ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0152; FRL–7355–7]

Imidacloprid; Order Denying Objections to Issuance of Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: On four occasions in the first half of 2002, the Natural Resource Defense Council (NRDC) and various other parties filed objections with EPA to final rules under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) establishing pesticide tolerances for various pesticides. The objections apply to 14 pesticides and over 70 separate pesticide tolerances. Although the objections raise numerous pesticide-specific issues, they all focus on the potential risks that the pesticides pose to farm children. This order responds to NRDC's objections as to the imidacloprid tolerance on blueberries. The objections are denied as moot because this imidacloprid tolerance has expired. Because EPA is elsewhere in today's **Federal Register** reestablishing the imidacloprid tolerance on blueberries, EPA has treated NRDC's objections as comments on the petition to reestablish the blueberry tolerance and has explained in full in this document why NRDC's objections are not well taken.

ADDRESSES: EPA has established a docket for this action under Docket ID number OPP–2004–0152 All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whosedisclosure 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

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SUPPLEMENTARY INFORMATION:

Response to NRDC Objections

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I. General Information

A. Does this Action Apply to Me?

In this document EPA denies as moot objections to a tolerance action filed by NRDC. In addition to NRDC, this action will be of interest to the pesticide manufacturers and pesticide registrants whose product was the subject of the objections. Further, this action may be of interest to the following parties who have filed similar objections with EPA on other pesticide tolerances: Boston Women's Health Book Collective, Breast Cancer Action, Californians for Pesticide Reform, Commonweal, Lymphoma Foundation of America, NRDC, Northwest Coalition for Alternatives to Pesticides, Pesticide Action Network, North America, Pineros y Campesinos Unidos del Noroeste, SF-Bay Area Chapter of Physicians for Social Responsibility, and Women's Cancer Resource Center. Finally, this action may be of interest to agricultural producers, food manufacturers, or other pesticide manufacturers. Potentially affected categories and entities may include, but are not limited to:

- Industry, e.g., NAICS 111, 112, 311, 32532, Crop production, Animal

production, Food manufacturing, Pesticide manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities who may be interested in this action.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/*. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the **Federal Register**—Environmental Documents. You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

2. *In person*. The Agency has opened a docket for this action under docket ID number OPP–2002–0057. Included in the docket are EPA documents specifically referenced in this action, any public comments received during an applicable comment period, and other information submitted by NRDC. The docket does not include any information claimed as CBI. The docket is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Introduction

A. What Action is the Agency Taking?

On four occasions in the first half of 2002, NRDC and various other parties filed objections with EPA to final rules under section 408 of FFDCA, 21 U.S.C. 346a, establishing pesticide tolerances for various pesticides. The objections apply to 14 pesticides and over 70 separate pesticide tolerances. Although the objections raise numerous pesticide-specific issues, they all focus on the potential risks that the pesticides pose to farm children. Further each of the objections makes two main assertions with regard to the pesticide tolerances in question:

1. That EPA has not properly applied the additional 10X safety factor for the protection of infants and children in section 408(b)(2)(C) of FFDCA.

2. That EPA has not accurately assessed the aggregate exposure of farm children to pesticide residues.

NRDC did not exercise the option provided in section 408(h) of FFDCA to request a hearing on its objections, but instead asked that the Agency rule on its objections on the basis of its written objections and attached submissions. Because the objections raised questions of broad interest, EPA published a representative copy of the objections in the **Federal Register** for comment, (67 FR 41628) (June 19, 2002) (FRL–7167–7), and made all of the objections available for public review on its website. This order responds to NRDC's objections as to the imidacloprid tolerance on blueberries.

EPA had planned to respond to the four sets of objections in a single order. That plan has been superceded by the December 31, 2003, expiration of the objected-to imidacloprid tolerance on blueberries, the demonstrable agricultural need for continuation of use of imidacloprid on blueberries, and NRDC's submission in June, 2003 of significant supplemental information on its objections. Technically, NRDC's objections to the imidacloprid tolerance on blueberries have become moot due to the expiration of the tolerance and this order denies them on that ground. Nonetheless, due to the fact that elsewhere in today's **Federal Register** EPA is re-establishing an imidacloprid tolerance on blueberries, EPA has treated the objections as a comment on the petition to re-establish the imidacloprid tolerance and is issuing in this denial order its planned response to the objections as a response to comments on the proposed establishment of the imidacloprid tolerance. If NRDC files the same objections to the re-established imidacloprid tolerance, EPA will re-issue this comment response as a response to NRDC's objection forthwith. EPA cannot issue its response to all four sets of NRDC's objections at this time because EPA has not completed reviewing supplemental information on the objections submitted by NRDC in June, 2003. As to imidacloprid, however, specific facts relating to that pesticide allow EPA to address all of the issues raised by the objections to that tolerance.

The body of this document contains the following sections. First, there is a background section which explains the applicable statutory and regulatory provisions, the relevant EPA science policy documents, and prior NRDC actions with regard to farm children. Second, there is a section setting forth in greater detail the substance of the objections. Third, a summary of the public comment is presented. Fourth, there is a section which denies theobjections to the imidacloprid tolerance as moot. Finally, EPA's detailed response to the issues raised by the objections on the imidacloprid tolerance is included as a part of its action in granting a permanent tolerance for imidacloprid on blueberries.

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

The procedure for filing objections to tolerance actions and EPA's authority for acting on such objections is contained in section 408(g) of FFDCA and regulations at 40 CFR part 178. 21 U.S.C. 346a(g).

III. Statutory and Regulatory Background

A. Statutory Background

EPA establishes maximum residue limits, or ''tolerances,'' for pesticide residues in food under section 408 of 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 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).

A pesticide tolerance may only be promulgated by EPA if the tolerance is ''safe.'' 21 U.S.C. 346a(b)(2)(A)(i). ''Safe'' is defined by the statute to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' 21 U.S.C. 346a(b)(2)(A)(ii). Section 408 of FFDCA directs EPA, in making a safety determination, to ''consider, among other relevant factors . . .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)(vi). Other provisions address in greater detail exposure considerations involving ''anticipated and actual residue levels'' and ''percent of crop actually treated.'' See 21 U.S.C. 346a(b)(2)(E) and (F). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to risks posed

to infants and children. This provision directs that ''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 notice as the ''children's safety factor.''] These provisions establishing the detailed safety standard for pesticides were added to section 408 of FFDCA by the Food Quality Protection Act of 1996 (FQPA), an Act that substantially rewrote this section of the statute.

Tolerances are established by rulemaking under the unique procedural framework set forth in FFDCA. Generally, the rulemaking is initiated by the party seeking the 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 along with a summary of the petition, prepared by the petitioner. 21 U.S.C. 346a(d)(3). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing the tolerance, issue a proposed rule, or deny the petition. 21 U.S.C. 346a(d)(4). Once EPA takes final action on the petition by either establishing the tolerance or denying the petition, any affected party has 60 days to file objections with EPA and seek an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2). EPA's final order on the objections is subject to judicial review. 21 U.S.C. 346a(h)(1).

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

B. Assessing Risk Under the FFDCA

In assessing and quantifying non-cancer risks posed by pesticides under the FFDCA as amended by the FQPA, EPA first determines the toxicological level of concern and then compares estimated human exposure to this level of concern. This comparison is done through either calculating a safe dose in humans (incorporating all appropriate safety factors) and expressing exposure as a percentage of this safe dose (the reference dose (RfD) approach) or dividing estimated human exposure into the lowest dose at which no adverse effects from the pesticide are seen in relevant studies (the margin of exposure (MOE) approach). How EPA determines the level of concern, chooses safety factors, and estimates risk under these two approaches is explained in more detail below.

For dietary risk assessment (other than cancer), the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. A safety or uncertainty factor is then applied to this toxicological level of concern to calculate a safe dose for humans, usually referred to by EPA as an acute or chronic reference dose (acute RfD or chronic RfD). The RfD is equal to the NOAEL divided by all applicable safety or uncertainty factors. Typically, a safety or uncertainty factor of 100 is used, 10X to account for uncertainties inherent in the extrapolation from laboratory animal data to humans and 10X for variations in sensitivity among members of the human population as well as other unknowns. Further, under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. To quantitatively describe risk using the RfD approach, estimated exposure is expressed as a percentage of the RfD. Dietary exposures lower than 100% of the RfD are generally not of concern.

For non-dietary, and combined dietary and non-dietary, risk assessments (other than cancer), the same safety factors are used to determine the toxicological level of concern. For example, when 1,000 is the appropriate safety factor (10X to account for interspecies differences, 10X for intraspecies differences, and 10X for FQPA), the level of concern is that there be a 1,000-fold margin between the NOAEL from the toxicology study identified as appropriate for use in risk assessment and human exposure. To estimate risk, a ratio of the NOAEL to aggregate exposures (MOE = NOAEL/exposure) is calculated and compared to the level of concern. In contrast, to the RfD approach, the higher the MOE, the safer the pesticide. Accordingly, if the level of concern for a pesticide is 1,000, MOE's exceeding 1,000 would generally not be of concern.

For cancer risk assessments, EPA generally assumes that any amount of exposure will lead to some degree of cancer risk. Using a model based on the slope of the cancer dose-response curve in relevant studies, EPA estimates risk in terms of the probability of occurrence of additional cancer cases as a result of exposure to the pesticide. An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. No further discussion of cancer risk assessment is included because imidacloprid has not been identified as posing a cancer risk.

C. Science Policies

As part of implementation of the major changes to section 408 of FFDCA included in FQPA, EPA has issued a number of policy guidance documents addressing critical science issues. Of particular interest to the NRDC objections are the science policies covering the children's safety factor, aggregate pesticide exposure, and the population percentile of exposureused in estimating aggregate exposure.

1. *Children's Safety Factor Policy*. On January 31, 2002, EPA released its science policy guidance on the children's safety factor. (Ref. 48), [hereinafter referred to in the text as the ''Children's Safety Factor Policy''']. That policy had undergone an intensive and extended process of public comment as well as internal and external science peer review. An EPA-wide task force was established to consider the children's safety factor in March 1998. Taking into account reports issued by

the task force on both toxicity and exposure issues, EPA's OPP released a draft children's safety policy document in May 1999. That document was subject to an extended public comment period as well as review by the FIFRA Scientific Advisory Panel. Id. at 5.

The Children's Safety Factor Policy emphasizes throughout that EPA interprets the children's safety factor provision as establishing a presumption in favor of application of an additional 10X safety factor for the protection of infants and children. Id. at 4, 11, 47, A-6. Further, EPA notes that the children's safety factor provision permits a different safety factor to be substituted for this default 10X factor only if reliable data are available to show that the different factor will protect the safety of infants and children. Id. Given the wealth of data available on pesticides, however, EPA indicated a preference for making an individualized determination of a protective safety factor if possible. Id. at 11. EPA stated that use of the default factor could under- or over-protect infants and children due to the wide variety of issues addressed by the children's safety factor. Id. EPA noted that ''[i]ndividual assessments may result in the use of additional factors greater or less than, or equal to 10X, or no additional factor at all.'' Id. Because EPA thought that individualized assessments would be able to be made in most cases, EPA indicated that ''this guidance document focuses primarily on the considerations relevant to determining a safety factor 'different' from the default 10X that protects infants and children. Discussions in this document of the appropriateness, adequacy, need for, or size of an additional safety factor are premised on the fact that reliable data exist for choosing a 'different' factor than the 10X default value.'' Id. at 12.

In making such individual assessments regarding the magnitude of the safety factor, EPA stressed the importance of focusing on the statutory language that ties the children's safety factor to concerns regarding potential pre- and post-natal toxicity and the completeness of the toxicity and exposure databases. Id. at 11-12. As to the completeness of the toxicity database, EPA recommended use of a weight of the evidence approach which considered not only the presence or absence of data generally required under EPA regulations and guidelines but also the availability of ''any other data needed to evaluate potential risks to children.'' Id. at 20. EPA indicated that the principal inquiry concerning missing data would center on whether the missing data would significantly affect calculation of a safe exposure level (commonly referred to as the Reference Dose (RfD)). Id. at 22; see 67 FR 60950, 60955 (Sept. 27, 2002) (finding no additional safety factor necessary for triticonazole despite lack of developmental neurotoxicity (DNT) study because the ''DNT is unlikely to affect the manner in which triticonazole is regulated.''). When the missing data are data above and beyond general regulatory requirements, EPA indicated that the weight of evidence would generally only support the need for an additional safety factor where the data ''is being required for 'cause,' that is, if a significant concern is raised based upon a review of existing information, not simply because a data requirement has been levied to expand OPP's general knowledge.'' (Ref 48 at 23). Finally, with regard to the developmental neurotoxicity study (DNT), EPA listed several important factors addressing the weight of evidence bearing on the degree of concern when such a study has been required but has not yet been completed. Id. at 24. Moreover, EPA reiterated that, like any other missing study, the absence of the DNT does not trigger a mandatory requirement to retain the default 10X value, but rather depends on an individualized assessment centering on the question of whether ''a DNT study is likely to identify a new hazard or effects at lower dose levels of the pesticide that could significantly change the outcome of its risk assessment . . . '' Id.

