a. Oral Route of Exposure

Toddler ingestion via hand-to-mouth activity was the only oral route of exposure considered in the residential portion of this assessment. Specifically, oral hand-to-mouth ingestion was considered only for children 1-2 and 3-5 years old for the lawn care and pet collar scenarios. OPP acknowledges that there are very limited data on exposure to young children; in general, however, children ages six and older no longer exhibit mouthing behavior to the degree seen in younger children (Freeman et al, 2001). In addition,OPP recognizes that non-dietary exposure may occur not only from hand-to-mouth activities but also from activities such as ingestion of soil and mouthing of grass. However, the latter two pathways were not considered in this assessment because these types of non-dietary exposures are expected to be small contributors to overall risk from residential NMC products[13].

[13] Typically, in single chemical human health risk assessment for pesticides, hand-to-mouth exposure is significantly higher than object-to-mouth (i.e., grass ingestion) exposure. However, in the carbaryl RED, the grass ingestion MOE for the lawn care scenario is 150 while the hand-to- mouth MOEs ranged from 71 to 720. Currently, the Agency does not have a methodology to assess grass ingestion exposure for granular lawn products. As a conservative assessment for granular turf products, the Agency used standard assumptions based on the use of surrogate liquid turf transferable (TTR) data. Specifically, the quantitative assessment of object-to-mouth exposure in the carbaryl assessment relies upon the assumption that residues on grass will be between 3 and 5% of the application rate (HED *Policy 12: Revised Residential SOP Assumptions, 2/2001*). This assumption is derived from liquid DFR turf studies for multiple chemicals using the dislodgeable foliar residue (DFR) method. The use of this method had been considered by investigators in the past, but is no longer used due to its high between-investigator variability. In addition the method had been used for measuring turf that is uniformly sprayed resulting in most grass leaves being contacted by the sprays. The DFR method involves shaking grass leaves in a dislodging solution for 20 minutes. The method itself is likely to be more a exhaustive estimate of transfer than may be expected when children's objects come in contact with turf treated with granular forms that are watered-in. Since all carbaryl liquid broadcast lawn products have been cancelled, the quantitative assessment for toddlers grass ingestion is highly conservative. Further, because the carbaryl hand-to-mouth MOEs for the lawn assessment were of concern when granular turf products were not watered-in, the Agency will modify all granular turf product labels to require watering-in after application. The target pests for the granular formulation are soil insects, consequently, it is important that the pesticide reach the soil for adequate control rather than remain on the grass. The Agency believes that watering-in, as demonstrated by the carbaryl handpress data, will significantly lower the residues of carbaryl on treated grass. However, the current methodology used to assess grass ingestion does not account for the reduction of residues following irrigation. For all of the above noted reasons, the Agency believes that grass ingestion exposure resulting from the use of carbaryl granular lawn products will result in minimal exposure and therefore was not included in the revised NMC CRA.

i. Modeling the Non-Dietary Ingestion Pathway

In the preliminary *N*-methyl carbamate cumulative risk assessment (preliminary NMC CRA), the non-dietary oral exposure pathway produced the lowest Margins of Exposure (MOEs), and would therefore be of greatest concern to the Agency. These low MOEs were mainly due to the incorporation of micro-activity data into our macro activity models (defined as human exposure models based on daily time step). The non-dietary ingestion pathway was the least refined of the residential exposure pathways modeled in the preliminary NMC CRA. This section highlights modifications made to the methodology used to assess this pathway. This refined methodology is based on comments and input from the FIFRA Scientific Advisory Panel, and the SHEDS and CARES developers.

The Calendex model used in the preliminary and the revised NMC CRAs is a macro activity model. Specifically, this model simulates exposures by randomly drawing age-appropriate values for each of the various exposure factors (e.g., exposure duration, frequency of hand to mouth events, surface area of hand mouthed per event, etc.) then multiplying these values together per the OPP Standard Operating Procedures (SOPs) for Residential Exposure Assessment algorithm (USEPA, 1997b). The distributions for many of these exposure factors were obtained from micro-activity data. For example, the distribution for frequency of hand-to-mouth events was based on data from observational studies in which all hand contacts were recorded as hand-to-mouth events, regardless of the fraction of hand mouthed. For the fraction of hand mouthed, no adjustment was made for the duration of time the hand remained in the mouth. As the August 2005 SAP panel discussed, utilizing such micro-activity data with macro activity models poses many challenges. For example, if two variables are negatively correlated (e.g., more frequent mouthing is associated with smaller areas of hand mouthed), then "modeling the product of two jointly distributed variables as independent draws will overestimate the variances…or overestimate exposure at the high end." Similarly, "fixing the residue on a child's hands (and/or other exposure factors) for a two hour play period…will yield 'greater variability in the modeled distribution of exposures than a run that updates the residue concentration hourly during the exposure". (FIFRA SAP, 2005b).

As recommended by the SAP, the Agency is exploring the use of SHEDS-Multimedia for future probabilistic risk assessments. In the revised NMC CRA, Agency staff addressed shortcomings in the non-dietary oral pathway by modifying the probabilistic hand-to-mouth algorithm as discussed below. This modified algorithm is a product of a

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collaborative effort between OPP scientists, and the developers of the SHEDS-Multimedia (Dr. Valerie Zartarian and Dr. Jianping Xue) and CARES models (Dr. Jeffrey Driver and Dr. Muhilan Pandian).

The refined algorithm for estimating daily hand-to-mouth ingestion in the revised NMC Calendex assessment is similar to the SHEDS-Multimedia and CARES Mass Balance algorithms in the manner in which it addresses residue replenishment between hand-to-mouth contacts. Specifically, the new algorithm establishes a maximum amount of residue which can be on the hand, or a maximum dermal hand loading. The amount of non-dietary oral ingestion increases with the exposure duration, the frequency of hand-to-mouth events per hour, and the surface area mouthed per event, while the hand loading serves as an upper constraint on oral ingestion between replenishment events.

New Hand-to-Mouth Algorithm

The following equation is the algorithm used in the Revised NMC CRA:

$$Exposure = \frac{HR}{2} * SA_{mouthed_fraction} * (N_replen) * [1-(1-SE)]^{N_events}$$

HR/2 = initial residues available on one hand [mg/day]
SA mouthed fraction = surface area of hand mouthed [unitless].
N_Replen = number of replenishment intervals per day. This is equivalent to the values used for Duration [hrs/day] in the preliminary NMC CRA since the residues are assumed to be "replenished" every hour of the exposure duration
SE = saliva extraction factor (i.e., mouthing removal efficiency) [unitless];
N_Events = number of hand-to-mouth contacts events per replenishment interval;

Each of these terms is discussed in detail below.

Hand Loading

Hand loading, or HR/2, is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA Child Specific Exposure Factors Handbook indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over (USEPA,

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2002c, table 8-3). The algorithm assumes mouthing one hand at a time; therefore, hand loading residues are divided by 2.

Frequency of mouthing events and fraction of surface area mouthed

The distributions for frequency of mouthing events (N_Events) and the fraction of surface area of hand mouthed (SA mouthed fraction), are based on observational studies (see scenario-specific discussions in section I.D.6 for more details on the information sources used for these parameters). This algorithm allows for only one draw (per simulated day), therefore, the interpretation is that this behavior continues at the same rate for the entire exposure duration selected. In reality, a high-end mouthing frequency recorded over a short time interval (e.g., one hour) may not be likely to continue at the same intensity over a longer time period (e.g., 6 or 8 hours).

Saliva extraction factor (i.e., mouthing removal efficiency)

The saliva extraction factor (SE) indicates the fraction of residues that is removed during each mouthing event. The greater the removal efficiency (i.e.,SE), the less residue remains on the hand after each mouthing event. For example, if the initial loading is 1000 ug on the thumb (part of hand mouthed), and the removal efficiency is 20%, then after one event, 200 ug is removed and 800 ug remains on the thumb; after two events, an additional 160 ug is removed (=800x.2), or a total of 360 ug ($=1000x(1-(1-.2)^2)$) is removed and ingested, and 640 ug ($=1000x((1-.2)^2)$) remains on the thumb.

The SE term is used in combination with the mouthing frequency term **(N_Events)** in the above equation as:

$$(1-SE)^{(N_Events)}$$

This portion of the new hand-to-mouth algorithm expresses the percent of initial loading remaining on hand after N hand-to-mouth events or, equivalently, the percent of initial loading mouthed that is ingested after N hand-to-mouth events.

Replenishment Interval

In the preliminary NMC CRA, the non-dietary ingestion algorithm assumed complete replenishment between each hand-to-mouth event. This new algorithm is more comparable to the SHEDS-Multimedia and the CARES Mass Balance algorithms in addressing the replenishment. The new algorithm assumes that replenishment occurs only once every

fixed time interval (SHEDS uses the Consolidated Human Activity Database (CHAD) time interval; CARES uses a daily time interval). Within each replenishment interval, a fraction of the remaining residues are removed and ingested during each hand-to-mouth event. The total amount of residues removed and ingested increases with the SE, the number of events per interval, and with the number of replenishment intervals per day (or exposure duration).

In this new algorithm, the hand is fully replenished with residues from a contaminated surface (e.g., the lawn, pet or hard flooring), on an hourly basis. The replenishment frequency (hrs/day) and the mouthing frequency per replenishment interval (events/hr) are expressed in the same time unit (hr). Therefore, the same distribution, total exposure duration (hrs/day) was used in the preliminary NMC CRA. This algorithm may be generalized to model replenishment at different (fixed) time intervals.[14]

b. Dermal Route of Exposure

The dermal route was assessed for adults applying consumer pesticide products to lawns, gardens, fruit trees, and ornamental plants. For both children and adults, post-application dermal exposure was assessed for the lawn and pet collar scenarios. The dermal route was also assessed for adults and teenagers reentering treated vegetable and ornamental garden to perform maintenance (weeding, pruning) and harvesting activities. Similarly, exposure was assessed for adults and teenagers involved in fruit tree cultivation. Dermal post-application exposure also was assessed for adults and teens playing golf on treated courses.

c. Inhalation Route of Exposure

The inhalation route of exposure was considered for adult populations only. Specifically, inhalation exposure was assessed for

[14] For example, if it is assumed that the hand is fully replenished every half hour, then both variables (N_Replen and N_Events) would be constructed using 30 minutes as the unit for duration. Similarly, if one replenishment per day (N_Replen=1) is assumed, this new algorithm reduces to the CARES Mass Balance equation. This is demonstrated by replacing the number of replenishment intervals per day (N_Replen=1/day), and the total mouthing events per replenishment interval (events/day) with the equivalent terms (N_Events = FREQEvents/hr x Duration hrs/day) in the following equation:

$$Exposure = \frac{HR}{2} * SA_{mouthed_fraction} * 1 * \left[1-(1-SE)\right]^{Freq_{events/hr} * Duration_{hrs/day}}$$

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adults applying pesticide formulations to lawns, vegetable gardens, ornamental plants and fruit trees.

5. Data Sources

Three basic types of data were considered in this assessment:

- pesticide use data;
- residue concentration and dissipation/decay data;
- exposure contact factor data.

These data are described in more detail below.

a. Pesticide Use Data

The probabilistic models require residential pesticide use inputs to aggregate exposure from multiple use scenarios. The percent of households applying the various products and the timing of those applications directly impact estimates of aggregate exposure. The REJV data can be used to generate empirically-based estimates to address those needs. Appendix II.D.1 provides further details regarding the REJV data. However, the REJV did not collect information on the purpose of use (pest treated), areas treated, or application rates. Since these factors may impact timing and frequency of application, REJV data was used in combination with professional judgment, product label information and pest pressure information from the Cooperative State Extension Services. The revised NMC CRA considered the Southeast Region of the United States for two reasons; 1) the growing season is longer in the South and the associated pest pressures are therefore greater, and 2) drinking water concentrations are highest in this region of the country. The residential and groundwater assessments are based on the most highly exposed localized areas within the southeastern region of the United States. Specifically, the drinking water exposure for Georgia was combined with residential exposure in Florida Pest pressure data for Florida are assumed to address pest pressure for other areas of the country where NMC water concentrations are high (such as Georgia and North Carolina). Due to longer periods of pesticide use coupled with higher concentrations of NMC in ground water, this assessment provides a worst case estimate of exposure.

The revised NMC CRA focuses on post-application exposures for children, including the broadcast lawn and the pet collar scenarios. Examples of how pesticide use data were incorporated into these scenarios are discussed below.

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i. Broadcast Lawn Scenarios

Current label revisions for carbaryl lawn care products restrict broadcast applications to granular formulations. Therefore, post-application exposure for children was assessed only for granular applications of carbaryl to lawns. The major turf pests treated with carbaryl are grubs, mole crickets, caterpillars, cinch bugs, scales, ticks, and a variety of spiders, and ants. However, pests that would mostly likely be treated with granular applications are mole crickets and white grubs. The other pests listed are more likely to be treated with spray applications. Therefore, this assessment focused on timing of applications for residential lawns treated for white grubs and mole crickets. Information from the University of Florida Cooperative State Extension Service indicates that grubs actively feed in Florida from April through October, depending on species and weather conditions. Additionally, tawny mole crickets become active in March, and granular applications are typically made in August and September. For these reasons, the broadcast lawn assessment considered the season of use to be early spring through fall. OPP assumed two applications to the lawn per year (based on REJV).

ii. Pet Collar Scenarios

Propoxur and carbaryl product labels indicate that pet collars are effective for 180 days and 120 days, respectively. Additionally, season of use is considered to be year-round since flea lifecycle information shows that in humid climates, fleas may be active year-round. Therefore, the pet collar assessment assumed that pet collars would be used year-round in southern climates.

b. Residue Concentration Data

Residue concentration data and associated pesticide decay/dissipation parameters were used to define the sources and magnitude of exposure resulting from human contact with transferable residues. In many cases, chemical-specific data were used to assess homeowner applicator and post-application exposure resulting from the registered uses of carbaryl. For the lawn and garden scenarios, data from the Outdoor Residential Pesticide Use and Usage Survey and National Gardening Association Survey (Johnson et al, 1999) submitted by the Outdoor Residential Exposure Task Force (ORETF) were also used. Surrogate data were used to determine exposure resulting from the ornamental garden use of methiocarb. Appendix II.D.2 contains a summary of all residue data used in the revised NMC CRA, as well as the derivation of various distributional parameters.

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c. Exposure Factor (Contact) Data

Exposure factors such as the amount of time spent in an area, frequency of hand-to-mouth contacts, size of area treated, and location of residue source (lawn, garden, or indoor surface) are critical for estimating exposures to a given substance. Appendix II.D.2 contains a summary of exposure factors used in the revised NMC CRA, as well as the derivation of various distributional parameters. Unless otherwise noted, all distributions were truncated at the 99th percentile in order to avoid a distribution which contained values that were well beyond those deemed reasonable.

6. Exposure Scenarios

This assessment considered a variety of exposure scenarios for consumer applicator and post-application exposures. Each of these is described in additional detail below. Since it is difficult to determine typical rates for homeowner products, OPP used the maximum application rate, as allowed by currently registered labels, to assess exposure for all scenarios. (8 lbs ai/A was used for lawns and fruit trees; and 2 lbs ai/A was used for vegetable gardens and ornamentals.) Table I.D-4 summarizes the selected inputs for all scenarios.

a. Lawn Care Exposure Scenarios

i. Lawn Applicator Exposure

Only carbaryl has registered lawn care uses. Applicator exposure was assessed for homeowners mixing, loading, and applying a variety of carbaryl products to their lawns. There are two formulations of carbaryl that are available for lawn use: granular and liquid sprayable formulations. OPP has amended the use pattern of carbaryl and the current cumulative assessment incorporates these changes. The label changes restrict broadcast lawn application to granular formulations. However, spot treatments of the liquid formulation are permitted. All liquid products must be packaged in ready-to-dispense containers. Such formulations will limit spot treatments to areas of less than 1000 square feet.

Total exposure is calculated as the product of the unit exposure (UE) (either dermal or inhalation), the application rate, and the lawn size.

Unit Exposures: Both dermal and inhalation exposure routes were considered. ORETF studies were used for the granular broadcast and liquid spot treatment scenarios.

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The ORETF submitted a report (Klonne, 1999) in which a variety of products were used on turf. In these studies, both homeowners and lawn care operators (LCOs) were monitored following broadcast applications to turf. All of the data submitted in this report were completed in a series of studies.

The two studies that monitored homeowner exposure resulting from granular spreader (Klonne, 1999/OMA003 Study) and hose-end sprayer (Klonne, 1999/OMA004 Study) applications were used in this assessment. Volunteers participating in these exposures studies were adult non-professionals who use pesticides on their own gardens and lawns. Many of the volunteers selected as subjects in these studies were members of garden clubs. All volunteers made their applications without specific instruction from the study investigators. Unit exposures estimated from these studies cover various clothing scenarios that range from wearing short pants and short-sleeved shirts, to long pants and long- sleeved shirts.

All dermal and inhalation unit exposure were normalized and expressed as milligrams exposure per pound of active ingredient handled (mg/lb ai) (referred to as unit exposures, or UE). The lognormal distributions of the UEs for the lawn applicator scenarios are shown in Table I.D-2.

Table I.D-2. Lognormal Distributions of Unit Exposures Used for Carbaryl Lawn Care Scenarios

Application Method	Exposure Route	Unit Exposure Distribution (mg/lb ai) LN(μ, σ)	Comments
Granular Rotary Spreader	Dermal	0.81, 0.57	This distribution was used for the broadcast lawn scenario
	Inhalation	0.0013, 0.0013	
Hose-end Sprayer on Turf	Dermal	8.4, 26	This distribution was used for the lawn SPOT treatment scenario ONLY
	Inhalation	0.022, 0.040	

NOTES:
LN(μ, σ) represents a lognormal distribution with μ = arithmetic mean and σ = arithmetic standard deviation.
For lawn scenarios, information was derived from carbaryl-specific data and studies conducted by the ORETF.
A more detailed explanation of the statistical analysis of this data is provided in Appendix II.D.2.

Application Rates: For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the lawn care scenario).

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Area Treated: An important variable for estimating home-owner applicator exposure is the size of the lawn. OPP considered the average and median lawn sizes reported in a journal article by Vinlove and Torla (1995). The means and medians were ~13,000 ft^2. However, the authors noted problems interpreting the data since it is based primarily on low income houses and consists of adjustments of the lot size by the house's foundation (footprint) only. The data do not consider other structures such as decks or other green space such as gardens, which can reportedly reduce the lot size by up to 50%. Similar lawn sizes were noted in the ORETF survey (Johnson et al, 1999) with similar problems encountered with respect to confounding variables such as decks and other green spaces. For this assessment, OPP used a uniform distribution for lawn size bounded by 1000 ft^2 and 20,000 ft^2. The lower end of this range considers smaller lawns for residences such as town houses. The upper bound of 20,000 ft^2 (~ ½ acre) appears reasonable given the type of application equipment assumed to be used by residential applicators. Information from the ORETF survey also indicates that many pesticide users make spot treatments of insecticides. Similarly for spot treatments, OPP assumed a uniform distribution for treated area bounded by 100 ft^2 and 1000 ft^2.

ii. Lawn Post-Application Dermal Exposure

The fate of pesticides applied to turf, and subsequent human contact, is a key variable for assessing post-application dermal exposure and can be an important exposure pathway to consider as part of a cumulative assessment. This exposure pathway was evaluated here in the revised NMC CRA by using data from a number of available studies (described in more detail below). Briefly, post-application dermal exposure (mg pesticide) is calculated by multiplying the residue concentration on the lawn (mg/cm^2) by the transfer coefficient (cm^2/hour) derived from literature and other studies and the time spent on the lawn (hours/day). For this assessment, the transfer coefficient and the time spent on lawns were represented by a distribution of values while the residue concentration on the lawn was represented by a time series of concentration values (which accounted for residue degradation over time and incorporated the relevant half-lives or decay coefficients). Due to the label revisions, post-application exposure was considered for the granular broadcast treatments only.

Residue Data: There are chemical-specific turf transferable residue (TTR) data for granular formulations of carbaryl (Krolski, 2005). This study was designed to determine transferable residues of carbaryl from both irrigated and non-irrigated turf treated with SEVIN® 2G (see Appendix II.D.2 for study summary). Measured carbaryl residues rapidly declined over the first 4 hours and then leveled off or rose slightly after 12 hours. By the 24-hour sampling interval, the residues declined to

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approximately 10 percent of the corresponding 0-time residue value and then steadily dropped to below 1.0 percent of the corresponding 0-time residue values by 3- to 5-days after treatment.

In order to provide a conservative estimate of exposure for the revised NMC CRA, only the samples in the above study from the non-irrigated site in Florida were used. This assessment assumes an initial concentration of 0.00021 mg/cm^2. Dissipation is based on a 0.8 day half-life, with residues set to zero 14 days after application. Although the carbaryl TTR studies show residues below 1% of the initial residues by 3- to 5-days after application, to provide a conservative estimate of exposure, it is assumed that carbaryl residues on the lawn would be available for up to 2 weeks after application.

Transfer Coefficients (TC): The transfer coefficients used in this assessment were developed by dividing the hourly dermal exposure (µg/hr) obtained from a set of activities by the measurement commonly referred to as turf transferable residues (TTR) (µg/ cm^2). Since none of the dermal exposure studies used to estimate hourly exposure permitted direct calculation of the TTR, the transfer coefficients for this assessment were developed by assuming a transfer efficiency of at least 0.5% for granular formulations. This was done for two reasons:

to make use of available dermal exposure measurements which are not influenced the methodology used to estimate TTR, and

to make use of the available residue dissipation data for which there are no corresponding dermal exposure measurements

The 0.5% value is within the range of efficiency for the existing chemical specific TTR data described above. To account for the additional uncertainty of assuming a certain transfer efficiency to develop the transfer coefficients, TTR data having transfer efficiencies lower than 0.5% (for granular applications) were adjusted upwards to make up the difference in efficiency. If the transfer efficiency of the TTR data was higher than 0.5% for granular formulations, it was not adjusted.

For a more detailed discussion of the relationship of transfer coefficients and TTRs please refer to the "Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment" presented to the FIFRA Scientific Advisory Panel on September 21, 1999.

Transfer Coefficients used to assess children's exposure to treated turf:

One study was used to assess children's dermal exposure resulting from granular applications to residential turf (Vaccaro, 1996). In this study, a granular formulation of chlorpyrifos was applied, after which seven adults performed pre-choreographed activities intended to mimic a typical child's behavior.

The subjects performed these activities for a period of four hours beginning after the turf had dried. Turf had been treated earlier with a granular form of chlorpyrifos and exposure was estimated in the study by monitoring the amount of a chlorpyrifos metabolite – 3,4,5,6-TCP – excreted over the following period of 6 days. This method directly measures internal dose and was used to back-calculate a generic "to the skin" transfer coefficient by using chemical specific dermal absorption data for chlorpyrifos (Nolan et al., 1984). These data were further adjusted to account for differences in surface area of adults and children.

The study data discussed above was fit to a lognormal distribution with an arithmetic mean of 1970 cm^2/hr with a standard deviation of 1426 cm^2/hr. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e. 7224 cm^2/hr for the granular application) in order to avoid a distribution which contained values that were well-beyond those that are deemed reasonable. (See Appendix II.D.2 for study summary and details of the distributional analysis.)

Transfer Coefficients used to assess adult exposure to treated turf:

The Vaccaro study data discussed above were also used to assess exposure to adults following granular applications.

The revised NMC CRA used a distribution of values for the transfer coefficient characterized by a lognormal distribution with an arithmetic mean of 5376 cm^2/hr and a standard deviation of 4717 cm^2/hr for the granular application. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e., 23436 cm^2/hr) for the granular application. (See Appendix II.D.2 for study summary and details of the distributional analysis.)

Duration: Another important variable for addressing post-application exposure from home lawn treatment is the duration of time spent on lawns. In this revised NMC CRA, cumulative distributions of durations on lawns of up to two hours were used to address adult exposure on lawns. These data are presented in Table 15-64 of the

Exposure Factor's Handbook (EFH) (USEPA, 1997a); however, OPP notes that the percentiles above the 95th have the same values (121 minutes). A similar cumulative distribution was given for children ages one to five. In order to be protective of children and to address the uncertainty in the upper percentiles of the exposure factor data, OPP selected an empirical distribution (which was expressed as a cumulative distribution function) from EPA's EFH (Table 15-80) with a bound of 3.5 hours for children. This distribution represents the amount of time spent outdoors rather than just on lawns. This adjustment allows for additional time that children may spend outdoors (such as parks and schools) where there is potential for additional contact with treated turf.

iii. Lawn Non-Dietary Hand-to-Mouth Exposure

The assessment also incorporates exposure resulting from toddler hand-to-mouth activity on lawns. The revised NMC CRA incorporates a new algorithm to estimate hand-to-mouth exposure. Details of this algorithm can be found in Section I.D.4.i of this document.

Initial Hand Loading: Hand loading (HR/2) is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA Child Specific EFH (USEPA, 2002c) indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over. The algorithm assumes mouthing one hand at a time, therefore, hand loading residues are divided by 2.

Frequency of Mouthing Behavior: For the revised NMC CRA, the frequency of hand-to-mouth events is based on Xue et al, 2007. The estimates of mouthing frequency were derived from several exposure studies and videotaping studies. Statistical analysis indicated that a Weibull distribution best fit the data. For the lawn care scenario, hand-to-mouth events per hour were based on outdoor frequencies as defined by a Weibull distribution (mean = 6 events/hour, standard deviation = 8). OPP believes that the meta-analysis cited above provides the best available data to assess children's hand-to-mouth exposures.

Surface Area of Hand Mouthed: The revised NMC CRA relied on Zartarian's (2003) analysis of surface area of hand mouthed. The analysis used the Leckie, et al., 2000 data to determine the fraction of the hand mouthed. The fraction of hand mouthed values were fit with a beta distribution (mean = 0.13 events/hour, standard deviation = 0.06).

Saliva Extraction Factor: To address the removal of residues from the hands by saliva during mouthing events, several studies were considered. The removal efficiency of residues on hands by saliva and

other substances (e.g., ethanol) suggests a range of removal efficiencies (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989). Based on the above studies, a uniform distribution of 20% to 50% was used in this assessment for saliva extraction factors.

Duration: The time spent on the lawn was estimated as a cumulative distribution ranging from 0 hours to 3.5 hours. To be protective of childrens' exposure and to address the uncertainty of the upper percentiles of the exposure factor data, OPP selected a cumulative distribution from EFH (USEPA, 1997a) Table 15-80 with a bound of 3.5 hours for children 1 to 5 years old. This distribution represents the amount of time spent outdoors. This allows for the time that children spend outdoors not only at home but also in parks and near schools.

Assessing exposure through the non-dietary ingestion pathway is difficult due, in part, to issues associated with measurement of the above-discussed variables as well as issues associated with the utility of using children's hand-to-mouth frequencies based on indoor activities for outdoor exposure scenarios. There are also differences in mouthing behavior based on active and quiet play with increased mouthing likely to be during activities of quiet play. Limited data evaluated by Groot et al., 1998 suggests that children aged six to 12 months can experience longer durations of mouthing activities (exceeding 160 minutes per day) than children 18 to 36 months (up to 30 minutes per day). However, children in this age group are not likely to be engaged in post-application lawn activities OPP is modeling that would result in higher estimated exposure. Additional data for very young children (under the age of two) are needed to delineate the frequency differences between hand-to-mouth events for children engaged in active and quiet play.

b. Vegetable Garden Exposure Scenarios

Carbaryl has registered uses in home vegetable gardens. This assessment includes scenarios for applications of carbaryl using dust formulations (hand/shake), ready-to-use trigger sprayers, and hose-end sprayers. While there are other possible application methods for use on these sites, these application methods were selected based on use and exposure considerations.

i. Applicator Exposure

Dermal and inhalation exposures for homeowners applying carbaryl to their vegetable gardens were calculated in a manner similar to that used to assess applicator exposure for the lawn care scenario. Both are the product of the unit exposure (mg/lb ai handled), application rate (lbs ai/ft^2), and area treated (ft^2).

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Unit Exposure: Dermal and inhalation unit exposures were derived from chemical-specific data (Mester, 1998a) for dust (shake/pour), trigger pump sprayer, and liquid hose-end sprayer applications to vegetable gardens. The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D-3.

Application Rate: An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lb ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lbs ai/container (see Table II.A). The exposure assessment for dust formulation applied to home gardens assumes use of one entire container per treatment.

Area Treated: For vegetable gardens, the area treated was entered as a lognormal distribution (mean = 4600 ft^2, standard deviation =1500 ft^2, and maximum = 8000 ft^2); these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999). In these assessments, it is assumed that the entire garden is treated. Home gardens consist of many types of vegetables which all may not be treated since they tend to have different pest pressures (e.g. squash vine borer and corn earworm may not appear at the same time).

Table I.D-3. Lognormal Distributions of Unit Exposures Used for Carbaryl Garden, Fruit Tree, and Ornamental Scenarios

Application Method	Exposure Route	Unit Exposure Distribution(mg/lb ai)	Comments
Hose-End Sprayer	Dermal	(51, 58)	This distribution used for the vegetable garden scenario ONLY
	Inhalation	(0.0024, 0.0015)	
Liquid Handwand	Dermal	(74, 64)	This distribution also used for the ornamental and fruit tree scenarios
	Inhalation	(0.009, 0.010)	
Dust Shaker/Powder	Dermal	(250, 330)	This distribution was used for vegetable garden and ornamental scenarios. This distribution was also used for the SPOT treatment on lawns.
	Inhalation	(2.9, 9.5)	
RTU Trigger Pump Sprayer	Dermal	(86, 110)	This distribution was used for the vegetable garden and ornamental scenarios.
	Inhalation	(0.10, 0.14)	

NOTES: LN(μ, σ) represents a lognormal distribution with μ = mean and σ = standard deviation
Studies for garden, fruit tree, and ornamental applications are carbaryl-specific.
A more detailed explanation of the statistical analysis of this data is provided in Appendix II.D.2.

ii. Post-Application Dermal Exposure

Post-application exposure for adults and teenagers harvesting vegetables or performing post-application gardens maintenance were assessed using a range of transfer coefficients to account for the diversity of activities. Post-application exposure was estimated as the product of dislodgeable residue concentration (mg/ cm^2) a transfer coefficient (cm^2/hour), and time spent in the activity (hours).

Residue Data: Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a) , the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. Statistical analysis of the carbaryl sunflower DFR data was performed. The initial residue concentrations and the half-life were determined to be 0.0061 mg/cm^2 and 5 days, respectively.

Transfer Coefficient: For the vegetable garden scenario, transfer coefficients were characterized by a uniform distribution ranging from 180 to 1000 cm^2/hour, to reflect a range of gardening tasks for a variety of crops of differing heights and foliage development. The TCs used in this assessment were derived from studies on chrysanthemum pinching (Rotondaro, 2000) and tomato harvesting (USEPA, 2000e). All transfer coefficients are based on individuals wearing short sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.

Duration: The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).

c. Ornamental Plants and Shrubs Exposure Scenarios

Carbaryl also has registered uses on ornamental plants and shrubs. This assessment includes scenarios for the RTU dust formulations, RTU trigger pump sprayers, and liquid hand wand uses on ornamental plants. While there are other possible application methods for use on this site, these methods were selected based on use and exposure considerations.

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i. Applicator Exposure

Dermal and inhalation exposures for homeowners treating ornamental plants were estimated as the product of the Unit Exposure (mg/lb ai handled), application rate (lbs ai/ft^2), and area treated (ft^2).

Unit Exposure: Dermal and inhalation unit exposures were derived from chemical-specific data for carbaryl used on ornamental plants (Mester, 1998a; Merricks, 1998). The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D.3.

Application Rate: An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lbs ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lb ai/container. The exposure assessment for dust formulation applied to ornamental gardens assumes use of one entire container per treatment.

Area Treated: The area treated was entered as a uniform distribution of 500 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al,1999) and professional judgment. The ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.

ii. Post-Application Dermal Exposure

Post-application exposure for adults and teenagers performing ornamental garden activities were assessed using a range of transfer coefficients to account for the diversity of activities. Post-application exposure was estimated as the product of dislodgeable residue concentration (mg/ cm^2), transfer coefficient (cm^2/hour), and time spent in the activity (hours).

Residue Data: Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure from harvesting or performing maintenance activities in ornamental gardens. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a), the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. A statistical analysis of this data was performed and the

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initial concentration was estimated to be 0.0061 mg/ cm^2. Residue dissipation is based on the half-life of 5 days. The half-life used in this assessment was determined from the statistical analysis of the carbaryl sunflower DFR data. A more detailed explanation of the statistical analysis of this data is provided in Appendix II.D.2.

Transfer Coefficient: For the ornamental garden scenario, a uniform distribution of transfer coefficients, ranging from 99 to 550 cm^2/hour, was used to reflect a range of gardening tasks. The TCs used in this assessment were derived from studies that evaluated chrysanthemum pinching (Rotondaro, 2000) and nursery stock pruning (Klonne et al, 2000b). All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.

Duration: The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post-application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).

d. Fruit Tree Exposure Scenarios

Carbaryl also has registered uses on fruit trees. This assessment addresses exposure for homeowners applying sprayable formulations of carbaryl via handwands. While there are other possible application methods for use on these sites, this method was selected based on use and exposure considerations.

i. Applicator Exposure

As described for the lawn applicator scenario, exposure is the product of the unit exposure (mg/lb ai handled), application rate (lbs ai/ft^2), and area treated (ft^2).

Unit Exposure: The dermal and inhalation unit exposures were derived from chemical-specific data for liquid handwand applications to fruit trees (Merricks, 1998). These unit exposures are based on study data in which applications were made with handwands, spraying below the waist as well as overhead. The UEs for fruit tree scenario are based on lognormal distribution as listed in Table I.D.3.

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Application Rate: For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the fruit tree scenario).

Area Treated: For fruit trees, most of which are of the dwarf variety and therefore occupy relatively small areas, the area treated was entered as a uniform distribution (minimum 500 ft^2, maximum 1000 ft^2). The maximum value in this distribution was based on label restriction for applications made at the maximum rate (8lbs ai/A) for fruit tree applications.

ii. Post-Application Dermal Exposure

Dermal post-application exposure for adults and teenagers harvesting or pruning fruit trees was assessed using TCs from an apple pruning study. Post- application exposure was estimated as the product of dislodgeable residue concentration (mg/ cm^2), transfer coefficient (cm^2/hour), and time spent in the activity (hours).

Residue Data: Chemical specific dislodgeable foliar residue data on olive trees (Klonne et al, 2000c) were used to assess dermal post-application exposure for this scenario. Statistical analysis of this data was performed and the initial residue concentrations were determined to be 0.0035 mg/ cm^2. Residue dissipation is based on the half-life of 7 days (as determined by the statistical analysis of the carbaryl olive DFR data).

Transfer Coefficient: For the fruit tree scenario, the distribution of transfer coefficient was characterized as lognormal, with a mean of 940 cm^2/hour and a standard deviation of 260 cm^2/hour. The TCs were based on an apple pruning study. All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.

Duration: The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).

e. Ornamental Garden - Snail and Slug Bait Scenarios

This assessment includes the bait use of methiocarb in ornamental gardens. Applicator exposure is calculated as the product of the unit exposure (mg/lb ai handled), application rate (lbs ai/ft^2), and area treated (ft^2).

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i. Applicator Exposure

Unit Exposure: The dermal and inhalation UEs for the methiocarb snail and slug bait scenario were based on study data for disulfoton applications to residential shrubs and flower beds (Merricks, 2001). The surrogate data consist of dermal and inhalation measurements of individuals using granular products. Specifically, the field study was conducted in Vero Beach, Florida. A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. Each volunteer applied granular disulfoton around shrubs while wearing gloves and then again without gloves. Exposure data from the 15 replicates who did not wear gloves were reported. A lognormal distribution with a mean of 0.23 mg/lb ai, a standard deviation of 5.8 mg/lb ai, and maximum value of 3.4 mg/lb ai (representing the estimated 99th percentile of the lognormal distribution) was used to assess dermal exposure. A single point estimate of 0.00001 mg/lb ai (1/2 LOQ) was used for the inhalation UE since all measured values for inhalation were non-detects.

Application Rate: The application rate used in this assessment is based on the maximum label application rate of 0.2 lbs ai/1000 ft^2.

Area Treated: The area treated was entered as a uniform distribution of 10 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999) and professional judgment. The low value of 10 sq ft was based on the label direction for treating small areas. The high value for ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.

ii. Post-Application Exposure

Since this product is formulated as a bait and is applied as a broadcast application over plant foliage or to the soil surrounding ornamental plants, post-application exposure is expected to be minimal in comparison to the post-application exposure assessed for the ornamental use of carbaryl. Therefore, post-application exposure was not evaluated for the methiocarb snail and slug bait scenario.

f. Pet Collar Scenarios

The revised NMC CRA also considered exposures through the use of flea collar products for carbaryl and propoxur. These assessments rely on Agency default assumptions for pet fur transferable residues. The dermal contact factor(s) for post-application exposure is based on a shampoo and groomer exposure study for carbaryl (each groomer shampooed, brushed and groomed 8 dogs) (Mester,1998b). Each groomer shampooed the dogs, picked them up wet to be placed in crates until all the dogs were shampooed. The dogs were then dried and groomed. These activities are likely to result in higher contact factors than intermittent contact with a pet wearing a collar.

i. Applicator Exposure

Applicator exposure was not directly considered in this assessment since it is expected to be minimal when compared to the post-application exposure.

ii. Post-Application Dermal Exposure

Post-application dermal exposure scenarios were considered for both adults and children while post-application non-dietary oral exposure scenarios (oral hand-to-mouth) were assumed to apply only to children ages 1-5 years old. These data, as described below, were used to assess the pet collar uses of both carbaryl and propoxur. Frequency, timing, and probability of collar treatments are also incorporated in the revised NMC CRA.

Dermal post-application exposure (to adults and children) was calculated as the product of residue concentration (mg/ cm^2), the transfer coefficient (in cm^2/hour), and the duration of exposure (hours/day). A further description of each of these terms is presented below:

Residue Concentration: The fur residue concentration for the pet collar assessment is based on the amount of active ingredient in the respective pet collars and Agency default assumptions from the OPP Standard Operating Procedures (SOPs) for Residential Exposure Assessment (USEPA, 1997b). The residue values for carbaryl and propoxur are 0.00012 and 0.000069 mg/ cm^2, respectively. Residues were assumed to be available on a daily basis since pet collar products are designed to emit residues throughout their active period (120 days for carbaryl and 180 days for propoxur).

Transfer Coefficient: The transfer coefficients used in the dermal post-application exposure assessment were derived from a groomer

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exposure study (Mester, 1998b) in which sixteen different veterinary personnel treated/handled eight dogs each, over a two to five hour time period. In this assessment, the transfer coefficients for adults and children were derived assuming an average transfer efficiency of 2.97% from the previous OP pet fur residue transfer efficiencies. For the revised NMC CRA, the data were used directly to generate an empirical distribution for the dermal transfer coefficient. The selected TCs ranged from 180 to 4700 cm^2/hour for adults and from 66 to 1800 cm^2/hour for children. These empirical distributions were used for both pet collar scenarios.

Duration: The time spent in this activity was assumed to follow a triangular distribution with a minimum value of 0.03 hours and a maximum value of 1.03 hours per day (Freeman et al, 2001). As part of this study, macroactivity and microactivity data were collected via questionnaires and videotaping of 19 children (aged 3 to 12) for a four hour period. The videotapes from the observational portion of this study were analyzed to determine frequency of contacts for several mouthing behaviors, as well as duration of time each child spent in various locations around the home. The results of this study include several measurements for the duration of time the observed children spent with their pets.

In this assessment, the duration of exposure is assumed to be continuous contact rather than the intermittent contact normally associated with pet care (e.g. walking, feeding). Furthermore, dog collar residues are likely to be localized around the neck, and therefore, contact with other areas of the pet will result in little to no exposure. OPP is attempting to draw the distinction between direct contact with a treated pet and the time spent with a pet where there is limited contact. For example, time spent with pets in and around the house or sleeping in the same bed may not result in direct contact for the entire duration. The pet collar scenario assessed in the revised NMC CRA uses pet fur residues transferred to individuals at a rate found during a study of shampooing and grooming, for a duration of approximately 1 hour. Use of these data to represent residential exposure to pets is likely to encompass all other potential exposure scenarios involving direct or indirect contact with treated pets.

iii. Oral (Hand-to-Mouth) Post-Application Exposure

Post-application exposure through the oral (hand-to-mouth) route was also assessed for children ages 1-5 using the approach detailed in Section I.D.4.i of this document.

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The approach taken to assess hand-to-mouth exposure is the same as that used to assess the lawn scenario oral non-dietary exposure. The initial hand loading values were determined as a portion of total dermal exposure variable to the hands. Additionally, contact factors, fraction of surface area of hand mouthed (Zartarian, 2003), saliva extraction factor (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989)) are the same as those used in the lawn care assessment. The estimates of mouthing frequency were derived from several exposure studies and videotaping studies. For the pet collar scenario, hand-to-mouth events per hour were based on indoor frequencies as defined by a Weibull distribution (mean = 13 events/hour, standard deviation = 18). The distribution for frequency of hand-to-mouth events for indoor exposures, (provided by ORD's Dr. Jiaping Xue), was calculated based on the same methodology for outdoor exposures in the lawn care assessment. OPP believes that this analysis provides the best available data to assess children's hand-to-mouth exposures. The duration of exposure values used for the non-dietary exposure assessment are the same as those used in the dermal post-application assessment for the pet collar scenarios presented above.

g. Golf Course Scenario

i. Post-Application Dermal Exposure

Carbaryl is also used on golf courses. The current assessment addresses dermal post-application exposure for adults and teens playing rounds of golf on treated courses. Post-application exposure was estimated as the product of turf-transferable residue (mg/ cm^2), transfer coefficient (cm^2/hour), and time spent in the activity (hours).

The percent of the population playing golf and the percent of golf courses that are treated with carbaryl was also considered and incorporated into the assessment. The 1992 Golf Course Operations: Cost of Doing Business/Profitability survey conducted by the Center for Golf Course Management (CGCM) was used to establish the percent of individuals playing golf. The CGCM survey reported that an average of 12% of the population plays golf. To determine the likelihood of playing golf on a treated golf course, percent of golf courses treated data provided by Doane's GolfTrak (1998-1999) were used. These data indicated up to 25% of golf courses are treated with carbaryl, depending upon the region of use.

Residue Data: Since liquid broadcast applications to golf course turf are permitted, the liquid TTR data (Mester, 1999) were used to assess post-application exposure for the golf course scenario. Statistical analysis of these data was performed and an initial concentration of

0.00065 mg/ cm^2 was calculated and used in this assessment. Dissipation is based on a 3.6 day half-life. For details of the statistical analysis see Appendix II.D.2.

