ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0347; FRL–8388–1]

Carbaryl; Order Denying NRDC's Petition to Revoke Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In this Order, EPA denies a petition requesting that EPA revoke all pesticide tolerances for carbaryl under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The petition was filed on January 10, 2005, by the Natural Resources Defense Council (NRDC).

DATES: This Order is effective October 29, 2008. Objections and requests for hearings must be received on or before December 29, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0347. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Christina Scheltema, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–2201; e-mail address: scheltema.christina@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

In this document, EPA denies a petition by the NRDC to revoke pesticide tolerances. 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0347 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before December 29, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0347, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Introduction

A. What Action Is the Agency Taking?

The NRDC filed a petition dated January 10, 2005 with EPA which, among other things, requested that EPA revoke all tolerances for the pesticide carbaryl established under section 408 of the FFDCA, 21 U.S.C. 346a (Ref. 1) This Order denies that aspect of the petition that sought the revocation of the carbaryl tolerances. This Order also denies NRDC's petition to cancel carbaryl pet collar registrations submitted as part of NRDC's comments on the *N*-methyl carbamate (NMC)

cumulative assessment and dated November 26, 2007, because NRDC is arguing that exposure to carbaryl pet collars makes the cumulative risks presented by carbaryl unsafe (Ref. 2).

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

Under section 408(d)(4) of the FFDCA, EPA is authorized to respond to a section 408(d) petition to revoke tolerances either by issuing a final rule revoking the tolerances, issuing a proposed rule, or issuing an order denying the petition. (21 U.S.C. 346a(d)(4)).

III. Statutory and Regulatory Background

A. FFDCA/FIFRA and Applicable Regulations

1. *In general.* EPA establishes maximum residue limits, or ''tolerances,'' for pesticide residues in food and feed commodities 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 or left in effect by EPA if the tolerance is ''safe.'' (21 U.S.C. 346a(b)(2)(A)(i)). This standard applies both to petitions to establish and petitions to revoke tolerances. ''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; and
>
> (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;
>
> (21 U.S.C. 346a(b)(2)(D)(v), (vi) and (viii)).

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. ...
>
> (21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

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 ''FQPA 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 establishing, amending, or revoking the tolerance or denying the petition, any party 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)). 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's Approach to Dietary Risk Assessment

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. A short summary is provided below to aid the reader. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA–PEST/1999/January/Day–04/p34736.htm*.(64 FR 162)

To assess the 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 three distinct steps: (1) identification of the toxicological hazards posed by a pesticide and determination of the exposure ''level of concern'' for humans; (2) estimation of human exposure; and (3) characterization of human risk based on comparison of human exposure to the level of concern.

1. *Hazard identification and determination of the level of concern.* Any risk assessment begins with an evaluation of a chemical's inherent properties, and whether those properties have the potential to cause adverse effects (i.e., hazard identification). EPA then evaluates the hazards to determine the most sensitive and appropriate adverse effect of concern, based on factors such as the effect's relevance to humans and the likely routes of exposure. 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). Another aspect is the determination of whether the effect is associated with a threshold dose (i.e., the effect is seen only at or above a certain dose) or whether the effect can occur at any dose (such as some tumors).

In evaluating a chemical's dietary risks for threshold effects, EPA uses a reference dose (RfD) approach, which involves a number of considerations including:

- A 'point of departure'(PoD) - the value from a dose-response curve that is at the low end of the observable data (the no observed adverse effect level, or NOAEL, the lowest-observed adverse effect level or LOAEL, or an extrapolated benchmark dose) and that is the dose serving as the 'starting point' in extrapolating a risk to the human population;
- An uncertainty factor to address the potential for a difference in toxic response between humans and animals used in toxicity tests (i.e., interspecies extrapolation);
- An uncertainty factor to address the potential for differences in sensitivity in the toxic response across the human population (for intraspecies extrapolation); and
- The need for an additional safety factor to protect infants and children, as specified in FFDCA section 408(b)(2)(C).

EPA uses the chosen PoD to calculate a safe dose or RfD. The RfD is calculated by dividing the chosen PoD by all applicable safety or uncertainty factors. Typically in EPA risk assessments, a combination of safety or uncertainty factors providing at least a hundredfold (100X) margin of safety is used: 10X to account for interspecies extrapolation and 10X to account for intraspecies extrapolation. Further, in evaluating the dietary risks for pesticide chemicals, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. In implementing FFDCA section 408, EPA also calculates a variant of the RfD referred to as a population adjusted dose (PAD). The PAD is the RfD divided by any portion of the children's safety factor that does not correspond to one of the traditional additional uncertainty/safety factors used in general Agency risk assessment. The reason for calculating PADs is so that other parts of the Agency, which are not governed by FFDCA section 408, can, when evaluating the same or similar substances, easily identify which aspects of a pesticide risk assessment are a function of the particular statutory commands in FFDCA section 408. For acute assessments, the risk is expressed as a percentage of a maximum acceptable dose or the acute PAD (i.e., the acute dose which EPA has concluded will be ''safe''). As discussed below in Unit V.C., dietary exposures greater than 100 percent of the acute PAD are generally cause for concern and would be considered ''unsafe'' within the meaning of FFDCA section 408(b)(2)(B). Throughout this document general references to EPA's calculated safe dose are denoted as an acute PAD, or aPAD, because the relevant point of departure for carbaryl is based on an acute risk endpoint.

In evaluating a chemical's dietary risk for non-threshold effects, such as cancer; EPA's default approach is to extrapolate a Q1* from the dose-response curve as a measure of cancer potency, and then to use this Q1* value in conjunction with estimated dietary exposure to estimate the probability of occurrence of additional adverse effects. The Q1*is the 95th percentile upper confidence limit from a tumor dose response curve extrapolated using a linear low-dose model. For non-threshold dietary cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million.

Animal studies show that carbaryl, like other NMC pesticides, causes transient, reversible inhibition of cholinesterase activity in brain, red blood cells, and plasma across all tested routes of exposure. Developmental toxicity was seen in rats and rabbits treated with carbaryl during gestation; effects included decreased fetal weight and incomplete ossification (bone formation). A carbaryl rat reproductive toxicity study showed decreased pup survival, and a rat developmental neurotoxicity study showed changes in fetal brain morphometry. In addition, a comparative cholinesterase study shows that young animals had increased sensitivity, compared with adults, to inhibition of brain cholinesterase from carbaryl. EPA used endpoints from the comparative cholinesterase study to assess human health risk in both the single chemical risk assessment for carbaryl and in the cumulative risk assessment for the NMC pesticides. Carbaryl is considered to be ''likely to be carcinogenic in humans'' based on tumors in male mice and EPA utilized the Agency default low-dose linear extrapolation (Q1*) approach to quantify cancer risk.

2. *Estimating human exposure levels.* Pursuant to section 408(b) of the FFDCA, EPA has evaluated carbaryl dietary risks based on ''aggregate

exposure'' to carbaryl. By ''aggregate exposure,'' EPA is referring to exposure to carbaryl alone by multiple pathways of exposure, including residues in food and water and exposure from use of carbaryl products in residential settings. EPA uses available data, together with assumptions designed to be protective of public health and standard analytical methods, to produce separate estimates of exposure for a highly exposed subgroup of the general population, for each potential pathway and route of exposure. For acute risks, EPA then calculates potential aggregate exposure and risk by using probabilistic techniques to combine distributions of potential exposures in the population for the dietary pathway, and uses single point estimates for the residential component in calculating aggregate exposure. For dietary analyses, the relevant sources of potential exposure to carbaryl are from the ingestion of residues in food and drinking water.

The Agency uses a combination of monitoring data and predictive models to evaluate environmental exposure of humans to carbaryl, which may occur from ingesting carbaryl residues in food or drinking water, or from using products containing carbaryl in residential settings. These are described below.

a. *Exposure from food*. Data on the residues of carbaryl in foods are available from a variety of sources. One of the primary sources of the data comes from federally-conducted surveys, including the Pesticide Data Program (PDP) conducted by the USDA. Further, market basket studies, which are typically performed by registrants, can provide additional residue data. These data generally provide a characterization of pesticide residues in or on foods consumed by the U.S. population that closely approximates real world exposures because they are sampled closer to the point of consumption in the chain of commerce than field trial data, which are generated to establish the maximum level of legal residues that could result from maximum permissible use of the pesticide. In certain circumstances, EPA will rely on field trial data, as it can provide more accurate exposure estimates. EPA estimated dietary exposure to carbaryl using residue data from a variety of sources, including USDA and FDA monitoring and crop field trial studies. These residue data were refined based on relevant processing factors. EPA also took into account information on the extent to which crops which may be treated with carbaryl are actually so treated.

EPA uses a computer program, the Dietary Exposure Evaluation Model (DEEM), and the USDA Food Commodity Intake database (FCID), to estimate exposure by combining data on human consumption amounts with residue values in food commodities. DEEM-FCID™ also compares exposure estimates to appropriate RfD or PAD values to estimate risk. EPA uses DEEM-FCID™ to estimate exposure for the general U.S. population as well as for 32 subgroups based on age, sex, ethnicity, and region. DEEM-FCID™ allows EPA to process extensive volumes of data on human consumption amounts and residue levels in making risk estimates. Matching consumption and residue data, as well as managing the thousands of repeated analyses of the consumption database conducted under probabilistic risk assessment techniques, requires the use of a computer.

DEEM-FCID™ contains consumption and demographic information on the individuals who participated in the USDA's Combined Survey of Food Intake by Individuals (CSFII) in 1994–1996 and 1998. The 1998 survey was a special survey required by the FQPA to supplement the number of children survey participants. DEEM-FCID™ also contains ''recipes'' that convert foods as consumed (e.g., pizza) back into their component raw agricultural commodities (e.g., wheat from flour, or tomatoes from sauce, etc.). This is necessary because residue data are generally gathered on raw agricultural commodities rather than on finished ready-to-eat food. Data on residue values for a particular pesticide and the RfD or PADs for that pesticide are inputs to the DEEM-FCID™ program to estimate exposure and risk.