As to potential pre- and post-natal toxicity, the Children's Safety Factor Policy lists a variety of factors that should be considered in evaluating the degree of concern regarding any identified pre- or post-natal toxicity. Id. at 27-31. As with the completeness of the toxicity database, EPA emphasized that the analysis should focus on whether any identified pre- or post-natal toxicity raises uncertainty as to whether the RfD is protective of infants and children. Id. at 31. Once again, the presence of pre- or post-natal toxicity, by itself, was not regarded as determinative as to the children's safety factor. Rather, EPA stressed the importance of evaluating all of the data under a weight of evidence approach focusing on the safety of infants and children. Id.

In evaluating the completeness of the exposure database, EPA explained that a weight of the evidence approach should be used to determine the confidence level EPA has as to whether the exposure assessment ''is either highly accurate or based upon sufficiently conservative input that it does not underestimate those exposures that are critical for assessing the risks to infants and children.'' Id. at 32. EPA described why its methods for calculating exposure through various routes and aggregating exposure over those routes generally produce conservative exposure estimates—i.e. health-protective estimates due to overestimation of exposure. Id. at 40-43. Nonetheless, EPA emphasized the importance of verifying that the tendency for its methods to overestimate exposure in fact were adequately protective in each individual assessment. Id. at 44.

2. *Aggregate exposure policies.* As mentioned above, the FQPA-added safety standard directs that the safety of pesticide residues in food be based on ''aggregate exposure'' to the pesticide. 21 U.S.C. 346a(b)(2)(A)(ii). Aggregate exposure to a pesticide includes all ''anticipated dietary exposure and all other exposures for which there is reliable information.'' Id. The statute makes clear that in assessing aggregate exposure pertaining to a pesticide EPA must consider not only exposure to the pesticide in the food covered by the tolerance in question but exposure to the pesticide as a result of other tolerances and from ''other non-occupational sources.'' Id. Section 346a(b)(2)(D)(vi). Further, the statute directs EPA to consider aggregate exposure to other substances related to the pesticide so long as that exposure results from a non-occupational source. Id. Section 346a(b)(2)(D)(vi). In November 2001, EPA released a science guidance document entitled *General Principles for Performing Aggregate Exposure and Risk Assessments.* This document deals primarily with the complex subject of integrating distributional and probabilistic techniques into aggregate exposure analyses. (Ref. 49).

More relevant to the current objections, is the science guidance document issued in March 2000 addressing the population percentile of exposure used in making acute exposure estimates for applying the safety standard under section 408 of FFDCA. (Ref. 52). Traditionally, EPA had used the 95th percentile of exposure in acute dietary exposure assessments as representing a reasonable worst case scenario. Id. at 15. Due to the very conservative (health-protective) assumptions used for acute exposure assessments, the 95th percentile was viewed as a reasonable approximation of an exposure level not likely to be exceeded by any individuals. Id. at 15-17. Generally, such an approach assumes that all crops for which there is a tolerance are treated with the

pesticide and all treated crops have residues at the highest level legally permitted.

More recently, because of the availability of better data on residue values and new risk assessment techniques, EPA has restructured its approach to the use of population exposure percentiles in making safety determinations for acute risks under section 408 of FFDCA. (Ref. 52). EPA has retained the 95th percentile as the starting point of analysis for worst case (tolerance level) assessments. EPA, however, generally uses higher percentiles of exposure when less conservative assumptions are made concerning residue values. Id. For example, beginning in the late 1990's, EPA has increasingly relied upon probabilistic assessment techniques for assessing acute dietary exposure and risk. Because EPA generally uses much more realistic exposure values (e.g., monitoring data on pesticide levels in food) in conducting probabilistic assessments, a higher population exposure percentile was generally found to be necessary to ensure that exposure for the overall population was not understated. The Percentile Policy explains and defends EPA's choice of the 99.9th percentile as a starting point for evaluating exposure and acute risk with probabilistic assessments.

EPA confirmed in the Percentile Policy document that it would generally continue to use the 95th percentile of exposure for deterministic acute risk assessments that used worst case exposure assumptions. Id. at 17, 29. The conservative (health-protective) nature of this approach was confirmed by data EPA cited showing that deterministic assessments of exposure at the 95th percentile assuming residues at tolerance levels regularly result in exposure predictions significantly higher than probabilistic exposure estimates of the 99.9th percentile using monitoring data. Id. at 16-17.

Importantly, EPA's Percentile Policy makes clear that in choosing a population percentile to estimate exposure, EPA is not intending to define the portion of the population that is to be protected. The policy explicitly states that: ''OPP's goal is to regulate pesticides in such a manner that everyone is reasonably certain to experience no harm as a result of dietary and other non-occupational exposures to pesticides.'' Id. at 28.

D. NRDC Farmworker Children Petition

On October 22, 1998, NRDC and 58 other public interest organizations and individuals submitted a petition to EPA asking that EPA ''find that farm children are a major identifiable subgroup and must be protected under FQPA when setting allowable levels of pesticide residue in food.'' (Ref. 36 at 2). The Petition claims that ''[a]n increasing body of scientific evidence, including biomonitoring data and residential exposure studies, indicates that farm children face particularly significant exposures and health risks from pesticides.'' Id. at 3. In addition to requesting the ''major identifiable subgroup'' designation, the Petition also asked that EPA use the children's safety factor to protect farm children, require additional exposure data on farm children exposure and not issue any new tolerances until such data are available, deny registration for any pesticide without a validated method for detecting residues in food, increase research into issues concerning farm children exposure to pesticides, and honor the President's Executive order on Environmental Justice.

Although EPA prior to this action has not issued a formal response to the petition, it has undertaken numerous steps to ensure that it is adequately protecting farm children including both initiating data gathering on exposure of children in agricultural areas to pesticides and programs to enhance compliance with label directions designed to minimize any bystander exposures to pesticides that could occur. Data gathering activities include EPA participation in the following studies:

National Agricultural Workers Survey (NAWS). EPA and the National Institute for Occupational Safety and Health (NIOSH) are currently providing funding for the NAWS, an ongoing effort by the Department of Labor. The NAWS is the only national information source on the working and living conditions of U.S. farmworkers and their families. EPA is working with the Department of Labor in analyzing over 20,000 interviews since the survey's onset to look at farm worker experiences over time. The interviews include questions concerning the following: Demographics, farmworkers' job mobility, day care arrangements, access to medical care, participation in pesticide training, exposures to pesticides, and reports of pesticide illness. Results from this survey, along with other studies, will assist EPA in addressing issues of pesticide exposures to farmworkers and any secondary exposures to their families. Additional information on the NAWS survey can be found at *http:// www.dol.gov/asp/programs/agworker/naws.htm.*

Agricultural health study. The National Cancer Institute (NCI), EPA, NIOSH, and the National Institute of Environmental Health and Safety are conducting a long-term epidemiology study of 90,000 certified pesticide applicators and their families in North Carolina and Iowa. The study is looking at both cancer and non-cancer endpoints using periodic surveys of the population. Pesticide use practices and health outcomes are being examined in detail. Additionally, scientists are conducting other studies on this cohort to learn further about exposures and potential effects, including birth defects, Parkinson's disease, asthma, and other disease endpoints. As part of the Agricultural Health Study, field work in Iowa is being conducted, and over the next three years detailed exposure analyses on a sub-sample of families using various agricultural pesticides will be completed. Some initial results have already been published for high exposure events and effects to the eye. A detailed listing of these studies and a number of publications already reporting the results of the Agricultural Health Study can be found at *http:// www.aghealth.org/.*

The Agency is also pursuing several other research efforts likely to provide additional information about any pesticide exposure to farmworkers and their children:

National Human Exposure Assessment Survey (NHEXAS). EPA developed this survey in the early 1990s to provide critical information about multi-pathway, multi-media population exposure distribution to chemicals. The data have been collected and the database is now being compiled. EPA expects to have the information accessible on the Internet later this year.

Children's total exposure to persistent pollutants. This study, conducted by EPA, will add to our understanding of any pesticide exposures to farmworker families. The data collection for this study, initiated this year, should be completed and available in 2004.

In terms of actions taken to enhance protections to children so as to avoid bystander-type exposures, EPA has numerous programs and materials focusing upon pesticide safety issues for farm workers and their families both at the national and regional level. A brief overview of EPA's approaches will be discussed here. However, more information about EPA's farm worker efforts across its regional offices can be found in the docket for this action.

An overview of what EPA is doing on the national level includes an assessment of the EPA's 1992 Worker Protection Standard (WPS). See 40 CFR part 170. The Worker Protection Standard is a regulation intended to

help reduce the risk of pesticide poisonings and injuries among agricultural workers and handlers of agricultural pesticides. The WPS offers protections to over three and a half million people who work with pesticides at over 560,000 workplaces. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. The national overview of implementation and enforcement of WPS programs has been completed and recommendations are being compiled. The national assessment of WPS was a collaborative effort of EPA, the USDA, the Department of Labor, the Department of Health and Human Services (HHS), States, farm workers, and farmers. The reassessment effort included a great amount of stakeholder input, and has led to the development of a variety of pilot programs intended to improve the Agency's outreach to farm workers.

Other examples of activities conducted at the national level include the Agency's cooperative agreement with the Association of Farm Worker Opportunity Programs (AFOP) through which EPA funds the National Pesticide Safety Education Program for agricultural workers and farm worker children. Working with Americorps members, AFOP trains 25,000 farm workers and farm worker children every year about pesticide safety using Americorps members in over 50 sites in 16 states. AFOP conducts pesticide safety training for children at childcare centers, schools, churches, and community centers, and has developed a handbook in Spanish. Also, through EPA funding, AFOP has developed radio programs targeted at preventing pesticide poisonings of children.

Also on the national level, EPA has initiated a program with the Migrant Head Start Program (MHS) to develop materials and training for MHS on pesticide safety for migrant families with specific attention to protecting children from pesticides. MHS is designed to provide comprehensive Head Start services and programming to migrant families and their children. A total of 25 grantees and 41 delegate agencies provide services in 33 States and serve over 30,000 migrant children, and 25,000 children of seasonal workers, ranging in age from birth to 5 years. The MHS program has a unique emphasis on serving infants and toddlers as well as pre-school age children, so they will not have to be cared for in the fields, or left in the care of very young siblings while parents are working. MHS also teams with Americorps to provide refresher training on pesticide safety.

EPA on a national level, has also been involved in the development of two videos on pesticide safety for farmworkers and their families. The video, ''Chasing the Sun/Siguiendo El Sol,'' is a bilingual farmworker pesticide safety training video designed to comply with the agricultural worker training requirements mandated under the Worker Protection Standard. It was developed by the National Center for Farmworker Health and funded through an interagency agreement between EPA and HHS Migrant Health Program. This video is available through NCEPI and the National Center for Farmworker Health.

Another video, entitled *The Playing Field* is a bilingual pesticide safety training video for farmworker families. Through a story about a girl poisoned by playing in a treated field, the video teaches farmworkers and farmworker children about the dangers of pesticides and how to protect themselves from pesticides. The video was developed by the National Center for Farmworker Health and funded through an interagency agreement between EPA and the HHS Migrant Health Program. The video is available through the National Center for Farmworker Health.

Finally, EPA's regional offices have performed, and are performing, a number of outreach activities. These activities can be divided into three general categories: Direct outreach; partnerships, where the Agency provides funding and/or technical assistance, and research. Examples of EPA's activities on pesticide safety for farm workers and their families can befound in EPA's docket.

IV. NRDC Objections

A. In General

During the first half of 2002, NRDC submitted four separate sets of objections on various pesticide tolerances. The dates of the objections and the pesticides involved are captured in Table 1 of this unit.

