Inert ingredients	Limits	Uses
* *	* * *	
Ammonium formate (CAS Reg. No. 540–69–2)		Complexing or fixing agent
* *	* * *	

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008–0347; FRL–8843–7]

40 CFR Part 180

Carbaryl; Order Denying NRDC's Objections and Requests for Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In this order, the Environmental Protection Agency (EPA) denies objections, and requests for hearing on those objections, to a prior order denying a petition requesting that EPA revoke all pesticide tolerances for carbaryl under section 408(d) of the Federal Food, Drug, and Cosmetic Act. The objections and hearing requests were filed on December 29, 2008, by the Natural Resources Defense Council (NRDC). The original petition was also filed by NRDC.

FOR FURTHER INFORMATION CONTACT: Jacqueline Guerry, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (215) 814–2184; e-mail address: *guerry.jacqueline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

In this document, EPA denies objections, and requests for hearing on those objections, submitted by NRDC in response to a prior order denying NRDC's petition requesting that EPA revoke all pesticide tolerances for carbaryl. In addition to NRDC, and others interested in food safety issues generally, this action may be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

• Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0347. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

II. Introduction

A. What Action Is the Agency Taking?

In this order, EPA denies objections, and requests for a hearing on those objections, to an earlier EPA Order, (73 FR 64229), denying a petition to revoke all tolerances established for the pesticide, carbaryl, under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, (Refs. 1 and 2). Both the objections and hearing requests, as well as the petition, were filed with EPA by NRDC.

NRDC's original petition, dated January 10, 2005, submitted to the carbaryl public docket during the public comment period for the 2004 Amended Interim Reregistration Eligibility Decision (IRED) for Carbaryl, and filed pursuant to FFDCA section 408(d)(1), asserted a number of grounds why carbaryl tolerances allegedly fail to meet the FFDCA's safety standard. The main arguments raised in the petition concerned EPA's drinking water assessment and EPA's decision on the statutory safety factor to protect infants and children that supported the 2004 IRED decision. NRDC also petitioned the Agency to cancel all carbaryl uses pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 7 U.S.C. 136(bb) and 136a, and argued unreasonable risks on the environment. Subsequently, on November 26, 2007, NRDC petitioned EPA to cancel all carbaryl pet collar uses under FIFRA. (Ref. 3). EPA consolidated this latter petition with the 2005 FFDCA petition because NRDC argued in it that exposure to carbaryl pet collars make the risks presented by carbaryl unsafe within the meaning of FFDCA section 408.

On October 29, 2008, EPA responded to both the 2005 petition to revoke all carbaryl tolerances and the 2007 petition to cancel all pet collar uses, denying them in their entirety. (73 FR 64229, October 29, 2008) (Ref. 4).

NRDC then filed objections to EPA's denial of NRDC's petition to revoke all carbaryl tolerances and requested a hearing on its objections. These objections and hearing requests were filed pursuant to the procedures in the FFDCA, section 408(g)(2). (21 U.S.C. 346a(g)(2)). The objections narrowed NRDC's claims to two main topics – that EPA lacks reliable data to reduce the Food Quality Protection Act (FQPA) Children's Safety Factor and that EPA's exposure assessment for carbaryl is flawed and underestimates the exposure to children from pet collar uses. After carefully reviewing the objections and hearing requests, EPA has determined that NRDC's hearing requests do not satisfy the regulatory requirements for such requests and that its substantive objections are without merit. Therefore, EPA, in this final order, denies NRDC's

objections and its requests for a hearing on those objections.

B. What is the Agency's Authority for Taking This Action?

NRDC petitioned to revoke the carbaryl tolerances pursuant to the petition procedures in FFDCA section 408(d)(1). (21 U.S.C. 346a(d)(1)). Under section 408(d), EPA may respond to such a petition by either issuing a final or proposed rule modifying or revoking the tolerances or issuing an order denying the petition. (21 U.S.C. 346a(d)(4)). Here, EPA responded by issuing an order under section 408(d)(4)(iii) denying the petition. (73 FR 64229, October 29, 2008).

Orders issued under section 408(d)(4)(iii) are subject to a statutorily-created administrative review process. (21 U.S.C. 346a(g)(2)). Any person may file objections to a section 408(d)(4)(iii) order with EPA and request a hearing on those objections. (Id.). EPA is required by section 408(g)(2)(C) to issue a final order resolving the objections to the section 408(d)(4)(iii) order. (21 U.S.C. 346a(g)(2)(C)).

III. Statutory and Regulatory Background

In this Unit, EPA provides background on the relevant statutes and regulations governing NRDC's objections and requests for hearing as well as on pertinent Agency policies and practices. As noted, NRDC's objections and requests for hearing raise two main claims: (1) that EPA has unlawfully failed to retain the full tenfold FQPA safety factor for the protection of infants and children and failed to apply an additional threefold factor due to a deficiency in a critical study; and (2) that EPA underestimated the exposure to children from pet collar uses. The first claim is based on assertions that additional safety factors are needed because of effects observed in a developmental neurotoxicity (DNT) study with carbaryl. The pet collar claim is primarily based upon allegations that EPA does not have sufficient or reliable data with which to assess pet collar exposures and that the assumptions made by EPA underestimate exposure to children. Background information on each of these topics is included in this Unit.

Unit III.A. summarizes the requirements and procedures in section 408 of the FFDCA and applicable regulations pertaining to pesticide tolerances, including the procedures for petitioning for revocation of tolerances and challenging the denial of such petitions and the substantive standards for evaluating the safety of pesticide tolerances. This unit also discusses the closely-related statute under which EPA regulates the sale, distribution, and use of pesticides, FIFRA, (7 U.S.C. 136 *et seq.*).

Unit III.B. provides an overview of EPA's risk assessment process. It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern (level of concern), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on Agency policies with particular relevance to this action.

A. FFDCA/FIFRA and Applicable Regulations

1. *In general.* EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of the FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, and the estrogenic substances screening program. (Public Law 104–170, 110 Stat. 1489 (1996)).

EPA also regulates pesticides under FIFRA, (7 U.S.C. 136 et seq). While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution, (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated by EPA if the tolerance is "safe." (21 U.S.C. 346a(b)(2)(A)(i)). "Safe" is defined by the statute to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (21 U.S.C. 346a(b)(2)(A)(ii)). Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

> consider, among other relevant factors- ...
> (v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;
> (vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;
> (viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. ... EPA must also consider, in evaluating the safety of tolerances, "safety factors which . . . are generally recognized as appropriate for the use of animal experimentation data."

(21 U.S.C. 346a(b)(2)(D)(ix).

Risks to infants and children are given special consideration. Specifically, section 408(b)(2)(C) states that EPA:

> shall assess the risk of the pesticide chemical based on— ...
> (II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and
> (III) available information concerning the cumulative effects

on infants and children of such residues and other substances that have a common mechanism of toxicity. ...

This provision also creates a presumptive additional safety factor for the protection of infants and children. Specifically, it directs that "[i]n 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 the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "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." (Id.). The additional safety margin for infants and children is referred to throughout this order as the "children's safety factor."

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)).

Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). Objections and hearing requests must be filed within 60 days. (Id.). The statute provides that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." (21 U.S.C. 346a(g)(2)(B). EPA regulations make clear that hearings will only be granted where it is shown that there is "a genuine and substantial issue of fact," the requestor has identified evidence "which, if established, resolve one or more of such issues in favor of the requestor," and the issue is "determinative" with regard to the relief requested. (40 CFR 178.32(b)). In addition, EPA regulations prescribe the form and manner of submissions for objections and for an evidentiary hearing. (40 CFR 178.25 and 178.27). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1)).

4. *Tolerance reassessment and FIFRA reregistration.* The FQPA required that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. (21 U.S.C. 346a(q)). EPA was given 10 years to reassess the approximately 10,000 tolerances in existence in 1996. In this reassessment, EPA was required to review existing pesticide tolerances under the new "reasonable certainty that no harm will result" standard set forth in section 408(b)(2)(A)(i). (21 U.S.C. 346a(b)(2)(A)(i)). This reassessment was substantially completed by the August 3, 2006 deadline. Tolerance reassessment was generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. (7 U.S.C. 136a-1). Reassessment and reregistration decisions were generally combined in a document labeled a Reregistration Eligibility Decision (RED).

B. EPA Risk Assessment for Tolerances—Policy and Practice

1. *The safety determination - risk assessment.* To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps:

- Identification of the toxicological hazards posed by a pesticide;
- Determination of the dose-response analysis in test animals and "level of concern" with respect to human exposure to the pesticide;
- Estimation of human exposure to the pesticide; and
- Characterization of risk posed to humans by the pesticide based on comparison of human exposure to the level of concern.

a. *Hazard identification.* In evaluating toxicity or hazard, EPA reviews toxicity studies, primarily in laboratory animals, to identify any adverse effects on the test subjects. Animal studies typically involve investigating a broad range of effects including gross and microscopic effects on organs and tissues, functional effects on bodily organs and systems, effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential), effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransfersase and cholinesterase), and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by different durations of exposure ranging from short-term (e.g., acute) to longer-term (e.g., chronic) pesticide exposure, and different routes of exposure (oral, dermal, inhalation). EPA also evaluates potential adverse effects in different age groups. EPA requires testing for different durations and routes of exposure and different age groups in multiple species of laboratory animals (e.g., rat, mouse, dog, rabbit).

EPA also considers whether the adverse effect has a threshold - a level below which exposure has no appreciable chance of causing the adverse effect. For non-threshold effects, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur. At present, EPA only considers one adverse effect, the chronic effect of cancer, to potentially be a non-threshold effect. (Ref. 5 at 8–9). Because this matter involves a pesticide with threshold effects, assessment of non-threshold effects is not further discussed. Moreover, the toxic effects of carbaryl are short in duration (1 day or less) and, as such, long-term, chronic threshold effects are not discussed further here.

b. *Level of concern/dose-response analysis.* Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis).

In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the next lower dose at which there are no observed adverse affect levels (NOAEL). Often, EPA will use the lowest NOAEL from the relevant available studies — for the duration and route for which risk is being assessed, as a starting point (called the Point of Departure (POD)) in estimating the level of concern for

humans. (Ref. 5 at 9 (The POD is simply the "dose that serves as the starting point in extrapolating a risk to the human population.")). At times, however, EPA will use a LOAEL from a study on the most sensitive endpoint as the POD when no NOAEL is identified in that study. Alternatively, in the absence of a NOAEL for the most sensitive adverse effect, EPA will use the LOAEL as the risk assessment POD, and determine an extrapolated NOAEL by dividing the LOAEL by an uncertainty factor.

EPA is increasingly using modeling to ascertain what is referred to as a Benchmark Dose (BMD) as a substitute for a NOAEL in selecting a POD. In its revised assessment of carbaryl, EPA used a BMD approach for deriving the POD from the available rat toxicity studies. (Ref. 8). A benchmark dose, or BMD, is a point estimate along a dose-response curve that corresponds to a specific response level. For example, a BMD_{10} represents a 10% change from the background level (the background level is typically derived from the control group). Generically, the direction of change from background can be an increase or a decrease depending on the biological parameter and the chemical of interest. In the case of carbaryl, a reduction in acetylcholinesterase (AChE) activity (referred to as "inhibition" of AChE) is the toxic effect of concern. In addition to a BMD, a "confidence limit" may also be calculated. Confidence limits express the uncertainty in a BMD that may be due to sampling and/or experimental error. The lower confidence limit on the dose used as the BMD is termed the BMDL, which the Agency uses as the POD. Use of the BMDL for deriving the POD rewards better experimental design and procedures that provide more precise estimates of the BMD, resulting in tighter confidence intervals. Use of the BMDL also helps ensure with high confidence (e.g., 95% confidence) that the selected percentage of AChE inhibition is not exceeded.