Transfer Coefficients: The surrogate data used to derive transfer coefficients were based on two measurements of four individuals playing golf on two golf courses treated with chlorothalonil (Ballee, 1990), and the exposure of golfers (four volunteers) to flurprimidol (Moran et al, 1987). For both studies, an assumed transfer efficiency of 1% was used to calculate the transfer coefficients, since the studies were conducted using sprayable formulations. Based on these two studies, a lognormal distribution with a mean of 480 cm^2/hour and a standard deviation of 160 cm^2/hour was used to represent the transfer coefficient. This distribution was truncated at the calculated 99th percentile value of 960 cm^2/hour. All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weight and surface area differences for adults and teenagers.

Duration: The exposure duration for individuals playing golf was assumed to be a uniform distribution bounded at the low end by two hours and at the upper end at four hours. The four-hour value was obtained from the CGCM survey.

7. Risk

For all subpopulations, the MOEs are greater than 10 when all uses are considered, at the 95th, 99th, and 99.9th percentiles. Graphs for all percentiles of regulation and all subpopulations are described in more detail in the cumulative chapter (F), of this document. (See Appendix III for detailed graphs.)

8. Summary

This assessment relied upon the best available data from all sources that could be identified. Sources included chemical specific and task force-generated data, as well as data from the scientific literature.

The revised NMC CRA assessment was performed for the Southeast region of the United States. While insect growth may slow during the winter months in the South, unlike other regions of the country, there is no period of dormancy. Since the growing season is longer in the South and the associated pest pressures are therefore greater, this assessment provides a worst case estimate of exposure. The residential assessment of the revised NMC CRA includes the carbaryl lawn and golf course use, the carbaryl vegetable and ornamental garden use, the methiocarb snail and slug bait use, the

carbaryl fruit tree use, and the carbaryl and propoxur pet collar uses. All MOEs are greater than 10 and therefore not of concern.

Table I.D-4. Summary of NMC Residental Exposure Scenarios

Lawn Care Scenario	
Applicator Exposure	
Unit Exposure	Both dermal and inhalation exposure routes were considered. ORETF studies were used for the granular broadcast and liquid spot treatment scenarios.The ORETF (Outdoor Residential Exposure Task Force) submitted a report (Klonne, 1999) in which a variety of products were used on turf. In these studies, both homeowners and lawn care operators (LCOs) were monitored following broadcast applications to turf. All of the data submitted in this report were completed in a series of studies. The two studies that monitored homeowner exposure resulting from granular spreader (Klonne, 1999/OMA003 Study) and hose-end sprayer (Klonne, 1999/OMA004 Study) applications were used in this assessment. Volunteers participating in these exposures studies were adult non-professionals who use pesticides on their own gardens and lawns. Many of the volunteers selected as subjects in these studies were members of garden clubs. All volunteers made their applications without specific instruction from the study investigators. Unit exposures estimated from these studies cover various clothing scenarios that range from wearing short pants and short-sleeved shirts, to long pants and long-sleeved shirts. All dermal and inhalation unit exposure were normalized and expressed as milligrams exposure per pound of active ingredient handled (mg/lb ai) (referred to as unit exposures, or UE). The lognormal distributions of the UEs for the lawn applicator scenarios are shown in Table I.D.2.
Application Rate	For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the lawn care scenario).
Area Treated	An important variable for estimating home-owner applicator exposure is the size of the lawn. OPP considered the average and median lawn sizes reported in a journal article by Vinlove and Torla (1995). The means and medians were ~13,000 ft2. However, the authors noted problems interpreting the data since it is based primarily on low income houses and consists of adjustments of the lot size by the house's foundation (footprint) only. The data do not consider other structures such as decks or other green space such as gardens, which can reportedly reduce the lot size by up to 50%. Similar lawn sizes were noted in ORETF study (Johnson et al, 1999) with similar problems encountered with respect to confounding variables such as decks and other green spaces. For this assessment, OPP used a uniform distribution for lawn size bounded by 1000 ft2 and 20,000 ft2. The lower end of this range considers smaller lawns for residences such as town houses. The upper bound of 20,000 ft2 (~ ½ acre) appears reasonable given the type of application equipment assumed to be used by residential applicators. Information from the ORETF survey also indicates that many pesticide users make spot treatments of insecticides. Similarly for spot treatments, OPP assumed a uniform distribution for treated area bounded by 100 ft2 and 1000 ft2.
Dermal Post-Application Exposure	
Residue	There are chemical-specific turf transferable residue (TTR) data for granular formulations of carbaryl (Krolski, 2005). This study was designed to determine transferable residues of carbaryl from both irrigated and non-irrigated turf treated with SEVIN® 2G (see Appendix II.D.2 for study summary). Measured carbaryl residues rapidly declined over the first 4 hours and then leveled off or rose

	slightly after 12 hours. By the 24-hour sampling interval, the residues declined to approximately 10 percent of the corresponding 0-time residue value and then steadily dropped to below 1.0 percent of the corresponding 0-time residue values by 3- to 5-days after treatment. In order to provide a conservative estimate of exposure for the revised NMC CRA, only the samples from the non-irrigated site in Florida were used. This assessment assumes an initial concentration of 0.00021 mg/ cm^2. Dissipation is based on a 0.8 day half-life, with residues set to zero 14 days after application. Although the carbaryl TTR studies show residues below 1% of the initial residues by 3- to 5-days after application, to provide a conservative estimate of exposure, it is assumed that carbaryl residues on the lawn would be available for up to 2 weeks after application.
TC	*Transfer Coefficients used to assess children's exposure to treated turf:* One study was used to assess children's dermal exposure resulting from granular applications to residential turf (Vaccaro, 1996). In this study, a granular formulation of chlorpyrifos was applied, after which seven adults performed pre-choreographed activities intended to mimic a typical child's behavior. The subjects performed these activities for a period of four hours beginning after the turf had dried. Turf had been treated earlier with a granular form of chlorpyrifos and exposure was estimated in the study by monitoring the amount of a chlorpyrifos metabolite – 3,4,5, 6-TCP – excreted over the following period of 6 days. This method directly measures internal dose and was used to back-calculate a generic "to the skin" transfer coefficient by using chemical specific dermal absorption data for chlorpyrifos (Nolan et al, 1984), These data were further adjusted to account for differences in surface area of adults and children. The study data discussed above was fit to a lognormal distribution with an arithmetic mean of 1970 cm^2/hr with a standard deviation of 1426 cm^2/hr. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e. 7224 cm^2/hr for the granular application) in order to avoid a distribution which contained values that were well-beyond those that are deemed reasonable. (see Appendix II.D.2 for study summary and details of the distributional analysis). *Transfer Coefficients used to assess adult exposure to treated turf:* The Vaccaro study data discussed above were also used to assess exposure to adults following granular applications. The revised NMC CRA used a distribution of values for the transfer coefficient characterized by a lognormal distribution with an arithmetic mean, of 5376 cm^2/hr and a standard deviation of 4717 cm^2/hr for the granular application. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e. 23436 cm^2/hr for the granular application. See Appendix II.D.2 for study summary and details of the distributional analysis).
Duration	Another important variable for addressing post-application exposure from home lawn treatment is the duration of time spent on lawns. In this revised NMC CRA, cumulative distributions of durations on lawns of up to two hours were used to address adult exposure on lawns. These data are presented in Table 15-64 of the EPA's Exposure Factor's Handbook (EFH) (USEPA, 1997a); however, OPP notes that the percentiles above the 95th have the same values (121 minutes). A similar cumulative distribution was given for children ages one to five. In order to be protective of children and to address the uncertainty in the upper percentiles of the exposure factor data, OPP selected an empirical distribution (which was expressed as a cumulative distribution function) from EFH Table 15-80 with a bound of 3.5 hours for children (USEPA, 1997a). This distribution represents the amount of time spent outdoors rather than just on lawns. This adjustment allows for additional time that children may spend outdoors (such as parks and schools) where there is potential for additional contact with treated turf.
Oral non-dietary Post-Application Exposure	
Initial Hand Loadings	Hand loading (HR/2) is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA EFH indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over (USEPA, 2002c). The algorithm assumes mouthing one hand at a time, therefore, hand loading residues are divided by 2.

Frequency of mouthing events	For the revised NMC CRA assessment, the frequency of hand-to-mouth events is based on Xue et al, 2007. The estimates of mouthing frequency were derived from several exposure studies and videotaping studies. Statistical analysis indicated that a Weibull distribution best fit the data. For the lawn care scenario, hand-to-mouth events per hour were based on outdoor frequencies as defined by a Weibull distribution (mean = 6 events/hour, standard deviation = 8). OPP believes that the meta-analysis cited above provides the best available data to assess children's hand-to-mouth exposures.
Surface Area Mouthed	The revised NMC CRA relied on Zartarian's (2003) analysis of surface area of hand mouthed. The analysis used the Leckie, et al, 2000 data to determine the fraction of the hand mouthed. The fraction of hand mouthed values were fit with a beta distribution (mean = 0.13 events/hour, standard deviation = 0.06).
Saliva Extraction Factor	To address the removal of residues from the hands by saliva during mouthing events, several studies were considered. The removal efficiency of residues on hands by saliva and other substances (e.g., ethanol) suggests a range of removal efficiencies (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989). Based on the above studies, a uniform distribution of 20% to 50% was used in this assessment for saliva extraction factors.
Duration	The time spent on the lawn was estimated as a cumulative distribution ranging from 0 hours to 3.5 hours. To be protective of childrens' exposure and to address the uncertainty of the upper percentiles of the exposure factor data, OPP selected a cumulative distribution from EFH (USEPA, 1997a) Table 15-80 with a bound of 3.5 hours for children 1 to 5 years old. This distribution represents the amount of time spent outdoors. This allows for the time that children spend outdoors not only at home but also in parks and near schools.
Vegetable Garden Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	Dermal and inhalation unit exposures were derived from chemical-specific data (Mester, 1998a) for dust (shake/pour), trigger pump sprayer, and liquid hose-end sprayer applications to vegetable gardens. The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D.3.
Application Rate	An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lb ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lbs ai/container (see Table I.A). The exposure assessment for dust formulation applied to home gardens assumes use of one entire container per treatment.
Area Treated	For vegetable gardens, the area treated was entered as a lognormal distribution (mean = 4600 ft^2, standard deviation =1500 ft^2, and Taximum = 8000 ft^2); these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999). In these assessments, it is assumed that the entire garden is treated. Home gardens consist of many types of vegetables which all may not be treated since they tend to have different pest pressures (e.g. squash vine borer and corn earworm may not appear at the same time).
Dermal Post-Application Exposure	
Residue	Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a), the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. Statistical analysis of the carbaryl sunflower DFR data was performed. The initial residue concentrations and the half-life were determined to be 0.0061 mg/ cm^2 and 5 days, respectively.

TC	For the vegetable garden scenario, transfer coefficients were characterized by a uniform distribution ranging from 180 to 1000 cm^2/hour, to reflect a range of gardening tasks for a variety of crops of differing heights and foliage development. The TCs used in this assessment were derived from studies on chrysanthemum pinching (Rotondaro, 2000) and tomato harvesting (USEPA, 2000e). All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.
Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Ornamental Plants and Shrub Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	Dermal and inhalation unit exposures were derived from chemical-specific data for carbaryl used on ornamental plants (Mester, 1998a; Merricks, 1998). The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D.3.
Application Rate	An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lb ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lbs ai/container (see Table II.A). The exposure assessment for dust formulation applied to ornamental gardens assumes use of one entire container per treatment.
Area Treated	The area treated was entered as a uniform distribution of 500 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999) and professional judgment. The ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.
Dermal Post-Application Exposure	
Residue	Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure from harvesting or performing maintenance activities in ornamental gardens. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a), the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. A statistical analysis of this data was performed and the initial concentration was estimated to be 0.0061 mg/ cm^2. Residue dissipation is based on the half-life of 5 days. The half-life used in this assessment was determined from the statistical analysis of the carbaryl sunflower DFR data. A more detailed explanation of the statistical analysis of this data is provided in Appendix II.D.2.
TC	For the ornamental garden scenario, a uniform distribution of transfer coefficients, ranging from 99 to 550 cm^2/hour, was used to reflect a range of gardening tasks. The TCs used in this assessment were derived from studies that evaluated chrysanthemum pinching (Rotondaro, 2000) and nursery stock pruning (Klonne et al, 2000b). All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.

Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post-application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Fruit Tree Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	The dermal and inhalation unit exposures were derived from chemical-specific data for liquid handwand applications to fruit trees (Merricks, 1998). These unit exposures are based on study data in which applications were made with handwands, spraying below the waist as well as overhead. The UEs for fruit tree scenario are based on lognormal distribution as listed in Table I.D.3.
Application Rate	For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the fruit tree scenario).
Area Treated	For fruit trees, most of which are of the dwarf variety and therefore occupy relatively small areas, the area treated was entered as a uniform distribution (minimum 500 ft^2, maximum 1000 ft^2). The maximum value in this distribution was based on label restriction for applications made at the maximum rate (8lbs ai/A) for fruit tree applications.
Dermal Post-Application Exposure	
Residue	Chemical specific dislodgeable foliar residue data on olive trees (Klonne et al, 2000c) were used to assess dermal post-application exposure for this scenario. Statistical analysis of this data was performed and the initial residue concentrations were determined to be 0.0035 mg/ cm^2. Residue dissipation is based on the half-life of 7 days (as determined by the statistical analysis of the carbaryl olive DFR data).
TC	For the fruit tree scenario, the distribution of transfer coefficient was characterized as lognormal, with a mean of 940 cm^2/hour and a standard deviation of 260 cm^2/hour. The TCs were based on an apple pruning study. All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.
Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post-application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Ornamental Garden - Snail and Slug Bait Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	The dermal and inhalation UEs for the methiocarb snail and slug bait scenario were based on study data for disulfoton applications to residential shrubs and flower beds (Merricks, 2001). The surrogate data consist of dermal and inhalation measurements of individuals using granular products. Specifically, the field study was conducted in Vero Beach, Florida. A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto

	the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. Each volunteer applied granular disulfoton around shrubs while wearing gloves and then again without gloves. Exposure data from the 15 replicates who did not wear gloves were reported. A lognormal distribution with a mean of 0.23 mg/lb ai, a standard deviation of 5.8 mg/lb ai, and maximum value of 3.4 mg/lb ai (representing the estimated 99th percentile of the lognormal distribution) was used to assess dermal exposure. A single point estimate of 0.00001 mg/lb ai (1/2 LOQ) was used for the inhalation UE since all measured values for inhalation were non-detects.
Application Rate	The application rate used in this assessment is based on the maximum label application rate of 0.2 lbs ai/1000 ft^2.
Area Treated	The area treated was entered as a uniform distribution of 10 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999) and professional judgment. The low value of 10 sq ft was based on the label direction for treating small areas. The high value for ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.
Pet Collar Scenarios	
Dermal Post-Application Exposure	
Residue	The fur residue concentration for the pet collar assessment is based on the amount of active ingredient in the respective pet collars and Agency default assumptions from the OPP SOPs for Residential Exposure Assessment (USEPA, 1997b). The residue values for carbaryl and propoxur are 0.00012 and 0.000069 mg/ cm^2, respectively. Residues were assumed to be available on a daily basis since pet collar products are designed to emit residues throughout their active period (120 days for carbaryl and 180 days for propoxur).
TC	The transfer coefficients used in the dermal post-application exposure assessment was derived from a groomer exposure study (Mester, 1998b) in which sixteen different veterinary personnel treated/handled eight dogs each, over a two to five hour time period. In this assessment, the transfer coefficients for adults and children were derived assuming an average transfer efficiency of 2.97% from the previous OP pet fur residue transfer efficiencies. For the revised NMC CRA, the data were used directly to generate an empirical distribution for the dermal transfer coefficient. The selected TCs ranged from 180 to 4700 cm^2/hour for adults and from 66 to 1800 cm^2/hour for children. These empirical distributions were used for both pet collar scenarios.
Duration	The time spent in this activity was assumed to follow a triangular distribution with minimum value of 0.03 hours, and a maximum value of 1.03 hours per day (Freeman et al, 2001). As part of this study, macroactivity and microactivity data were collected via questionnaires and videotaping of 19 children (aged 3 to 12) for a four hour period. The videotapes from the observational portion of this study were analyzed to determine frequency of contacts for several mouthing behaviors, as well as duration of time each child spent in various locations around the home. The results of this study include several measurements for the duration of time the observed children spent with their pets.
Oral non-dietary Post-Application Exposure	
Initial Hand Loadings	Hand loading (HR/2) is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA Exposure Factors Handbook indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over (USEPA, 2002c). The algorithm assumes mouthing one hand at a time, therefore, hand loading residues are divided by 2.

Frequency of mouthing events	The estimates of mouthing frequency were derived from several exposure studies and observational studies. For the pet collar scenario, hand-to-mouth events per hour were based on indoor frequencies as defined by a Weibull distribution (mean = 13 events/hour, standard deviation = 18). The distribution for frequency of hand-to-mouth events for indoor exposures, provided by ORD's Dr. Jiaping Xue, was calculated using the same methodology used to determine the frequency of mouthing events for outdoor exposures that was used in the lawn care assessment.
Surface Area Mouthed	The revised NMC CRA relied on Zartarian's (2003) analysis of surface area of hand mouthed. The analysis used the Leckie, et al, 2000 data to determine the fraction of the hand mouthed. The fraction of hand mouthed values were fit with a beta distribution (mean = 0.13 events/hour, standard deviation = 0.06).
Saliva Extraction Factor	To address the removal of residues from the hands by saliva during mouthing events, several studies were considered. The removal efficiency of residues on hands by saliva and other substances (e.g., ethanol) suggests a range of removal efficiencies (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989). Based on the above studies, a uniform distribution of 20% to 50% was used in this assessment for saliva extraction factors.
Duration	The duration of exposure values used for the non-dietary exposure assessment are the same as those used in the dermal post-application assessment for the pet collar scenarios presented above.
Golf Course Scenario	
Dermal Post-Application Exposure	
Residue	Since liquid broadcast applications to golf course turf are permitted, the liquid TTR data (Mester, 1999) used to assess post-application exposure for the golf course scenario. Statistical analysis of this data was performed and an initial concentration of 0.00065 mg/ cm^2 was calculated and used in this assessment. Dissipation is based on a 3.6 day half-life. For details of the statistical analysis see Appendix II.D.2.
TC	The surrogate data used to derive transfer coefficients were based on two measurements of four individuals playing golf on two golf courses treated with chlorothalonil (Ballee, 1990), and the exposure of golfers (four volunteers) to flurprimidol (Moran et al, 1987). For both studies, an assumed transfer efficiency of 1% was used to calculate the transfer coefficients, since the studies were conducted using sprayable formulations. Based on these two studies, a lognormal distribution with a mean of 480 cm^2/hour and a standard deviation of 160 cm^2/hour was used to represent the transfer coefficient. This distribution was truncated at the calculated 99th percentile value of 960 $cm^{2/}$hour. All transfer coefficients are based on individuals wearing short sleeved shirts and short pants. A reduction factor was applied to account for body weight and surface area differences for adults and teenagers.
Duration	The exposure duration for individuals playing golf was assumed to be a uniform distribution bounded at the low end by two hours and at the upper end at four hours. The four-hour value was obtained from the CGCM survey.
Applicator Exposure	

Unit Exposure	Both dermal and inhalation exposure routes were considered. ORETF studies were used for the granular broadcast and liquid spot treatment scenarios.The ORETF (Outdoor Residential Exposure Task Force) submitted a report (Klonne, 1999) in which a variety of products were used on turf. In these studies, both homeowners and lawn care operators (LCOs) were monitored following broadcast applications to turf. All of the data submitted in this report were completed in a series of studies. The two studies that monitored homeowner exposure resulting from granular spreader (Klonne, 1999/OMA003 Study) and hose-end sprayer (Klonne, 1999/OMA004 Study) applications were used in this assessment. Volunteers participating in these exposures studies were adult non-professionals who use pesticides on their own gardens and lawns. Many of the volunteers selected as subjects in these studies were members of garden clubs. All volunteers made their applications without specific instruction from the study investigators. Unit exposures estimated from these studies cover various clothing scenarios that range from wearing short pants and short-sleeved shirts, to long pants and long- sleeved shirts. All dermal and inhalation unit exposure were normalized and expressed as milligrams exposure per pound of active ingredient handled (mg/lb ai) (referred to as unit exposures, or UE). The lognormal distributions of the UEs for the lawn applicator scenarios are shown in Table I.D.2.
Application Rate	For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the lawn care scenario).
Area Treated	An important variable for estimating home-owner applicator exposure is the size of the lawn. OPP considered the average and median lawn sizes reported in a journal article by Vinlove and Torla (1995). The means and medians were ~13,000 ft^2. However, the authors noted problems interpreting the data since it is based primarily on low income houses and consists of adjustments of the lot size by the house's foundation (footprint) only. The data do not consider other structures such as decks or other green space such as gardens, which can reportedly reduce the lot size by up to 50%. Similar lawn sizes were noted in ORETF study (Johnson et al, 1999) with similar problems encountered with respect to confounding variables such as decks and other green spaces. For this assessment, OPP used a uniform distribution for lawn size bounded by 1000 ft^2 and 20,000 ft^2. The lower end of this range considers smaller lawns for residences such as town houses. The upper bound of 20,000 ft^2 (~ ½ acre) appears reasonable given the type of application equipment assumed to be used by residential applicators. Information from the ORETF survey also indicates that many pesticide users make spot treatments of insecticides. Similarly for spot treatments, OPP assumed a uniform distribution for treated area bounded by 100 ft^2 and 1000 ft^2.
Dermal Post-Application Exposure	
Residue	There are chemical-specific turf transferable residue (TTR) data for granular formulations of carbaryl (Krolski, 2005). This study was designed to determine transferable residues of carbaryl from both irrigated and non-irrigated turf treated with SEVIN® 2G (see Appendix II.D.2 for study summary). Measured carbaryl residues rapidly declined over the first 4 hours and then leveled off or rose slightly after 12 hours. By the 24-hour sampling interval, the residues declined to approximately 10 percent of the corresponding 0-time residue value and then steadily dropped to below 1.0 percent of the corresponding 0-time residue values by 3- to 5-days after treatment. In order to provide a conservative estimate of exposure for the revised NMC CRA, only the samples from the non-irrigated site in Florida were used. This assessment assumes an initial concentration of 0.00021 mg/ cm^2. Dissipation is based on a 0.8 day half-life, with residues set to zero 14 days after application. Although the carbaryl TTR studies show residues below 1% of the initial residues by 3- to 5-days after application, to provide a conservative estimate of exposure, it is assumed that carbaryl residues on the lawn would be available for up to 2 weeks after application.

TC	*Transfer Coefficients used to assess children's exposure to treated turf:* One study was used to assess children's dermal exposure resulting from granular applications to residential turf (Vaccaro, 1996). In this study, a granular formulation of chlorpyrifos was applied, after which seven adults performed pre-choreographed activities intended to mimic a typical child's behavior. The subjects performed these activities for a period of four hours beginning after the turf had dried. Turf had been treated earlier with a granular form of chlorpyrifos and exposure was estimated in the study by monitoring the amount of a chlorpyrifos metabolite – 3,4,5, 6-TCP – excreted over the following period of 6 days. This method directly measures internal dose and was used to back-calculate a generic "to the skin" transfer coefficient by using chemical specific dermal absorption data for chlorpyrifos (Nolan et al, 1984). These data were further adjusted to account for differences in surface area of adults and children. The study data discussed above was fit to a lognormal distribution with an arithmetic mean of 1970 cm^2/hr with a standard deviation of 1426 cm^2/hr. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e. 7224 cm^2/hr for the granular application) in order to avoid a distribution which contained values that were well-beyond those that are deemed reasonable. (See Appendix II.D.2 for study summary and details of the distributional analysis.) *Transfer Coefficients used to assess adult exposure to treated turf:* The Vaccaro study data discussed above were also used to assess exposure to adults following granular applications. The revised NMC CRA used a distribution of values for the transfer coefficient characterized by a lognormal distribution with an arithmetic mean, of 5376 cm^2/hr and a standard deviation of 4717 cm^2/hr for the granular application. The lognormal distribution was truncated at the calculated 99th percentile of the distribution (i.e. 23436 cm^2/hr for the granular application). (See Appendix II.D.2 for study summary and details of the distributional analysis.)
Duration	Another important variable for addressing post-application exposure from home lawn treatment is the duration of time spent on lawns. In this revised NMC CRA, cumulative distributions of durations on lawns of up to two hours were used to address adult exposure on lawns. These data are presented in Table 15-64 of the EPA's Exposure Factor's Handbook (EFH) (USEPA, 1997a); however, OPP notes that the percentiles above the 95th have the same values (121 minutes). A similar cumulative distribution was given for children ages one to five. In order to be protective of children and to address the uncertainty in the upper percentiles of the exposure factor data, OPP selected an empirical distribution (which was expressed as a cumulative distribution function) from EFH Table 15-80 with a bound of 3.5 hours for children (USEPA, 1997a). This distribution represents the amount of time spent outdoors rather than just on lawns. This adjustment allows for additional time that children may spend outdoors (such as parks and schools) where there is potential for additional contact with treated turf.
Oral non-dietary Post-Application Exposure	
Initial Hand Loadings	Hand loading (HR/2) is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA EFH indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over (USEPA, 2002c). The algorithm assumes mouthing one hand at a time, therefore, hand loading residues are divided by 2.
Frequency of mouthing events	For the revised NMC CRA assessment, the frequency of hand-to-mouth events is based on Xue et al, 2007. The estimates of mouthing frequency were derived from several exposure studies and videotaping studies. Statistical analysis indicated that a Weibull distribution best fit the data. For the lawn care scenario, hand-to-mouth events per hour were based on outdoor frequencies as defined by a Weibull distribution (mean = 6 events/hour, standard deviation = 8). OPP believes that the meta-analysis cited above provides the best available data to assess children's hand-to-mouth exposures.

Surface Area Mouthed	The revised NMC CRA relied on Zartarian's (2003) analysis of surface area of hand mouthed. The analysis used the Leckie, et al, 2000 data to determine the fraction of the hand mouthed. The fraction of hand mouthed values were fit with a beta distribution (mean = 0.13 events/hour, standard deviation = 0.06).
Saliva Extraction Factor	To address the removal of residues from the hands by saliva during mouthing events, several studies were considered. The removal efficiency of residues on hands by saliva and other substances (e.g., ethanol) suggests a range of removal efficiencies (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989). Based on the above studies, a uniform distribution of 20% to 50% was used in this assessment for saliva extraction factors.
Duration	The time spent on the lawn was estimated as a cumulative distribution ranging from 0 hours to 3.5 hours. To be protective of childrens' exposure and to address the uncertainty of the upper percentiles of the exposure factor data, OPP selected a cumulative distribution from EFH (USEPA, 1997a) Table 15-80 with a bound of 3.5 hours for children 1 to 5 years old. This distribution represents the amount of time spent outdoors. This allows for the time that children spend outdoors not only at home but also in parks and near schools.
Vegetable Garden Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	Dermal and inhalation unit exposures were derived from chemical-specific data (Mester, 1998a) for dust (shake/pour), trigger pump sprayer, and liquid hose-end sprayer applications to vegetable gardens. The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D.3.
Application Rate	An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lb ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lbs ai/container. The exposure assessment for dust formulation applied to home gardens assumes use of one entire container per treatment.
Area Treated	For vegetable gardens, the area treated was entered as a lognormal distribution (mean = 4600 ft^2, standard deviation =1500 ft^2, and maximum = 8000 ft^2); these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999). In these assessments, it is assumed that the entire garden is treated. Home gardens consist of many types of vegetables which all may not be treated since they tend to have different pest pressures (e.g. squash vine borer and corn earworm may not appear at the same time).
Dermal Post-Application Exposure	
Residue	Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a), the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. Statistical analysis of the carbaryl sunflower DFR data was performed. The initial residue concentrations and the half-life were determined to be 0.0061 mg/ cm^2 and 5 days, respectively.
TC	For the vegetable garden scenario, transfer coefficients were characterized by a uniform distribution ranging from 180 to 1000 cm^2/hour, to reflect a range of gardening tasks for a variety of crops of differing heights and foliage development. The TCs used in this assessment were derived from studies on chrysanthemum pinching (Rotondaro, 2000) and tomato harvesting (USEPA, 2000e). All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.

Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Ornamental Plants and Shrub Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	Dermal and inhalation unit exposures were derived from chemical-specific data for carbaryl used on ornamental plants (Mester, 1998a; Merricks, 1998). The UE for all garden scenarios are based on lognormal distribution as listed in Table I.D.3.
Application Rate	An application rate of 2 lbs ai/A was used for all liquid vegetable garden scenarios (hose-end sprayers and trigger pump sprayers) even though trigger pump sprayer rates are considerably lower. This assessment conservatively uses the 2 lb ai/A application rate for all liquid scenarios. Due to recent mitigation, the maximum application rate for dust formulations is 0.5 lbs ai/container. The exposure assessment for dust formulation applied to ornamental gardens assumes use of one entire container per treatment.
Area Treated	The area treated was entered as a uniform distribution of 500 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999) and professional judgment. The ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.
Dermal Post-Application Exposure	
Residue	Chemical-specific dislodgeable foliar residue data on sunflowers (Klonne et al, 1999) were used to assess dermal post-application exposure from harvesting or performing maintenance activities in ornamental gardens. Although OPP has additional information regarding carbaryl specific DFR data on cabbage (Klonne et al, 2000a), the sunflower DFR data were used since the residues detected in the sunflower study were higher than those detected in the cabbage study. A statistical analysis of this data was performed and the initial concentration was estimated to be 0.0061 mg/ cm^2. Residue dissipation is based on the half-life of 5 days. The half-life used in this assessment was determined from the statistical analysis of the carbaryl sunflower DFR data. A more detailed explanation of the statistical analysis of this data is provided in Appendix II.D.2.
TC	For the ornamental garden scenario, a uniform distribution of transfer coefficients, ranging from 99 to 550 cm^2/hour, was used to reflect a range of gardening tasks. The TCs used in this assessment were derived from studies that evaluated chrysanthemum pinching (Rotondaro, 2000) and nursery stock pruning (Klonne et al, 2000b). All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.
Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Fruit Tree Scenario	

Dermal and Inhalation Applicator Exposure	
Unit Exposure	The dermal and inhalation unit exposures were derived from chemical-specific data for liquid handwand applications to fruit trees (Merricks, 1998). These unit exposures are based on study data in which applications were made with handwands, spraying below the waist as well as overhead. The UEs for fruit tree scenario are based on lognormal distribution as listed in Table I.D.3.
Application Rate	For all scenarios assessed, OPP used the maximum application rate to assess exposure (8 lbs ai/A was used for the fruit tree scenario).
Area Treated	For fruit trees, most of which are of the dwarf variety and therefore occupy relatively small areas, the area treated was entered as a uniform distribution (minimum 500 ft^2, maximum 1000 ft^2). The maximum value in this distribution was based on label restriction for applications made at the maximum rate (8lbs ai/A) for fruit tree applications.
Dermal Post-Application Exposure	
Residue	Chemical specific dislodgeable foliar residue data on olive trees (Klonne et al, 2000c) were used to assess dermal post-application exposure for this scenario. Statistical analysis of this data was performed and the initial residue concentrations were determined to be 0.0035 mg/ cm^2. Residue dissipation is based on the half-life of 7 days (as determined by the statistical analysis of the carbaryl olive DFR data).
TC	For the fruit tree scenario, the distribution of transfer coefficient was characterized as lognormal, with a mean of 940 cm^2/hour and a standard deviation of 260 cm^2/hour. The TCs were based on an apple pruning study. All transfer coefficients are based on individuals wearing short-sleeved shirts and short pants. A reduction factor was applied to account for body weights and surface area differences between adults and teenagers.
Duration	The time spent harvesting or performing post-application maintenance activities was represented by a uniform distribution ranging from 0.17 hour/day to 1 hour/day. These estimates of time spent in the garden performing post application activities (as well as the frequency of applications) were based on the ORETF survey (Johnson et al, 1999).
Ornamental Garden - Snail and Slug Bait Scenario	
Dermal and Inhalation Applicator Exposure	
Unit Exposure	The dermal and inhalation UEs for the methiocarb snail and slug bait scenario were based on study data for disulfoton applications to residential shrubs and flower beds (Merricks, 2001). The surrogate data consist of dermal and inhalation measurements of individuals using granular products. Specifically, the field study was conducted in Vero Beach, Florida. A total of 15 volunteers were monitored using passive dosimetry (hand/forearm wash solutions and personal air monitors). Application of the product was made by pouring the granules into the measuring cup/lid attached to the product package, and then distributing the granules onto the soil around the base of a shrub or onto a flower bed. The granules were then soil-incorporated with a garden rake. Each volunteer applied granular disulfoton around shrubs while wearing gloves and then again without gloves. Exposure data from the 15 replicates who did not wear gloves were reported. A lognormal distribution with a mean of 0.23 mg/lb ai, a standard deviation of 5.8 mg/lb ai, and maximum value of 3.4 mg/lb ai (representing the estimated 99th percentile of the lognormal distribution) was used to assess dermal exposure. A single point estimate of 0.00001 mg/lb ai (1/2 LOQ) was used for the inhalation UE since all measured

	values for inhalation were non-detects.
Application Rate	The application rate used in this assessment is based on the maximum label application rate of 0.2 lbs ai/1000 ft^2.
Area Treated	The area treated was entered as a uniform distribution of 10 to 2000 ft^2; these dimensions are based on data from the National Gardening Association Survey (Johnson et al, 1999) and professional judgment. The low value of 10 sq ft was based on the label direction for treating small areas. The high value for ornamental bed size was determined by estimating the perimeter of 2200 ft^2 house. It is assumed that the majority of ornamental beds are located around the perimeter of the house.
Pet Collar Scenarios	
Dermal Post-Application Exposure	
Residue	The fur residue concentration for the pet collar assessment is based on the amount of active ingredient in the respective pet collars and Agency default assumptions from the OPP SOPs for Residential Exposure Assessment (USEPA, 1997b). The residue values for carbaryl and propoxur are 0.00012 and 0.000069 mg/ cm^2, respectively. Residues were assumed to be available on a daily basis since pet collar products are designed to emit residues throughout their active period (120 days for carbaryl and 180 days for propoxur).
TC	The transfer coefficients used in the dermal post-application exposure assessment was derived from a groomer exposure study (Mester, 1998b) in which sixteen different veterinary personnel treated/handled eight dogs each, over a two to five hour time period. In this assessment, the transfer coefficients for adults and children were derived assuming an average transfer efficiency of 2.97% from the previous OP pet fur residue transfer efficiencies. For the revised NMC CRA, the data were used directly to generate an empirical distribution for the dermal transfer coefficient. The selected TCs ranged from 180 to 4700 cm^2/hour for adults and from 66 to 1800 cm^2/hour for children. These empirical distributions were used for both pet collar scenarios.
Duration	The time spent in this activity was assumed to follow a triangular distribution with minimum value of 0.03 hours, and a maximum value of 1.03 hours per day (Freeman et al, 2001). As part of this study, macroactivity and microactivity data were collected via questionnaires and videotaping of 19 children (aged 3 to 12) for a four hour period. The videotapes from the observational portion of this study were analyzed to determine frequency of contacts for several mouthing behaviors, as well as duration of time each child spent in various locations around the home. The results of this study include several measurements for the duration of time the observed children spent with their pets.
Oral non-dietary Post-Application Exposure	
Initial Hand Loadings	Hand loading (HR/2) is based on loading concepts used in SHEDS and CARES. The initial amount of residue available on the hand is determined as a percentage of total dermal exposure. The EPA Exposure Factors Handbook indicates that the surface area of the hands is approximately 6% of the total surface area of the body for children age 4 and under; 5% for children age 5 and over (USEPA, 2002c). The algorithm assumes mouthing one hand at a time, therefore, hand loading residues are divided by 2.
Frequency of mouthing events	The estimates of mouthing frequency were derived from several exposure studies and observational studies. For the pet collar scenario, hand-to-mouth events per hour were based on indoor frequencies as defined by a Weibull distribution (mean = 13 events/hour, standard deviation = 18). The distribution for frequency of hand-to-mouth events for indoor exposures, provided by ORD's Dr. Jiaping Xue, was calculated using the same methodology used to determine the frequency of mouthing events for

	outdoor exposures that was used in the lawn care assessment.
Surface Area Mouthed	The revised NMC CRA relied on Zartarian's (2003) analysis of surface area of hand mouthed. The analysis used the Leckie, et al, 2000 data to determine the fraction of the hand mouthed. The fraction of hand mouthed values were fit with a beta distribution (mean = 0.13 events/hour, standard deviation = 0.06).
Saliva Extraction Factor	To address the removal of residues from the hands by saliva during mouthing events, several studies were considered. The removal efficiency of residues on hands by saliva and other substances (e.g., ethanol) suggests a range of removal efficiencies (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989). Based on the above studies, a uniform distribution of 20% to 50% was used in this assessment for saliva extraction factors.
Duration	The duration of exposure values used for the non-dietary exposure assessment are the same as those used in the dermal post-application assessment for the pet collar scenarios presented above.
Golf Course Scenario	
Dermal Post-Application Exposure	
Residue	Since liquid broadcast applications to golf course turf are permitted, the liquid TTR data (Mester, 1999) used to assess post-application exposure for the golf course scenario. Statistical analysis of this data was performed and an initial concentration of 0.00065 mg/ cm^2 was calculated and used in this assessment. Dissipation is based on a 3.6 day half-life. For details of the statistical analysis see Appendix II.D.2.
TC	The surrogate data used to derive transfer coefficients were based on two measurements of four individuals playing golf on two golf courses treated with chlorothalonil (Ballee, 1990), and the exposure of golfers (four volunteers) to flurprimidol (Moran et al, 1987). For both studies, an assumed transfer efficiency of 1% was used to calculate the transfer coefficients, since the studies were conducted using sprayable formulations. Based on these two studies, a lognormal distribution with a mean of 480 cm^2/hour and a standard deviation of 160 cm^2/hour was used to represent the transfer coefficient. This distribution was truncated at the calculated 99th percentile value of 960 $cm^{2/}$hour. All transfer coefficients are based on individuals wearing short sleeved shirts and short pants. A reduction factor was applied to account for body weight and surface area differences for adults and teenagers.
Duration	The exposure duration for individuals playing golf was assumed to be a uniform distribution bounded at the low end by two hours and at the upper end at four hours. The four-hour value was obtained from the CGCM survey.

E. Cumulative Risk from NMC Pesticides in Drinking Water

1. Introduction

The Food Quality Protection Act (FQPA) of 1996 requires the Agency to assess the risks from different pesticides having a common mechanism of action, focusing on the likelihood that a person will be concurrently exposed to multiple pesticides from multiple sources (food, drinking water, and residential uses). Ideally, data to support the drinking water portion of this exposure assessment would consist of information on multiple pesticides and their transformation products, collected from sufficient drinking water sources throughout the U.S. and at a sufficient frequency to reflect the range in spatial and temporal patterns of pesticide occurrence in water. The great diversity of geographic-, climatic-, and time-dependent factors that affect the levels of pesticide residues in water creates unique challenges in characterizing drinking water exposure. EPA's Office of Pesticide Programs (OPP) must rely on both available monitoring data and modeling to develop sufficient data for use in the exposure assessment.

The Agency used the same methods for estimating surface water exposure in the revised NMC CRA as it did in the OP CRA (USEPA, 2002b; FIFRA SAP, 2002) because of similarities in use (both NMCs and OPs are insecticides), hazard endpoints (ChE inhibition occurring in the acute- or short-term), and exposure requirements (estimates of peak concentrations and time-series distributions).

Unlike the OP pesticides for which surface water is the likely source of concern for drinking water, the NMCs also are likely to reach ground-water sources of drinking water. The Agency presented a conceptual model for ground water exposure and a plan for evaluating the capability of three ground water models to estimate NMC concentrations to the FIFRA SAP in February, 2005. Based on feedback from the SAP (FIFRA SAP, 2005a), EPA followed up with a revised conceptual model and analysis plan using one of the models evaluated in the preliminary assessment (FIFRA SAP, 2005b).

The revised NMC CRA follows the same approach as outlined in the preliminary assessment (USEPA, 2005b), and includes several additional ground water exposure scenarios to further capture the range of high leaching potential areas in high NMC use areas, as well as a more representative assumption for the depth to groundwater. Based on analysis of additional monitoring data, the Agency has been better able to identify the specific conditions that are likely to result in high NMC

exposure in private drinking water wells and to better characterize the spatial extent of potential high NMC exposure areas.

In addition, the reported cumulative NMC exposures in this section reflect the revised relative potency, inter-species, and FQPA safety factors documented in the Hazard chapter (I.B) of this revised assessment.

2. Problem Formulation

Pesticide concentrations found in drinking water are not random, but are in large part determined by the amount, method, timing and location of pesticide application, the physical characteristics of the watersheds and/or aquifers in which the community water supplies (CWS) or wells are located, and other environmental factors, such as rainfall, which can cause the pesticide to move from the location where it was applied.

a. Drinking Water Exposure Needs for the NMC Cumulative Assessment

For the NMC group, the toxicity endpoint of concern results from short-term exposure (acute effects). To adequately characterize the potential impacts of pesticide residues in drinking water, the estimated residue concentrations need to reflect a sufficient frequency in time to capture peak concentrations. Because pesticide loads in surface water tend to move in relatively quick pulses in flowing water, frequent sampling is necessary to reliably capture peak concentrations for surface water sources of drinking water. Pesticide concentrations in ground water are generally the result of longer-term processes and less frequent sampling can sufficiently characterize peak ground water concentrations.

The drinking water exposure assessment needs to account for the potential for any or all of the NMC residues included in the cumulative assessment group (Table I.E-1) to occur together in drinking water sources. To realistically estimate exposures, the assessment must take into account those factors (crop uses, pest pressures, timing of application, etc.) that determine whether more than one NMC pesticide can occur together in time and place. Although multiple NMC pesticides may be registered for use on the same crop, they may not necessarily be used at the same time. Monitoring data could provide real-time estimates of co-occurrence but needs to account for all of the potential NMCs used in the monitoring area, be of sufficient frequency to capture short-term peaks in pesticide exposure, particularly in surface water, and span sufficient years to capture the impact of variability in use and weather patterns on pesticide transport.

