

January 10, 2005

Environmental Protection Agency
Public Information and Records Integrity Branch (7502C)
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Carbaryl Interim Reregistration Eligibility Decision (IRED)

Federal Register: October 27, 2004, Volume 69, Number 207, Page 62663-62666

Submitted by email to opp-docket@epa.gov and britten.anthony@epa.gov
Attention: Docket ID Number OPP-2003-0376

Dear Sir or Madam;

These comments are being submitted on behalf of the Natural Resources Defense Council (NRDC). NRDC is an environmental action organization. We use law, science and the support of more than 1 million members and online activists to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for all living things. We do not have any direct or indirect financial or fiduciary interest in the manufacture or sale of carbaryl or any of the N-methyl carbamate pesticides.

At our request, EPA granted a deadline extension for submission of these comments, to January 10, 2005 (Britten.Anthony@epamail.epa.gov Sent: Wed 12/15/2004 2:29 PM To: Sass, Jennifer Cc: opp-docket@epamail.epa.gov Subject: Re: OPP-2003-0376 Carbaryl IRED). We appreciate this deadline extension, and EPA's assurance that these comments will be considered fully.

For the reasons stated in our previous comments and below, and based upon EPA's risk assessments, RED, and the full record before the agency, which are all incorporated by reference, we hereby petition EPA to cancel carbaryl, due to its unreasonable risks on the environment, as prohibited by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136(bb) & 136a. We also hereby petition EPA to revoke all tolerances for carbaryl, because EPA cannot make a finding that there is a reasonable certainty of no harm from carbaryl, and therefore must revoke all tolerances under the Federal Food, Drug, and Cosmetic Act, (FFDCA) §408. While we strongly believe that the evidence and findings that the agency already has made justify cancellation and revocation of tolerances without further review, if EPA decides not to cancel and not to revoke all tolerances for carbaryl, we urge EPA take certain measures noted below to improve its risk assessment and review (without conceding the lawfulness or reasonableness of such a decision). We, the petitioners, agree that such summary or any information it contains may be published as a part of the notice of filing of the petition under this subsection 408(d)(2)(A).

A summary of our concerns is listed below, and are discussed in more detail in these comments:

I. Dietary risks: We recommend that EPA either accept its modeling estimates of drinking water contamination, or provide robust data to demonstrate that ecological and

human health will be protected despite the modeling predictions that surface water contamination poses an unacceptable risk to children and the general population.

II. Residential risks: We recommend that flea collar uses also be cancelled, because of their high risk concerns. We insist that EPA revoke tolerances for all uses that are being voluntarily cancelled, to indicate to the public and regulatory agencies worldwide that the EPA considers these uses unacceptable.

III. Occupational risks: We recommend that EPA re-calculate its acceptable exposure levels, incorporating data from recorded worker exposure events for both handlers and post-application workers. We additionally recommend that all uses be cancelled where margins of exposure (MOE) are less than 100 for occupational exposures, particularly handlers or harvesters/thinners.

IV. Ecological risks: We recommend that EPA review its bee caution label to prevent carbaryl applications during bloom periods, so as to adequately protect bees. We request that EPA require data on chronic exposure to bees. We request that EPA provide documentation that its mitigation proposals are adequate. We request that the EPA provide more detail regarding the reported incidents, including whether label requirements were followed.

V. Endangered species: We support EPA in seeking consultations with the US Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) regarding carbaryl impacts on endangered species, and recommend that the results be received and reviewed in a timely manner, and made public.

VI. Benefits: We recommend that EPA reduce carbaryl applications for both California and Florida citrus to mitigate drinking water exceedances, and encourage EPA to increase its consultations with experts in Integrated Pest Management (IPM). We discourage EPA from issuing tolerances to combination pesticide products. We request that EPA either provide better documentation demonstrating that the benefits of increased carbaryl use exceed the identified risks, especially for those uses where many alternatives exist, or revoke tolerances where benefits cannot be demonstrated.

VII. Tolerances: The Agency has proposed to revoke 9 carbaryl tolerances, lower 31 tolerances, and reassign 49 tolerances. We request that EPA refrain from issuing recommendations of new or increased tolerances in this IRED. We recommend that EPA revoke all tolerances that are being cancelled or voluntarily withdrawn.

VIII. Outstanding data requirements: We request that EPA provide an accessible list of all outstanding data requirements for carbaryl, and ensure that these data are received and reviewed in a timely manner so as to inform the carbaryl risk assessment and mitigation recommendations. Further, these data should be made publicly accessible.

IX. Outstanding concerns raised in previous comments, that EPA has inadequately addressed: We respond to the EPA response to public comments: a) NRDC doc 39; EPA response July 14, 2003. b) NRDC OPP-2003-0101-0039; EPA response October 26, 2004.

Below we discuss our concerns in more detail:

I. Dietary risks:

EPA reports that the results of its screening-level modeling estimates, based on normal agriculture use, indicate that acute dietary risks from carbaryl residues in surface water sources of drinking water are above the Agency's level of concern for children and the general population (IRED at 17). Unfortunately, EPA asserts that "actual concentrations of carbaryl in drinking water derived from surface water are likely to be much lower than estimated", based on the results of monitoring data. We request that EPA define the magnitude of "much lower", and provide to support its contention. It is a fatal weakness in this assertion that EPA makes no attempt to quantify the uncertainty and magnitude of the model overestimation of residue levels. We request that EPA either accept the model predictions that the risk cup is overflowing, or quantify the magnitude of the error within the model, and provide a quantification of the model uncertainty.

The model used is fairly robust, and includes usage scenarios from five crops across several States. It uses percentage of crop treated (PCA) defaults of 87% for most crops, 38% for Florida citrus and Georgia pecans, and 46% for field crops such as corn. EPA provides no data to estimate the magnitude of overestimation of PCA defaults for Florida citrus, determined to be the risk driver for drinking water residues. We request that EPA provide an estimate of the magnitude of uncertainty and error with these estimates, if it intends to dismiss them as overestimates. In fact, the model and monitoring data are in fairly good agreement. The surface water modeled concentrations of carbaryl residues range from peaks of 646 ppb (for FL citrus) to averages ranging from 1.3 ppb (CA citrus) to 23.3 ppb (FL citrus), depending on the crop scenario (IRED at 20-21). This is in very good agreement with the monitoring data, which reports a maximum detected concentration of 610 ppb in a well in New York (IRED at 21), a maximum from non-targeted USGS NAWQA study of 5.5 ppb (IRED at 18). EPA reports that carbaryl is the second most widely detected insecticide (IRED at 18).

Monitoring data is derived from sampling that is often spotty, and is not designed to coincide with high use sites, seasonal application times, watershed characteristics, or urban and agriculture application methods (IRED at 18). It is highly unlikely that inadequate monitoring will detect the peaks and fluctuations of residue that are recognized to take place with pesticide runoff into surface water. Absence of evidence is not evidence of absence. We request that EPA provide justification and quantification for its assertion that the modeling data, which is in fact in fairly good agreement with monitoring data, is unreliable.

The IRED reports that "the acute drinking water level of comparison (DWLOC)¹ for children 1-2 years old, the most highly exposed population subgroup, is 7.4 ppb whereas the DWLOC for the general population is 200 ppb. Modeled acute surface water estimated environmental concentrations (EECs) for carbaryl range from 23 to 410 ppb, indicating that residues in surface water sources of drinking water are unacceptably high, and may pose unacceptable health risks to children and the general population. The highest EEC is based on the citrus use in Florida. EPA acknowledges that "the probabilistic acute aggregate assessment for carbaryl shows exposures exceeding

¹ The DWLOC represents the maximum drinking water concentration which, when considered together with exposure through food, does not exceed EPA's level of concern. If the DWLOC is greater than the drinking water EEC, then the risk is not of concern to the Agency.