Numerous scientific peer review panels over the last decade have supported the Agency's application of the BMD approach as a scientifically supportable method for deriving PODs in human health risk assessment, and as an improvement over the historically applied approach of using NOAELs or LOAELs. The NOAEL/LOAEL approach does not account for the variability and uncertainty in the experimental results, which are due to characteristics of the study design, such as dose selection, dose spacing, and sample size. With the BMD approach, all the dose response data are used to derive a POD. Moreover, the response level used for setting regulatory limits can vary based on the chemical and/or type of toxic effect (Refs. 6, 7 and 8).

The POD is, in turn, used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and correspondingly levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation). In estimating and describing the level of concern, the POD is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the POD to calculate an acceptable level of exposure or safe dose. This safe dose has been traditionally referred to as the reference dose (RfD). The RfD is defined as the risk assessment POD divided by all uncertainty/safety factors (UF/SFs) except those specific to FQPA. The Population Adjusted Dose (PAD), on the other hand, is defined as the POD divided by all UF/SFs, including those specific to FQPA. In cases where there are no UF/SFs specific to FQPA, the RfD and PAD are numerically identical. Typically, EPA uses a baseline safety/uncertainty factor equal to 100. These factors include a factor of 10 (10X) where EPA is using data from laboratory animals (inter-species factor) to reflect potentially greater sensitivity in humans than laboratory animals and a factor of 10X to account for potential variations in sensitivity among members of the human population (intra-species factor) as well as other unknowns. Additional uncertainty factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, a safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA safety factor largely replaces pre-FQPA EPA practice regarding additional safety factors. (Ref. 9 at 4–11).

c. *Estimating human exposure*. Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)). EPA considers multiple routes of exposure (oral, dermal, and inhalation) and aggregates these exposures where scientifically appropriate. Because EPA exposure estimates are not involved in EPA's determination of this matter, no further description of EPA exposure assessment practices is included.

d. *Risk characterization*. The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, where appropriate, EPA aggregates exposures across different routes in characterizing risk.

In estimating and describing the level of concern, the POD is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For threshold risks, EPA estimates risk in one of two ways. Where EPA has calculated a RfD/PAD, risk is estimated by expressing human exposure as a percentage of the RfD/PAD. Exposures lower than 100 percent of the RfD/PAD are generally not of concern. Alternatively, EPA may express risk by comparing the Margin of Exposure (MOE) between estimated human exposure and the POD with the acceptable or target MOE. The acceptable or target MOE is the product of all applicable safety factors. To calculate the actual MOE for a pesticide, estimated human exposure to the pesticide is divided into the POD. In contrast to the RfD/PAD approach, the higher the MOE, the less risk posed by the pesticide. Accordingly, if the target MOE for a pesticide is 100, MOEs equal to or exceeding 100 would generally not be of concern.

As a conceptual matter, the RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if exposure to a pesticide were found to be acceptable under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa. However, for any specific pesticide, risk assessments for different exposure durations or routes may yield different results. This is a function not of the choice of the RfD/PAD or MOE approach but of the fact that the levels of concern and the levels of exposure may differ depending on the duration and route of exposure.

2. *EPA policy on the children's safety factor*. As the above brief summary of EPA's risk assessment practice indicates, the use of safety factors plays

a critical role in the process. This is true for traditional 10X safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species safety factor) and potential differences among humans (intra-species safety factor) as well as the FQPA 10X children's safety factor.

In applying the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying a 10X safety factor to the 10X inter-species and 10X intra-species safety factors. (Ref. 9 at 4, 11). Thus, EPA generally refers to the 10X children's safety factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the 10X children' safety is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (Id.). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) - the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Id. at 24–25, 35).

3. *EPA policy on cholinesterase inhibition*. Carbaryl is a member of the *N*-methyl carbamate class of pesticides. Each member of this class shares the ability to inhibit the enzyme, acetylcholinesterase, leading to neurotoxicity. *N*-methyl carbamate neurotoxicity is characterized by the rapid onset (often 15–30 minutes) and rapid recovery (within hours). Cholinesterase inhibition is a disruption of the normal process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (i.e., another nerve cell, a muscle fiber, or a gland) is facilitated by the chemical, acetylcholine. When a nerve cell is stimulated it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to receptors in the target cell, stimulating the target cell in turn. As EPA has explained, "the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (e.g., in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (e.g., sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system." (Ref. 10 at 10).

Acetylcholinesterase (AChE) is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When AChE is inhibited, acetylcholine builds up, prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition these effects can be serious, even fatal.

EPA's cholinesterase inhibition policy statement explains EPA's approach to evaluating the risks posed by cholinesterase-inhibiting pesticides such as carbaryl. (Ref. 10). The policy focuses on three types of effects associated with cholinesterase-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) physiological and behavioral/functional effects; (2) cholinesterase inhibition in the central and peripheral nervous system; and (3) cholinesterase inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving a POD for a cholinesterase-inhibiting pesticide.

EPA uses a weight-of-the-evidence approach to determine the toxic effect that will serve as the appropriate POD for a risk assessment for AChE inhibiting pesticides, such as carbaryl (Id). The neurotoxicity that is associated with these pesticides can occur in both the central (brain) and the peripheral nervous system. In its weight-of-the-evidence analysis, EPA reviews data, such as AChE inhibition data from the brain, peripheral tissues and blood (e.g., red blood cell (RBC) or plasma), in addition to data on clinical signs and other functional effects related to AChE inhibition. Based on these data, EPA selects the most appropriate effect on which to regulate; such effects can include clinical signs of AChE inhibition, central or peripheral nervous tissue measurements of AChE inhibition, or RBC AChE measures (Id). Although RBC AChE inhibition is not adverse in itself, it is a surrogate for inhibition in peripheral tissues when peripheral data are not available. As such, RBC AChE inhibition provides an indirect indication of adverse effects on the nervous system (Id.). Measures of AChE inhibition in the peripheral nervous system are very rare for *N*-methyl carbamate pesticides and no such peripheral data exists for carbaryl. For these reasons, other state and national agencies such as California, Washington, Canada, the European Union, as well as the World Health Organization (WHO), all use blood measures in human health risk assessment and/or worker safety monitoring programs.

4. *EPA policy on assessing risk from cumulative effects from pesticides with a common mechanism of toxicity*. Section 408(b)(2)(D) of the FFDCA directs EPA to consider available information on the cumulative effects on human health resulting from exposure to multiple pesticide chemicals that have a common mechanism of toxicity. EPA begins a cumulative risk assessment by identifying a group of pesticides, called a common mechanism group, that bring about the same toxic effect by a common mechanism of toxicity. Pesticides share a common mechanism of toxicity if they act the same way in the body; that is, if the same toxic effect occurs in the same organ or tissue by essentially the same sequence of major biochemical events.

There are many steps involved in quantitatively assessing the potential human health risk associated with exposure to the *N*-methyl carbamate pesticides. The complex series of evaluations involve hazard and dose-response analyses; assessments of food, drinking water, residential/non-occupational exposures; combining exposures to produce a cumulative risk estimate; and risk characterization. Given the complexity of the analyses, EPA's policy is to only conduct a cumulative assessment if each of the individual chemicals in the assessment has been determined to be "safe," based on aggregate exposures only to that individual chemical.

IV. Regulatory History of Carbaryl

A. In General

Carbaryl is a carbamate insecticide and molluscide that was first registered in 1959 for use on cotton. Carbaryl has many trade names, but is most commonly known as Sevin®. At the time carbaryl was assessed for purposes of reregistration, carbaryl was registered for use on over 400 agricultural and non-agricultural use sites, and there were more than 140 tolerances for carbaryl in the Code of Federal Regulations (40 CFR 180.169). The primary risk of concern from exposure to carbaryl is acute neurotoxic effects. Carbaryl is a member of the *N*-methyl carbamate class of pesticides. This group shares a common mechanism of toxicity; namely, the ability to inhibit

the enzyme acetylcholinesterase (AChE) through carbamylation of the active site. Pesticides included is this group, other than carbaryl, are aldicarb, carbofuran, formetanate hydrochloride, methiocarb, methomyl, oxamyl, pirimicarb, propoxur, and thiodicarb.

B. FFDCA Tolerance Reassessment and FIFRA Pesticide Reregistration

1. *Interim reregistration eligibility decision.* EPA completed an interim reregistration eligibility decision (IRED) for carbaryl on June 30, 2003 (2003 IRED). The decision on reregistration was treated as interim because of carbaryl's membership in the *N*-methyl carbamate cumulative group. When EPA determines that a pesticide shares a common mechanism of toxicity with other substances, EPA cannot complete either the assessment or reassessment of a tolerance or a registration or reregistration determination until it has assessed available information regarding exposures to the other substances. For these pesticides, EPA's practice is to issue an IRED pending completion of the tolerance reassessment activities. An IRED memorializes EPA's determination on a narrowly defined issue: Whether a given active ingredient alone is eligible for reregistration under FIFRA and tolerance reassessment under the FFDCA, pending a cumulative assessment for pesticides sharing a common mechanism of toxicity.

Although EPA found in the 2003 IRED that carbaryl dietary exposures from food and water were below the relevant safe doses (i.e., the acute PAD (aPAD) and chronic PAD (cPAD)), EPA concluded that numerous residential uses posed a risk of concern. Accordingly, the 2003 IRED specified various changes to the carbaryl registration to address these risks, including: Canceling liquid broadcast applications to home lawns pending EPA review of pharmacokinetic data to refine post-application risk estimates; repackaging home garden/ornamental dust products in ready-to-use shaker can containers, with no more than 0.05 lbs. active ingredient (ai) per container; canceling the following uses and application methods — all pet uses (dusts and liquids) except collars, aerosol products for various uses, belly grinder applications of granular and bait products for lawns, hand applications of granular, and bait products for ornamentals and gardens.

2. *Amended interim reregistration eligibility decision.* The Agency amended the 2003 IRED on October 22, 2004 (2004 Amended IRED), and published a formal Notice of Availability for the document, which provided for a 60–day public comment period. EPA received numerous comments on the carbaryl 2004 Amended IRED, including the NRDC petition requesting that EPA cancel all carbaryl registrations and revoke all tolerances. The mitigation detailed in the 2004 Amended IRED for residential uses included limiting applications of liquid formulations to residential turf areas to spot treatment only; requiring dust formulations to be packaged in a ready-to-use container containing no more than 0.05 lbs ai/container; and cancelation of all pet uses, except for carbaryl treated pet collars. On March 9, 2005, EPA issued a cancellation order for the liquid broadcast use of carbaryl on residential turf to address post-application risk to toddlers. (Ref. 11). In March 2005, EPA also issued generic and product-specific data call-ins (DCIs) for carbaryl. The carbaryl generic DCI required several studies of the active ingredient carbaryl, including additional toxicology, worker exposure monitoring, and environmental fate data. The product-specific DCI required acute toxicity and product chemistry data for all pesticide products containing carbaryl; these data are being used for product labeling. EPA has received numerous studies in response to these DCIs, and, where appropriate, these studies were considered in the tolerance reassessment.