For carbaryl's assessment, EPA used DEEM-FCID™ to calculate risk estimates based on a probabilistic distribution. DEEM-FCID™ combines the full range of residue values for each food with the full range of data on individual consumption amounts to create a distribution of exposure and risk levels. More specifically, DEEM-FCID™ creates this distribution by calculating an exposure value for each reported day of consumption per person (''person/day'') in USDA's CSFII, assuming that all foods potentially bearing the pesticide residue contain such residue at the chosen value. The exposure amounts for the thousands of person/days in the CSFII are then collected in a frequency distribution. EPA also uses DEEM-FCID™ to compute a distribution taking into account both the full range of data on consumption levels and the full range of data on potential residue levels in food. Combining consumption and residue levels into a distribution of potential exposures and risk requires use of probabilistic techniques.

Probabilistic analysis is used to predict the frequency with which variations of a given event will occur. By taking into account the actual distribution of possible consumption and pesticide residue values, probabilistic analysis for pesticide exposure assessments ''provides more accurate information on the range and probability of possible exposure and their associated risk values'' (Ref. 3). In capsule, a probabilistic pesticide exposure analysis constructs a distribution of potential exposures based on data on consumption patterns and residue levels and provides a ranking of the probability that each potential exposure will occur. People consume differing amounts of the same foods, including none at all, and a food will contain differing amounts of a pesticide residue, including none at all.

The probabilistic technique that DEEM-FCID™ uses to combine differing levels of consumption and residues involves the following steps:

(1) Identification of any food(s) that could bear the residue in question for each person/day in the CSFII;

(2) Calculation of an exposure level for each of the thousands of person/days in the CSFII database, based on the foods identified in Step #1 by randomly selecting residue values for the foods from the residue database;

(3) Repetition of Step #2 up to one thousand times for each person/day; and

(4) Collection of all of the hundreds of thousands of potential exposures estimated in Steps # 2 and 3 in a frequency distribution.

The resulting probabilistic assessment presents a range of exposure/risk estimates.

b. *Exposure from water*. EPA may use field monitoring data and/or simulation water exposure models to generate pesticide concentration estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of the specific agricultural or residential pesticide practices in specific locations, under the environmental conditions associated with a sampling design (i.e., the locations of sampling, the times of the year samples were taken, and the frequency by which samples were collected). Although monitoring data

can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable basis for estimating spatial and temporal variability in exposures because sampling may not occur in areas with the highest pesticide use, and/or when the pesticides are being used and/or at an appropriate sampling frequency to detect high concentrations of a pesticide that occur over the period of a day to several days.

Because of the limitations in most monitoring studies, EPA's standard approach is to use simulation water exposure models as the primary means to estimate pesticide exposure levels in drinking water. EPA's computer models use detailed information on soil properties, crop characteristics, and weather patterns to estimate water concentrations in vulnerable locations where the pesticide could be used according to its label. (69 FR 30042, May 26, 2004). These models calculate estimated water concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment at these vulnerable locations. The modeling provides an estimate of pesticide concentrations in ground and surface water. Daily concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide.

EPA relies on models it has developed for estimating pesticide concentrations in both surface water and ground water. Typically EPA uses a two-tiered approach to modeling pesticide concentrations in surface and ground water. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more ined model is used as a second tier assessment. For surface water assessments, the second tier model is actually a combination of two models: The Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS).

A detailed description of the models routinely used for exposure assessment is available from the EPA web site: *http://www.epa.gov/oppefed1/models/water/index.htm*. These models provide a means for EPA to estimate daily pesticide concentrations in surface water sources of drinking water (a reservoir) using local soil, site, hydrology, and weather characteristics along with pesticide application and agricultural management practices, and pesticide environmental fate and transport properties. Consistent with the recommendations of the FIFRA Science Advisory Panel (SAP), EPA also considers percent cropped area factors (PCA) which takes into account the potential extent of cropped areas that could be treated with pesticides in a particular area. The PRZM and EXAMS models used by EPA were developed by EPA's Office of Research and Development (ORD), and are used by many international pesticide regulatory agencies to estimate pesticide exposure in surface water. EPA's use of the percent cropped area factors and the Index Reservoir scenario was reviewed by the FIFRA SAP in 1999 and 1998, respectively (Refs. 4 and 5).

In modeling potential surface water concentrations, EPA attempts to model areas of the country that are highly vulnerable to surface water contamination rather than simply model ''typical'' locations occurring across the nation. Consequently, EPA models exposures occurring in small highly agricultural watersheds in different growing areas throughout the country. The scenarios are designed to capture residue levels in drinking water from reservoirs with small watersheds with a large percentage of land use in agricultural production. EPA believes these assessments are likely reflective of a small subset of the watersheds across the country that maintain drinking water reservoirs, representing a drinking water source generally considered to be more vulnerable to frequent high concentrations of pesticides than most locations that could be used for crop production.

When EPA completed the carbaryl Interim Reregistration Eligibility Decision (IRED)[1] in June 2003, EPA compared the estimated drinking water concentrations (EDWCs) of pesticides, from the PRZM/EXAMS model, with a drinking water level of concern (DWLOC), a value representing the concentration of a pesticide in drinking water that would represent the upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses of that pesticide. The DWLOC approach was developed in the mid 1990s as part of EPA's review of pesticides under FQPA, before the current risk assessment methodologies became available. EPA now uses the output of daily concentration values from tier two modeling as an input to DEEM-FCID™, which combines water concentrations with drinking water consumption information in the daily diet to generate a distribution of exposures from consumption of drinking water containing pesticide residues. These results are then used to calculate a probabilistic assessment of the aggregate human exposure and risk from residues in food and drinking water.

EPA also considers available surface water monitoring data, including data from the US Geological Survey (USGS) National Water Quality Assessment Program (NAWQA), in conducting drinking water assessments. For the 2007 carbaryl RED, EPA considered data from a variety of sources, including NAWQA, the joint USGS-EPA Mini Pilot Monitoring Program, Washington and California state monitoring data, and registrant voluntary water monitoring study measuring carbaryl in targeted community water systems associated with watersheds having high carbaryl use.

c. *Residential exposures*. Generally, in assessing residential exposure to pesticides EPA relies on its Standard Operating Procedures (SOPs) for Residential Exposure Assessment and subsequent amendments (Refs. 6, 7, and 8). The Residential SOPs establish the approaches used for estimating application and post-application exposures in a residential setting. SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack and crevice treatments. The SOPs are based on existing monitoring and survey data including information on activity patterns, particularly for children. Where available, EPA relies on pesticide-specific data in estimating residential exposures. Although limited carbaryl specific data were available at the time the carbaryl IRED was completed, additional data were submitted in response to the 2005 Data Call-In (DCI) for carbaryl. These data were reviewed and incorporated into the revised residential risk assessment used to support the final carbaryl RED. Residential exposure from carbaryl was estimated using EPA's Residential SOPs (as amended) as well as a turf dissipation study for carbaryl which quantified turf transferable residues after carbaryl application to turf and other monitoring data available to the Agency (e.g., residue decline studies on garden crops).

3. *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

[1] Because carbaryl is a member of the NMC group of pesticides, which share a common mechanism of toxicity, EPA was unable to complete the carbaryl Reregistration Eligibility Decision (RED) before completion of the NMC cumulative risk assessment in September 2007.

quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

For threshold risks, EPA estimates risk in one of two ways. Where EPA has calculated an 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 dividing the estimated human exposure into the PoD to derive a margin of exposure (MOE). The MOE is compared with a level of concern, which is the product of all applicable uncertainty/safety factors. In contrast to the RfD/PAD approach, the higher the MOE, the lower the risk concern for the pesticide. Accordingly, if the level of concern 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.

For non-threshold risks (generally, cancer risks), EPA uses the slope of the dose-response curve for a pesticide in conjunction with an estimation of human exposure to that pesticide to estimate the probability of occurrence of additional adverse effects. For non-threshold cancer risks, EPA generally considers cancer risk to be negligible if the probability of increased cancer cases falls within the range of 1 in 1 million. Risks exceeding values within that range would raise a risk concern.

C. Science Policy Considerations

1. *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's additional 10X children's safety factor.

In general, Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses acceptable risk to humans.

In applying the children's safety factor provision, EPA has interpreted the statutory language as imposing a presumption in favor of applying an additional 10X safety factor (Ref. 9). Thus, EPA generally refers to the additional 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that 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.).

When EPA evaluated the carbaryl toxicological database in 2003 to determine the appropriate FQPA Safety Factor for use in the IRED, available studies included rat and rabbit teratology (developmental toxicity) studies, a rat developmental neurotoxicity study, a rat reproductive toxicity study, a 4–week dermal rat study, acute and subchronic neurotoxicity screening studies, and a chronic oral dog study (Ref. 10). Based on the weight of the evidence as evaluated in 2003, the FQPA Safety Factor was determined to be 3X due to the lack of a NOAEL in the chronic dog study. This was what the weight of the evidence showed in 2003.

The science has advanced since 2003; additional information on pharmacokinetics as well as additional acute cholinesterase data have become available for carbaryl and other NMCs. Due to the rapid recovery of cholinesterase activity, chronic exposure is no longer considered to be a concern for carbaryl. As the science has advanced, science policy has also evolved. As EPA acquired developmental neurotoxicity and comparative cholinesterase data on the NMCs, it became apparent that comparative cholinesterase studies measuring red blood cell (RBC) and brain cholinesterase inhibition in both maternal and young animals (postnatal day 11 (PND11) and postnatal day 17 (PND17)) were a more accurate predictor of age-related sensitivity than developmental neurotoxicity studies measuring behavioral and histopathological changes. Therefore, EPA informed registrants that, in the absence of comparative cholinesterase data for each pesticide, a 10X FQPA Safety Factor would be applied to that pesticide in the NMC cumulative risk assessment. If comparative cholinesterase data were available, EPA used a data derived approach for the FQPA Safety Factor by comparing the benchmark dose (BMD) at the 10% inhibition level for either brain or RBC acetyl cholinesterase inhibition between maternal animals and the juvenile animals (typically PND11).