100% of the aPAD for certain regional use scenarios” but incorrectly argues that, “the Agency believes that the actual risks are much lower and not of risk concern because of uncertainties with specific fate data; conservative inputs to the water model, including the default PCA and assumption of 100% crop treated; the expected effects of water treatment; and the overall results of available monitoring data” (IRED at vii). However, none of these statements is supported by data. On the contrary, the Agency did not actually use a “assumption of 100% crop treated”, but rather used a default assumption of 87% for most crops, and only 38% for Florida citrus, the risk driver (IRED at 20-21). In addition, it seems that the Agency has received preliminary data from the registrant that may indicate that conventional drinking water treatments do not remove carbaryl residues at all (Bayer preliminary data). Given the Agency’s reliance on inaccurate statements, how can the Agency disregard the model results, while still preventing surface water contamination from carbaryl? We recommend that the Agency invoke additional mitigation measures, including cancellations and revocation of tolerances, to address the unacceptably high exposures that may occur from surface water contamination.

II. Residential risks:

We support EPA assumptions that residential use scenarios are based on use of short-sleeved shirts, short pants, and shoes and socks. We think that these assumptions are reasonable, and reflect homeowner attire during pesticide applications. We support the registrant and EPA in cancellations of the highest risk scenarios, such as dog dusting (MOE of 4), belly grinder applications of granular and baits for lawns (MOE of 60) and aerosol products (IRED at 5, 26). However, while EPA has determined that pet collar uses are safe (MOE>1 million), we are concerned that these calculations do not consider that pets sleep with household children, share intimate play space with children (floors, rugs, dusty corners, etc.), and share hugs and kisses with children. While this seems like an enviable life for the dog, exposure levels from flea collars for household children may be significantly higher than EPA estimates. A child could spend literally hours of each 24 hr period with hands going between the child’s mouth and the dogs neck fur. We request that EPA provide information on assumptions used to calculate flea collar exposures.

Healthier alternatives to these pesticides are readily available. Easy physical measures like frequent bathing and combing of pets can make the use of pesticides unnecessary. Pet products containing non-pesticide growth regulators also can stop fleas from reproducing successfully. In addition, newer insecticides, sprayed or spotted onto pets, have been developed that are effective against fleas and ticks without being as toxic to humans. The safety and effectiveness of these alternatives makes the continued use of older, more toxic pet products tragically unnecessary. We recommend that EPA cancel all pet uses of carbaryl, including collars, in light of the unnecessary dangers posed to children, pets, and pet groomers.

III. Occupational risks:

EPA determined that worker risks can be mitigated, but fails to consider that actual worker poisoning events occur at occupational exposure levels that EPA currently considers “safe”. In the face of sick or cholinesterase depressed workers, blind adherence to an allegedly “safe” estimate is not scientifically defensible and not data-driven. We recommend that EPA re-calculate its acceptable exposure levels, incorporating data from recorded worker exposure events, including both the 2003

Florida incident and the 2004 Washington State cholinesterase monitoring data. We additionally recommend that all uses with MOE's for handlers of less than 100 be canceled; and, that restricted entry intervals (REI) be set so that the MOE is at least 100 for high exposure post-application tasks.

We remain concerned that the Agricultural Re-Entry Task Force (ARTF), an industry-financed group, has developed a methodology for establishing a transfer coefficient and estimating field worker exposure to pesticides. Although neither its study protocol nor its data have been fully reviewed by the EPA's Scientific Advisory Panel (SAP) or subjected to public scrutiny through the notice and comment process, the EPA has already begun using this approach in setting restricted entry intervals (REIs). There are also many reasons to be skeptical about the accuracy of the ARTF data. The method chosen for collecting pesticide residue samples appears to underestimate the extent of exposure. In addition, its categorization of crops and tasks, leads to inappropriate exposure estimates. We oppose the use of this untested data and call on the EPA to refrain from further use of this information until it has been fully evaluated by the SAP and subjected to a public notice and comment review.

In its previous comments, Farmworker Justice Fund alerted EPA that its methods of risk calculation underestimates occupational risk and proposes inadequate risk mitigation measures. EPA has underestimated the duration of worker exposure, both in terms of hours worked per day and days per year. Many handlers and field workers routinely work 10-12 hour days for 6 or 7 days/week. US Department of Labor's National Agricultural Worker Survey (2000) reports that 56% of crop workers works 31 to 50 hours/week and 15% worker more than 50 hours/week. For postapplication workers, EPA has assumed 10 days/year for private growers and 30 days/year for commercial farmworkers. Many farmworkers are on crews receiving greater exposure; for example, apple harvesters in Virginia, New York, and Washington state routinely work 6 days/week for 2 to 3 months. Apple thinners in Washington typically work 6 days/week for 6 weeks, and citrus harvesters often work 6 days/week for 4 months. EPA responded that, "Current methods used by the Agency are based on data from the Agricultural Reentry Task Force (ARTF)" (EPA. Carbaryl: Agency Response to Comments on Phase 5 Risk Assessment; DP Barcodes: D295080; PC Code: 056801. October 26, 2004). However, Farmworker Justice Fund and NRDC continue to recommend that "EPA should not rely on data from the Agricultural Reentry Task Force (ARTF) until these data have been independently validated." (Farmworker Justice Fund, et. al. (OPP-2003-0101-0046). In its defense, EPA notes that, "ARTF also has conducted its own peer review in which noted researchers such as Fenske and Popendorf participated, as well as representatives from other organizations such as commodity groups." (EPA response to comments). We note concern that: a) an internal ARTF peer review is not a public process, and does not have the credibility of an EPA Scientific Advisory Panel, and b) that Fenske and others knowledgeable of that flawed process raised many serious concerns with the accuracy of the ARTF data and validity of its research methods, but these concerns remain unaddressed. We request that EPA refrain from using ARTF data until it has been publicly and appropriately peer reviewed .

The EPA has determined that margins of exposure (MOE) of 100 or greater are required to ensure handler safety for short or intermediate term exposures. For this reason, the Agency has accepted the voluntary cancellation of a number of uses involving wheat as well as a few other high risk methods of application, which have MOEs of less than 100. Nonetheless, the Agency is continuing to permit many carbaryl uses with unacceptable MOEs (of less than 100). These include agricultural scenarios (other than wheat) which include the following: scenarios 1F, 3A, 3F, 4A, 4B, 4F, 5A, 5B,

5C, 12 and 17. Since the EPA has not provided an adequate benefits justification for these unsafe uses, as such all of them should be canceled.

In its previous comments, the Farmworker Justice Fund Inc. raised concerns about the EPA's failure to establish REIs for citrus which would have prevented the poisoning incident that occurred in Duette, FL in April 2003. This incident is particularly instructive because over a few hour period, 21 workers in a single orange harvesting crew reported symptoms consistent with carbaryl poisoning and at least one worker required on-going medical care over an extended period of time. In its response to this incident, EPA asserts that the data is "inconclusive" as to whether a carbaryl poisoning occurred in that instance; this claim is incorrect. After an evidentiary hearing, a workers compensation judge, relying on expert testimony and other evidence, unequivocally determined that a Duette worker had been poisoned by carbaryl and this worker was awarded benefits. (See JM and Dunson Harvesting Inc., OJCC # 03-023945 Order, certified June 14, 2004, attached). That case has since been settled and this ruling stands unchallenged. Consequently, the EPA must reconsider the MOEs it has established for post-application workers in light of the evidence amassed in the Duette investigation.

