s] Assessment for Carbaryl Use on Residential Lawns*. EPA has also reviewed available data on use of carbaryl and various other pesticides in pet collars. In 2005, pet collars occupied an estimated 9% of the market share for pet flea and tick products, compared with liquids (including shampoos, dips, and spot-on treatments) with approximately 66% market share; oral tablets with approximately 17% market share; and other products (aerosols, foggers, soaps, etc) with <10% market share⁵. Further, carbaryl is one of several available insecticides used in impregnated flea collars. Propoxur, methoprene, and tetrachlorvinphos are more commonly formulated in flea collars than carbaryl. Details of EPA's analysis of alternative pet collars may be found in the September 24, 2007 document, *Alternatives Assessment for Carbaryl Impregnated Flea and Tick Collars on Dogs and Cats*. Because of the small market share for each of these products, EPA does not believe that a toddler will be exposed simultaneously or sequentially to carbaryl residues from a pet collar and carbaryl residues on a treated lawn.

3. Aggregate Risk

Acute Aggregate (Food and Water)

When exposure from food and drinking water are combined, dietary exposure comprises 61-66% of the aPAD for children 1-2 years old and 40-85% of the aPAD for infants less than 1 year old, the most highly exposed population subgroup. Therefore, acute aggregate risk is below the Agency's level of concern.

Short-term Aggregate (Food, Water, and Residential)

EPA considered short-term aggregate risk for both adults (handler and post-application exposure) and children (post-application exposure only). Short-term aggregate risk to adults is expressed as an MOE. Aggregate risk to children is expressed as an ARI derived by combining exposure and risk from food, drinking water, and post-application residential exposure. EPA has risk concerns for an aggregate MOE less than 100 and for an ARI less than 1.

When average exposure to carbaryl residues in food and drinking water is combined with short-term exposure to adults applying carbaryl dust products in their home gardens, the aggregate MOE is 510 and not of risk concern. Likewise, aggregate risk from post-application exposure to adults who are performing heavy, high contact work in the yard or garden, results in MOEs ranging from 640 to 800, which are not of concern. Short-term aggregate risks to adults are summarized in Table 11 below. Aggregate MOEs for adults range from 510 to 800 and are not of concern.

⁴ The REJV did not distinguish between liquid and granular lawn care products. EPA has limited use of liquid products in a residential setting to spot treatment.

⁵ EPA proprietary data.

Table 11. Summary of Carbaryl Aggregate Risks to Adults

Residential Exposure Scenario	Dietary MOE (food + water)	Residential MOE (dermal)	Aggregate MOE
Residential Handlers			
Application of carbaryl garden dust	5600	560*	510
Residential Post-application			
Thinning Deciduous Trees	5600	930	800
Heavy Yard Work (after application of granular carbaryl to lawn)	5600	720	640

* Represents combined dermal and inhalation exposure.

Short-term aggregate risks for children are summarized in Table 12 below. When risk from average exposure to carbaryl residues in food and drinking water is combined with post application risk to children working in a home orchard, the ARI is 5, and not of concern. Likewise, when risk from dietary exposure to carbaryl residues is combined with post-application risk to toddlers, the ARI ranges from 0.9 to 1.5 and is not of concern. As previously mentioned, EPA does not have a risk concern for a toddler who could receive post-application exposure from both dermal exposure (crawling on a treated lawn immediately after carbaryl application) and from incidental oral exposure from eating grass treated with carbaryl (residential ARI of 0.92).

Table 12. Summary of Carbaryl Post-application Aggregate Risks to Children

Residential Exposure Scenario	Dietary ARI (food + water)	Residential ARI	Aggregate ARI
Children Age 10-12			
Thinning Fruit Trees in Home Orchard	57	5.5 (dermal only)	5.0
Toddler Age 1-2			
Playing with Pet wearing carbaryl collar	33	1.6 (dermal only)	1.5
Playing on Treated Turf (dermal only)	33	1.3 (dermal only)	1.3
Playing on Treated Turf (dermal + incidental oral)	33	1.6 (dermal + hand-to-mouth)	1.5
Playing on Treated Turf (dermal + incidental oral)	33	0.92 (Dermal + object-to-mouth)	0.9

Chronic Aggregate Risk

As previously mentioned, EPA did not consider chronic risk from carbaryl exposure due to the rapid reversibility of the toxic effect, cholinesterase inhibition. Therefore, EPA does not have a concern for chronic aggregate risk. In addition, when the Agency evaluated chronic aggregate risk for the 2003 carbaryl IRED, risks were below the level of concern.