2. *EPA Policy on cholinesterase inhibition as a regulatory endpoint.* 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. 11 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. 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. (Id). 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 an acceptable dose (RfD/PAD) for a cholinesterase-inhibiting pesticide.

Clinical signs or symptoms of cholinesterase inhibition in humans, the policy concludes, provide the most direct evidence of the adverse consequences of exposure to cholinesterase-inhibiting pesticides. Nonetheless, as the policy notes, due to strict ethical limitations, studies in humans are ''quite limited.'' (Id. at 19). Although animal studies can also provide direct evidence of cholinesterase inhibition effects, animal studies cannot easily measure cognitive effects of cholinesterase inhibition such as effects on perception, learning, and memory. For these reasons, the policy recommends that ''functional data obtained from human and animal studies should not be relied on solely, to the exclusion of other kinds of pertinent information, when weighing the evidence for selection of the critical effect(s) that will be used as the basis of the RfD or RfC.'' (Id. at 20).

After clinical signs or symptoms, cholinesterase inhibition in the nervous system provides the next most important endpoint for evaluating cholinesterase-inhibiting pesticides. Although cholinesterase inhibition in the nervous system is not itself regarded as a direct adverse effect, it is ''generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects.'' (Id. at 25). As such, the policy states that it should be treated as ''direct evidence of potential adverse effects'' and ''data showing this response provide valuable information in assessing potential hazards posed by anticholinesterase pesticides.'' (Id.). AChE inhibition in brain and the peripheral nervous system is the initial adverse biological event which results from exposure to NMC pesticides, such as carbaryl, and with sufficient levels of inhibition leads to other effects. Thus, AChE inhibition provides the most appropriate effect to use in risk extrapolation for derivation of RfDs and PADs. Protecting against AChE inhibition ensures that the other adverse effects mentioned above do not occur.

In summary, EPA uses a weight of 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., 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.). Due to technical difficulties regarding dissection of peripheral nerves and the rapid nature of carbaryl toxicity, measures of AChE inhibition in the peripheral nervous system are very rare for NMC pesticides. 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.

3. *Benchmark dose.* EPA has relied on a benchmark dose approach for deriving the PoD from the available rat toxicity studies (Ref. 12). 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 or typical value for the response of concern. 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, inhibition of AChE is the toxic effect of concern. Following exposure to carbaryl, the normal biological activity of the AChE enzyme is decreased (i.e., the enzyme is inhibited). Thus, when evaluating BMDs for carbaryl, the Agency is interested in a decrease in AChE activity compared to normal activity levels, which are also termed ''background'' levels. Measurements of ''background'' AChE activity levels are usually obtained from animals in experimental studies that are not treated with the pesticide of interest (i.e., ''negative control'' animals).

In addition to the BMD, a ''confidence limit'' was also 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. From the PoD, EPA calculates the RfD and aPAD.

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. 12, 13, 14, and 15). Specific to carbaryl and other NMCs, the FIFRA SAP has reviewed and supported the statistical methods used by the Agency to derive BMDs and BMDLs on two occasions, February 2005 and August 2005 (Refs. 14 and 15).

IV. Carbaryl Tolerances

A. Regulatory Background

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®. In 1980, the Agency published a position document summarizing its conclusions from a Special Review of carbaryl, and concluded that risk concerns, particularly those related to teratogenicity, did not warrant cancellation of the registration for carbaryl. A Registration Standard, issued for carbaryl in 1984 and revised

in 1988, described the terms and conditions for continued registration of carbaryl. 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). For example, carbaryl was registered for domestic outdoor uses on lawns and gardens, and indoors in kennels and on pet sleeping quarters. It was also registered for direct application to cats and dogs (collar, powder, and dip) to control fleas and ticks.

EPA completed an IRED for carbaryl on June 30, 2003 (2003 IRED). The Agency amended the 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 (Ref. 16). EPA received numerous comments on the carbaryl IRED, including the NRDC petition requesting that EPA cancel all carbaryl registrations and revoke all tolerances. The Agency published a Notice of Receipt for the petition in the **Federal Register**, which provided a public comment period. *Petition to Revoke or Modify Tolerances Established for Carbaryl; Notice of Availability*, 70 FR 16281 (March 30, 2005). The mitigation detailed in the 2004 Amended IRED for residential uses included: canceling liquid broadcast applications to home lawns pending EPA review of pharmacokinetic data to refine post-application risk estimates; home garden/ornamental dust products must be packaged in ready-to-use shaker can containers, with no more than 0.05 lbs. active ingredient per container; cancellation of 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.

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. 17). In March 2005, EPA also issued generic and product-specific 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 this request 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.

In addition, Bayer, the sole remaining technical registrant responsible for developing data, requested waivers of required exposure monitoring or residue studies because these use scenarios are not on any Bayer technical or product labels or were to be deleted from Bayer labels: 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 fpr 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.

Bayer subsequently requested that all of their carbaryl registrations bearing any of these uses be amended to delete these uses; EPA published a Notice of receipt of this request in the **Federal Register** on August 20, 2008 (73 FR 49184), and plans to approve Bayer's request and issue a final order amending these registrations at the end of the comment period for the Notice. As a consequence, EPA has notified all affected registrants that these uses and application methods must be deleted from their carbaryl product labels. EPA has identified thirty four (34) product labels from 14 registrants (other than Bayer) bearing these end uses. All of these registrants have requested that their affected carbaryl product registrations be amended to delete these uses. EPA published a Notice of receipt of these requests in the **Federal Register** on August 20, 2008 and will publish a second Notice of Receipt of these requests on or about October 8, 2008.

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

Carbaryl is a member of the NMC class of pesticides which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition. Specifically, carbaryl is a reversible inhibitor of AChE. A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures resulting from registered uses of NMC pesticides, including carbaryl.

In late November 2006, EPA received data from a carbaryl comparative cholinesterase study, conducted to determine the comparative sensitivity of adults and offspring to cholinesterase inhibition by carbaryl. These data were used to revise the FQPA Safety Factor for carbaryl for the NMC cumulative risk assessment and to select new toxicology endpoints (PoDs) for the risk assessment. The Agency determined that it was appropriate to use the new FQPA Safety Factor and revised PoDs in both the NMC cumulative risk assessment and the carbaryl-specific human health risk assessment. Because this necessitated a revision of the carbaryl human health aggregate risk assessment, EPA also considered additional new data generated in response to the DCI, new methodologies, and other new information in performing its most recent assessment of carbaryl and in responding to this Petition. EPA has thus, in effect, revised the carbaryl single chemical assessment in response to the issues raised during the public comment process as well as based upon more recent data and analytical methods.

On September 26, 2007, EPA issued the NMC cumulative risk assessment. EPA concluded that the cumulative risks associated with the NMC pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCA, provided that the mitigation specified in the NMC 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. 18 for additional information).

In conjunction with the NMC cumulative risk assessment, EPA completed a RED for carbaryl on September 24, 2007 and issued this RED on October 17, 2007 with a formal Notice of Availability in the **Federal Register** (72 FR 58844). In addition to relying on the NMC cumulative risk assessment to determine that the cumulative effects from exposure to all NMC 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). In addition, 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. Subsequently, on August 25, 2008, EPA completed an addendum to the Carbaryl RED incorporating the results of a revised occupational risk assessment and modified mitigation measures for the protection of workers. Elsewhere in this issue of the **Federal Register** EPA is announcing the availability of the amendments to the Carbaryl RED.

B. FFDCA Tolerance Reassessment and FIFRA Pesticide Reregistration

As required by the Food Quality Protection Act of 1996, EPA reassessed the safety of the carbaryl tolerances under the safety standard established in the FQPA. In the September 2007 RED for carbaryl, EPA evaluated the human health risks associated with all currently registered uses of carbaryl and determined that there is a reasonable certainty that no harm will result from aggregate non-occupational exposure to the pesticide chemical residue. In making this determination, EPA considered dietary exposure from food and drinking water and all other non-occupational sources of pesticide exposure for which there is reliable information (Ref. 18). The Agency has concluded that with the adoption of the risk mitigation measures identified in the NMC cumulative risk assessment, all of the tolerances for carbaryl meet the safety standard as set forth in section 408(b)(2)(D) of the FFDCA. Therefore, the tolerances established for residues of carbaryl in/on raw agricultural commodities were considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA, in September 2007. These findings satisfied EPA's obligation to review the carbaryl tolerances under the FQPA safety standard.

To implement the carbaryl tolerance reassessment, EPA commenced with rulemaking in 2008. The Agency published a Notice of proposed tolerance actions in the May 21, 2008 **Federal Register** (73 FR 29456). This proposed rule provided for a 60 day public comment period. No comments relevant to carbaryl tolerances were received and EPA published a Notice of final tolerance actions in the September 10, 2008 **Federal Register** (73 FR 52607). This rule codifies the carbaryl tolerances in 40 CFR 180.169.

V. The Petition to Revoke Tolerances

NRDC filed a petition dated January 10, 2005 (Petition), requesting, among other things, that EPA cancel all carbaryl registrations and revoke all carbaryl tolerances (Ref. 1). In response to EPA's publication of the Petition pursuant to section 408(d) of the FFDCA, NRDC resubmitted its Petition and earlier comments in support of its Petition. (See Docket ID EPA–HQ–OPP–2005–0077–0066).

It should be noted that NRDC's January 10, 2005 submission is 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; (Ref. 16). Nonetheless, in the introduction to the comments, NRDC included a statement that NRDC is also petitioning the Agency to revoke all carbaryl tolerances. Among other things, NRDC raises issues with the dietary assessment and in particular its drinking water assessment that supported the 2004 IRED decision. NRDC also raises concerns about the data surrounding EPA's selection of a children's safety factor. NRDC's petition also includes some generic disagreements with how EPA conducts its assessments.