Similarly, although the Agency claims to have considered the "best available" data, it has failed to consider the information collected by Washington State in its cholinesterase monitoring program. Beginning in January 2004, Washington State has required cholinesterase monitoring of all mixers, loaders and applicators who will be exposed to Toxicity Category I or II organophosphates or n-methyl carbamates for 50 hours or more in any 30 day period. As part of this program, the state required handlers to submit to a baseline cholinesterase tests and have a follow-up test in any month in which the 50 hour or more threshold was reached. All blood samples were sent to a single state laboratory which analyzed them and produced the results. Whenever workers suffered a 20% or more cholinesterase depression, the employer was required to conduct a workplace audit and the Washington Department of Labor and Industries (WDL&I) was required to investigate. Whenever a worker suffered a 30% or more red blood cell cholinesterase depression or a 40% or more plasma cholinesterase depression, the worker was required to be removed from handling tasks until her/his cholinesterase levels rebounded. Over the course of the 2004 spray season, 130 (21.2%) pesticide handlers out of 612 who received both baseline and follow-up tests had depressions of more than 20%. Of these 26 (4.2% of the 612 workers) had depressions low enough to trigger removal. Four pesticides were involved in the vast majority of workplaces with depressions: Sevin (carbaryl), Lorsban (chlorpyrifos), Carzol (formetanate) and Guthion (azinphos methyl). The greatest proportion of handlers qualifying for workplace audits had been using only 1 insecticide, Sevin or Lorsban, with a significant but lower proportion using mixtures. The greatest proportion of handlers needing removal used a mixture of Sevin and an organophosphate insecticide (Lorsban or Guthion). (Washington State Scientific Advisory Committee to Washington State Department of Labor & Industries Draft Report November 10, 2004, p. 37). In 10 of the 19 case summaries prepared by WDL&I, Department investigator expressly stated that no deficiencies in compliance with label requirements were identified. Thus, the Washington State data shows that current carbaryl label requirements have led to significant numbers of handler overexposure incidents. This data should be carefully considered in setting PPE requirements and other mitigation measures for agricultural pesticide handlers. They also cast doubt on the EPA's discounting of non-occupational incident data as due to careless use of the product. Rather, the incident and monitoring data from Florida and Washington State shows that use of carbaryl is extremely

dangerous, causing cholinesterase depression or injury even when used according to label requirements.

IV. Ecological risks:

Carbaryl has very significant harmful effects on beneficial insects, fish, and wildlife, some of which have been described in the IRED. Carbaryl is determined to be moderately toxic to mammals and fish, and highly toxic to bees and aquatic invertebrates “on an acute exposure basis” (IRED at 45). EPA reports risks to wildlife as a calculated RQ (risk quotient) values, where the RQ is the ratio of the EEC to the toxicity endpoint value (IRED at 46). Thus, an RQ of 1 means that the concentration of residue that may be found in water is equal to the level that may be toxic to an exposed species. The higher the RQ, the greater the risk of harm to an exposed species. We are very concerned that the EPA IRED reports calculated RQ values that are extremely high.

Beneficial Insects

Our comments support those of Beyond Pesticides (Docket OPP-2003-0376), and we refer EPA to those comments for more detail than we provide here.

Pollinators provide an essential ecological function in both agricultural and wildlife ecosystems. Protection of pollinators and other beneficial insects should be the highest priority of the EPA, as without them crops would not produce harvests and wild plant communities would decline. The EPA’s Bee Precautionary Labeling Statements must recognize the paramount importance of bees as pollinators and ensure adequate protection for both managed and feral colonies of honey bees and populations of native bees.² The current EPA bee caution statement is inadequate, “*This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area*” (IRED at 5-6). We are recommending that EPA improve the bee caution statement to match the intent of the law and protect pollinators. We recommend that EPA modify the second sentence of the label caution to prohibit application to bloom, as “*Do not apply this product to blooming crops or weeds*”. All pesticide labels that carry the bee caution should also be modified under the “directions for use” section and in the special directions for all specific crops to incorporate a protection of pollinators, to reflect this.

There are no data on long-term exposures to bees, although one dozen environmental and public health groups and beekeepers associations have requested these data be collected from the registrant (letter to EPA, Sept 24, 2003).³ We again recommend that EPA require a chronic honey bee study to evaluate the sublethal,

² This section from comments submitted by Beyond Pesticides, and in there provided by The Xerces Society (<http://www.xerces.org>), an international non-profit organization dedicated to protecting biological diversity through invertebrate conservation.

³ Letter from one dozen environmental and public health groups and beekeepers to EPA, Anthony Britton and Tom Steer. Re: Carbaryl: concern regarding bee kills associated with carbaryl use, and request for chronic use study. September 24, 2003

NRDC letter from Jennifer Sass and Aaron Colangelo to Gene Huoson, Minnesota Dept Ag. Re: concern that pesticide use is threatening honey bee operations in Minnesota, and suggestions for consideration by the Minnesota Apiary Advisory Committee. February 24, 2004

chronic effects of carbaryl on bee behavior, colonies and pollinator production. At this time, no such data exists, despite the fact that carbaryl formulations are designed to be long-lasting, and are predicted to inflict chronic damage to exposed wildlife.

Birds

EPA assessed only chronic effects on birds. In that assessment, it found that for all of the assessed uses, risk quotients for birds were exceeded. That is, EPA's assessment is that chronic exposure to carbaryl is likely to harm birds. However, there are no significant actions taken to address this risk, and the continued allowance of the use of granular carbaryl in particular is likely to lead to harmful exposures for birds. How is EPA planning to address these risks? EPA did not assess the acute toxicity of carbaryl to birds, despite incidents in which birds were killed by carbaryl. We question this omission and request that EFED perform this assessment. In addition, no studies from the open literature were incorporated into the assessment; we consider this an omission and request that the IRED be amended to include these studies into its assessment and risk management decisions.

Mammals

EFED's assessment found high risks for mammals, particularly small and medium-sized mammals:

- The chronic LOC is exceeded for mammals for all assessed uses (IRED at 48-50);
- the acute risk LOC is exceeded for small and intermediate-sized mammals for all 40 granular uses;
- for large-sized mammals, acute restricted use and endangered species LOCs are exceeded following application for trees and ornamentals, turfgrass, and tick control; and
- chronic mammalian exposure to carbaryl resulted in decreased second-generation pup survival in a two-generation rat reproduction study.

The highest reported chronic mammal RQ values for nongranular uses were 51 (CA citrus), 31 (turfgrass), 26 (olives), 22 (tree nuts), and 17 (citrus). Bird and mammal chronic RQ values exceed the chronic risk Level of Concern (LOC) of 1 for all (100%) of the assessed uses (IRED at 48-50), assuming maximum allowable use rates. When assuming average use rates, a full 50% of uses still exceed the chronic risk LOC for birds (IRED at 50). For granular formulations, acute RQs for mammals ranged from 1-21, and therefore exceeds the LOC for all 40 registered granular uses. We refer to the IRED at 48-51 for a detailed list of the RQ analysis for birds and mammals.

Thus, EPA's own conclusion is that carbaryl is highly likely to harm mammals of all sizes when used in what are very common applications, such as for trees, ornamentals, and turfgrass, and when used in granular form. EPA must adjust the registration to ensure that mammals are not harmed by carbaryl use. These extremely elevated RQ values pose an unacceptable risk; EPA has provided no calculations or evidence that would support its assumption that the proposed mitigation will be adequate. We request that EPA run the mitigation assumptions through its PRZM-EXAMS model to determine if the proposed mitigation will adequately reduce the EEC values, and then re-calculate the RQ values, and provide these amended calculations in the IRED.

Fish

For freshwater fish, acute and chronic RQ values were exceeded only for citrus. However, the endangered species level of concern (LOC) is met or exceeded for all crops, indicating that carbaryl poses a threat to endangered fish. In addition, because of carbaryl's very high toxicity to invertebrates, its use is likely to affect the food supply for fish such as salmon.