TABLE 1.—OBJECTIONS SUBMITTED

Date submitted	Pesticides involved	FR citations (respectively)
February 25, 2002	Halosulfuron-methyl, pymetrozine	66 FR 66,333 (December 26, 2001); 66 FR 66,778 (December 27, 2002); 66 FR 66,786 (December 27, 2001)
March 19, 2002	Imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, diflubenzuron	67 FR 2580 (January 18, 2002); 67 FR 3113 (January, 23, 2002); 67 FR 4913 (February 1, 2002); 67 FR 6422 (February 12, 2002); 67 FR 7085 (February 15, 2002)
May 7, 2002	2,4-D	67 FR 10622 (March 8, 2002)
May 20, 2002	Isoxadifen-ethyl, acetamiprid, propiconazole, furilazole, fenhexamid, fluazinam	67 FR 12,875 (March 20, 2002); 67 FR 14,649 (March 27, 2002); 67 FR 14,866 (March 28, 2002); 67 FR 15,727 (April 3, 2002); 67 FR 19,114 (April 18, 2002); 67 FR 19,120 (April 18, 2002)

See Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Halosulfuron-methyl and Pymetrozine Tolerances (filed February 25, 2002) [hereinafter cited as Halosulfuron-methyl Objections]; Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Imidacloprid, Mepiquat, Bifenazate, Zeta-cypermethrin, and Diflubenzuron Tolerances (filed March 19, 2002) [hereinafter cited as Imidacloprid et al. Objections], Objections to the Establishment of Tolerances for Pesticide Chemical Residues: 2,4-D Tolerances (filed May 7, 2002) [hereinafter cited as 2,4-D Objections]; Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Isoxadifen-ethyl, Acetamiprid, Propiconazole, Furilazole, Fenhexamid, and Fluazinam Tolerances (filed May 20, 2002) [hereinafter cited as Isoxadifen-ethyl et al. Objections]. NRDC was joined in the objections concerning 2,4-D by the following

public interest and/or advocacy organizations: Boston Women's Health Book Collective, Breast Cancer Action, Californians for Pesticide Reform, Commonweal, Lymphoma Foundation of America, Northwest Coalition for Alternatives to Pesticides, Pesticide Action Network North America, Pineros y Campesinos Unidos del Noroeste, SF-Bay Area Chapter of Physicians for Social Responsibility, and Women's Cancer Resource Center.

This order responds to the objections filed on March 19, 2002, but only to the extent those objections apply to the pesticide imidacloprid and the tolerance for imidacloprid on blueberries.

B. Generic Issues

NRDC raises a myriad of claims in its objections to the imidacloprid tolerance. Most of these claims fall fairly neatly into three categories:

- Children's safety factor issues.
- Aggregate exposure issues.
- Issues regarding use of findings from hazard studies in calculating safe exposure levels— the ''no observed effect level'' (NOEL) versus ''no observed adverse effect level'' (NOAEL) and the ''lowest observed adverse effect level'' (LOAEL) questions.

In describing these objections, citation is made generally to the objections filed on the imidacloprid tolerance; however, one of the other sets of objections is referenced if it provides further clarification.

1. *Children's safety factor issues*. For imidacloprid, EPA decided to use an additional safety factor for the protection of infants and children that is different from the default 10X value. NRDC claims that EPA erred in doing so due to the ''significant toxicity and exposure data gaps'' corresponding to the tolerance established. See, e.g., Imidacloprid et al. Objections at 3. Three types of data gaps are cited by NRDC. First, NRDC notes that EPA has required a developmental neurotoxicity study but such study has not yet been submitted. Pointing to various EPA documents recommending that this study be widely required and EPA's specific finding that this study is required as to imidiclopri d, NRDC argues that use of a factor different than 10X is precluded. Second, NRDC claims EPA lacks ''pesticide-specific data on water-based exposure'' on imidacloprid. See, e.g., Imidacloprid et al. Objections at 6. NRDC argues that exposure estimates EPA calculated through the use of models cannot qualify as the ''reliable data'' needed to vary from the default 10X value. Id. Third, NRDC claims that ''EPA failed to consider important exposure routes for millions of infants and children, including exposure to children living on farms and who accompany their parents into farm fields [], and exposure from spray drift.'' Isoxadifen-ethyl et al. Objections at 5. Fourth, NRDC asserts that EPA is missing a prospective groundwater study on imidacloprid and a short-term residential risk assessment. Imidacloprid Objections at 5. Finally, NRDC argues that EPA lacks data on regional blueberry consumption and thus has potentially underestimated exposure in blueberry-producing states.

2. *Aggregate exposure issues*. NRDC raises several issues relating to whether EPA properly estimated ''aggregate exposure'' for imidacloprid. First, NRDC argues that farm children are a ''major identifiable subgroup'' and that EPA has failed ''to consider information concerning the sensitivities and exposures of farm children as a major identifiable subgroup'' in conducting its aggregate exposure assessment. According to NRDC, farm children have unique exposures to pesticides ''from their parents' clothing, dust tracked into their homes, contaminated soil in areas where they play, food eaten directly from the fields, drift from aerial spraying, contaminated well water, and breast milk.'' Imidacloprid et al. Objections at 12. Further, NRDC asserts farm children's exposure is increased because they ''often accompany their parents to work in the fields . . . .'' Id. NRDC cites various studies collected in its Farm Children Petition as well as more recent studies in support of these claims. Imidacloprid et al. Objections at 12–13. Second, NRDC argues that EPA's aggregate exposure assessment is flawed for these pesticides because EPA did not consider the added exposure to pesticides that farmworkers receive as a result of their occupation. Id. at 14. NRDC states that EPA's interpretation of the statute as excluding occupational exposure is incorrect. Id. Third, NRDC argues that for imidacloprid, EPA has, in effect, underestimated aggregate exposure by using the 95th population percentile of exposure instead of the 99.9th percentile in determining whether exposure to the pesticide meets the safety standard. Imidacloprid et al. Objections at 19. NRDC claims that this is inconsistent with existing Agency policy. Id.

3. *Reliance on LOAELs and NOAELs*. NRDC asserts that, in the absence of identifying a NOEL in relevant animal studies, EPA cannot make a safety finding under section 408(b)(2)of FFDCA. In support of this argument, NRDC cites to legislative history using the term NOEL. NRDC calls particular attention to the instances where EPA determined safety relying on a LOAEL. In this regard, it asserts that EPA used a LOAEL in making a safety finding for acute and chronic toxicity for imidacloprid. Imidacloprid et al. Objections at 18.

4. *Other issues*. NRDC claims that the EPA failed to comply with the statutory requirements pertaining to the use of percent crop treated for chronic risk assessments with regard to the imidacloprid blueberry tolerance. NRDC asserts that the use of national percent crop treated data cannot provide a valid basis for estimating exposure in Michigan and New Jersey, and, in fact, is likely to understate exposure in those states. Further, NRDC argues that EPA erred by relying on national consumption data instead of regional data from New Jersey and Michigan in estimating the risk posed by imidacloprid. Finally, NRDC, in comments it filed on its objections, claims that the emergency exemption approved under FIFRA authorizing the use of imidacloprid on blueberries in Michigan did not meet the standard in 40 CFR 166.3(d) for the granting of such exemptions.

V. Public Comment

A. General

On June 19, 2002, EPA published a notice in the **Federal Register** calling attention to and requesting comments on the Halosulfuron-methyl et al. Objections, Imidacloprid et al. Objections, and the 2,4-D Objections. 67 FR 41628 (June 19, 2002). As part of that notice, EPA published the full text of the Imidacloprid et al. Objections in the **Federal Register**. A period of 60 days was initially allowed for comment but that period was extended twice and was closed on October 16, 2002. See 67 FR 58536 (September 17, 2003); 67 FR 53505 (August 16, 2002). In addition to a large number of form letters (principally supporting the objections) and the NRDC's comments mentioned in Unit V.B., EPA received roughly 20 sets of substantive comments. These comments were for the most part from pesticide manufacturers and each requested denial of the objections. The most significant of these comments that pertain to imidacloprid are summarized in Unit V.B. EPA has not repeated comments in instances where they were made by more than one commenter.

B. Individual Comments

1. *The FQPA Implementation Working Group*. Extensive comments were filed by the FQPA Implementation Working Group (IWG), an organization comprised of associations representing pesticide

manufacturers, growers, and food processors. (Ref. 21). The IWG comments provided two alternative approaches as to why the NRDC's objections should be denied. First, the IWG asserted that EPA has misinterpreted the concept of ''aggregate exposure'' ever since passage of the FQPA, and once this interpretation is corrected, it becomes clear that the objections, for the most part, are flawed. Second, in the alternative, the IWG, assuming the EPA's aggregate exposure interpretation is retained, explained why the objections still are without merit.

The IWG argues that, under the safety standard in section 408 of FFDCA, 21 U.S.C. 346a, the concept of aggregate exposure to pesticide chemical residues is restricted to aggregate exposure to pesticide residues in food. Id. at 5-6. To support this interpretation, the IWG cites to language in the safety standard tying aggregate exposure to exposure to ''pesticide chemical residues.'' The term ''pesticide chemical residue,'' the IWG notes, is defined as ''a residue in or on raw agricultural commodity or processed food of . . . a pesticide chemical . . . .'' 21 U.S.C. 321(q). Under the IWG interpretation, EPA would not be permitted to consider, in making safety determinations on tolerances, exposures to pesticides in drinking water, exposures to pesticides resulting from application of pesticides in residences or public spaces, or most of the farm children exposures forming the basis of NRDC's objections. Such an interpretation clearly defeats most of the NRDC's claims regarding the children's safety factor and estimation of aggregate exposure.

The IWG also offers a backup legal argument which would, in execution, reach much the same result. It asserts that even if non-food exposure is properly considered under section 408 of FFDCA, any non-food exposure must meet the ''reliable data'' requirement in section 408(b)(2)(ii) of FFDCA. The IWG defines ''reliable data'' to mean ''information to allow OPP to make a reasonable estimate of the actual, real-world exposure distribution to add to information on dietary exposure so that probabilistic estimates of aggregate exposure can be made.'' Id. at 10. According to the IWG, the EPA generally does not have data meeting this standard as to ''exposure from drinking water or from residential or other non-occupational exposure routes.'' Id. at 9. Thus, the IWG's legal interpretation of the ''reliable data'' requirement basically gets the IWG to the same place—EPA should not be considering non-food pesticide exposures in making safety determinations under section 408.

Not resting on these legal arguments, the IWG provided detailed comments on several other of the claims in the NRDC objections, including the following:

a. *Drinking water exposure models.* Noting that NRDC claims that EPA's drinking water models are not conservative, the IWG points out that NRDC ''gives no reasons for this assertion.'' Id. at 12. The IWG takes the contrary view arguing that the models are very health protective (conservative) ''because their input parameters are extremely conservative.'' Id. at 11. In support, the IWG notes that EPA models ''assume maximum [pesticide] application rates, 100% of crop area treated with a maximum fraction of the watershed planted to the modeled crop, maximum number of applications per year, minimum application intervals for multiple applications of the pesticide, and upper-bound aerobic half-life estimates in soil.'' Id. at 12. The IWG also cites to data collected by EPA and the U.S. Geological Survey showing ''concentrations of 178 pesticides and their degradation products in both raw surface water and finished drinking water from twelve water-supply reservoirs were all substantially less than those predicted by EPA's computer models, FIRST and PRZM/EXAMS-Index Reservoir.'' Id.

b. *Farm children subgroup.* The IWG argues that NRDC's farm children subgroup is not an ''identifiable subgroup'' within the meaning of the statute. Rather, the IWG contends the NRDC's subgroup is ''a whole series of different groups, including children who live on farms, children who play near agricultural land, children who attend schools near agricultural land, children who work on farms, children whose family members work on farms, children whose family members handle pesticides as part of their jobs (whether on farms or not), and children who live in ''agricultural communities'' (whatever that means).'' Id. at 13. The IWG asserts that these groups ''have nothing in common other than that they are all children.'' Id. Further, the IWG argues that the FQPA directs EPA to consider ''major identifiable subgroups of consumers'' and that NRDC has not demonstrated that there is anything identifiable about the consumption patterns of its farm children subgroup. Id. at 14.