VI. Public Comment

In response to that portion of NRDC's petition seeking revocation of the carbaryl tolerances, EPA published notice of the Petition for comment on March 30, 2005 (70 FR 16281). EPA received approximately 5,230 comments in support of the Petition. The vast majority of these comments followed an identical or similar format expressing the commenters support for the Petition in general terms. These commenters uniformly protested the Agency's decision to continue allowing the use of carbaryl ''a chemical [EPA] consider[s] likely to cause cancer.'' As a preliminary note, although the Agency considers carbaryl to have the potential to cause cancer, exposure to carbaryl residues is so low that the actual risk of cancer from carbaryl is negligible. EPA is generally not concerned about cancer risks at or below the range of 1×10^{-6}, or 1 in a million. For carbaryl, the dietary cancer risk from residues in food and drinking water is estimated to be 3×10^{-8}, or 3 in 10 million. The estimated cancer risk from exposure to carbaryl in products used in a residential setting range from 1×10^{-8} to 10^{-13} (from 1 in 10 million to 1 in 10 trillion). Because EPA considers carbaryl to be a non-threshold carcinogen, the Agency uses the conservative, default linear low-dose linear method to quantify cancer risk. Even using this conservative approach to evaluate potential cancer risk from food, drinking water, and residential uses of carbaryl, EPA has not identified any cancer risks of concern.

Of the subset of comments not based upon a form letter, most related to ecological issues and in particular toxicity to bees and apple thinning uses. These comments are not relevant to the requested revocation of pesticide tolerances. EPA is responding to the Petition insofar as it seeks the cancellation of all carbaryl registrations separately and, therefore, these comments are not directly relevant here. One commenter, Bayer, the sole technical product registrant, submitted comments that purport to address all of the issues raised by NRDC (Ref. 19). In any event, these comments as a whole did not add any new information pertaining to whether the tolerances were in compliance with the FFDCA. Comments on the specific claims by NRDC are summarized in Unit VII immediately following the summary of NRDC's claim but prior to EPA's response to the claim.

VII. Ruling on Petition

This Order addresses NRDC's petition to revoke carbaryl tolerances. As noted above, this ''Petition'' was included as part of NRDC's comments on the carbaryl IRED. Thus, the Petition contains a number of comments that are just that, comments, and that do not provide a basis upon which to either cancel all carbaryl registrations or revoke all carbaryl tolerances. Where those comments are directly related to suggestions that the carbaryl tolerances do not meet the safety standard in section 408 of the FFDCA, the Agency has tried to address those comments in this petition response. However, EPA has not attempted to respond to every comment or suggestion for improvement made in NRDC's filing.

EPA has, to the extent possible, construed NRDC's comments as asserting various grounds as to why the carbaryl tolerances do not meet the

FQPA safety standard and should be revoked. EPA has divided NRDC's grounds for revocation into four categories - toxicology; dietary exposure; residential exposure; and risk characterization - and addressed separately each claim under these categories. Each specific claim of NRDC is summarized in Unit VII immediately prior to EPA's response to the claim.

This Order also constitutes a response to a petition dated November 26, 2007, to cancel carbaryl pet collar registrations submitted as part of NRDC's comments on the NMC cumulative assessment (NMC Petition) (Ref. 2). EPA's response to NRDC's petition to cancel pet collar registrations is addressed here because the basis for the petition to cancel pet collars rests on issues related to EPA's assessment of cumulative effects under the FFDCA.

EPA has not addressed claims that concern carbaryl uses that have been canceled, or application methods that have been discontinued since the time of the Petition. Nor is EPA addressing claims that concern carbaryl uses for which the registrant(s) has requested that the use be deleted or registration cancelled pursuant to section 6(f) of FIFRA. These include the liquid broadcast use of carbaryl on residential lawns and turf, cancelled in March 2005 (Ref. 17), and several other uses and application methods which have been or are in the process of cancellation because the registrants are not supporting these uses and application methods with the necessary data (73 FR 49184, August 20, 2008). The following carbaryl uses are in the process of being cancelled: wheat, millet, and fresh/succulent beans and peas (crop subgroup 6B); use of carbaryl drench or dip treatments of seedlings or seed pieces, dust formulations in agricultural crops, granular applications to leafy vegetables (except Brassica), direct applications of carbaryl (except for flea collars) to domestic animals (including dogs, cats, and other pets), and all indoor applications. Carbaryl registrations are also being amended to discontinue the following application methods: drenching dipping, hand held fogger, mosquito adulticide ULV, power backpack sprayer, and tree injection.

A. Dietary Exposure Issues

1. *Revised dietary exposure and risk assessment*. NRDC's petition challenges some aspects of EPA's 2003 proposed dietary exposure and risk assessment of carbaryl (Ref. 1 at 16-20). EPA has since updated its dietary exposure and risk assessment. These revisions were incorporated in and provided the basis for the RED. The main changes in the revised assessment include: (1) Use of the half-life value for carbaryl from a study that measures how quickly carbaryl degrades in an aerobic aquatic environment; (2) inclusion of updated percent crop treated data for evaluation of dietary exposure from residues in food; (3) inclusion of a comprehensive review of recent surface water monitoring data, including an investigation into the high carbaryl detection in groundwater reported in the 2003 IRED; (4) incorporation of the most recent food residue data from USDA's PDP; and (5) inclusion of drinking water exposure modeling and monitoring data for agricultural and nonagricultural uses of carbaryl. In addition, in a change from the 2003 assessment, the revised risk assessment did not evaluate dietary risk for long term (> 6 months) and chronic exposure to carbaryl due to the rapid reversibility of cholinesterase inhibition, the toxicological endpoint of concern. Specifically, recent data for carbaryl and the other NMCs show that cholinesterase inhibition is reversible, with recovery in less than 24 hours. Because the acute exposure from carbaryl is the main duration of concern, EPA determined that a chronic assessment is not appropriate for carbaryl.

These revisions effectively address NRDC's concerns and EPA is not reopening the issues here. Nonetheless, EPA is providing more specific information concerning the revised risk assessment in the context of the specific issues raised by NRDC.

2. *Drinking water assessment*—a. *NRDC's claims*. NRDC criticizes the Agency's drinking water assessment because it only considered agricultural sources. NRDC urged EPA to include all available information in its surface water assessment, including non-agricultural sources (Ref. 1 at 16). NRDC further notes that the drinking water levels of comparison (DWLOCs) ''exceeds acceptable levels.'' (Ref. 1 at 16). NRDC disagrees with EPA's conclusion that the DWLOC was nonetheless acceptable because the modeling is overly conservative and that actual concentrations of carbaryl in drinking water are likely to be ''much lower.'' NRDC faults the Agency for not defining the magnitude of ''much lower'' and not providing any support for this contention. In particular, NRDC argues that the modeling estimates are actually in agreement with some of the monitoring data, and therefore EPA should accept the modeling estimates as an accurate indicator of exposure. Specifically, NRDC argues that peak modeling estimates from Florida citrus use (646 ppb) match monitoring data from a well in New York (610 ppb), and therefore EPA should accept the modeling estimates as an accurate indicator of exposure. NRDC further argues that the Agency's rationale for concluding that the models overestimate actual concentrations in surface water is faulty.

b. *Public comments*. In its comments, Bayer took issue with NRDC's characterization that the monitoring data are in agreement with the model calculations, based upon a detection of 610 ppb in a well in New York and a maximum concentration value of 6.5 ppb in the USGS NAWQA data. Bayer argues that comparing an isolated ground water finding with predicted concentrations in surface water is scientifically inappropriate because of the different transport processes in ground water as compared to surface water. Bayer characterizes the ground water detection in NY as anomalous and notes that it has not been investigated or confirmed, and argues that it is not likely to be the result of normal movement though the soil.

Further, Bayer submitted a voluntary drinking water monitoring study for carbaryl, Surface Water Monitoring for Residue of Carbaryl in High Use Areas in the United States: Final Report (MRID 45788101). Bayer defends its drinking water study, stating that it was targeted to community water systems having watersheds with high carbaryl use and that showed lower concentrations than the NAWQA data. Bayer further argues that NRDC's assertion that monitoring can be spotty and is not designed to coincide with high use sites, seasonal application times, watershed characteristics, and urban and agricultural methods is misplaced. Bayer asserts that the monitoring program was targeted and did focus on high use sites, with a sampling program tailored to the application times, and covered both agricultural and non-agricultural uses.

Bayer also argues that the modeling is a worst case scenario and gives several reasons why EPA's model can overestimate movement of surface water, including assumptions regarding use intensity (100% of field treated at maximum rates for the maximum number of times). Bayer then asserts that the worst-case predictions are not confirmed by monitoring data ''specifically designed to capture high use areas and application times.'' (Ref. 19 at 5).

Another commenter from the Department of Entomology, Virginia Tech, notes that while NRDC complains that EPA makes assumptions in its risk

models, NRDC makes questionable assumptions of its own; namely, that EPA's model is more reliable than actual monitoring data. Similarly, NRDC emphasizes that most acreage is treated, implying that most acres received the full allowable rate. However, although carbaryl is allowed to be applied to apples during the growing season, apple growers use carbaryl mainly as a chemical thinner, which occurs early in the season and is much less likely to cause harvest residues. Other commenters (apple growers) submitted similar comments regarding the actual use and that the use of carbaryl for thinning is not likely to result in residues at harvest time as well as the importance of carbaryl for chemical thinning.