EPA also reports that fish-kill incidents were reported for carbaryl, but could not be verified. We are extremely concerned at the inability of EPA to reliably document and verify reported incidents for wildlife, despite label requirements that certain investigative procedures are followed to enable appropriate documentation. We request that the EPA provide more detail regarding the reported incidents, the steps that should have been taken to document and verify the incidents, and the steps that were taken. Without attention to these procedures wildlife may suffer serious harm or even death at exposure levels or use scenarios considered "safe" by EPA.

Aquatic Invertebrates

For freshwater invertebrates, acute RQ values range from 4.5-30, and chronic RQ values range from 8.7-55 (IRED at 52-53) for maximum label rates. For average use rates, the RQ values also far exceeded the LOC for acute risks, ranging from 1.4-20, and for chronic risks, ranging from 2-34. These are extremely high RQ values, and raise concern that carbaryl poses an unacceptable harm to freshwater invertebrates. No living aquatic ecosystem can survive without invertebrates, which provide a basic food source for more complex aquatic species and are critical to healthy ecosystems. We request that EPA run the mitigation assumptions through its PRZM-EXAMS model to determine if the proposed mitigation will adequately reduce the EEC values, and then re-calculate the RQ values, to assure itself and the public that the proposed mitigation is adequate to protect these valuable species.

For estuarine/marine invertebrates, EPA reports that the acute risk LOC is exceeded for all five carbaryl uses assuming average rates of carbaryl use (RQ range 1.2-18) (IRED at 53). EPA indicates that it has requested chronic toxicity data for these species from the registrant. Since carbaryl formulations are specifically made to be long-lasting, we emphasize that these data are very important. We encourage EPA to ensure that they are received and reviewed in a timely manner, and that the results are incorporated into the IRED mitigation recommendations so as to ensure that these species are adequately protected.

Laboratory studies have found harm to aquatic invertebrates at very low levels. The lowest level at which effects have been seen is 0.1 µg/l for two species of marine organisms: delayed molting of Dungeness crab (Buchanan et al. 1970) and reduced cholinesterase activity in prawn (Bocquene & Galgani 1991). Based on those and other data, the Washington State Department of Ecology has suggested 0.1-0.7 µg/l as an effects threshold range for marine organisms and recommended .06 µg/l as a "probable safe concentration" for the protection of marine organisms in Willapa Bay (WSDE 2001). The U.S. EPA has not established water quality criteria for carbaryl, but the Canadian government has issued an interim guideline of 0.20 µg/l for freshwater and 0.32 µg/l for protection of saltwater organisms (Can 2002).

Amphibians

EPA does include an assessment of information in the open literature in its assessment of carbaryl effects on amphibians. EPA cites studies that found that a large percentage of tadpoles exposed to carbaryl developed malformations, and that tadpoles exposed to carbaryl had lower growth. In addition, a recent study found that levels of carbaryl thought to be non-lethal to treefrog tadpoles became lethal when administered

to the tadpoles in the presence of a caged predator (Relyea and Mills 2001). Predator cues made the pesticide four times more lethal. This study raises the concern that safety levels deduced from laboratory tests are likely to be insufficiently protective.

Surface Water Contamination

Carbaryl is widely found as a pollutant in surface water. Based on the United States Geological Survey (USGS) National Ambient Water Quality Assessment (NAWQA) database, carbaryl is the second most widely detected insecticide, with a significant portion apparently transported to streams (USEPA 2003a). Out of 5220 surface water samples analyzed, about 21% (1082) had detections greater than the minimum detection limit (0.063 ppb). EPA's modeling estimates acute carbaryl surface water concentrations of 44.9 to 410.4 µg/l and chronic carbaryl concentrations of 2.05 to 18.6 µg/l. Although national water quality criteria have not been established for carbaryl, criteria using essentially the same procedure have been derived for California. All of the estimated acute concentrations exceed the California carbaryl acute water quality criteria, and most of the estimated chronic concentrations exceed the carbaryl chronic water quality criteria.

The maximum observed concentration for carbaryl in surface water from the non-targeted USGS NAWQA study is 5.5 µg/l. However, a Washington State Department of Agriculture/ Department of Ecology study found carbaryl at 10 µg/l in 2004 in an agricultural drainage. Generally, USGS has found that streams draining urban areas show more frequent detections and higher concentrations than streams draining agricultural or mixed land use areas.

Because EPA does not have the capability to model pesticide water pollution in urban areas, monitoring data must be considered to assess risk to aquatic species. EPA has concluded on this basis that "concentrations detected in urban drainages are not high enough to exceed level of concern thresholds for either human health through drinking water or for fish." However, much of the data upon which this statement was based, predates recent EPA cancellations of consumer uses of diazinon and chlorpyrifos, which seem to be driving large increases in urban carbaryl use. We question the relevance of the earlier data and believe that they may result in an overly optimistic picture of the current and future water quality situation. We request that EPA consider these market changes in its assessment of carbaryl.

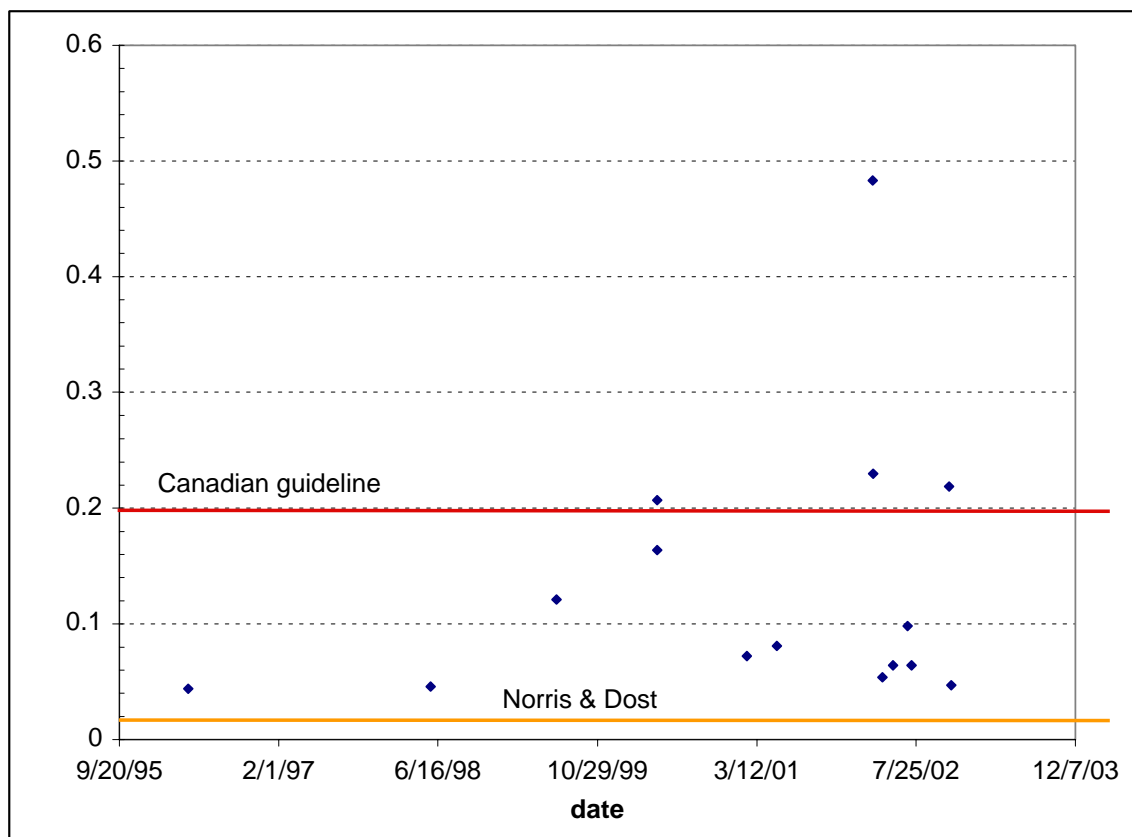
The King County Department of Natural Resources (Washington state) obtained data on retail sales of insecticides from "big box" retailers between 1997 and 2001. These data show that the annual retail sales for diazinon and carbaryl were relatively constant between 1997 and 2001, with sales of diazinon more than ten times higher than sales of carbaryl. In 2002, however, the situation changed, with diazinon sales dropping by about a factor of two and carbaryl sales jumping more than tenfold. Retail sales of both chlorpyrifos and diazinon began to decrease substantially well before their phaseout dates, while carbaryl sales showed the largest increase of any insecticide in 2002. Thus, carbaryl can be expected to be an increasingly significant contaminant in urban and mixed-use areas, particularly in the Pacific Northwest where it is used extensively on turf for crane fly control. Increasing carbaryl use has also been seen in California, where landscape use grew by almost 40% from 2000 to 2003 and structural pest control use more than doubled during the same period.