In response to the DCIs, many carbaryl registrants chose to voluntarily cancel their carbaryl products, rather than revise their labels or conduct studies to support these products. EPA published a notice of receipt of these requests in the **Federal Register** on October 28, 2005 (70 FR 62112), followed by a cancellation order issued on July 3, 2006. One technical registrant, Burlington Scientific, chose to cancel their technical product, leaving Bayer CropScience (Bayer) as the sole technical registrant for carbaryl. Approximately two-thirds of all of the carbaryl products registered at the time of the 2003 IRED have been canceled through this process.

Bayer subsequently requested that all of their carbaryl registrations be amended to delete the following uses: carbaryl use in or on pea and bean, succulent shelled (subgroup 6B); millet; wheat; pre-plant root dip for sweet potato; pre-plant root dip/drench for nursery stocks, vegetable transplants, bedding plants, and foliage plants; use of granular formulations on leafy vegetables (except Brassica); ultra low volume (ULV) application for adult mosquito control; and dust applications in agriculture. EPA notified all affected registrants that these uses and application methods must be deleted from their carbaryl product labels. EPA identified 34 product labels from 14 registrants (other than Bayer) bearing these end uses. All of these registrants requested that their affected carbaryl product registrations be amended to delete these uses. EPA published Notices of receipt of these requests from Bayer and all 14 registrants in the **Federal Register** on August 20, 2008 and October 15, 2008. On March 18, 2009, the Agency published an order granting the requests to delete uses (74 FR 11553). Most recently, in a letter dated September 30, 2009, Wellmark International submitted a request to voluntarily cancel its pet collar registrations pursuant to section 6(f) of FIFRA (74 FR 54045, October 21, 2009). These are the only carbaryl pet collar registrations and the last remaining pet product registrations for carbaryl. EPA issued its final order cancelling carbaryl registrations for pet collar uses on December 16, 2009. (74 FR 66642, December 16, 2009).

3. *Reregistration eligibility decision.* As noted, the reregistration eligibility decision had to remain interim in nature until the *N*-methyl carbamate cumulative risk assessment was completed. That assessment was issued on September 26, 2007, and EPA concluded that the cumulative risks associated with the *N*-methyl carbamate pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCA, provided that the mitigation specified in the *N*-methyl carbamate cumulative risk assessment is implemented, such as cancellation of all uses of carbofuran, termination of methomyl use on grapes, etc. EPA has therefore terminated the tolerance reassessment process under 408(q) of the FFDCA. (See Ref. 12 for additional information).

In conjunction with the *N*-methyl carbamate cumulative risk assessment, EPA completed a RED for carbaryl on September 24, 2007 (the RED was issued on October 17, 2007 with a formal Notice of Availability in the **Federal Register** (72 FR 58844)). (Ref. 12). In addition to relying on the *N*-methyl carbamate cumulative risk assessment to determine that the cumulative effects from exposure to all *N*-methyl carbamate residues, including carbaryl, was safe, the carbaryl RED relied upon the revised assessments and the mitigation that had already been implemented (e.g., cancellation of pet uses except for collars). Additionally, the RED included additional mitigation with respect to granular turf products for residential use; namely, that product labels direct users to water the product in immediately after application. EPA

subsequently completed an addendum to the carbaryl RED, dated August 25, 2008, which incorporated the results of a revised occupational risk assessment and modified mitigation measures for the protection of workers. The Agency issued a Notice of Availability for the RED addendum in the October 29, 2008 **Federal Register** (73 FR 64317).

4. *Risk assessment issues with the IRED and RED relevant to NRDC petition*—a. *selection of POD.* When deriving Points of Departure and assigning uncertainty/safety factors in risk assessment, EPA looks at all the appropriate data available at a given time. In cases when new data become available improving the quality of the overall toxicological database, it is typical practice to re-consider previous decisions of the most appropriate Point(s) of Departure and uncertainty factors. Specific to carbaryl, Points of Departures and uncertainty/safety factors have changed over time as new data have become available to fill data gaps, provide additional information on existing data, and describe the effects in juvenile animals.

For the 2003 IRED and 2004 Amended IRED, the POD for acute exposure was from a developmental neurotoxicity (DNT) study. The POD used for risk assessment was 1 milligrams/kilogram/day (mg/kg/day) based upon the results of the DNT study. In the DNT study the LOAEL was 10 mg/kg/day based upon functional observational changes (pinpoint pupils, tremors, and gait abnormalities). Also occurring in this study were morphometric changes in the brain with a LOAEL of 10 mg/kg/day: bilateral decrease in the size of the forebrain in adult males; a bilateral decrease in the length of the cerebella in female pups; and a bilateral increase in the length of the cerebella in female adults. A NOAEL for these effects was not identified in the study because a morphometric analysis was conducted in only the control and high-dose groups (10 mg/kg/day), but not in low-dose (0.1 mg/kg/day) or mid-dose (1.0 mg/kg/day) groups. Initially, upon review of the data, EPA had requested that morphometric analysis of the low-dose and mid-dose groups be conducted, but this was not possible because the brain tissues had dried during the preservation process. Nonetheless, EPA determined that the developmental NOAEL was likely 1 mg/kg/day. This conclusion was based on the finding that the morphometric changes, although statistically significant, were minimal in nature and, therefore, judged not likely to be present at the mid-dose of 1 mg/kg/day. (Refs. 13, 14, and 15).

Subsequently, in November of 2006, OPP received data from a carbaryl comparative cholinesterase assay study (CCA study) performed by EPA's Office of Research and Development. CCA studies are specially designed toxicity studies that evaluate comparative sensitivity in adult and juvenile rats with respect to inhibition of cholinesterase activity. In the case of the carbaryl CCA study, the juvenile rats were aged post-natal day 11 and 17 (PND11 and PND17).

In the carbaryl CCA, a time course study was first conducted to determine the time to peak ChE effects followed by a dose-response study where rats were dosed by oral gavage with corn oil or 3, 7.5, 15, or 30 mg carbaryl/kg body weight. All ages received the same dose so as to better compare the effects across ages. The dose was given at 2 ml/kg. Therefore, the dosing solutions were 0, 1.5, 3.75, 7.5, or 15 mg/ml. In 2007, EPA conducted a BMD analysis for the carbaryl CCA study, using the same modeling methodology used in the *N*-methyl carbamate cumulative risk assessment. This BMD analysis demonstrated sensitivity of PND11 and PND17 pups compared to adult ORD ChE data. Previously, in 2005 and in support of the *N*-methyl carbamate cumulative risk assessment, the Agency also conducted a BMD analysis of brain and RBC cholinesterase inhibition in rat oral toxicity studies for adults. (Ref. 16, see also Refs. 17 and 18). The BMD_{10} is the estimated benchmark doses that results in 10% cholinesterase inhibition (a level generally regarded as not an adverse effect), and the $BMDL_{10}$ is the lower 95% confidence interval on the BMD_{10}, for the data evaluated. Generally, the BMD_{10} is used to compare across compartments and across ages but the $BMDL_{10}$ is used as the POD. The results of the study are presented in the following table in terms of the BMD_{10} and $BMDL_{10}$:

Age	Brain (mg/kg)		RBC (mg/kg	
	BMD_{10}	$BMDL_{10}$	BMD	$BMDL_{10}$
PND11	1.46	1.14	1.11	0.78
PND17	3.00	2.37	1.41	1.05
Adults	2.63	2.03	0.96	0.73

As the table shows, juvenile 11–day old (PND11) pups were 1.8 times more sensitive to inhibition of brain cholinesterase than adult rats in terms of BMDs. The BMD analyses show that the brain BMD for pups is protective of adults since the pup BMD values are lower than adult values. For the red blood cell cholinesterase (RBC ChE) compartment, the RBC BMD_{10} in PND11 pups is similar to that in adults. Although the RBC $BMDL_{10}$ for PND11 pups is numerically lower (0.8 mg/kg) than the $BMDL_{10}$ for PND11 brain AChE inhibition (1.1 mg/kg), the magnitude of this difference is not biologically meaningful, particularly in light of the similarity in BMD_{10}s, and considering the higher variability typically seen in RBC measurements relative to brain. Brain represents the target tissue for the *N*-methyl carbamates as opposed to using a surrogate measure (RBC) and the brain $BMDL_{10}$ of 1.1 mg/kg would be protective of both central nervous system and peripheral nervous system effects. (Refs. 17 and 18).

For the carbaryl risk assessment, the $BMDL_{10}$ for inhibition of brain cholinesterase in PND11 juveniles from the CCA study was chosen as the most sensitive and appropriate POD for calculating a safe dose instead of using an extrapolated NOAEL from the DNT study. Several factors were critical to that determination. First, the CCA study is considered a sentinel study for the *N*-methyl carbamates as it evaluates the most sensitive endpoint (cholinesterase inhibition) in the most sensitive age group (PND11) at the time of peak effect. For each *N*-methyl carbamate with a valid CCA study, this study is being used in the risk assessment to inform the children's safety factor or the POD. EPA has high confidence in the quality of the data from the carbaryl study because it used a broad range of doses and used the radiometric method of measuring AChE inhibition. (Ref. 19). The radiometric method for assaying

ACHe inhibition provides the most appropriate method for measuring cholinesterase inhibition due to *N*-methyl carbamate exposure because factors (i.e., assay temperature, dilution, and incubation time) which promote reversibility are minimized.

Second, gavage studies, such as the CCA study, are the preferred and most sensitive studies for carbaryl. The toxicity profile of carbaryl and other *N*-methyl carbamates is characterized by a rapid onset of toxicity with a peak time of effect around 15 to 60 minutes and rapid recovery (typical half-lives in adult rats are 1 to 2 hours). This pattern of toxicity is shown in Figure 1 for carbaryl.

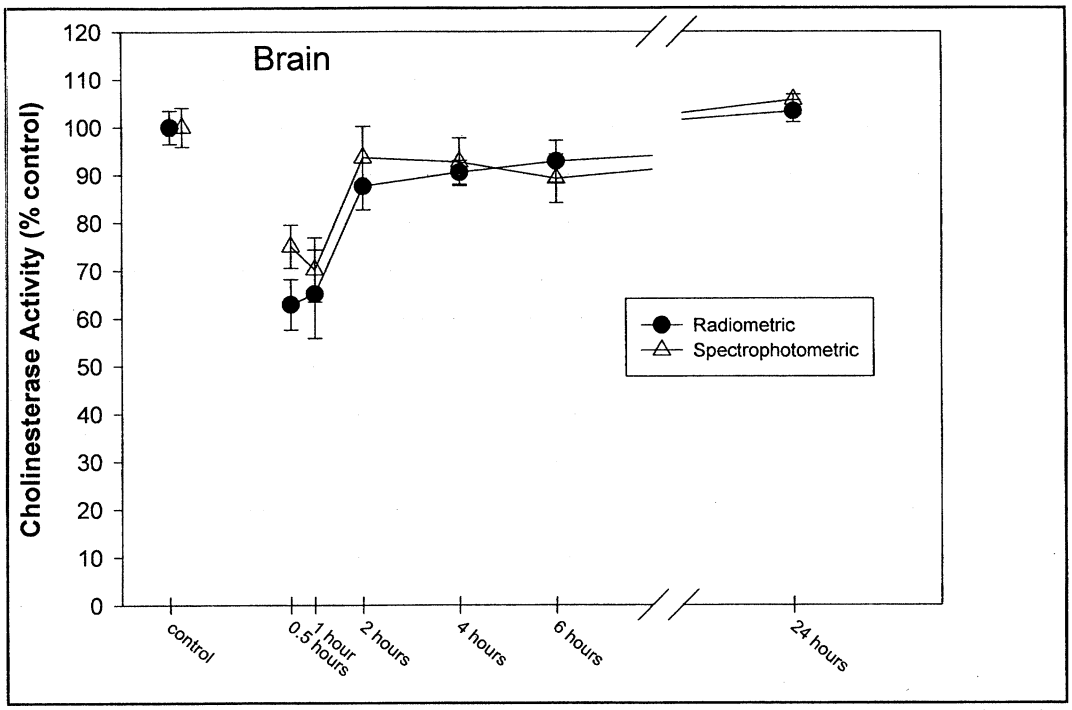

Figure 1. Time course of brain AChE inhibition in adult rats exposed to carbaryl

With *N*-methyl carbamates, due to rapid recovery, toxicity does not accumulate in juveniles or adults with repeated exposures. As such, EPA is most concerned about acute effects, particularly those which occur at the peak time of effect. The Agency has found for these pesticides that acute studies, particularly via gavage administration, provide the most sensitive effects (i.e., more health protective) for risk assessment. Specifically, acute gavage studies provide more sensitive effects than studies administered in the diet, even studies of much longer durations. For example, the NOAEL and LOAEL for RBC AChE inhibition in the carbaryl dietary 2–year rat chronic/carcinogenicity study are 10/12[1] mg/kg/day and 60.2/78.6 mg/kg/day in adult rats, whereas the BMD_{10}/$BMDL_{10}$ for RBC AChE inhibition in adult rats in acute gavage studies are 0.96 and 0.73 mg/kg. Based on this comparison, the acute gavage study provides toxicity values almost tenfold more sensitive than in the 2–year feeding study.