Another commenter from the University of Florida asserts that the acute drinking water concern is driven by Florida modeling, based upon a 38% crop treated assumption. According to the commenter, actual use in Florida is ''probably closer'' to one tenth of that amount. Again, according to the commenter, the National Agricultural Statistics Service (NASS) 2003 fruit data report percent crop treated amounts of 3% for Florida and 5% for grapefruit nationally. The commenter takes issue with NRDC's claim that the greater than 600 ppb spike in New York ''conforms'' to the results from the modeling. In so doing, the commenter asserts that carbaryl in New York degrades much slower than in Florida. The commenter then implies that it is significant that there are no Florida monitoring values that were in the hundred parts per billion concentration range.

c. *EPA's response*. EPA has addressed NRDC's concerns in the revised drinking water assessments supporting the carbaryl RED, which includes all available information including surface water monitoring data, new environmental fate data, and other new information and methodologies. EPA incorporated new half-life data from an aerobic aquatic metabolism study, regional percent cropped area factors, and the mitigation required in the carbaryl IRED into modeled estimates of carbaryl levels in surface water. In addition, the Agency used the PRZM-EXAMS model to generate a distribution of approximately 11,000 values, representing daily peak values over 30 years. This data set was used to create water residue data files for use in DEEM-FCID™. The range of annual peak water values was 13 to 108 parts per billion (ppb) over 30 years (Ref. 20 for further details of EPA's refined drinking water modeling). EPA incorporated this distribution of drinking water values directly into the exposure component of the dietary assessment, using the DEEM-FCID™ model. EPA also incorporated drinking water consumption data and reported body weights from the CSFII into the exposure assessment.

As mentioned above, the carbaryl drinking water assessment is no longer based upon the DWLOC approach. EPA officially withdrew the science policy paper describing the DWLOC approach on August 1, 2007 (72 FR 42082). In addition, EPA believes that the new approach is more protective of sensitive population subgroups, including infants and children, than the DWLOC approach used in the carbaryl IRED.

Although EPA did not model nonagricultural use of carbaryl, the Agency considered these uses in the process of evaluating all available water monitoring data for carbaryl for the 2007 carbaryl RED. EPA reviewed the most recent surface water monitoring data for carbaryl in urban and suburban areas for both the carbaryl IRED and the RED. Specifically, EPA considered data from NAWQA, the joint USGS-EPA Mini Pilot Monitoring Program, Washington and California state monitoring data, and a registrant voluntary water monitoring study measuring carbaryl in targeted community water systems associated with watersheds having high carbaryl use. The Agency also considered California monitoring data targeted to urban use of pesticides (Ref. 21).

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

Finally, both the commenter from the University of Florida and NRDC are mistaken in their statements that that EPA's drinking water assessment relied on default percent crop treated assumptions. In particular, NRDC appears to have confused percent crop treated (PCT) data for the percentage of a food commodity treated with carbaryl with EPA's use of percent crop area (PCA) in the carbaryl drinking water assessment. The default PCA (87%) represents the largest fraction of a watershed that can be planted to any crop. This default PCA, which is based on Geographic Information Systems (GIS) analysis of fairly large watersheds[2], is used in drinking water assessments to account for the fact that not all land in a watershed is agricultural land (planted with crops). Regional PCAs reflect the greatest fraction of a watershed used in agriculture in each of the major drainage basins in the United States. In either case, the drinking water assessment assumes that carbaryl is applied to 100% of the agricultural land in the watershed, regardless of the fraction of the watershed that is used in agriculture.

In sum, the revised dietary risk assessment for food shows that acute dietary exposure and risk are below the Agency's level of concern for the general U.S. population and all population subgroups. The revised drinking water assessment also does not rely on the old methodology, using DWLOCs. The drinking water assessment was not limited to agriculture uses; EPA included the most recent available monitoring data for carbaryl in urban and suburban areas in the revised assessment. Last, estimated pesticide residues in drinking water were incorporated directly into the exposure component of the dietary assessment.

3. *CARES dietary exposure model*—a. *NRDC's claims*. NRDC asserts that EPA improperly relied upon Cumulative and Aggregate Risk Evaluation System (CARES), a ''confidential'' industry model to assess human health risks. While NRDC acknowledges that EPA may rely on a proprietary model, it insists that EPA has not provided sufficient detail about the model's ''built-in assumptions and calculation methodologies.'' (Ref. 1 at 19).

b. *Public comments*. Bayer asserts that during its development by industry, with input from EPA and USDA, CARES was ''freely'' available from CropLife

[2] Large watershed having an 8 digit hydrologic unit code (HUC-8).

America by request. Bayer also notes that the model was reviewed at two FIFRA SAP meetings in 2002 and 2004 (US EPA, SAP April 30 to May 1, 2002. CARES Model Review *http://www.epa.gov/scipoly/sap*; USEPA, SAP April 29 to 30, 2004. A Model Comparison: Dietary and Aggregate Exposure in Calendex, CARES and Lifeline. *http://www.epa.gov/scipoly/sap*). On completion of the model, it was donated to The International Life Sciences Institute (ILSI). CARES is now freely available from the ILSI web site (*http://www.ilsi.org*).

c. *EPA's Response*. In the 2003 IRED, EPA used the DEEM- FCID™ model to estimate dietary risks from carbaryl. The carbaryl registrant submitted an assessment derived from CARES, which EPA reviewed and compared with the Agency's results. However, the Agency did not rely upon the CARES model in the Carbaryl IRED. EPA relied upon the DEEM-FCID™ model for both the 2003 human health risk assessment supporting the IRED and the revised 2007 dietary assessment supporting the carbaryl RED. Thus, any concerns regarding the public availability of the CARES model are irrelevant to EPA's risk assessment for the 2003 IRED.

Nonetheless, it is worth noting that the CARES model has been transferred to the ILSI Research Foundation and the CARES program and source code is publicly available at no charge. In addition, in 2002, the FIFRA SAP reviewed the underlying science, computational approaches and ease of use of the CARES model. The FIFRA SAP's June 13, 2002 report (Ref. 22) provides results of the panel's deliberations. The FIFRA SAP provided a series of recommendations designed to improve the technical basis of the model and software system. In any case, CARES meets OPP's criteria for use in regulatory decision making with respect to public availability, transparency, and compliance with Agency policy guidelines and NRDC's objection in this regard are without merit.

4. *Farmers' markets and roadside produce stands*—a. *NRDC's claims*. NRDC asserts that EPA did not explicitly consider food purchased at farmer's markets, farm stands, ''U-PIK'' farms, or eaten from household gardens (Ref. 1 at 19-20). NRDC suggests that, in the absence of data to support EPA's belief that its exposure assessment adequately accounts for food purchased at such locals, EPA include an uncertainty factor to account for children who consume this source of food (Ref. 1 at 20).

b. *Public comments*. Bayer noted that EPA adequately responded to this issue in its October 26, 2004 Response to Comments on Phase 5 Risk Assessment (Docket ID No. EPA–HQ–OPP–2003–0376–00008).

c. *EPA's response*. In an Order responding to NRDC objections to tolerances for different pesticides, EPA has addressed NRDC's claims regarding pesticide exposure to persons who purchase food at roadside stands or farmers' markets. (70 FR 733; 72 FR 662, December 5, 2007). This is equally applicable to ''U-PIK'' farms and household gardens. As EPA explained there, whether EPA relies on data from crop field trials or monitoring data in estimating pesticide exposure, given the sampling methods in field trials and food monitoring residue levels identified from these sources are unlikely to understate residue levels at farm stands. Moreover, EPA does not believe it is reasonable to assume that farm stands sell food containing a significantly different residue profile than found in PDP monitoring data. Therefore, this factor introduces little to no uncertainty concerning the possibility of underestimation of residues into EPA's analysis. In any case, EPA hereby incorporates its prior response to these issues EPA relies on its prior response to this issue and finds NRDC's contentions without merit.

5. *Tolerances for cancelled uses*—a. *NRDC's claims*. NRDC is concerned that EPA proposed to increase tolerances for 20 commodities and establish new tolerances for 7 commodities (Ref. 1 at 14-15). Specifically, NRDC urges EPA not to make any tolerance reassessment determination prior to completion of the carbamate cumulative risk assessment. NRDC also insists that EPA revoke tolerances for all uses of carbaryl that have been voluntarily cancelled. NRDC is particularly concerned about imported food and products entering the United States with carbaryl residues without triggering action by the FDA. NRDC is also concerned about the effect that the failure to ''ban'' products will have on the international community and in particular developing countries. Specifically, NRDC asserts that manufacturers voluntarily cancel the registration of high risk products to avoid Prior Informed Consent (PIC) listings.

b. *Public comments*. Bayer asserts in its comments that in the carbaryl IRED EPA addressed NRDC's concern regarding the reassessment of tolerances prior to the completion of the NMC cumulative risk assessment. Bayer notes, however, that the IRED specifically provides that the establishment of new tolerances or raising tolerances will be deferred pending consideration of cumulative risk for the NMCs. The IRED further provides that, for purposes of that document, the term ''reassessed'' does not imply that all of the tolerances for carbaryl have been reassessed as required by FQPA, since these tolerances may only be reassessed once the cumulative risk assessment of all carbamate pesticides is considered. Rather, the IRED provided reassessed tolerances for carbaryl in/on various commodities, supported by all of the submitted residue data, only for the single carbamate chemical carbaryl (Ref. 16 at 67).

Bayer further expressed its belief that EPA's practice of revoking tolerances after a sufficient period of time that allows existing stocks bearing the use being cancelled to clear the channels of trade is in compliance with the requirements of the FQPA. Finally, Bayer argues that NRDC's concern about potential risk from new or increased tolerances being established for carbaryl are not justified because the tolerance reassessment process is not associated with labeling changes that increase the maximum application rates or frequency of application allowed by current labels. Bayer further notes that many of the labeling amendments required by the IRED serve to reduce potential human health and environmental risks. Bayer also notes that the pursuant to the IRED most tolerances will be either reduced, revoked, or left unchanged.

c. *EPA's response*. Notwithstanding NRDC's insistence that EPA revoke tolerances for uses that have been voluntarily canceled, NRDC has not provided any basis for determining that tolerances for uses that have been voluntarily cancelled do not meet the FFDCA standard such that the tolerance must be revoked. Be that as it may, EPA has now completed and released the cumulative risk assessment for the NMCs and, therefore, all carbaryl tolerances are considered reassessed at this time. With respect to tolerances associated with uses that have been cancelled and/or deleted pursuant to section 6(f)(1) of FIFRA, EPA has revoked the associated tolerances, except for the wheat tolerance, which is still needed to cover imported wheat and any domestic wheat that may receive inadvertent residues of carbaryl resulting from carbaryl use to control grasshoppers and/or Mormon crickets on pasture and rangeland. The Agency included carbaryl residues on wheat in the cumulative risk assessment for the NMCs.