In an article recently submitted to Environmental Toxicology and Chemistry (Dickey and Wilson 2004), we estimated that, because of carbaryl's higher mobility, if all uses of diazinon in an urban watershed were to be replaced with carbaryl, observed concentrations of carbaryl in streams could be three to four times higher than historic diazinon concentrations. The estimate was based on the Surface Water Mobility Index

(Chen et al). Significant replacement of diazinon with carbaryl could result in peak concentrations exceeding 1 µg /l. Despite carbaryl's lower aquatic toxicity compared with diazinon, these increased carbaryl concentrations would be of concern for endangered species and could have subtle effects on other species as well.

Recent surface water testing shows rising carbaryl concentrations coincident with increased use. In the Puget Sound area in Washington, a study in the late 1990s detected carbaryl in about two-thirds of streams tested during spring storm events (Voss et al. 1999). Concentrations ranged from less than 0.01 µg /l to about 0.05 µg /l. A few detections exceeded established chronic toxicity guidelines of .017 (Norris and Dost 1991) and .02 µg /l (NAS 1973), raising concerns about risks to aquatic life. More recent USGS testing in King County streams shows increasing levels of carbaryl, with at least six detections over .05 ppb and three over 0.3 µg /l in 2002. Figure 1 (see below) compares recent USGS measurements of carbaryl concentrations in King County streams with toxicity guidelines. (Note: only detections over reporting limits are shown, and all detections for carbaryl are coded "E" for estimated by USGS.) Most streams contain multiple pollutants, including several insecticides (e.g. diazinon, carbaryl, malathion) that inhibit the enzyme acetylcholinesterase. The effects from multiple pollutants with a common mode of action can reasonably be expected to be additive. If so, the appropriate safety guidelines for each individual chemical will underestimate the risk from the mixture. We request that when EPA looks at stream monitoring data for carbaryl, product use patterns be considered and trends in pesticide concentrations be evaluated.

Figure 1. Carbaryl Concentrations (dots) in King County Streams 1996-2002 (Source: USGS NWIS Database)



Ecological Assessment Methods and Mitigation Measures

In general, the EPA bases its analysis of ecological effects almost completely on comparisons between lethal concentrations (LC50) and expected concentrations based on modeling. Typically, EPA risk assessments conclude that a “level of concern” is exceeded if the expected concentration exceeds half the LC50 value, and for endangered species if it is more than 1/20th of the LC50 value. This method has a number of flaws. The most major flaw is that it focuses only on acute effects with lethality as an endpoint. There is significant evidence that sublethal effects on many species can be significant and can affect individuals as well as the population. Effects include immune system suppression, hormone disruption, behavioral effects, mutagenicity, carcinogenicity, and others.

In addition, EPA does not substantially address indirect effects, such as effects on food supply and habitat, or assess the potential for synergistic or additive effects. In the case of carbaryl, additive effects are particularly pertinent, since fish and wildlife are likely to be exposed not only to carbaryl but to other acetylcholinesterase-inhibiting pesticides.

No specific mitigation measures have been identified to address ecological concerns. While reduced application rates will reduce environmental concentrations, a number of problematic uses remain.

For example:

- all granular applications are likely to harm small and medium-sized mammals;
- all uses have been assessed to exceed the threshold for chronic effects on birds; and
- all uses have unacceptable impacts on invertebrates.

We request that EPA revisit the uses that have been identified as harmful to fish, beneficial insects, and wildlife. EPA should rerun exposure models to determine whether the mitigation measures identified will be sufficient to prevent harm. Where they are not, EPA must reduce or eliminate uses to ensure that fish, beneficial insects, and wildlife will be protected. Since EPA has not established runoff models for urban areas, urban uses should be eliminated until EPA can establish a model and determine likely exposure.

Use on Tidelands in Washington State

The IRED states, “Although concern has been raised regarding this use and its potential impact to nontarget animals outside of treated areas, very little data have been provided to substantiate these concerns.” However, EPA’s own risk assessment details much of the data that show impacts. The ecological risk assessment (EFED 2002) states,

“Estimates of potential fish kills range from 15,000 to 96,000 following each treatment (MRID 419826-06). Exposure to sublethal carbaryl levels may also inhibit acetylcholinesterase in fish in subtidal areas near treated sites, resulting in a temporary impairment of burying behavior and increasing exposure to predators (Pozorycki, 1999). Along with the burrowing shrimp, other invertebrate populations inhabiting treated mudflats, which constitute a food source for fish, are temporarily reduced or eliminated. There may be up to 100% mortality of Dungenese crab populations following carbaryl applications.”

In comments to EPA (Barry 2002), The US Fish and Wildlife Service expressed

significant concerns about this use, and in particular, the effects on cutthroat trout, a threatened species that forages in the estuary. Specifically, the Service noted that “Although a small percentage of the estuary’s mudflats receive direct application of carbaryl, the total area potentially affected is greater since the incoming tide transports the chemical throughout the estuarine system. Johnson (2001) reported that carbaryl was detected by WDOE several miles from application areas, supporting the fact that the area affected by the spray is greater than the area treated.” The Service concludes, “The Service believes that the pesticide regulatory agencies cannot come to the ‘no unreasonable adverse effects determination’ needed prior to the approval and subsequent issuance of the Section 24(c) SLN Registration of carbaryl for use on oyster beds, without considering the insufficiencies of the ecological risk assessment outlined in our comments.”

While this use is being phased out as a result of a settlement between EPA and the Washington Toxics Coalition, the phaseout timeline is long and there are likely to be significant impacts between now and 2012. We request that EPA develop a shorter timeline for phaseout and assist the oyster growers in developing a safer alternative.

V. Endangered species:

The IRED reports serious risks to endangered species from maximum and even average carbaryl use rates. The numbers of scenarios that exceeded the level of concern (LOC), therefore posing unacceptably high risks, are too numerous to list here (see IRED at 54-56). Unfortunately, EPA does not provide the RQ values in the IRED, so the magnitude of excess risk is not revealed. This is concerning to us, and we request that EPA report the RQ values for endangered species, since they’ve clearly calculate them. For herbivore mammals, all carbaryl uses exceed the acute endangered species LOC (no RQ value provided). For insect-eating mammals, 45-70% of uses exceed the acute endangered LOC (for intermediate- and small-sized mammals respectively; no RQ values provided). EPA reports that chronic LOC’s are exceeded for all modeled uses for all mammals feeding on all food items except seeds/fruits and large insects. EPA reports that even when RQ’s (not provided in IRED) were based on average use rates, “acute and chronic endangered species LOC’s are exceeded for all of the modeled uses” (IRED at 55). For freshwater fish “the endangered species LOC is exceeded for all of the crops modeled for all sure rates, except sugar beets” (IRED at 55). For freshwater invertebrates, “the acute and chronic endangered species LOC’s are exceeded for all of the uses modeled. These reports can be loosely summarized as indicating that almost every use of carbaryl, at all legal rates, pose unacceptable chronic and acute risks of harm to aquatic species, and most mammals. This is obviously of great concern to the public.