This pattern of toxicity is somewhat unique to this class of pesticides and can be attributed to the pharmacokinetic and pharmacodynamic properties of *N*-methyl carbamates, like carbaryl. The parent active ingredient, carbaryl, is the toxicologically active compound. As such, no metabolic activation is required; instead, metabolism results in detoxification of carbaryl. As evidenced by the rapid onset of toxicity, these pesticides are rapidly absorbed, distributed, and cleared from the body.

For this class of pesticides, neurotoxicity is correlated to peak concentrations of carbaryl. Specifically, brain tissue levels and inhibition of brain AChE at the time of peak effect are highly correlated. In dietary administration studies like the 2–year study and the DNT study, rats are exposed to carbaryl over several hours of feeding. This is in contrast to a bolus dose in gavage studies where the entire dose is given at one time. In the dietary studies, the total *administered dose* of carbaryl consumed may be equal or even higher than the gavage dose. However, it is the *internal dose* of carbaryl at the target tissues which is related to the magnitude to toxicity. In the dietary studies, due to the rapid metabolism and clearance, carbaryl does not reach a peak level like that in gavage studies at the target tissues and thus the degree of toxicity in dietary studies is far less than that for gavage studies. As a result, acute gavage studies tend to be far more sensitive than dietary studies for *N*-methyl carbamates. This is the case for carbaryl as shown by the high quality and sensitive data from the CCA study.

Finally, the changes in brain morphometrics (10 mg/kg) from the DNT study originally used in the POD derivation were determined to be a marginal effect not consistently seen in carbarmate pesticides. (See Unit IV.B.4.b. for a full discussion of EPA's review of the DNT study.) Although a 10X uncertainty factor was originally applied to the marginal brain morphometric endpoint, the real NOAEL is likely greater than 1 mg/kg and less than 10 mg/kg.

In any event, the extrapolated NOAEL from the DNT study is essentially

[1] Two values are provided for males/females.

equivalent to the $BMDL_{10}$ for PND11 juveniles in the CCA study (i.e., 1 mg/kg/day as compared to 1.1 mg/kg/day). As explained below, if the LOAEL from the DNT was used in calculating a safe dose, EPA would retain a children's safety factor of no greater than 10X due to the lack of a NOAEL in that study. Retention of a children's safety factor of 10X would make the extrapolated NOAEL for the DNT study essentially equivalent to the $BMDL_{10}$ for PND11 juveniles in the CCA study (i.e., 1 mg/kg/day as compared to 1.1 mg/kg/day).

b. *Children's safety factor.* With respect to the children's safety factor, in preliminary reviews undertaken in 1999 and 2001, EPA initially retained the full 10X safety factor for carbaryl. The reasons for retaining the 10X children's safety factor were that EPA was missing a two-generation reproduction study for carbaryl and the DNT study showed changes in brain morphometric measurements of the offspring which raised concerns. The data from the DNT study showed that for the first generation pups, there were *no* treatment-related effects on pup weight, pup survival indices, developmental landmarks (tooth eruption and eye opening), Functional Observational Battery (FOB) measurements or motor activity assessments. There were also *no* treatment related effects on brain weight and gross or microscopic pathology. There were, however, changes noted in brain morphometric measurements at the high dose (10 mg/kg/day): Bilateral decrease in the size of the forebrain in adult males; a bilateral decrease in the length of the cerebella in female pups; and a bilateral increase in the length of the cerebella in female adults. EPA requested that a morphometric analysis of the low-dose and mid-dose groups be conducted, but this was not possible because brain samples had not been prepared for measurement and the tissues had dried during the preservation process. At the time, EPA found these changes at the high dose to be significant. (See generally Refs. 20, 21, 22, 23, 24, 25 and 26).

When new information became available in 2002, EPA removed the 10X safety factor for acute dietary and short- and intermediate-term exposures. (Refs. 13, 14 and 15). Not only did EPA receive a new two-generation reproduction study (and therefore no longer had any data gaps) but EPA also obtained new brain morphometric measurements from the DNT study for the control and high-dose groups. The new measurements demonstrated that even at the high dose, the morphometric changes, although statistically significant, were minimal in nature. This is consistent with the DNT study results for other *N*-methyl carbamates (aldicarb and carbofuran), which did not show any changes in morphometrics. In addition, the DNTs available for all three *N*-methyl carbamates have not shown any long-term effects, including effects on behavior. The Agency is also not aware of any literature studies that have shown any changes in brain histopathology following *N*-methyl carbamate exposure to animals of any age. Based on this information, EPA concluded that the brain morphometic effects were not likely to be present at the mid-dose. (Refs. 13, 14 and 15). Because the developmental effects in the DNT were now well-characterized and the evidence strongly indicated that no brain morphometric changes would have been present at the mid-dose (1 mg/kg/day), EPA determined that the children's safety factor was not needed. In addition, there were no concerns or residual uncertainties for pre- and/or postnatal toxicity from other carbaryl development studies.

After EPA received the CCA study in 2006, it modified its decision on the children's safety factor slightly. As explained above, the $BMDL_{10}$ for PND11 juveniles from the CCA study was chosen for the POD in calculating a safe dose. Because (1) EPA had a complete data set for carbaryl including high quality data comparing the relative sensitivity of adults and the young, (2) the effects in the young had been well-characterized, and (3) the most sensitive effect in the young (the $BMDL_{10}$ from the CCA study) was being used to calculate the safe dose (i.e., the $BMDL_{10}$ was divided by inter- and intra-species safety factors), EPA determined that a children's safety factor was not needed for risk assessments based on the CCA study. Where carbaryl assessments relied on other data not involving the testing of juveniles, EPA retained a children's safety factor of 1.8X reflecting the degree of sensitivity of the young observed in the CCA study.

c. *Calculation of safe dose/aPAD for carbaryl.* For dietary risks, EPA calculated the aPAD by dividing the dietary POD (the $BMDL_{10}$ for PND11 juveniles in the CCA study) by the inter-species and intra-species safety factors (100X) to yield a value of 0.01 mg/kg. For dermal risks, instead of calculating an aPAD, EPA assessed risk under a MOE approach. The acceptable or target MOE was calculated using a POD of 86 mg/kg. The POD was obtained by multiplying the $BMDL_{10}$ of 30.56 mg/kg from the dermal toxicity study by 2.8, because in an *in vitro* dermal absorption study, rat skin was 2.8 times more permeable than human skin to carbaryl. The target MOE for risk assessment is 100 for adults because the inter-species and intra-species safety factors total 100X. The target MOE for risk assessment for infants and children is 180 because, in addition to the 100X, the children's safety factor is 1.8X.

V. NRDC Petitions Regarding Carbaryl

In the underlying petition, NRDC requested, among other things, that EPA cancel all carbaryl registrations and revoke all carbaryl tolerances. (Ref. 2). NRDC's January 10, 2005 petition was submitted in the form of comments on and requests for changes to the Carbaryl Interim Reregistration Eligibility Decision published in the **Federal Register** on October 27, 2004, 70 FR 62663. Nonetheless, in the introduction to the comments, NRDC included a statement that NRDC was also petitioning the Agency to revoke all carbaryl tolerances. Among other things, NRDC raised issues with the dietary assessment, and in particular, EPA's drinking water assessment that supported the 2004 IRED decision. NRDC also raised concerns about the data surrounding EPA's selection of a children's safety factor. NRDC raised other safety factor issues, particularly as they relate to EPA use of the DNT study. NRDC's petition also included generic disagreements with how EPA conducts its assessments.

Subsequently, as part of its comments on the *N*-methyl carbamate cumulative assessment dated November 26, 2007, NRDC requested that EPA cancel all carbaryl pet collar registrations. (Ref. 3). The basis for NRDC's petition to cancel all pet collar registrations rested on issues related to EPA's assessment of cumulative effects under the FFDCA. In addition, NRDC incorporated by reference its earlier petition to revoke all carbaryl tolerances. Accordingly, EPA addressed the exposure issues raised in the subsequent pet collar petition as part of its response to the earlier petition to revoke all carbaryl tolerances.

VI. EPA's Response to the Petitions to Revoke Carbaryl Tolerances

On October 29, 2008, EPA denied NRDC's petition to revoke all pesticide tolerances for carbaryl under section 408(d) of the FFDCA. (73 FR 64229). EPA's Order also constituted a response to NRDC's petition dated November 26, 2007, to cancel carbaryl pet collar registrations submitted as part of NRDC's comments on the *N*-methyl carbamate cumulative assessment. Again, EPA's response to NRDC's petition to cancel pet collar registrations was addressed in that Order because the

basis for the petition to cancel pet collars rested on issues related to EPA's assessment of cumulative effects under the FFDCA.

VII. NRDC's Objections and Requests for Hearing

On December 28, 2008, NRDC filed, pursuant to FFDCA section 408(g)(2), objections to EPA's denial of its tolerance revocation petition and requested a hearing on those objections. As indicated above, NRDC's objections and requests for hearing raise two main claims: (1) that EPA lacks reliable data to reduce the default tenfold safety factor and (2) that EPA's exposure assessment for carbaryl is flawed and underestimates the exposure to children from pet collar uses.

NRDC asserts that EPA failed to consider the available developmental neurotoxicity data and, therefore, unlawfully lowered the 10X children's safety factor. Specifically, NRDC argues that the DNT study showed adverse developmental abnormalities in juvenile test animals at doses that had no effect on adult test animals. According to NRDC, this finding alone supports a full 10X children's safety factor. In addition, NRDC asserts that the DNT study did not identify a no-effect level in juvenile animals, supporting a further 3X safety factor. Thus, NRDC argues that EPA should have applied a 30X safety factor (10X for age sensitivity and 3X for failure to identify a no-effect level) to the end-point from the DNT to establish a final POD. According to NRDC, to do otherwise is "arbitrary and capricious, and contrary to the law." (Ref. 1 at 8.)