c. *Farm children's pesticide exposure.* The IWG questions whether NRDC has shown that children who live on farms face higher exposure to pesticides noting that ''NRDC has cited selective results from epidemiological studies that relied on retrospective self-reporting regarding use of pesticides.'' Id. The IWG presented preliminary data from a study funded by pesticide and chemical companies and associations. According to the IWG, the results of this study showed that ''urinary concentration [of pesticides] was associated with direct handling and application of pesticides. However, for children and spouses not involved in pesticide handling and application, exposures were low and did not vary appreciably by day of study.'' Id. at 15 (emphasis in original).

d. *Pesticide exposure from food purchased at farm stands.* The IWG challenges the NRDC's assertion that levels of pesticide residues in foods purchased at farm stands are higher than residue levels in food purchased at other retail outlets. The IWG notes that ''NRDC does not provide information to support its allegations, and we are not aware of any credible data to suggest that this is the case.'' Id. at 16. The IWG cites two demonstrable reasons undermining NRDC's claim: First, label directions and restrictions on pesticide use apply equally to food grown for sale at farmstands and food grown for distribution through broader channels of trade; and second, ''[t]he various circumstances (weather, pest pressure, etc.) that affect residue levels resulting from a given treatment regimen are the same for those who grow crops to market through wholesale channels and for those who grow crops to sell at retail.'' Id. Finally, the IWG notes that assuming residue levels are at the tolerance value would vastly overstate exposure amounts given that FDA data has shown ''no pesticide residues in 41% and 73.5% of fruit and vegetable samples and either no residues or below tolerance residues in 99.5% and 98.9% of fruit and vegetable samples.'' Id. at 17.

e. *Regional consumption of blueberries.* The IWG disputes NRDC's assertions regarding higher consumption of blueberries in regions that produce the crop. The IWG notes that there is both a national and international market for blueberries that makes blueberries widely available throughout the United States for several months of the year as a fresh commodity and available year round in the frozen state, the condition in which over half of the U.S. blueberry crop is marketed. Id. at 18.

2. *Inter-Regional Research Project Number 4 (IR–4).* The IR-4 is a program sponsored by USDA and land grant universities and directed toward obtaining regulatory approval for pesticide uses on minor and speciality

food crops that are not likely to be supported by private sector companies. In its comments, the IR–4 notes that several of the pesticides covered in the objections—diflubenzuron, imidacloprid, halosulfuron-methyl, and fenhexamid—are both ''critical to minor crop growers'' and safer, reduced risk pesticides. (Ref. 27). The IR–4 asserts that diflubenzuron and imidacloprid provide alternatives to the organophosphate pesticides and that halosulfuron-methyl is a methyl bromide alternative. Id.

3. *Bayer CropScience.* Bayer CropScience notes that the required DNT has been submitted for imidacloprid. (Ref. 3 at 1). Bayer CropScience asserts that the 3X children's safety factor imposed by EPA should now be removed because the ''a clear NOEL was established'' in the DNT. Id. at 2. Bayer CropScience also claims NRDC errs in contending that percent crop treated data was relied upon by EPA for blueberries. Bayer CropScience cites 66 FR 18554, 18556 (April 10, 2001) as showing that 100% crop treated was assumed for blueberries in EPA's risk assessment. Id. at 10.

VI. Response to Objections

NRDC objected to EPA's extension of a temporary tolerance for the residues of imidacloprid on blueberries. See Imidacloprid et al. Objections at 1. That tolerance extension expired on December 31, 2003. See 67 FR 2580 (January 18, 2002). As the objected-to tolerance is no longer in existence, NRDC objections are denied as moot. Nonetheless, NRDC's objections remain relevant to the petition that Interregional Research Project Number 4 filed to establish a permanent tolerance for imidacloprid on blueberries. 68 FR 5880 (February 5, 2003) (petition for imidacloprid tolerance on the crop group bushberries which includes blueberries). EPA has analyzed NRDC's objections, and considering them in light of the currently available information on imidacloprid, has decided to establish the permanent tolerance for imidacloprid on blueberries. EPA's analysis of the NRDC objections and the comments received on the objections is below.

As noted in Unit II.A., if NRDC refiles the same objections to the re-established imidacloprid tolerance relying solely on the information and arguments already presented, EPA will re-issue this comment response as a response to NRDC's objection forthwith. If, however, NRDC adds new issues, cites new information, or makes new arguments in support of its objections, EPA will have to analyze and respond to these new items before issuing a response.

VII. Analysis of the Issues Raised by NRDC's Objections

EPA has considered all of the issues raised by NRDC in its imidacloprid objections in acting on the petition to re-establish the imidacloprid tolerance on blueberries. For the reasons explained below, EPA concludes that the safety concerns with the imidacloprid tolerance asserted by NRDC are without merit.

One consistent theme emphasized by NRDC in its objections is the potential heightened exposure of ''farm children'' to pesticides. Accordingly, EPA begins analysis of the issues raised by the objections, in Unit VII.A., with an examination of the data bearing on children's exposure to pesticides in agricultural areas. Then EPA turns to NRDC's more specific claims. Unit VII.B. addresses issues regarding the children's safety factor. Unit VII.C. covers aggregate exposure questions. Unit VII.D. responds to claims regarding use of LOAELs and NOAELs.

A. Children's Exposure to Pesticides in Agricultural Areas

Children can be exposed to pesticides through multiple sources and pathways. The Agency currently considers children's exposure to pesticides by three broad pathways: Food, drinking water, and residential use. NRDC, however, has asserted that children residing in agricultural communities also are significantly exposed to agricultural pesticides through additional exposure pathways.

Children in agricultural areas may be exposed to agricultural pesticides through pathways such as contact with treated fields, roadsides and other areas; contact with moving spray drift while near application areas; contact with spray drift residues left by any spray drift that may reach their homes, yards or other areas they frequent, such as schools and schoolyards; and contact with pesticide residues that have volatilized after application. In addition, some of these children may also be exposed to agricultural pesticides in their homes via other pathways.

In analyzing the potential exposure of children in agricultural areas, EPA first focused on data from studies relied upon by NRDC or otherwise known to EPA that attempted: To measure levels of pesticides in the homes of children in agricultural areas; to measure levels of pesticide metabolites in body fluids of children in agricultural areas; and/or to compare levels of pesticide exposure of farm children to those experienced by non-farm children, based on similar types of measurements. In addition, EPA examined data NRDC submitted relating to airborne levels of pesticides (stemming from spray drift or volatilization) in farm communities. Finally, EPA reviewed data it has concerning the potential for pesticides to drift offsite during application.

Although EPA discusses its views concerning this data in more detail below, those views can be summarized as follows. First, the data concerning levels of pesticides in homes or children's bodily fluids are limited and inconclusive, and do not demonstrate that children in agricultural areas as a group receive more pesticide exposure than children in non-agricultural areas. (In fact, some data suggest that pesticide residues in houses in urban or non-agricultural areas may be higher than those in houses in agricultural areas.) Second, even if airborne pathways such as volatilization may lead to significant exposures to some pesticides, imidacloprid would not be one of those pesticides. Finally, data already gathered by EPA and processed through EPA's Spray Drift Model show that the highest off-target deposition levels from agricultural applications occur adjacent to the treated area and that deposition levels decrease with increasing distance from the treatment area; moreover, and in any event, any spray drift from agricultural applications of imidacloprid, which has residential uses on turf and pets, is largely irrelevant to the pesticide's aggregate exposure assessment, because any estimated exposure from spray drift would be dwarfed by estimated exposure from the lawn and pet use.

1. *Studies focusing on exposure to children in agricultural areas.* In examining the first set of data, EPA found it useful to concentrate first on what the cited studies showed regarding exposure levels in the children's immediate environment. These types of studies have tended to focus on exposure levels in the children's homes, with an emphasis on the level of pesticide residues in house dust. Second, EPA examined the data bearing on the actual exposure children received in agricultural areas as compared to the actual exposure levels of children in non-agricultural areas.

a. *Potential for exposure due to heightened pesticide levels in the homes of farm children.* NRDC's argument that farm children experience higher pesticide exposures than other children relies primarily on studies purporting to show that there are higher environmental levels of pesticides in and around the homes of farm children.

Leaving to one side, for the moment, the issue of whether such elevated environmental levels of pesticides actually increase farm children's exposures, EPA first has focused on whether such elevated levels actually exist. In evaluating this question, EPA has concentrated on the levels of pesticides in house dust, because nearly all the contemporary literature addressing the potential exposure of farmworker children to agricultural pesticides includes a discussion or measurements of pesticide concentrations in house dust. This matrix is now widely recognized as a potential reservoir for many environmental pollutants, including pesticides. In addition, EPA has reviewed not only studies submitted by NRDC, but also other studies known to EPA. (Ref. 40).

The house dust evidence, contrary to NRDC's view, is fragmentary at best as to whether there exists a potential for higher exposure to ''farm children'' due to higher environmental contamination of the homes of such children. For example, house dust samples collected from diverse locations such as Cape Cod, MA; Long Island, NY; Iowa City, IA; Detroit, MI; Seattle, WA; and Los Angeles County, CA have been compared to house dust samples taken from the homes of farm workers in agriculturally intensive Yuma County, AZ. Contrary to NRDC's general hypothesis, in Yuma County, the 90th percentile dust concentrations (µg)/g) for the pesticides chlorpyrifos, diazinon, carbaryl, propoxur, and the disinfectant ortho phenylphenol all were lower than those in most, if not all, of the aforementioned urban areas.(Ref. 8). This may well be due to the fact that, in addition to being agricultural pesticides, all of these pesticides are widely used residential pesticides, which may be used substantially in urban areas as well.

Studies also have been performed in the agricultural area around Wenatchee, WA, which is situated in the heart of the apple growing region in that state. For example, Simcox et al. (Ref. 63) designed a study of housedust and soil samples in this area in an attempt to determine whether children of agricultural families were exposed to higher levels of pesticides than children whose parents were not involved in agriculture. Forty-eight applicator and fourteen reference families were recruited to participate. Families living within 200 feet of an orchard were classified as agricultural families, while families living in homes more than one-quarter mile from an orchard were classified as reference families. Pooled house dust measurements were taken from two locations in each house:

- Three feet inside the entry way.
- In the children's play area.

This study's authors reported significantly higher indoor dust levels of azinphos-methyl, chlorpyrifos, and parathion in agricultural homes as compared to the reference homes. Analysis of the pesticide residues in the soil and house dust samples showed that the pesticide residues present were of agricultural origin, demonstrating in the authors' view that children of agricultural families have a higher potential for exposure to agricultural pesticides than children of non-farm families. In addition, the authors concluded that proximity to agricultural spray areas appeared to be the predominant but not exclusive explanation of the increased soil concentrations.

The study's authors, however, focused on a specific and perhaps unique geographic area. As other study authors have reported, Wenatchee, WA, can be characterized as being situated in an area of canyons ''conducive to wind patterns responsible for spray drift'' (Ref. 11). The site-specific characteristics of this area may not necessarily apply to other agricultural areas, such as those like Yuma County, which, as mentioned in this unit, is situated on a riparian flood plain, and is distinct from the canyons of the Wenatchee area in terms of cropping systems, application techniques and topography. In fact, when University of Washington investigators began assessing house dust concentrations of farm worker houses in the Lower Yakima Valley of Washington, an area of that state that is more expansive than the Wenatchee area, they did not observe an association between proximity to fields and house dust concentrations. Rather, these investigators observed a stronger correlation between house dust concentrations and dust concentrations in vehicles used by farm workers to commute to and from work. (Ref. 11). In addition, for chlorpyrifos, a pesticide once having both residential and agricultural uses, the range of house dust concentrations reported by Simcox (Ref. 63) (<0.02–3.6 µg/g) was exceeded by the median value house dust concentration from non-agricultural family homes (4.7 µg/g; n=9) reported in Jacksonville, FL. (Ref. 22).

b. *Whether farm children actually experience increased exposure.* Assuming for the purposes of argument, moreover, that contaminated house dust may indicate activity patterns (in addition to tracked-in drift) that can lead to the potential exposure of young children to agricultural pesticides in residential environments (Ref. 9 and Ref. 5), the challenge would remain to find an association between house dust concentrations and indications of dose based on measurements of biomarkers of pesticides in farm worker's children. The evidence likewise is fragmentary, at best, on this point.