When EPA consulted with US Fish and Wildlife Service in 1989 for various uses of carbaryl, the Service concluded that the registration and subsequent uses of carbaryl would likely result in jeopardy for 86 species. It is inexcusable that EPA has not implemented the reasonable and prudent alternatives developed by the Service to avoid jeopardy, which include measures such as no use within a certain distance (40 yards to 0.5 miles) of sites of known populations and buffers upstream of occupied habitat. Moreover, EPA has failed to re-initiate consultation, which the Service has requested. EPA should act to implement the reasonable and prudent alternatives immediately, and consult with the Service on new species that have been listed and critical habitat that has been designated since 1989.

We are encouraged that EPA has requested a consultation with the National Marine Fisheries Service (NMFS) to address possible effects to Pacific salmon and

steelhead in affected states, as well as “additional consultations with both the USFWS and NMFS” to consider other terrestrial and aquatic species listed as endangered. We request that EPA conduct these consultations and implement the results in a timely manner. In the interim, we request that EPA implement mitigation measures that will eliminate harmful exposures to endangered species.

VI. Benefits:

The EPA considered the benefits associated with the use of carbaryl on citrus and grapes, to evaluate occupational and ecological risks. However, use of carbaryl on citrus was determined to be driving drinking water exposures above the Agency level of concern for children and the general population. In its assessment, EPA notes that the main targets of carbaryl in California citrus is for two species of scale, both of which can be effectively controlled by natural predators. We recommend that EPA reduce carbaryl applications for both California and Florida citrus to mitigate drinking water exceedances, and encourage EPA to increase its consultations with experts in Integrated Pest Management (IPM), to ensure that beneficial species are not being harmed by pesticide uses, while agriculture needs are being adequately met.

EPA has not provided adequate documentation demonstrating that the benefits of increased carbaryl use exceed the identified risks, especially for urban uses where many alternatives exist. We request that the Agency consider cancellation of uses that involve the highest ecological risks and for which alternative methods exist. For example, we request that EPA consider revocation of tolerances for turf uses and for slug and insect baits. Carbaryl used on urban turf has a high probability of leaching to surface water. The combination of large application area, compacted and thatch-covered soils, and adjacent impervious surfaces such as sidewalks and streets combine to enhance the runoff and transport of carbaryl to surface water. In addition, broadcast application of carbaryl insecticide over clover-containing turf will cause significant bee mortality. Slug and insect baits that are combination pesticide products undermine Integrated Pest Management by encouraging unnecessary applications of additional chemicals. Broadcast application of wide-spectrum insecticides are highly likely to kill beneficial or harmless insects. EPA should use its registration powers to encourage the use of more selective pest management tools and discourage the widespread use of combination pesticides.

VII. Tolerances:

The Agency has proposed to revoke 9 carbaryl tolerances, lower 31 tolerances, and reassign 49 tolerances. The Agency states that, “for all carbamates, including carbaryl, tolerances will not be raised and new tolerances will not be established until cumulative risks have been considered.” (letter to registrant at 6). In an apparent contradiction to this statement, EPA lists 20 tolerance reassessment recommendations that are higher than the current tolerance, and 7 new tolerances (IRED, Table 23). We are concerned that such determinations were made prior to a cumulative risk assessment, and request that EPA refrain from issuing recommendations of new or increased tolerances in this IRED. Further, we recommend that EPA revoke all tolerances that are being cancelled or voluntarily withdrawn.

We insist that EPA revoke tolerances for all uses of carbaryl that are being withdrawn or cancelled. If this is not done, then imported food and products that enter the U.S. with carbaryl residues will not trigger action by the Food and Drug Administration (FDA). It is the FDA and not the EPA that checks imports for such

violations, and so only by updating the list of tolerances to reflect risk management decisions correctly will appropriate action be taken to keep America's food supply safe.

There is a second reason to revoke tolerances that are voluntarily withdrawn or cancelled. The pesticide manufacturers prefer to voluntarily cancel high risk products, or voluntarily withdraw high risks uses, rather than have EPA issue a ban on those products. If a ban is issued, then this will trigger Prior Informed Consent (PIC)⁴ listing, thus alerting all countries that a particular pesticide or residue has been determined to be of such high risk that it has been banned by a country. To avoid PIC listing, that is, to avoid alerting the international community of an unacceptably high risk residue in a product, the manufacturer prefers to issue a quiet voluntary withdrawal, thereby leaving open international markets and trade options. We find this practice morally reprehensible and note that it results in the transfer of high risk chemicals to the developing countries, where environmental, occupational, and public health protections are far weaker than the U.S. Such countries often rely on the U.S. risk evaluations and risk management decisions as guides and goals in managing their own chemical risks. The U.S. can best serve the international community, and best protect U.S. imports, by making public its risk assessments and risk management determinations, including tolerance revocations.

VIII. Outstanding data requirements:

We request that EPA provide an accessible list of all outstanding data requirements for carbaryl, and ensure that these data are received and reviewed in a timely manner to as to inform the carbaryl risk assessment and mitigation recommendations. Further, these data should be made publicly accessible.

Throughout the IRED, and discussed throughout these comments, the EPA has indicated that there are outstanding data that have been requested by the registrant, or by other federal agencies. These data include but are not limited to: chronic toxicity data for bees; chronic toxicity data for estuarine/marine invertebrates; and consultation packages with the National Marine Fisheries Service (NMFS) to address possible affects to Pacific salmon and steelhead in affected states, as well as "additional consultations with both the USFWS and NMFS" to consider other terrestrial and aquatic species listed as endangered. We are encouraged that EPA has requested these consultations, and request that these data be received and reviewed in a timely manner, and made available to the public.

In our previous comments (Natural Resources Defense Council OPP-2003-0101-0039) we raised concern that no appropriate exposure data exist for the following scenarios: animal grooming dust applications, dust applications in agriculture, handheld fogging for mosquito and other pest treatments, power backpack application, tree injection, drenching/dripping seedlings. In its response, EPA stated that it "agrees with

⁴ PIC: In the 1980s Governments began to address the problem of the international trade of hazardous chemicals by establishing a voluntary Prior Informed Consent procedure. PIC required exporters trading in a list of hazardous substances to obtain the prior informed consent of importers before proceeding with the trade. The Rotterdam Convention made PIC legally binding in February, 2004. The Convention establishes a first line of defense by giving importing countries the tools and information they need to identify potential hazards and exclude chemicals they cannot manage safely. With respect to the exchange of information, the Convention establishes a requirement for a Party to inform other Parties of each national ban or severe restriction of a chemical. <http://www.pic.int/>

NRDCs concern about the lack of available data to assess these scenarios. In October 2004, EPA plans to send a Data Call In (DCI) to the carbaryl technical registrants seeking this data" (Carbaryl: Agency Response to Comments on Phase 5 Risk Assessment; DP Barcodes: D295080; PC Code: 056801. October 26, 2004). We are encouraged that EPA has requested these data, and request that these data be received and reviewed in a timely manner, and made available to the public.