4. 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 Office of Pesticide Programs' (OPP) 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 Incident Data System reported 160 cases for carbaryl between the years 2000 and 2006. Of these, nearly 20 cases were the results 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 only 75 cases involving carbaryl alone (of 5,899 reported cases of pesticide poisonings from 1998 to 2003).

The Poison Control Center (PCC) Data from 1993 to 2005 show that of a total of 10,781 exposure cases to children from all pesticides, 4,030 cases were from exposure to carbaryl. However, in 2003 EPA initiated a data call-in (DCI) for carbaryl which resulted in the voluntary cancellation of more than 200 carbaryl products, many of which were registered for use in and around the home environment. As a result of the 2003 IRED, EPA implemented action to cancel numerous carbaryl products, including all pet uses and all carbaryl aerosol products. Therefore, EPA performed additional analyses to determine which products were associated with incidents in the recent years (2003-2005). The data show that 75% the health care facility reported incidents for non-occupational exposures are due to carbaryl products that are now cancelled. As these products become unavailable as existing stocks are depleted, the Agency anticipates these carbaryl incidents will continue to decline.

Since the IRED was issued in 2003, approximately 35% of the residential use carbaryl products have been cancelled and significant mitigation designed to reduce exposures have been applied to residential use carbaryl products. EPA believes that these mitigation measures have addressed the root cause of many of the incidents reported. The Agency will continue to monitor the incident reports as mitigation measures are incorporated onto product labels and will impose additional mitigation as needed.

III. Risk Management, Reregistration Eligibility, and Tolerance Reassessment

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 the dietary, residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient carbaryl. In addition, the Agency has re-evaluated the human health risks associated with all remaining registered uses and completed the cumulative risk assessment for the N-methyl carbamate group of pesticides.

Based on the carbaryl data, the revised human health risk assessment, and the N-methyl carbamate cumulative risk assessment, the Agency has sufficient information on the human health and ecological effects of carbaryl to complete its tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA. EPA has determined that remaining products containing carbaryl will be eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document and in the October 22, 2004 Carbaryl IRED amendment are adopted; and (ii) all remaining carbaryl product labels are amended to reflect these measures. At this time, the Agency is requiring additional mitigation for granular turf products for residential use; product labels must be amended to require that the product be watered in immediately after application. Because most granular turf product labels currently recommend that the product be watered in, and because this is necessary for efficacy for soil-borne insect pests, the Agency does not believe this should pose an unreasonable burden on homeowners.

Based on the evaluation of carbaryl described in this document and in the October 2004 carbaryl IRED amendment, the Agency has determined that carbaryl products, unless labeled and used as specified in this document and the October 22, 2004 IRED amendment, would present risks inconsistent with FIFRA and FFDCA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, and the October 2004 IRED amendment, the Agency may take regulatory action to address the risk concerns from the use of carbaryl. If all changes outlined in this document and in the 2004 carbaryl IRED amendment are incorporated into the product labels, then all current risks for carbaryl will be adequately mitigated for the purposes of this determination under FIFRA.

If the Agency determines that any aspect of the reregistration and tolerance reassessment decisions described in this document and in the October 22, 2004 carbaryl IRED amendment are no longer appropriate, then EPA will pursue appropriate action,

including but not limited to reconsideration of any portion of this RED decision. The Agency is currently revisiting the revised occupational risk assessment, which does not identify any additional risk concerns, and will amend this RED to incorporate any resulting changes in the regulatory decision. In addition, as a separate action, EPA is preparing a response to petitions to cancel all uses of carbaryl and revoke all carbaryl tolerances. The Agency's response to these petitions will be released at a later date.