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Table I.E-1. NMC use patterns and availability of national monitoring data

Pesticide	Use pattern likely to result in water exposure?	Availability of national water monitoring data?
Aldicarb (including sulfoxide, sulfone degradates)	Yes (agricultural uses)	Yes: NAWQA, Reservoir monitoring; state monitoring; registrant studies
Carbaryl	Yes (agricultural and residential uses)	Yes: NAWQA, Reservoir monitoring; registrant studies
Carbofuran (including 3-hydroxycarbofuran)	Yes[1] (agricultural uses)	Yes: NAWQA, Reservoir monitoring; state monitoring
Formetanate HCl	Yes (agricultural uses)	No
Methiocarb	Insignificant impact from limited use	Some limited NAWQA monitoring
Methomyl	Yes (agricultural uses)	Yes: NAWQA, Reservoir monitoring
Oxamyl	Yes (agricultural uses)	Yes: NAWQA, Reservoir monitoring
Pirimicarb	Insignificant impact from limited use	No
Propoxur	No (indoor uses; voluntarily cancelled)	Some limited NAWQA monitoring
Thiodicarb (including methomyl degradate)	Yes (agricultural uses)	No

[1] EPA proposed to cancel all domestic uses in 2006 IRED, in which case exposure would not be likely

b. Nature of NMC Exposure in Drinking Water Sources

This section briefly summarizes the nature of expected NMC exposure in drinking water sources based on individual chemical assessments, available water monitoring data, and published literature on the potential impact of conventional drinking water treatment processes on NMCs in water.

Re-registration eligibility documents (REDs), interim REDs (IREDs), drinking water assessments, or ecological risk assessments are available for all of the NMC pesticides in Table I.E.1 except for pirimicarb (USEPA, 1997c. 1997d, 1999f, 2003a, 2005c, 2005d, 2005e, 2006c, 2006d, 2007b, 2007d, 2007e).

Seven NMC pesticides – aldicarb (including its sulfoxide and sulfone degradates), carbaryl, carbofuran, formetanate HCl, methomyl, oxamyl, and thiodicarb – have the potential to reach surface and/or ground water sources of drinking water based on use and chemical fate and transport properties. Propoxur has been detected in a few, predominantly non-agricultural monitoring sites in the US Geological Survey (USGS) National Water Quality Assessment (NAWQA) monitoring program (Appendix II.E.1). However, the current indoor uses are not expected to contribute to the NMC cumulative load in drinking water sources. When the Agency gathered usage information on the NMC pesticides for the regional cumulative drinking water exposures,

usage of methiocarb and pirimicarb were of such a limited extent that they did not factor into the NMC cumulative exposure for drinking water (see Appendix II.E.4). These pesticides were not used in areas of high combined NMC use identified in the regional assessments described below.

The individual chemical assessments indicate that the NMC pesticides are likely to reach surface water sources of drinking water via runoff or sediment transport, and have been detected in monitoring studies. Two carbamates – aldicarb and carbofuran – are likely to reach and persist in ground water sources of drinking water, especially in shallow, acidic aquifers. Three other carbamates – carbaryl, methomyl, and oxamyl – may also reach ground water, but are not likely to persist.

The most extensive source of national water monitoring data for pesticides is the USGS NAWQA program, which includes seven of the carbamates in its list of pesticides (Table I.E-2). The NAWQA program focuses on ambient water rather on than on drinking water sources, is not specifically targeted to pesticide use areas, and is sampled at a frequency (generally weekly or bi-weekly during the use season) not sufficient to provide reliable estimates of peak pesticide concentrations in surface water. However, the program provides a good understanding on a national level of the expected occurrence of pesticides in flowing water bodies that may be representative of drinking water sources. The monitoring data are better indicators of the nature of occurrence of pesticides with widespread use rather than of pesticides that are limited to a few crops or pests. USGS (2004) provides a detailed description of the pesticide monitoring component of the NAWQA program.

A summary of the first cycle of NAWQA monitoring from 1991 to 2001 indicates that the seven NMC pesticides were not frequently detected in the NAWQA study units (Table I.E-2). Carbaryl and carbofuran were the most frequently detected NMC pesticides in streams and ground water, reflecting the broader use patterns of these particular insecticides. In most instances, maximum reported detections of the NMC pesticides were in the single parts per billion or sub-parts per billion range.

As expected, co-occurrence of NMC pesticides in monitored water samples reflects use patterns and overall intensity of use. Carbaryl and carbofuran are the most common NMCs occurring together in the NAWQA sampling; up to three different NMCs have been detected in the same surface water samples in the NAWQA study units. Although less commonly observed, more than one carbamate was also detected in a small number of ground water samples. More detailed summaries of the

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USGS NAWQA monitoring data can be found in Appendices II.E.1 (surface water monitoring) and II.E.2 (ground water monitoring).

Table I.E-2. Summary of carbamate detections in the USGS NAWQA study, 1991-2001 (provisional data published by USGS in 2003)

Pesticide	Agricultural Land Use			Mixed Land Use			Urban Land Use		
	% detect	Max ug/L	95th %ile	% detect	Max ug/L	95th %ile	% detect	Max ug/L	95th %ile
Surface Water Monitoring (Martin et al, 2003)									
Aldicarb	0.2%	0.5	nd	0%	Nd	nd	0%	Nd	nd
Carbaryl	9.2%	5.2	nd	15.4%	0.5	nd	43.8%	5.2	0.3
Carbofuran	9.6%	7.0	0.04	3.3%	0.7	nd	2.1%	0.1	nd
Methiocarb	0.1%	0.1	nd	0%	Nd	nd	0%	Nd	nd
Methomyl	1.6%	0.7	nd	0.3%	0.3	nd	0%	Nd	nd
Oxamyl	0.8%	0.2	nd	0%	Nd	nd	0%	Nd	nd
Propoxur	0.2%	0.1	nd	0.2%	0.2	nd	0.2%	0.3	nd
Ground Water Monitoring (Koplin and Martin, 2003)									
Aldicarb (incl.degradates)	0.3%	1.8	nd	0.1%	0.1	nd	0%	Nd	nd
Carbaryl	0.4%	0.02	nd	0.8%	0.5	nd	1.6%	0.03	nd
Carbofuran	1.6%	1.3	nd	0.4%	0.2	nd	0.7%	0.09	nd
Methiocarb	0%	nd	nd	0.1%	0.03	nd	0%	Nd	nd
Methomyl	0.1%	0.04	nd	0.1%	0.1	nd	0.2%	0.4	nd
Oxamyl	0.8%	2.1	nd	0.1%	0.03	nd	0.2%	0.3	nd
Propoxur	0.1%	0.06	nd	0.1%	0.06	nd	0.2%	0.3	nd

NAWQA and other surface-water monitoring programs show that pesticide concentrations in surface water are highly variable in location and in time. This is particularly true for insecticides, such as the NMCs, where usage is often in response to specific pest pressures which are likely to be concentrated in some areas but not in others and in some years but not necessarily every year. In addition to variable use patterns, NMC concentrations in surface water are influenced by local soil, hydrology, and weather patterns and by the timing of rainfall events in relation to pesticide use.

In 2001, The U.S. Department of Agriculture (USDA) expanded its Pesticide Data Program (PDP) to include drinking water. Over the following three years, between 21 and 36 surface water systems were monitored, the majority of which were located in California and New York. Sampling frequency varied from site to site, but was no more frequent than two times a month. Treated (finished) water samples were collected at different locations at different times; several NMC chemicals were included in the analyses. Several NMC compounds (carbaryl, carbofuran, and oxamyl) were found in finished drinking water at a number of sites. Concentrations found were low, none exceeding 80 ppt. The magnitude of these detections can be interpreted as a minimum exposure level at these sites, but cannot be interpreted to be representative of overall exposure. Given the site to site variability in

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factors associated with pesticide exposure, limited frequency of sampling, and limited number of sites, the study cannot be used to represent national exposure to pesticides in finished drinking water. Monitoring is most representative of sites sampled in California and New York. More information on the results can be found in Appendix II.E.1.

Aldicarb is the NMC that has been the focus of the most extensive monitoring in water resources. While aldicarb has not been detected frequently or in high concentrations in ground water in the NAWQA program, extensive targeted monitoring by others (registrant, state and local governments, universities – see Appendix II.E.2) shows that, under certain conditions, aldicarb residues (parent and degradates) can occur in ground water and private wells at concentrations as high as several tens to several hundred parts per billion (μg/l).

The frequency and magnitude of detection of aldicarb residues in ground water is dependent not only on pesticide use but also on the leaching potential of the overlying soil and vadose zone and, for the sulfoxide and sulfone transformation products, the pH of the soil and ground water. For example, while no aldicarb residues were detected in ground-water monitoring conducted by the USGS in the Biscayne and surficial aquifers of southern Florida (McPherson et al, 2000), roughly one-third of the monitoring wells located under citrus groves in the central ridge of Florida had detections of aldicarb residues (USGS, 2006). Monitoring data for private wells collected by the state of Florida showed few detections of aldicarb residues (<2% of wells sampled). However, the detections, as high as 47μg/l were clustered along the central ridge in the vicinity of citrus groves (FLDEP, 2005).

Label changes for aldicarb now restrict use from certain areas (such as the northeastern states and Wisconsin) and add well-setbacks in other areas. In addition, total aldicarb residues (primarily the sulfoxide and sulfone transformation products) can persist in ground water for years or decades after use. Twenty years after aldicarb use on Long Island, NY, was halted, aldicarb residues are still the most frequently detected pesticide compounds in ground water in Suffolk County (Suffolk County Dept. of Health Services, 2000).

A recent survey of private wells by Bayer CropScience (MRIDs 46793701, 46793702, 46793703, 46793704, 46793705, 46793706) found aldicarb residues – predominantly sulfoxide and sulfone metabolites – in 10 percent of the wells sampled, with the greatest frequencies of detections in the Southeastern US (16%, with a maximum detect of 2.9 ug/L) and the Mississippi Delta (9%, with a maximum detect of 2.6 ug/L) regions. Aldicarb detections showed a regional pattern, with this highest frequency of detects in Alabama (22%) and South Carolina

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(21%) in the Southeast region and southeastern Missouri/northeastern Arkansas (23%) in the Mississippi Delta region. Because the detections come from a single sample, the concentrations should be compared against median concentrations from a distribution of ground water concentrations over time (USEPA, 2007a).

Carbofuran was another NMC for which extensive monitoring has occurred; however, the extent of ground water monitoring has decreased significantly in the last decade, so current impacts are not as well documented. Several inferences can be drawn from the body of available data on carbofuran. Targeted ground water monitoring studies show a clear pattern of carbofuran movement into ground water, with maximum detections in the same range as that reported for aldicarb. Because transport to ground water typically takes longer than transport to surface water, measured concentrations of carbofuran in ground water, especially in deep groundwater, may represent usage that occurred years before the samples were collected. As with aldicarb, carbofuran will also persist in ground water for long periods of time after use has been discontinued. This is particularly true for acidic ground water because carbofuran is stable to hydrolysis (the major route of degradation in ground water) at pH values of 6.0 or less.

EPA' s review of available laboratory studies and monitoring data indicates that conventional water treatment processes such as coagulation, sedimentation, and conventional filtration will not reliably remove or transform the NMCs in drinking water sources (Appendix II.E.3). This is further substantiated by USDA PDP monitoring that shows detections of NMC residues in finished/treated water samples (Appendix II.E.1). Lime softening and activated carbon filtration can be effective in removing the NMC pesticides. With the exception of parent aldicarb, lime softening processes will break down NMC pesticides through alkaline-catalyzed hydrolysis. Sorption on activated carbon by granular activated carbon (GAC) or powdered activated carbon (PAC) appears to be at least partially effective in removing NMCs from drinking water (percent removal ranges from 20 to 38% for aldicarb and oxamyl to 60 to 80% for carbofuran, carbaryl, and methiocarb). Other treatment methods, such as chlorination, chloramination, chlorine dioxide, and potassium permanganate, are only effective in oxidizing NMC compounds containing a methylthio group (CH_3-S-), e.g., methiocarb and aldicarb. These compounds are expected to oxidize to sulfoxide and sulfone carbamates that hydrolyze rapidly at alkaline pH values. The Agency estimates that lime softening is used on 7% or less of community ground water systems serving populations of 10,000 or less and less than a third of systems serving more than 10,000 people (USEPA, 2001b). Carbon filtration is used on less than half of the large

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community water systems, with decreasing percentages of smaller systems using GAC or PAC (USEPA, 2001b).

c. Summary

The goal of the NMC drinking water exposure assessment is to provide estimates of distributions of NMC residues (concentrations in drinking water) that account for:

- daily and seasonal variations in residues over time associated with time of application(s) and runoff/leaching events (surface water concentrations are expected to be more variable in time than ground water concentrations)
- year-to-year variations related to weather patterns, pest pressures, and use
- variability in residues from place to place, resulting from the source and nature of drinking water and from the regional / local factors (soil, geology, hydrology, climate, crops, pest pressures, usage) that affect the vulnerability of those sources
- the potential for co-occurrence of more than one NMC in location and time only when this is likely to happen

3. Conceptual Model

Risk is a function of both hazard and exposure, and estimation of the exposure portion for drinking water requires data on concentrations of the pesticides in the drinking water and consumption of drinking water for different demographic populations. Drinking water is locally derived and concentrations of pesticides in source water fluctuate over time and location for a variety of reasons. Pesticide residues in water fluctuate daily, seasonally, and yearly as a result of the timing of the pesticide application, the vulnerability of the water supply to pesticide loading through runoff, spray drift and/or leaching, and changes in the weather. Concentrations are also affected by the method of application, the location and characteristics of the sites where a pesticide is used, the climate, and the type and degree of pest pressure.

While monitoring data provide a picture of the occurrence of NMC pesticides in drinking water resulting from variable use in selected locations, monitoring data alone are not sufficient for the NMC cumulative drinking water exposure assessment, due to the spatial and temporal scale of monitoring networks. This section describes the approach used to estimate cumulative NMC residues in drinking water using models, to ensure that peak concentrations from registered uses are addressed and can be incorporated into the aggregate dietary risk

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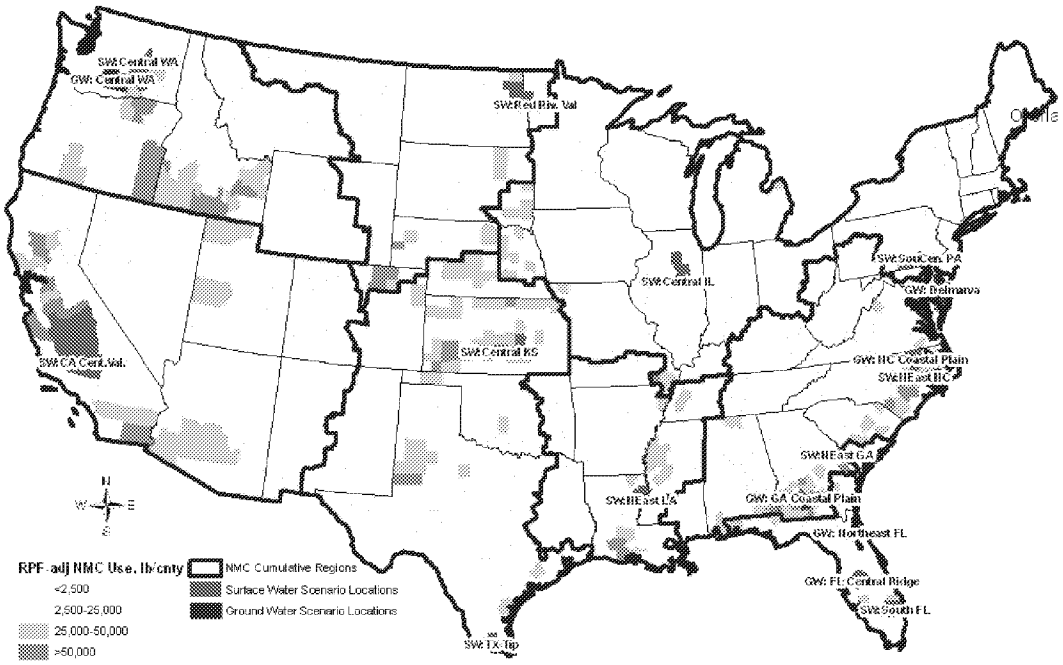
assessment. The model estimates are evaluated against available monitoring data.

Based on the needs of the probabilistic cumulative exposure assessment and the information from monitoring data, OPP designed a drinking water assessment that provides multiple years of daily residue concentrations from drinking water sources in regions where high NMC use coincides with vulnerable drinking water sources. While the available monitoring studies were not designed to provide data for a multi-chemical drinking water exposure assessment and were not of sufficient frequency to provide a time series for use in a probabilistic exposure assessment, the data were used to make sure that estimated exposures from modeling were within the same range or that any discrepancies could be explained.

a. Regional Screening Approach for Vulnerable Sources of Drinking Water

Drinking water exposure will vary locally as a result of pesticide use, agricultural practices, the nature and vulnerability of drinking water sources, and weather patterns. Thus, the water exposure assessment focused on specific geographic areas of relatively high NMC use in a manner that would be realistically protective of all NMC use areas. To facilitate the regional screening approach, the Agency adapted a modification of the USDA Farm Resource Region map (Heimlich, 2000) as a framework for identifying one or more locations which represent an area of the greatest concern for drinking water exposure in each region (Figure I.E-1). In this way, the Agency chose a set of locations to represent vulnerable drinking water sources throughout the U.S.

Figure I.E-1. NMC CRA regions for drinking water exposure assessment showing high NMC use areas and regional drinking water exposure sites



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Locations where NMC residues in drinking water sources are likely to be of greatest concern based on:

- **Relatively high NMC use:** both total NMC use by county and relative potency-adjusted NMC use were considered; for ground water sources, EPA also looked at the areas with the highest aldicarb and carbofuran uses;

- **Nature and source of drinking water**: EPA used the USGS report on water use in the U.S. (USGS, 1998, 1999) to identify the drinking water sources (public surface water, public ground water, domestic private) by county and information on surface water intake locations to identify the dominant drinking water sources in high NMC use counties;

- **Vulnerability of the drinking water sources**: vulnerability of surface water sources was based on the relative runoff potential of the watershed area around surface water intakes; vulnerability of ground water sources was based on the leaching potential of the overlying soils and vadose zone.

For each region, the Agency used the estimated NMC cumulative distribution from the vulnerable water source to represent the drinking water portion of the dietary exposure estimate for the entire region. If NMC levels in water from these vulnerable sites are not major contributors to the total regional cumulative exposure, then the Agency can reasonably conclude that drinking water exposures will not be a concern in other less vulnerable areas in that region. If drinking water exposure from one or more of these vulnerable sites is a significant contributor to the total cumulative exposure, then additional evaluations may be necessary to characterize the extent of the potential exposure.

For the cumulative assessment, the Agency considered exposure from both surface- and ground-water sources of drinking water. In both cases, the Agency simulated potential exposure to sensitive populations in a geographic sense. Surface-water sources of water consisted of source water from small reservoirs in predominantly agricultural watersheds with high NMC use. Ground-water sources of water were shallow private wells located in highly permeable soils in high NMC use areas.

b. Conceptual Model for Surface Water Sources of Drinking Water

EPA identified regional surface water exposure scenarios where high NMC use areas coincided with potentially vulnerable surface water sources. The Agency bases its drinking water exposure assessment for

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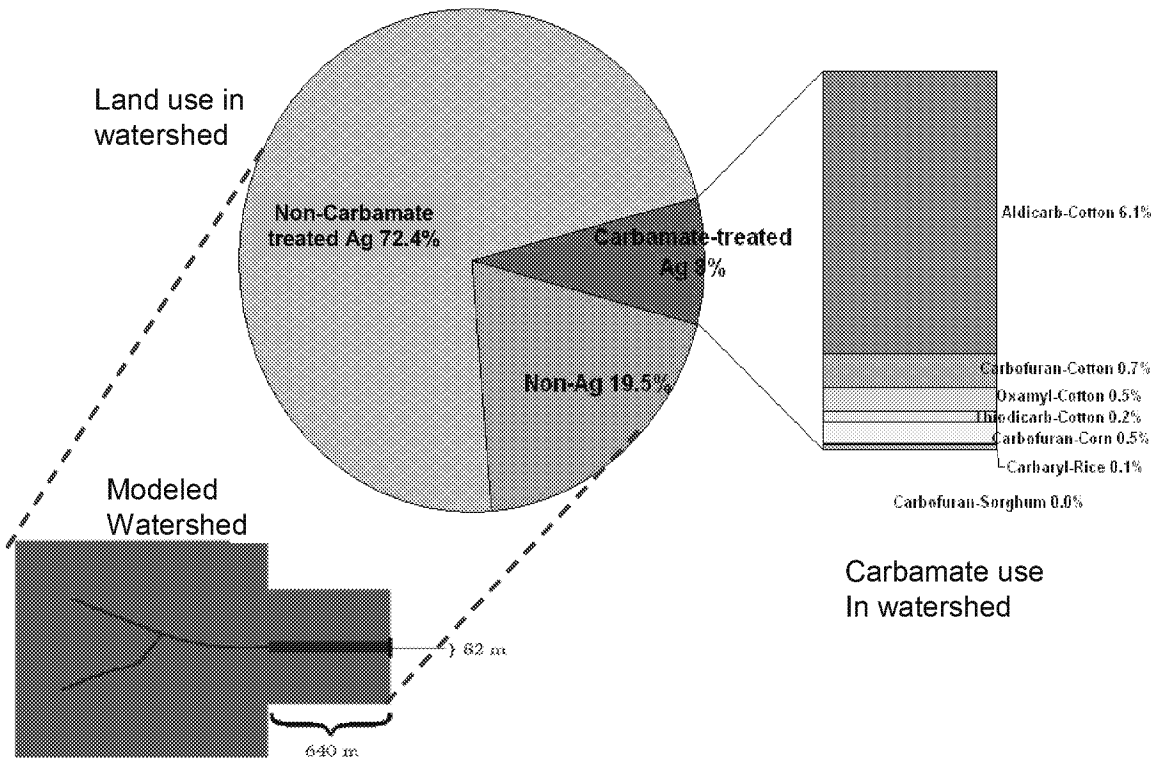
surface-water sources on a small reservoir in an agricultural watershed. An analysis of available monitoring data indicates that such reservoirs are likely to be among the most vulnerable surface drinking water sources (FIFRA SAP, 1998; USEPA, 1999c, 2000b). The NMC CRA focused on watershed-scale impacts from multiple NMC uses occurring in multiple fields in a watershed (Figure I.E-2).

Co-occurrence of NMC pesticides in surface water sources of drinking water is based on the amount and timing of pesticide use in the watershed. EPA used county- or multi-county level pesticide use information, based on agricultural chemical use surveys (Appendix II.E.4), to identify the potential for co-occurring NMC uses in the same location. The potential for co-occurrence of NMC residues in water at the same time depends upon application timing, pesticide persistence and transport characteristics. The relative proportions of each NMC used in the watershed are based on the amount applied in a given year (a function of the rate and frequency of application, combined with the crop area treated); pesticide fate and transport properties that affect the amount of pesticide available at the surface for runoff; the runoff susceptibility of the soil; and the timing, amount, and frequency of rainfall.

Figure I.E-2. Conceptual model for surface water sources of drinking water illustrating how multiple NMC uses are proportioned in the watershed



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For the watershed approach, OPP estimated pesticide concentrations over time (30-year simulation) for each crop-NMC combination. The temporal distributions allowed the Agency to determine the likelihood of co-occurrence of the NMCs in water over time. The Agency used regional crop areas based on USDA Ag Census data (USDA, 2002, as described in USEPA, 2000b) and acre treatments to adjust the estimated daily concentrations for each of the NMCs for the portion of the watershed that is treated by that particular NMC. These crop-adjusted concentrations are converted to a concentration equivalent for the index chemical (in this case, oxamyl) and combined into a single set of daily NMC cumulative concentrations (spanning multiple years) for each region.

For exposure from surface water sources of drinking water, the Agency used estimated concentrations derived for the source water from a reservoir, assuming no treatment effects. As noted, available studies indicate that conventional drinking water treatment processes will not fully remove NMC residues from water. At the same time, the Agency has no reason to expect that the standard drinking water treatment process will result in more toxic transformation products (see Appendix II.E.3).

c. Conceptual Model for Vulnerable Ground Water Sources of Drinking Water

The potential for pesticide movement to ground water sources of drinking water depends on such factors as hydrologic properties of the overlying soil and vadose zone that affect downward movement of water and chemicals, travel time through the unsaturated zone to ground water, aquifer properties (conductivity, porosity, depth, type, location of recharge area), the leaching potential of the pesticide (persistence and mobility), and the type of well drawing water for drinking purposes (Focazzio et al, 2002). These factors vary geographically and cause certain wells in one region to be more vulnerable than those in another region. EPA based its ground water exposure assessment on private rural wells which draw water from a shallow, unconfined aquifer (also known as a water table aquifer). In general, such drinking water sources tend to be more vulnerable than public water supply wells and provide estimates of drinking water exposure representative of people living in agricultural areas and relying on shallow wells for drinking water.

Figure I.E-3 illustrates the conceptual model used to estimate pesticide transport to private wells. The pesticide is applied to the soil surface or plant canopy and precipitation or irrigation moves the pesticide through the vadose zone into a saturated zone. Simultaneously, physical and chemical properties of the individual NMCs determine the degree to which they are degraded or sorbed to soils.

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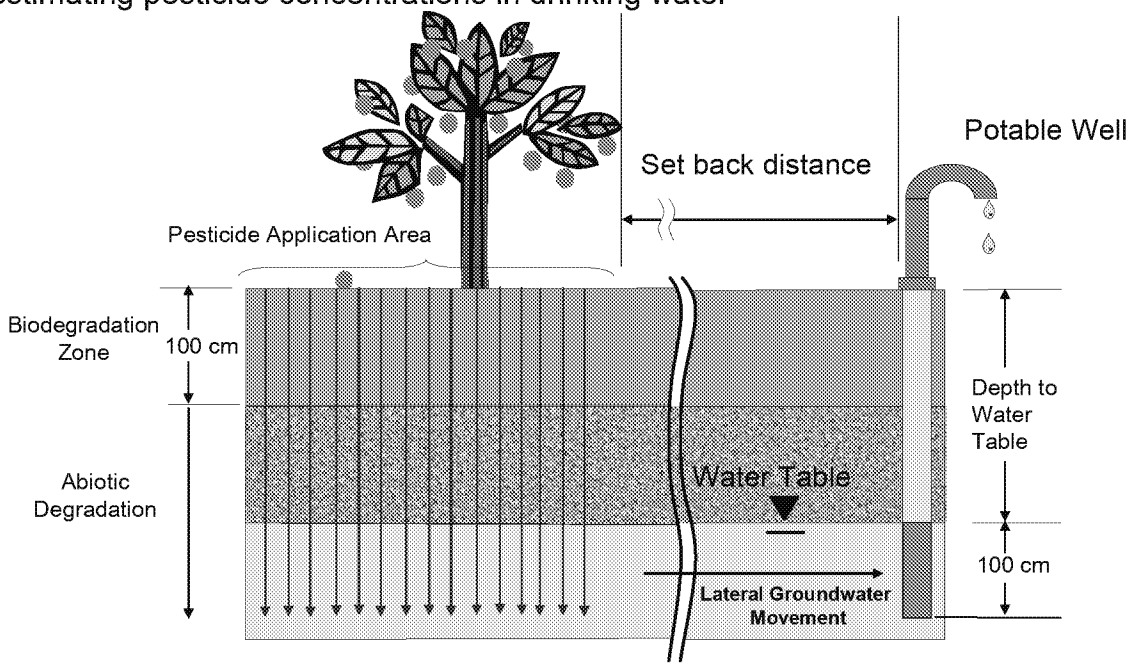
EPA assumed a depth to the top of a shallow, surficial aquifer of 9.1 m (30 ft) in this revised assessment. While such information is not readily available, sources ranging from USGS NAWQA (Berndt et al, 1998; McPherson et al, 2000) and ground water atlases (USGS, 1990) to FL water management districts, suggest that 30- to 50-feet is representative of the depth to shallow ground water supplying private wells. The concentration in the well is the average saturated pore water concentration across a one-meter length of the screen, extending down from the top of the water table.

Degradation occurs at different rates through the soil profile. Generally, faster degradation from microbial processes occurs in the top of the profile and decreases with depth. The model assumes that NMC degradation resulting from aerobic metabolism occurs in the top 25 cm, with rates declining linearly to 1 meter. Below a meter, only abiotic processes (in this case, hydrolysis) are simulated.

For some pesticides, well setbacks (Figure I.E-3) are specified by state or federal labels. For such cases, the additional travel time for a pesticide to reach a drinking water well and the degradation that occurs during that time is taken into consideration by modeling lateral plug flow movement toward the well (see Appendix II.E.7 for details).

Figure I.E-3. Depiction of general ground water scenario concept used for estimating pesticide concentrations in drinking water



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Pesticide fate properties (persistence under acid hydrolysis) and available monitoring data (Suffolk Co. Dept. of Health, 2000; USGS, 2006) indicate that several NMC residues are likely to persist in acidic ground waters. In addition, cumulative exposure in ground water is likely to reflect past as well as current uses, particularly for deep wells.

Available monitoring data, primarily from the USGS NAWQA program, confirm that more than one NMC residue may occur together in ground water (Appendix II.E.2). Co-occurrence in ground water can result when more than one NMC pesticide is used at different times on the same crop, on different crops in rotation on the same fields, or on different crops grown on adjacent fields

4. Analysis Plan

This section provides a brief description of the methods of analysis EPA used in generating the cumulative NMC concentrations in drinking water sources for use in the cumulative dietary exposure assessment. The dietary baseline analysis assumes that all carbofuran uses other than import tolerances are removed. The impacts of currently registered domestic uses of carbofuran on drinking water sources were modeled in this assessment, but results are summarized separately in a sensitivity analysis.

a. NMC Properties

The predicted persistence and movement of each NMC pesticide in the environment are based on environmental fate and transport studies submitted by the registrants as a requirement of registration and/or re-registration. Inputs for the water models are based on environmental fate data reviewed by EPA and described in the individual chemical assessments. Table I.E-3 summarizes the dominant persistence and mobility characteristics of the NMCs included in the drinking water exposure assessment. Appendix II.E.5 provides detailed chemical inputs used in the water exposure models. For aldicarb and its sulfoxide and sulfone degradates included in the common assessment group, the Agency used half-life values for the combined aldicarb residues (parent plus degradates) and the sorption value for the most mobile of the degradates.

Table I.E-3. Summary of *N*-methyl carbamate fate and transport properties

Pesticide	Persistence / Degradation Pathway	Mobility / Sorption
Aldicarb, including sulfoxide and sulfone degradates (USEPA, 2006c, 2006d)	**Field**: Aerobic soil metabolism (55 d half-life); pH-dependent hydrolysis for degradates (2-3 d @ pH9 for sulfoxide; 60-63 d @ pH7, 6 d @pH8, 1 da @ pH9 for sulfone) **Water**: Aerobic aquatic metabolism (12 d half-life); pH-dependent hydrolysis for degradates	Kd = 0.12 mL/g (Koc = 10 mL/g)

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Pesticide	Persistence / Degradation Pathway	Mobility / Sorption
Carbaryl (USEPA, 2003a, 2007b)	**Field**: Aerobic soil metabolism (12 d half-life); hydrolysis (12 d @ pH7, 0.1 d @ pH9) **Water**: Aerobic aquatic metabolism (30 d half-life); pH-dependent hydrolysis	Koc = 196 mL/g
Carbofuran (USEPA, 2005c, 2005d)	**Field**: Hydrolysis (28 d @ pH7, 9 d @ pH7.5, 3 d @ pH8, <1 d @ pH9); aerobic soil metabolism (321 d half-life) **Water**: pH-dependent hydrolysis	Koc = 36 mL/g
Formetanate HCl (USEPA, 2005e)	**Field**: Aerobic soil metabolism (6 d half-life); hydrolysis (24 d @ pH7,9) **Water**: Aerobic aquatic metabolism (13 d half-life); hydrolysis	Koc = 340 mL/g
Methomyl (USEPA, 1997c, 2007d)	**Field**: Aerobic soil metabolism (79 d half-life); alkaline hydrolysis (30 d @ pH9) **Water**: Aerobic aquatic metabolism (7 d half-life); hydrolysis	Koc = 24 mL/g
Oxamyl (USEPA, 1999f, 2007e)	**Field**: Hydrolysis (7 d @ pH7, 0.1 d @ pH9); aerobic soil metabolism (20 d half-life) **Water**: Hydrolysis; aerobic aquatic metabolism (40 d); anaerobic aquatic metabolism (7 d)	Koc = 6 mL/g
Thiodicarb, degrades to methomyl (USEPA, 1997d)	**Field**: Aerobic soil metabolism (2 d half-life); hydrolysis (32 d @ pH7, 0.5 d @ pH9) **Water**: Aerobic aquatic metabolism (3 d half-life); anaerobic aquatic metabolism (<1 d); pH-dependent hydrolysis	Koc = 485 mL/g

Most of the NMC pesticides exhibit pH-dependent hydrolysis (Table I.E.3). They tend to be stable or degrade slowly under acidic conditions. As the pH increases to neutral and alkaline conditions, they hydrolyze more rapidly. Unless otherwise indicated, EPA used the hydrolysis rates for acidic conditions in modeling. These rates are generally slower and would result in likely overestimates of actual exposures in neutral to alkaline conditions. Where the Agency had information that showed that the dominant pH of the soil/vadose zone/groundwater system was neutral to alkaline, hydrolysis rates (appropriate to the pH) were used.

b. Identifying Regional Exposure Scenarios

The selection of specific locations for regional drinking water assessments involves several steps. First, the Agency identified the high NMC usage areas within each region. The Agency used data collected by Thelin and Gianessi (2000) for county-level estimates of NMC usage. EPA evaluated the relative high NMC use areas several different ways:

- Summing total pounds of each NMC by county to calculate both total pounds of NMC pesticide per county and total pounds per acre;

- Adjusting the county-level estimates of pounds of each NMC by their respective relative potency factors to identify areas of greatest use of the most potent of the NMCs;

- In addition, for ground water exposure, identifying the aldicarb and carbofuran use areas, which were driving NMC exposure, to determine if additional scenarios were needed and for sensitivity analysis.

Next, EPA identified the types of drinking water sources in each high usage area. The Agency used a spatial dataset that describes water use for all the counties in the continental US (USGS, 1999) to determine the dominant source of drinking water – (1) public supply served by surface water, (2) public supply served by ground water, or (3) domestic self-supplied drinking water (primarily private wells). For surface water exposures, the Agency overlaid the public surface water supply data, along with locations of drinking water intakes (based on SDWIS data), with the NMC use maps to identify counties in which high NMC use coincided with surface water sources of drinking water. For ground water exposures, the Agency focused on private wells, which are generally shallower than public supply wells and typically have no water treatment applied. The Agency overlaid the domestic drinking water supply data with NMC use to identify those counties where high NMC use coincided with populations drinking from private wells.

The final step in choosing regional locations for modeling was to assess the vulnerability of drinking water sources within the high NMC usage areas. For surface water sources of drinking water, OPP compared relative vulnerabilities of the areas based on average annual runoff, average 2-month runoff (beginning of the growing season), and average soil loss, as developed by the USDA Natural Resources Conservation Service (Kellogg et al, 1997). The regional drinking water scenario sites are shown in Figure I.E-1 and summarized in Table I.E-4.

Table I.E-4. Regional drinking water exposure sites and dominant NMC pesticide uses

Region	Exposure scenario sites (1)	Dominant use crops	NMC pesticides used (2)
Southeast	NC coastal plain (SW, GW), eastern GA (SW), southern GA (GW)	Cotton, peanuts, tobacco, pecans	Aldicarb, carbaryl, carbofuran, methomyl, oxamyl
Florida	South FL (SW), Central FL (GW, SW), Northeastern FL (GW)	Citrus, sweet corn, sugarcane, cucumber, pepper, potato	Aldicarb, carbaryl, carbofuran, methomyl, oxamyl, thiodicarb
Mid-south	Northeast LA (SW)	Cotton, corn, sorghum	Aldicarb, carbofuran, oxamyl, thiodicarb
North / north	South central PA (SW),	Apples, corn,	Carbaryl, carbofuran,

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Region	Exposure scenario sites (1)	Dominant use crops	NMC pesticides used (2)
central	Central IL (SW), Delmarva (GW) (3)	peaches, sweet corn, alfalfa, pumpkin, potato, beans, cucurbits	formetanate HCl, methomyl, oxamyl, thiodicarb
Lower Midwest	Southern tip of TX (SW)	Grapefruit, cotton, vegetables	Aldicarb, carbofuran, formetanate HCl, methomyl, oxamyl
Northern Great Plains	Red River Valley (SW)	Potatoes, sugar beets, wheat	Aldicarb, carbaryl, carbofuran, oxamyl
Northwest	Central WA (SW, GW)	Potatoes, apples, cherries, beans, carrots, onions	Aldicarb, carbaryl, carbofuran, formetanate HCL, methomyl, oxamyl
Southwest	CA Central Valley (SW)	Citrus, stone fruit trees, cotton, melons, grapes, tomatoes, various cole, root, tuber vegetables	Aldicarb, carbaryl, carbofuran, formetanate HCl, methomyl, oxamyl

(1) SW = surface water scenario site; GW = ground water scenario site
(2) EPA proposed canceling all domestic uses of carbofuran; carbofuran model results are presented as separate sensitivity analysis.
(3) The Delmarva scenario was used for the carbofuran sensitivity analysis only.

For potentially vulnerable ground water sources of drinking water, EPA relied on a variety of sources, including Nolan et al (2002), USGS NAWQA reports and Ground Water Atlases, USDA/NRCS county soil datasets (SSURGO), and other state/local information. EPA also used monitoring data from Florida (FL DEP, 2005; USGS, 2006) to identify specific site, soil, and hydrologic properties that might serve as indicators of potential high NMC exposure conditions. Regional ground water exposure scenario sites are listed in.

c. Regional Usage

The regional exposure areas of interest consist of multi-county areas that encompass the vulnerable drinking water source in high NMC use areas. EPA collected information on the target crops, estimated NMC usage, and timing of application for these multi-county areas.

The drinking water exposure assessments require information on crop use, pounds applied, application rate, number of applications, percent of crop treated, and application timing. Much of this information is not easily available or does not exist at the geographic scale needed for the exposure assessment. As a result, EPA used the best available information to provide the regional estimates for the NMC pesticide-crop combinations that actually occur in scenario areas. Because county-level pesticide usage data is based on surveys and is uneven in quality, EPA created county clusters that surrounded the initial scenario areas

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shown in Figure I.E-1. EPA also used multiple data sources and multiple years of data to improve the robustness of the use data.

For each regional scenario site, EPA used USDA National Agricultural Statistics Service (USDA NASS) and Doane's databases to estimate usage (acres planted, total pounds used, percent of crop treated, application rate, and number of applications) for each NMC and crop reported in the use cluster. Usage was averaged for the years 1998 through 2002. The Agency identified those NMC-crop uses that accounted for at least 95% of the total NMC usage in the scenario area.

For the crop/chemical combinations identified in a given area, USDA crop profiles, typical planting/harvesting dates and various other sources were used to identify most likely windows of application for each use. Typically, all the NMC pesticides discussed here target multiple pests or pests that can occur multiple times during a given crop's growing season, so applications often occur over a broad time period. EPA systematically selected the beginning of the most active window for the initial application date of each NMC. Where multiple applications were identified, the Agency spread those evenly over the most active window. Details of the methods and resulting regional usage information can be found in Appendix II.E.4.

d. Surface Water Exposure Assessment

The Agency estimated the daily drinking water exposure from surface water sources using the simulation models PRZM (Pesticide Root Zone Model) and EXAMS (EXposure Analysis Modeling System). With PRZM/EXAMS modeling for a drinking water reservoir, the Agency can:

- Account for potential co-occurrence of NMC residues by modeling all uses in a region/area, as described in the conceptual model
- Combine daily time series over multiple years (using 30 years of recorded weather data) to account for year-to-year variations in weather and to separate peak concentrations that are not likely to occur together in time
- Estimate peak concentrations (on a daily time step); adjustments to pesticide use inputs ("typical" rates, frequencies) reflect estimated concentrations in a "typical" year
- Model vulnerable surface water sources in regions to reflect spatial variations in crops, use, weather, soils, and hydrology

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- Adjust for crop area, acres treated in order to prevent double-counting overlapping uses

A detailed description of the models is available from the EPA OPP Water Models web site (USEPA, 2007f).

The model estimates daily pesticide concentrations in surface water sources of drinking water (a reservoir) using local soil, site, hydrology, and weather characteristics along with pesticide application and agricultural management practices, and pesticide environmental fate and transport properties. The input parameters are specific for each NMC-crop scenario in each region. For example, in the eastern North Carolina exposure site representing the Southeast region of the US, the cotton, peanut, and tobacco scenarios consist of properties for soils on which the crops are grown in the coastal plain of North Carolina. The weather data used in the simulations come from 30 years of weather collected at a NOAA weather station in Raleigh/ Durham, just west of the scenario area. Appendix II.E.6 provides details on the site-specific inputs for the surface water exposure.

The cumulative assessment focuses on the likelihood of concurrent exposure to multiple pesticides from food, water, and residential use. This involves using average application rates, average numbers of applications, and estimates of acres treated to adjust concentrations, and specific application windows so that only those NMC pesticides that have overlapping use periods may potentially occur together in water. The implications of these assumptions are discussed in the risk characterization chapter.

PRZM is a field-scale model, while the cumulative water assessment focuses on watershed-scale impacts (i.e., the contributions of multiple NMC uses on multiple crops occurring in multiple fields in a watershed). The Agency used PRZM to model multiple fields in a watershed. While this approach provides a more realistic depiction of multiple chemical usage in a watershed, it provides no spatial context for those fields. It also assumes that the runoff from each of those fields goes into the reservoir.

To adapt PRZM for this watershed approach, EPA adjusted the estimated pesticide concentrations generated for each crop-NMC combination to account for the portion of the watershed treated by a particular NMC pesticide:

- The NMC-crop combination was modeled with PRZM/EXAMS, using the region-specific usage, application timing, soil, site,

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and weather data. The result is a time-series of daily pesticide concentrations in a reservoir spanning a 30-year period.

- Each daily concentration is adjusted by the fraction of the watershed occupied by the crop being modeled. The fraction is calculated by dividing the acres of crop grown in the multi-county region by the total acres in that region (percent crop area).

- The daily concentrations are then adjusted by the fraction of acres of the crop treated by the particular pesticide. The fraction is calculated by dividing the acres of crop treated by the total crop acres in the multi-county region (percent crop treated).