IX. Outstanding concerns raised in previous comments, that EPA has inadequately addressed:

NRDC: The water assessment did not consider non-agricultural sources of carbaryl, a total of 40% of carbaryl by weight, and the dominant source of water pollution. EPA: However, the concentrations detected in urban drainages are not high enough to exceed level of concern thresholds for either human health through drinking water or for fish. Exceedances of risk thresholds for aquatic invertebrates might be expected based on this data, but these data indicate that those concentrations would occur infrequently. EFED acknowledges that having the capability to model urban uses would greatly strengthen our assessments in that area. (NRDC doc 39; EPA response July 14, 2003, p. 3 of 20). NRDC: We maintain that EPA must include all information available in its water assessment, including non-agricultural sources, and encourage EPA to continue to gather information to strengthen its assessment.

NRDC: The acute drinking water level of concern (DWLOC) for combined food and water exposure exceed acceptable levels. EFED: The commenter is correct in noting that the DWLOC is exceeded for carbaryl. Consequently, the assessment was refined beyond the screening level using an approach that uses combined food and water in a more fully probabilistic manner, similar to what was done by the Agency in the OP cumulative assessment. (NRDC doc 39; EPA response July 14, 2003, p. 4 of 20). NRDC: We agree with EPA that the refined probabilistic assessment offers a more refined estimate, but point out that EPA has disregarded the findings of its own assessment. We recommend that EPA either accept its modeling estimates of drinking water contamination, or provide robust data to demonstrate that ecological and human health will be protected despite the modeling predictions that surface water contamination poses an unacceptable risk to children and the general population.

NRDC: Carbaryl poses unacceptably high risks to mammals and aquatic animals; all granular uses are unsafe for mammals. EPA: The NRDC is correct that the EFED chapter indicates acute risk LOCs are exceeded for mammals on all 40 registered uses of granules (RQ range 0.99 - 21). However, except in cases of unusually high rain events, granular formulations tend to reduce the runoff potential of carbaryl into aquatic habitats due to the slow release of active ingredient from the granules. ...The Agency believes that the voluntary cancellation of a number of uses and proposed mitigation measures for the remaining uses will reduce potential risks to non-target animals. (NRDC doc 39; EPA response July 14, 2003). NRDC: EPA has provided no calculations or evidence that would support its assumption that the proposed mitigation will be adequate. We request that EPA run the mitigation assumptions through its PRZM-EXAMS model to determine if the proposed mitigation will adequately reduce the EEC values, and then re-calculate the RQ values, and provide these amended calculations in the IRED.

NRDC: EPA must ensure that the Agency's actions do not jeopardize endangered species. EPA: The EFED chapter identifies risks to endangered/threatened terrestrial and aquatic animals and discusses previous biological opinions rendered by the U. S. Fish and Wildlife Service on carbaryl. Additionally, the Agency has already

developed a consultation package for the National Marine Fisheries Service on listed Pacific salmon and steelhead and is committed to fulfilling its responsibilities to consult with the Services under the Endangered Species Act. (NRDC doc 39; EPA response July 14, 2003). NRDC: We request that EPA conduct these consultations and implement the results in a timely manner. In the interim, we request that EPA implement mitigation measures that will eliminate harmful exposures to endangered species.

NRDC: Carbaryl is highly toxic to honey bees. EPA: The NRDC is correct in asserting that the EFED chapter states that carbaryl is highly toxic to beneficial insects and that bee kill incidents have been associated with some uses of carbaryl. However, many bee kill incidents do not contain sufficient detail to clearly implicate carbaryl ... EFED has recommended that additional studies be conducted to determine whether chronic exposure to carbaryl impacts bee hives. With this additional information, EFED may be able to make more reliable recommendations to mitigate the potential effects of carbaryl on honey bees. (NRDC doc 39; EPA response July 14, 2003). NRDC: We encourage EPA to obtain and incorporate these chronic and subchronic data in a timely manner. In addition, we recommend that EPA improve the bee caution statement to match the intent of the law and protect pollinators. We recommend that EPA modify the second sentence of the label caution to prohibit application to bloom, as "*Do not apply this product to blooming crops or weeds*". All pesticide labels that carry the bee caution should also be modified under the "directions for use" section and in the special directions for all specific crops to incorporate a protection of pollinators, to reflect this.

NRDC: EPA should include carbaryl and other N-methyl carbamates in a cumulative risk assessment with the organophosphates (OPs). EPA: EPA is not grouping n-methyl carbamates and organophosphates for cumulative assessment at this time. Pharmacokinetic, pharmacodynamic, and exposure issues all need to be considered in the final grouping of a cumulative assessment group. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We recommend that EPA have its decision re-addressed by its Scientific Advisory Panel; this has not been done following EPA's decision to consider the carbamates and OP's separately.

NRDC: EPA has disregarded adverse effects on developing brain structure and function, and relied on extrapolations from unpublished, uninformative data to remove the FQPA factor. It was impossible to examine low- and mid-dose animals, as requested by EPA, because the tissues had dried. EPA: Morphometric changes were considered by HED to be treatment related, but as likely minimum effect levels. That is, the consistent but small changes in the high dose group would likely not have been present in the mid dose group. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We support EPA's assessment that significant treatment-related effects were observed in the high dose, but because EPA has determined that the low- and mid-dose tissue samples were damaged and uninterpretable, we maintain that it consistent with standard EPA approach to use designate the lowest study dose that produces observable effects to be the "LOEL". In fact, this is the definition of the LOEL, the "lowest observed effect level". Since this test did not in fact produce a "no observed effect level", a NOEL, than EPA standard approach is to declare that no "NOEL" was identified, that the LOEL was the high dose, and that an additional UF of 3X would be applied to account for the failure to identify a NOEL in the study. In addition, a 10X FQPA factor is required, because the study demonstrated treatment-related effects in young animals at levels that did not produce effects in adults.

NRDC: In [EPA's] March 11, 2003 response [to comments], EPA reports that a two-generational study was received, and the industry re-measured the same brain morphometric data (control and high-dose only), and that, based on this, elimination of the FQPA factor is justified (Appendix A, p. 33). Re-reading high-dose morphometric

data does not compensate for the lack of data from the mid- and low-dose groups. EPA: The FQPA factor was eliminated because the toxicity database for assessing developmental toxicity is now complete, and EPA used a “weight-of-evidence” approach that included a consideration of the level of concern for toxicity effects, and identification of any residual concerns. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We remain concerned that EPA has wandered from its standard approach, and from the legal requirements of FQPA to protect vulnerable populations such as infants and children. The developmental neurotoxicity study (DNT) is the most sensitive test available to EPA to identify developmental neurotoxicants. This test demonstrated consistent morphometric alterations in treated young animals, that is, changes in brain structure and organization, at the highest dose tested. This must be considered a serious effect, no matter how “small”, because it has permanent and direct implications for brain function. It is brain damage, and this is always a serious effect. Due to poor laboratory practices, the mid- and low-dose data were damaged. EPA acknowledges that the high-dose demonstrated treatment related effects, and that no “safe” or no-effect level was identified in the study. Therefore, the EPA should use a 10X FQPA factor because pups had effects at doses that did not produce effects in adults, and an additional 3X uncertainty factor because no “NOEL” was identified in the study. This is consistent with EPA practices.

NRDC is concerned that comparative cholinesterase data cited by EPA as support for waiving the mandatory FQPA factor is unpublished, unclear, and preliminary. EPA: EPA acknowledges that the data cited by HED were preliminary, and should not have been used by HED. EPA then cites a 1985 study, also unpublished, claiming that this recently re-discovered study does demonstrate that cholinesterase activity and motor activity were decreased to a greater degree in adults compared with weanling rats. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We remain concerned that these 1985 data did not undergo appropriate review, and neither the data nor the EPA data evaluation report (DER) have been made available for public scrutiny. However, our primary concern is that these data are limited to a comparison of adults with weanlings, and did not examine the full age span from gestation through birth, neonate, and weanling. Disruptions of cholinesterase activity throughout this developmental period may have permanent effects on the developing brain, such as the brain morphometric alterations observed in the young animals treated in the developmental neurotoxicity study (DNT). While the 1985 cholinesterase data may be interesting and informative, they are limited in their scope of developmental stages examined, they were never designed to substitute for a DNT study, and therefore they cannot be used to over-turn the serious structural effects observed in the brain of treated young animals in the DNT study. EPA should retain a full 10X FQPA because pups had effects at doses that did not produce effects in adults in the DNT study, and an additional 3X uncertainty factor because no “NOEL” was identified in the study.