NRDC also asserts that EPA's exposure assessment underestimates exposure to children from pet collar uses. NRDC further asserts that EPA relied on flawed studies and data, and, therefore, the Agency's determination that tolerances are safe is improper. Among other things, NRDC argues that at the time of EPA's determination, data on exposure from use of carbaryl in pet collars required by a 2005 DCI had not been submitted and that without the data EPA's decision is "arbitrary and capricious and contrary to law." (Ref. 1 at 9).

EPA regulations make clear that to be considered by the Administrator, a request for an evidentiary hearing must meet certain criteria. (40 CFR 178.27). One such criteria is that the request must include a copy of any report, article, survey, or other written document (or the pertinent pages thereof) upon which the objector relies to justify an evidentiary hearing, unless the document is an EPA document that is routinely available to any member of the public.

In support of its request for a hearing, NRDC submitted the following documents as evidence that a hearing is appropriate: (1) Poisons on Pets Health Hazards from Flea and Tick Products, David Wallinga, MD., MPA and Linda Greer, Ph.D (NRDC, November 2000); and (2) Opportunities to Improve Data Quality and Children's Health through the Food Quality Protection Act (EPA-OIG Evaluation Report; Report # 2006–P-00009) (January 10, 2006).

In addition, NRDC cited to the following EPA documents: (1) Amended Carbaryl Reregistration Eligibility Decision (RED) (August, 2008); (2) Carbaryl RED (September, 2007); (3) Carbaryl Interim RED (IRED) (June, 2003); Organophosphate Cumulative Risk Assessment (2006); and, Revised *N*-Methyl Carbamate Cumulative Risk Assessment [DRAFT] (2007).

VIII. Response to Objections and Requests for Hearing

A. Overview

EPA denies NRDC's objections as well as its hearing requests. NRDC's hearing requests fail to meet the statutory and regulatory requirements for holding a hearing. NRDC has failed to proffer evidence on its hearing requests which would, if established, resolve one or more issues in its favor. Most significant, however, is that NRDC's claims do not present genuine and substantial issues of fact. On the merits, NRDC's objections with respect to the use of particular studies to establish an appropriate POD as well as appropriate safety factors are denied on scientific, policy, and legal grounds. Finally, NRDC's objection with respect to EPA exposure assessment of pet collars is denied as moot because EPA has already issued a cancellation order under section 6(f) of FIFRA for the last remaining carbaryl pet collar product registration.

The remainder of this Unit is organized in the following manner. Unit VIII.B. describes in greater detail the requirements pertaining to when it is appropriate to grant a hearing request. Unit VIII.C. examines the evidence proffered by NRDC in support of its hearing requests. Unit VIII.D. provides EPA's response to the NRDC's objections and hearing requests.

B. The Standard for Granting an Evidentiary Hearing

EPA has established regulations governing objections to tolerance rulemakings and tolerance petition denials and requests for hearings on those objections. (40 CFR part 178; 55 FR 50291, December 5, 1990). Those regulations prescribe both the form and content of hearing requests and the standard under which EPA is to evaluate requests for an evidentiary hearing.

As a threshold matter, EPA's regulations limit the issues that can be raised in any hearing as well as in objections. In general, the provisions of FFDCA section 408(g) establish an informal rulemaking process that is governed by section 553 of the Administrative Procedure Act (APA) and the case law interpreting these requirements, except to the extent that section 408 provides otherwise. For example, section 408(d) allows the Agency to proceed to a final rule after publication of a submitted petition, rather than requiring publication of a proposal. In this regard, it is well established that the failure to raise factual or legal issues during the comment period of a rulemaking constitutes waiver of the issues in further proceedings. *See generally*, 74 FR 59608, 59624–59629, November 18, 2009.

The fact that FFDCA section 408 in certain limited circumstances supplements the informal rulemaking with a hearing does not fundamentally alter the requirements applicable to informal rulemakings. Nor does it convert this into a formal rulemaking, subject to the exception in section 553 of the APA. Section 408 of the FFDCA establishes a unique statutory structure with multiple procedural stages, and delegates to EPA the discretion to determine the implementation that best achieves the statutory objectives. Accordingly, EPA interprets the notice and comment rulemaking portion of the FFDCA section 408 process as an integral part of the FFDCA process, inextricably linked to the administrative hearing. The point of the rulemaking is to resolve the issues that can be resolved, and to identify and narrow any remaining issues for adjudication. Consequently, the administrative hearing does not represent an unlimited opportunity to supplement the record, particularly with information that was available during the comment period, but that commenters have chosen to withhold.

EPA has consistently interpreted FFDCA section 408 in this fashion since the 1996 amendments. For example, EPA previously ruled that a petitioner could not raise new issues in filing objections to EPA's denial of its original petition. (See 72 FR 39318, 39324, July 18, 2007.) (EPA's tolerance revocation procedures "are not some sort of 'game,'

whereby a party may petition to revoke a tolerance on one ground, and then, after the petition is denied, file objections to the denial based on an entirely new ground not relied upon by EPA in denying the petition."). EPA reasoned that new issues were not cognizable because they are "not an objection to the 'provisions of the ... order [denying the petition]' " (Id.). Similarly, EPA denied a request for a hearing because the requestor had failed in their original petition to raise the claim asserted in their objection. (73 FR 42683, 42696, July 23, 2008). EPA noted that although requestor did argue in its petition that EPA cannot make a safety finding without completing the endocrine screening program under FFDCA section 408(p), it did not assert claims regarding the endocrine data and the children's safety factor. Citing its previous decision, EPA denied the objections and hearing requests as to the children's safety factor. (Id.). In that same decision, EPA also denied a number of hearing requests on the ground that the requestor failed to proffer supporting evidence; EPA opined that a failure to offer evidence at an earlier stage of the administrative proceeding could not be cured by suddenly submitting such evidence with a hearing request. See 73 FR 42710 ("Presumably Congress created a multi-stage administrative process for resolution of tolerance petitions to give EPA the opportunity in the first stage of the proceedings to resolve factual issues, where possible, through a notice-and-comment process, prior to requiring EPA to hold a full evidentiary hearing, which can involve a substantial investment of resources by all parties taking part .... Accordingly, if a party were to withhold evidence from the first stage of a tolerance petition proceeding and only produce it as part of a request for a hearing on an objection, EPA might very likely determine that such an untimely submission of supporting evidence constituted an amendment to the original petition requiring a return to the first stage of the administrative proceeding (if, consideration of information that was previously available is appropriate at all")). Finally, in a recent decision, the United States Court of Appeals for the District of Columbia Circuit upheld this interpretation of section 408. *See Nat'l Corn Growers Assn. v. EPA*, No 09-1284, slip op. at 9-10 (C.A.D.C. July 23, 2010)("We agree with EPA....[T]he comment period would be redundant and superfluous is the same concerns could be raised at the objections stage.")

Nonetheless, EPA does not interpret the statute and regulations to preclude the submission of any new information as part of the objections phase. Such a position would in fact be inconsistent with EPA's own regulations and past practice, which require that in order to support a hearing request, a party submit more than "mere allegations or denials." (40 CFR 178.32(b)(2)). Rather, EPA's interpretation in this regard is analogous to the determination of whether a final rule is the logical outgrowth of the proposal and the comments. Ultimately, EPA's policy is merely that the objections phase does not present an opportunity for parties to begin the process entirely anew, by raising issues or information that could have been fairly presented as comments on the proposed rule or Notice of Filing of the pesticide petition. Nor is the statute's additional procedural step an excuse to withhold information that was clearly available at the time of the rulemaking.

As to the form and content of a hearing request, the regulations specify that a hearing request must include: (1) a statement of the factual issues on which a hearing is requested and the requestor's contentions on those issues; (2) a copy of any report, article, or other written document "upon which the objector relies to justify an evidentiary hearing;" and (3) a summary of any other evidence relied upon to justify a hearing. (40 CFR 178.27).

The standard for granting a hearing request is set forth in 40 CFR 178.32. That section provides that a hearing will be granted if EPA determines that the "material submitted" shows all of the following:

> (1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.
> (2) There is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary. An evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions, nor if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged.
> (3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(40 CFR 178.32(b)).

This provision essentially imposes four requirements upon a hearing requestor. First, the requestor must show it is raising a question of fact, not one of law or policy. Hearings are for resolving factual issues not for debating law or policy questions. Second, the requestor must demonstrate that there is a genuine dispute as to the issue of fact. If the facts are undisputed or the record is clear that no genuine dispute exists, there is no need for a hearing. Third, the requestor must show that the disputed factual question is material, i.e., that it is outcome determinative with regard to the relief requested in the objections. Finally, the requestor must make a sufficient evidentiary proffer to demonstrate that there is a reasonable possibility that the issue could be resolved in favor of the requestor. Hearings are for the purpose of providing objectors with an opportunity to present evidence supporting their objections; as the regulation states, hearings will not be granted on the basis of "mere allegations, denials, or general descriptions of positions or contentions." (40 CFR 178.32(b)(2)).

EPA's hearing request requirements are based heavily on FDA regulations establishing similar requirements for hearing requests filed under other provisions of the FFDCA. (53 FR 41126, 41129, October 19, 1988). FDA pioneered the use of summary judgment-type procedures to limit hearings to disputed material factual issues and thereby conserve agency resources. FDA's use of such procedures was upheld by the Supreme Court in 1972, (*Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973)), and, in 1975, FDA promulgated generic regulations establishing the standard for evaluating hearing requests. (40 FR 22950, May 27, 1975). It is these regulations upon which EPA relied in promulgating its hearing regulations in 1990.

Unlike EPA, FDA has had numerous occasions to apply its regulations on hearing requests. FDA's summary of the thrust of its regulations, which has been repeatedly published in the **Federal Register** in orders ruling on hearing requests over the last 26 years, is

instructive on the proper interpretation of the regulatory requirements. That summary states:

> A party seeking a hearing is required to meet a 'threshold burden of tendering evidence suggesting the need for a hearing.' [] An allegation that a hearing is necessary to sharpen the issues' or fully develop the facts' does not meet this test. If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. [] FDA need not grant a hearing in each case where an objection submits additional information or posits a novel interpretation of existing information. [] Stated another way, a hearing is justified only if the objections are made in good faith and if they "draw in question in a material way the underpinnings of the regulation at issue." Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy.

(49 FR 6672, 6673, February 22, 1984; 72 FR 39557, 39558, July 19, 2007) (citations omitted)). EPA has been guided by FDA's application of its regulations in this proceeding. Congress confirmed EPA's authority to use summary judgment-type procedures with hearing requests when it amended FFDCA section 408 in 1996. Although the statute had been silent on this issue previously, the FQPA added language specifying that when a hearing is requested, EPA "shall..." hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." (21 U.S.C. 346a(g)(2)(B)). This language explicitly grants EPA broad discretion to deny a hearing. Specifically, the language in section 408 provides that EPA is to determine whether a hearing is "necessary to receive factual evidence" as well as whether the issues raised in objections are "material" issues of fact. Thus, even where evidence relevant to an issue of material fact is proffered (essentially the standard set forth in 40 CFR 178.32), EPA construes the statutory language as requiring it to hold a hearing only where EPA determines a hearing is necessary to receive proffered evidence. In other words, the statute grants EPA the discretion to determine that the issues could be resolved entirely on the basis of the existing written record. *See* 74 FR at 59627.