The Agency has completed rulemaking proceedings to revoke and modify the existing carbaryl tolerances,

and correct commodity definitions. EPA published a proposed tolerance rule for carbaryl on May 21, 2008 (73 FR 29456) and a final tolerance rule on September 10, 2008 (73 FR 52607). The final carbaryl tolerance rule revokes tolerances associated with uses that have been cancelled and/or deleted to date pursuant to section 6(f)(1) of FIFRA, allowing sufficient time for existing stock to clear channels of trade, with the exception of the tolerance for wheat. As a result of the final tolerance rule, many existing carbaryl tolerances have been reassigned to crop groups, and old commodity specific tolerances have been revoked as new tolerances have been established for residues in/on various crop groups and subgroups. New tolerances were also established for carbaryl residues in/on the following raw agricultural commodities: aspirated grain fractions, proso millet hay, sorghum stover, and sugar beet roots. At the present time, sufficient data are available to determine an appropriate tolerance for residues in/on aspirated grain fractions (70 ppm), sugar beet roots (0.5 ppm), and sorghum stover (30.0 ppm). Separate tolerances have been established for residues in the following processed food/feed items: wet apple pomace (15.0 ppm), citrus fruit oil (20.0 ppm), raisins (12.0 ppm), and rice hulls (30.0 ppm).

Finally, to the extent that NRDC argues that tolerances must be revoked simply because an active ingredient or use is not registered in the United States, EPA disagrees. Nothing in the FFDCA requires that tolerances be limited to pesticides that have a U.S. registration. In fact, FIFRA explicitly recognizes that EPA may set import tolerances under the FFDCA. See Section 33 of FIFRA (establishing fees and decision review times for import tolerance applications). While EPA often proposes to revoke tolerances after the cancellation of associated uses because EPA believes the tolerances may no longer be necessary, EPA has always recognized that a revocation can not proceed on such grounds if foreign growers wish to rely on the tolerance. In such circumstances, a tolerance can only be revoked if necessary data to support the tolerance are not provided or if EPA determines that the tolerance does not meet the safety standard.

B. Risk Characterization

1. *New data*. In keeping with science policy developments for the NMCs, EPA used data from a comparative cholinesterase study comparing carbaryl-induced cholinesterase inhibition in adult and juvenile rats to calculate a revised FQPA Safety Factor for carbaryl and to derive the toxicology points of departure for risk assessment. Specifically, this study was conducted to determine whether young animals are more susceptible to the effects of carbaryl than adults. This oral study showed that juvenile 11–day-old (PND11) pups were more sensitive to inhibition of brain cholinesterase from carbaryl than adult rats.

EPA conducted a benchmark dose analysis for the carbaryl comparative cholinesterase study, using the same modeling methodology used in the NMC cumulative risk assessment. A benchmark dose analysis models the dose-response relationship with a dose-response curve, which allows selection of doses corresponding to a specified level of response, called a benchmark response. This analysis allows EPA to determine a more appropriate point of departure from a toxicology study rather than using the study NOAEL or LOAEL. (See Refs. 12, 23, and 24 for more information on benchmark dose modeling).

The Agency estimated the 10% benchmark dose response (BMD_{10}) and the $BMDL_{10}$, or lower 95% confidence limit of the benchmark dose, for this study. The Agency also conducted a full benchmark dose analysis of all rat oral toxicity studies for adults; this analysis showed that the BMDL10 for pups is also protective for adults. Because the brain is the target tissue for carbaryl, and the brain $BMDL_{10}$ of 1.1 milligrams/kilogram (mg/kg) is also protective of cholinesterase inhibition in blood, then the brain $BMDL_{10}$ is the appropriate point of departure for both children and adults in the revised carbaryl risk assessment. (See Ref. 23 and Ref. 24 for additional details regarding the comparative cholinesterase study).

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

As previously mentioned in Unit III.C.1. of this document, EPA has revised the FQPA Safety Factor for carbaryl using the most recent data on carbaryl age sensitivity. The new comparative cholinesterase study data was used to derive a new FQPA Safety Factor by comparing the BMD_{10} for brain cholinesterase inhibition between adults and pups at postnatal day 11. Pups were 1.8x more sensitive to brain cholinesterase inhibition than the adults; therefore, a 1.8X FQPA Safety Factor was applied to both the NMC cumulative and the carbaryl-specific risk assessments. This safety factor of 1.8X is applied to the dermal endpoint because there are no comparative cholinesterase data in offspring from dermal exposure, and because juvenile rats are 1.8X more sensitive than adults based on the oral comparative cholinesterase study in rats. The FQPA Safety Factor is 1X for oral and inhalation endpoints because these endpoints are selected from the comparative cholinesterase data for the most sensitive population (PND11 pups).

3. *Issues raised by NRDC concerning the FQPA safety factor*—a. *NRDC's claims*. NRDC objects to EPA's decision to reduce the FQPA Safety Factor to 1X in the IRED and repeats earlier arguments that a developmental neurotoxicity study (DNT) used by EPA in the 2004 IRED does not provide a basis for removing the FQPA Safety Factor because pups had effects at doses that did not produce effects in adults in the DNT study. (Ref. 1 at 17, 18) In addition, NRDC maintains that EPA should have applied an additional 3X uncertainty factor to account for the failure to identify a No Observable Adverse Effect Level (NOAEL) for brain morphometric changes in pups in the DNT study. Specifically, NRDC argues that the low and mid-dose samples were ''damaged and uninterpretable'' and thus this test did not produce a ''no observed adverse effect level.'' (Ref. 1 at 17-19).

b. *Public comments*. Bayer noted that EPA adequately responded to this issue in its October 26, 2004 Response to Comments on Phase 5 Risk Assessment (Docket ID No. 2003–0376–00008).

c. *EPA's response*. Since the 2004 IRED, EPA has incorporated new data into its assessment of carbaryl. In the process of completing the carbaryl RED and the cumulative risk assessment for the NMCs, EPA re-evaluated the toxicology database for carbaryl, which includes studies submitted since the completion of the IRED. EPA received pharmacokinetic data on the rapid reversibility of carbaryl effects (Ref. 25), a comparative cholinesterase study to inform age-related sensitivity to carbaryl (Ref. 23), and a dermal penetration study for carbaryl (Ref. 26). As a result, the Agency revised the FQPA Safety Factor in 2007 and selected new points

of departure using the new comparative cholinesterase data and benchmark dose modeling.

The comparative cholinesterase study was conducted specifically to provide age-related sensitivity data for carbaryl to be used in the NMC cumulative risk assessment. Experience with other NMCs has shown that comparative cholinesterase studies provide a more accurate indication of comparative adult and offspring sensitivity than the behavioral and histopathological changes evaluated in the DNT study. The carbaryl comparative cholinesterase study involved oral dosing of three age groups of rats, adults (97 days old) and juveniles 11 or 17 days old (postnatal day, PND, 11 or 17), followed by measurement of both brain and blood cholinesterase. Based on a benchmark dose analysis of the results of this study, EPA identified a clear point of departure (the equivalent of a NOAEL) for brain cholinesterase effects in the young and thus the sensitivity in the young is well-characterized. In these circumstances, EPA finds that it has reliable data on pre- and post-natal toxicity to remove (oral and inhalation) or reduce (dermal) the 10X FQPA Safety Factor.

Based on the results of the benchmark dose analysis from the comparative cholinesterase study, which provide the most sensitive data available to date on age related sensitivity to carbaryl, juvenile animals are 1.8X more sensitive to carbaryl induced cholinesterase inhibition than adults. EPA has thus derived an FQPA Safety Factor of 1.8X. This safety factor of 1.8X is applied to the dermal endpoint because there are no comparative cholinesterase data in offspring from dermal exposure, and because juvenile rats are 1.8X more sensitive than adults based on the oral comparative cholinesterase study in rats. The FQPA Safety Factor is 1X for oral and inhalation endpoints because these endpoints are selected from the comparative cholinesterase data for the most sensitive population (PND11 pups).

Moreover, NRDC's concern that EPA failed to apply an additional 3X uncertainty factor to account for the failure to detect a NOAEL in the DNT study is no longer relevant. Specifically, brain cholinesterase inhibition in the PND 11 animals in the comparative cholinesterase study was the most sensitive endpoint in this study; therefore, this endpoint of 1.1 mg/kg/day was used as the point of departure for the 2007 carbaryl risk assessment. This new endpoint occurs at a lower dose than NRDC's suggested extrapolated NOAEL (i.e., including a 3X uncertainty factor) of 3.3 mg/kg/day for brain morphometry from the DNT study. Because EPA's assessment is now based upon a lower endpoint, NRDC's contention that EPA failed to apply an additional 3X uncertainty factor to the point of departure derived from the DNT study is no longer relevant.

C. Residential Exposure

1. *Aggregating exposures.* The safety standard in FFDCA section 408 for tolerances requires that there be a reasonable certainty of no harm from ''aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposure for which there is reliable information.'' (21 U.S.C. 346a(b)(2)(A)(ii)). Further, in evaluating the safety of tolerances EPA is directed to ''consider . . . available information concerning the aggregate exposures of consumers . . . to the pesticide chemical residue . . . including dietary exposure under [all] tolerance[s] . . . in effect for the pesticide chemical residue and exposure from other non-occupational sources.'' (21 U.S.C. 346a(b)(2)(D)(vi)).

Unit VII.B. discusses EPA's assessment of aggregate dietary exposure to carbaryl from residues in foods and water. That assessment showed that the dietary exposure and risk are below the Agency's level of concern for the general U.S. population and all population subgroups; exposure to carbaryl residues in food comprises <100% of the aPAD at the 99.9th percentile of exposure. Estimated dietary exposure for the general U.S. population is 29% of the aPAD; exposure to children age 1 to 2 years, the most highly exposed population subgroup, comprises 60% of the aPAD. Although refined, these exposure estimates still are likely to overstate exposure and risk.