The resulting concentrations for each crop-NMC combination must be converted to a concentration equivalent for an index chemical. The concentrations were normalized to an index equivalent by multiplying each of the daily concentrations by the relative potency and FQPA safety and inter-species factors for the respective NMC pesticide. The normalized outputs for each crop-NMC combination were summed day-by-day to give a daily time series of total NMC residues in water over 30 years.

e. Ground Water Exposure Assessment

EPA used the Pesticide Root Zone Model (PRZM) to estimate NMC concentrations in ground water sources of drinking water. Specifically, the ground water exposure assessment must account for:

- **Variations in Residues Over Time**: Pesticide residues in ground water are likely to fluctuate less drastically than residues in surface water; however, the dietary exposure estimates require a concentration time series for co-occurrence in time.

- **Variations in Residues Over Location**: As with the surface water assessment, EPA focused on regional ground water sources of drinking water that are expected to be among the most vulnerable to NMC contamination based on soil, geology, hydrology, climate, crops, and usage.

- **Co-occurrence**: USGS NAWQA monitoring shows that co-occurrence of NMC residues, though infrequent, does occur in ground water. Therefore, EPA estimated ground water concentrations for multiple NMC pesticides in ground water, based on regional usage data.

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The model simulates pesticide movement through the soil and underlying vadose zone to a saturated zone, representing the surficial aquifer, at a depth of 30 feet (see Figure I.E-3). The saturated zone can be created in PRZM by setting the field capacity input parameter equal to the porosity. Output concentrations are the average from the top of the saturated zone to a depth 1 meter below the water table.

Because co-occurrence of NMC residues in ground water is likely to be more localized than for surface water, EPA considered co-occurrence based on the potential for more than one NMC to be used at different times on the same crop or on different crops in rotation on the same fields. This resulted in less crop-chemical combinations than for the surface water scenarios, which encompassed a larger area of contribution (watershed rather than fields). The Agency modeled multiple NMC uses on a crop at the same ratio of pounds used as that reported in the usage summary for the region.

As with surface water, the concentrations for each crop-NMC combination was converted to a concentration equivalent for an index chemical based on the relative potency and FQPA safety and inter-species factors. The adjusted concentrations were summed day-by-day for a cumulative time series of NMC residues in ground water distribution.

Appendix II.E.7 provides details on groundwater scenario development, model inputs, and comparisons with monitoring. It also provides site-specific inputs for the ground water model scenarios.

5. NMC Concentrations in Surface Water Sources of Drinking Water

The Agency estimated drinking water concentrations for individual and cumulative NMC load for each of the regional surface water scenario sites listed inTable I.E-4. Details and results of these exposure estimates can be found in Appendix II.E.6.

a. Individual NMC Levels in Surface Water

Estimated peak concentrations of the individual NMC pesticides in each of the regional surface water scenario sites were in the sub-parts per billion range (Table I.E-5), except for aldicarb, which had estimated peaks as high as a single part per billion in the NC coastal plain scenario. Aldicarb had the highest estimated peak concentrations in 4 scenarios (NC coastal plain, GA coastal plain, central FL, northeast LA), methomyl in 5 scenarios (south FL, south-central PA, central WA, CA Central Valley, south TX tip), and carbaryl in 2 scenarios (central IL, Red River Valley, MN/ND).

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Table I.E-5. Estimated peak concentrations for NMC residues for the regional surface water drinking water scenarios (30-year period)

Region / Scenario	Pesticide	Crops	Concentration, ug/l (ppb)		
			Max.	99th %ile	95th %ile
SE: NC coastal plain	Aldicarb	cotton, peanut, tobacco	1.26	0.28	0.06
	Carbaryl	cotton, peanut, cucumber, tobacco	0.04	0.02	0.007
	Methomyl	peanut, tobacco	0.03	0.004	0.001
	Oxamyl	peanut	0.23	0.008	0.002
SE: GA coastal plain	Aldicarb	cotton, peanut, pecan	0.37	0.09	0.02
	Carbaryl	pecan	0.05	0.01	0.004
Florida (South)	Aldicarb	oranges, grapefruit	0.02	0.004	0.001
	Carbaryl	oranges, grapefruit	0.01	0.002	0.001
	Methomyl	sweet corn, pepper, cucumber	0.63	0.18	0.08
	Oxamyl	pepper, oranges, cucumber	0.14	0.02	0.006
	Thiodicarb	sweet corn	0.06	0.007	0.003
Florida (Central)	Aldicarb	oranges, grapefruit	0.46	0.07	0.01
	Carbaryl	oranges, grapefruit	0.11	0.03	0.009
	Oxamyl	oranges	0.05	0.008	0.002
Midsouth (northeast LA)	Aldicarb	Cotton	0.70	0.14	0.02
	Methomyl	thiodicarb degradate (cotton)	0.34	0.05	0.009
	Oxamyl	cotton	0.19	0.01	0.001
	Thiodicarb	cotton	0.08	0.003	0.001
Northeast/ Central (south central PA)	Carbaryl	apple, peach, sweet corn	0.02	0.003	0.001
	Formetanate	apple	0.001	<0.001	<0.001
	Methomyl	apple, peach, potato, sweet corn	0.07	0.02	0.006
	Oxamyl	apple	0.003	<0.001	<0.001
	Thiodicarb	sweet corn	<0.001	<0.001	<0.001
Northeast/ Central (IL)	Carbaryl	corn, sweet corn	0.04	0.01	0.003
	Methomyl	lima beans	0.02	0.002	0.001
Lower Midwest (South TX tip)	Aldicarb	Grapefruit, cotton	0.07	0.02	0.005
	Formetanate	Grapefruit	0.04	0.008	0.001
	Methomyl	Onions, cucumber, spinach	0.21	0.03	0.01
	Oxamyl	Cotton, carrots, onions, cucumber, cantaloupe, watermelon, peppers	0.19	0.07	0.02
Northern Great Plains (Red River Valley)	Aldicarb	Potatoes, sugar beets	0.004	0.001	<0.001
	Carbaryl	Spring wheat	0.10	0.02	0.007
	Oxamyl	Potatoes	0.003	0.001	<0.001
Northwest (Central WA)	Aldicarb	Beans, potatoes	0.03	0.01	0.002
	Carbaryl	Apples, Cherries	0.04	0.004	0.003
	Formetanate	Apples	<0.001	<0.001	<0.001
	Methomyl	Beans, sweet corn	0.09	0.01	0.006
	Oxamyl	Carrots, onions, potatoes	0.02	0.005	0.003
Southwest (CA Central Valley)	Aldicarb	Cotton, beans/peas, potatoes	0.08	0.02	0.001
	Carbaryl	Apples, cantaloupe, cotton,	0.02	0.005	0.002

Region / Scenario	Pesticide	Crops	Concentration, ug/l (ppb)		
			Max.	99th %ile	95th %ile
		nectarine, oranges, peaches, pistachios, plums			
	Formetanate	Grapefruit, lemons, nectarine, oranges, plums, tangerines	0.03	0.004	0.001
	Methomyl	Alfalfa, asparagus, broccoli, cantaloupe, carrots, garlic, lettuce, nectarine, onions, oranges, peaches, potatoes, sugar beets, tomatoes, watermelon	0.40	0.08	0.03
	Oxamyl	Cantaloupe, cotton, garlic, oranges, peaches, tomatoes	0.02	0.01	0.005

A comparison with available surface water monitoring data (Appendix II.E.I) indicates that the estimated peak NMC residues are similar to or less than the maximum reported detections from NAWQA, with a couple of exceptions where reported NAWQA detections were greater.

- Estimated maximum aldicarb residues (parent, sulfone, sulfoxide) are similar to maximum reported detections in the southeast (NC, GA, FL). Maximum and upper percentile estimates for total aldicarb residues for the Mid-South were less than the maximum detection reported in the region (Mississippi Embayment study unit) for aldicarb sulfoxide, but greater than the 99th percentile of detections. However, even if if the modeled peak was adjusted by the difference (2.5X), the resulting cumulative NMC exposures would still be below drinking water levels of concern.

- Estimated carbaryl concentrations were less than reported detections in NAWQA, primarily because the NMC cumulative scenarios were not focused on the highest carbaryl use areas. However, the impact of this on overall NMC cumulative exposures is not expected to be significant because carbaryl has a lower adjusted RPF than do the other NMC pesticides estimated to dominate exposure in source drinking water.

- Estimated methomyl and oxamyl concentrations were similar to maximum reported detections in NAWQA.

Overall, the estimated NMC concentrations in surface water are similar to or less than reported peak concentrations from monitoring data in the same or similar regions.

b. Cumulative NMC Levels in Surface Water

The highest estimated cumulative NMC concentrations in surface water sources of drinking water occurred in the southern United States

(Table I.E-6), with the highest estimated peak following the trend: Eastern NC > northeastern LA > south FL > central FL = central IL > southeast GA. The concentrations in Table I.E-6 reflect adjustments for individual chemical FQPA safety and inter-species factors in addition to relative potencies. Thus, the concentrations cannot be directly compared to measured values in the environment.

Table I.E-6. Percentile concentrations for estimated NMC cumulative distributions in the surface water scenario sites (30-year period), adjusted for relative potency, inter-species and FQPA safety factors for children

Region/Site	Percentile concentration in ug/L (oxamyl equivalents, adjusted for uncertainty factors)						Major contributors[1]
	Max	99th	95th	90th	75th	50th	
Florida / South	8.5	2.5	1.0	1.0	0.2	0.03	Methomyl, thiodicarb, oxamyl
Lower Midwest / TX	2.8	1.0	0.4	0.3	0.1	0.03	Aldicarb, formetanate, methomyl, oxamyl
Midsouth / LA	12.6	2.9	0.5	0.2	0.03	0.002	Aldicarb
Southeast / NC	20.2	4.4	1.0	0.4	0.02	<0.001	Aldicarb
Southwest / CA	4.3	1.0	0.4	0.2	0.1	0.03	Aldicarb, formetanate, methomyl
Florida / Central	7.3	1.2	0.2	0.09	0.02	0.004	Aldicarb
Northeast-central / IL	0.2	0.04	0.01	0.007	0.002	<0.001	Carbaryl, methomyl
Southeast / GA	5.9	1.5	0.3	0.09	0.02	<0.001	Aldicarb
Northeast-central / PA	0.7	0.2	0.06	0.04	0.02	0.006	Methomyl
Northwest / WA	1.3	0.3	0.1	0.07	0.03	0.007	Aldicarb, methomyl, oxamyl
N. Great Plains/ MN-ND	0.3	0.06	0.02	0.01	0.001	<0.001	Carbaryl

[1]Major contributors, after adjusting concentrations for relative potency and FQPA safety and inter-species factors.

c. Spatial Extent of NMC Exposures in Surface Water

Many surface water sources of drinking water in the southern portions of the US occur where total NMC pesticide use is relatively low (Figure I.E-4). The watersheds that are most vulnerable to runoff in the high NMC use areas tend to occur in areas where ground water is the dominant source of drinking water. For these southern regional scenarios (Southeast, Florida, Mid-south, Lower Midwest), the estimated exposures represent a few drinking water intakes located in relatively high NMC use watersheds.

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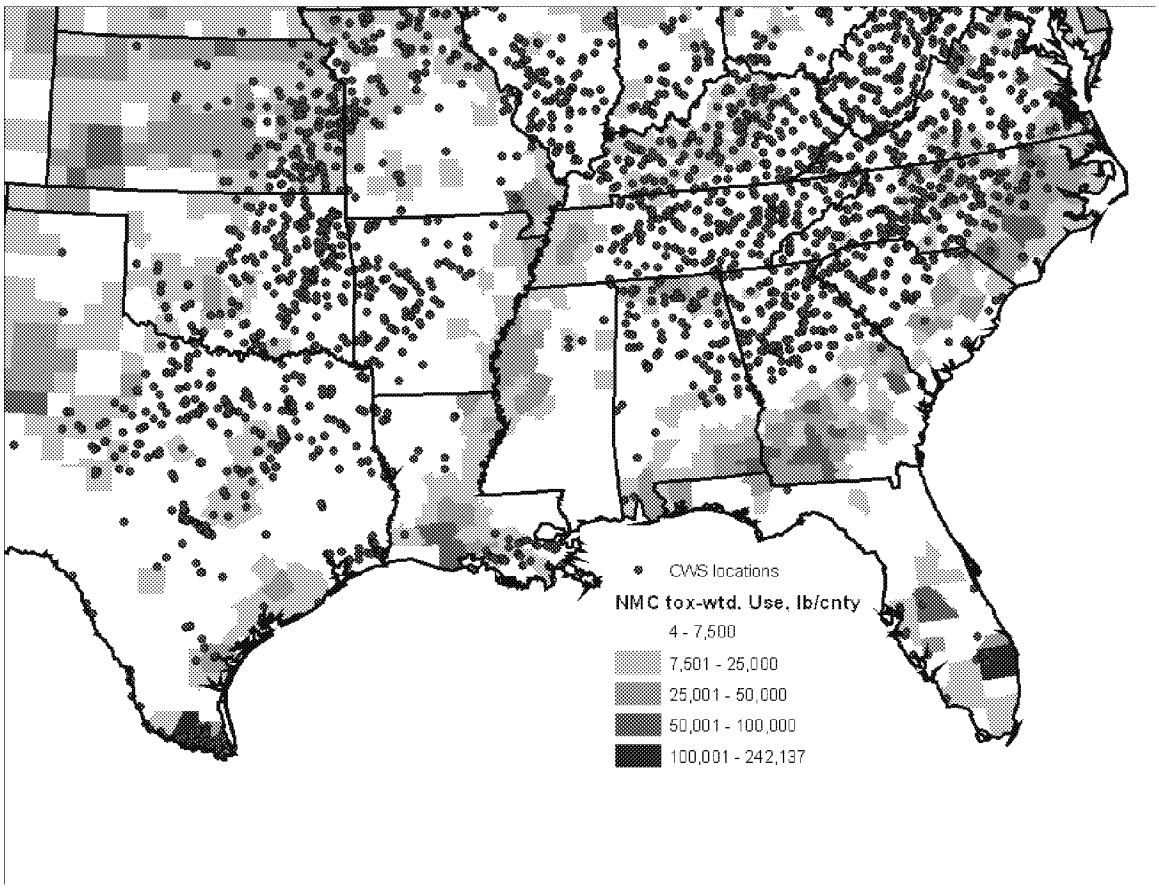
Figure I.E-4. Location of surface water intakes (blue dots) in relation to relative NMC pesticide usage (high use areas in dark orange) in the southeastern/south-central U.S.



The south Florida scenario represents a handful of community water systems (CWS) around the Everglades Agricultural Area (EAA). Dominant uses are sugarcane, vegetables (sweet corn, pepper, cucumber), and citrus. Drainage canals from sugarcane fields and other agricultural areas in and around the EAA are not used directly for drinking water, but eventually feed water bodies used in southern Florida for drinking water supply. Three community water systems (CWS) draw from the southern end of Lake Okeechobee. The city of West Palm Beach draws water from Clear Lake, which is fed in part by drainage water from the EAA.

The North Carolina and Georgia surface water sites represent high NMC use areas within the coastal plain from southeastern Virginia to southeastern Alabama. The dominant NMC uses in the region are on cotton, peanuts, and tobacco. A few CWS occur in this area; many are located to the west, with watersheds draining relatively low NMC use areas.

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The high-use region around northeastern Louisiana and west central Mississippi has few surface water intakes, but represents the most vulnerable area in the Mid-south region in terms of NMC usage and runoff vulnerability. Transport of pesticides in surface water is complicated by levees on the Mississippi River and a system of drainage canals. Consequently, the surface water assessment scenario is likely to be health-protective for other CWS in lower NMC-use areas in the region.

The scenario for the southern Texas tip represents a number of small CWS intakes that draw from channels in a highly-irrigated agricultural area.

d. Sensitivity Analysis: Carbofuran in Surface Water

Including carbofuran in regional surface water modeling would impact modeled surface water exposures, as carbofuran was a major contributor to cumulative NMC concentrations in a number of regions. The estimated peak concentrations of the carbofuran were in the same range as other individual NMC pesticides (the sub-parts per billion range). Table I.E-7 summarizes the estimated carbofuran concentrations in the regional scenarios. In comparison to the NMC concentrations in Table I.E-7, carbofuran had the highest estimated peak concentrations in 4 scenarios (south FL, south-central PA, central IL, south TX tip); when carbofuran was removed the NMC that replaced it was methomyl (3 scenarios) or carbaryl (1 scenario), with the maximum estimated concentration differing by less than 0.2 ppb.

Table I.E-7. Estimated peak concentrations for carbofuran residues for the regional surface water drinking water scenarios (30-year period)

Region / Scenario	Crops[1]	Concentration, ug/l (ppb)		
		Max.	99th %ile	95th %ile
SE: NC coastal plain	Tobacco	0.002	0.001	<0.0001
Florida (South)	sugarcane, sweet corn, cucumber	0.82	0.18	0.08
Midsouth (northeast LA)	cotton, corn, sorghum	0.33	0.15	0.07
Northeast/ Central (south central PA)	alfalfa, corn, pumpkin, sweet corn	0.09	0.02	0.008
Northeast/ Central (IL)	alfalfa, corn, sweet corn	0.11	0.04	0.01
Lower Midwest (South TX tip)	Cotton, corn	0.35	0.17	0.07
Northern Great Plains (Red River Valley)	Potatoes, sugar beets, sunflowers	0.008	0.003	0.001
Northwest (Central WA)	Potatoes	0.04	0.02	0.005
Southwest (CA Central Valley)	Alfalfa, cotton, grapes	0.08	0.04	0.02

[1] The estimated exposures depicted here represent current uses for carbofuran. However, the Agency has proposed cancellation of all domestic carbofuran uses.

A comparison with available surface water monitoring data (Appendix II.E.I) indicates that the estimated peak NMC residues are similar to or less than the maximum reported detections from NAWQA,

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with a couple of exceptions where reported NAWQA detections were greater. While estimated peak carbofuran concentrations reported above were similar to or greater than reported detections in most USGS NAWQA units, they were well below the maximum reported detections (3-32 ug/l) from Zollner Creek in the Willamette Valley study unit. The maximum detections reported for Zollner Creek are of the same magnitude as the upper percentile of estimated ground water concentrations for carbofuran (see the sensitivity analysis for carbofuran in ground water below), which resulted in MOEs of less than 10. While peak concentrations of carbofuran in surface water are not expected to remain elevated for as long as those estimated in ground water, peak exposures of the same magnitude found in the monitoring might result in an MOE of less than 10. The Agency's analysis of potential carbofuran exposures in drinking water in the single chemical assessment includes scenarios with a use intensity similar to Zollner Creek but with greater rainfall.

In the remaining NMC scenarios (Table I.E-8), the percentile concentrations increase, in some regions by almost an order of magnitude when currently registered carbofuran uses are incorporated. However, it did not result in NMC concentrations that resulted in MOEs of less than 10.

Table I.E-8. Percentile concentrations for estimated NMC cumulative distributions with and without carbofuran in the surface water scenario sites (30-year period), adjusted for relative potency, inter-species and FQPA safety factors for children

Region/Site	Percentile concentration in ug/L (oxamyl equivalents, adjusted for uncertainty factors)						Major contributors[1]
	Max	99th	95th	90th	75th	50th	
Florida / South with carbofuran	54.5	12.1	5.3	2.6	0.8	0.3	Carbofuran
without carbofuran	8.5	2.5	1.0	1.0	0.2	0.03	Methomyl, thiodicarb, oxamyl
Lower Midwest / TX with carbofuran	24.5	11.7	5.0	3.0	1.1	0.2	Carbofuran
without carbofuran	2.8	1.0	0.4	0.3	0.1	0.03	Aldicarb, formetanate, methomyl, oxamyl
Midsouth / LA with carbofuran	21.9	7.5	2.4	1.1	0.3	0.03	Aldicarb, carbofuran
without carbofuran	12.6	2.9	0.5	0.2	0.03	0.002	Aldicarb
Southeast / NC	20.2	4.4	1.0	0.4	0.02	<0.001	Aldicarb
Southwest / CA with carbofuran	7.4	3.2	1.5	0.9	0.4	0.2	Aldicarb, formetanate, methomyl, carbofuran
without carbofuran	4.3	1.0	0.4	0.2	0.1	0.03	Aldicarb, formetanate, methomyl
Florida / Central	7.3	1.2	0.2	0.09	0.02	0.004	Aldicarb
Northeast-central / IL with carbofuran	7.2	2.5	0.9	0.5	0.1	0.02	Carbofuran
without carbofuran	0.2	0.04	0.01	0.007	0.002	<0.001	Carbaryl, methomyl

Region/Site	Percentile concentration in ug/L (oxamyl equivalents, adjusted for uncertainty factors)						Major contributors[1]
	Max	99th	95th	90th	75th	50th	
Southeast / GA	5.9	1.5	0.3	0.09	0.02	<0.001	Aldicarb
Northeast-central / PA with carbofuran	5.7	1.7	0.6	0.3	0.1	0.03	Carbofuran
without carbofuran	0.7	0.2	0.06	0.04	0.02	0.006	Methomyl
Northwest / WA with carbofuran	3.6	1.3	0.4	0.3	0.2	0.03	Aldicarb, carbofuran, methomyl, oxamyl
without carbofuran	1.3	0.3	0.1	0.07	0.03	0.007	Aldicarb, methomyl, oxamyl
N. Great Plains/ MN-ND with carbofuran	0.6	0.3	0.1	0.07	0.03	0.005	Carbofuran, carbaryl
without carbofuran	0.3	0.06	0.02	0.01	0.001	<0.001	Carbaryl

[1] Major contributors, after adjusting concentrations for relative potency and FQPA safety and inter-species factors.

6. NMC Concentrations in Ground Water Sources of Drinking Water

Individual NMC risk assessments and monitoring data indicate that aldicarb (primarily its sulfoxide and sulfone degradates) and carbofuran are the two NMC pesticides most likely to reach and persist in ground water sources of drinking water, especially in shallow, acidic aquifers. Three other NMC pesticides – carbaryl, methomyl, and oxamyl – may also reach ground water, but are not as likely to persist.

High NMC use areas occurred in counties where substantial portions of the population obtained their drinking water from private wells along the southeastern Coastal Plain, in Florida, and the Delmarva Peninsula. EPA also included a scenario in central Washington to represent potential exposures in the western US. Based on the conceptual model, the Agency focused on private wells drawing from the surficial aquifer in these regions. Details and results of these exposure estimates can be found in Appendix II.E.7.

a. Individual NMC Levels in Ground Water

The Agency estimated drinking water concentrations for individual NMC pesticides and for the cumulative NMC load based on high leaching potential scenarios representing specific high NMC uses in Florida, the southeastern coastal plain and the northwest (Tables I.E-4, I.E-9). Each ground water scenario reflects shallow wells in high leaching potential soils and vadose zones with ground water at a depth of 30 feet, with the exception of the northwestern scenario, which represents deeper groundwater. The estimated concentrations in Table I.E-9 reflect typical application rates for the NMC pesticides (Appendix II.E.4) and well setback distances specified on the existing label for aldicarb.

Table I.E-9. Estimated concentrations for NMC residues for the regional ground water scenarios (25-year period) for ground water at 30 feet

NMC pesticide	Well setback distance	Crop(s)	Concentrations, ug/l					
			Max-imum	99th %ile	95th %ile	90th %ile	75th %ile	50th %ile
Florida Central Ridge, acidic ground water								
Aldicarb	1000 ft	Citrus	3.0	2.8	2.6	2.5	2.0	1.7
Oxamyl	0 ft	Citrus	0.7	0.7	0.5	0.4	0.3	0.2
Northeastern FL, neutral ground water								
Aldicarb	300 ft	Potatoes	1.7e-05	1.3e-05	8.0e-06	5.7e-06	2.7e-06	9.9e-07
Southern Coastal Plain - southern GA, acidic ground water								
Aldicarb	300 ft [1]	Peanuts	6.5	6.0	5.1	4.8	4.1	3.1
	500 ft [1]	Peanuts	3.7	3.4	2.9	2.7	2.4	1.8
Eastern Coastal Plain - eastern NC, acidic ground water								
Aldicarb	300 ft	Peanuts	1.3	1.2	1.1	1.0	0.8	0.6
Oxamyl	0 ft	Peanuts	0.01	0.01	0.01	0.01	<0.01	<0.01
Northwestern US - Central WA, alkaline ground water, 15-foot well depth								
Aldicarb	300 ft	Potatoes	0.001	0.001	<0.001	<0.001	<0.001	<0.001

[1] The current label for aldicarb specifies a 300-foot setback between the field of application and drinking water wells for use on peanuts. A proposed setback of 500 feet, based on the IRED (USEPA, 2006d), was modeled to determine the impact on exposure that would be expected from this modification to the label. Aldicarb use on peanuts is included in the dietary baseline assessment.

This comparison of model estimates with monitoring relies heavily on aldicarb monitoring data, as it is the most extensive. Estimated concentrations of total aldicarb residues (the parent plus its sulfoxide and sulfone transformation products) are comparable to existing monitoring data from a number of studies:

- Estimated concentrations with no setback distance between the well and field of application are similar to recent in-field monitoring concentrations from wells in and around citrus groves in the FL Central Ridge (Lake Wales Ridge) conducted by USGS and the Florida Department of Agriculture (USGS, 2006).

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- Estimated aldicarb concentrations with no well setbacks were also similar to monitoring detections from the early 1990's from private wells in Florida (FL DEP, 2005). Those detections do not reflect subsequent label changes and required well setbacks. While aldicarb residues in recent years have been below the analytical limits of detection in the FL monitoring program, estimated concentrations modeled with a 1000-foot well setback are also below those limits of detection.

- A 2006 study by Bayer CropScience of private wells in selected aldicarb use areas (excluding FL) found detections of aldicarb residues in 10% of the wells, with detections as high as 2.9 ug/l (USEPA, 2007a). Because the single samples represent a snapshot of aldicarb concentrations over time, they are best compared to the median concentrations of the estimated exposures. The highest detections in the monitoring study (2.6-2.9 ug/l range) are similar to the median concentrations estimated for the southern coastal plain scenario represented by peanut use in GA.

Additional information on the monitoring studies for aldicarb is in Appendix II.E.2; more detail on monitoring-modeling comparisons can be found in Appendix II.E.7.

b. Cumulative NMC Levels in Ground Water

The cumulative NMC residues in the high-exposure ground water scenarios (Table I.E-10) represent the combined contributions of the individual NMC residues listed in Table I.E-9 weighted for relative potency and uncertainty factors and converted to oxamyl equivalents. For this NMC assessment, high-exposure conditions refer to shallow wells (30 ft to ground water) extending through soils with a high leaching potential rating (according to USDA NRCS ratings) into an unconfined aquifer. Except where noted, the ground water is acidic, an environment that favors persistence of the NMC chemicals.

The greatest estimated cumulative NMC concentrations in ground water sources of drinking water occurred in the southern portions of the coastal plain (representing the coastal plain provinces of SC, GA, AL, and northern FL). Concentrations estimated in the Washington scenarios were substantially lower than those estimated in other areas. Because the concentrations in Table I.E.10 reflect adjustments for individual chemical FQPA safety and uncertainty factors in addition to relative potencies, they cannot be directly compared to measured values in the environment.

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Table I.E-10. Percentile concentrations for estimated NMC cumulative distributions in the ground water scenario sites adjusted for relative potency and using safety factors for children

Region/Site	Percentile concentration in ug/L (oxamyl equivalents, adjusted for uncertainty factors)						Major RPF/UF-adj contributor(s)
	Max	99th	95th	90th	75th	50th	
NMC Cumulative Distributions incorporating FQPA factors for children [1]							
Southern Coastal Plain / GA, 300-ft setback	104.7	96.9	82.8	76.8	66.1	49.6	Aldicarb (peanuts)
GA, 500-ft setback	59.6	55.2	47.1	43.7	37.6	28.2	Aldicarb (peanuts)
FL Central Ridge, 1000-ft setback	48.1	45.5	41.6	39.7	33.0	27.6	Aldicarb (citrus)
Eastern Coastal Plain / NC, 300-ft setback	21.6	20.0	17.5	15.7	13.5	10.3	Aldicarb (peanuts)
Northeast FL, neutral GW	2.7E-04	2.0E-04	1.3E-04	9.2E-05	4.2E-05	1.6E-05	Aldicarb, (potatoes)
NMC Cumulative Distributions incorporating FQPA factors for adults [1]							
Southern Coastal Plain / GA, 300-ft setback	52.3	48.5	41.4	38.4	33.0	24.8	Aldicarb (peanuts)
GA, 500-ft setback	29.8	27.6	23.6	21.9	18.8	14.1	Aldicarb (peanuts)
FL Central Ridge, 1000-ft setback	23.9	22.6	20.7	19.8	16.4	13.8	Aldicarb (citrus)
Eastern Coastal Plain / NC, 300-ft setback	10.8	10.0	8.8	7.8	6.8	5.2	Aldicarb (peanuts)
Northeast FL, neutral GW	1.3E-04	1.0E-04	6.4E-05	4.6E-05	2.1E-05	7.9E-06	Aldicarb, (potatoes)

[1] Concentrations have been adjusted for relative potency and inter-species factors in addition to children- or adult-specific FQPA factors.

Figure I.E-5 illustrates the difference in exposure as a result of different well setbacks in the southern coastal plain scenario. The cumulative margin of exposure (MOE) for drinking water exposure for infants is less than 10 when the setback distance between the field and the well is 300 feet. Taking into account a larger (500-foot) well setback distance, the resulting drinking water exposure is greater than an MOE of 10. The drinking water exposure concerns are being addressed in the single chemical assessment for aldicarb. For other scenarios modeled (representing high leaching potential) the cumulative exposures for drinking water are greater than an MOE of 10 (see Figure I.E-7).

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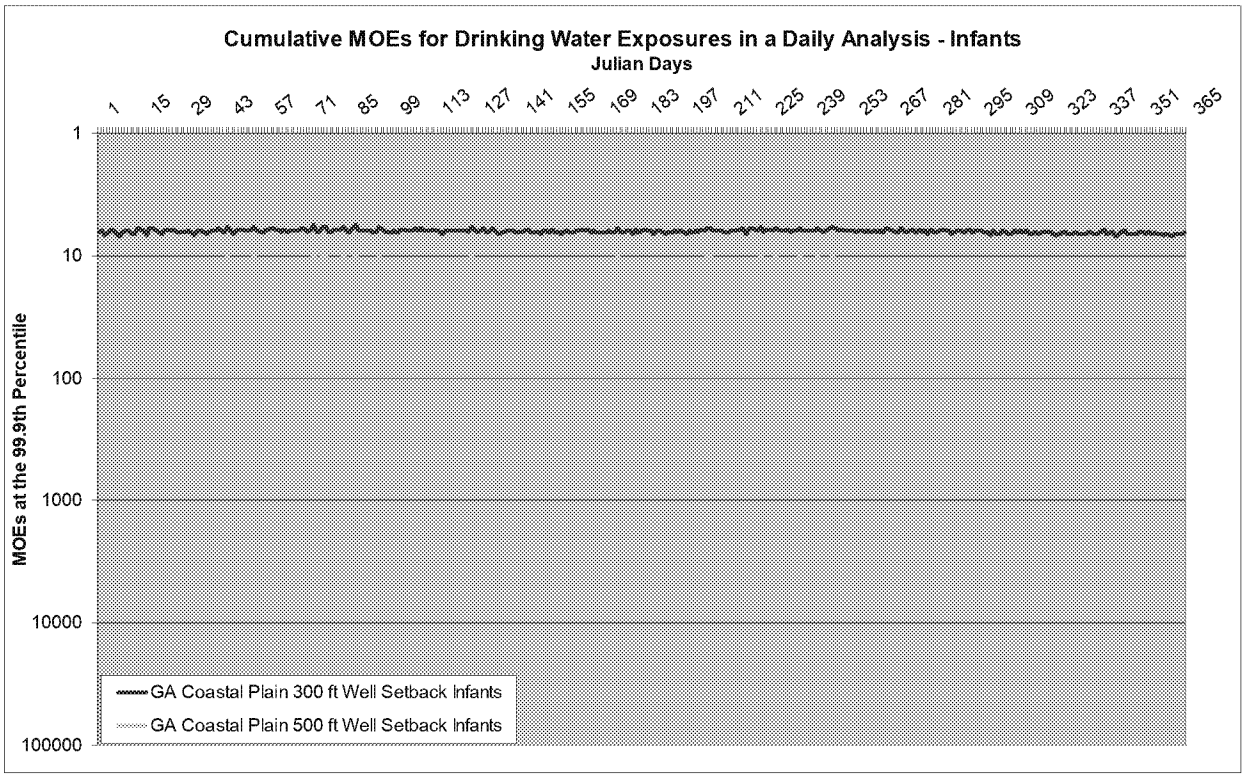
Figure I.E-5. Cumulative margins of exposure for drinking water from private wells in high leaching potential soils in the southern coastal plain (GA Peanuts), infants



c. Spatial Extent of High NMC Exposures in Ground Water

The ground water exposure assessment focused on areas where combined NMC exposure is likely to be among the highest within the region as a result of total NMC usage, adjusted for relative potencies, and vulnerability of the drinking water sources. Based on the fate and transport characteristics of the NMC pesticides, interpretations of existing monitoring data, and results of exposure modeling, the following conditions are likely to result in elevated concentrations of NMC residues in ground water:

- **Shallow wells**. Concentrations will vary with varying depths to ground water and well depths (the depth from which the well draws water). Higher concentrations would be expected in more shallow wells while lower concentrations would be likely in deeper wells.

- **High leaching potential soils** as classified by the USDA Natural Resources Conservation Service (USDA NRCS, 2003), with similarly permeable conditions extending through the vadose zone to ground

water. Such soils are well-drained, highly permeable, and have a low organic matter content.

- **Acidic soil and ground water**, which favor the persistence of the NMC chemicals, particularly the sulfoxide and sulfone transformation products of aldicarb.

In most of the country, NMC residues in drinking water sources are at levels that are not likely to contribute substantially to the multi-pathway cumulative exposure. However, some areas of the Delmarva Peninsula, the southeastern coastal plain, and Florida (primarily along the central ridge) and the southeastern coastal plain have conditions that could result in elevated NMC concentrations in ground water. These areas represent what the Agency believes to be the most vulnerable private well drinking water sources for the NMCs based on available monitoring, current use patterns, and known soil and hydrologic conditions. In those vulnerable areas, which represent a relatively small area of the country, the estimated ground water residues are reasonable estimates of drinking water exposure for residents who get their drinking water from private wells that draw water from shallow depths in unconfined aquifers.

Figure I.E-6 illustrates the spatial extent of high leaching potential soils (shown in red) in the NMC use areas (shown in green) in the southeastern US. Although county-level soil information was not available for the entire region at the time of the spatial assessment, such soils can be identified. While the map includes acidic, high leaching potential soils, it does not reflect depth or pH of the ground water, or the relative permeability of the underlying vadose zone and aquifer. Information on the location or depth of private drinking water wells available is also not available.

Anticipated exposures in other parts of the country are expected to be lower than surface water estimates in other regions of the country. In the north and north-central regions, total NMC use, particularly aldicarb, is relatively low. Aldicarb is no longer labeled for use in a number of northern and northeastern states because of a history of ground water contamination. In the mid-south, drinking water comes predominantly from a public ground water supply drawing from deep, protected aquifers. NMC contamination is not expected, except in an area around southeastern Missouri and northeastern Arkansas, which had several detections in the Bayer CropScience monitoring study (USEPA, 2007a). In the Great Plains and Lower Midwest, anticipated exposure is expected to be lower than surface water estimates because of low rainfall and deeper aquifers than in the southeast and Florida.

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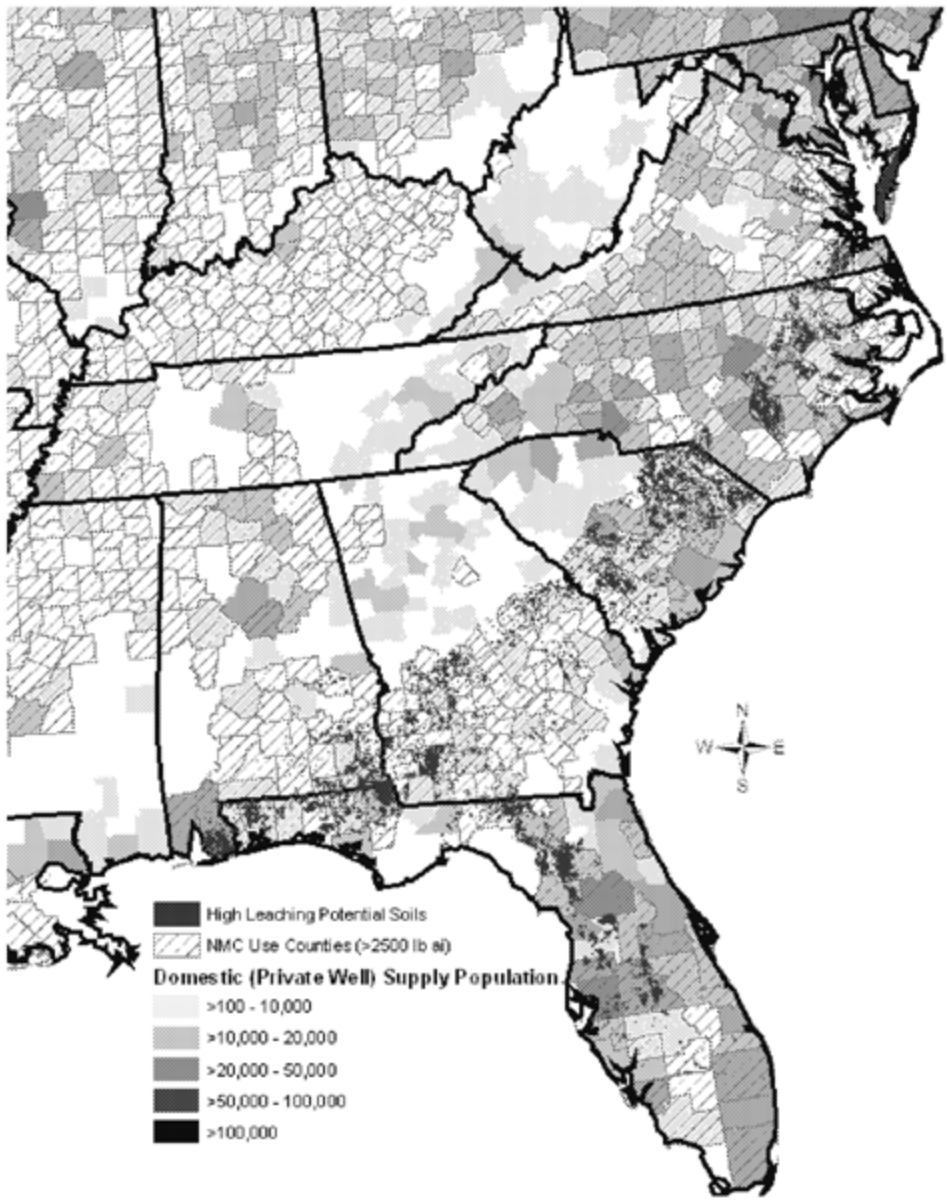
Figure I.E-6. Extent of high leaching potential soils in NMC use areas in the Southeastern U.S.



d. Sensitivity Analysis: Carbofuran in Ground Water

Carbofuran was modeled in two NMC scenarios: one representing use on potatoes in Northeastern Florida, and the other representing cucurbits in the Delmarva Penninsula in the North/North central region (Table I.E-11). The Delmarva scenario was not included in the NMC assessment, but was developed specifically for the sensitivity analysis for carbofuran to represent a high-leaching potential area for cucurbit use.

Table I.E-11. Estimated concentrations for NMC and carbofuran for regional ground water scenarios (25-year period) for ground water at 30 feet

NMC pesticide	Well setback distance	Crop(s)	Concentrations, ug/l					
			Max-imum	99th %ile	95th %ile	90th %ile	75th %ile	50th %ile
Northeastern FL, neutral ground water								
Aldicarb	300 ft	Potatoes	1.7e-05	1.3e-05	8.0e-06	5.7e-06	2.7e-06	9.9e-07
Carbofuran[1]	0 ft	Potatoes	2.7e-11	1.7e-11	9.3e-12	4.8e-12	1.5e-12	1.5e-13
Delmarva Peninsula, acidic ground water								
Carbofuran[1]	0 ft	Cucurbits, high typ. rate	38.5	36.4	28.8	25.6	20.6	15.5
	0 ft	Cucurbits, low typ. rate	10.2	9.6	7.6	6.8	5.4	4.1

[1] The Agency has proposed a cancellation of all domestic carbofuran uses. The estimated exposures depicted here represent current uses for carbofuran.

Carbofuran concentrations estimated in Northern Florida were six orders of magnitude lower than those estimated for aldicarb, and therefore would not be a significant contributor to the NMC in that region. However, carbofuran concentrations estimated on the Delmarva Peninsula are the highest estimated for any NMC. Estimated carbofuran concentrations in private wells in the Delmarva Peninsula are in line with monitoring data summarized in the 2006 Carbofuran IRED and suitable for human health exposure assessments (Appendix II.E.7).

The greatest estimated cumulative NMC concentrations in ground water sources of drinking water occurred in the Delmarva Peninsula for carbofuran-driven NMC exposures (

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Table I.E-12). The Delmarva Peninsula (carbofuran on cucurbits) would result in cumulative exposures for drinking water with a MOE of less than 10 (Figure I.E-7). These drinking water exposure concerns are being addressed through cancellation of all domestic carbofuran uses. All other estimated exposures from high leaching potential ground water sites result in MOEs greater than the target of 10.