Fenske et al., for example, ''were unable to demonstrate a strong relationship between housedust concentrations and biological levels,'' i.e., levels in study participants, in Wenatchee area residents. (Ref. 14). These researchers suggested that this was due to several factors, including the tendency of the vacuum system used to capture ''particles from deep carpet'' areas that ''may not represent chemical available to children during normal residential activity.'' The researchers also pointed to ''the complexity inherent in children's exposures'' through ''intermittent contact with surfaces [and] variable hand-to-mouth behaviors,'' as well as the ''relatively high variability'' associated with the spot urine sampling method used to obtain biological values.

Similarly, although Simcox et al. demonstrated the potential migration of agricultural chemicals from an application site to a residence under the unique circumstances of the Wenatchee study, they also questioned the relevance of house dust concentrations in samples collected by the vacuum system used in the study. Like Fenske et al., Simcox and colleagues were not sure if the house dust measurements taken with the system were representative of the house dust routinely encountered by children living in those homes. It was suggested that biological monitoring of these young children ''may serve as an appropriate and noninvasive means of sampling exposure among small children.''

For other reasons as well, these and other studies have provided little data to support either the hypothesis that pesticide levels in house dust are correlated to exposure levels or the hypothesis that children in agricultural areas generally receive significantly higher exposure to pesticide residues than children in the general population.

i. *Studies allowing comparison of children from agricultural and non-agricultural areas.* In Fenske 2000a, for example, Fenske et al. compared the DMTP (dimethylthio phosphate) concentrations reported in a 1995 study of the Wenatchee population with those measured in Seattle children, and found that concentrations from the Seattle

children (Ref. 32) appeared to be similar to those of the Wenatchee reference population—*i.e.,* children in an agricultural area. This suggested that biological pesticide metabolite levels for agricultural and non-agricultural children were very similar. Therefore, even if agricultural children could be said to have the potential for more routes of exposure, they were not more highly exposed. (Quite possibly, the metabolites found in the urine represent exposure to the breakdown products themselves rather than to the parent compounds. (Ref. 15).

Work performed by Higgins et al. (2001) also allows a comparison of agricultural children to non-agricultural children. This study measured cholinesterase levels as a biomarker of organophosphate pesticide exposure in a group of migrant farm workers and their children. The researchers collected blood samples from two groups of Hispanic children (age 3—6 years) in the summer of 1997 to compare cholinesterase levels in populations with varying degrees of contact with agriculture, and hypothetically varying levels of contact with organophosphate pesticides. Ninety-eight migrant Hispanic farm worker children (50% male, 50% female) were recruited from two counties in Oregon. (Ref. 25). A seasonally and age-matched comparison group of 53 Hispanic, non-agricultural family children (64% male, 36% female) was also recruited in 1998 from two non-agricultural areas in Oregon. Results from these two groups showed that cholinesterase levels were not significantly different between the agricultural and non-agricultural children (analysis of variation (ANOVA), p=0.69). (Ref. 25). A further analysis of the data using a multiple regression model to account for potential age and gender effects also supported the conclusion of no significant difference between the two groups. (Ref. 25).

Finally, in its report entitled *Pesticide Exposure and Potential Health Effects in Young Children Along the U.S.-Mexico Border*, EPA concluded that:

> population distributions of OP [organophosphate] pesticide exposure in children (either living in close proximity to agricultural fields, i.e., Yuma Study, or being admitted to health clinics with flu-like symptoms, i.e., Symptomatic Children Study) as measured by alkyl phosphate metabolites are not significantly different than population distributions of OP pesticide exposure for the general population as measured by NHANES III Studies [National Health and Nutrition Examination Survey conducted by the Department of Health and Human Services].

(Ref. 67)

ii. *Studies focusing solely on children from agricultural areas.* Other studies have focused solely on children in agricultural areas, including studies performed in the Wenatchee area by Fenske and his colleagues at the University of Washington. Loewenherz et al. (1997), for example, used members of the Wenatchee study population (48 applicator families and 14 Wenatchee-area reference families) to evaluate and compare levels of OP pesticide metabolites in urine. Their study aimed specifically to:

- Measure urinary metabolite levels of OP pesticides in children living with occupationally exposed parents.
- Compare these with a reference population.
- Evaluate the relative importance of the para-occupational exposure pathway.

One hundred sixty spot urine samples were collected from 88 children, including repeated measures 3–7 days apart. Because the researchers detected DMTP with far greater frequency than any other alkylphosphate, they chose it as this population's most appropriate biomarker of exposure. Over two sampling rounds, however, Loewenherz and colleagues detected statistically significant differences in the frequency of DMTP detectability among applicator and reference children in only one round, and those differences were only marginally statistically significant. From this one exposure event, there was no way to conclude what the potential for exposure could be for each population participating in this study. Moreover, the sample sizes represented by the populations were small, and thus diminished the value of the study in general.

The Loewenherz team, moreover, did not address the potential sources of exposure to pesticides from gardens, pets, lawns, and diet. Although the researchers recognized that this population's use of residential pesticides was less than the national average, it is still possible that exposures from air, dietary intake, and pesticide use in other settings where the children may have spent time (i.e., day care centers, homes of others) may also have contributed to observed urinary metabolite concentrations. (Ref. 31). In fact, misuse of a non-residential pesticide for residential purposes was reported in the study. This may have had a significant impact on the urinary metabolite levels reported in this paper, as two of the three highest measurements in the study came from these households.

In addition, a comparison of the exposures of the farm worker children to the farm workers themselves suggested that it was unlikely that the exposures experienced by the applicator children in the Loewenherz study were sufficient to produce acute health effects. (Ref. 31). Finally, a strong relationship between pesticide house dust concentrations and biological levels in these children was not found. (Ref. 14).

Using a larger cohort (109 children) from the same region, Lu et al. (2000) collected environmental and biological samples to evaluate the total potential exposure of agricultural and reference children. The researchers took spot urine samples, as well as hand wipe samples, house and vehicle dust samples, and surface wipe samples from various surfaces (including steering wheels and work boots). Environmental measurements indicated that children living with parents who work with agricultural pesticides (applicator children), or who live in close proximity to pesticide-treated farmland, have the potential for higher exposures than do other children living in the same community. (Ref. 33). However, dimethyl OP pesticide metabolite levels in the urine of agricultural and reference children showed only a marginally significant difference. Id. The children of farm workers, moreover, had the same range of urinary DMTP as the reference children, and less urinary DMDTP (dimethyldithio phosphate) than applicator children. Diet is likely to have been an important contributor to metabolite concentrations. Id. Interestingly, 23 agricultural families that participated in this study also participated in the study reported by Simcox et al. (Ref. 63). Of these, the four homes that had the highest house dust concentrations in 1992 had lower concentrations in 1995. Overall, 16 of 23 households reported lower house dust concentrations than in the previous study, suggesting that changes in activity patterns can influence levels of pesticides in house dust.

In addition to the azinphos-methyl and phosmet results reported in Lu et al. (2000), Fenske et al. (2002) measured chlorpyrifos and parathion in environmental samples from the homes of the same 109 children and those chemicals' metabolic by-products in biological samples from the children themselves. In their study, Fenske et al. relied on more specific urinary metabolites of the diethyl, OP parent compounds. For chlorpyrifos, the researchers used the metabolite 3,4,6-trichloro-2-pyridinol (TCPy) as a biological measure, and for parathion they used 4-nitrophenol as the biological measure. Environmental

pesticide loadings, however, could not explain the biological levels measured. (Ref. 13). Fenske et al., stated that the use of OP pesticides in gardens was associated with an increase in the TCPy concentrations in children's urine. However, no explanation was offered for this association. Unfortunately, TCPy is a ubiquitous compound in the environment and exposure could still be associated with exposure to both chlorpyrifos and TCPy. The authors reported that most children studied did not have measureable urinary levels of metabolites of either chlorpyriphos or parathion. The study concluded that children living in homes including household members who worked with agricultural pesticides or that were close to pesticide treated farmland did not appear to have increased pesticide exposures, even though their homes showed elevated levels of pesticide concentrations in house dust.

Using the data gathered in their field studies, Fenske and colleagues (2000b) also compared spray season and single-day dose estimates for agricultural and reference children, but only showed a marginal difference between the two cohorts. (Ref. 15). Moreover, a majority of the children classified as reference children had measurable dialkylphosphates in their urine, and a substantial fraction had doses that exceeded the reference values for azinphos-methyl. Id.

An additional team based at the University of Washington examined 571 farm workers involved in a community intervention project in the Washington State's Lower Yakima Valley. This project is presented in Thompson et al. (2003) and Curl et al. (2002) (Refs. 66 and 11). The cohort consisted of field workers and pesticide handlers (e.g., applicators). Questionnaires regarding self reported pesticide exposure and common sense methods to reduce para-occupational exposure were evaluated. Sub-samples of urine and other environmental media (house and vehicle dust) were taken to establish baseline exposure levels of the intervention and control groups. Intervention was described as individuals performing common sense hygiene practices such as removing footwear prior to entering the house.

Based on this research, both Thompson et al and Curl et al. reported a significant association between levels of dialkyl phosphates (DAP, a class of breakdown products of organophosphate pesticides) in urine of adults and their children. There was also a significant association between house dust and vehicle dust. However, Curl et al did not report an association between house dust and proximity to fields and orchards. The DAP metabolites measured were DMP (dimethyl phosphate), DMTP, DMDTP, DEP (diethyl phosphate), and DETP (diethylthio phosphate), and may represent exposure to numerous pesticides from several pathways including diet and pathways associated with residential use of pesticides. The authors speculate that it is also possible that some workers may have taken agricultural chemicals from work for home use.

It has been suggested that the removal of shoes prior to entering the house, or the use of entry mats, can significantly lower the amount of pesticide tracked-indoors. (Ref. 38). Other investigators have observed mixed or inconclusive results. (Refs 33, 11 and 66). When Curl et al. (Ref. 11) compared concentrations of urinary DAPs and OP concentrations in house dust and vehicle dust between two groups (Intervention and Control, Lower Yakima Valley), no significant differences were seen. The intervention group performed activities such as washing hands after work, removing footwear prior to entering the house, washing work clothing separately, and removing work cloths before holding children. If intervention has no impact, it is not clear then whether para-occupational pathways are indeed significant. In general, Thompson et al. (Ref. 66) saw no differences regarding hygiene practices such as removing shoes prior to entering the house between households having children and those that did not. However, the authors suggested the need for continuing current educational efforts. As compared to field workers, pesticide handlers were more likely to perform protective practices such as washing hands immediately after work and removing work clothing before holding children. Yet, in other studies, concentrations in urine were higher among children of applicators than among children of field workers. (Ref. 33).

Finally, Mills and Zahm (Ref. 34) conducted a feasibility study to obtain urine samples from farm workers and their children in an area of extensive OP use. They tested for six urinary metabolites of OPs, including DMP, DEP, DMTP, DMDTP, DETP, and DEDTP. They also compared the levels between adults and children living in the same households. A total of 27 individuals from 9 families (18 adults and 9 children) were selected to participate. Levels of OP metabolites were generally very low in both adults and children in this survey. The frequencies of detection of DMP, DMTP, and DETP were higher among Fresno-area farm workers and their children than among the general population sampled during the National Health and Nutrition and Examination Survey (NHANES) II survey. However, informational data on pesticide use practices in the U.S. general population supplied by the authors suggested that this comparison was unfair, since NHANES II was survey data collected through 1980, when the prevalence of OP pesticide use was only just beginning to increase. In a second comparison, Mills and Zahm showed that the frequencies of detection and mean levels of DMTP among Fresno children were intermediate between those found by Fenske and his co-workers among Wenatchee, Washington applicator and reference children. Id. No statistical analyses were conducted on these data comparisons. Thus, it was unclear whether the urinary metabolite levels seen in the Fresno children were significantly different from the applicator and reference children studied in Washington State.

iii. *Ongoing research on farm children exposures.* Preliminary information from the Farm Family Exposure Study (FFES) conducted by investigators at the University of Minnesota and Emory University bears on the question of whether farm children have higher levels of pesticide exposure than non-farm children, and whether farm children should be identified as a major, identifiable subgroup of consumers. In this study, researchers identified urinary pesticide concentrations for 95 farm families before, during, and for 3 days after an application of glyphosate, 2,4-D or chlorpyrifos. In their preliminary reporting of results, the researchers stated that they found '' appreciable variation by chemical in the proportion of farm family members with detectable urinary concentrations.'' See *http://www.farmfamilyexposure.org/html/abstracts.html#ser/*. However, it was only in the case of farmers—not spouses and children—that the researchers claimed to have detected significant differences in urinary pesticide concentrations and patterns of uptake and elimination. Id. ''For the vast majority of spouses and children, urinary concentrations did not change appreciably after pesticide application.'' Id. Moreover, the researchers asserted, based on their findings, that ''little pesticide exposure is received through . . . living on a farm, per se,'' and that it is the following, specific behaviors instead that are associated with elevated pesticide exposure for farm children:

- ''[d]irect contact with chemicals in the mixing or application area.''