C. Evidentiary Proffer by NRDC

As noted above, the purpose for holding hearings is "to receive factual evidence." (21 U.S.C. 346a(g)(2)(B); 53 FR 41126, 41129, October 19, 1988 ("Hearings are for the purpose of gathering evidence on disputed factual issues . . . ."). A requestor must identify evidence relied upon to justify a hearing and either submit copies of that evidence or summarize it. (40 CFR 178.27). After reviewing the proffer, EPA must find that there is a reasonable possibility that the proffered evidence, if established, would resolve one or more genuinely-disputed, material factual issues in a requestor's favor. (40 CFR 178.32(b)). Because a substantial portion of NRDC's evidentiary proffer is deficient on its face, EPA finds it most efficient to preliminarily review the proffer before turning to the individual issues raised by NRDC.

NRDC identifies the following as "relevant documentation": Order denying NRDC's petition to revoke tolerances (October 29, 2008); Amended Carbaryl Registration Eligibility Decision (RED) (August 2008); Carbaryl RED (September 2007); and Carbaryl Interim RED (2003 IRED) (June 2003). NRDC also includes a reference to information on EPA's reregistration of carbaryl, available online at *http://www.epa.gov/pesticides/reregistration/carbaryl/*. EPA assumes that these are the documents NRDC intends to proffer as evidence in support of its request for a hearing.

In addition, throughout it objections and request for a hearing, NRDC includes footnotes with citations to additional documents. As a general matter, EPA assumes NRDC is doing so in the context of it supporting its objections, rather than as a proffer of evidence to justify a hearing. Indeed, merely citing to a document in a footnote does not constitute a proffer of evidence. Nevertheless, in an effort to address NRDC's hearing request as comprehensibly as possible, EPA will address these footnote citations as well. In the future, however, NRDC would be well advised to make clear exactly what evidence it is proffering as a justification for its hearing request.

The documents cited in footnotes generally fall into three categories. The first are EPA documents that can be grouped in the same category as the documents NRDC identified as "relevant documents." These documents are: EPA Fact Sheet for Carbaryl (revised on 10/22/04); EPA's Organophospate Cumulative Risk Assessment (USEPA 2006); EPA's Revised *N*-Methyl Carbamate Cumulative Risk Assessment [DRAFT] (USEPA 2007).

This group of EPA documents, combined with the other EPA documents identified by NRDC as "relevant documents" (including "[i]nformation on EPA's reregistration of carbaryl [] available online at *http://www.epa.gov/pesticides/reregistration/carbaryl/*") do not present evidence of a genuinely-disputed, material issue of fact. (73 FR 42694–95, July 23, 2008) (citing to EPA decision-making record is vague and fails to identify new evidence which, if established, would resolve an issue in petitioner's favor)). First, given that the purpose of a hearing is to gather or receive evidence, proffering evidence already considered and relied upon by EPA is not sufficient justification for holding a hearing. Second, as a matter of law, EPA does not understand how it can be argued that a proffer consisting of a general reference to the decision-making record—which EPA has found supports one result, could constitute evidence that if established would justify the opposite conclusion. Third, EPA concludes that the non-specific citation to numerous documents related to the multi-year process of conducting FIFRA reregistration and FFDCA tolerance reassessment is so vague a proffer as to not constitute a proffer at all. (Id.)

It should be noted, however, that in two cases, NRDC does offer a specific citation in the 2008 Amended Carbaryl RED. First, NRDC cites to a specific page as a reference for the largest uses of carbaryl (based upon pounds of active ingredient used per year): apples, asparagus, cherries, corn, grapefruit, grapes, hay, oranges, peaches, pecans, soybeans, and turf. While use information is relevant to EPA's overall reregistration decision, it is not material to NRDC's objections or its request for a hearing. As such it does not identify evidence that would justify holding a hearing.

Similarly, NRDC cites to a specific page in the 2008 Amended Carbaryl RED for the proposition that EPA issued a data call-in for data on exposure from the use of carbaryl in pet collars but that those results had not been submitted. NRDC objects to EPA's assessment of carbaryl tolerances in part because EPA did not have these data. However, EPA has since received the data. Moreover, while this issue may be relevant to NRDC's objection, arguing that EPA did not have sufficient data upon which to make a decision (without offering into evidence data EPA should have but did not consider) is not a basis upon which to grant a hearing. Again, a hearing is for

the purpose of gathering or receiving evidence and to resolve material factual disputes. It is undisputed that at the time, EPA had not received the data. It is also undisputed that the data has since been submitted. Thus, there is no issue in dispute over the submission of the data or evidence to suggest otherwise. In sum, EPA does not consider NRDC's citations to EPA's decision-making record a sufficient proffer of evidence to justify a hearing.

The second category of documents cited in footnotes consists of the following documents, loosely described as articles and reports: "Poisons on Pets. Health Hazards from Flea and Tick Products" NRDC November, 2000; NRDC's 2008 Green Paws report available at *http://www.greenpaws.org/better.php;* Opportunities to Improve Data Quality and Children's Health through the Food Quality Protection Act (FQPA) (EPA Inspector General Report No. 2006–P-00009 (January 10, 2006)); 2007/2008 American Pet Products Manufacturing Association (APPA) National Pet Owners Survey; and Kansas State University Press Release. "K-State Expert Says Fleas Can Be An Itchy Situation" (November 16, 1999). None of these documents proffer evidence of a genuinely-disputed, material issue of fact. EPA will address each in turn.

The NRDC publication "Poison on Pets" focuses on seven organophosphate insecticides used in flea and tick control products; namely, chlorpyrifos, dichlorvos, phosmet, naled, tetrachlorvinpos, diazinon, and malathion. As a preliminary matter, EPA need not determine whether the information in this publication raises a material issue of fact about which a meaningful hearing might be held because, as explained in Unit VIII.D.2, the cancellation of all carbaryl pet collar product registrations renders NRDC's hearing request moot. In addition, factually, the document's relevance to carbaryl is at most tangential. While the report does mention carbaryl, it does so primarily in the context of arguing against the use of carbamates. Specifically, on page 49 of 67, the report notes that carbaryl and propoxur are the two major carbamates used for flea control, combining for approximately 8% of all active ingredients used to treat pets and kennels. The report states that NRDC scientists believes that carbaryl is one of the most significant pesticide disrupters of the endocrine system, interfering with sperm structure and function as well as increasing the risk of miscarriage. The report concludes its paragraph on carbamates by noting that "[f]ortunately, use of pet products with carbaryl already has decreased." (Poisons on Pets at 50). In its objections, NRDC relies on the report to reiterate generally applicable arguments that NRDC made regarding organophosphate pesticides to argue why NRDC also believes EPA's exposure assessment of carbaryl is flawed. This document, however, adds no justification for a hearing not otherwise included in NRDC's objections. In short, the report does not proffer evidence of a genuinely-disputed, material issue of fact related specifically to carbaryl.

As best EPA can determine, NRDC's Green Paws report is a website page devoted to alternative, non-toxic methods of flea and tick control, such as using a flea comb and regular bathing. Again, EPA need not determine whether the information in this "report" raises a material issue of fact about which a meaningful hearing might be held because, as explained in Unit VIII.D.2, the cancellation of all carbaryl pet collar product registrations renders NRDC's hearing request moot. In addition, this "report" does not contain carbaryl-specific information and does not provide any evidence of a genuinely-disputed, material issue of fact related to NRDC's objections or request for a hearing. As such, it does not provide factual evidence justifying a hearing.

Similarly, NRDC generally relies on the EPA Inspector General Report to emphasize the importance of DNT test data. This report, however, does not contain carbaryl-specific information and does not provide any evidence of a genuinely-disputed, material issue of fact related to NRDC's objections or request for a hearing. At best, the report implies that registration decisions should not be made in the absence of a DNT study. However, EPA's assessment of carbaryl included the submission and review of a DNT study. In sum, the report does not identify factual evidence that would, if established, resolve an issue in NRDC's favor.

NRDC also cites to the 2007/2008 American Pet Product Association (APPA) National Pet Owners Survey for the proposition that "nearly two out of every three households owns a pet, which equates to 88.3 million cats and 74.8 million dogs." First, although NRDC asserts the survey is available at the APPA website on-line, as far as EPA is able to determine this is proprietary information. For non-members, the 2009/2010 survey (at the time of this writing) was available at a cost of $1,695. EPA did not purchase a copy for purposes of responding to NRDC's hearing request and, therefore, was unable to independently verify the survey results. Second, EPA need not determine whether the information in this survey raises a material issue of fact about which a meaningful hearing might be held because, as explained in Unit VIII.D.2, the cancellation of all carbaryl pet collar product registrations renders NRDC's hearing request moot. Third, a statement—even a factual one, as to the number of households that own a pet does not present evidence of a genuinely-disputed, material issue of fact related to NRDC's objections or request for a hearing. At best, this information implies that because there are so many pet owners, the probability that some owners use carbaryl pet collars and would be exposed is not insignificant. However, EPA's assessment of carbaryl pet collars assumes exposure, including exposure to children. Accordingly, even if the evidence here were established, it would not resolve the issue identified by NRDC in its favor; namely, that EPA underestimated the exposure of children that come into contact with pets wearing carbaryl pet collars. In sum, a survey on the number of households that have pets does not present evidence to justify a hearing regarding the assumptions EPA made regarding children's exposure to pets wearing carbaryl pet collars.

Finally, NRDC cites to a 1999 press release for the proposition that "[e]very year Americans spend over one billion dollars on products designed to kill fleas and ticks on our pets." First, EPA was unable to access a copy of the press release through the web link provided by NRDC. Thus, it is unclear that this document could even be introduced as evidence. Second, EPA need not determine whether the information in this press release raises a material issue of fact about which a meaningful hearing might be held because, as explained in Unit VIII.D.2, the cancellation of all carbaryl pet collar product registrations renders NRDC's hearing request moot. Third, a statement as to the sales of flea and tick control products generally does not present any factual evidence specific to carbaryl or information related to NRDC's objections or request for a hearing. Fourth, the reference is more than a decade old. Thus, even if it were relevant to a current genuinely-disputed, material issue of fact, this information is simply out-of-date. In sum, there can be no serious contention that the proffer of an outdated press release that generally refers to the amount Americans spend on pesticides to control fleas and ticks presents evidence to justify a hearing.

The third category consists of one document: Xue J, Zartarian V, Moya J,

Freeman N, Beamer P, Black K, Tulve N, Shalat S: A meta-analysis of children's hand-to-mouth frequency data for estimating nondietary ingestion exposure (Risk Anal. 2007 Apr.; 27(2): 411–20). The Xue, *et al.* 2007 paper collected hand-to-mouth frequency data from 9 available studies representing 429 subjects and more than 2,000 hours of behavior observation. A meta-analysis was conducted on these data to study differences in hand-to-mouth frequency based on study, age group, gender, and location (indoor vs. outdoor), to fit variability and uncertainty distributions that can be used in probabilistic exposure assessments, and to identify any data gaps. Results of this analysis indicate that age and location are important for hand-to-mouth frequency, but study and gender are not. This paper represents the first comprehensive effort to fit hand-to-mouth frequency variability and uncertainty distributions by indoor/outdoor location and by age groups, using the new standard set of age groups recommended by the U.S. Environmental Protection Agency for assessing childhood exposures.