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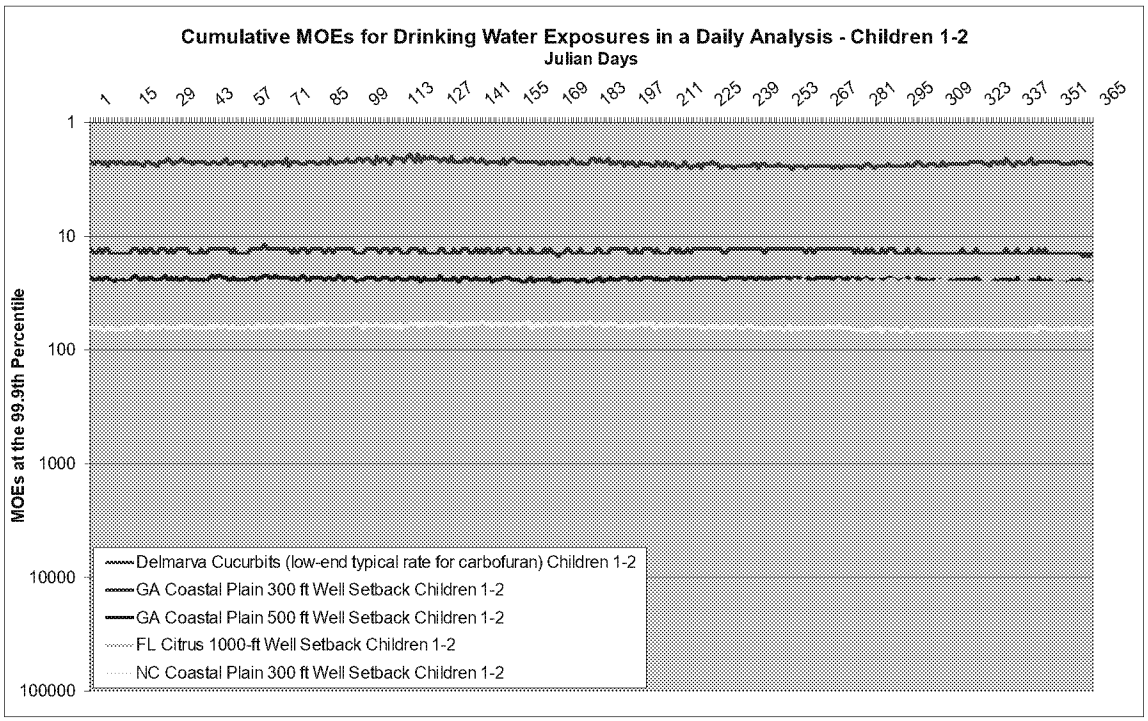
Table I.E-12. Percentile concentrations for estimated NMC cumulative distributions in the ground water scenario sites adjusted for relative potency and using safety factors for children

Region/Site	Percentile concentration in ug/L (oxamyl equivalents, adjusted for uncertainty factors)						Major RPF/UF-adj contributor(s)
	Max	99th	95th	90th	75th	50th	
NMC Cumulative Distributions incorporating FQPA factors for children (1)							
Delmarva / high-end typical rate	2540	2400	1898	1689	1357	1024	Carbofuran (cucurbit)
Delmarva / low-end typical rate	670.6	633.8	501.2	445.9	358.3	270.5	Carbofuran (cucurbit)
Northeast FL, neutral GW	2.7E-04	2.0E-04	1.3E-04	9.2E-05	4.2E-05	1.6E-05	Aldicarb, carbofuran (potatoes)
NMC Cumulative Distributions incorporating FQPA factors for adults (1)							
Delmarva / high-end typical rate	923.7	873.0	690.3	614.2	493.5	372.6	Carbofuran (cucurbit)
Delmarva / low-end typical rate	243.9	230.5	182.2	162.2	130.3	98.4	Carbofuran (cucurbit)
Northeast FL, neutral GW	1.3E-04	1.0E-04	6.4E-05	4.6E-05	2.1E-05	7.9E-06	Aldicarb, carbofuran (potatoes)

(1) Concentrations have been adjusted for relative potency and inter-species factors in addition to children- or adult-specific FQPA factors.

Figure I.E-7. Cumulative margins of exposure for drinking water from private wells in high leaching potential scenarios, children 1-2 years old



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7. Summary

The drinking water assessment focuses on areas where combined NMC exposure is likely to be among the highest within each region as a result of total NMC usage and vulnerability of drinking water sources. This analysis is based on a probabilistic modeling approach that considers the full range of data and not a single high-end estimate. EPA estimated NMC exposures in drinking water to individuals in the CRA for both ground water and surface water sources of drinking water by region. The regional drinking water exposure assessments are intended to represent exposures from vulnerable drinking water sources resulting from typical NMC usage and reflect seasonal variations as well as regional variations in cropping and NMC use. Each regional assessment focuses on areas where combined NMC exposure is likely to be among the highest within the region as a result of total NMC usage, adjusted for relative potencies, and vulnerability of the drinking water sources. For ground water, private wells extending through highly permeable soil and vadose zone materials into shallow, acidic ground water are expected to be most vulnerable. For surface water, drinking water reservoirs in small, predominantly agricultural watersheds are likely to be most vulnerable. The co-occurrence of NMC residues in water is primarily estimated from modeling. Monitoring data are not available consistently enough to be the sole basis for the assessment. However, monitoring data are used to corroborate the modeling results and have helped confirm locations of potentially vulnerable drinking water sources.

In most of the country, NMC residues in drinking water sources are at levels that are not likely to contribute substantially to the multi-pathway cumulative exposure. Estimated NMC exposures from surface water sources of drinking water resulted in MOEs well in excess of 10. For most ground water sources of drinking water, NMC exposures were similarly low. Private wells in highly permeable soils that draw water at shallow depths in acidic, unconfined aquifers represent what the Agency believes to be the most vulnerable drinking water sources for the NMCs based on available monitoring, current use patterns, and known soil and hydrologic conditions. Those instances where NMC concentrations resulted in MOEs of less than 10 are being addressed with mitigation measures in the single chemical assessments – an increase in the well setback distance from 300 feet to 500 feet for aldicarb use on peanuts in the southern portion of the Coastal Plain and cancellation of all domestic carbofuran uses. With these mitigation measures, NMC exposures from drinking water result in MOEs that are greater than 10.

F. The Multi-Pathway Cumulative Assessment

The previous chapters of this document have described the development of the primary components of the risk assessment. They describe a highly complex process of combining multiple data sets to generate a description of the potential risks from NMC pesticides by each of the pathways described. OPP has had to generate new methods for each component of the assessment in order to produce an assessment, which presents as realistically as possible the potential exposure to NMC pesticides. The purpose of this chapter is to explain the concepts used to accumulate risk from each pathway into a total risk estimate, summarize some of the major revised findings, and to provide a basis for understanding the graphical temporal exposure profiles that are provided in the Appendices.

1. Basic Concepts

The definition of cumulative risk developed as a result of the passage of FQPA requires OPP to conduct a risk assessment for a group of pesticides with a common mechanism of toxicity that is multi-pathway, multi-route, and multi-chemical in scope and nature. As described in Chapter I.B of this revised cumulative assessment for the NMCs, the RPF method was used to address the issue of combining toxic responses from NMCs with varying propensities to inhibit acetyl cholinesterase. Exposure to each NMC was normalized to equivalent exposure to the index compound, oxamyl. The toxicity data currently available for conducting this analysis are estimates of response by route-specific dosing, and do not support estimating delivered dose to the target tissue. OPP decided to address this problem by comparing route-specific exposures to route-specific points of departure (PoD) to produce unitless margins of exposure for each route. Thus, each exposure route is associated with an MOE for that route. A total (or combined) MOE was calculated by taking the inverse of the MOE for each route, adding these together, and then taking the inverse of that sum. This process was used to produce a distribution of daily estimates of MOEs for the subpopulation of concern that reflects regional and seasonal variation[15] in the patterns of exposure that are likely to occur throughout the US across the year. OPP used a probabilistic assessment procedure to capture the full range of exposure possibilities from all sources analyzed. The intent was to produce an estimate of risk that is as realistic as possible. The NMC cumulative risk assessment is not a high end risk assessment for the specific situation, e.g., geographic location. OPP

[15] Note that seasonal variation was only considered for the residential and drinking water pathways. No seasonal variation was considered for the food pathway.

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believes it reflects the full range of likely exposures and exposure possibilities for consideration in a regulatory context and avoids developing exposure estimates based upon combination of exposure scenarios and assumptions that are not reasonable or are unlikely to co-occur in practice. This method has been standard practice for developing total MOE estimates for aggregate and cumulative assessments and is further described in OPP's 2001 Aggregate guidance document
http://www.epa.gov/pesticides/trac/science/aggregate.pdf

2. Framing the Population-Based Assessment

OPP used the above-described methodologies to develop a series of daily exposure distributions and array them as a distribution across time. The distribution of daily exposures and resulting MOEs are developed such that the exposures from NMCs in foods, drinking water and from residential uses are all calculated simultaneously for each hypothetical individual in the subpopulation. OPP used the Calendex software to develop the distributions and resulting MOEs. Calendex permits incorporation of time-course information with regard to residential uses of pesticides and exposures through drinking water, but does not permit specific allowance for regional variability. As described in Chapter I.E of this document, OPP addressed this issue by focusing on and developing separate assessments for regional locations that represent what is likely to be the most vulnerable drinking water sources in high NMC use areas. Based on a comparison of estimated drinking water exposures from surface- and ground-water sources in three regions as part of the preliminary NMC CRA, OPP selected drinking water exposures representing what have been determined to be the three most vulnerable areas –southern coastal plains (Georgia), Florida central ridge, and Eastern coastal plains (North Carolina) regions – for the multi-pathway assessment. NMC exposures in drinking water from the remaining parts of the country are expected to be substantially lower than from these three sites.

To generate a daily distribution of exposure for the subpopulation of interest, a consumption record is selected from the CSFII that corresponds to the age group of interest. Calendex uses this consumption record to estimate NMC exposure from food commodity by randomly assigning a residue value for each food commonly included. After multiplying each amount of food commodity consumed by its selected residue value, the total exposure for this individual from food is summed. At the same time, all appropriate residential scenarios that may be encountered for the calendar day 1 (January 1) are reviewed. A probability-based decision is made as to whether or not that scenario will be encountered (e.g., a lawn treatment; not likely in January). If the

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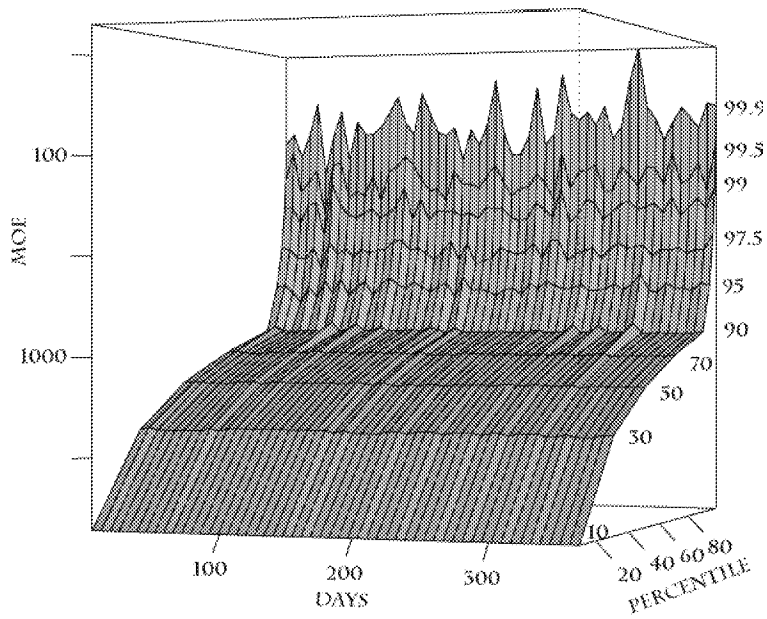
scenario is assigned a "yes" answer, then the appropriate values defining the exposure are selected from the many distributions of input parameters for residential exposure scenarios. Dermal, oral and inhalation exposures are calculated for all selected residential scenarios. A drinking water value taken from the estimated distribution of water residues for January 1 is selected and paired with the water consumption reported in the CSFII consumption record. These values are used to calculate exposure from drinking water for that date. All of the exposures are converted to route-specific MOEs to define the total exposure to the hypothetical individual on January 1. The process is repeated for each consumption record for the age group in the CSFII one hundred times to build a distribution of exposures for January 1. This process is repeated for January 2, January 3 and so forth across the same year.

The 365 daily exposure distributions are arrayed together in order to provide a profile of possible exposures by each route and in total as MOEs. A hypothetical example of such a distribution of distributions is presented in **Figure I.F-1**. In this figure, each daily distribution is arrayed on the yz plane of the plot. Day 365 can be clearly seen on the right side of the plot. This distribution of total risk is expressed as a cumulative distribution function of MOEs versus percentile of exposure. Percentile of exposure refers to that portion of the population that has less than or equal exposure. For example, 80 % of the population has an exposure level that is equal to or less than the 80th percentile.

Figure I.F-1. Three-dimensional plot of the total MOE by day of the year and percentile of exposure



3. Interpreting the Outputs

The results of the final assessment are presented in graphical form in the appendices. They reflect year-long slices across the 3-dimensional plot in Figure I.F-1. In that plot, dark lines can be seen across the total MOE surface. For instance, the top line in the 3-dimensional plot represents the 99.9th percentile of exposure for the population. A slice through the surface parallel to the xy plane at the 99th percentile would look like the plot presented in Figure I.F.2. This plot presents the potential total MOE for the population exposed to NMCs by the exposure scenarios included in this assessment. In addition, the contributions from various pathways and routes of exposure are arrayed separately to assist the risk manager in identifying contributors to risk for further evaluation. Other percentiles of exposure may also be of interest.

OPP will use the changes in graphical presentations of data such as these to evaluate the significance of various sources of exposure, considering the percentile at which the exposure becomes significant and the duration over which the exposure route and source remain dominant in the risk assessment results.

4. Attributes of the Revised *N*-Methyl Carbamate Cumulative Risk Assessment

The current revised assessment focuses on estimating the potential risk from exposure to ten NMC pesticides in food and drinking water and from residential uses. The assessment is limited in geographic scope to the Southern area of the U.S. This limitation was placed on the assessment to ensure that the water and residential components of the assessment would reflect what a coherent set of pesticide uses are likely to exist. Understanding the likelihood of co-occurrence of pesticide uses is critical to developing a reasonable estimate of total cumulative risk. In the absence of direct measures of co-occurrence, overlapping exposures must be extrapolated from use data. The residential and groundwater assessments are based on the most highly exposed localized areas within the southeastern region of the United States.

As indicated previously in this report, Table I.B.7 for the food and residential components of the cumulative risk assessment, a PoD was used for the oral component of the total cumulative risk assessment. The estimated $BMDL_{10}$ (0.18 mg/kg body wt/day) for brain AChE inhibition by the index compound (oxamyl) was used. The inhalation and dermal components of the assessment were compared to $BMDL_{10}$s of 0.66 and 17.05 mg/kg body wt/day, respectively.

Integrated cumulated risk assessments were conducted for the following age groups: Children 1-2 years, Children 3-5 years, Adults 20-49 years, and Adults 50+ years of age. These four groups were chosen to emphasize the effects of differences in behavior and food consumption patterns on estimating the risk from exposure to pesticides. The assessments reflect the same assumptions about use scenarios, timing of exposures, and exposures to pesticides in food and water as used in the previous pathway specific assessments. An entire year of exposure is simulated. Three different water scenarios from the south were matched with a residential scenario that used application timing patterns that are characteristic of the South. Three water scenarios simulated ground water sources in Georgia, Florida, and North Carolina.

The food component of the cumulative risk assessment contains as many commodities as could reasonably be extrapolated from the available PDP and FDA monitoring data. This component of the assessment is regarded as highly refined and reflective of exposures likely to be encountered by the U.S. population. Because data on residential exposure are more limited, the residential component of the assessment was also designed to reflect some overestimation bias to ensure that risk from these sources of exposure were not likely to be underestimated. The water components of the assessment focused on what OPP believes are the most vulnerable drinking water sources. While the estimated drinking water concentrations are reasonable reflections of actual exposures in those particular areas, the rest of the country is expected to have substantially lower combined (or "cumulative") NMC residue levels in its drinking water.

As discussed earlier, exposure estimates are specific to the regions discussed; they take into account region-specific water and residential use practices and cannot – as a general matter – be necessarily extrapolated to different regions. The Florida central ridge groundwater scenario is specific to an area in Florida in which the use of NMC pesticides, particularly aldicarb, is high, soils are highly permeable, the depth to groundwater is shallow, and the soils and water are acidic. These conditions are favorable to potentially high levels of NMC residues in drinking water sources. The North Carolina and Georgia coastal plain groundwater scenarios represent another area where high NMC use (dominantly aldicarb), highly permeable soils, shallow ground water and acidic conditions are likely to favor potentially high combined NMC levels. Further description of these sites, conditions, and characteristics that led OPP to select these sites as high-end with respect to ground water concentrations for this cumulative assessment is in Chapter I.D of this document. OPP notes that drinking water concentrations from a combination of multiple NMCs in the much of the rest of the U.S. would be expected to be substantially lower than estimated for this

assessment. It is possible, however, that the concentration of a single NMC in drinking water could be higher than that of the concentration of that single chemical's contribution to this cumulative exposure assessment.

Estimates of cumulative risk from 10 NMCs associated with exposure through foods, drinking water, and residential uses are presented in Appendices III.F.1-24 for Children 1-2 years old, Children 3-5 years old, Adults 20-49 years old and for Adults 50+. The contributions of each of the major routes of exposure and the likely sources of those exposures are discussed in previous chapters of this revised assessment. Graphical presentations are provided for the 95th, 97.5th, 99.5th, 99th, and 99.9th percentiles but written characterizations are limited to the 95th, 99th, and the 99.9th because these percentiles capture the range of exposure which has traditionally been of most interest to the Agency. As described in the residential chapter of this document, exposures through the inhalation route were not assessed and are considered to be very small. Thus, this exposure route is not specifically discussed in each of the following descriptions.

a. Children, 1-2 years, Georgia Coastal Plain Ground Water

The results of the total cumulative assessment for Children 1-2 years using the $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Georgia Coastal Plain Ground Water appear in Figure III.F.2.

95th Percentile – The significant source of pesticide risk from exposure to pesticides at this percentile of exposure is through both the drinking water pathway with MOEs ranging from 117 to approximately 125 and the food component with an MOE that is generally near 142 across the year (Figure III.F.1). Dermal exposure that is associated with residential use does not occur at this percentile because typically only a small percentage of the population uses such products.

99th Percentile – The daily total MOEs ranged from 26 to 28. At this percentile, MOEs associated with food pathways were generally approximately 35 and comprise the major source for total exposure. The daily MOE values from drinking water sources ranged from 64 to 70. MOEs from oral non-dietary ingestion which are associated with residential use (i.e., hand-to-mouth) were higher than drinking water exposure and generally the MOEs for oral non-dietary exposure pathway ranged from ca. 296 to greater than 350 (Figure

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III.F.1). MOEs associated with the dermal route are generally greater than 110 but as low as 99.

99.9th Percentile – At the 99.9th percentile, the total cumulative risk (all pathways) was as low as ca. 7 for this age group and nearly all of the estimated exposure came through the oral route that included significant contributions from the food pathway (Figure III.F.1). Oral non-dietary exposure (hand-to-mouth) resulted in MOEs remaining consistent through the year between ca 76 and 90. Dermal MOEs go down to 24 with an average MOE of 27.

b. Children 3-5 years, Georgia Coastal Plain Ground Water

The results of the total cumulative assessment for Children, 3-5 years old using the estimated $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Georgia Coastal Plain Ground Water appear in Figure III.3.

95th Percentile – Total MOEs at this percentile range from 90 to 94 throughout the year. The significant contributor to total cumulative exposure comes through the drinking water pathway (Figure III.F.3) with a range of MOEs of ca. 170 to ca. 180. The next most significant contributor to total cumulative exposure is through the food pathway; this pathway has fairly stable MOEs of slightly greater than 180.

99th Percentile – At this percentile the total (cumulative) exposure resulted in MOEs from 32 to 34 MOEs associated with food were generally near 41. MOEs from drinking water sources generally remained in the 93 to 102 range. MOEs associated with the dermal route appear for the first time here and average ca. 160. Exposures from oral non-dietary ingestion (i.e., hand-to-mouth) was less than exposure from drinking water and food and MOEs for this source generally ranged from ca. 422 to greater than 480 (Figure III.F.3). .

99.9th Percentile – At the 99.9th percentile, the total MOE (all pathways) was in the 7 to 9 range and this was nearly all contributed through food exposure (Figure III.F.3). Drinking water MOEs average 53. MOEs varied for oral non-dietary exposure around 115. MOEs from dermal exposures generally ranged between ca. 35 and 40.

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c. Adults, 20-49 years, Georgia Coastal Plain Ground Water

The results of the total cumulative assessment for Adults, 20-49 years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Georgia Coastal Plain Ground Water appear in Figure III.F.6.

95th Percentile – Total MOEs at this percentile are in the 290 to 340 range with contributions from drinking water dominant and persistent throughout the year; exposures through the food pathway contribute a relatively small amount compared to total exposure, with MOEs for food above 1400 (Figure III.F.6). Dermal MOEs were all greater than 4,000.

99th Percentile – Total MOEs are generally in the 100 to 150 range at this percentile. Exposure from drinking water results in MOEs between 220 and 240 (Figure III.F.6). MOEs associated with food are generally 230. Dermal exposures are associated with MOEs of approximately 280 to greater than 2,300.

99.9th Percentile –Total MOEs at this percentile are generally in the 30-43 range, with exposure from food dominant throughout the year (Figures III.F.1-9). MOEs associated with drinking water are generally about 115. Dermal exposures are associated with MOEs of approximately 50 to greater than 500.

d. Adults, 50+ years, Georgia Coastal Plain Ground Water

The results of the total cumulative assessment for Adults, 50+ years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Georgia Coastal Plain Ground Water appear in Figure III.F.7.

95th Percentile – Total MOEs at this percentile are in the 220 to 260 range with contributions from drinking water and food contributing all year long a relatively similar exposure resulting in MOEs above 400 and dermal MOEs were all greater than 4,000 (Figure III.F.7).

99th Percentile – Total MOEs are generally in the 71 to 90 range at this percentile, with food significantly contributing throughout the entire year with food MOEs of ca. 100 (Figure III.F.7). MOEs associated with drinking water are generally about 230. Dermal exposures are associated with MOEs of approximately 280 to greater than 2,300.

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99.9th Percentile –Total MOEs at this percentile are generally in the 15 to 20 range, with exposure from food dominant throughout the year (Figure III.F.7). MOEs from exposure through the food pathway were in ca. 20. Drinking water exposure resulted in MOEs of approximately 110. Dermal exposures are associated with MOEs of generally ca. 56 to 543.

e. Children, 1-2 years, Florida Citrus Ground Water

The results of the total cumulative assessment for Children, 1-2 years using the estimated $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Florida Citrus Ground Water appear in Figure III.F.9.

95th Percentile – Total MOEs at the 95th percentile ranged from 67 to 74 (Figure III.F.9). One source of pesticide risk from exposure to pesticides at this percentile of exposure is through the drinking water pathway with total MOEs ranging from 121 to 143. The food component of the assessment was stable across time with an MOE that is generally near 140 across the year.

99th Percentile – At this percentile, the daily MOE values from drinking water sources were ca. 75. Total MOEs averaged about 27. Exposures from oral non-dietary ingestion which are associated with residential use (i.e., hand-to-mouth) were somewhat lower than drinking water exposure and generally the MOEs for oral non-dietary exposure pathway ranged from ca. 290 to greater than 350 (Figure III.F.9). MOEs associated with food were generally around 35. MOEs associated with the dermal pathway are as low as ca. 99.

99.9th Percentile – At the 99.9th percentile, the total cumulative risk (all pathways) generally was in the 6-8 range for this age group and nearly all of the estimated exposure came through the food pathway (Figure III.F.9). Drinking water exposures resulted in MOEs of about 40. Oral non-dietary exposure (hand-to-mouth) resulted in MOEs remaining consistent through the year between 76 and 90. Dermal MOEs generally ranged between ca. 25 and 30.

f. Children 3-5 years, Florida Citrus Ground Water

The results of the total cumulative assessment for children, 3-5 years old using the estimated $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix II.B.2. Temporal

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Exposure Profile Plots for Florida Citrus Ground Water appear in Figure III.F.10.

95th Percentile – Total MOEs at this percentile are approximately 95 throughout the year. The significant contributor to total cumulative exposure comes through the drinking water and food pathways (Figure III.F.10) with a MOE of ca. 185 each

99th Percentile – At this percentile, the MOE from food sources generally remained in the 40 range and are essentially equivalent to total (cumulative) exposure since the food pathway predominated. MOEs associated with drinking water were generally near 100. Exposures from oral non-dietary ingestion (i.e., hand-to-mouth) was less than exposure from drinking water and food and MOEs for this source generally ranged from ca. 420 to greater than 480 (Figure III.F.10). MOEs associated with the dermal route appear for the first time here and always exceed ca. 140

99.9th Percentile – At the 99.9th percentile, the total MOE (all pathways) was in the 7 to 10 range for this age group and this was nearly all contributed by food (Figure III.F.10). Dermal is next in importance with MOEs as low as 35. Drinking water MOEs averaged around 60. MOEs varied for exposure through oral non-dietary exposure (hand-to-mouth) around 110. MOEs for dermal exposures generally ranged between 35 and 40.

g. Adults, 20-49 years, Florida Citrus Ground Water

The results of the total cumulative assessment for Adults, 20-49 years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Florida Citrus Ground Water appear in Figure III.F.14.

95th Percentile – Total MOEs at this percentile are in the 420 to 500 range with contributions from drinking water dominant and persistent throughout the year; exposures through the food pathway contribute a relatively small amount compared to total exposure, with MOEs for food above 1300 (Figure III.F.14). Dermal MOEs were all greater than 4,000.

99th Percentile – Total MOEs are generally in the 110 to 160 range at this percentile, with exposure from food and drinking water dominating during the entire year. Drinking water MOEs were consistently about 250. MOEs associated with food are generally

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about 260 (Figure III.F.14). Dermal exposures are associated with MOEs of approximately 300 to greater than 2,000.

99.9th Percentile –Total MOEs at this percentile are generally in the 30 to 44 range, with exposure from food which was dominant throughout the year. Drinking water resulted in MOEs of 125 (Figure III.F.14). Dermal exposures are associated with MOEs of generally ca. 50 to greater than 500.

h. Adults, 50+ years, Florida Citrus Ground Water

The results of the total cumulative assessment for Adults, 50+ years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for Florida Citrus Ground Water appear in Figure III.F.15.

95th Percentile – Total MOEs at this percentile are ca. 340 with contributions from drinking water all year long of MOEs around 500 and food contributing a relatively small amount of exposure resulting in MOEs above 1000. Dermal MOEs were all greater than 4,000 (Figure III.F.15).

99th Percentile – Total MOEs were generally around 140 at this percentile, with exposure from food dominating during the entire year. MOEs associated with drinking water are generally about 300 (Figure III.F.15). Dermal exposures are associated with MOEs of approximately 330 to greater than 2,000.

99.9th Percentile –Total MOEs at this percentile are generally in the 30 to 40 range, with exposure from food dominant throughout the year (Figure III.F.15). MOEs from exposure through the drinking water pathway were in ca. 160. Dermal exposures are associated with MOEs of generally ca. 80 to 550.

i. Children, 1-2 years, North Carolina Coastal Plains Ground Water

The results of the total cumulative assessment for Children, 1-2 years using the estimated $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for North Carolina Coastal Plain Ground Water appear in Figure III.F.18.

95th Percentile – The significant source of pesticide risk from exposure to pesticides at this percentile of exposure is through the food pathway with total MOEs ranging from 88 to 95 (Figure

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III.F.18). The food component of the assessment was stable across time with an MOE that is generally near 140 across the year. Drinking water exposure resulted in MOEs as low as ca. 300. Dermal exposures (associated with residential use) do not occur at this percentile because typically only a small percentage of the population uses such products.

99th Percentile – MOEs associated with food were generally around 35 and comprise the major source for total exposure. Exposures from oral non-dietary ingestion which are associated with residential use (i.e., hand-to-mouth) were somewhat lower than drinking water exposure and generally the MOEs for oral non-dietary exposure pathway ranged from ca. 290 to greater than 350 (Figure III.F.18). At this percentile, the daily MOE values from drinking water sources ranged from 166 to greater than 186. MOEs associated with the dermal pathway are generally greater than 100.

99.9th Percentile – At the 99.9th percentile, the total cumulative risk (all pathways) generally was about 8 for this age group and was nearly all of the estimated exposure came through the oral route comprised mostly of food pathways (Figure III.F.18). Drinking water and oral non-dietary exposure (hand-to-mouth) is next in terms of magnitude of contribution with MOEs from about 70 to 100. Dermal MOEs ranged between 24 and 30.

j. Children 3-5 years, North Carolina Coastal Plains Ground Water

The results of the total cumulative assessment for Children, 3-5 years old using the estimated $BMDL_{10}$ of the index chemical (oxamyl) for the PoD are presented in Appendix III.F.19 Temporal Exposure Profile Plots for North Carolina Coastal Plain Ground Water appear in Figure III.F.19.

95th Percentile – Total MOEs at this percentile are approximately 110 to 120 throughout the year. The significant contributor to total cumulative exposure comes through the food pathway (Figure III.F.19) with MOEs of ca. 185. The next most significant contributor to total cumulative exposure is through the drinking water pathway; this pathway has MOEs of greater than 400. Dermal exposures do not occur at this percentile because typically only a small percentage of the population uses such products.

99th Percentile – The total (cumulative) exposure was ca. 35 with most of the exposure through exposure to food. At this percentile, the MOE from food sources generally remained between 39 and

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42. The drinking water pathway averaged in MOEs of ca. 250. MOEs for oral non-dietary ingestion (i.e., hand-to-mouth) generally ranged from ca. 420 to greater than 480 (Figure III.F.19). As with Children 1-2 years old dermal exposures do not occur at this percentile.

99.9th Percentile – At the 99.9th percentile, the total MOE (all pathways) was in the 7 to 9 range for this age group and this was nearly all contributed by exposure through the oral route (drinking water, oral non-dietary and food pathways all contributed to these MOEs) (Figure III.F.19). Oral non-dietary exposure (hand-to-mouth) resulted in MOEs generally in the 110 to 120 range throughout the year. MOEs varied for exposure through food around 9. MOEs for dermal exposures were above 30.

k. Adults, 20-49 years, North Carolina Coastal Plains Ground Water

The results of the total cumulative assessment for Adults, 20-49 years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for North Carolina Coastal Plain Ground Water appear in Figure III.F.22.

95th Percentile – Total MOEs at this percentile are around 600 with contributions from food a major contributor and persistent throughout the year with MOEs of around 1200; exposures through the drinking water pathway contribute a similar amount compared to total exposure, with MOEs for drinking water above 1100 (Figure III.F.22). Dermal MOEs were all greater than 4,000

99th Percentile – Total MOEs are generally in the 120 to 210 range at this percentile, with exposure from food dominating during the entire year (Figure III.F.22). MOEs associated with food are generally about 230. Drinking water MOEs ranged from ca. 560 to greater than 600. Dermal exposures are associated with MOEs of approximately 280 to greater than 2,300.

99.9th Percentile –Total MOEs at this percentile are generally in the 30-50 range, with exposure from food dominant almost throughout the year (Figure III.F.22). Drinking water MOEs average ca. 300. Dermal exposures are associated with MOEs of generally ca. 50 to 500.

l. Adults, 50+ years, North Carolina Coastal Plains Ground Water

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The results of the total cumulative assessment for Adults, 50+ years using the $BMDL_{10}$ for the PoD are presented in Appendix II.B.2. Temporal Exposure Profile Plots for North Carolina Coastal Plain Ground Water appear in Figure III.F.23.

95th Percentile – Total MOEs at this percentile are in the 480 to 630 range with contributions from food all year long. Drinking water contributed a relatively similar amount of exposure as food, both resulting in MOEs above 1000. Dermal MOEs were all greater than 4,000 (Figure III.F.23).

99th Percentile – Total MOEs are generally in the 130 to 180 range at this percentile, with exposure from food dominating during the entire year. MOEs associated with drinking water range from 650 to greater than 700 (Figure III.F.23). Dermal exposures are associated with MOEs of approximately 300 to greater than 2,300.

99.9th Percentile –Total MOEs at this percentile are generally in the 40 range, with exposure from food dominant throughout the year (Figure III.F.23). MOEs associated with drinking water range from 300 to greater than 400. Dermal exposures are associated with MOEs of generally ca. 80 to 550

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G. Risk Characterization

1. Introduction

Risk characterization is the interpretation phase of the assessment process. This chapter characterizes the risks identified as part of the revised NMC CRA. The intent is to note and discuss uncertainties and strengths in the hazard and exposure elements of risk estimates and to assess quantitatively (when possible) or qualitatively the potential impact of those uncertainties on the risk estimates.

Proper and appropriate risk characterization is particularly important for an assessment as complex as the NMC CRA. Many types of data derived from a variety of sources have been combined to produce estimates of risk from exposure to multiple NMCs in food, drinking water, and from residential use. The outputs of the assessment should be evaluated in a variety of ways. Potential biases in input parameters, the direction of the bias, and the uncertainty surrounding the inputs and the exposure model must be considered with regard to their potential impact on the results of the assessment. Sensitivity analyses are important as is a description of how changes in input assumptions might – or might not—affect the assessment.

This revised NMC CRA reflects the impacts on the risks from implementing the risk mitigation measures from the single chemical assessments. The current document presents the estimates of risks associated with exposures to NMCs in food, drinking water, and from residential uses. For the multi-pathway assessment, food, drinking water, and residential exposures are cumulated as a set of temporal or time-series plots of MOEs over a period of 365 days. Contributions from various pathways and routes of exposure are arrayed separately. The assessment presents and discusses results for the 1-2 year old, 3-5 year old, 20-49 year old, and 50+ year old age groups for the three geographic regions of interest. While the results for infants, 6-12 year old children, 13-19 year old youths, and females 13-49 are not discussed in this chapter, these analyses were performed and are presented in Part III.F of this assessment with the other four age groups.

No single value in the assessment should be used to independently arrive at the interpretation of the results. As discussed below, interpretation of the assessment depends upon the synthesis of a vast body of information about the input data and the processing of that data to determine whether estimated risk is below OPP's level of concern.

2. Hazard and Dose-Response Assessment

The hazard and dose-response assessment is presented in detail in Chapter I.B. That chapter outlines the steps in developing the dose-response

relationships for each pesticide based on inhibition of acetylcholinesterase via carbamylation of the active site. It includes a description of all of the data used in the dose-response analyses. Reasons for the selection of oxamyl as the index chemical for the NMC CRA are also discussed. In addition, Chapter I.B describes the dose-time-response model used to develop the dose response curves and half-life to recovery estimates that provided the basis for developing the RPF for each chemical, the PoDs for the index chemical for each route of exposure (i.e., oral, dermal, and inhalation), the FQPA 10X factors, and the inter-species extrapolation factors.

a. Acetylcholinesterase Inhibition: Data Quality & Common Effect

The first step in deciding that a cumulative risk assessment was needed was the determination that the NMCs were toxic by a common mechanism, i.e., AChE inhibition via carbamylation of the active site of the enzyme. Once a common mechanism was identified, the next step in the process was to select an appropriate method for combining the risks from exposures to several pesticides from more than one source/route. Data describing the inhibition of AChE in RBCs and brain has been generated for each registered NMC. Studies developed for registration along with studies performed by EPA's NHEERL have been used in this risk assessment. OPP has elected to use the brain AChE data from adult rats as the basis for developing RPFs and PoDs for use in the assessment. Brain AChE inhibition was selected as it reflects a response in a target tissue of concern that is relevant to humans. Although RBC cholinesterase inhibition data do reflect exposure to NMCs and, therefore, the potential for adverse effects, brain AChE inhibition is an indication of direct effects upon the target tissue itself. Error due to the extrapolation between the response in a surrogate tissue (i.e., red blood cell and plasma) and a target tissue itself (brain) is eliminated. In addition, the data for the brain compartment have very narrow confidence limits when compared to those from the blood, suggesting that there is much less variability in this compartment across the data base. As described in Chapter I.B, human studies on RBC ChE are available for aldicarb, oxamyl, and methomyl. EPA has determined, after considering the advice of the HSRB, that these studies are ethically and scientifically acceptable and appropriate for use in this risk assessment. For these three chemicals, inter-species factors were derived by comparing this ChE data from human RBCs with similar RBC ChE data from rats: this comparison was used to replace the standard 10x inter-species uncertainty factor for the three NMC pesticides.

Due to the nature of AChE inhibition with NMCs (i.e., rapid time-to-peak effect followed by recovery), accurate measurements of inhibition can be challenging in the laboratory. The Agency acknowledges this and also the importance of data quality on estimates of potency. As part of the cumulative risk assessment and in an effort to aid in the evaluation of data submitted for registration, ORD performed a series of dose-response studies where data on AChE inhibition derived from a radiometric method were compared with data

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derived from a standard Ellman method. When evaluating the toxicity of NMCs, data from the radiometric studies are considered the highest quality. The Agency has also compared results from modified Ellman assays from studies submitted for registration with the radiometric data and has requested and reviewed the SOPs for AChE measurements for NMCs. The review of these SOPs is provided in Appendix II.B.5. Overall, the Agency has concluded that the available database of AChE studies is high quality and appropriate for deriving relative potencies. The Agency is confident that the assessment, as performed, is scientifically and statistically sound and based upon a reliable data set.

A BMD_{10} was selected as the basis for comparison of the dose-response curves for the NMCs. OPP's goal in selecting a point of comparison was to choose a point where the magnitude of the response (cholinesterase inhibition) was reliably distinguishable from background but still be protective of behavioral and functional effects. As described in detail in Chapter I.B, the response level of 10% from control provides this balance. A power analysis has shown that 10% inhibition can be reliably detected in the majority of toxicity studies submitted to EPA. The Agency believes that the BMD_{10} is protective of functional and behavioral effects as none have been observed at levels at or below 10% inhibition.

b. Dose-Response Analysis

This assessment uses the RPF approach. Briefly, the RPF approach uses an index chemical as the point of reference for standardizing the common toxicity of the chemical members of the cumulative assessment group. RPFs (i.e., the ratios of the toxic potency of a given chemical to that of the index chemical) are then used to convert exposures of all chemicals in the cumulative assessment group into exposure equivalents of the index chemical. The RPF approach utilizes dose-response information to provide an estimate of each NMC's potency for the common toxicity, and thus allows for the quantification of exposure as it relates to the joint risk of the cumulative assessment group. OPP selected the RPF approach based upon the relatively rich toxicity data base on cholinesterase inhibition available for the NMCs. Although a biological or pharmacokinetic modeling approach would have advantages in determining the cumulative risk for these NMCs, the input parameters for such an approach are not available for most of the NMCs. Thus, OPP has applied simple dose addition and has used an empirical curve fitting model to determine RPFs and PoDs. OPP, in collaboration with ORD, has used an exponential model to describe the dose-time-response curves for each NMC. This dose-time-response model has been used to fit cholinesterase activity data from different studies to derive a BMD in addition to estimation of half-life to recovery. Use of the exponential model to describe cholinesterase data has been subjected to extensive public comment and peer review by the SAP (FIFRA SAP 2001b, 2002, 2005a, 2005b). OPP believes that the model fitting procedure used in

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this assessment provides reliable estimates of relative potency and PoDs for all routes.

c. Selecting the Index Chemical

OPP selected oxamyl as the index chemical for the NMC CRA; this selection was supported by the FIFRA SAP (2005b). Certainty in the PoDs for risk extrapolation is considered to be of great importance in cumulative risk assessment as the PoDs impact the overall uncertainty in the entire risk assessment. Oxamyl has sufficient data for cholinesterase inhibition to support modeling of a BMD_{10} and $BMDL_{10}$ in adult and juvenile rats and human subjects. Moreover, oxamyl studies in adult rats are available for all three routes of exposure (oral, dermal, inhalation) in addition to half-life to recovery in rats and humans. The high quality dose response data for oxamyl permit reliable estimates of PoDs for all routes.

d. Assumption of Dose-Additivity

The cumulative risk assessment for the NMCs is based on the assumption of dose-additivity. Dose-additivity is the Agency's assumption when evaluating the joint risk of chemicals that are toxicologically similar and act at the same target site (USEPA, 2001a). The SAP (FIFRA SAP, 2001a) indicated that substantial reliance would have to be placed on what is known about the mechanism of toxicity because it is very difficult to prove dose-additivity at human exposure levels. They further pointed out that studies available on individual chemicals were usually not designed to address the issue of dose-additivity.

Although there are a few interaction studies of *N*-methyl carbamate and OP pesticides in the literature (e.g., Gupta and Dettbarn, 1993; Takahashi *et al.*, 1987), the Agency did not identify any studies conducted using mixtures of more than two *N*-methyl carbamates and which use low dose levels (i.e., that do not produce lethality or profound toxicity). NHEERL scientists have conducted a mixture study using seven *N*-methyl carbamates (carbaryl, carbofuran, formetanate HCl, methiocarb, methomyl, oxamyl, and propoxur) (Padilla et al., 2006). In the mixture study, a dose-additive experimental design was used and the proportion of the NMCs in the mixture was based on their potency using the individual-chemical benchmark dose values as the point of comparison. In general, increasing dosages of the mixture produced increasing decrements in brain ChE activity. Moreover, the dose-additive model predicted the degree of ChE inhibition (RBC and brain) and changes in motor activity within the 95% confidence limits of each predicted value (Padilla et al, 2006; Manuscript in preparation).

The NMCs all act on the same target site– namely, the inhibition of acetylcholinesterase by carbamylation in nerve tissue, which elicits a variety of

cholinergic effects. Dose addition is regarded as a reasonable and appropriate approach for estimating the cumulative risk associated with joint exposure to the NMC common mechanism group.

3. Food Assessment

The food component of the NMC cumulative risk assessment is based primarily upon two extensive, reliable data sets: 1) USDA's Continuing Survey of Food Intakes by Individuals, 1994-1996 and 1998 (CSFII) and 2) USDA's Pesticide Data Program (PDP). The CSFII provides a detailed representation of the food consumption patterns of the U.S. public across all age groups, during all times of the year, and across the U.S. The PDP data provide a very reliable sample of pesticide residues in the major children's foods, including fruits, vegetables, milk, grains and beef/poultry/pork. The PDP program utilizes multi-residue analytical methods such that co-occurrence of several pesticides in individual samples is captured, alleviating much of the uncertainty that otherwise might exist about co-occurrence in foods that are monitored in the program. These two sources of data – CSFII consumption data and PDP petisticide residue data -- provide a firm foundation upon which to assemble other data to develop the NMC cumulative risk assessment and are discussed in more detail below.

a. Consumption Data

As with the previous cumulative risk assessments performed by OPP, this revised NMC assessment is based on dietary consumption data obtained from the USDA's CSFII 1994-96/98. This is an extensive, two-phase (1994-1996, and then 1998) survey and includes more than 20,000 individuals sampled over four years. The CSFII 1998 provided an additional 5,559 consumption diaries for children ages newborn through nine years of age, which supplemented the 4,253 children sampled in the CSFII 1994-96. This additional, supplemental children's survey was specifically requested of USDA by OPP in order to improve the means to assess exposures to children. In each year of the survey, approximately 5,500 participants in 62 geographical areas across the country were interviewed on their dietary consumption over two separate (non-consecutive) days. The survey was designed to provide a nationally representative sample of non-institutionalized persons residing in the U.S. USDA also provides sampling weights, which allow the survey results to be projected to the U.S. population.