- ''[w]orking as a co-applicator.''
- ''[t]ouching containers without gloves.''
- ''[p]laying barefoot in the area where pesticides are being mixed and loaded[.]''

See *http://www.farmfamilyexposure.org/html/the_study.html*.

EPA recognizes that these representations of the researchers are only preliminary. Nevertheless, the fact that the FFES researchers' preliminary views point in the same direction as the analysis above should not escape note.

In sum, as discussed in this unit the studies and information, whether concerning children in agricultural areas and non-agricultural areas or children in agricultural areas alone, and whether concerning environmental levels, biological levels, or both, shows that there is little or no evidence to indicate that EPA has ignored a significant source of exposure in calculating the potential aggregate exposure from pesticides.

c. *Conclusion*. In conclusion, the limited number of studies containing data relevant to NRDC's arguments, taken together, fail to demonstrate that children in agricultural areas experience significantly higher levels of exposure than children in non- agricultural areas. In EPA's judgment, the weight of currently available evidence relating to pesticide residues in house dust or on other surfaces fails to establish that children living in agricultural areas or children living nearer to agricultural pesticide use areas experience higher exposures to pesticides than children in the general population. Similarly, biomonitoring data available for comparing the levels of pesticide exposure experienced by agricultural children with other children is fragmentary and does not show that there are significant differences between these groups of children. Thus, regardless of whether such children constitute a ''major identifiable subgroup of consumers,'' it does not appear that such children consistently receive more pesticide exposure than the groups of children (those at the upper percentile of estimated exposure) used by EPA in its current approach to assessing aggregate risk.

This is not to say, however, that issues addressed in these materials do not bear further research. On the contrary, the government is engaged in or supporting, or has recently engaged in or supported, relevant research in a number of ways. These efforts include, for example, the Minnesota and South Carolina study discussed in this unit. These efforts also include:

- A similar study which the federal government itself is conducting with children in North Carolina and Iowa.
- A systematic analysis which EPA is undertaking to review the raw data underlying the Wenatchee, WA area and Yuma County, AZ studies discussed in this unit.
- A study of pesticide exposure pathways for farm workers' children in the Yakima Valley.
- An assessment of sources of pesticide contamination, concentrations in pathways, and exposure-prone behavior in Salinas, CA.
- A study of ingestion of pesticides by children in an agricultural community on the U.S./Mexico border.
- An assessment of exposure of children to pesticides in Yuma County, AZ.

EPA will review the results of this ongoing research and take appropriate steps to address any exposure concerns regarding children that are documented.

2. *Supplemental information regarding spray drift and drift of volatilized residues*. On June 19, 2003, NRDC supplemented its submission to the Agency with several pieces of additional information. Included was a report generally addressing the issue of spray drift from pesticide applications in California (Ref. 7) (hereinafter cited as the CFPR Report). Although EPA defines spray drift as the movement of droplets off-target during or shortly after application, which is independent of the chemical properties of the pesticide being sprayed, the CFPR Report looked more broadly at atmospheric pesticide transport including pesticide volatilization as a potential mechanism by which pesticides travel beyond treated fields.This section of the document discusses drift as a result of volatilization. Drift of the pesticide spray is addressed in the following section of the document. Also included in NRDC's supplemental information was a research article entitled ''Community Exposures to Airborne Agricultural Pesticides in California: Ranking of Inhalation Risks,'' containing an analysis of the degree of inhalation risk posed by certain migrating pesticides in California, based on ambient air monitoring data gathered, in part, by the California Air Resources Board and the California Department of Pesticide Regulation. (see Ref. 29, hereinafter referred to as the Ranking Study). EPA is still examining the information in these studies but presents its preliminary views on these studies in this unit.

The Ranking Study conducted screening level assessments for many of the pesticides ranked as having the highest potential as toxic air contaminants as well as several pesticides categorized as hazardous air pollutants. The screening level assessment only identified four soil fumigants as potentially presenting non-cancer acute or chronic risks of concern. Id. at 1179. The study concluded that ''vapor pressure is a significant predictor of [] ranking of inhalation risks.'' Id. at 1182. The CFPR Report examined the potential health risks from air levels of three pesticides characterized as moderate to highly volatile (chlorpyrifos, diazinon, and molinate) measured at the field boundary and at more distant locations. The Report concluded that in many instances the measured air levels of these pesticides posed risks of concern. The Report also concluded that drift due to volatilization was not a concern for pesticides that are not highly volatile. CFPR Report at 40.

Even assuming that volatilization may lead to significant exposures to some pesticides, imidacloprid would not be one of those pesticides. EPA is in general agreement that vapor pressure is the key factor in predicting whether a pesticide has the potential to volatilize and drift offsite in significant amounts. Because soil fumigants traditionally have very high vapor pressures, and thus are highly volatile, EPA is now accounting for potential exposure due to volatilization of these pesticides in calculating their aggregate exposure. Imidacloprid is a solid at room temperature with a low vapor pressure (1.5×10^{-9} mmHg). In fact, imidacloprid's vapor pressure is not only much lower than pesticides used as soil fumigants, it is also substantially lower than the pesticides presented in NRDC's supplementary submission: chlorpyrifos (1.87×10^{-5} mmHg); diazinon (1.4×10^{-4} mmHg); molinate (5.3×10^{-3} mmHg). Thus, any losses due to volatilization for imidacloprid are expected to be minimal at most.

3. *EPA Data on Spray Drift and the Spray Drift Model*. EPA has gathered substantial data on the potential of pesticides, as applied, to drift offsite through the work of the Spray Drift Task Force (SDTF). The SDTF is a group of pesticide registrants who have worked collaboratively to develop a database to meet the majority of their collective spray drift data requirements under 40 CFR 158.440. The group was chartered on April 17, 1990, and its formation was announced in PR Notice 90–3. Since its formation, the SDTF has generated standardized data on spray drift levels resulting from different application methods under varying meteorological conditions. The data developed by the

SDTF was reviewed by EPA internally, through external peer review workshops, and through FIFRA Scientific Advisory Panel meetings. The reviews generally identified the data set associated with aerial applications to be the most robust, followed by the data sets from ground boom applications, orchard/vineyard airblasting, and chemigation, respectively. After the spray drift data were available, the SDTF worked with EPA's Office of Research and Development, as well as the USDA's Agricultural Research Service and Forest Service to use the data in the development/evaluation of the AgDRIFT model. (See generally Refs. 4, 24, and 65).

The AgDRIFT model and the SDTF data show that the highest off-target deposition levels from agricultural applications occur adjacent to the treated area and that deposition levels decrease with increasing distance from the treatment area. See Table 2 of this unit.

TABLE 2.—HIGH-END DOWNWIND SPRAY DRIFT DEPOSITION LEVELS BY APPLICATION METHOD

Lawn placement relative to application area	Spray drift deposition (percent of application rate)				
	aerial[1]	ground boom[2]	airblast[3]		granular[4]
			dormant orchards	dense or tall canopies	
10 to 60 ft downwind	34.1	9.3	25.0	8.4	0
20 to 80 ft downwind	31.6	6.4	16.1	6.0	0
40 to 90 ft downwind	27.9	4.1	8.0	3.7	0
80 to 130 ft downwind	22.0	2.4	3.0	1.9	0
160 to 210 ft downwind	14.9	1.3	0.8	0.9	0

[1] ASAE very fine to fine spray, 10 mph wind, 10 ft release height and other standard AgDRIFT 2.01 default inputs.
[2] Tier 1 AgDRIFT 2.01 ground boom inputs: 90th percentile, high boom, fine spray.
[3] Tier 1 AgDRIFT 2.01 airblast inputs: model outputs multiplied by 3 to approximate an upper 90th percentile value.
[4] Particle drift from granular applications is generally considered to be insignificant in EFED assessments.

The AgDRIFT model helps EPA assess the relative [upper bound] magnitude of residues from direct residential use of a pesticide versus residues that might occur as a consequence of spray drift. As of yet, EPA has not included data from the AgDRIFT model as a standard component of its residential exposure assessments. In responding to NRDC's objections other than as to imidacloprid, EPA is still examining how this data informs the understanding of aggregate exposure generally and how this data can be considered in a meaningful way in assessing aggregate exposure. Nonetheless, even prior to completing this analysis, some conclusions can be made concerning pesticides such as imidacloprid which have broad residential uses. What the data for imidacloprid show is that predictions of exposure based on the spray drift model are largely irrelevant to the pesticide's aggregate exposure assessment because any estimated exposure from spray drift would be dwarfed by estimated exposure from the lawn and pet use. An explanation of EPA's residential exposure assessment for imidacloprid and the operation of the AgDRIFT model for imidacloprid will clarify this point.

EPA estimates residential exposure by incorporating pesticide-specific information in exposure scenarios that are built based on data on human behavior and human physical statistics (e.g., body surface area). (See Refs. 35, 55, and 61) EPA's scenario for estimating exposure due to turf uses assumes that children play for a substantial period (2 hours) on lawns immediately after treatment with the pesticide. The scenario models both dermal exposure from contact between skin (arms and legs) and the lawn and oral exposure resulting from soil ingestion, mouthing grass, and hand-to-mouth behavior (placing hands repeatedly in mouth after being in contact with treated lawn) (Refs. 35, 55 and 61). With the pet treatment, EPA also uses scenarios for both dermal and oral exposure. For dermal exposure, EPA uses a pet hug scenario which assumes a child hugs the pet immediately after treatment. EPA assumes that 20% of the applied dose is available on the surface of the pet for transfer to the child and that the child essentially wraps its full body around the pet such that one-half of the child comes in contact with the pet. The child is assumed to be wearing a short-sleeved shirt and short pants. EPA assumes 100% transfer where the child's skin touches the pet and 50% transfer to the child's skin where the child's clothing touches the pet (Refs. 35, 55 and 61). For oral exposure, EPA used a combination of imidacloprid specific data and its standard exposure scenario. EPA had imidacloprid data on the transfer of imidacloprid to hands from petting dogs that was gathered by petting a treated dog 10 minutes after imidacloprid application wearing cotton gloves. EPA assumed that a child put its hand in its mouth 20 times/hour for 2 hours and each time the hand contained the exposure level measured on the glove. (See Ref. 44 at 51-57 and Refs. 35, 55 and 61)

Using these scenarios, EPA estimated the exposures and MOE's for imidacloprid residential exposures presented in Table 3 of this unit.

TABLE 3.— RESIDENTIAL EXPOSURES FOR IMIDACLOPRID

Use	Route of exposure	Exposure in milligram/kilogram/day (mg/kg/day)	MOE
Lawn	oral	0.0059	1,700
	dermal	0.001	10,000
Pet	oral	0.0027	3,600
	dermal	0.036	280

(Ref. 44 at 51-52).

In calculating potential drift, it is important to consider the maximum amount that may be applied and the manner of application. Imidacloprid is approved for use on residential turf at 0.4 lb/acre/year. This amount may be applied in a single application. This application rate is comparable to the maximum agricultural yearly rate (0.5 lb/acre/year) and exceeds most single agricultural application rates. Imidacloprid application methods differ for various crops with some uses being restricted to soil incorporation of granules and others permitting aerial spraying. The agricultural use that has the potential for the greatest spray drift is on cranberries. The label permits imidacloprid to be applied at 0.5 lb/acre/year for cranberries and that amount of pesticide may be applied in a single application. Further, the label does not prohibit, and therefore permits aerial application. For cranberries this would generally mean application from a helicopter. In EPA's experience aerial application to cranberries is relatively uncommon. The use having the second highest potential for drift is on artichokes where 0.25 lb/acre may be applied aerially in a single application.

To calculate exposure and risk (in terms of MOEs) from imidacloprid spray drift, EPA multiplied the agricultural application rates by the high-end prediction of spray drift deposition (shown in Table 2 of this unit) and then applied the standard residential exposure estimation methods. The estimated exposure and MOE's from spray drift from these uses are presented in Table 4 of this unit.