Pesticide residues to which humans are exposed from residential uses of pesticides must be considered as part of section 408's aggregate exposure calculus. The concern, of course, is that pesticide tolerances should not be established or left in effect if dietary exposures when combined with other sources of exposure exceed safe levels.

2. *Residential exposure and risk assessment.* Since the 2004 Amended IRED, the Agency has revised the residential risk assessment for carbaryl to incorporate the revised toxicology endpoints and FQPA Safety Factor, the mitigation specified in the IRED (as well as the mitigation specified in the RED for residential use of granular formulations; namely, that granular formulations must be watered in immediately), and confirmatory data received as a result of the generic DCI for carbaryl. EPA received turf transferable residue (TTR) data for granular formulations of carbaryl, as well as additional data to support the use of carbaryl in pet collars. The granular TTR data were incorporated into the revised risk assessment; however, the pet collar data were considered but not incorporated because of data quality issues. In addition, the Agency incorporated data from several studies for pesticides applied to turf to estimate the percent of carbaryl transferred from turf to a person's hand. (See Ref. 27 for details of the revised carbaryl residential risk assessment).

3. *Pet collars*—a. *NRDC's claims.* In its Petition, NRDC expressed concern that EPA's assessment of pet collars significantly underestimates exposure. (Ref. 1 at 4). NRDC therefore requested that EPA provide information on the assumptions used to calculate flea collar exposures. In particular, NRDC is concerned that EPA's calculations do not take into account the possibility that pet sleep with children, share intimate spaces or share hugs/kisses with children. NRDC also contends that there are safer ''non-pesticide'' alternatives available.

In addition, in a November 2007 petition to cancel all carbaryl pet collar registrations, NRDC asserts that changes in this algorithm made from the preliminary NMC cumulative assessment result in a repeated and additive bias towards reducing the exposure estimate so that it ''appears'' that the pet collar uses do not exceed the Agency's level of concern. (Ref. 2 at 5-7). Specifically, NRDC takes issue with the following modifications made in the probabilistic assessment for carbaryl as part of the NMC cumulative risk assessment:

- Assuming a child mouths only one hand at a time, thereby dividing the hand-loading residues by 2X.
- Assuming the hand is fully replenished with residues from a contaminated surface on an hourly basis rather than assuming (as done previously with flea collar assessments) full replenishment between each mouthing event, which NRDC contends is a more likely scenario for children actively engaged with their pets.
- Assuming that the maximum time spent with a pet is 1.03 hrs./day. NRDC contends that EPA's assumption in previous assessments of 2 hrs./day is a much more likely scenario for pre-schoolers who are home all day with their pets and for school age children lying with their pets watching TV.
- Assuming that only 1% of the surface area of a single hand is mouthed, which is approximately 1/75

cm^2 surface area. NRDC contends that EPA's assumption in previous assessments of 20 cm^2 is a more reasonable and realistic estimate of the surface area likely to contact a child's mouth repeatedly.

• Assuming that only 20 to 50% of the pesticide is removed per mouthing event (saliva extraction factor). NRDC contends that EPA's assumption in previous assessments that all of the pesticide is removed is more reasonable and realistic.

NRDC also criticizes the Agency for not including inhalation as an exposure route for residential post-application of flea collars. NRDC also points out that inhalation was the only route of exposure that EPA estimated in an earlier RED decision on another pesticide used in flea collars.

NRDC argues that all of these modifications in the Agency's algorithm for calculating non-dietary hand-to-mouth exposures for children bias towards reducing the exposure estimate. NRDC also criticizes the Agency for stating that the modifications result from the recommendations from the August 2005 FIFRA SAP. To the contrary, NRDC contends that these modifications were never reviewed or recommended by the FIFRA SAP. NRDC therefore asserts that EPA cannot use this new method presented in the NMC cumulative assessment to ''reduce protections for children from pet uses of [carbamate] pesticides''. (Ref. 2 at 7).

b. *Public comments*. Bayer contends that NRDC is misinformed regarding ''non-pesticide'' alternatives. In particular, Bayer takes issue with NRDC's statement that ''[p]et products containing non-pesticide growth regulators also can stop fleas from reproducing successfully''. (Ref. 19 at 7, citing Ref. 1 at 4). Bayer points out that by definition any product that controls pest growth is a pesticide and that making pesticidal claims without registration is a violation of federal law. Bayer further asserts that unspecified ''non-pesticide'' alternatives have not been rigorously tested for efficacy or safety. Thus, Bayer asserts that NRDC offers no real alternative to the use of carbaryl-containing flea collars.

c. *EPA's response*. NRDC is concerned that while EPA has determined that pet collar uses are safe (with MOEs of greater than 1 million), EPA's calculations significantly underestimate exposure[3]. NRDC therefore requested that EPA provide information on the assumptions used to calculate flea collar exposures. In particular, NRDC is concerned that EPA's calculations do not take into account the possibility that pets sleep with children, share intimate spaces or share hugs/kisses with children.

As a preliminary matter, it is important to note that EPA assessed pet collars both in the individual chemical assessment and as part of the NMC cumulative risk assessment. The single chemical assessment done for carbaryl was a deterministic assessment. For the NMC cumulative risk assessment, EPA performed a probabilistic assessment.

With respect to the single chemical, deterministic assessment, the assumptions used are based upon Agency standard values for estimating exposure to pets as defined in the 1997 Draft SOPs for Residential Exposure Assessments and amendments. (Refs. 6, 7, and 8). Specifically, SOPs 9.2.1—*Postapplication Dermal Dose from Pesticide Residues on Pets* and 9.2.2 - *Postapplication Potential Dose Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Pets from Hand-to-Mouth Transfer* describe the algorithms that provided the basis for EPA's assessment. In addition, to the extent that EPA had chemical specific data (e.g., transferable residue data) or made chemical specific adjustments to the algorithms, they are explained in the Revised Phase 5, *Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document (RED)*, dated February 20, 2003.

In sum, for the single chemical assessment, exposures to children after contact with treated pets were addressed using the latest EPA methodology, as described below:

• Only toddlers are considered because their exposures are considered to be the most highly exposed population by the Agency;

• An equilibrium approach based on a single child ''hug'' of the treated animal is used to assess dermal exposure (i.e., the skin loads after a single contact with the treated animal and additional contacts don't proportionally add exposures) as described in the amendments to the residential SOPs (Ref. 6), the surface area of the dermal hug is based on a toddler's skin surface area and typical clothing;

• The Agency default for transferability of residues from fur is 20%; however, a pet collar transferable residue study (MRID 45792201) was submitted and used in the assessment for comparative purposes with the Agency's standard approach. The data from this study were used to develop an alternative transferability factor of 2.6% for dusts and liquid applications;

• The active lifetime of a collar is expected to be 120 days based on label statements which were used by the Agency, a daily emission term from the collar of 0.000290 mg/cm/gram ai/day[2] is also based on measured data from Mississippi State University for a pet collar. Additionally, data from a pet collar transferable residue study (MRID 45792201) was submitted and used in the assessment for comparative purposes with the Agency's standard approach the data from this study were used to complete risk calculations using direct measurements of transferable residue concentration on dogs;

• Risks are based on an even loading of residues across the entire surface of a 30 lb dog which has been chosen as a representative animal. The animal surface area was calculated using (12.3 * Body Weight (g) 0.65) from the Agency's 1993 Wildlife Exposure Factors Handbook (i.e., dog surface area of 5986 cm^2);

• The approach used to address the hand-to-mouth exposure pathway has been modified since the previous risk assessment. In the previous assessment, contact with dogs was based on 40 events per day, in each event, the palmar surface of the hands (i.e., 20 cm^2/event) is placed in the mouth of the child contributing to nondietary ingestion exposure. In the revised approach, the frequency term has been modified to an equilibrium approach analogous to the dermal exposure component (i.e., the frequency = 1) because the transferable residue concentrations are from measured concentrations on the hands following heavy rubbing/petting of a dog for 5 minutes. This would result in significantly higher concentrations on the hands than would be expected from a single contact.

With respect to the single chemical assessment, NRDC asserts that the Agency failed to properly take into account children hugging and sleeping with pets. To the contrary, EPA's assessment is in fact based upon toddler exposure through hugging and petting. Indeed, for maximum exposure, EPA's assessment is based upon assumptions of hugging and petting followed by mouthing activity. Thus, NRDC's concerns about EPA's assessment not taking hugging into account are misplaced.

The estimation of risk from dermal and oral exposures related to pet collars is best described by means of combining both routes of exposure. The Agency

[3] NRDC asserts that a MOE of 1 million relates to residential postapplication exposures associated with pet collars. This is incorrect. The MOE referred to relates to residential handler (applicator) exposure as assessed in the 2003 carbaryl IRED.

combines risks resulting from total exposures to individual chemicals when it is likely that they can occur simultaneously based on the use pattern and the behavior associated with the exposure population. For carbaryl, the Agency combined risk values (i.e., MOEs) for different kinds of exposures associated with the pet collar scenario (dermal and hand-to-mouth). These represent the standard set of exposures that are typically added together when chemicals are used on pets because it is logical that they can co-occur. It should be noted that the dermal and hand-to-mouth assessments are considered conservative and that combining the assessments is expected to provide a highly conservative assessment of children's incidental oral exposure.

EPA did not, however, separately assess exposure to toddlers while sleeping with (near or next to) pets wearing a pet collar impregnated with carbaryl. This is because EPA assumes that the ''hug'' or equilibrium approach is adequately protective for all activities in which a child engages that result in dermal exposure. EPA presented the concept of a pet hug to assess dermal exposure to the FIFRA SAP on September 21, 1999 (64 FR 48394, Ref. 28); this was considered to be a reasonable approach. (Ref. 26). As described in the 1999 Overview document presented to the SAP (Ref. 21), the residential pet SOP ''assumes a one to one transfer to the skin of surface area representing both hands. This assumption suggests equilibrium is established between the transferable residues on the pet and the residues on the hand after contact. The concept of equilibrium ... has utility in constructing scenarios such as a child hugging a dog or a child sleeping with a dog. This is possible by assuming direct transfer or transferable residue estimates to human surface area values.'' (Ref. 22 at 38 to 39).