The sampling procedure was designed to account for inter-individual variability in individual consumption patterns (e.g., types and amounts of foods eaten) due to differences in age, gender, ethnicity, regional location, and socioeconomic status. Also, survey respondents are interviewed on different days of the week throughout the year to account for seasonal and within week variability in consumption patterns. A number of other aspects of the survey are also controlled in order to maximize the prospect that the results are representative not only of the entire U.S. population, but also particular

subgroups, including those for which OPP generates acute dietary food exposure distributions.

While the USDA food consumption surveys are designed to be generally representative of the U.S. population, it is clear that some factors that can influence dietary choices are not addressed in the survey design. For example, the CSFII surveys do not purport to be representative of people in institutional living arrangements (colleges, nursing homes, etc.) or of different religions or health status. Specific subpopulations such as vegetarians, those on restricted diets, or those on specialized diets were not specifically surveyed. In addition, smaller specialized subpopulations such as Native Americans or subsistence fishermen are not specifically targeted[16]. Overall, however, the dietary information which OPP used for the cumulative assessment of NMC pesticides is the highest quality data available and is representative of many subgroups in the U.S. population. The consumption data available from the CSFII 1994-96/1998 provide a reasonable basis for estimating NMC food exposure for the subpopulations surveyed.

b. PDP Monitoring Data in the Assessment

USDA PDP data are used for all of the measured pesticide residues in the revised NMC CRA. PDP samples fruits, vegetables, juices, meats, grains, and dairy products at central distribution centers and warehouses immediately prior to distribution to supermarkets or grocery stores. The samples are washed and inedible portions (e.g., cores, peels, etc.) are removed prior to analysis. PDP data, thus, closely reflect residues in foods, as consumed. OPP has applied factors, where available, to the PDP data to account for cooking and processing that might further reduce residues (e.g., cooked potatoes, canned beans). Thus, pesticide residue data used directly from PDP or adjusted with processing factors accurately represent pesticide concentrations to which consumers are exposed.

The use of PDP as a source of residue data has a number of inherent benefits that minimize the need to incorporate conservative assumptions in the assessment and produces more realistic exposure estimates. The PDP sampling design and procedures provide OPP with a nationally representative sample of selected food commodities available to the U.S. population in grocery stores. OPP assumes a uniform distribution of these food commodities across the U.S. While the assumption of nationally uniform distribution of foods does not reflect highly localized consumption events that may be occur as a result of individuals obtaining foods at road side stands or local farmers markets and consuming it closer to the time of harvest than the foods available in larger grocery stores, it is believed that only a small percentage of food consumed is actually obtained from these sources and would be affected by this assumption.

[16] Although populations that rely primarily on fish consumption were not specifically targeted in CSFII, available residue data indicate that fish consumption is not a major source of pesticide exposure for currently registered pesticides in general, nor NMCs in particular.

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In addition, as noted above, PDP uses multi-residue methods and so provides a direct measure of the co-occurrence of multiple pesticides in each sample analyzed. Thus, the PDP data inherently reflect existing use patterns of pesticides. Given the size, scope, quality, and breadth of the PDP sampling program, these data provide the best available information regarding pesticide residues in the U.S. food supply.

c. Data Translation from PDP

Not all food commodities treated with NMC pesticides are monitored in PDP. OPP has developed a procedure by which commodities that are sampled by PDP serve as surrogate data sources for some commodities that are not. This approach is outlined in OPP/HED SOP 99.3 (USEPA, 1999b). It is based upon the concept that families of commodities with similar cultural practices and insect pests are likely to have similar insecticide use patterns. Although this approach is generally sound, it introduces uncertainty with regard to how similar the use patterns for a given pesticide are to those for even closely related commodities.

For example, the same pesticide may be applied to several crops belonging to the same crop group (or family) on a similar time schedule. However, the application rates and/or the number of treatments may differ between the treated crops. Such issues should be taken into consideration when conducting sensitivity analyses of the results of the risk assessment. When such translations are done in a cumulative risk assessment, the assumption of similar agricultural practices is inherently applied to all the pesticides in the cumulative assessment group and the co-occurrence of pesticides on the surrogate commodity is extended to the commodities to which the residues are being translated if the translated commodity is a registered use. Whether any such potentially inappropriate translations overestimate or underestimate exposure will differ from one commodity to another. However, the impact of any such potential translation errors on total exposure is not likely to be significant since the commodities for which PDP data were translated represent less than 1% of the mean per capita consumption by small children.

d. Other Sources of Residue Data

The PDP program provides pesticide residue data for a variety of fruits, vegetables, juices, meats, grains, and dairy products. Never-the-less, PDP data -- and its associated surrogate data for translated commodities -- still do not cover all food commodities of interest. For example, PDP does not currently include data for seafood and eggs; for these commodities, FDA's Total Diet Study and FDA Monitoring data were reviewed. No NMC residues were found in seafood or eggs in either of these programs. Thus, the analytical results suggest that eggs and seafood contain negligible residues of NMCs and OPP used a zero to represent NMC pesticide concentrations in these

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commodities. OPP considers this factor neutral with regard to the impact on the results of the assessment.

Approximately 3% of the foods consumed by children 1-2 years of age still remains unaccounted for after considering the PDP data, the FDA Total Diet Study data, and the FDA surveillance monitoring data. This includes sugar, molasses, and various oils and syrups which were assigned a residue value of zero. Evidence suggests that these commodities would have *de minimis* pesticide residues. These products are highly processed commodities that are unlikely to retain any significant residues following the intensive commercial processing they undergo. PDP has sampled high fructose corn syrup during 1998 and 1999 and did not find residues of any pesticide. PDP has also sampled field corn during the 2006-2007 period and only found one sample containing an NMC pesticide (carbaryl) at a very low (ppb) concentration. The limited data from the Total Diet Study found no residues in pancake syrup or sugar. OPP believes that the assumption of zero residues for highly processed commodities such as those described above will not result in a significant under-estimation of exposure to NMC pesticides from food for children or any other subpopulation.

No data are available for commodities such as dried beans, spices, seeds, nuts, and low consumption specialty crops (such as avocado, kiwi, raspberry, and mango). OPP believes that the omission of various low consumption and specialty foods from the assessment will not significantly under-estimate exposure to NMC pesticides from food for children or any other subpopulation.

e. Impact of Regulatory Actions

There has been significant mititgation measures implemented on many NMCs as a result of the individual chemical decisions, including canceling uses, lengthening pre-harvest intervals, and reducing the number and/or application rates. As a result, during the period since the issuance of the preliminary NMC CRA in August 2005, the Agency has identified, and in some cases imposed, risk reduction measures on some of the major contributors to carbamate cumulative risk, as discussed below. The risk estimates presented in the revised NMC CRA reflect the risk mitigation measures identified for or taken on individual carbamates since FQPA was signed into law in August 1996. A table summarizing these mitigation measures is provided in Appendix II.A. These mitigation measures generally reflect determinations of risk based on EPA's assessment of the single chemical's risks. For all of the risk mitigation measures that are reflected in this document, EPA has either commenced the processes necessary to implement its selected risk mitigation or intends to commence the appropriate processes in the near future. Having already determined that the identified risk mitigation is warranted for the individual chemical regardless of the cumulative assessment, EPA has chosen to reflect that mitigation in this assessment, and consequently has excluded uses that are

slated for cancellation from this assessment.[17] More specifically: in cases for which agreements have been signed or voluntary cancellations are being implemented or have been requested by the pesticide registrant, the uses have been excluded from the assessment. Examples include use of methomyl on strawberries and grapes. In addition, EPA has excluded all uses where specific mitigation measures such as cancellation have been identified and proposed based on single-chemical risk assessments. For example, EPA has excluded all carbofuran uses from the cumulative assessment except the few import tolerances that the Agency is not proposing to revoke. (See Chapter I.A for additional details regarding the specific cancellation actions that have taken place.)

For other pesticides, pre-harvest intervals have been extended or application rates have been reduced. For example, pesticide use labels for commodities such as apples, peaches, pears, potatoes, nectarines, oranges, and strawberries were modified at various times in the past several years to reduce residues of a number of NMCs such as aldicarb, carbaryl, and formetanate HCl. To reflect the impact of these risk mitigation measures, EPA used residue data only from years after the measures had been implemented (i.e. the more recent years that reflect the changes in pesticide use practices). PDP data from prior years – that reflect older, discontinued use patterns – were not included. To the extent that the impacts of risk mitigation measures on residue level are not yet apparent in the available PDP monitoring data, the PDP residue data will not reflect the expected decrease in exposure and the assessment likely overestimates risk on this basis.

f. Impact of Assumptions: Sensitivity Analyses

The following section describes sensitivity analyses conducted on the cumulative food assessment. These analyses focus on four areas:

- Limit of detection in PDP and the use of 'zero' assumption for non-detectable residues;
- Comparison of exposure estimates using all available PDP data deemed appropriate for the CRA with those using only the PDP data from recent years;

[17] As a practical matter, EPA determined that it would serve no purpose to include such uses in the cumulative assessment. Other than by adding a new issue that might delay action, adding these uses would not likely have any impact on the timing or substance of any cancellation decision relating to such uses. Given that the purpose of tolerance reassessment is to determine whether regulatory action should be initiated to modify or revoke tolerances that the Agency finds do not meet the safety standard of section 408, there seems to be little value in including uses in the assessment that will disappear regardless of their impact on cumulative risk; the critical issue for determining whether regulatory action will have to be initiated under section 408 is whether the uses that will remain result in unacceptable dietary risk. EPA recognizes, however, that to the extent that any risk mitigation measures are not subsequently implemented as envisioned in this assessment, the N-methyl Carbamate cumulative assessment will have to be revised as necessary.

- Summation of exposure over 24 hours instead of smaller time increments or individual eating events that would better account for rapid reversibility on NMCs; and

- Consideration of a chemical-specific adjustment factor approach for the inter-species extrapolation factor

Each of these sensitivity analyses is discussed below.

i. Limit of Detection in PDP: Use of 'zero' assumption for non-detectable residues

One of the important attributes of a cumulative risk assessment is that its scope and complexity, unless carefully considered, can potentially lead to inflated estimates of risk due to compounding conservatisms which would reduce the interpretability and ultimately the utility of the assessments. When little or no information is available to inform potential sources of exposure, a single chemical assessment may incorporate conservative assumptions to reflect reasonable worst case exposure estimates. In cumulative risk assessments, the incorporation of such conservative assumptions would imply multiple *simultaneous* reasonable worst case exposure estimates for each individual chemical. As such, some of the conservative assumptions appropriately used in the single chemical risk assessments are not appropriate or reasonable for use in a cumulative risk assessment.

One example is the way in which assumptions for single chemical versus cumulative (multiple) chemical assessments differ for PDP samples with no detectable residues. For any analytical method, there is a minimum concentration at which a compound must be present in order for it to be reliably detected in the sample. This minimum level is referred to as the analytical method's limit of detection (LOD). With respect to a specific pesticide, a sample having no detectable residue (i.e. a residue below the LOD) is referred to as a non-detect. A non-detect does not necessarily imply that no residues are present; instead, a non-detect simply indicates that residues, if present, are present at concentrations less than the LOD. In single chemical assessments, certain non-detects are assumed to be present at one-half the LOD of the analytical method (more specifically: those non-detects for which percent crop treated information suggests were actually treated with the pesticide of interest). In contrast, *all* PDP samples with non-detectable residues are assumed to be "zero" for this and other cumulative risk assessments. Although the result of replacing all non-detectable residues with "zero" values might intuitively suggest a bias toward under-estimation of risk, OPP has conducted a sensitivity analysis and determined that this assumption has little impact on the upper end of the exposure distribution for the NMCs covered by this assessment and upon which EPA has based its regulatory decisions. The most highly exposed individuals tend to be associated with relatively high consumption of high

residue values, not residues below PDP's limits of detections. The details of this sensitivity analysis are provided below.

The sensitivity analysis is presented in Table I.G-1 and indicates that assuming residues of one-half LOD for all non-detects of the most frequently detected NMC pesticide on each commodity increased the estimated exposure by 4.2% for both groups of children ages 1-2 and 3-5 years at the 99.9th percentile.

Table I.G-1. Sensitivity Analyses for NMC Cumulative Food Assessment: Limit of Detection Assumption[a]

Age Group		Estimated Exposure at the 99.9th Percentile (mg/kg oxamyl equivalents)	MOE at the 99.9th Percentile	Percentile at which Target of 10 is Reached
Baseline CRA	Children 1-2	0.0229	7.9	99.848th
	Children 3-5	0.0209	8.6	99.870th
LOD of PDP: Replace 0s with one-half LOD	Children 1-2	0.0238	7.6	99.833th
	Children 3-5	0.0217	8.3	99.859th

[a] The sensitivity analyses performed here in the CRA with the LOD differ from those that are typically performed for LOD values in the single chemical assessments in two ways: (1) rather than assuming that every chemical in the assessment group is present on the non-detect samples, only the most frequently detected chemical on each commodity is assumed to be present at one-half the LOD. The rationale behind this approach is that the most commonly detected pesticide on each commodity is likely to be the most widely used pesticide on that particular commodity and thus most likely to be present at level lower than the PDP LOD; and (2) in contrast to single chemical assessments for which only treated commodities are assigned one-half LOD values, all non-detect samples of a particular commodity are given a value of one-half the LOD rather than only some of the non-detects in the cumulative assessment.

As can be seen from the baseline analysis using zero residues for all PDP non-detect data, the calculated MOEs at the 99.9th percentile of exposure are 7.9 and 8.6 for children 1-2 and 3-5, respectively, with MOEs reaching the target of 10 at the 99.848th and 99.870th percentiles of exposures[18], respectively. After replacing the zero values with one-half LOD values in the manner described above, the calculated MOEs at the 99.9th percentile of exposure decrease to 7.6 and 8.3 for children ages 1-2 and 3-5 years, respectively, with MOEs reaching the target of 10 at the 99.833th and 99.859th percentiles of exposures, respectively. This indicates that the use of zero for PDP non-detect data has only a minimal effect on estimated high-end exposures. The results of this sensitivity analysis are not unexpected:

[18] In this table --and all subsequent tables which provide summary information regarding the Agency's sensitivity analyses -- EPA has elected to express exposures to three significant digits and percentiles at which the target MOE of 10 is reached to 5 digits. The Agency fully recognizes that its exposure assessment tools are insufficient to produce this level of precision, but has chosen to display the results of its sensitivity analysis to this level in order to more effectively illustrate the changes that occur in the CRA when assumptions or other input parameters are modified. The reader should note that any perceived differences in exposure or risk at this level are well beyond the ability of the Agency to measure or detect.

generally, the LODs for PDP data are very low (the average LOD for the entire data base is about 0.01 ppm) and the vast majority of exposures at the upper percentiles are derived from detectable residues in a single commodity rather than from multiple commodities having one-half LOD residue values. Therefore, it seems reasonable that the effect of assumptions related to estimation of values below the LOD would not significantly influence exposure estimates at the highest percentiles of exposure and this sensitivity analysis has demonstrated that the manner in which non-detects are handled in the dietary assessment does not significantly impact exposure estimates of the most highly exposed children.

ii. Use of Recent PDP Data Only

As described above, PDP data provide a critical component of the cumulative food risk assessment as this database provides reliable residue data for commonly consumed commodities sampled near their point of sale. As such, the PDP data provide a realistic estimate of pesticide residues actually consumed by the public. Except in cases where the Agency has mitigated exposures through modification of pesticide labels, has cancelled uses, and/or has revoked tolerances, essentially all available PDP data (1994-2006) have been used in the revised NMC CRA.[19] The practice of incorporating all available PDP data is consistent with previous preliminary, revised, and updated cumulative risk assessments conducted by the Agency, including the OP CRA (USEPA, 2006a). Use of all relevant data takes advantage of more samples, and thus more data, for use in the Monte Carlo simulations. Moreover, incorporation of a wide range of years of PDP data may better capture the typical and ever-present transient shifts in pesticide use practices due to temporal variations in weather and/or pest pressures. Any of these changes may ultimately result in higher or lower pesticide residues or an increased or decreased frequency of residues found in food. On the other hand, it is possible that PDP data that are older than five years may not best represent current agricultural practices and expected dietary exposures. For example, changes in the pesticide market resulting in less expensive or more effective alternatives and/or gradual decline or shifts in use due to pesticide resistance may make older PDP pesticide data less representative of current and (expected) future conditions than more recent data (e.g., within 5 years).

To evaluate the degree to which changes in pesticide use practices over time may or may not have affected the estimated exposures and risks, OPP performed a sensitivity analysis in which only the most recent PDP data (2002-2006) were used. Specifically, OPP ran a second, supplemental analysis which used only the last five years of PDP data (except for a few commodities like frozen green beans, grape juice, and fresh cherries that were not sampled in any year from 2002 to 2006) instead of using all PDP data (1994-2006) that defines the baseline. The purpose of this analysis was to determine if the elimination of earlier (pre-2002) PDP data -- which might be considered less

[19] For reasons described in the food chapter, PDP data from 1992 and 1993 were not used.

typical of current use patterns and practices -- would significantly affect the exposure and risk estimates. The details and results of this sensitivity analysis are provided in Table I.G-2.

Table I.G-2. Sensitivity Analyses NMC Cumulative Food Assessment: Recent PDP Data Assumption

Age Group		Estimated Exposure at the 99.9th Percentile (mg/kg oxamyl equivalents)	MOE at the 99.9th Percentile	Percentile at which Target of 10 is Reached
Baseline CRA	Children 1-2	0.0229	7.9	99.848th
	Children 3-5	0.0209	8.6	99.870th
Recent PDP Data Only	Children 1-2	0.0185	9.8	99.895th
	Children 3-5	0.0170	10.6	N/A

As can be seen in this table, the calculated MOEs at the 99.9th percentile of exposure are 7.9 and 8.6 for children ages 1-2 and 3-5 years, respectively, using all relevant PDP data (1994-2006). MOEs reach the target of 10 at the 99.848th and 99.870th percentiles of exposures for children ages 1-2 and 3-5 years, respectively. When using only the most recent PDP data (2002-2006), the calculated MOEs at the 99.9th percentile of exposure are 9.8 and 10.6 for children ages 1-2 and 3-5 years, respectively, with the MOE for children 1-2 reaching the target of 10 at the 99.895th percentile of exposure. The results of this sensitivity analysis suggests that EPA has not significantly underestimated – and may have overestimated -- exposures by using all years of PDP instead of only the most recent years. To the extent that the most recent years of PDP data are more representative of present and future-expected exposures, an MOE of 10 was reached at the 99.895th percentile for children 1-2 and were greater than 10 for children 3-5.

iii. Summing food exposures over 24 hours

Another key principle in cumulative risk assessment is the proper matching of duration of the toxic effect (What is the time to peak effect? What is the time to recovery?) and the duration of exposure (When do exposures occur? How long or how often do exposures last? Do exposures overlap?). As described in Chapter I.B, the nature of NMC toxicity is rapid onset (typically 30 min to 1 hour) followed by rapid recovery (one-half life to recovery is typically approx. 2 hours). Conceptually, a robust multi-chemical, multi-pathway PBPK or PBPK/PD model would be ideal to account for the timing of environmental exposure(s) and the timing for AChE inhibition and recovery. However, at this time, such a model is not available. In lieu of such a model, EPA has used the RPF method to quantify chemical potency. In this assessment, each NMC was converted into units of the index chemical, oxamyl. The probabilistic exposure models (DEEM-Calendex, Lifeline, SHEDS) used in this assessment sum

exposures to oxamyl equivalents over 24 hour periods. These models do not allow the typical user to separate exposures into time steps smaller than 24 hours or to separate exposures by exposure events (i.e., breakfast, lunch). Due to the rapid recovery associated with NMC toxicity, 24 hour exposure periods may or may not, *a priori*, be appropriate. More specifically, to the extent that a day's eating occasions leading to high total daily exposure are close together in time or occur from a single eating event, the approach used in this revised assessment which sums eating events over a 24 hour period provides reasonable estimates of risk from food. Under this assumption, minimal AChE recovery would occur between eating occasions (i.e., exposure events) since exposure events are assumed to occur close together. Conversely, if eating occasions leading to high total daily exposures are widely separated in time (within one day), then substantial AChE recovery would occur between eating occasions and the estimated risks in the cumulative risk assessment could be overstated.

In the absence of a fully developed PBPK model and in the absence of probabilistic exposure models that can evaluate exposure durations shorter than 24 hours, OPP began an examination of the exposure patterns for food records from the high end of exposure distribution with the case study presented to the SAP in February, 2005 and followed this work in a presentation of the preliminary NMC CRA to the SAP in August 2005. OPP acknowledged this aspect of the limitations in the currently available probabilistic food exposure models and these early exercises were an attempt at determining the degree to which high-end food exposures in the NMC CRA could be attributed to specific eating occasions (within a day) that may (i) occur closely spaced in time, (ii) occur widely separated by time, or (iii) come from single eating events. This was done by looking at actual individual eating occasions as recorded in the USDA's CSFII. The records in the CSFII capture detailed information not only about the identity and amount of foods consumed, but also about the timing of each eating occasion within a 24-hour period; it was these consumption diary records that were examined for those survey respondents at the upper end (99.8th to 100th percentile) of the exposure distribution. To the extent that a day's eating occasions leading to high total daily exposure might be found close together in time or to occur from a single eating event such that minimal AChE recovery occurs between eating occasions (i.e., exposure events), the "24 hour sum" approach, which sums eating events over a 24-hour period, would provide reasonable estimates of risk from food. To the extent that eating occasions leading to high total daily exposures are widely separated in time such that substantial AChE recovery occurs between eating occasions, the estimated risks under any 24 hour sum approach may be overstated and a more sophisticated approach – one that accounts for intra-day eating patterns and the recovery of AChE between exposure events -- may be more appropriate.

The updated analyses described here as part of this revised NMC confirms EPA's prior analysis that daily exposures to NMC pesticides in the upper extremes of the distribution (99.8+ percentile) for exposures from food

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mainly involve single eating events. Specifically, OPP found that a large fraction (~80%) of daily records for children 1-2 and children 3-5 years old contributing to the upper tail of the food exposure distribution represent single eating occasions. Less than about 3% of these upper-end diary records result from exposures that are divided among three or more eating occasions. (Figures I.G-1& I.G-2).

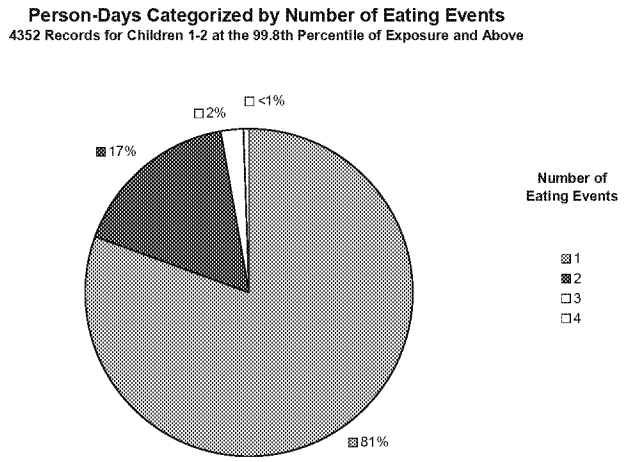

Figure I.G-1. Number of Eating Events Contributing to Exposures at 99.8+ Percentile for Children 1-2

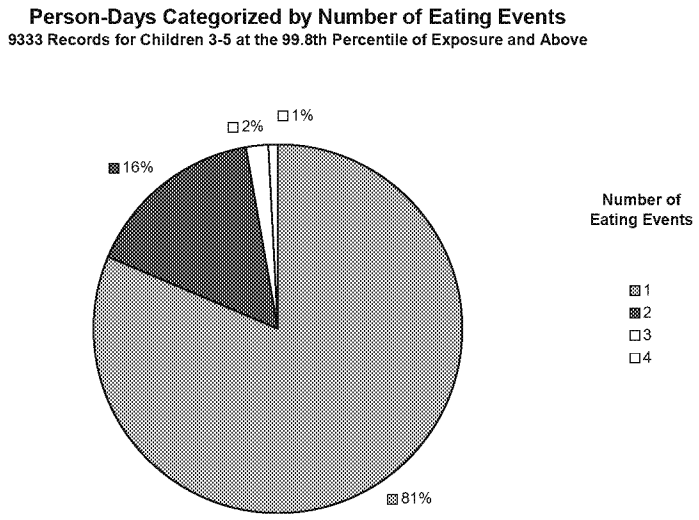

Figure I.G-2. Number of Eating Events Contributing to Exposures at 99.8+ Percentile for Children 3-5

These pie charts represent exposures from the 99.8th to 100th percentile of exposure distribution, use PDP data through 2006, and exclude eating events that contribute small amounts (<10%) of total daily exposure. Similar pie charts

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representing PDP data through 2004 were presented to the SAP in February 2005 as part of the NMC Case Study and August 2005 as part of the preliminary NMC CRA. At these SAP meetings, EPA concluded and the SAP agreed that since most food exposure to NMCs occurred in a single eating event, a more sophisticated, temporal-based approach which evaluated food exposure patterns throughout the day was not warranted.

As part of the risk characterization phase of this revised NMC CRA, the Agency has further refined its assessment of within-day consumption of food and used a second approach to characterizing the effect of eating occasions with respect to the timing of exposure events. In this second approach, OPP worked collaboratively with ORD's National Exposure Research Laboratory (NERL) to use the SHEDS (Stochasistic Human Exposure Dose Simulation) model to evaluate the impact of rapid AChE recovery on estimates of food exposure. Specifically, the ORD SHEDS model was used to bound the maximum extent to which accounting for NMC reversibility could potentially reduce estimates of exposure. The SHEDS model provides the user with greater ability to perform "what if" analysis, particularly with respect to dietary consumption data which is hard-coded in DEEM and the other dietary exposure models. This greater ability to specify the use of specific dietary records affords the risk assessor the ability to select specific eating occasions to include in the assessment. With respect to investigating the effect of NMC half-lives on exposure estimates, this capability permitted the Agency to exclude -- from each individual CSFII food consumption record -- all eating events resulting in NMC exposures *except the eating event resulting in the largest exposure to each individual*. Here, all other eating events were assumed to result in zero exposure and only the eating event associated with each individual's maximum exposure was retained. This is equivalent to assuming an infinitesimal half-life for all NMCs (i.e., complete and instantaneous recovery) and provides a bounding estimate that demonstrates the maximum theoretical effect that quantitative incorporation of half-lives could have on exposure estimates. The results of this bounding exercise are shown below in Table I.G-3.

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Table I.G-3. Sensitivity Analyses NMC Cumulative Food Assessment: 24 Hour Food Summation

Age Group		Estimated Exposure at the 99.9th Percentile (mg/kg oxamyl equivalents)	MOE at the 99.9th Percentile	Percentile at which Target of 10 is Reached
Baseline CRA	Children 1-2	0.0229	7.9	99.848th
	Children 3-5	0.0209	8.6	99.870th
Summing Exposure over 24 Hours	Children 1-2	80% of individuals at the 99.8th percentile of exposure and above were due to exposures from one eating event		
	Children 3-5			
	Children 1-2	0.0220	8.2	99.86th [a]
	Children 3-5	0.0196	9.2	99.88th [a]

[a] These percentiles are reported to only four significant digits: these are produced by the ORD SHEDS model and only reported to two decimal places

This bounding exercise reduces exposure at the 99.9th percentile by no more than about 3-9% depending on age group. For 1-2 and 3-5 year old children, exposure estimates are reduced by 6% and 7%, respectively. MOEs would be expected to change in a similar (proportionate) manner.

As described above, two approaches have been used to evaluate the extent to which the Agency's 24-hour approach to food risk assessment overestimates risk from the NMCs. The results of both approaches indicate that the cumulative risk to NMCs is indeed not substantively overestimated using the current exposure models and the 24-hour approach. This is due to the fact that exposure to NMCs occurs predominantly through single eating events and not from multiple events that occur throughout the day. Based on these analyses, the Agency concludes that the current exposure assessment methods used in the revised NMC CRA provide realistic and high confidence estimates of risk to the NMCs through food.

iv. Consideration of Chemical Specific Adjustment Factor Approach for the Inter-species Uncertainty Factor

The Agency has applied a 10X factor for inter-species extrapolation in the NMC cumulative risk assessment for those NMCs without human studies. This 10X factor is consistent with typical Agency practice for most single chemical and cumulative risk assessments. The following text describes a sensitivity analysis employing an alternative approach used by the WHO for performing inter-species extrapolation.

In 2005, the WHO published its guidance for deriving chemical specific adjustment factors (CSAFs) (WHO, 2005). This CSAF guidance describes approaches for use of kinetic and mechanistic data to refine inter-species and

intra-species extrapolation factors. The International Programme on Chemical Safety (IPSC) guidance is based in large part on analyses by Renwick (1993) and Renwick and Lazarus (1998) which describe the use of toxicokinetic and toxicodynamic data as a means of replacing the traditional 10-fold safety factors for human sensitivity and animal-to-human extrapolation. Although EPA does not yet have guidance for developing CSAFs, the Agency has used these concepts in a few risk assessments. One such example includes the recent risk assessment for dimethyl arsenic acid (DMA) where the available *in vivo* and *in vitro* mode of action and metabolism data supported toxicodynamic equivalence between rats and humans and thus the inter-species factor was reduced to 3X for DMA.

Understanding mode of action is an important component of deriving CSAFs in that it provides the foundation for understanding what toxicokinetic and/or toxicodynamic characteristics are critical for evaluating inter- or intra-species extrapolation. In the case of NMCs, the mode of action is well understood in both animals and humans. Specifically, in rodents and humans, NMCs cause neurotoxicity via the inhibition of AChE by carbamylation of the serine hydroxyl group located in the active site of the enzyme leading to accumulation of acetylcholine and ultimately clinical signs. As part of the risk characterization for the revised NMC CRA, the Agency has considered the extent to which available data support a CSAF-type approach for those NMCs without human toxicity studies. Regarding toxicokinetics, unlike many OPs, NMCs do not require activation; the parent compound is an active AChE inhibitor. Although some metabolites of NMCs have been shown to be active AChE inhibitiors, none have been shown to be more potent than the parent active ingredient. Thus, metabolism is considered to be a detoxification process. As such, species differences in tissue dosimetry are likely correlated with differences in body weight to the ¾ power and are also consistent with a 3X factor to account for inter-species differences in toxicokinetics (USEPA, 2006).

Regarding toxicodynamic characteristics, as noted above, the mode of action of NMCs is applicable to animals and humans such that inhibition of AChE leads to clinical signs of neurotoxicity. The AChE enzyme in humans and rats has similar function and structure. (See reviews by Radic and Taylor, 2006 and Sultatos, 2006.) The half-life to recovery values for rats and humans provided in Table I.B-9 range from approximately 1 to 2 hours and demonstrate the similarity of the half-lives of the two species. Based on this information, given a similar dose or concentration at the target site, it is likely that human and rat AChE would respond similarly. It may be possible to use *in vitro* studies using human and rat tissues and human and rat AChE to test this hypothesis. In other words, it may be possible to use *in vitro* studies to demonstrate toxicodynamic equivalence between rats and humans. If these data were available and they showed toxicodynamic equivalence, the Agency could reduce the inter-species factor for those NMCs without human toxicity studies to 3X. Because of the lack of these *in vitro* studies, the Agency does not believe it appropriate at this time to further refine the standard 10X factor for inter-species

extrapolation. Instead, the Agency has used the CSAF approach as a sensitivity analysis in its risk characterization.

The Agency also notes that *in vivo* studies with human subjects are available for three NMCs (aldicarb, oxamyl, methomyl). These studies were determined by EPA, after considering the advice of the Human Studies Review Board, to be ethically and scientifically acceptable for use in this risk assessment. The Agency has developed BMD estimates in rats and humans for RBC AChE inhibition. This analysis has shown that the ratio of the BMDs for rat/human ranges from 2 to 5 for these NMCs. This range would tend to support the CSAF approach described here to reduce the standard 10X inter-species factor to 3X as part of the sensitivity analysis in the risk characterization for those NMCs without human data and which make meaningful contributions to the cumulative risk.

In this sensitivity analysis, the 10X inter-species factor was reduced to 3X based on the assumption of toxicodynamic equivalence for carbaryl, carbofuran, and formetanate HCl. These three NMCs were selected as they contribute to the overall cumulative MOEs. The results of this sensitivity analysis are shown below in Table I.G-4.

Table I.G-4. Sensitivity Analyses NMC Cumulative Food Assessment: CSAF Approach for Inter-species UF

Age Group		Estimated Exposure at the 99.9th Percentile (mg/kg oxamyl equivalents)	MOE at the 99.9th Percentile	Percentile at which Target of 10 is Reached
Baseline CRA	Children 1-2	0.0229	7.9	99.848th
	Children 3-5	0.0209	8.6	99.870th
CSAF Approach for Inter-species UF	Children 1-2	0.0183	9.8	99.896th
	Children 3-5	0.0171	10.5	N/A

Using the standard 10X inter-species factor for all NMCs without human data, the (baseline) MOEs at the 99.9th percentile of exposure reach the target of 10 at the 99.848th and 99.870th percentiles of exposures for children 1-2 and 3-5 years, respectively as shown in Table I.G-4. However, when considering an alternative approach to the inter-species factor which assumes a 3X inter-species factor for carbaryl, carbofuran, and formetanate HCl, the MOEs at 99.9th percentile of exposure increase to 9.8 and 10.5 for children 1-2 and 3-5 years, respectively, with the exposure for the younger age group reaching the target MOE of 10 at the 99.896th percentile of exposures. [Note: because of the lack of key *in vitro* studies to confirm the assumption of toxicodynamic equivalence, the Agency did not believe it appropriate at this time to use a 3X factor for inter-species extrapolation in the baseline assessment. Instead, the

Agency has used the CSAF approach as a sensitivity analysis in its risk characterization.]

g. Model Outputs & Discussion

The food component of the NMC cumulative risk assessment was conducted using the DEEM software. This software program evaluates the full range of dietary exposures and permits a detailed evaluation of the source of exposures with regard to which foods and pesticides are the predominant sources of the exposure. The results of the food portion of the revised NMC cumulative risk assessment using baseline assumptions as wel as the various sensitivity analyses are summarized in Tables I.G-1 through 4 with detailed discussion of methods and approaches presented in Chapters I.C and I.G.

Table I.G-5 below presents a summary of the NMC Cumulative food assessment baseline MOE estimates and the percentiles at which the target MOE of 10 is reached.

Table I.G-5. Summary of NMC Cumulative Food Assessment: Baseline Estimates

Age Group	Percentiles of Exposure	MOE at the Selected Percentiles	Percentile at which Target of 10 is Reached
Baseline cumulative risk assessment			
Children 1-2	95	141	99.848th
	99	35	
	99.9	7.9	
Children 3-5	95	185	99.870th
	99	40	
	99.9	8.6	
Adults 20-49	95	1278	N/A
	99	236	
	99.9	42	
Adults 50+	95	1035	N/A
	99	193	
	99.9	40	

The results are presented in the form of MOEs for children 1-2 and 3-5 years of age and for adults 20-49 and 50+ years of age. MOEs at the 95th, 99th, 99.5th, and 99.9th percentiles of exposure are presented for each age group. Children 1-2 and 3-5 years old are consistently the most highly exposed subgroups in the analysis.

Due to the complex nature of cumulative risk assessments, it is important not to use any single point or any MOE estimate alone or in isolation. Each estimated MOE is derived from a combination of data from multiple sources that describe multiple areas of exposure or hazard. Each dataset and assumption used to derive the MOEs includes its own variability and uncertainty. Moreover,

some datasets contain more or less precision than others. As such, MOEs and the percentile of regulation are not "bright lines." The Agency has focused its sensitivity analyses on MOEs of 10 and the 99.9th percentiles of exposure as points of reference, not as required thresholds, values, or cut-points.

When developing any risk assessment, assumptions must be made in areas where data are not available; this is the also case for the NMC CRA. In the NMC CRA, the Agency has made health protective assumptions in its baseline analysis, particularly regarding which years of PDP data are most appropriate for use in the CRA and the inter-species extrapolation factors for those NMCs without human data. The sensitivity analyses shown and discussed here are designed to evaluate the degree to which key areas of the risk assessment under- or over-estimate the cumulative risk in an effort to characterize and understand the MOEs presented in this assessment. As described in detail above, the Agency has conducted four sensitivity analyses on the food assessment. The results of these sensitivity analyses were discussed earlier in this chapter and are summarized in Table I.G-6.

Table I.G-6. Summary of NMC Cumulative Food Assessment: Sensitivity Analyses.

Sensitivity Analysis	Age Group	Estimated Exposure at the 99.9th Percentile (mg/kg oxamyl equivalents)	MOE at the 99.9th Percentile	Percentile at which Target of 10 is Reached
1. Baseline CRA	Children 1-2	0.0229	7.9	99.848th
	Children 3-5	0.0209	8.6	99.870th
2. LOD of PDP: Replace 0s with one-half LOD	Children 1-2	0.0238	7.6	99.833th
	Children 3-5	0.0217	8.3	99.859th
3. Recent PDP Data Only (2002-2006)	Children 1-2	0.0185	9.8	99.895th
	Children 3-5	0.0170	10.6	N/A
4. Summing Exposure over 24 Hours	Children 1-2	80% of individuals at the 99.8th percentile of exposure and above were due to exposures from one eating event		
	Children 3-5			
	Children 1-2	0.0220	8.2	99.86th [a]
	Children 3-5	0.0196	9.2	99.88th [a]
5. CSAF Approach for	Children	0.0183	9.8	99.896th

Inter-species UF	1-2			
	Children 3-5	0.0171	10.5	N/A
Recent PDP Data only & CSAF Approach for Inter-species UF	Children 1-2	0.0160	11.3	N/A
	Children 3-5	0.0147	12.3	N/A
[a] These percentiles are reported to only four significant digits since they are produced by the ORD SHEDS model and only reported to two decimal places				

As can be seen, these four sensitivity analyses result in only minimal changes to the estimated cumulative exposure to the NMCs through the food pathway and did not result in meaningful changes in the associated MOEs. These results support the Agency's assumptions and findings that:

- residues below the LOD can be assumed to be "zero" for the cumulative risk assessment without underestimating to any substantial degree the cumulative risk to these pesticides. For children 1-2 and 3-5 years, MOEs reach the target of 10 at the 99.833th and 99.859th percentiles of exposure when the one-half LOD assumption is applied. These percentiles at which MOEs of 10 are reached are not meaningfully different from those under the Agency's baseline assumption.

- using only the most recent PDP data (as opposed to all relevant PDP data from 1994-2006[20]) does not result in substantive changes in exposure estimates or associated MOEs. For children 1-2 and 3-5 years, MOEs reach the target of 10 at the 99.895th and >99.9th percentiles of exposure respectively, when only the most recent PDP data is used. These percentiles at which MOEs of 10 are reached are not meaningfully different from those under the Agency's baseline assumption.

- the cumulative estimates of food exposure provided by summing exposure over 24 hours do not substantively overestimate cumulative exposure to food. Food exposure to NMCs most often occurs at one eating event such that incorporating recovery between eating events is not necessary.

- using the CSAF approach for the inter-species UF does not result in substantive changes in exposure estimates or associated MOEs. For children 1-2 and 3-5 years, MOEs reach the target of 10 at the 99.896th and >99.9th percentiles of exposure, respectively, when using the CSAF approach to adjust the inter-species UF from 10x to 3x for carbaryl, carbofuran, and formetanate. These percentiles at which a MOE of 10 is reached are not meaningfully different from those under the Agency's baseline assumption.

[20] The Agency has used all years of PDP except in cases where use patterns have been changed in the baseline analysis. Specifically, use patterns have changed for carbaryl, methomyl, formetante HCl, and carbofuran.

In addition, Table I.G-6 shows the combined impact of using only the recent PDP data and the CSAF approach for the inter-species factors on the cumulative food estimates. When evaluating these two aspects simultaneously, MOEs for all age groups, including children 1-2 and 3-5 years increase to 11 or greater.

The food risk assessment is considered highly refined and is designed to provide realistic estimates of exposure to NMCs. Some assumptions used in single chemical risk assessments have been removed in the CRA to prevent compounding conservative assumptions when assessing the combined risk to the 10 NMC pesticides comprising the cumulative assessment group. Even with the highly refined nature of this cumulative risk assessment, there are still conservative assumptions used in the baseline estimates of cumulative risk. The Agency has evaluated the effect of a number of these assumptions in its sensitivity analyses conducted for the food assessment and found that they result in only minimal changes to the estimated cumulative exposure to the NMCs through the food pathway and did not result in meaningful changes in the associated MOEs. Further, the Agency has a high level of confidence that the cumulative risks are not under- or over-estimated based on these results.

4. Residential Assessment

The residential component of the revised NMC cumulative risk assessment is a probabilistic assessment, which applies distributional analysis to residential exposure assessments. In addition to incorporating distributional analysis, the assessment also factors in the seasonal and regional aspects of pesticide use. Three types of data are used in the residential assessment:

- Pesticide use,
- Pesticide residue dissipation, and
- Exposure contact/human exposure factors.

Pesticide use data are used to determine the percent of households using a pesticide, the timing of the pesticide treatments, and frequency and duration of exposure. In the revised NMC CRA, all pesticide use data were based on pest pressures in the Southeast region of the U.S. While insect growth may slow during the winter months in the South, unlike other regions in the country, there is no period of dormancy. Residential exposure to pesticides is greatest in this region due to the longer periods of pest pressure. Consequently, this assessment as a whole is assumed to provide a worst case estimate of exposure.

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Pesticide residue dissipation data address the fate of the pesticides once applied to an environment (e.g., lawns). Exposure contact data are exposure-specific metrics that relate human exposure to pesticide residues. Humans come in contact with the residues by contacting the product directly or by contacting the residues left after the pesticide applications are made. Distributions of human exposure factors, such as the body weight assumption used in this assessment, come from the Agency's Exposure Factors Handbook (USEPA, 1997a). The exposure factors taken from the Agency's Exposure Factors Handbook have been previously characterized and are used throughout the Agency.

a. Pesticide Use Data

Accurate pesticide use data, including information on regional site/pest markets, timing of application and the percent of households using NMC products, are key to the residential risk assessment. In the absence of that specific pesticide use information, OPP developed residential exposure scenarios based on timing aspects found in survey data from the Residential Exposure Joint Venture (REJV), regional Cooperative Extension Service publications, and Doane's GolfTrak. While the REJV data contains a complete 12-month pesticide use diary for 1,217 household-users, use of these NMCs by homeowners is a relatively infrequent event, leading to relatively high uncertainty around the various pesticide use estimates. Additionally, the REJV did not collect information on the purpose of use (pest treated), areas treated, or application rates. Therefore, REJV data was used in combination with professional judgement, and product label and pest pressure information from the Cooperative State Extension Services to estimate application frequency and timing. Doane's GolfTrak was used to identify the percent of golf courses treated with pesticides. OPP believes this is a robust data source.

b. Pesticide Residue and Exposure Contact Data

i. Dermal Exposure

Applicator Exposure

Dermal exposure to pesticides may occur during application and post-application activities. Examples of application activities that might result in pesticide exposure include, but are not limited to, spraying liquid pesticide formulations on ornamental plants, or applying granular formulations to residential turfgrass.