B. Food Quality Protection Act Findings

The Agency has evaluated the human health risks associated with all currently registered uses of carbaryl and has determined that there is a reasonable certainty that no harm will result from aggregate non-occupational exposure to the pesticide chemical residue. In making this determination, EPA has considered dietary exposure from food and drinking water and all other non-occupational sources of pesticide exposure for which there is reliable information. The Agency has concluded that with the adoption of the risk mitigation measures identified in the N-methyl carbamate cumulative risk assessment, all of the tolerances for carbaryl and the other N-methyl carbamates meet the safety standard as set forth in section 408(b)(2)(D) of the FFDCA. Therefore, the tolerances established for residues of carbaryl in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA. The basis for EPA's safety finding and the carbaryl tolerance reassessment summary are described herein.

1. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with carbaryl. The Agency has determined that human health risks as a result of exposures to carbaryl are within acceptable levels. In other words, EPA has concluded that all of the tolerances for carbaryl meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to carbaryl from all possible sources. Because carbaryl is a member of the N-methyl carbamate class of pesticides, which share a common mechanism of toxicity, EPA has conducted a cumulative risk assessment to evaluate exposures and risks resulting from all registered uses of N-methyl carbamate pesticides, including carbaryl. EPA has concluded that the cumulative risks associated with the N-methyl carbamate pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCA. EPA is thereby terminating the tolerance reassessment process under 408(q) of the FFDCA. For additional information, refer to the document, *Revised N-methyl Carbamate Cumulative Risk Assessment*, which is available in the EPA docket EPA-HQ-OPP-2007-0935 and on the web, <http://www.epa.gov/pesticides/cumulative/>.

2. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for carbaryl meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or

any subgroup from the use of carbaryl. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of carbaryl. As discussed in section II of this document, the aggregate risks from carbaryl from food, drinking water, and residential exposure are not of concern.

3. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for carbaryl, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCFA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the toxicity, use practices, and environmental behavior for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of carbaryl residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of carbaryl, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. As previously mentioned, EPA received a comparative cholinesterase study for carbaryl in November 2006 to inform the FQPA safety factor decision. A new FQPA safety factor was derived from the comparative cholinesterase study data by comparing the BMD₁₀ for brain cholinesterase inhibition between adults and pups at postnatal day 11. Because these pups were 1.8x as sensitive to cholinesterase inhibition as the adults, the FQPA safety factor was set at 1.8x, and applied to both the N-methyl carbamate cumulative and the carbaryl-specific risk assessments. This safety factor is applied to the dermal endpoint because the endpoint was selected from a dermal toxicity study, because there are no comparative cholinesterase data in offspring from dermal exposure, and because juvenile rats are 1.8x more sensitive than adults based on the oral comparative cholinesterase study in rats. However, the FQPA safety factor is reduced to 1x for oral and inhalation endpoints because these endpoints are selected from the comparative cholinesterase data for the most sensitive population (postnatal day 11 pups).

4. Endocrine Disruptor Effects

EPA is required under the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation

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

5. Cumulative Risks

Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Other substances are considered to account for the possibility that low-level exposures to multiple chemical substances that cause a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance.

Carbaryl is a member of the N-methyl carbamate class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures resulting from registered uses of N-methyl carbamate pesticides, including carbaryl. EPA has concluded that the cumulative risks associated with the N-methyl carbamate pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCFA. EPA is thereby terminating the tolerance reassessment process under 408(q) of the FFDCFA. For additional information, refer to the document, *Revised N-methyl Carbamate Cumulative Risk Assessment*, which is available in the EPA docket EPA-HQ-OPP-2007-0935 and on the website, <http://www.epa.gov/pesticides/cumulative/>.