This document is "proffered" in connection with NRDC's objections and request for a hearing on issues related to EPA exposure assessment of carbaryl pet collar products. EPA need not determine whether the information in this meta-analysis raises a material issue of fact about which a meaningful hearing might be held because, as explained in Unit VIII.D.2, the cancellation of all carbaryl pet collar product registrations renders NRDC's hearing request moot. Nonetheless, EPA notes that NRDC's proffer is improper. NRDC's original Petition did not address this information because it pre-dated the Xue paper. However, NRDC's subsequent petition, dated November 26, 2007, regarding pet collars, which in essence amended its previous petition, also did not reference or rely in any manner on this information. To the contrary, in its pet collar petition, NRDC generally takes issue with modifications EPA made to the assumptions underlying the carbaryl pet collar residential exposure component of the probabilistic risk assessment of the *N*-methyl carbamate cumulative assessment (as compared to the carbaryl, single chemical, determinative assessment). In so doing, NRDC generally asserted that the net result of these changes is that EPA underestimated the exposure of children to carbaryl from pet collars. It is only in its request for a hearing and objections that NRDC raises for the first time a host of specific issues based upon the analysis in the Xue paper related to the carbaryl pet collar residential exposure component of the *N*-methyl carbamate cumulative assessment. Thus, even if the issues concerning pet collars were not moot, it would be inappropriate to allow NRDC to now cure a poorly drafted petition by recasting its arguments or raising issues for the first time—and proffering evidence that was previously available in support of such arguments had they been raised earlier—at the hearing and objections stage of the process. *See Nat'l Corn Growers Assc. v. EPA*, No. 09–1284, slip op. at 8–9 (C.A.D.C. July 23, 2010) (upholding EPA's refusal to consider at the objections stage evidence and arguments that could have been but were not submitted during the comment period); *see also* 72 FR at 39324 (tolerance revocation procedures are not "game," whereby a party may file objections to denial based on entirely new ground(s) not relied upon in denying the petition.); 73 FR at 42710 (inappropriate to cure failure to offer evidence at an earlier stage of administrative proceeding by submitting such evidence with a hearing request).

In sum, NRDC has failed to identify factual evidence sufficient to justify a hearing. Specifically, NRDC has failed to proffer evidence that, if established, would resolve one or more genuinely-disputed, material factual issues in its favor. Accordingly, in addition to the reasons discussed below, NRDC's hearing request is denied.

D. Response to Specific Issues Raised in Objections and Hearing Requests

1. *Failure to apply a 10X children's safety factor and another 3X additional safety factor to the DNT study LOAEL in calculating a safe dose for carbaryl or to otherwise rely on the DNT study in assessing the risk of carbaryl.* In its objection to EPA's calculation of a safe dose for carbaryl, NRDC makes three, separate but related arguments: (1) it was unlawful for EPA to calculate the safe dose for carbaryl without applying a 10X children's safety factor (in addition to the inter- and intra-species safety factors) to the LOAEL from the DNT study; (2) it was unlawful for EPA to calculate the safe dose for carbaryl without applying an additional 3X safety factor (in addition to the inter- and intra-species and children's safety factors) to the LOAEL from the DNT study to account for the lack of a NOAEL in this study; and (3) "[e]ven if the DNT data were not used to derive a [safe dose], EPA's failure to incorporate the important information on age-sensitivity that is provided by the DNT is arbitrary and capricious, and contrary to law." (Ref. 1 at 8).

NRDC's arguments concerning the application of additional safety factors of 10X and 3X to the DNT study LOAEL is material to its request for the revocation of the carbaryl tolerances only if both arguments are accepted – i.e., it is determined that both additional safety factors should be used in assessing the safety of carbaryl. This is because there is already essentially a tenfold difference between the DNT study LOAEL (10 mg/kg/day) and the POD used in calculating the safe dose for carbaryl. That POD is the $BMDL_{10}$ of 1.1 mg/kg/day for brain cholinesterase inhibition in PND11 juveniles in the CCA study. Use of either the 10X safety factor or the 3X factor alone applied to the DNT study LOAEL would not produce a value lower than the existing POD, only a combined 30X would do that. For this reason, for NRDC to sustain on materiality grounds its objection and hearing request as to its first two arguments it must either show (1) it is entitled to a hearing on both arguments; (2) it is entitled to a hearing on one argument and, as to the other, even if it is not entitled to a hearing, its substantive argument is meritorious, or (3) if it is not entitled to a hearing on either argument, that both of its substantive arguments are meritorious. As explained below, NRDC has not made such a showing.

a. *Application of a 10X children's safety factor and a 3X safety factor for lack of a NOAEL to the DNT study.* NRDC states that it "provides a scientific and legal argument that EPA must apply a 30X adjustment factor, based on a 10X FQPA factor to account for evidence for permanent structural brain damage in juvenile animals in the DNT study ..., and a 3X factor for the failure of the DNT study to identify with confidence an observable no-effect level for juvenile animals exposed to carbaryl." (Obj. at 7). Its legal argument appears to be that the children's safety factor provision in FFDCA section 408(b)(2)(C) compels EPA to apply a 10X safety factor when a study reveals juveniles are more sensitive than adults. EPA bases this conclusion on three considerations: (1) the children's safety factor is a statutory requirement; (2) NRDC has phrased its argument regarding juvenile sensitivity and the 10X children's safety factor in mandatory terms (Ref. 2 at 4 ("Based on the reports available in the EPA documents demonstrating increased susceptibility in fetuses and newborn animals, the EPA is obligated to retain the FQPA 10X factor, in accordance with the law.")); and (3) there are not specific legal requirements in FFDCA

section 408 regarding a safety factor to address the lack of a NOAEL in a toxicity study.

Hearings are not granted on legal questions. (40 CFR 178.32(b)(1)). EPA has repeatedly concluded, and NRDC appears to have admitted, that its argument regarding retention of the children's safety factor to address juvenile sensitivity is a question of law. (73 FR 5439, 5445, January 30, 2008; 72 FR 52108, 52115–52117, September 12, 2007; 71 FR 43906, 43919, August 2, 2006). Accordingly, NRDC's hearing request on this issue is denied.

Turning to the merits of the objection—at least insofar as EPA is able to discern the basis for the objection, NRDC's objection, as well as its corresponding hearing request, is initially denied for a lack of particularity in the objection. EPA should not have to guess at the substance or basis for an objection. NRDC's objection is also being denied on the following separate grounds. EPA finds no basis for NRDC's interpretation of FFDCA section 408(b)(2)(C). EPA has on a number of occasions rejected the interpretation that the children's safety factor provision mandates that the absence of a particular study or a finding of pre- or post-natal toxicity or increased sensitivity in the young removes EPA's discretion to choose a different safety factor. (73 FR 5439, 5444, January 30, 2008; 72 FR 52108, 52115–52117, September 12, 2007; 71 FR 43906, 43919, August 2, 2006). EPA explained its rationale recently in responding to NRDC objections that made the same argument as in this case:

> The statute does direct EPA to consider "susceptibility of infants and children" to pesticides. (21 U.S.C. 346a(b)(2)(C)(i)(II)). It also states that an additional safety factor to protect infants and children shall be applied "to take into account potential pre- and post-natal toxicity . . . ." (21 U.S.C. 346a(b)(2)(C)). Nonetheless, in clear and unmistakable language, Congress decreed that, "[n]otwithstanding such requirement for an additional margin of safety" to take into account potential pre- and post-natal toxicity, EPA is authorized to choose a different safety factor if EPA has reliable data showing a different factor is safe. (Id.). Interpreting the statute as creating a rigid, per se rule that the identification of sensitivity in the young removes EPA's discretion to choose a different safety factor is inconsistent with this language and the flexibility granted to the Agency.

(72 FR at 52117; see also 73 FR at 5444). NRDC has raised no arguments in its current objections that convince EPA to vary from its long-held interpretation. Accordingly, EPA denies NRDC's objection with respect to retaining a 10X children's safety factor.

Even giving NRDC every benefit of the doubt, and assuming it did not intend its argument on the 10X children's safety factor to be only a legal question, NRDC is still not entitled to a hearing or relief on the merits. Perhaps NRDC was suggesting that (1) its assertion that the brain effects in the DNT were "severe and permanent" and (2) its claim that the DNT is a particularly important study due to its focus on cognitive effects, were sufficient factual reasons, when combined with the sensitivity finding, to compel EPA to retain the 10X children's safety factor even if EPA was not legally required to do so solely based on a finding of sensitivity in the young.

There are several reasons no hearing is required on this re-articulation of NRDC's claim. First, NRDC has proffered no evidence in support of its assertion on sensitivity and nature of the effects in the young. EPA reached quite different conclusions on the significance of the effects seen in the pups at the LOAEL in the DNT study. Nonetheless, NRDC has merely recycled its prior comments without acknowledging EPA's findings or attempting to assert that there is a disputed question of fact regarding how EPA has characterized the effects in the study. Critically, NRDC proffers no evidence (or even arguments) in support of its assertions. As such, NRDC's claims about sensitivity and the nature of the effects in pups in the DNT study are nothing more than "mere allegations" and hardly qualify as a relevant objection. Indeed, EPA's regulations specifically state that "[a]n evidentiary hearing will not be granted on the basis of mere allegations, denials, or general descriptions of positions and contentions . . . ." (40 CFR 178.32(b)(2)).

Second, NRDC's argument that, as between the carbaryl CCA and the DNT study, EPA failed to give proper consideration and weight to the DNT study does not present a genuine issue of material fact to be resolved at a hearing. *Nat'l Corn Growers Assc. v. EPA*, No. 09–1284, slip op. at 13 (C.A.D.C. July 23, 2010) ("there is no material issue of fact based upon '[m]ere differences in the weight or credence given to particular scientific studies.'"); (47 FR at 55474) ("[Objectors] assertion about this evidence is, at best, an argument that a different inference (i.e., that the pieces are not 'reasonably uniform' and 'cube shaped') should be drawn from established fact (the dimensions of the pieces) than the agency has drawn. No hearing is required in such circumstances."); C.f. Norvich, 773 F.2d 1363 ("differences in the weight or credence given to particular scientific studies ... are insufficient [to show a material issue of fact for a hearing]"). Here, all NRDC has done is point to a study already in the record that EPA has reviewed and considered numerous times. Thus, NRDC has failed to proffer any evidence to suggest that there is a factual, rather than an interpretive, matter to be resolved at a hearing. *See Nat'l Corn Growers Assc. v. EPA*, No. 09–1284, slip op. at 13 (a "dispute between experts" as to the weight or credence given a particular scientific study does not present a material issue of fact for a hearing).

Third, NRDC's claims regarding the unique endpoints examined in the DNT study and its importance in evaluating the safety of pesticides are not disputed facts. EPA does not contest these points. A hearing will only be granted if there is a "genuine and substantial issue of fact for resolution at a hearing." (40 CFR 178.32(b)(1)).

Finally, a hearing is also denied on this re-articulated claim because at bottom it calls for a policy determination. NRDC is claiming that based on certain facts an additional safety factor is needed. This is a policy judgment for EPA not a factual determination on which evidence could be submitted for adjudication. "An evidentiary hearing will not be granted on issues of policy or law." (Id.)