TABLE 4.—SPRAY DRIFT EXPOSURES FOR IMIDACLOPRID ON LAWNS

Use	Route of exposure	Exposure in mg/kg/day on lawns 10–60 feet from edge of field	MOE
Cranberries	oral	0.0025	4,000
	dermal	0.00035	29,000
Artichokes	oral	0.00127	7,900
	dermal	0.000175	57,000

(Ref. 39).

Comparing the potential exposure from spray drift onto lawns from cranberries with the highest residential exposure already incorporated into EPA's aggregate assessment, the pet hug scenario, shows that worst case exposure at the edge of the field from drift is an order of magnitude lower. Thus even assuming that a child who received maximum exposure from hugging a treated dog was exposed to imidacloprid at the edge of a treated cranberry bog, the exposure and risk assessment for that child would not be meaningfully different.

B. Failed to Retain Children's 10X Safety Factor

1. *Introduction*. NRDC's objections concerning the children's safety factor focus on the question of whether EPA properly applied a children's safety factor of other than 10X given that EPA is allegedly missing data on each of the pesticides. Particular emphasis is placed by NRDC on the fact that a DNT has been required for imidacloprid but not yet submitted. In addressing the issues raised by these objections, EPA first has summarized its children's safety factor decision that was relied upon in approving the imidacloprid tolerance and a re-analysis of that decision that has been performed in light of the objections and the revision to EPA's children's safety policy released in mid-2002. Second, EPA addresses NRDC's contentions regarding the lack of a DNT study. Third, EPA explains its response to each allegation NRDC makes regarding general and pesticide-specific data that NRDC asserts is missing and necessitates retention of the 10X factor.

2. *EPA's children safety factor decision*—a. *In general*. In making decisions regarding the children's safety factor, EPA's OPP, from 1999 until early 2002, looked primarily to an internal committee to make recommendations on the children's safety factor decision and to articulate a rationale for that decision. This committee, the FQPA Safety Factor Committee, was constituted solely for this purpose. To a lesser extent, during this period, OPP relied upon the another internal committee, the Hazard Identification and Assessment Review Committee (HIARC) to explain EPA's rationale. Within the last year or so, OPP has administratively restructured such that most of the work regarding toxicity issues and the children's safety factor falls within the jurisdiction of the HIARC. Consideration of exposure issues falls in the first instance to the team of scientists of OPPs' HED assigned to the specific pesticide. That judgement is then reviewed by the Risk Assessment Review Committee (RARC). It is the RARC's responsibility to ensure adequate rationale is provided for the decision on the children's safety factor and to ensure consistency with current policy and similar pesticides/circumstances. The RARC's recommendation and complete rationale

is included in the risk assessment document for the pesticide.

Two particular aspects of that new policy are worthy of mention. First, the policy emphasizes that in applying the provision the focus should not be simply on whether the young have a greater sensitivity to a pesticide but rather on what reliable data show with regard to the safety of infants and children in situations where studies have shown that the young are more sensitive to a pesticide. Thus, where increased sensitivity is demonstrated, EPA examines how well-defined that sensitivity is by the existing toxicity data and whether that sensitivity has been adequately taken into account in calculating a safe MOE.

Second, the policy stresses that when data are missing or inadequate the focus should be on whether there are reliable data to show that any additional safety factor different than the 10X default value is protective of the safety of infants and children. This issue has arisen frequently with regard to the developmental neurotoxicity study (DNT), a study that EPA is now requiring to be submitted for more pesticides. In evaluating whether a different factor than 10X would be protective of infants and children where a required DNT is absent, EPA examines related studies in the database to develop a sense for the likely range in which effects may be seen in the DNT (and therefore, the range of doses which will be used in the DNT). When the expected doses in the DNT are substantially higher than the doses that are presently providing the regulatory endpoint, a different and lower additional safety factor may be appropriate depending on the degree of difference between the doses for the DNT study and the current regulatory endpoint. On the other hand, where the range of expected doses in the DNT parallels the levels at which effects have already been identified in the database, it is less likely that there will be a reliable basis for assigning an additional factor lower than 10X.

b. *Imidacloprid.* The FQPA Safety Factor Committee recommended an additional safety factor of 3X for imidacloprid for the protection of infants and children. Although available studies demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to imidacloprid, the Committee concluded that an additional factor of 3X was needed due to the fact that there was data indicating a potential for developmental neurotoxicity (and, therefore, a need for a DNT study) and the potential for exposure to young children given the pet and outdoor residential uses of imidacloprid. The data indicating a potential for developmental neurotoxicity included structure activity relationship information and data from a 2-year study in rats showing neurotoxic effects following a single oral dose. (Ref. 56 at 6).

The DNT has now been submitted and reviewed. It showed evidence of an increased qualitative susceptibility in the rat. At the highest dose tested (750 parts per million (ppm)), maternal effects consisted largely of slight decreases in food consumption and body weight gain during early lactation, while pup effects included decreased body weight, decreased motor activity, decreased caudate/putamen width, females only (post-natal days 11 and adult), and slight changes in performance in the water maze, males only, at the same dose. The NOAEL identified in the DNT (20 mg/kg/day) was higher than the NOAELs previously identified (ranging from 5.7 to 10 mg/kg/day) and thus the DNT results had no impact on regulatory endpoint selection and the risk assessment. The HIARC concluded the DNT indicated no residual concerns regarding post-natal toxicity based on:

- The effects in pups are well-characterized with a clear NOAEL.
- The pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams.
- The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study. (Ref. 46 at 9).

EPA ultimately determined that, other than a 3X factor for acute risk assessments to address the lack of a NOAEL in an acute study, no other additional safety factors were needed to protect the safety of infants and children. This conclusion was based upon:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
- There is evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study, but the concern is low since:

1. The effects in pups are well-characterized with a clear NOAEL.

2. The pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams.

3. The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study. Therefore, there are no residual uncertainties for pre-/post-natal toxicity in this study.

- The toxicological database is complete for FQPA assessment.
- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100% [crop-treated] CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and % CT data verified by [OPP's Biological and Economic Analysis Division] BEAD for several existing uses. For all proposed uses, 100% CT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.
- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.
- The residential handler assessment is based upon the residential [Standard Operating Procedures] SOPs in conjunction with chemical-specific study data in some cases and [Pesticide Handlers Exposure Database] PHED unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific [Turf Transferable Residue] TTR data or other chemical-specific post-application exposure study data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to imidacloprid. (Ref. 44 at 22).

Although the HIARC's conclusions regarding exposure are stated in terms of the imidacloprid exposure estimates not being expected to ''underestimate risk,'' in all likelihood, the imidacloprid exposure assessments substantially

overstate exposure. This overestimate of exposure is a result of the aggregation of worst case or, at the least, very conservative (health protective) estimates of, exposure through each pathway of exposure - food, water, and residential. For food, EPA used a worst case approach of assuming all food which can be legally treated with imidacloprid bears imidacloprid residues at the tolerance level for assessing acute risk. Tolerance values are chosen to be slightly higher than any expected residue values at the time of harvest assuming maximum application practices are followed (See Ref. 51 at 11). Assuming tolerance values in food fails to take into account that pesticides are infrequently used on more than a relatively small fraction of a crop, that pesticides are not uniformly applied at the maximum application rate, that even when pesticides are applied at the maximum application rate much of the treated crop will have residues well below the tolerance level, and that pesticides often degrade substantially between the time of harvest and consumption naturally or as the result of food processing or cooking. Id. at 10-12, 17-30. For assessing chronic risk, EPA took only a slightly less conservative approach by incorporating percent crop treated data for approximately $\frac{1}{3}$ of the commodities having tolerances. All treated commodities were still assumed to bear tolerance level residues.

For water, EPA estimated possible exposure with a surface water exposure model (Pesticide Root Zone Model and the Exposure Analysis Model System) that generally produces very conservative (health protective) estimates of exposure. As the analysis in Unit VII.B.4.b.ii. shows, this model generally substantially over predicts residue levels in water, frequently by orders of magnitude. Finally, for residential exposure, EPA relied on models using conservative (health protective) assumptions that are also likely to overstate actual exposure. These assumptions are described in detail in Unit VII.A.3.

3. *Missing toxicity data - lack of DNT*. NRDC contends that ''the absence of required developmental (DNT) tests for imidacloprid, mepiquat, and zeta-cypermethrin is a crucial data gap that by itself should prohibit EPA from overturning the default 10X safety factor.'' See, e.g., Imidacloprid Objections at 6. Given, however, that the DNT has now been submitted and incorporated into the imidacloprid risk assessment, this objection is no longer relevant to the imidacloprid tolerance on blueberries.

4. *Missing exposure data - general*—a. *Farm children exposure*. NRDC argues that EPA is lacking data on exposure to farm children and thus may not remove the additional 10X safety factor. EPA disagrees. As discussed above, the data submitted by NRDC have not shown that there are significant exposures to farm children that occur as a result of living in close proximity to agricultural operations. EPA concluded that the evidence presented by NRDC is fragmentary, at best, as to whether pesticide exposure levels in homes of children living in agricultural areas are significantly different than levels in other homes and whether children living in agricultural areas have significantly different exposures than non-agricultural children.

After reviewing all of this data, EPA concludes it has sufficient reliable data to find that an additional 10X factor is not needed to protect the safety of infants and children with regard to any uncertainties due to lack of data on exposure of farm children to pesticides. Specifically with regard to imidacloprid, EPA is confident that its exposure assessment is protective of all children given that it has taken into account, in its aggregate exposure assessment, that imidacloprid is registered for use on pets and turf. EPA's aggregate assessment has assumed that children will come in direct contact with treated pets and turf. Indirect exposure from agricultural uses is unlikely to be significant compared to direct exposure to treated pets and turf. Additionally, EPA has found the chance of pesticide exposure as a result of the volatilization of pesticide residues in the field to be extremely slight given the vapor pressure of imidacloprid.

b. *Lack of comprehensive DW monitoring data*. NRDC contends that because EPA used a model for calculating drinking water exposure to imidacloprid that, as a definitional matter, EPA does not have ''reliable data'' for choosing a factor different than the 10X default value. Similar comments were made during the development of EPA's Children's Safety Policy. For the reasons below, EPA rejects NRDC's claims.

i. *Models and data*. Modeling is a necessary part of both the hazard and exposure components of risk assessment. In the absence of perfect data, EPA must extrapolate through the use of modeling from the individual data available to more general conclusions concerning hazard, exposure, and risk. (See Ref. 48 at A-7). As EPA noted in responding to NRDC's comments on its Children's Safety Factor Policy, ''short of measuring the pesticide residues in every sip of water and every bite of food as it is being consumed, OPP must model or estimate exposure values for residues in drinking water and food. The need for models exists whether the exposure estimate is based on monitoring values in drinking water and food, residue values from field studies, or data on a pesticide's properties and characteristics which are used to predict anticipated residue levels in water and food.'' (See Ref. 47 at 149) Accordingly, NRDC errs to the extent it attempts to cast models as the antithesis of data. The question is not whether EPA is relying on reliable data or a model but whether the model EPA is using is based on reliable data. Id. (''[T]he reliability of any method of estimating exposure will have to be evaluated based on what data the method relies upon'').

For imidacloprid, EPA relied on a combination of modeling information and pesticide-specific data. EPA concluded that use of this information was unlikely to underestimate exposure to the imidacloprid in drinking water. EPA believes that a description of its drinking water models and their underpinnings, an evaluation of how these models have performed generally, and a review of the data pertaining to imidacloprid demonstrates that this conclusion was reasonable. Hence, EPA finds that in using these models and the pesticide-specific imidacloprid data it was acting on the basis of reliable data. (See Ref. 48 at A-7) (''OPP does not interpret the reliable data requirement in the infants and children's provision as mandating that any specific kind of data be available, just that the data and information that form the basis for the selection of a different safety factor must be sufficiently sound such that OPP could routinely rely on such information in taking regulatory action.'')

ii. *EPA's drinking water models*. Although the availability of drinking water monitoring data has increased dramatically in the last several years, EPA still finds it necessary to rely for most pesticides upon various exposure models to estimate exposure levels in drinking water. As explained below these models are based on generic data regarding fate and transport of pesticides in the environment, and they operate by combining this generic data with pesticide-specific data on chemical properties to estimate exposure.