C. Tolerance Reassessment Summary

Tolerances for residues of carbaryl in/on plant commodities [40 CFR §180.169] are presently expressed in terms of the combined residues of carbaryl (1-naphthyl N-methylcarbamate), including its hydrolysis product 1-naphthol, calculated as 1-naphthyl N-methylcarbamate. The tolerance expression for carbaryl in/on plant commodities should be modified to include only the parent compound. Tolerances for residues of carbaryl in livestock commodities (meat and milk) are presently expressed as the combined residues of carbaryl (1-naphthyl N-methylcarbamate) and its metabolites: 1-naphthol (naphthyl sulfate); 5,6-dihydrodihydroxycarbaryl; and 5,6-dihydrodihydroxy naphthol, calculated as 1-naphthyl N-methylcarbamate. The tolerance expression for livestock commodities should be amended to also include free and conjugated residues of carbaryl: 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl

The Agency's tolerance summary is provided in Table 13. EPA considered 120 of the carbaryl tolerances to be reassessed on June 29, 2006, because these tolerances cover commodities that are not significant contributors to the N-methyl carbamate cumulative risk assessment. Because EPA has now completed and released the

cumulative risk assessment for the N-methyl carbamates, the remaining 11 carbaryl tolerances are considered reassessed at this time. Table 13 lists several tolerances associated with uses that are no longer registered, as announced in several FIFRA 6(f)(1) Notices of Receipt of Requests from the registrant for cancellation and/or use deletion. Because EPA approved these requests for cancellation or use deletion, the associated tolerances should be revoked, except for the wheat tolerance, which is still needed to cover imported wheat and any domestic wheat that may receive inadvertent residues of carbaryl resulting from carbaryl use to control grasshoppers and/or Mormon crickets on pasture and rangeland. (The Agency has included carbaryl residues on wheat in the cumulative risk assessment for the N-methyl carbamates.)

Many existing carbaryl tolerances will be reassigned to crop groups, and these tolerances will be revoked as new tolerances are established for residues in/on various crop groups and subgroups. New tolerances need to be established for carbaryl residues in/on the following raw agricultural commodities: aspirated grain fractions, proso millet hay, sorghum stover, and sugar beet roots. At the present time, sufficient data are only available to determine an appropriate tolerance for residues in/on aspirated grain fractions (70 ppm), sugar beet roots (0.5 ppm), and sorghum stover (30.0 ppm). Additional residue data are required before appropriate tolerances can be determined for residues in/on proso millet hay. Separate tolerances also need to be established for residues in the following processed food/feed items: wet apple pomace (15.0 ppm), citrus fruit oil (20.0 ppm), raisins (12.0 ppm), and rice hulls (30.0 ppm). The Agency will commence rulemaking proceedings to revoke and modify the existing tolerances, and correct commodity definitions.

Table 13. Tolerance Reassessment Summary Table for Carbaryl

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
Tolerance Listed Under 40 CFR §180.169(a)(1) Raw Agricultural Commodities			
Alfalfa*	100	50	Residue data indicate tolerance should be lowered to 50 ppm. [<i>alfalfa, forage</i>]
Alfalfa, hay*	100	75	Residue data indicate that the tolerance should be lowered to 75 ppm.
Almond*	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on [<i>nut, tree, group 14, except walnut</i>].
Almond, hulls*	40	50	Residue data indicate tolerance should be increased to 50 ppm.
Apricot	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on [<i>fruit, stone, group 12</i>].
Asparagus*	10	15	Residue data indicate that the tolerance should be increased to 15 ppm.
Banana*	10	5	Residue data indicate that the tolerance