On the merits, this re-articulated claim fails as well. First, it is denied because it has not been made with the particularity required. The statute requires that objections "specif[y] with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefore," and EPA's regulations make clear that for an objection to be properly presented it must explain "with particularity . . . [its] basis . . . ." (40 CFR 178.25(a)(2)); *see Nat'l Corn Growers Assc. v. EPA*, No. 09–1284, slip op. at 11. Second, EPA's conclusions on sensitivity and the nature of the effects on the pups in the DNT study differ significantly from NRDC's assertions and are well supported in the record. On the nature of the effects, EPA concluded that the changes in brain morphometrics for pups seen in the DNT were minimal. (See Unit IV.B.4.b). In addition, the data from the DNT study showed that for the

first generation pups, there were no treatment-related effects on pup weight, pup survival indices, developmental landmarks, FOB measurements, or motor activity assessments. These conclusions are found on a careful analysis of the DNT study. On the other hand, NRDC merely restates its previous comments and neither offers an explanation for its characterization of the DNT study results nor proffers any evidence in support of its allegation. (Id.) ("by simply resubmitting their Comments, without addressing the responses the EPA had made to them ... [petitioners] 'failed to lodge a relevant objection'"). On the sensitivity of the young, EPA concluded that the brain morphometric effects in the juvenile rats in the DNT study would not be present at 1 mg/kg/day. Thus, EPA has determined that the LOAELs and NOAELs for adults and juveniles in the DNT study were the same. NRDC has offered no reasons as to why EPA's findings on these points was in error. (Id.) Indeed, there is nothing to suggest that EPA's conclusion that these findings on sensitivity and the nature of the effects in the young did not require retention of a 10X factor was unreasonable. To the contrary, this conclusion is consistent with both EPA policy and practice. While on occasion EPA has applied an additional children's safety factor based solely on the nature of the effects seen in the young, such additional safety factors have only been utilized in situations involving significantly different factual circumstances. (See 74 FR 39545, 39549–39550, August 7, 2009) (for pesticide that showed sensitivity in the young, 3X children's safety factor retained due to very narrow dose range (3X) from NOAEL to fatal dose level). Third, as to the NRDC's assertions regarding the importance of the DNT study, EPA would note that there is a DNT study for carbaryl and it has been fully considered in assessing the risk of carbaryl. Importantly, in evaluating that study, EPA determined based on the effects seen in that study at what level a NOAEL for pup effects was likely to have been seen and that level is nearly identical to the level used as the POD for assessing carbaryl risks. For all of these reasons, this objection is denied.

Having denied NRDC's objection that a 10X children's safety factor is required due to the alleged identification of age sensitivity, NRDC's claim regarding a 3X factor due to the lack of a NOAEL in the DNT study becomes immaterial. As noted above, additional factors of 10X or below applied to the DNT study LOAEL for pups (along with the standard inter- and intra-species safety factors) will not result in a lower aPAD for carbaryl and thus granting NRDC's objection would not change EPA's safety determination. Because NRDC's objection on this issue is not outcome-determinative, it is denied on the basis of immateriality. *See Nat'l Corn Growers Assc. v. EPA*, No. 09–1284, slip op. at 13; 72 FR 39318, 39323–39324, July 18, 2007. In addition, there are no disputed facts with regard to the question of whether an additional safety factor is needed to address the lack of a NOAEL in the DNT study. NRDC asserts that an additional 3X safety factor should be applied to the DNT study LOAEL for pups because no NOAEL was identified for that test group. EPA agrees that if it were using the pup LOAEL from the DNT study as a POD, at least a 3X factor is needed to account for the lack of a NOAEL in that study. In fact, in its risk assessment, EPA essentially applied a safety factor of 10X to the DNT study's LOAEL (10 mg/kg/day) by its determination that no brain morphometric effects would be expected at the mid-dose (1 mg/kg/day). Thus, EPA does not disagree with NRDC's assertion that an additional safety factor is needed to address the lack of a NOAEL in the DNT study. In sum, because this objection is immaterial and there are no disputed material facts, NRDC's hearing request and objection on this issue are denied. (40 CFR 178.32(b)).

b. *Arbitrary and capricious.* NRDC argues that even if EPA uses the $BMDL_{10}$ for PND11 juveniles from the CCA study for the POD for calculating the carbaryl safe dose, it must "incorporate the important information on age-sensitivity that is provided by the DNT [study]" into its risk assessment and that EPA's failure to do so was arbitrary and capricious. (Ref. 1 at 8). The only hint that NRDC provides as to what it means by this vague allegation is a table appearing on page eight of its objections in which NRDC suggests that the additional 10X and 3X safety factors it argues are needed for the DNT study should be applied to the $BMDL_{10}$ for PND11 juveniles in the CCA study in computing the safe dose. NRDC advances no specific argument as to why this approach should be taken and proffers no evidence in support of it. As an initial matter, therefore, this objection and its corresponding hearing request is denied for a lack of particularity in the objection. EPA should not have to guess at the substance of an objection.

Even assuming the objection passes the particularity requirement, it is without merit. The predicate to this argument is that additional safety factors are needed as to the pup LOAEL in the DNT study. Thus, this objection and hearing request stand in the shoes of the objections and hearing requests regarding the alleged need for additional 10X and 3X safety factors on the pup LOAEL in the DNT study. As to the additional 10X children's safety factor, NRDC's objection and hearing request is denied for the identical reasons that EPA denied NRDC's direct claims regarding an additional 10X children's safety factor. As to the 3X safety factor, NRDC's assertion that a lack of a NOAEL in the DNT study necessitates the application of an additional safety factor to the POD in the CCA study does not warrant a hearing and is substantively meritless because it is nothing more than a mere allegation without any supporting basis. (40 CFR 178.32(b)(2)). NRDC offers no evidence as to why a LOAEL-to-NOAEL safety factor should be transferred from a study where it is needed (the DNT study) to a study where a clear NOAEL or its equivalent (a $BMDL_{10}$) is identified (the CCA study). Further, to the extent that NRDC intended to make some other point by its vague claim that it was arbitrary and capricious for EPA not to take the DNT study results into account in its carbaryl safety determination, its hearing request is denied as being no more than a "general description of [a] position[]," 40 CFR 178.32(b)(2), and the objection is denied on the ground that the record, on its face, shows that EPA carefully considered the results of the DNT study in making its safety determination on carbaryl. (See Unit IV.B.4.b).

2. *Improper reliance on flawed data for exposure assessment resulting in underestimation of exposure to children from pet collars.* NRDC makes several arguments as to why EPA's exposure assessment is flawed and, therefore, EPA cannot make its tolerance safety finding for carbaryl. NRDC first argues that EPA cannot make its safety finding because required transferable residue studies have not yet been submitted. NRDC further argues that the exposure studies that EPA did rely on are highly variable and unreliable and, therefore, EPA cannot be reasonably certain that children in the highly exposed tails of the exposure curve will be protected. NRDC also argues that EPA made several unfounded or faulty assumptions in it exposure assessment such that EPA cannot show that there is an unreasonable certainty of no harm from the aggregate exposures to carbaryl.

EPA denies both the hearing request and the objections as moot because all carbaryl pet collar registrations have

been cancelled. In a letter dated September 30, 2009, Wellmark International submitted a request to voluntarily cancel its pet collar registrations pursuant to section 6(f) of FIFRA. (74 FR 54045, October 21, 2009). These are the only carbaryl pet collar registrations and the last remaining pet product registration for carbaryl. EPA issued its final order cancelling carbaryl registrations for pet collar uses on December 16, 2009. (74 FR 66642).

E. Conclusion on Objections and Request for a Hearing

For the reasons stated above, all of the NRDC's objections as well as its request for a hearing are denied.

IX. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's final order regarding objections filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

XI. References

1. Natural Resources Defense Council, "Objections to the Order Denying NRDC's Petition to Revoke All Tolerances for Carbaryl, and Request for Public Evidentiary Hearing" (December 29, 2008).

2. Natural Resources Defense Council, Petition to Revoke All Carbaryl Tolerances and Cancel All Carbaryl Registrations, (January 10, 2005).

3. Natural Resources Defense Council, Petition to Cancel Carbaryl and Propoxur for Pet Collar Uses, (November 26, 2007).

4. US EPA, Carbaryl; Order Denying NRDC's Petition to Revoke Tolerances, 73 FR 64229, October 29, 2008.

5. US EPA, "A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food" (June 21, 2000).

6. FIFRA Science Advisory Panel. 2002. Methods Used to Conduct a Preliminary Cumulative Risk Assessment for Organophosphate Pesticides. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 5–7, 2002 (Report dated March 19, 2002). FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. SAP Report 2002–01.

7. FIFRA Science Advisory Panel. 2005a. Final report on *N*-Methyl Carbamate Cumulative Risk Assessment: Pilot Cumulative Analysis. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 2005 (Report dated September 2, 1998). Available at: *http://www.epa.gov/scipoly/sap/2005/february/minutes.pdf.*

8. FIFRA Science Advisory Panel. 2005b. Final report on Preliminary *N*-Methyl Carbamate Cumulative Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of July 29–30, 2005 (Report dated September -, 2005). Available at: *http://www.epa.gov/scipoly/sap/2005/august/minutes.pdf.*

9. Office of Pesticide Programs, US EPA, "Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process" (February 28, 2002).

10. US EPA Office of Pesticide Programs, "The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides" (August 18, 2000).

11. US EPA Office of Pesticide Programs. March 9, 2005 letter to Peg Cherney, Bayer Crop Science, Final Cancellation Order for Carbaryl Liquid Broadcast Application to Lawns/Turf; EPA Registration Numbers 264–324, 264–325, and 264–328.

12. US EPA Office of Pesticide Programs. 2007. Office of Prevention, Pesticides and Toxic Substances, EPA, Reregistration Eligibility Decision for Carbaryl (September 24, 2007).

13. US EPA Office of Pesticide Programs. 2002. Hazard Identification Assessment Review Committee (HIARC) report (March 5, 2002).

14. US EPA Office of Pesticide Programs. 2002. FQPA SF Committee report (April 3, 2002).

15. US EPA Office of Pesticide Programs. 2002. HIARC report (May 9, 2002).

16. Moser, G. (2007) Report of Cholinesterase Comparative Sensitivity Study of Carbaryl. Unpublished study prepared by US EPA, ORD, NHEERL. (MRID 47143001).

17. US EPA Office of Pesticide Programs. 2007. Carbaryl: Updated Endpoint Selection for Single Chemical Risk Assessment (June 29, 2007).

18. US EPA Office of Pesticide Programs. 2007b. Carbaryl. HED Chapter of the Reregistration Eligibility Decision Document (RED). EPA–HQ–OPP–2007–0941–0003. PC Code: 056801, DP Barcode: D334770. (June 28, 2007).

19. Johnson, C.D. and Russell, R.L. (1975) A rapid, simple radiometric assay for cholinesterase, suitable for multiple determinations. Analytical Biochemistry. 64:229–238.

20. US EPA Office of Pesticide Programs. 1998. Hazard Identification Assessment Review Committee (HIARC) report (July 7, 1998).

21. US EPA Office of Pesticide Programs. 1998. FQPA SF Committee report (August 27, 1998).

22. US EPA Office of Pesticide Programs. 1999. HIARC report (April 27, 1999).

23. US EPA Office of Pesticide Programs. 1999. HIARC report (November 15, 1999).

24. US EPA Office of Pesticide Programs. 1999. FQPA SF Committee report (December 13, 1999).

25. US EPA Office of Pesticide Programs. 2001. HIARC report (April 5, 2001).

26. US EPA Office of Pesticide Programs. 2001. FQPA SF Committee report (April 30, 2001).

List of Subjects in 40 CFR Part 180

Environmental protection, Carbaryl, Pesticides and pests.

Dated: September 8, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0756; FRL–8844–7]

Technical Amendments to Pesticide Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing this technical amendment to change references in several sections of 40 CFR part 180. These changes are necessary because of a final rule which was issued in the **Federal Register** of June 8, 2005. That final rule made miscellaneous changes to 40 CFR part 180 to update generic provisions of EPA's procedural regulations relating to pesticide chemicals. The update was made necessary because of various changes made by the Food Quality Protection Act of 1996.

DATES: This final rule is effective September 15, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0756. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m.