The application of pesticides is one of the more straight-forward activity patterns to measure because it represents easily defined activities. As a result, dermal exposure contact data used to assess exposures during application of consumer-oriented pesticides are the most robust information used in the residential

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portion of this assessment. Recent data generated by ORETF have been used to assess the use of hose-end sprayers (lawn care products), rotary granular spreaders (lawn care products), and hand-pump sprayers (home gardens and orchards) and hand-held dusters (home vegetable gardens). Another study, submitted by a registrant, was also used to assess residential applicator exposure using granular shaker cans. All studies meet or exceed current Agency guideline requirements (in particular regarding the number of monitoring units) and can be extrapolated to include clothing scenarios ranging from short-sleeved shirts and short pants to long-sleeved shirts and long pants. OPP has high confidence in these data.

Post-Application Exposure

Examples of post-application activities that might result in pesticide exposure include, but are not limited to, weeding and harvesting home gardens, mowing and playing on lawns, and playing golf. There are several post-application dermal exposure scenarios addressed in this assessment. These are: post-application dermal exposure resulting from lawn care products, garden and home orchard products, pet collar products, and contact with treated golf courses.

Like the applicator scenarios, the post-application garden and home orchard exposure scenarios are easily defined. For harvesting vegetables or weeding, there is a substantial amount of data on farm worker exposures. These contact values have the potential to overestimate residential exposure, since they are based on activity patterns of individuals whose pay is based largely on their productivity. Professional harvesters are likely to be more efficient than most home gardeners, and therefore exposed to a greater amount of treated surface. Because home gardens consist of a wide variety of plants, the use of a uniform distribution of values represents activities as diverse as hoeing and harvesting. These values may overestimate early season activities that consist predominantly of potential exposure to small plants.

There are a variety of dislodgeable foliar residue data available for carbaryl. Dislodgeable residue data for sunflowers were used to assess the vegetable and ornamental garden scenarios, while olive tree dislodgeable data were used to assess the fruit tree scenario. These dislodgeable data were scaled in accordance with the label application rates for the carbaryl home garden and orchard products. Chemical-specific residue data for crops with foliage similar to those typically found in home gardens and orchards are expected to adequately represent residues found on home-grown ornamentals, fruit, and vegetables.

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Dermal exposure from post-application contact with lawn chemicals is varied. Contact data, representative of the range of human activities on lawns has been difficult to model.[21] Dermal contact exposure values were identified for adults who performed scripted activities (Vaccaro, 1996). Rates of transfer in the studies with surrogate compounds were similar to those observed in the chemical specific dissipation data available to OPP.

Granular turf transferable residue (TTR) data are available for carbaryl, the only chemical registered for residential lawn use considered in this assessment. These residue data were used to calculate post-application dermal exposure for the broadcast use of carbaryl on residential lawns. Because the current mitigation for carbaryl lawn products limits broadcast applications to granular formulations only, these data are expected to adequately estimate dermal exposures resulting from broadcast applications to the lawn.

The current assessment also addresses dermal post-application exposure for adults and teens playing rounds of golf on treated courses. Carbaryl liquid TTR data were used to assess risk for this scenario. Because golf course turf is intensively maintained (generally watered and mowed every day), these residue data are assumed to overestimate residues on treated golf course turf. The exposure contact factors used to estimate post-application dermal exposure are based on a few measurements from two studies that assessed golfer exposure. The exposure duration for individuals playing golf was assumed to be two to four hours per day based on information obtained from a 1992 survey conducted by the Center for Golf Course Management. These assumptions are expected to adequately estimate potential exposure for golfers.

The revised NMC CRA also considered exposures through the use of flea collar products for carbaryl and propoxur. Estimates of exposure for these scenarios were developed using an approach similar to the one taken with the turf care products. The dermal

[21] The August 2005 SAP recommended performing a sensitivity analysis to compare exposure estimates that result when distributions are entered both with and (then) without truncation of distributions that extend (at least theoretically) to infinity. More specifically, the preliminary NMC CRA that was presented to the SAP in September 2005 truncated any lognormally distributed input parameter at a high end percentile (99th) since values associated with higher percentiles were considered to be unrealistic. As part of this revised NMC CRA, OPP performed a sensitivity analysis to evaluate the impact of truncation on the residential scenario that was found to have the greatest influence on the NMC CRA results. Specifically, OPP utilized the full (untruncated) lognormal distribution for the transfer coefficient parameter to estimate dermal exposure to treated lawns. This full (untrucated) distribution extends to infinity implying no limit to how high the transfer coefficient can be. The results of this sensitivity analysis (not presented here) indicate that truncation at the 99th percentile in our baseline assessment had no significant effect on the results of the NMC CRA.

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contact factor(s) for post-application exposure is based on a shampoo and groomer exposure study for carbaryl in which each groomer shampooed the dogs, picked them up wet, and placed them into crates. The dogs were then dried and groomed. These activities are likely to result in higher contact factors than intermittent contact with a pet wearing a collar and thus provide a conservative estimate of exposure.

ii. Non-dietary ingestion

Toddler ingestion via hand-to-mouth activity was the only oral route of exposure considered in the residential portion of this assessment. Specifically, oral hand-to-mouth ingestion was considered only for children 1-2 and 3-5 years old for the lawn care and pet collar scenarios.

In the preliminary NMC CRA, the non-dietary oral exposure pathway produced the lowest Margins of Exposure (MOEs), and would therefore be of greatest concern to the Agency. These low MOEs were mainly due to the incorporation of micro-activity data into our macro activity models which are based on daily average activities (and thus use a daily time step). The non-dietary ingestion pathway was the least refined of the residential exposure pathways modeled in the preliminary NMC CRA. In the revised NMC CRA, OPP has modified the methodology used to assess this pathway. This refined methodology is based on comments and input from the FIFRA Scientific Advisory Panel, and the SHEDS and CARES developers.

The Calendex model used in the preliminary and the revised NMC CRA is a macro activity model. Specifically, this model simulates exposures by randomly drawing values for each of the various exposure factors (e.g., exposure duration, frequency of hand to mouth events, surface area of hand mouthed per event) then multiplying these values together per the OPP Residential Standard Operating Procedures algorithm (USEPA, 1997b). The distributions for many of these exposure factors were obtained from micro-activity data. For example, the distribution for frequency of hand-to-mouth events was based on data from observational studies in which all hand contacts were recorded as hand-to-mouth events, regardless of the fraction of hand mouthed. For the fraction of hand mouthed, no adjustment was made for the duration of time the hand remained in the mouth. Utilizing such micro-activity data with macro activity models poses many challenges. For example, if two variables are negatively correlated (e.g., more frequent mouthing is associated with smaller areas of hand mouthed), then "modeling the product of two jointly distributed variables as independent draws will overestimate the variances…or

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overestimate exposure at the high end." Similarly, "fixing the residue on a child's hands (and/or other exposure factors) for a two hour play period…will yield 'greater variability in the modeled distribution of exposures than a run that updates the residue concentration hourly during the exposure." (FIFRA SAP, 2005b).

The new algorithm establishes a maximum amount of residue that can be on the hand, or a maximum dermal loading. The amount of non-dietary oral ingestion increases with the exposure duration, the frequency of hand-to-mouth events per hour, and the surface area mouthed per event, while the hand loading serves as an upper constraint on oral ingestion between replenishment events. This approach is a refinement of the approach used in the preliminary NMC CRA and is better suited for assessing children's hand-to-mouth exposure in a probabilistic model.

The MOEs for all residential scenarios assessed in the NMC CRA were derived from a combination of data from multiple sources. The data sources used in the NMC residential assessment rely upon the best available data. However, each data set introduces possible uncertainties in the outcome of the exposure assessment. Post-application exposures from the lawn and pet uses are considered to be the most significant source of uncertainty in the residential risk assessment. A summary of these uncertainties and their direction and magnitude, is presented in Table I.H.1. The assumptions made in this assessment provide a reasonable, high-end estimate of cumulative exposure to NMC residential products. OPP is confident that the residential assessment is sufficiently conservative and will not underestimate exposure or risk.

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Table I.G-7. Input Parameters Used in the Exposure Models: Bias, Assumptions, Uncertainties, and Strengths

Model	Input Parameter	Exposure Bias	Assumptions, Uncertainties, or Strengths and Other Comments
Exposure Model for Residential Pathway	Human Activity Pattern	+ = upward ~ = neutral - = downward	
Lawn Exposure	Unit Exposure: push-type rotary spreader (mg exposure per amount of active ingredient applied)	+	Assumptions/Uncertainties This unit exposure value is based on 30 replicates consisting of individuals using a push-type rotary spreader. A number of clothing scenarios are possible to be generated from these data. In this assessment short-sleeved shirt and short pants were assumed. This may overestimate exposure as large portion of exposure is to the lower legs. Although a surrogate compound was used, exposure is believed to be more influenced by the type of equipment used rather being chemical specific. OPP has high confidence in these data. A lognormal distribution was used for the Unit Exposure (UE). Assumed gloves are not worn. Survey data do indicate that some residential handlers use gloves and thus this may overestimate exposure for these residential handlers. However, because consumers are unlikely to use, remove and care for PPE in the manner of professionals, it is unclear what impact this may have on actual use. The surrogate compound (dacthal) used in the exposure study may be dustier than the granular formulations of the NMC compounds assessed. This factor increases confidence that this variable will not underestimate exposure.
	Area treated (square feet)	- to ~	Assumptions/Uncertainties A difficult variable to estimate. However, the assumption is reasonable given the application equipment used. Although may underestimate areas that have larger lawns (Midwest), margins of exposure are large.

Model	Input Parameter	Exposure Bias	Assumptions, Uncertainties, or Strengths and Other Comments
Exposure Model for Residential Pathway	Human Activity Pattern	+ = upward ~ = neutral - = downward	
	Dermal Contact Transfer	~ to +	Adults: activities performed with tank tops and short pants, lognormal distributions may be reflective of study design rather than actual activities (choreographed) Children: Based above scripted activities study and adjusts transfer factors for differenced in body weight and surface area between adults and children. Assumes all adults and children living in households being treated with lawn care products are exposed (enter treated area).
	Turf Residues: dermal and hand-to-mouth	~	Chemical specific data for granular formulation of carbaryl.
	Frequency of hand-to-mouth events and surface area of hand mouthed	~	Based on analysis of the best available observational data (Xue et al, 2007).
	Duration on lawn	+	For children, the value used actually measured time spent outdoors and not just time spent on lawns. Does not account for survey responses of individuals that did not play on lawns or go outside.
Home Garden, Fruit Trees, and Ornamental Plants	Applicator: Hose-End Sprayer, Dust Shaker Can, Trigger Pump Sprayer, Handwand	~ to +	All UE data for these scenarios are chemical-specific. In this assessment short-sleeved shirt and short pants were assumed. This may overestimate exposure as large portion of exposure is to the lower legs and upper arms. Although a surrogate compound was used, exposure is believed to be more influenced by the type of equipment used rather being chemical specific. OPP has high confidence in these data. A lognormal distribution was used. Assumed gloves are not worn. Survey data do indicate that some residential hand

Model	Input Parameter	Exposure Bias	Assumptions, Uncertainties, or Strengths and Other Comments
Exposure Model for Residential Pathway	Human Activity Pattern	+ = upward ~ = neutral - = downward	
	Area treated: ornamentals	~ to +	Assumes all plants are treated around the perimeter of an average-sized house.
	Area treated: vegetables	~	A lognormal distribution of a well studied variable.
	Area treated: fruit trees	+	Assumes all fruit trees are treated with the maximum labeled application rate. Little data to determine actual area occupied by home orchard.
	Postapplication: vegetables/fruits	~ to +	Contact values represent a wide range of activities. All plants are assumed to be treated.
	Postapplication: fruit trees	~ to +	Based on olive dfr study data.
	Plant residues	~	Based on chemical specific DFR data.
Ornamental Snail/Slug Bait	Applicator: Granular	~ to +	This unit exposure is based on 15 replicates. Used study assessing exposure while treating shrubs which had higher unit exposures than for flowers. A lognormal distribution was used.
Pet Collars	Postapplication	~ to +	Dermal contact value from studies in which there was substantial contact. Assumptions for pet fur residues are based on the OPP's SOPs for Residential Exposure Assessment. Based on analysis the best available observational data (Xue et al, 2007).
	Duration	~	Based on data from the Freeman et al, 2001 (few replicates).
Golf	Post-application: Dermal Contact Transfer	~	The surrogate data used to derive transfer coefficients were based on two measurements of four individuals playing golf on two golf courses treated with chlorothalonil (Ballee, 1990), and the exposure of golfers (four volunteers) to flurprimidol (Moran et al., 1987).

Model	Input Parameter	Exposure Bias	Assumptions, Uncertainties, or Strengths and Other Comments
Exposure Model for Residential Pathway	Human Activity Pattern	+ = upward ~ = neutral - = downward	
	Duration	~	Estimate based on 1992 Golf Course Management Report, describing amount of time spent golfing.
	Turf Residues: dermal	~	Chemical specific data for liquid formulation of carbaryl.

5. Drinking Water Assessment

The regional drinking water exposure assessments are intended to represent exposures from vulnerable drinking water sources resulting from typical NMC pesticide usage. Each regional assessment focuses on areas where combined NMC exposure is likely to be among the highest within the region as a result of total NMC usage, adjusted for relative potencies, and vulnerability of the drinking water sources. The estimated drinking water concentrations for each scenario are not national numbers but are reasonable for people living in those vulnerable areas. For ground water, shallow private wells in highly permeable soil and vadose zone materials with acidic (pH < 7) soil and ground water are expected to be most vulnerable. For surface water, drinking water reservoirs in small, predominantly agricultural watersheds are likely to be most vulnerable.

Because the selection process took into account the relative potencies of the NMC pesticides, the sites used for the initial drinking water exposure estimates are biased toward the areas in which the more toxic NMC pesticides are used. Since the purpose of the assessment is to identify the impact from multiple NMCs occurring in water in the same area, the area(s) selected for the assessment do not necessarily represent the highest exposure of a single chemical, but rather the highest multiple NMC exposure within the region. Since pesticide use may vary from year to year and cropping and usage patterns may change, some areas in other parts of the region may have greater water exposure in a given year.

a. Ground Water Exposure

Based on monitoring studies, pesticide fate and transport properties, and model projections, the Agency believes that the highest overall cumulative NMC concentrations in drinking water sources will be associated with:

- **Shallow wells:** Concentrations will vary with varying depths to ground water and well depths. Higher concentrations would be expected in more shallow wells while lower concentrations would be likely in deeper wells.

- **High leaching potential soils and vadose zone:** Such soils are well-drained, highly permeable, and have low organic matter content.

- **Acidic soil and ground water:** Which favor the persistence of the NMC chemicals, which degrade more rapidly in neutral to alkaline pH conditions.

These conditions have been identified in some areas of the Delmarva Peninsula, the southeastern coastal plain, and Florida (primarily along the central ridge). Estimated NMC exposures in other NMC use areas underlain by less permeable soils or with neutral to alkaline soil and ground water are expected to be considerably lower. While areas of potential concern are illustrated in Figure I.E.7, it does not take into account localized conditions such as type and depth of well, local variations in soil/vadose zone permeability, or acidity/alkalinity of the ground water. It also can not account for the locations of private wells or the population that may be drawing their drinking water from such vulnerable wells.

The estimated NMC concentrations for these vulnerable wells are comparable to available monitoring data under similar conditions, particularly for aldicarb and carbofuran, which are the dominant NMC pesticides in ground water. High concentrations of these pesticides (including both the parent pesticide and degradation products) have been found in wells across the country where the pesticide use coincided with highly permeable soils, shallow ground water, and acidic conditions (summarized in Chapter I.E and Appendices II.E.2 and II.E.7). These detections led to voluntary label changes that restricted the use of those pesticides in some regions or placed conditions under which the pesticides could be used in some soils (for example, the well setback distances added to the aldicarb labels for certain soil and groundwater conditions).

Actual NMC concentrations in private wells may vary from the estimated concentrations as a result of a number of factors. Important conditions that may affect NMC residue levels in drinking water from private wells including depth to ground water, distance between the well and the field of application (setback distance), amount of NMC pesticide applied over time, and soil/vadose zone properties that affect the downward movement of water and pesticides.

i. Depth to ground water

EPA set the water table at 30 feet to represent a shallow private well, based on a number of sources (Berndt et al, 1998; McPherson et al, 2000; USGS, 1990; FL water management districts; monitoring study by Bayer CropScience reviewed by USEPA, 2007a). In the Bayer CropScience study, which surveyed wells in selected aldicarb use areas, 37% of the 800 wells sampled in the southeast (exclusive of Florida) had

reported groundwater depths <50 feet below the surface, with a total of 21% of the wells with reported depths <25 feet below the surface (however, the depth to groundwater was unknown for 45% of the sampled wells). Other factors, such as type of well construction, presence of casing, and depth to well screen will also influence the concentration of NMC residues found in the water. With deeper wells, travel time between the soil surface and ground water will increase, allowing more time for degradation in transit and lower concentrations.

EPA evaluated the potential impact of varying well depth on estimated NMC concentrations in groundwater in Appendix II.E.7. In the central ridge of Florida, estimated concentrations of total aldicarb residues and oxamyl ranged from an order of magnitude greater for wells at 15 feet to a factor of 2-to-4 times lower for wells at 50 feet. A similar range in concentrations was found for total aldicarb concentrations in the southern coastal plain (GA) scenario.

ii. Setback distances between the well and the treated field

For aldicarb, EPA simulated a setback distance between the well and treated field, based on the label specifications: 1000 feet for citrus in Florida; 300-500 feet for other uses in the other regional scenarios. The Agency evaluated the impacts of the assumed label setbacks in Appendix II.E.7. The conceptual model accounted for setback distances by increasing the travel time between the treated field and the well. The effect of the setback is based on the assumption of first-order degradation of aldicarb by hydrolysis during the extra travel time from the field of application to the well.

For aldicarb, a 300-foot setback distance reduced estimated concentrations by a factor of 2 while a 1000-foot setback distance reduced estimated concentrations by a factor of 20. Actual reductions will vary, depending on the direction and velocity of lateral groundwater flow in the field. The Agency does not have any monitoring data in similarly vulnerable areas with which to judge estimated concentrations. While the Bayer CropScience monitoring study showed some differences in frequencies of detection based on soil leaching potential, the study only identified distance between the well and the field, not the area of application.

The well setbacks only apply for certain high-leaching soils where groundwater is within 25 feet of the surface and the well is not cased. For other soils, no setback is specified.

iii. Hydraulic conductivity of the soil/vadose zone

The soils in the central ridge of Florida have very high saturated hydraulic conductivities. Less permeable soils and soils without substantial macropore flow are likely to result in lower than predicted concentrations because of the longer transport time.

iv. Soil/vadose zone and ground water pH

All of the NMC pesticides, except for the parent aldicarb, are susceptible to pH-dependent hydrolysis. Under acidic conditions (low pH), these chemicals persist; under alkaline conditions (high pH), they degrade rapidly. The estimated concentrations reflect acidic conditions. Where soils and water are neutral to alkaline, the concentrations are expected to be lower than those estimated for the preliminary assessment. In general, the soils and ground water in the ground water scenario locations in the NMC CRA – the Central Ridge of Florida, the southeastern Coastal Plain, and the Delmarva Peninsula – are expected to be acidic.

v. Other factors

Label changes for aldicarb, a major contributor to the NMC residue levels in ground water, made in the mid- to late-1990's were intended to reduce the amount of total aldicarb residues reaching ground water in vulnerable areas. These included well setbacks and some water management changes. While the Agency addressed well setbacks in the conceptual model, it did not explicitly account for recommended water management changes on the label. As noted in Chapter I.E, while the private well monitoring data from FL DEP, which analyzed water from the tap rather than from the well, indicate a reduction in total aldicarb residues detected in later years, interpretation of these results has been confounded because the state of Florida has also been placing carbon filters on the taps of those homes with aldicarb detections in well water.

The ground water exposure represents private drinking water wells. The Agency assumed in this assessment that, in general, public water supplies supplied by ground water will typically draw from deeper aquifers and/or aquifers that have a relatively impermeable layer between the surface and the water supply. Such supplies are expected to be much less vulnerable to pesticide contamination. Public water supplies have a higher probability of being treated, although conventional treatments processes are likely to result in little or no reduction of NMC residues in water. However, where lime softening, which will accelerate pH-dependent hydrolysis for all but parent aldicarb, or activated carbon

filtration is used, some reduction in NMC residues between untreated and treated water may occur (Appendix II.E.3).

b. Surface Water Exposure

The Agency does not expect cumulative NMC residues in surface water sources of drinking water to reach levels that will contribute substantially to the cumulative exposure. Estimated NMC levels in drinking water surface water sources from the coastal plain of North Carolina were greater than predicted for any of the other regional surface water exposure sites. When the drinking water component was combined with the food and residential exposure routes in the cumulative assessment, the highest seasonal exposures from surface water sources of drinking water were approximately an order of magnitude less than those estimated for food or for the total NMC exposure from all routes. For most of the year, predicted exposures from drinking water were much lower.

For the surface water sources of drinking water, OPP used PRZM/EXAMS to predict pesticide concentrations in a small reservoir. This modeling approach makes certain assumptions regarding the nature of the drinking water source, the watershed, and year-to-year variability.

The reservoir used for the exposure assessment is based on the specific geometry (watershed and reservoir size) of an actual reservoir (Shipman City) in the Midwestern US. As such, it is more representative of potential transport to similar drinking water sources in high rainfall areas such as the Midwest and Eastern U.S. than in the west.

PRZM is not a basin-scale model, but a field-scale model which estimates edge-of-field pesticide loads in runoff. It does not explicitly account for the relative contributions of each field to the reservoir. OPP used a cumulative adjustment factor (a combination of the regional percentage of the total watershed area in crops with carbamate uses and the percentage of acres treated by each carbamate on each crop) to adjust the resulting reservoir concentrations calculated by EXAMS (see USEPA, 2000b, for assumptions involved in applying percent crop area factors for drinking water assessments).

PRZM does not account for location in the watershed: all fields are assumed to be uniformly distributed within the watershed, with runoff going directly into the reservoir. Each crop use simulated in PRZM assumes that the entire area of the watershed planted in the crop consists of a single soil. In each of the regions, OPP used data from local soils on which the crops are grown. When possible, the soil selected for each scenario was a benchmark soil that was prone to runoff

(classified as hydrologic group "C" or "D" soils). While an assessment using a single soil assumes that each part of the watershed will be equally vulnerable to runoff, areas of higher and lower runoff vulnerability will exist in an actual watershed.

Because the application rates, frequencies, and timing are held constant, the PRZM/ EXAMS simulations over multiple years evaluate the impact of the variability in precipitation on the amount of pesticide that reaches surface water. Because weather data spanning 30 years is available for many locations across the country, PRZM/ EXAMS can account for pesticide runoff from a wide range of weather patterns not otherwise possible with monitoring studies that span relatively few years. The age of the weather data (1961 to 1990) limits OPP's ability to compare of the modeling output to more recent monitoring data.

Weather data files for PRZM are available for weather stations across the country. The weather station nearest to the county or counties used for the simulations was chosen for the cumulative assessment. To the extent that precipitation in these counties over the period of record might have been greater or less than that recorded at the nearest weather station, runoff for that area may have been over- or underestimated by PRZM.

c. Usage Information

Typical application rates and frequencies for each NMC pesticide on each crop were generated by taking the average (spanning multiple years) of agricultural chemical usage surveys. This assumes that all applications were made at this typical or average rate and that frequencies of applications were constant year to year. Using these typical application rates and frequencies may underestimate water concentrations in years when pest pressure is higher than in our reported years and may overestimate in years when lower amounts of pesticide are used. The usage data were generally not sufficient to conduct a probabilistic assessment over a distribution of actual application rates.

The Agency used typical application rates and acres treated for the NMC assessment because of a low likelihood that all of the NMC pesticides will be used at maximum rates on all of the crop acreage at the same time. In the case of citrus, which resulted in the highest estimated NMC residues in drinking water for this assessment (for private wells along the central ridge), the maximum label rate for aldicarb, the major contributor to total NMC residues, is 4.95 lb ai/A, while the typical rate used was 3.9 lb ai/A. Given that estimated ground water residues are expected to be proportional to the application rate, the total NMC residues for private wells in the central ridge of FL would

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be no more than 20 percent greater than that used in the exposure assessment. In the earlier OP cumulative risk assessment, the Agency compared cumulative OP concentrations in surface water estimated using the average application rates with those estimated using maximum label rates. Estimated peak exposures assuming maximum application rates for all pesticides ranged from no difference for the Florida region to 2 to 4 times greater in the Southeast and Mid-south Regions (USEPA, 2002b).

The typical application rates and percent acres treated are derived from state-level data and assume uniform use practices across the state. In actuality, an uneven distribution of application rates and percent acres treated is expected in response to differing pest pressures. Thus, this assumption will underestimate areas where pest pressures may dictate a higher percentage of acres treated in a given year; similarly, it will overestimate areas where low pest pressures will require fewer acre treatments.

d. Timing of Exposure

OPP used crop profiles and other relative crop production publications to establish a window for the application date of the pesticide on a particular crop. This window doesn't necessarily reflect the range over which a pesticide will be applied in a particular year, but captures the year-to-year variation in the application dates over time. Thus, in any given year, the timing of application may be clustered within a shorter time-frame than suggested by the application window. However, because of weather and other environmental factors, the timing of intensive pest pressure and/or pesticide application may vary across the window. Thus, while the time series estimated in the drinking water exposures show a definite time period of peak exposures for surface water sources, the actual time of that peak may vary by several weeks, depending on the size of the window of application. Because of the interaction of processes in subsurface transport, there is a damping effect in the concentrations observed in shallow groundwater. A slight seasonal pattern in ground water residue levels is evident in the ground water estimates, but the seasonal patterns in concentrations in ground water are less affected by timing of application.

The date of application can have an effect on the predicted concentrations generated by PRZM/EXAMS for surface water exposure, depending on how near in time the pesticide application coincides with rainfall events in any given year. OPP evaluated the impact of varying the dates of application across the application window on the OP cumulative distribution (USEPA, 2002b). The impact of varying dates of application was most evident at the extremes in the distributions. The ratio in maximum concentrations between the lowest and highest

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estimates was a factor of 5 to 6. For 99th and lower percentiles, the differences were not as dramatic, with the ratio between lowest and highest values generally two or less. This analysis only looked at the cumulative OP distribution and did not evaluate variations in individual chemical distributions. This analysis has not been conducted for the NMC cumulative.

In the absence of data to show otherwise, OPP assumed that all of the pesticide applied on a particular crop is done on the same date. While this may be an unreasonable assumption for a large watershed, it is not unrealistic for the size of the watershed or fields overlying shallow aquifers supplying private wells used in this assessment. This assumption may result in higher peaks for surface water, but similar overall average concentrations than if applications are spread out over time. The resulting estimate of exposure may result in a small overestimation bias in the results that will be greater in large than in small watersheds. Little change is expected for ground water.

6. FQPA 10X Factor for the Protection of Infants and Children

The FQPA (1996) instructs EPA, in making its "reasonable certainty of no harm" finding, that in "the case of threshold effects, **an additional tenfold margin of safety** for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account **potential pre- and post-natal toxicity and completeness of data with respect to *exposure* and *toxicity* to infants and children**." Section 408 (b)(2)(C) further states that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." The following discussion synthesizes information discussed in previous sections of this characterization and information from the hazard, food, water, and residential chapters of the NMC CRA to inform FQPA 10X factor for infants and children. Overall, the Agency believes that there are quality data and scientifically supportable methods to account for specific exposure and behavioral patterns of children. Because characteristics of children are directly accounted for in the exposure assessment and the Agency's methods are not expected to underestimate exposure to NMCs, evaluating the potential for increased toxicity to juveniles is the key component in determining the magnitude of the FQPA factors in the CRA.

The previous sections of this risk characterization describe the data sources and models used to generate the food, drinking water, and residential exposure assessments. Overall, there is a high degree of confidence in the exposure data and methodologies used when assessing cumulative risk to children from food, drinking water and

residential exposure. The cumulative exposure assessments are considered to be protective of children and do not understate risk. As such, the Agency has focused its evaluation of the FQPA 10X safety factor on post-natal exposure to juvenile rats.

Comparative cholinesterase studies with post-natal exposures have been shown to provide more sensitive results than DNT studies or from studies using *in utero* only exposures. Thus, comparative cholinesterase studies have been identified for use in the cumulative risk assessment as the most appropriate studies for developing the chemical-specific factor to address the potential susceptibility of infants and children to the effects of NMC exposure. Data from comparative cholinesterase studies have been used to refine the FQPA safety factor for aldicarb, carbaryl, carbofuran, formetanate, methomyl, and oxamyl. For those NMCs (methiocarb, pirimicarb, propoxur, thiodicarb) without such data, the FQPA 10X safety factor is retained. The Agency believes that the refined FQPA factors are protective of infants and children in that high quality data from sensitive populations were used. Moreover, the methods used to perform dose-response have been peer-reviewed multiple times. These methods provide a quality statistical fit to the toxicity data in juvenile and adults.

7. Physiologically-Based Pharmacokinetic Models

PBPK models, which describe the time course disposition of chemicals and their metabolites, could help assess cumulative risk and to evaluate the relationship between variable environmental exposures and dynamic biological processes. Appropriate PBPK models could quantify the cumulative toxicity that can result from multiple exposures (multiple chemicals and multiple pathways) and from exposure to multiple chemicals with a common mechanism or mode of action. While these models are excellent tools, numerous input parameters are necessary for each chemical. Organ-specific thermodynamic parameters (such as tissue to blood equilibrium partition coefficients) are required for each pesticide entering the body and for each of its metabolites. Additionally, values for all of the metabolic rates governing all the biotransformation steps for each pesticide would be necessary as would information on cholinesterase inhibition and potential mixture effects.

Exploratory PBPK models have been developed for some NMCs. Appendix II.B.6 includes a description and results from EPA's work on such a model for carbaryl. Because PBPK modeling techniques offer good promise, continued development and testing of the models is necessary and should be pursued despite the current limitations with respect to the amount of input information required. Pharmacokinetic

studies (*in vivo* and *in vitro* experiments to determine key values for pharmacokinetic parameters and the time course disposition of the compounds in the body) need to be performed with many compounds to determine the key parameters of use in PBPK modeling. It is anticipated that data and methods will continue to improve and evolve as more experience is gained in this area. Although a biological or pharmacokinetic modeling approach would provide another means to determine the cumulative risk for these NMCs, the input parameters for such an approach are not available. Therefore, OPP has applied simple dose addition and used an empirical curve fitting model (i.e., the exponential model) to determine RPFs and PoDs.

8. Conclusions

With the passage of the FQPA (1996), the Agency is required to consider the cumulative risk of pesticides that share a common mechanism of action. The Agency designated the NMCs as a common mechanism group in 2001 and published its preliminary CRA in 2005. Since that time, the Agency has incorporated new hazard and exposure data, assigned uncertainty and safety factors, evaluated comments from the public, addressed comments by the SAP, and made appropriate adjustments due to risk mitigation actions. The NMC CRA is a highly complex, highly refined risk assessment that uses data from multiple sources and multiple models. Because of this complexity, no single value in the assessment should be used to independently arrive at the interpretation of the results. Instead, it is necessary to consider the results as a whole in order to appropriately interpret the results and arrive at conclusions.

This NMC CRA assessment reflects the completed risk mitigation measures that have been proposed or completed as a result of the single chemical assessments as of September, 2007. Since the publication of the preliminary CRA in 2005, many uses of NMCs have been voluntarily cancelled, have had voluntary cancellation requests submitted or have been determined to be ineligible for re-registration. Specifically, the registrations of methomyl on strawberries is undergoing voluntary cancellation, and the registrant has requested that methomyl use on grapes be cancelled. In addition, carbofuran was determined to be ineligible for reregistration and EPA has initiated the process to cancel all domestic uses and to revoke most tolerances; this cancellation impacts risk to the food and drinking water pathway. Residential indoor spray uses of propoxur that may result in non-occupational exposure for children have been voluntarily cancelled. The registrant of aldicarb has agreed to an increase in the well setback distance from 300 feet to 500 feet for aldicarb use on peanuts in the southern portion of the Coastal Plain. Each of these risk mitigation measures provides substantive

reductions in the exposure to NMCs and improvements to the cumulative risk estimates.

Consistent with the mode of action of NMCs, the revised NMC CRA focuses on acute, single day exposures. It presents the estimates of cumulative risks associated with exposures to NMCs in food, drinking water and from residential uses. Contributions from various pathways and routes of exposure are arrayed separately in a set of temporal or time-series plots of MOEs over a period of 365 days so that the reader can assess and evaluate -- on a pathway and/or route- specific basis -- the significant contributors to risk. This practice permits expression of the full range of values for each parameter and facilitates interpretation of the complete risk picture. OPP is confident that the results reasonably represent exposures and risks from food, water, and residential use to the U.S. population.

The food component of the NMC cumulative risk assessment is based primarily upon two extensive, reliable data sets: 1) USDA's CSFII 1994-96/98 and 2) USDA's PDP. The CSFII provides a detailed representation of the food consumption patterns of the U.S. public across all age groups, during all times of the year, and across the US. The PDP data provide a consistent and reliable sample of pesticide residues in the major children's foods, including fruits, vegetables, dairy products, meats, and grains. The data from PDP are collected so as to closely reflect residues in foods, as consumed and are statistically representative of the U.S. food supply. The PDP program utilizes multi-residue analytical methods such that co-occurrence of pesticides in individual samples is captured. These two sources of data provide a firm foundation upon which to assemble other data to develop the NMC cumulative risk assessment. Oxamyl serves as the index chemical and the residue values for the other NMC pesticides were converted to oxamyl equivalents using the RPF approach. After adjustment for processing, these index equivalent residues were then compiled as distributions of cumulative residues by summing them on a sample-by-sample basis. These cumulative residue distributions were combined with distributions of daily food consumption values via a probabilistic procedure to produce a distribution of potential exposures for the general U.S. population and sub-populations using the DEEM-FCID software. The primary advantage of using distributions of pesticide concentrations and consumption values to assess cumulative exposure is that distributions of exposure values are obtained that represent a distribution of realistic scenarios of exposure that describe both probabilities and magnitudes of multi-chemical cumulative exposure through the food pathway.

The drinking water assessment focuses on areas where combined NMC exposure is likely to be among the highest within each region as a result of total NMC usage and vulnerability of drinking water sources. This analysis is based on a probabilistic modeling approach that considers the full range of data and not a single high-end estimate. EPA estimated NMC exposures in drinking water to individuals in the CRA for both ground water and surface water sources of drinking water by region. The regional drinking water exposure assessments represent exposures from vulnerable drinking water sources resulting from typical NMC usage and reflect seasonal variations as well as regional variations in cropping and NMC use. For the majority of the U.S., NMC residues in drinking water sources are at levels that are not likely to contribute substantially to the multi-pathway cumulative exposure. Estimated NMC exposures from surface water sources of drinking water resulted in MOEs well in excess of 10. For most ground water sources of drinking water, NMC exposures are expected to be similarly low. Private wells extending through highly permeable soils and drawing from shallow depths in acidic, unconfined aquifers (also known as water table aquifers) represent what the Agency believes to be the most vulnerable drinking water sources for the NMCs based on available monitoring, current use patterns, and known soil and hydrologic conditions. Those instances where NMC concentrations resulted in MOEs of less than 10 are being addressed with mitigation measures in the single chemical assessments – an increase in the well setback distance from 300 feet to 500 feet for aldicarb use on peanuts in the southern portion of the Coastal Plain and notice of intent to cancel all domestic carbofuran uses. With these mitigation measures, NMC exposures from drinking water result in MOEs that are greater than 10.

There are three NMC chemicals with currently registered residential uses considered as part of the revised NMC CRA in the residential/non-occupational exposure pathway assessment. The residential uses considered in this assessment include the carbaryl lawn and golf course uses, the carbaryl vegetable and ornamental garden use, the methiocarb snail bait use, the carbaryl fruit tree use, and the carbaryl and propoxur pet collar uses. Several reliable data sources were used to define how pesticides are used, how quickly the residues dissipate, how people may come into contact with pesticides (e.g., via dermal or inhalation exposure), and the length of time people might be exposed based on certain activities (e.g., playing on a treated lawn). As with the drinking water assessment, the residential exposure assessment considers seasonal applications and timing as well as regional differences. In the case of regional differences, the revised NMC CRA focused on the Southeast Region of the United States for two reasons; 1) the growing season is longer in the South and the associated pest pressures are therefore greater, and 2) drinking water concentrations are highest in this

region of the country. The residential and groundwater assessments are based on the most highly exposed localized areas within the southeastern region of the United States. Specifically, the drinking water exposure for Georgia was combined with residential exposure in Florida. Pest pressure data for Florida are assumed to address pest pressure for other areas of the country where estimated NMC water concentrations are the highest (such as Georgia and North Carolina). Due to longer periods of pesticide use coupled with higher concentrations of NMCs in ground water, this assessment provides a reasonable worst case estimate of exposure. The results of the residential risk assessment indicate that remaining uses of NMCs in a residential setting– as borne out by the analyses here -- are below OPP's level of concern for all subpopulations.

EPA also evaluated total (combined) MOEs for all three pathways (e.g., multi-pathway, which is the sum of food + water + residential) simultaneously. The multi-pathway MOEs at the 99.9th percentile are approximately 8 and 9 for children 1-2 and children 3-5 years of age, respectively, for the single day results from Calendex. At the 99.9th percentile of exposure, the food pathway is the most significant contributor. These multi-pathway results are consistent with – and essentially dominated by -- the food results found in Table I.G-5. Because the exposure through food is the dominant exposure pathway for the revised NMC CRA, the total MOEs derived from the multi-pathway assessment are virtually identical to the MOEs from exposure through the food pathway.

The sensitivity analyses shown and discussed here are designed to evaluate the degree to which key areas of the risk assessment may or may not under- or over-estimate the cumulative risk in an effort to characterize and understand the MOEs estimated in this assessment. When developing any risk assessment, assumptions must be made in areas where data are not available; this is the also case for the NMCs. In the revised NMC CRA, the Agency has made health protective assumptions in its baseline analysis, particularly with regard to the years of PDP data which are used (for which it used all years of PDP data except in cases where use patterns have been proposed or changed) and the use of inter-species extrapolation factors for those NMCs without human data. The sensitivity analyses shown here demonstrate that the Agency has not under-estimated exposures and associated risks since many of the modified scenarios result in only small changes in the percentile at which an MOE of 10 is reached.[22]

[22] More specifically, the complex nature of this CRA has been stressed, and the many, varied data sources used to develop quantitative estimates of exposure have been described. Although there is a high level of confidence in this assessment, it is important to recognize the limits on the precision of the estimates generated by the assessment. For example, although the percentiles

The Agency has developed a highly refined and complex cumulative risk assessment for the NMCs that represents the state of the science regarding existing hazard and exposure data and the models and approaches used. The Agency notes that the risk mitigation efforts of the past several years have significantly reduced risk from NMCs in the food, drinking water and from residential use in the US. Taking into account these reductions and acknowledging that several key assumptions are designed to minimize the potential to underestimate exposure and risk, the Agency concludes that, based on the results of the revised NMC CRA, there is a reasonable certainty that no harm will result from exposure to the NMC pesticides covered by this assessment, taking into account the cumulative effects of such residues. Accordingly, the pesticide tolerances for the NMCs covered by this risk assessment are considered to be "safe" as defined in FFDCA section 408(b)(2)(A), and to be reassessed for purposes of FFDCA section 408(g).

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have been reported out to 5 significant figures (e.g., 99.854), the Agency does not believe that the assessment has the power to discriminate between different tenths or hundredths of percentiles of exposure. Put another way, there is no meaningful difference between the exposure received by the 99.9th and the 99.8th percentile of a subgroup, much less between the 99.85th and 99.86th percentiles. The magnitude of actual exposure experienced by a particular percentage of the population is likely to be close to, but somewhat below, EPA's estimate for that percentile. Actual exposure for, say, the 99.9th percentile may fall within the values estimated for the 99.85th and the 99.95th percentiles. But EPA does not believe that the assessment reliably predicts the precise difference in exposure levels for people falling at different points on the distribution when the points are separated by no more than 0.1% difference. Therefore, for risk management purposes, it is also appropriate to considere the percentile at which the estimated MOE for a subgroup reaches 10. If that percentile is not meaningfully different from the 99.9th percentile, as is the case here, it can be regarded as an additional consideration to support the conclusion that there is reasonable certainty no harm will result from cumulative exposure to NMCs.

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II. Appendices

A. Summary of Risk Mitigation for Individual N-Methyl Carbamates[23]

Decision Document	Use Site	Mitigation	Residential Uses Remaining
ALDICARB			
09/2007 RED	Alfalfa grown for seed	Cancelled	None
	Coffee	Cancelled	
	Ornamentals	Cancelled	
	Pecans	Cancelled	
	Sorghum	Cancelled	
	Sugarcane	Cancelled	
	Tobacco	Cancelled	
	Cotton	Rate Reductions	
	Soybean		
	Dry Beans	Geographic Use Restrictions	
	Soybean		
	Sugar Beet		
	Sweet Potato		
	Peanuts	500 foot well setback and application restrictions	

[23] This summary only captures those mitigation measures likely to impact the cumulative risk assessment. It does not include specific mitigation measures intended to protect workers (e.g., REIs, PPE) or to address ecological risks (e.g., spray drift measures, buffer zones for non-target plants).