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
			should be lowered to 5 ppm.
Bean	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance for [vegetable, legume, edible-podded, subgroup 6A], and a 1.0 ppm tolerance for [pea and bean, dried shelled, except soybean, subgroup 6C].
Bean, forage	100	Revoke	Tolerance should be revoked. Bean forage and hay are no longer considered significant livestock feed items.
Bean, hay	100		
Beet, garden, roots*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Beet, garden, tops*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the [vegetable, leaves of root and tuber, group 2, except sugar beet tops].
Beet, sugar, tops*	100	25	Residue data indicate that the tolerance should be lowered to 25 ppm.
Blackberry*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Blueberry*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [bushberry subgroup 13B].
Boysenberry*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Broccoli*	10	10	[vegetable, brassica, leafy, group 5, except cabbage].
Brussels sprouts*	10	10	Residue data on broccoli translates to Brussels sprouts. [vegetable, brassica, leafy, group 5, except cabbage].
Cabbage*	10	21	Residue data indicate that tolerance should be increased to 21 ppm.
Cabbage, Chinese*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [vegetable, brassica, leafy, group 5, except cabbage].
Carrot, roots*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetables, root and tuber, group 1, except sugar beet and sweet potato]; considered reassessed on June 29, 2006.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments <i>[Correct Commodity Definition]</i>
Cauliflower*	10	10	Data on broccoli translates to cauliflower. <i>[vegetable, brassica, leafy, group 5, except cabbage]</i> .
Celery*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the <i>[leaf petioles subgroup 4B]</i> .
Cherry	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[fruit, stone, group 12]</i> .
Chestnut*	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on <i>[nut, tree, group 14, except walnut]</i> .
Clover*	100	50	Residue data indicate that the tolerance should be lowered to 50 ppm. <i>[clover, forage]</i> .
Clover, hay*	100	70	Residue data indicate that the tolerance should be lowered to 70 ppm.
Collards*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the <i>[vegetable, brassica, leafy, group 5, except cabbage]</i> .
Corn, sweet kernal plus cob with husks removed *	5	0.1	Residue data indicate that a separate tolerance on sweet corn should be established at 0.1 ppm <i>[corn, sweet, kernel plus cob with husks removed]</i> .
		0.02	Residue data indicate that a separate tolerance should be established for corn, grain at 0.02 ppm. <i>[corn, field, grain]</i> and <i>[corn, pop, grain]</i> .
Corn, stover*	100	20	Residue data indicate that the tolerance for field and pop corn stover should be lowered to 20 ppm. <i>[corn, field, stover]</i> and <i>[corn, pop, stover]</i> .
		215	Residue data indicate that the tolerance for sweet corn stover should be increased. to 215 ppm. <i>[Corn, sweet, stover]</i> .
Corn, forage*	100	30	Residue data indicate that the tolerance for field corn forage should be lowered to 30 ppm. <i>[Corn, field, forage]</i> .
		185	Residue data indicate that the tolerance for field corn forage should be increased to 185 ppm. <i>[Corn, sweet, forage]</i> .
Cottonseed, undelinted seed*	5	Revoke	Use on cotton has been cancelled; therefore, the tolerance is no longer needed.
Cowpea*	5	Reassign	Tolerance should be reassigned concomitant

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
			with establishing a 1 ppm tolerance for [pea and bean, dried shelled, except soybean group 6C].
Cowpea, forage*	100	Reassign	Tolerances should be reassigned concomitant with establishing a 60 ppm tolerance for [vegetable, foliage of legume, group 7].
Cowpea, hay*	100		
Cranberry*	10	3	Residue data indicate that the tolerance should be lowered to 3 ppm.
Cucumber*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [vegetable, cucurbit, group 9].
Dandelion leaves*	12	22	Residue data on spinach translated to dandelion, indicate that tolerance should be increased to 22 ppm. [dandelion, leaves].
Dewberry*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Eggplant*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the [vegetable, fruiting, group 8]
Endive*	10	10	Residue data on lettuce may be translated to endive. [endive]
Filbert (hazelnuts)*	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on the [nut, tree, group 14, except walnut].
Flax, seed*	5	0.5	Residue data indicate that the tolerance should be lowered to 0.5 ppm.
Fruit, citrus	10	10	[Fruit, citrus, group 10]
Grape	10	10	
Grass*	100	100	Residue data on rangeland grass forage harvested at a 0-day PGI support the current tolerance of 100 ppm. [Grass, forage].
Grass, hay*	100	15	Residue data on pasture hay indicate that the tolerance should be lowered to 15 ppm.
Horseradish*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Kale*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [vegetable, brassica, leafy, group 5, except cabbage].
Kohlrabi*	10	10	Residue data on broccoli translates to kohlrabi. [brassica, leafy, group 5, except