NRDC: Removal of the FQPA factor requires validation, not speculation. AND EPA derives an NOAEL by extrapolation rather than observation. EPA: This comment was addressed previously (EPA memo, Carbaryl: Agency response to comments. March 11, 2003. D286511). The effects at the high dose were considered “minimal” and not “significant” effects. Both the HIARC (March 5, 2002 and May 9, 2002) and the FQPA SF Committee (April 3, 2002) determined that it was unlikely that there would be any adverse effects on brain morphometry at the next lower dose of 1 mg/kg/day, which was 1/10th the dose at which the minimal effects were noted. Had the effects been more severe or had the dose for the high-dose group been closer to that for the mid-dose group, then it would have been prudent to apply an additional safety factor to compensate for the weakness in the data. (NRDC OPP-2003-0101-0039, EPA response

October 26, 2004). NRDC: EPA acknowledges that the high-dose demonstrated treatment related effects, and that no “safe” or no-effect level was identified in the study. Therefore, the EPA should use a 10X FQPA factor because pups had effects at doses that did not produce effects in adults, and an additional 3X uncertainty factor because no “NOEL” was identified in the study. This is consistent with EPA practices.

NRDC: Farm children are especially vulnerable to pesticide exposure, and are not adequately considered. NRDC cited studies related to farm children exposure. EPA: EPA's most comprehensive response to date on this issue can be found in the Agency's response to objections on an imidacloprid tolerance (see <http://www.epa.gov/EPA-PEST/2004/May/Day-26/p11779.htm>, Sections III D. and VII. A). In short, for carbaryl, EPA has considered the data referenced by NRDC and found that it is too limited to conclude that children in agricultural areas experience significantly higher levels of exposure than children in nonagricultural areas. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: The Agency has not adequately addressed this issue, and had not provided a comprehensive expert review of the data submitted and referenced by NRDC. Thus, this issue remains an outstanding concern.

NRDC: EPA improperly relied on a confidential industry model (CARES) to assess human health risks. EPA: EPA received a CARES assessment completed by Bayer CropScience, the primary (data developing) technical registrant for carbaryl. EPA reviewed this submission to determine its adherence to guidelines for probabilistic assessment promulgated by the Agency. EPA did use results from this assessment when characterizing risks in the IRED document. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: EPA legally may not rely on a proprietary model without providing substantial detail about its built-in assumptions and calculation methodologies. As the D.C. Circuit has held, “EPA has undoubted power to use predictive models so long as it explains the assumptions and methodology used in preparing the model and provides a complete analytic defense should the model be challenged.”⁵ In so doing, EPA can keep proprietary data confidential, but must provide enough information about the underlying facts supporting its decision to the public to show that it has engaged in reasoned decision making.⁶ We support the EPA CREM recommendations that proprietary models be accompanied by comprehensive, publicly available documentation that describes the conceptual and theoretical basis for the model, the process used to evaluate the model, and access to input and output data such that the public can replicate results derived from the model.⁷

NRDC: EPA did not consider food purchased at farmer's markets, farm stands, "U-Pik" farms, or eaten from household gardens. EPA: EPA does not explicitly assess potential exposures from food obtained from roadside stands or "pick-your-own" operations due to lack of data on how many people consume foods from these sources

⁵ *Appalachian Pwr. Co. v. EPA*, 249 F.3d 1032, 1052 (D.C. Cir. 2001) (internal punctuation and quotations omitted).

⁶ See *NRDC v. Thomas*, 805 F.2d 410, 418 n.13 (D.C. Cir. 1986) (rejecting challenge to confidential data where EPA “combine[d] the data from the confidential reports . . . and plot[ted] them on a graph that was made part of the public record . . . then discussed the plotted data at some length”).

⁷ The Council for Regulatory Environmental Modeling. Draft Guidance on the development, evaluation, and application of regulatory environmental models. November, 2003. http://www.epa.gov/osp/crem/library/CREM%20Guidance%20Draft%2012_03.pdf

and what proportion of their individual diets is from such sources. However, it is believed that the exposure assessment adequately accounted for food purchased at "U-Pik" farms. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: Without data to support the belief of EPA, we suggest that EPA include an uncertainty factor to account for children who consume this source of pesticide-contaminated food.

NRDC: EPA should not have used the percentage of crop treated to adjust the acute dietary risk assessment. EPA: OPP has chosen to incorporate percent crop treated into acute probabilistic exposure estimates as well as chronic assessments for the food pathway since use of these data provide a better estimate of the range and associated probabilities of exposures. By generally using the 99.9th percentile of the population in estimating reasonable high-end exposure and using upper end percent crop treated forecast estimates, EPA continues to properly and appropriately account for the higher-end exposures. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: EPA does not always use the 99.9th percentile, does not always use the upper end percent crop treated, and does not always incorporate the most protective assumptions in its models and calculations. We remind EPA that all people deserve a safe food source, and deserve protection from EPA under the law.

NRDC expressed specific concerns about residential handler exposures (e.g., applicators), and residential postapplication exposures. EPA: The technical registrants are voluntarily canceling the pet uses for shampoos and dusts. An end-use registrant, Wellmark International, is providing data in support of carbaryl use as an ingredient in pet collars. Preliminary data reviewed by the Agency shows short-term MOEs exceeding the target MOE of 300 for short-term exposure. The end-use registrant also submitted for EPA review (currently pending) confirmatory data for intermediate and long-term exposure durations. Regarding lawn use, June, 2003, the carbaryl technical registrants agreed to cease production of carbaryl technical labeled for residential lawn broadcast application of carbaryl liquid formulations until EPA could consider data being submitted to refine the Agency's risk assessment for post-application exposures to toddlers. BayerCrop Science has since submitted to the Agency new pharmacokinetic data, and a method for using the data in a deterministic calculation to refine risk estimates. EPA is planning to seek independent scientific review of the information through an SAP meeting in December 2004. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We remind EPA that the pharmacokinetic data submitted by Bayer and reviewed by the SAP was considered over-simplistic, poorly described, and inadequate to support any decisions by EPA. NRDC requests that EPA cancel all uses of carbaryl that exceed safe exposure levels, including all pet uses where children could be exposed at unsafe levels.

NRDC: No appropriate exposure data exist for the following scenarios: animal grooming dust applications, dust applications in agriculture, handheld fogging for mosquito and other pest treatments, power backpack application, tree injection, drenching/dripping seedlings. EPA: EPA agrees with NRDCs concern about the lack of available data to assess these scenarios. In October 2004, EPA plans to send a Data Call In (DCI) to the carbaryl technical registrants seeking this data. (NRDC OPP-2003-0101-0039, EPA response October 26, 2004). NRDC: We did not see these data requested in a DCI in the carbaryl IRED. EPA should issue a DCI for these data, and obtain and assess the data in a timely manner, so as to ensure that all uses of carbaryl that pose unacceptable risks are cancelled or mitigated adequately so as to protect workers and the public from toxic carbaryl exposures.

Thank you for your careful consideration of these comments,

Respectfully submitted,

Jennifer Sass, NRDC, submitting comments on behalf of the following groups:

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