NRDC also criticizes the Agency for not including inhalation as an exposure route for residential post-application of flea collars. In so doing, NRDC points out that inhalation was the only route of exposure that EPA estimated in an earlier RED decision on another pesticide used in flea collars.

EPA did not assess inhalation exposure to pet collars impregnated with carbaryl because EPA generally assumes that residential post-application inhalation exposures are negligible due to the low vapor pressures associated with many pesticides. In the case of carbaryl, this assumption is warranted. The vapor pressure of carbaryl is sufficiently low (4.1×10^{-5} mmHg at 25 °C) so that the inhalation route of exposure will contribute insignificantly to the overall estimated daily dose when compared to the combined exposures resulting from the combination of the dermal and oral (i.e., hand-to-mouth) routes. In other cases, this assumption might not be warranted. For example, dichlorvos, another pesticide used in impregnated pet collars, has a vapor pressure of 1.2×10^{-3} at 20 °C, which is considerably higher than that of carbaryl. The higher vapor pressure suggests rapid volatilization at room temperature; therefore, the Agency considered inhalation a potential route of exposure when assessing residential exposure to dischlorvos from impregnated pet collars. The Agency also considered dermal and hand-to-mouth routes of exposure, in addition to inhalation. All potential routes of exposure are considered for each pesticide on a case-by-case basis to determine which routes will be the most significant contributors to exposure and risk.

In addition, as the basis for petitioning the Agency to cancel all carbaryl pet collar registrations (submitted as part of NRDC's comments on the NMC cumulative assessment), NRDC asserts that changes in this algorithm made from the preliminary NMC cumulative assessment result in a repeated and additive bias towards reducing the exposure estimate so that it ''appears'' that the pet collar uses do not exceed the Agency's level of concern. NRDC also criticizes the Agency for stating that the modifications result from the recommendations from the August 2005 FIFRA SAP. To the contrary, NRDC contends that these modifications were never reviewed or recommended by the FIFRA SAP. NRDC then asserts that EPA cannot use this new method presented in the NMC cumulative assessment to ''reduce protections for children from pet uses of [carbamate] pesticides.'' (Ref. 2 at 7).

EPA disagrees with NRDC's assertion that the techniques used in the NMC cumulative assessment for pet collars results in an additive bias towards reducing exposures and risks. The main difference between the approach used to assess exposure to carbaryl from pet collars in the 2003 RED and the cumulative exposure assessment of the carbaryl pet collar is that the cumulative exposure assessment uses probabilistic techniques to estimate exposures and the single chemical assessment uses deterministic techniques to assess exposures. Probabilistic techniques have the advantage of using distributions of all available data to describe the myriad of potential combinations of residues and activity patterns that may occur as a child is interacting with a pet wearing a carbaryl-impregnated collar. These potential combinations of residues and activities provide a distribution of exposures for use in risk assessment. Deterministic techniques rely on point estimates of both residues and activity patterns. These point estimates may, for example, represent averages or absolute maximum values for residues and activity patterns.

The specific modifications and the reasons for adopting the modification are provided below:

- Assuming a child mouths only one hand at a time, thereby dividing the hand-loading residues by 2X.

This assumption is consistent with the way EPA has assessed hand-to-mouth exposure in the past. Both the EPA Residential SOP methodology (deterministic) and the revised hand-to-mouth algorithm used in the Revised NMC cumulative risk assessment (probabilistic) are based upon the assumption that a child can only place one hand in his/her mouth at a time.

- Assuming the hand is fully replenished with residues from a contaminated surface on an hourly basis rather than assuming (as done previously with flea collar assessments) full replenishment between each mouthing event, which NRDC contends is a more likely scenario for kids actively engaged with their pets.

As stated in the preliminary NMC cumulative risk assessment, previous assumptions regarding replenishment were overly conservative when used in a probabilistic model. These low MOEs were mainly due to the incorporation of micro-activity data into EPA's macro activity models (defined as human exposure models based on daily time step). The non-dietary ingestion pathway was the least refined of the residential exposure pathways modeled in the preliminary revised NMC cumulative risk assessment. This input is part of the revised approach that was developed in collaboration with ORD and is currently being used in the Stochastic Human Exposure and Dose Simulation (SHEDS) model. (For a full explanation of the implications of using microactivity data in a macro activity model, see Ref. 29 p. 91.) The data used in the revised assessment are based on a meta analysis provided by ORD. The meta analysis relies upon the best available observational data on children's mouthing frequency.

- Assuming that the maximum time spent with a pet is 1.03 hours/day. NRDC contends that EPA's assumption in previous assessments of 2 hours/day is a much more likely scenario for pre-

schoolers who are home all day with their pets and for school age kids lying with their pets watching TV.

This assumption is based on data that involved videotaping children's time spent with pets. (Ref. 30). As stated in the NMC Cumulative Risk Assessment document, the duration of exposure is assumed to be continuous contact rather than the intermittent contact normally associated with pet care (e.g. walking, feeding). OPP is attempting to draw the distinction between direct contact with a treated pet and the time spent with a pet where there is limited contact. For example, time spent with pets in and around the house may not result in direct contact for the entire duration. The pet collar scenario assessed in the revised NMC Risk Assessment uses pet fur residues transferred to individuals at a rate found during a study of shampooing and grooming for a duration of approximately 1 hour. Use of these data to represent residential exposure to pets is likely to encompass all other potential exposure scenarios involving direct or indirect contact with treated pets.

- Assuming that only 1% of the surface area of a single hand is mouthed, which is approximately 1/75 cm^2 surface area. NRDC contends that EPA's assumption in previous assessments of 20 cm2 is a more reasonable and realistic estimate of the surface area likely to contact a child's mouth repeatedly.

The Agency is unclear how NRDC determined that a surface area of 1% was used in the NMC cumulative risk assessment. It should be noted that the revised algorithm does not use a surface area (cm^2), but rather a distribution of fraction of the hand mouthed (unitless). The distribution of fraction of surface area of hand mouthed ranged from a mean of 0.129 to a maximum of 0.305. This is equivalent to approximately 13 to 30.5 cm^2, respectively (assuming a 100 cm^2 total palmar surface area of the hand). In addition, as a part of the algorithm used in SHEDS and CARES, the fraction of the surface area of the hand mouthed is based on the best available data. In some places in the revised NMC cumulative risk assessment, the fraction of hand mouthed is referred to as surface area mouthed in error.

- Assuming that only 20 to 50% of the pesticide is removed per mouthing event (saliva extraction factor). NRDC contends that EPA's assumption in previous assessments that all of the pesticide is removed is more reasonable and realistic.

The assumptions used in the hand-to-mouth assessment are based upon data from several studies (Refs. 31, 32, and 33). The studies were conducted to address the removal efficiency of residues from the hands by saliva and other substances (e.g., ethanol) during mouthing events. The resulting range, 20–50% removal efficiency, is the same used for hand-to-mouth assessment in the Draft Residential SOPs and in the NMC cumulative risk assessment; however, the Residential SOPs rely upon the upper percentile of the range (50%) while the NMC cumulative risk assessment made use of all available data to better estimate exposure using a probabilistic approach.

In sum, EPA made modifications in part because of the FIFRA SAP's comments with respect to the limitations of the approach used in the preliminary NMC cumulative risk assessment—most notable of which was that the approach used in the preliminary NMC cumulative risk assessment was likely to overestimate exposure and EPA should consider not assessing this exposure pathway at all until it has better data. EPA assessed this pathway (which the FIFRA SAP also suggested EPA) but modified the algorithm in an effort to further refine the assessment.

Furthermore, the FIFRA SAP provides independent scientific advice to the EPA on health and safety related issues related to pesticides. Thus, whether the FIFRA SAP reviewed and offered its recommendations on the specifics of the modifications does not preclude EPA from making such modifications (especially where the FIFRA SAP recommends that EPA consider how the approach should be modified). Similarly, review by the FIFRA SAP is not required in order for EPA to make a safety finding. Accordingly, the issues raised by NRDC do not provide a basis for revoking all carbaryl tolerances or cancelling pet collar registrations.

4. *Farm children*—a. *NRDC's claims*. Previously, NRDC had asserted that farm children are especially vulnerable to pesticide exposure and are not adequately considered. (Ref. 1. at 19). Notwithstanding EPA's previous response to this issue, NRDC maintains that the Agency still has not adequately addressed this issue.

b. *Public comments*. Bayer noted that EPA adequately responded to this issue in its October 26, 2004 Response to Comments on Phase 5 Risk Assessment (Docket ID No. 2003–0376–00008).

c. *EPA's response*. Simply asserting that the Agency has not (in NRDC's opinion) adequately addressed an issue is not a basis upon which to revoke a tolerance. In particular, NRDC has not provided any additional information or data, nor has NRDC suggested in what respect it finds the Agency's previous analysis and response to this issue is inadequate. See Imidacloprid; Order Denying Objections to Issuance of Tolerance, Final Order, 69 FR 30042 (May 26, 2004). EPA hereby incorporates its prior response to this issue and finds NRDC's contention without merit.

D. Conclusion

NRDC's petitions to revoke all carbaryl tolerances are denied. NRDC's arguments have not demonstrated that carbaryl tolerances are unsafe; to the contrary, EPA continues to believe that its risk assessments appropriately support its finding that the carbaryl tolerances pose a reasonable certainty of no harm.

VIII. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying a petition filed, in part, under section 408(d) 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.

IX. 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).

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List of Subjects in 40 CFR Part 180

Environmental protection, Carbaryl, Pesticides and pest.

Dated: September 30, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0609; FRL–8384–7]

Pyrimethanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances in the 40 CFR 180.518 for residues of the fungicide, pyrimethanil, 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, in or on pome fruit crop group 11, establishes tolerances for the residues of pyrimethanil in or on apple wet pomace, and amends the tolerances for residues of pyrimethanil