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
			<i>cabbage]</i>
Lentil, seed*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 1 ppm tolerance on the [pea and bean, dried shelled, except soybean group 6C].
Lettuce*	10	10	
Loganberry*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Melon*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [vegetable, cucurbit, group 9].
Millet, proso, grain*	3	1	Residue data for wheat grain indicate that the tolerance should be lowered to 1 ppm. Data for wheat grain translates to millet.
Millet, proso, straw*	100	20	Residue data on wheat straw indicate that the tolerance should be lowered to 20 ppm. Data for wheat straw translates to millet straw.
Mustard greens*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [vegetable, brassica, leafy, group 5, except cabbage].
Nectarine	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [fruit, stone, group 12].
Okra*	10	4	The available data indicate that the tolerance should be lowered to 4 ppm.
Olive*	10	10	
Oyster*	0.25	0.25	
Parsley, leaves*	12	22	Available residue data on spinach indicate that the tolerance on parsley should be increased to 22 ppm. Spinach data translates to parsley. [Parsley, leaves]
Parsnip*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Peach	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [fruit, stone, group 12].
Peanut*	5	0.05	Residue data indicate that the tolerance should be lowered to 0.05 ppm.
Peanut, hay*	100	20	Residue data indicate that the tolerance should be lowered to 20 ppm.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
Pea (with pods)*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance for [vegetable, legume, edible podded, subgroup 6A].
Pea, field, vines*	100	Reassign	Tolerance should be reassigned concomitant with establishing a 60 ppm tolerance for the [vegetable, foliage of legume, group 7].
Pecan*	1	Reassign	Tolerance should be reassigned concomitant with establishing a 0.1 ppm tolerance on the [nut, tree, group 14, except walnut].
Pepper	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the [vegetable, fruiting, group 8].
Pistachio*	1	0.1	Residue data indicate that the pistachio tolerance should be lowered to 0.1 ppm. [pistachio]
Plum, prune, fresh	10	Reassign	Tolerance should be reassigned concomitant with establishing a 10 ppm tolerance on the [fruit, stone, group 12].
Poultry, fat	5	Revoke	Poultry tolerances are no longer needed because there is no reasonable expectation of finite residues. Also, the direct use on poultry and in poultry houses has been cancelled.
Poultry, meat	5	Revoke	
Potato*	0.2(N)	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Prickly pear cactus, fruit*	12	5	Residue data indicate that the tolerance should be lowered to 5 ppm. [cactus, fruit]
Prickly pear cactus, pads*	12	12	[cactus, pads]
Pumpkin*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the [vegetable, cucurbit, group 9].
Radish*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Raspberry*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 12 ppm tolerance on the [caneberry subgroup 13A].
Rice, grain*	5	15	Residue data indicate that the tolerance should be increased to 15 ppm. [Rice, grain]
Rice, straw*	100	60	Residue data indicate that the tolerance