Decision Document	Use Site	Mitigation	Residential Uses Remaining
CARBARYL			
06/2003 IRED	Wheat	Cancelled - tolerance retained	Liquid lawn use is limited to spot treatment only (<1000 ft.); packaged in pint-size ready-to-use (RTU) hose-end sprayers For garden/ornamental dust products used on vegetables/ornamentals, all end-use products are to be packaged in RTU shaker can containers with ≤0.05 lb ai/container. Granular products are available for lawncare (drop or rotary spreader); for home-garden use granular products packaged in RTU containers only.
	Broadcast applications of liquid formulations to turf EXCEPT sod farms, golf courses, commercial landscape areas and cemeteries	Cancelled	
	Applications by hand, spoon, and belly grinder	Cancelled	
	Pet uses EXCEPT pet collars	Cancelled	
	Corn	Granular and Bait Formulations Prohibited	
	Grain sorghum		
	Alfalfa		
	Rice		
	Sunflowers		
	Asparagus	Rate Reductions	
	Citrus		
	Field Corn		
	Stone Fruit		

Decision Document	Use Site	Mitigation	Residential Uses Remaining
CARBOFURAN			
08/2006 IRED	Alfalfa	Not eligible for reregistration - Import tolerances retained for banana, coffee, sugarcane and rice	None
	Artichoke		
	Banana		
	Barley		
	Coffee		
	Corn		
	Cotton		
	Curcubits		
	Grapes		
	Oats		
	Pepper		
	Plantain		
	Potato		
	Sorghum		
	Soybean		
	Sugar Beet		
	Sugarcane		
	Sunflower		
	Wheat		
	Spinach for seed	Cancelled with a 4 year phase out	
	Chili Peppers		
	Sunflowers		
	Artichoke		
	Cucurbits- granular formulation		

Decision Document	Use Site	Mitigation	Residential Uses Remaining
FORMETANATE HYDROCHLORIDE			
03/2006 IRED	Plums	Cancelled	None
	Prunes	Cancelled	
	Pome Fruit	Application Restrictions	
	Stone Fruit		
	Citrus		
	Orchard crops- aerial application	Prohibited	
METHIOCARB			
03/1994 RED	All food uses	Cancelled	Ornamental woody shrubs and vines, household/ dwellings outdoor premises
	Granular formula	Package size restrictions	
METHOMYL			
12/1998 RED	Grapes*	Cancelled in 2007	None
	Strawberries**		
	Broccoli	Reduction in Max. Seasonal Rates	
	Cabbage		
	Cauliflower		
	Celery		
	Chinese Cabbage		
	Corn, Sweet		
	Lettuce, Head		
	Tomato		
	Peaches	Reduced Max. Single Application Rate	
	Commercial sod farms		
OXAMYL			
12/2000 IRED	Seed piece dip (yams)	**Cancelled**	None
	Soybean		
	Soil broadcast treatment for cotton		
	All Crops	Rate Reductions	
PIRIMICARB- No Mitigation Necessary			
PROPOXUR			

Decision Document	Use Site	Mitigation	Residential Uses Remaining
09/1997 RED	Indoor Residential Uses for Crack and Crevice Treatments***	Cancelled in 2007	Indoor: pastes, tape/strip/patches, baits, and shelf paper Outdoor uses: Structural perimeter applications, spot treatments to wasp nests and ant hill, insecticidal tape for boat mooring lines
THIODICARB			
12/1998 RED	Cole crops	Reduced Single and Seasonal Application Rates	None

* Voluntary cancellation request received September 14, 2007.
** FR Notice announcing receipt of voluntary cancellation published on April 25, 2007 with a 180 day comment period which closes 10/22/07.
*** Use deletion finalized on September 10, 2007.

B. Hazard

1. Data Spreadsheets of the NMC Pesticides

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

2. Dose-Response modeling of the NMC pesticides

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
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3. N-M-Carbamate Dose Response

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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4. R-packages with file names

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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Revised NMC Cumulative Risk Assessment - 2007

5. Summary AChE protocol evaluations, mixture experiments, motor activity measurements

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
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Revised NMC Cumulative Risk Assessment - 2007

6. Physiologically-Based Pharmacokinetic Modeling for the NMC CRA

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
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C. Food

1. The Sources of Residue Inputs for the Assessment of the Cumulative Dietary Exposure to N-Methyl Carbmate Pesticides on Foods

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
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2. Summary of PDP Residue Analyses of N-Methyl Carbamate Pesticides on Food Commodities Included in Revised NMC CRA

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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Revised NMC Cumulative Risk Assessment - 2007

3. Processing Factors Used to Estimate Residues of N-Methyl Carbamate Pesticides in Food Forms*

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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Monday through Friday, 8:30 am – 4:00 pm

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Revised NMC Cumulative Risk Assessment - 2007

4. Translation of Residue Source Data to FCID Food Forms

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
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703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

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5. Summary of Residue Distribution Inputs to DEEM-FCID for the Revised NMC CRA

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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6. Analysis of Chemicals and Foods in the Upper Portion of the Revised NMC CRA. Exposure Distribution for Children 1-2 Years Old

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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Revised NMC Cumulative Risk Assessment - 2007

7. Co-Occurrence of N-Methyl Carbamate Pesticides on PDP Samples, 1994-2006

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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8. Comparison of DEEM-FCID version 2.03 and Lifeline version 4.30 Exposure and Risk Estimates through the Food Pathway Only

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

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D. Residential

1. Residential Pesticide Use Inputs from REJV Survey Data

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
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Monday through Friday, 8:30 am – 4:00 pm

2. Residential Exposure Scenarios Appendix

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

E. Drinking Water

1. Summary of Surface Water Monitoring Data for NMC Pesticides

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

E-2 Summary of Ground Water Monitoring Data for NMC Pesticides

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

ED_005427A_00004764-00271

E-3 Drinking Water Treatment Effects on N-methyl Carbamate Pesticides

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

ED_005427A_00004764-00272

E-4 N-methyl Carbamate Usage Estimates

T

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

E-5 Chemical-Specific Fate and Transport Properties Used For the Water Exposure Models

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

E-6 NMC Surface Water Exposure Assessment Methods

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
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Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

E-7 NMC Ground Water Exposure Assessment Methods

A CD contatining the data in this appendix may be obtained by contacting the Office of Pesticide Programs Public Docket

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One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

III.Multi-Pathway Graphs

A CD contatining the data in this section may be obtained by contacting the Office of Pesticide Programs Public Docket

Docket # EPA-HQ-OPP-2007-0935

One Potomac Yard
12777 S. Crystal Drive
Room S-4400
Arlington, Virginia. 22202

703-305-5805

Monday through Friday, 8:30 am – 4:00 pm

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/19/2020 1:04:30 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: revised slides - Aldicarb
Attachments: Draft Aldicarb Briefing Slides 061920.pptx

Hi Marion, Shanta,

Attached are the aldicarb slides. I removed the comments and made some text updates to the summary and recommendations. I also split the HH slides into 2 slides to increase readability.

Please let me know what you think and if you think they are ready to be sent to the team and/or Mike G.
Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Aldicarb - Background

- N-methyl carbamate (NMC): to control certain insects, mites, and nematodes.
- There are no registered residential uses of aldicarb.
- Currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.
- Restricted use pesticides due to acute oral, dermal and inhalation toxicity, and to protect ground water.

Aldicarb – Background (cont'd)

- **In 2010,** Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), due to unacceptable dietary risk, especially to infants and young children.
  - Existing tolerances remained for citrus to allow for treated imports.

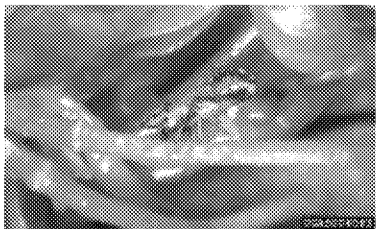
- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
  - Risk estimates for dietary (food only) exposure below the level of concern (included imported citrus commodities only).
  - Drinking water risks were mitigated by appropriate well setbacks and with in-furrow applications.
  - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Aldicarb – Proposed New Uses

- Proposed use for oranges and grapefruit in Texas and Florida
  - Submitted April 9, 2019
- Apply granules in furrows 2 to 3 inches deep.
  - Apply only with granular applicators which use Positive Displacement Metering Units.
  - Cover or immediately deep-disk any granules spilled to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
- Well set-back restrictions apply based on soil types.

Benefits in Citrus

- Aldicarb controls a broad spectrum of pests[4] and has a longer period of residual activity[1,2] than most alternatives.
- Different mode of action (carbamate; IRAC group 1A) than currently registered alternatives for psyllid control on citrus
- Low impact on natural enemies[4], compared to currently registered alternatives[3]
- Based on historical usage patterns of aldicarb in citrus, growers are likely to use aldicarb for control of Asian citrus psyllid (ACP) – the insect vector of the pathogen that causes the disease citrus greening or Huanglongbing (HLB).
- Registrant claims root growth and plant health claims but lacked supporting evidence – and suggests low insecticidal benefits.



An adult Asian citrus psyllid
1/6 to 1/8 inch long
Photo by David Hall, USDA
Agricultural Research Service
Bugwood.org

[1] Qureshi et al. 2014 *PLoS ONE;* [2]Childers et al. 1987 *J. Econ. Entomol.;* [3]Diepenbrock et al. 2019 IFAS Extension;
[4] Rogers 2008 *Citrus Industry*

4

Huanglongbing = yellow dragon disease
Images from bugwood.org (hosted by the University Georgia) can be used as long as they are properly attributed. Only commercial uses are not allowed unless permission of the "author" is given.

Alternatives in Citrus

- Over 30 currently registered insecticides for ACP control in citrus.
  - Aldicarb, as a carbamate (IRAC group 1A), is a different mode of action compared to alternatives; carbaryl is the only registered alternative in the same group.
- For ACP control, aldicarb is less efficacious than some alternative insecticides but provides longer residual control.
- Aldicarb is likely to be quickly readopted in rotational programs in an effort to control ACP - alternative chemicals do not provide adequate control.

5

Ex. 5 Deliberative Process (DP)

Projected Percent Crop Treated (PCTn)

PCTn is the estimated percent crop treated (PCT) for a proposed new use, developed with historical usage data of market leader pesticide(s)

National analysis not appropriate

- Proposed new use is for FL and TX only
- >80% grapefruit and orange acres are in these two states
- Juice oranges grown primarily in FL

State-level PCTn for aldicarb:

Crop	State	Minimum PCTn	Maximum PCTn
Grapefruit	FL	85%	90%
Grapefruit	TX	90%	100%
Oranges (and Juice)	FL	90%	90%

AgLogic Comments and EPA Responses

- *PCTn estimates should be based on "the most current and reliable statistics, such as those provided by the USDA National Agricultural Statistics Service (NASS)"*
  - Derived from usage data available from Kynetec (Best Available Data)
    - Annual survey
    - Pest-specific data
    - Data for last 5 years of previous registration available (2007-2011)
- *PCTn should be analyzed using Florida and Texas citrus production data;*
  - Developed using state-level data
  - Interpret as percentage of crop acres grown in FL and TX that may be treated with aldicarb should the proposed new use be approved
- *Imported juice concentrate does not contain aldicarb*
  - EPA assumed 100% of imported product was treated when calculating orange PCTn
- *An appropriate PCTn for of all US orange and grapefruit acreage is 14.6%*
  - Registrant-proposed PCTn calculated using national crop production data

7

Ex. 5 Deliberative Process (DP)

Aldicarb Human Health Risks

- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risk (Orange Juice is the risk driver):
  - Ex. 5 Deliberative Process (DP)
  -
  -

Aldicarb Human Health Risks
(cont'd)

- Food only using drinking water level of comparison (DWLOC) approach :
  - Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup.

Ex. 5 Deliberative Process (DP)

Aldicarb Ecological Risks

Based on previous risk assessments – Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
  - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.

Aquatic Organisms:

- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.

Terrestrial Organisms:

- Highly acutely toxic to honey bees on a contact basis.
  - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide Ex. 5 Deliberative Process (DP)

    Ex. 5 Deliberative Process (DP) Citrus is attractive to bees.

Drinking Water - Surface Water

FLcitrusSTD scenario file was used to model the citrus use. Considering the different soil incorporation depths, the 1-day average EDWCs are presented below:

Soil Depth	1-day average EDWC (ppb)	DWLOC (0.87 ppb) as percent of 1-day average EDWC	EDWC as multiple of DWLOC (0.87 ppb)
2 inches	39.2	2.22%	45
3 inches	17.0	5.12%	19.5
6 inches	4.24	20.52%	4.9

- Depending on the soil incorporation depth, the resulting EDWCs represent between 4.87 to 45 times the DWLOC (0.87 ppb).
- The citrus use label restricts use to only Florida and Texas. Since aldicarb is only registered for use on cotton and peanuts in FL and TX, the use of regional PCA was used to refine the EDWCs.

Surface Water: Regionally Refined

The regional PCAs at HUC-2 scale for Florida and Texas on cotton, orchard and vegetables combined are shown below:

HUC-2	PCA cotton+orchard+vegetables
3 (Florida)	14.2%
12 (Texas)	20.8%
13 (Texas)	3%

The adjusted EDWCs for three regional PCA adjustments are tabulated below:

Soil Depth	1-day average EDWC (ppb)	HUC-2 3 (FL) 14.2%	HUC-2 12 (TX) 20.8%	HUC-2 13 (TX) 3%
2 inches	39.2	5.57	8.15	1.18
3 inches	17.0	2.41	3.54	0.51
6 inches	4.24	0.60	0.88	0.13

Drinking Water - Groundwater

- GW drinking water concentrations modeled using Florida Central Ridge Scenario (co-located with citrus use) with 0.5 ft/day groundwater flow velocity.
- Additional characteristics including aldicarb's sensitivity to water pH levels and co-location with drinking water watersheds and orchards could be considered (degrades faster with increasing pH).
- For levels below the DWLOC, required well setbacks: 700 ft at pH6; 175 ft at pH7; 50 ft at pH 8.

Summary

Ex. 5 Deliberative Process (DP)

Recommendations

Options:

Ex. 5 Deliberative Process (DP)

Proposed Steps Forward

- Brief upper management on risks/assessments
- Communication again with the company regarding their request for refinement of the PCTn and rebuttal claims.
- Ex. 5 Deliberative Process (DP)
-

Message

From: Johnson, Marion [Johnson.Marion@epa.gov]
Sent: 6/18/2020 9:08:44 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: draft of aldicarb PCTn for your review

I'm sure we have time to get it how we want it. I don't think he's expecting anything this week, necessarily.

MJJ

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, June 18, 2020 4:47 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: draft of aldicarb PCTn for your review

Hi Marion,

I haven't had a chance yet to polish the summary slide today with competing meetings. Did you want to send it to him with that caveat, or wait until tomorrow after you/Shanta have had a chance to look it over?

Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Thursday, June 18, 2020 3:35 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: draft of aldicarb PCTn for your review

Thanks, Debra, Shanta:

I just got off the phone with Mike, and he said that because of all the changes occurring at the senior management level due to Rick's leaving, he would just like to see the slide presentation materials for aldicarb, prior to scheduling a briefing with him. Apparently, Ed who's of course acting OPP Director will be out next week; so whenever you think we're ready to send them, let me know. I think he just wants to ensure that Alex gets some sort of heads up and that he can tailor the conversation to whomever may in subsequent positions.

Best,

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Thursday, June 18, 2020 3:10 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: FW: draft of aldicarb PCTn for your review

Hi Marion and Shanta,

I have reread the BEAD draft review. I don't have any further questions. Do either of you have any questions or comments that you would like to communicate to Rebeccah?

Thanks.
Debra

From: Waterworth, Rebeccah <Waterworth.Rebeccah@epa.gov>
Sent: Friday, June 12, 2020 2:29 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Crowley, Matthew <Crowley.Matthew@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Anderson, Neil <Anderson.Neil@epa.gov>; Nesci, Kimberly <Nesci.Kimberly@epa.gov>
Subject: draft of aldicarb PCTn for your review

Hi Debra,

The aldicarb team respectfully submits a draft of our memo for your review. We wanted to let you know that the version you are viewing addresses PRP, BC, and OGC questions and comments. Kimberly and Neil have read this version of our memo, and we are currently addressing their comments separately.

We would like to give you time to view this draft before we finalize and ask if you have questions about the calculations, assessment of additional factors, and responses to the registrant claims. Please let the team know at the meeting on Monday or by email/phone at any time if you need clarification on anything in the document. I won't be at the meeting on Monday but look forward to gathering with my teammates to discuss the next steps.

Thanks for your patience.

Sincerely,
Rebeccah

Rebeccah Waterworth, Ph.D.
Entomologist
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biological and Economic Analysis Division
Biological Analysis Branch

Mailing address:

US EPA Headquarters
William Jefferson Clinton Building
Mail Code 7503P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

phone: 703-347-8617

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/18/2020 11:30:27 AM
To: Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]; Federoff, Nicholas [Federoff.Nicholas@epa.gov]
Subject: RE: Rate, Debra shared the folder "Aldicarb" with you.

Thank you!

From: Waterworth, Rebeccah <Waterworth.Rebeccah@epa.gov>
Sent: Wednesday, June 17, 2020 4:34 PM
To: Rate, Debra <Rate.Debra@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Blankinship, Amy <Blankinship.Amy@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Donovan, William <donovan.william@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Federoff, Nicholas <Federoff.Nicholas@epa.gov>
Subject: RE: Rate, Debra shared the folder "Aldicarb" with you.

Hi Debra,

BEAD has finished reviewing the DD briefing slides. Our version is attached. We added slides to this version. You will find that BEAD has been involved with editing/commenting on slide numbers 3, 4, 5, 6, 11, 12, and 13.

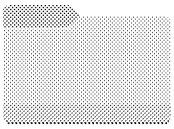
We will talk to you in the morning.

Rebeccah

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, June 15, 2020 9:12 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Blankinship, Amy <Blankinship.Amy@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Donovan, William <donovan.william@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Waterworth, Rebeccah <Waterworth.Rebeccah@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Federoff, Nicholas <Federoff.Nicholas@epa.gov>
Subject: Rate, Debra shared the folder "Aldicarb" with you.

Here is the link to the draft slides for Aldicarb. Please let me know if you have any difficulties accessing the file. Thank you! Debra

This link only works for the direct recipients of this message.



Aldicarb

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Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

Message

From: Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]
Sent: 6/17/2020 8:34:21 PM
To: Rate, Debra [Rate.Debra@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]; Federoff, Nicholas [Federoff.Nicholas@epa.gov]
Subject: RE: Rate, Debra shared the folder "Aldicarb" with you.
Attachments: Draft Aldicarb Briefing Slides 061420 V2 (1).pptx

Hi Debra,

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Sent: Monday, June 15, 2020 9:12 AM
To: Johnson, Marion <Johnson.Marion@epa.gov>; Adeeb, Shanta <Adeeb.Shanta@epa.gov>; Blankinship, Amy <Blankinship.Amy@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Donovan, William <donovan.william@epa.gov>; Costello, Kevin <Costello.Kevin@epa.gov>; Suarez, Mark <Suarez.Mark@epa.gov>; Waterworth, Rebeccah <Waterworth.Rebeccah@epa.gov>; Hansel, Jeana <Hansel.Jeana@epa.gov>; Hendrick, Lindsey <hendrick.lindsey@epa.gov>; Kaul, Monisha <Kaul.Monisha@epa.gov>; Becker, Jonathan <Becker.Jonathan@epa.gov>; Lin, James <lin.james@epa.gov>; Wente, Stephen <Wente.Stephen@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Federoff, Nicholas <Federoff.Nicholas@epa.gov>
Subject: Rate, Debra shared the folder "Aldicarb" with you.

Here is the link to the draft slides for Aldicarb. Please let me know if you have any difficulties accessing the file. Thank you! Debra

This link only works for the direct recipients of this message.

Aldicarb

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Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

Aldicarb - Background

- N-methyl carbamate (NMC): to control certain insects, mites, and nematodes.
- Restricted use pesticides due to acute oral, dermal and inhalation toxicity, and to protect ground water.
- Currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.
- There are no registered residential uses of aldicarb.
- **In 2010,** Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), due to unacceptable dietary risk, especially to infants and young children.
  - Existing tolerances remained for citrus to allow for treated imports.

Aldicarb – Background (cont'd)

- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
  - Risk estimates for dietary (food only) exposure below the level of concern (included imported citrus commodities only).
  - Drinking water risks were mitigated by appropriate well setbacks and with in-furrow applications.
  - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

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- Citrus in Texas and Florida
- Apply granules in furrows 2 to 3 inches deep.
  - Apply only with granular applicators which use Positive Displacement Metering Units.
  - Cover or immediately deep-disk any granules spilled to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
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PCTn is the estimated percent crop treated (PCT) for a proposed new use, developed with historical usage data of market leader pesticide(s)

National analysis not appropriate

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- >80% grapefruit and orange acres are in these two states
- Juice oranges grown primarily in FL

State-level PCTn for aldicarb:

Crop	State	Minimum PCTn	Maximum PCTn
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  - Derived from usage data available from Kynetec (Best Available Data)
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    - Pest-specific data
    - Data for last 5 years of previous registration available (2007-2011)
- *PCTn should be analyzed using Florida and Texas citrus production data;*
  - Developed using state-level data
  - Interpret as percentage of crop acres grown in FL and TX that may be treated with aldicarb should the proposed new use be approved
- *Imported juice concentrate does not contain aldicarb*
  - EPA assumed 100% of imported product was treated when calculating orange PCTn
- *An appropriate PCTn for of all US orange and grapefruit acreage is 14.6%*
  - Registrant-proposed PCTn calculated using national crop production data

5

Ex. 5 Deliberative Process (DP)

Aldicarb Human Health Risks

- Acutely toxic through oral, dermal and inhalation routes of exposure.
- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risk:
  - Ex. 5 Deliberative Process (DP)
- Food only using drinking water level of comparison (DWLOC) approach :
  - Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup.

Ex. 5 Deliberative Process (DP)

Aldicarb Toxicity Profile

Birds and Mammals:

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
  - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.

Aquatic Organisms:

- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.

Terrestrial Organisms:

- Highly acutely toxic to honey bees on a contact basis.
  - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide Ex. 5 Deliberative Process (DP)
    Ex. 5 Deliberative Process (DP) Citrus is attractive to bees.

Surface Water

FLcitrusSTD scenario file was used to model the citrus use. Considering the different soil incorporation depths, the 1-day average EDWCs are presented below:

Soil Depth	1-day average EDWC (ppb)	DWLOC (0.87 ppb) as percent of 1-day average EDWC	EDWC as multiple of DWLOC
2 inches	39.2	2.22%	45.06
3 inches	17.0	5.12%	19.54
6 inches	4.24	20.52%	4.87

Depending on the soil incorporation depth, the resulting EDWCs represent between 4.87 to 45.06 times of DWLOC. The citrus use label restricts to apply in only two states: Florida and Texas. Since aldicarb is only registered for use on cotton and peanuts in FL and TX, the use of regional PCA can be explored to potentially refine the EDWCs.

Surface Water: Regionally Refined

The regional PCAs at HUC-2 scale for Florida and Texas on cotton, orchard and vegetables combined are shown below:

HUC-2	PCA cotton+orchard+vegetables
3 (Florida)	14.2%
12 (Texas)	20.8%
13 (Texas)	3%

The adjusted EDWCs for three regional PCA adjustments are tabulated below:

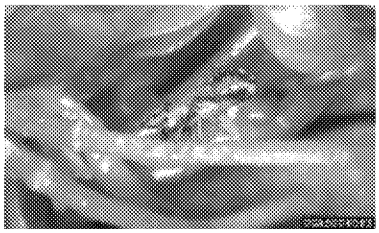
Soil Depth	1-day average EDWC (ppb)	HUC-2 3 (FL) 14.2%	HUC-2 12 (TX) 20.8%	HUC-2 13 (TX) 3%
2 inches	39.2	5.57	8.15	1.18
3 inches	17.0	2.41	3.54	0.51
6 inches	4.24	0.60	0.88	0.13

Groundwater

- GW drinking water concentrations modeled using Florida Central Ridge Scenario (co-located with citrus use) with 0.5 ft/day groundwater flow velocity.
- Further refinements of the water modeling were considered including co-location of drinking water watersheds with orchard locations. Additional characteristics including aldicarb's sensitivity to water pH levels was also considered.
- For levels below the DWLOC, required well setbacks: 700 ft at pH6; 175 ft at pH7; 50 ft at pH 8.

Benefits in Citrus

- Aldicarb controls a broad spectrum of pests[4] and has a longer period of residual activity[1,2] than most alternatives.
- Different mode of action (carbamate; IRAC group 1A) than currently registered alternatives for psyllid control on citrus
- Low impact on natural enemies[4], compared to currently registered alternatives[3]
- Based on historical usage patterns of aldicarb in citrus, growers are likely to use aldicarb for control of Asian citrus psyllid (ACP) – the insect vector of the pathogen that causes the disease citrus greening or Huanglongbing (HLB).
- Registrant claims root growth and plant health claims but lacked supporting evidence – and suggests low insecticidal benefits.



An adult Asian citrus psyllid
1/6 to 1/8 inch long
Photo by David Hall, USDA
Agricultural Research Service
Bugwood.org

[1] Qureshi et al. 2014 *PLoS ONE;* [2]Childers et al. 1987 *J. Econ. Entomol.;* [3]Diepenbrock et al. 2019 IFAS Extension;
[4] Rogers 2008 *Citrus Industry*

Huanglongbing = yellow dragon disease
Images from bugwood.org (hosted by the University Georgia) can be used as long as they are properly attributed. Only commercial uses are not allowed unless permission of the "author" is given.

Alternatives in Citrus

- Over 30 currently registered insecticides for ACP control in citrus.
  - Aldicarb, as a carbamate (IRAC group 1A), is a different mode of action compared to alternatives; carbaryl is the only registered alternative in the same group.
- For ACP control, aldicarb is less efficacious than some alternative insecticides but provides longer residual control.
- Aldicarb is likely to be quickly readopted in rotational programs in an effort to control ACP - alternative chemicals do not provide adequate control.

Ex. 5 Deliberative Process (DP)

Proposed Steps Forward

- Brief upper management on risks/assessments
- Communication again with the company regarding their request for reassessment of the PCTn and rebuttal claims.

Ex. 5 Deliberative Process (DP)

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/17/2020 6:50:38 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]

Subject: Pre-Meet Aldicarb
Location: Microsoft Teams Meeting

Start: 6/18/2020 1:00:00 PM
End: 6/18/2020 1:30:00 PM
Show Time As: Tentative

Required Attendees: Johnson, Marion; Adeeb, Shanta

Join Microsoft Teams Meeting

+1 Ex. 6 Conference Code 7 United States, Washington DC (Toll)

Conference ID: Ex. 6 Conference Code 7

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Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/17/2020 4:41:04 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]

Subject: Accepted: Aldicarb planning meeting
Location: Microsoft Teams Meeting

Start: 6/17/2020 6:00:00 PM
End: 6/17/2020 7:00:00 PM
Show Time As: Busy

Appointment

From: Coleman, Anita [Coleman.Anita@epa.gov]
Sent: 7/6/2020 8:57:07 PM
To: Goodis, Michael [Goodis.Michael@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Rate, Debra [Rate.Debra@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; federoff.nicolas@epa.gov; Wente, Stephen [Wente.Stephen@epa.gov]; Lin, James [lin.james@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]
CC: Vogel, Dana [Vogel.Dana@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov]; Arrington, Linda [Arrington.Linda@epa.gov]; Bartow, Susan [Bartow.Susan@epa.gov]

Subject: Scheduling chemical meeting/briefing for aldicarb actions
Attachments: Draft Aldicarb Briefing Slides 070120 - Revised.pptx
Location: SKYPE

Start: 7/7/2020 7:00:00 PM
End: 7/7/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Goodis, Michael; Messina, Edward; Echeverria, Marietta; Rosenblatt, Daniel; Aubee, Catherine; Johnson, Marion; Adeeb, Shanta; Rate, Debra; Metzger, Michael; Donovan, William; Blankinship, Amy; federoff.nicolas@epa.gov; Wente, Stephen; Lin, James; Kaul, Monisha; Crowley, Matthew; Suarez, Mark; Waterworth, Rebeccah; Hendrick, Lindsey; Becker, Jonathan; Hansel, Jeana
Optional Attendees: Vogel, Dana; Nesci, Kimberly; Reaves, Elissa; Arrington, Linda; Bartow, Susan

Join Skype Meeting

Trouble Joining? Try Skype Web App

Join by phone

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Find a local number

Conference ID: Ex. 6 Conference Code

Aldicarb – Proposed New Uses

- Proposed use for oranges and grapefruit in Texas and Florida
  - Submitted April 9, 2019
- Apply granules in furrows 2 to 3 inches deep.
  - Apply only with granular applicators which use Positive Displacement Metering Units.
  - Cover or immediately deep-disk any granules spilled to ensure the granules are completely covered with at least 2 to 4 inches of soil.
- Apply granules in furrow beside individual trees and cover with at least 2 inches of soil by mechanical means.
- The maximum single application rate is 33 pounds product (4.95 lbs a.i.) per acre per year.
- Do not make more than one application per tree per year.
- Well set-back restrictions apply based on soil types.

Summary

Ex. 5 Deliberative Process (DP)

2

Ex. 5 Deliberative Process (DP)

Recommendations

Options: PRIA due date **7/15/2020**

Ex. 5 Deliberative Process (DP)

3

Proposed Steps Forward

- Brief upper management on risks/assessments
- Communication again with the company regarding their request for refinement of the PCTn and rebuttal claims.
- Ex. 5 Deliberative Process (DP)
-

4

Aldicarb - Background

- N-methyl carbamate (NMC): to control certain insects, mites, and nematodes.
- There are no registered residential uses of aldicarb.
- Currently registered for use in various agricultural areas on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.
- Restricted use pesticides due to acute oral, dermal and inhalation toxicity, and to protect ground water.

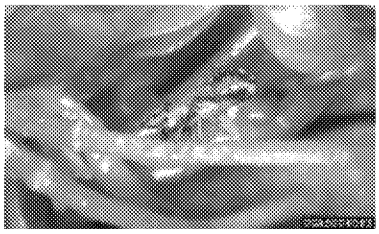
Aldicarb – Background (cont'd)

- **In 2010,** Bayer (the registrant at that time) voluntarily cancelled the domestic aldicarb uses on citrus (and potatoes), after EPA identified unacceptable dietary risk, especially to infants and young children.
  - Existing tolerances remained for citrus to allow for treated imports.

- The Aldicarb Registration Review Interim Decision (ID) was signed 12/22/2017.
  - Risk estimates for dietary (food only) exposure below the level of concern (included registered domestic uses plus imported citrus commodities only).
  - Drinking water risks were mitigated by appropriate well setbacks and with in-furrow applications.
  - By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the agency no longer expected exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Benefits in Citrus

- Aldicarb controls a broad spectrum of pests[4] and has a longer period of residual activity[1,2] than most alternatives.
- Different mode of action (carbamate; IRAC group 1A) than currently registered alternatives for psyllid control on citrus
- Low impact on natural enemies[4], compared to currently registered alternatives[3]
- Based on historical usage patterns of aldicarb in citrus, growers are likely to use aldicarb for control of Asian citrus psyllid (ACP) – the insect vector of the pathogen that causes the disease citrus greening or Huanglongbing (HLB).
- Registrant claims root growth and plant health claims but lacked supporting evidence – and suggests low insecticidal benefits.



An adult Asian citrus psyllid
1/6 to 1/8 inch long
Photo by David Hall, USDA
Agricultural Research Service
Bugwood.org

[1] Qureshi et al. 2014 *PLoS ONE;* [2]Childers et al. 1987 *J. Econ. Entomol.;* [3]Diepenbrock et al. 2019 IFAS Extension;
[4] Rogers 2008 *Citrus Industry*

Huanglongbing = yellow dragon disease
Images from bugwood.org (hosted by the University Georgia) can be used as long as they are properly attributed. Only commercial uses are not allowed unless permission of the "author" is given.

Alternatives in Citrus

- Over 30 currently registered insecticides for ACP control in citrus.
  - Aldicarb, as a carbamate (IRAC group 1A), is a different mode of action compared to alternatives; carbaryl is the only registered alternative in the same group.
- For ACP control, aldicarb is less efficacious than some alternative insecticides but provides longer residual control.
- Aldicarb is likely to be quickly readopted in rotational programs in an effort to control ACP - alternative chemicals do not provide adequate control.

8

Ex. 5 Deliberative Process (DP)

Projected Percent Crop Treated (PCTn)

PCTn is the estimated percent crop treated (PCT) for a proposed new use, developed with historical usage data of market leader pesticide(s)

National analysis not appropriate

- Proposed new use is for FL and TX only
- >80% grapefruit and orange acres are in these two states
- Juice oranges grown primarily in FL

State-level PCTn for aldicarb:

Crop	State	Minimum PCTn	Maximum PCTn
Grapefruit	FL	85%	90%
Grapefruit	TX	90%	100%
Oranges (and Juice)	FL	90%	90%

AgLogic Comments and EPA Responses

- *PCTn estimates should be based on "the most current and reliable statistics, such as those provided by the USDA National Agricultural Statistics Service (NASS)"*
  - Derived from usage data available from Kynetec (Best Available Data)
    - Annual survey
    - Pest-specific data
    - Data for last 5 years of previous registration available (2007-2011)
- *PCTn should be analyzed using Florida and Texas citrus production data;*
  - Developed using state-level data
  - Interpret as percentage of crop acres grown in FL and TX that may be treated with aldicarb should the proposed new use be approved
- *Imported juice concentrate does not contain aldicarb*
  - EPA assumed 100% of imported product was treated when calculating orange PCTn
- *An appropriate PCTn for of all US orange and grapefruit acreage is 14.6%*
  - Registrant-proposed PCTn calculated using national crop production data

Ex. 5 Deliberative Process (DP)

Aldicarb Human Health Risks

- A highly refined acute dietary (food only) exposure assessment was conducted.
- Food only risk (Orange Juice is the risk driver):
  - Ex. 5 Deliberative Process (DP)
  -

BEAD refined PCTn - 99% aPAD for children 1-2 years old (no imported fresh oranges)

Aldicarb Human Health Risks
(cont'd)

- Food only using drinking water level of comparison (DWLOC) approach :
  - Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup.

Ex. 5 Deliberative Process (DP)

Aldicarb Ecological Risks

Based on previous risk assessments – Ex. 5 Deliberative Process (DP)

Birds and Mammals:

- Primary risk is for birds and mammals consuming granules (1 granule can cause mortality).
  - Numerous incidents involving mortality from accidental or misuse of aldicarb. Modeling with 99.9% incorporation of granules produced RQs that exceeded the LOCs for small and medium birds and mammals.

Aquatic Organisms:

- Most aquatic organism acute and all chronic RQs exceeded all LOCs for all registered labeled uses of aldicarb.

Terrestrial Organisms:

- Highly acutely toxic to honey bees on a contact basis.
  - Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide and Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Drinking Water - Surface Water

FLcitrusSTD scenario file was used to model the citrus use. Considering the different soil incorporation depths, the 1-day average EDWCs are presented below:

Soil Depth	1-day average EDWC (ppb)	DWLOC (0.87 ppb) as percent of 1-day average EDWC	EDWC as multiple of DWLOC (0.87 ppb)
2 inches	39.2	2.22%	45
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6 inches	4.24	20.52%	4.9

- Depending on the soil incorporation depth, the resulting EDWCs represent between 4.87 to 45 times the DWLOC (0.87 ppb).
- The citrus use label restricts use to only Florida and Texas. Since aldicarb is only registered for use on cotton and peanuts in FL and TX, the use of regional PCA was used to refine the EDWCs.

Surface Water: Regionally Refined

The regional PCAs at HUC-2 scale for Florida and Texas on cotton, orchard and vegetables combined are shown below:

HUC-2	PCA cotton+orchard+vegetables
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13 (Texas)	3%

The adjusted EDWCs for three regional PCA adjustments are tabulated below:

Soil Depth	1-day average EDWC (ppb)	HUC-2 3 (FL) 14.2%	HUC-2 12 (TX) 20.8%	HUC-2 13 (TX) 3%
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3 inches	17.0	2.41	3.54	0.51
6 inches	4.24	0.60	0.88	0.13

Drinking Water - Groundwater

- GW drinking water concentrations modeled using Florida Central Ridge Scenario (co-located with citrus use) with 0.5 ft/day groundwater flow velocity.
- Additional characteristics including aldicarb's sensitivity to water pH levels and co-location with drinking water watersheds and orchards could be considered (degrades faster with increasing pH).
- For levels below the DWLOC, required well setbacks: 700 ft at pH6; 175 ft at pH7; 50 ft at pH 8.

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/17/2020 12:53:19 PM
To: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: meet at 2 pm to discuss aldicarb?

Hi Shanta,

I just realized that I won't be having my general with Marion today, since he is out. Would you mind meeting at 2 pm to discuss Aldicarb, the slides and help me plan the meeting for tomorrow?

Let me know if you are willing.
Thanks.
Debra

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Appointment

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/16/2020 11:35:13 AM
To: Federoff, Nicholas [Federoff.Nicholas@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Donovan, William [donovan.william@epa.gov]; Costello, Kevin [Costello.Kevin@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]; Hansel, Jeana [Hansel.Jeana@epa.gov]; Hendrick, Lindsey [hendrick.lindsey@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Becker, Jonathan [Becker.Jonathan@epa.gov]; Lin, James [lin.james@epa.gov]; Wente, Stephen [Wente.Stephen@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]

Subject: Aldicarb team meeting
Location: Microsoft Teams Meeting

Start: 6/18/2020 2:30:00 PM
End: 6/18/2020 3:00:00 PM
Show Time As: Tentative

Required Attendees: Federoff, Nicholas; Johnson, Marion; Adeeb, Shanta; Blankinship, Amy; Metzger, Michael; Donovan, William; Costello, Kevin; Suarez, Mark; Waterworth, Rebeccah; Hansel, Jeana; Hendrick, Lindsey; Kaul, Monisha; Becker, Jonathan; Lin, James; Wente, Stephen; Gsell, Alyssa

Hold for team meeting to finalize proposal/briefing to Senior Management to discuss findings with Registrant per OGC advice.

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Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 6/15/2020 8:44:34 PM
To: Johnson, Marion [Johnson.Marion@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Questions on the scheduling of next aldicarb meetings.....?

Hi Marion,

Thank you! I think I have a ½ hour opening on Thursday (6/18) morning that most will be available for. I need to confirm with a couple of people that are questionable to see if they can move a conflict (i.e., generals with BCs). This way the team will have through Wed. to make adjustments to the slides and be ready to discuss on Thursday morning.

Thanks again.
Debra

From: Johnson, Marion <Johnson.Marion@epa.gov>
Sent: Monday, June 15, 2020 4:39 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Questions on the scheduling of next aldicarb meetings.....?

Thanks, Debra! The 6/17 date was intended to be a target date for completion of the presentation materials/subject matter, so that we'd have everything ready for an upcoming briefing.

Marion J.

Marion J. Johnson, Jr.
Chief, Invertebrate-Vertebrate Branch 2
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
(703) 305-6788
johnson.marion@epa.gov
Visit: http://www/epa.gov/pesticides

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, June 15, 2020 4:02 PM
To: Johnson, Marion <Johnson.Marion@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: Questions on the scheduling of next aldicarb meetings.....?

Hi Marion,

Can you help clarify the next steps in the timeline for me? I thought I was on top of it until questioned in the meeting this morning. Did you intend for the 6/17 meeting to be an internal team meeting or was that the meeting with RD management/DDs to prepare for briefing with IO management?

Please confirm which meetings are next (i.e., internal team or with management).
Thanks!
Debra

Proposed Timetable to Decision (PRIA date 7/15/2020):

- 6/8/2020 IVB2 meeting with OGC's Alyssa Gsell, successor to Bob Perlis on aldicarb.
- 6/10/2020 HED feedback on MOEs based upon 14.6% PCT (Prod. Cap as proposed by AgLogic).
- 6/12/2020 Draft BEAD memo (OGC comments addressed) on PCTn.
- 6/15/2020 Internal Chemical Team Meeting to consider any remaining items: (RD/HED/EFED/BEAD/PRD)

- 6/17/2020 Finalize proposal/briefing to Senior Management to discuss findings with Registrant per OGC advice.
- 6/23/2020 Possible Briefing with Senior Management (RD and HED Director) with options, prior to contacting registrant.
- 6/24/2020 Call to Registrant to provide withdrawal, denial options.

Debra Rate, Ph.D.
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 2
Registration Division
U.S. Environmental Protection Agency

Phone: 703-306-0309

Message

From: Rate, Debra [Rate.Debra@epa.gov]
Sent: 7/6/2020 7:57:45 PM
To: Coleman, Anita [Coleman.Anita@epa.gov]
CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.

Hi Anita,

I think I may have used the term "hold" incorrectly earlier.

We need to have the meeting this week as the PRIA date is next week. (Hopefully that will work out with schedules.)

Thank you!
Debra

From: Coleman, Anita <Coleman.Anita@epa.gov>
Sent: Monday, July 06, 2020 3:35 PM
To: Rate, Debra <Rate.Debra@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.

Hi Debra,

Is this still a HOLD placement for this week only?

Thanks.

Anita

From: Rate, Debra <Rate.Debra@epa.gov>
Sent: Monday, July 6, 2020 12:27 PM
To: Coleman, Anita <Coleman.Anita@epa.gov>
Cc: Adeeb, Shanta <Adeeb.Shanta@epa.gov>
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.

Hi Anita,

Thank you so much for your help with the scheduling of this meeting.

We are looking for an hour time slot for the Aldicarb – New uses (Oranges/Grapefruit). The draft slides are attached. The team may be editing in the next day, but I will let you know if they need to be updated on the invite.

Thank you so much and the invitees are listed below. Let me know if you need anything else.
Debra

Invitees:

IO: Michael Goodis
Ed Messina

DDs: Marietta Echeverrria (Acting RD DD)
Dan Rosenblatt
Catherine Aubee
Dana Vogel (Optional)
Kimberly Nesci (Optional)
Elissa Reaves (Optional)

The Aldicarb Team:
RD: Marion Johnson
Shanta Adeeb
Debra Rate

HED: Michael Metzger
William Donovan

EFED: Amy Blankinship
Nicolas Federoff
Stephen Wente
James Lin

BEAD: Monisha Kaul
Matthew Crowley
Mark Suarez
Rebeccah Waterworth
Lindsey Hendrick
Jeana Hansel
Jonathan Becker

OGC: Alyssa Gsell
Angela Huskey
Erin Koch

PRD: Linda Arrington (Optional)
Susan Bartow (Optional)

From: Coleman, Anita <Coleman.Anita@epa.gov>
Sent: Monday, July 06, 2020 8:41 AM
To: Rate, Debra <Rate.Debra@epa.gov>
Subject: RE: Scheduling chemical meeting/briefing for aldicarb actions.

Good morning Debra,

I am well and safe, thank you for asking. I hope you and your family are also well and safe.

I am not sure if I can place a hold on E. Messina's calendar, I will try.

I will need the names of the DDs, Aldicarb team and length of meeting.

Thank you. Have a nice day.

Anita