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments <i>[Correct Commodity Definition]</i>
			should be lowered to 60 ppm.
Rutabagas*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet and sweet potato]</i> .
Salsify (roots)*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the <i>[vegetable, root and tuber, group 1, except sugar beet tops]</i> .
Salsify, tops*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the <i>[vegetable, leaves of root and tuber, group 2, except beet, sugar, tops]</i> .
Sorghum, forage*	100	30	Residue data indicate that tolerance should be lowered to 30 ppm <i>[sorghum, grain, forage]</i>
Sorghum, grain*	10	10	<i>[Sorghum, grain, grain]</i>
Soybean*	5	0.5	Residue data indicate that the tolerance should be lowered to 0.5 ppm. <i>[Soybean, seed]</i>
Soybean, forage*	100	15	Residue data indicate that the tolerance should be lowered to 15 ppm.
Soybean, hay*	100	15	Residue data indicate that the tolerance should be lowered to 15 ppm.
Spinach*	12	22	Residue data on spinach indicate that the tolerance should be increased to 22 ppm.
Squash, summer*	10	Reassign	Tolerances should be reassigned concomitant with establishing a 3 ppm tolerance on the <i>[vegetable, cucurbit, group 9]</i> .
Squash, winter*	10		
Strawberry	10	4	Residue data indicate that the tolerance should be lowered to 4 ppm.
Sunflower, seed*	1	0.5	Residue data indicate that tolerance should be lowered to 0.5 ppm.
Sweet potato, roots*	0.2	0.2	<i>[Sweet potato, roots]</i>
Swiss chard*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 3 ppm tolerance on the <i>[leaf petioles subgroup 4B]</i> .
Tomato*	10	Reassign	Tolerance should be reassigned concomitant with establishing a 5 ppm tolerance on the <i>[vegetable, fruiting, group 8]</i> .
Trefoil, forage*	100	15	Residue data on alfalfa forage translates to <i>[trefoil, forage]</i> and indicates that the tolerance should be lowered to 15 ppm.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
Trefoil, hay*	100	25	Residue data on alfalfa hay translates to [trefoil, hay] and indicates that the tolerance should be lowered to 25 ppm.
Turnip, roots*	5	Reassign	Tolerance should be reassigned concomitant with establishing a 2 ppm tolerance on the [vegetable, root and tuber, group 1, except sugar beet and sweet potato].
Turnip, greens*	12	Reassign	Tolerance should be reassigned concomitant with establishing a 75 ppm tolerance on the [vegetable, leaves of root and tuber, group 2, except sugar beet tops].
Walnut*	1	1	
Wheat, grain*	3	1	Residue data indicate that the tolerance should be lowered to 1 ppm.
Wheat, hay	100	100	
Wheat, straw	100	100	
Tolerances Listed Under 40 CFR §180.169(a)(2) Livestock Commodities			
Cattle, fat	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Cattle, kidney	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [cattle, meat byproducts].
Cattle, liver	1		
Cattle, meat	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Cattle, meat byproducts	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Goat, fat*	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Goat, kidney*	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [goat, meat byproducts].
Goat, liver*	1		
Goat, meat*	0.1	1	Residue data indicate that the tolerance should be increased to 1 ppm.
Goat, meat byproducts*	0.1	3	Residue data indicate that the tolerance should be increased to 3 ppm. Reassessed tolerance should include kidney and liver.
Horse, fat*	0.1	0.5	Residue data indicate that the tolerance should be increased to 0.5 ppm.
Horse, kidney	1	Reassign	Tolerance should be increased to 3 ppm and reassigned to [horse, meat byproducts].
Horse, liver	1	Reassign	

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

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments [Correct Commodity Definition]
Tolerances to be Established Under 40 CFR §180.169(a)(1) Raw Agricultural Commodities			
Apple, wet pomace	None	15	Residue data support establishing a 15 ppm tolerance on wet apple pomace. [apple, wet pomace]
Grain, aspirated fractions	None	70	Residue data indicate that a tolerance of 70 ppm should be established for residues in/on aspirated grain fractions. [grain, aspirated fractions]
Beet, sugar, roots	None	0.5	The available data indicate that a tolerance of 0.5 ppm should be established for residues in/on sugar beet roots. [beets, sugar, roots]
Citrus, oil	None	20	Residue data support establishing a 20 ppm tolerance on citrus fruit oil. [citrus, oil]
Grape, raisin	None	12	Residue data support establishing a 12 ppm tolerance on raisin. [grape, raisin]
Millet, proso, hay	None	TBD ²	Residue data are required.
Rice, hulls	None	30	Residue data support establishing a 30 ppm tolerance for residues in/on rice hulls.
Sorghum, grain, stover	None	30	Residue data support establishing a 30 ppm on [sorghum grain, stover].

* Considered reassessed on June 29, 2006 because associated commodity is not a significant contributor to cumulative risk from the N-methyl carbamates. TBD, to be determined pending completion of outstanding residue studies required in the March 2005 generic DCI for carbaryl. Pineapple tolerance will be determined pending review of field trial data (OPPTS Guideline 860.1500). Proso millet hay tolerance will be determined pending receipt of field trials for wheat hay, which will be translated to millet (OPPTS Guideline 860.1500).

Technical Support Documents for Carbaryl

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USEPA, 2000. *Benchmark Dose Technical Guidance Document*. Draft report. Risk Assessment Forum, Office of Research and Development, U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-00/001

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