EPA has primarily used its drinking water models to ''screen'' those pesticides that may pose unacceptable risks due to exposures in drinking water from pesticides not likely to result in such exposures. To accomplish this

goal, the models are based on data from studies at sites that are highly vulnerable to runoff of pesticides to surface water or leaching of pesticides to ground water. If a pesticide fails this conservative (health-protective) screen, EPA would investigate whether the model is significantly overstating the residue levels that actually occur.

EPA has developed models for estimating exposure in both surface water and ground water. EPA uses a two-tiered approach to modeling pesticide exposure in surface water. In the initial tier, EPA uses the FQPA Index Reservoir Screening Tool (FIRST) model. FIRST replaces the GENeric Estimated Environmental Concentrations (GENEEC) model that was used as the first tier screen by EPA from 1995-1999. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. The second tier model is actually a combination of the models, Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS). For estimating pesticide residues in ground water, EPA uses the Screening Concentration In Ground Water (SCI-GROW) model. Currently, EPA has no second tier ground water model.

Whether EPA assesses pesticide exposure in drinking water through monitoring data or modeling, EPA uses the higher of the two values from surface and ground water in assessing overall exposure to the pesticide. In most cases, pesticide residues in surface water are significantly higher than in ground water.

Table 5 describes what models were used to estimate drinking water residue levels with regard to imidacloprid both for the 2002 tolerance and the 2004 tolerance. The table also indicates which model estimates were used in assessing overall exposure to the pesticide.

TABLE 5.—DRINKING WATER MODEL PROJECTIONS FOR IMIDICLOPRID

Year	Residue	Surface Water Model	Ground Water Model	Surface Water acute	Surface Water chronic	Ground Water acute and chronic	Model Used for Exposure Assessment
1998	Imidacloprid parent	PRZM/ EXAMS	SCI-GROW	4.1 ppb	0.1 ppb	1.1 ppb	PRZM/EXAMS (acute); SCI-GROW (chronic)
2003	Parent and degradates	FIRST	SCI-GROW	36.04 ppb	17.24 ppb	2.09 ppb	FIRST (acute and chronic)
2003	Parent	FIRST	SCI-GROW	35.89	16.52	1.43	N/A

The increase in estimated levels in surface and ground water in the 2003 assessment is due to the use of different models (for surface water), the addition of new uses, and more updated information on aerobic soil and water half-lives and use of the organic carbon normalized soil/water equilibrium partition coefficient (K_{OC}) instead of the soil/water equilibrium partition coefficient (K_D) (Refs. 45 and 59) For the recent tolerance action, EPA used the surface water estimates for calculating aggregate exposure because they are higher than the levels projected for ground water.

a. Surface water—i. GENEEC. GENEEC uses readily-available pesticide properties to estimate peak and time-averaged pesticide concentrations in a ''farm pond,'' 20 million liters (5.3 million gallons) in capacity, located at the edge of a 10-hectare (approximately 25 acres) treated field. GENEEC is designed to simulate reasonable worst case pesticide levels in this farm pond following a major rainfall event. It assumes that a maximum of 10% of the applied pesticide is removed by rainfall and washed into the adjacent waterbed. The underlying data supporting GENEEC is an extensive study of the level of pesticide residues in runoff studies. (Ref. 69). That paper provided a summary of 122 study values and revealed that the amount of pesticide transport off of the treated field by rainfall ranged from a low of 0.00% to a high of 22% of the applied pesticide, with most of the values clustered toward the lower end. Only 4 of the 122 study values were above 10%. The study author recommended that percentage loss estimates for the pesticides most likely to be carried away by runoff should be from 2 to 5% based on slope of the field. (Id.; see Ref. 30) (''Under natural conditions, pesticide runoff losses in the 10% range would be rare.''). GENEEC assumes that the 10% figure corresponds to pesticides with the greatest solubility and that pesticides which have a greater tendency to bind to soils are transported to the farm pond in lower amounts on a percentage basis. The capacity of a chemical to dissolve in water or, conversely, to bind to soil is generally expressed as the soil/water equilibrium partition coefficient (K_D) or the organic carbon normalized soil/water equilibrium partition coefficient (K_{OC}). The higher the K_D or K_{OC} value for a pesticide, the greater tendency it has to adsorb or bind to soil; there is a partial correlation with the solubility of the pesticide with strong adsorption generally associated with lower solubility. An individual pesticide's K_D or K_{oc} value is used to estimate the percentage of pesticide applied that is likely to enter the farm pond. In estimating the amount of pesticide entering the pond and hence the concentration of the pesticide in the pond, the instructions for the model recommend use of the assumption that the pesticide was applied at the maximum rate permitted on the pesticide label. The concentration of the pesticide in the pond over time is calculated taking into account the aerobic aquatic metabolic half-life, the hydrolysis half-life, and the photolysis half-life, of the pesticide in question.

GENEEC produces a conservative estimate of levels in surface water due to the fact that the model is constructed based on the highest values of pesticide residues found in farm ponds and that it assumes pesticides are applied at maximum application rates. Further conservatism is added by, among other things, the assumption that the entire drainage area surrounding the farm pond is planted to crops for which the pesticide is registered and 100% of those crops are treated. Additionally, GENEEC tends to overstate residue values in a drinking water location because it is designed to represent a water body in the upper reaches of the agricultural watershed. Drinking water reservoirs typically have contributions from multiple sources. (Ref. 54 at 6)

In the SAP's review of GENEEC in 1997, ''nearly all the Panel members agreed that the pesticide concentration estimates provided by GENEEC are most likely overly conservative.'' (Ref. 18 at 18). In late 1999, EPA revised GENEEC by substituting a reservoir for the farm pond in the model. As indicated above, this model is designated the FQPA Index Reservoir Screening Tool (FIRST).

ii. FIRST. FIRST provides a slightly more realistic model for estimating pesticide residues in drinking water than GENEEC because it models a small drinking water reservoir instead of a static farm pond. It maintains, however, many of the conservative features of GENEEC. Like GENEEC, FIRST is based on data concerning residue in actual water bodies and the data chosen to construct the model represent a reasonable worst case scenario.

The drinking water reservoir that EPA chose to use as the Index Reservoir for modeling pesticide levels is Shipman City Lake in Shipman, Illinois (Ref. 60 at 17). Shipman City Lake is representative of a number of reservoirs in the central midwestern United States that are known to be vulnerable to pesticide contamination. Id. at 18. The site at Shipman, Illinois was chosen for the IR because of extremely high pesticide concentrations found there by the Acetochlor Registration Partnership (ARP) monitoring program and because of its hydrologic simplicity for modeling purposes (Refs. 1 and 2). In 1996, Shipman City Lake had one of the highest atrazine concentrations of the lakes monitored. (Ref. 60 at 8). Two or three of the other ARP reservoirs had slightly higher annual peak concentrations but presented substantial modeling difficulties.

The FIRST model was constructed in a very similar manner to GENEEC. FIRST assumes that up to a given percentage of a pesticide may run off into an adjacent drinking water reservoir with the precise percentage being a factor of the pesticide's K_D or K_{oc} value. After considering the concentrations of atrazine found in Shipman City Lake and other ARP reservoir monitoring sites, atrazine's K_D value, atrazine application rates, and various potential percentages of pesticide runoff, EPA determined that, with a reservoir model, assuming that up to 8% of the pesticide applied could reach the reservoir was a conservative (health protective) value. Like GENEEC, FIRST assumes that a pesticide is applied at its maximum application rate.

Although FIRST, also like GENEEC, assumes that all cropped area is 100% treated with the pesticide in question, FIRST attempts to be slightly more realistic and does not assume that 100% of the drainage area for the reservoir is planted to the treated crop. As to four major crops (corn, soybeans, wheat, cotton), FIRST uses a value representing the maximum drainage area for a reservoir that could be expected to be planted to the crop in question. These values are derived from geoprocessing analysis that combines U.S. Department of Agriculture data on crop coverage with U.S. Geological Service data on watershed boundaries. (Ref. 57 at 8). For all other crops, EPA assumes that 87% of the pond's drainage area is cropped and 100% of that cropped area is treated. (See Ref. 53 at 24) (explaining choice of 87% is based on fact that 87% cropped was the largest cropped area in any 8-digit hydrologic unit in the continental United States).

The SAP has endorsed the concept of using a reservoir as reasonable, but questioned the representativeness of the reservoir EPA chose to model. (See Ref. 17 at 3). Based on SAP comments, EPA undertook a comprehensive review of its Index Reservoir model. EPA considered 82 reservoirs as candidates for modeling (Ref. 54 at 15) and selected 20 for further investigation. Factors evaluated included depth and volume of the reservoirs, percentage of the reservoir that is cropped, the ratio of drainage area to normal reservoir capacity, and the availability of sufficient years of monitoring data. Following this evaluation, EPA again selected Shipman City Lake as the most appropriate reservoir to serve as a basis for modeling. The other three best candidate reservoirs which were not selected were Springfield, Illinois (watershed too large for the model), Gillespie, Illinois (two reservoirs used alternatively by the city) and Higginsville (reservoir has a pre-settling basin which cannot be accurately modeled.)

iii. PRZM/EXAMS. The EPA PRZM and EXAMS models used together are a more complex modeling system that provide a more realistic estimate of residue levels in surface water by incorporating more site-specific information than GENEEC or FIRST. The PRZM component of the model is designed to predict the pesticide concentration dissolved in runoff waters and carried on entrained sediments from the field where a pesticide has been applied into an adjoining edge-of-field surface water body. The model can simulate specific site, pesticide, and management properties including soil properties (organic matter, water holding capacity, bulk density), site characteristics (slope, surface roughness, field geometry), pesticide application parameters (application rate, application frequency, spray drift, incorporation depth, application efficiency, application methods), agricultural management practices (tillage practices, irrigation, crop rotation sequences), and pesticide environmental fate and transport properties (aerobic soil metabolism half-life, soil:water partitioning coefficients, foliar degradation and dissipation, and volatilization). EPA selects a combination of these different properties to represent a site-specific scenario for a particular pesticide-crop regime.

The EXAMS component of the model is used to simulate environmental fate and transport processes of pesticides in surface water, including: abiotic and biotic degradation, sediment:water partitioning, and volatilization. Currently, OPP is using an index reservoir and a farm pond as benchmark surface water bodies for human health and aquatic exposure assessments, respectively.

For each component of PRZM/EXAMS, the values used are derived from real world data. For example, the EPA-approved product label is the source of the application rate, frequency, and method of pesticide application. Pesticide environmental fate properties used in PRZM and EXAMS modeling come from registrant-submitted data used for pesticide registration or reregistration. The values used for soil properties and site characteristics are chosen from real world databases appropriate for the sites on which the pesticide may be used. For example, if the pesticide is approved for use on cotton, OPP uses data reflecting the soil types in the Cotton Belt. The index-reservoir being modeled is based on and represents an actual, fairly typical, small flow-through reservoir used for drinking water. Finally, the weather inputs for the model are taken from site-specific weather data, based on the USDA Major Land Resource Areas. PRZM modeling is generally simulated for 30 or 36 years in order to calculate the variability of the pesticide concentration in the surface water body due to variations in weather over time and the value used for risk assessment is the 90th percentile value.

Despite the fact that PRZM/EXAMS uses much greater site-specific information than either GENEEC or FIRST, it still provides high end or upper bound estimates of pesticide values in surface water. The high end/upper bound estimates result from the conservative manner in which PRZM/EXAMS selects and combines values

derived from real world data. EPA intentionally chooses values for the model which are likely not to underestimate the potential levels of pesticide residue in surface water. For example, the application rate and frequency used in the model are the highest allowed by the product label. In addition, PRZM/EXAMS modeling is assumed to be conservative because both the farm pond and index reservoir represent a vulnerable water supply; conservative fate parameters are used in the model; 100% of the cropped area in the watershed is assumed to be treated with pesticide; for all but four major crops (corn, soybeans, wheat, and cotton) 87% of the watershed is assumed to be cropped and treated; site conditions (annual rainfall and soil) are chosen to represent a site especially vulnerable to runoff taking into account all of the sites on which the specific crop is grown across the United States; and the simulation is run for up to 36 years and the results are reported at the 90% highest year. For the crops corn, soybeans, wheat, and cotton, 46%, 41%, 56%, and 20%, respectively of the watershed is assumed to be cropped and treated. Further compounding the tendency of these assumptions to overstate exposure, EPA also assumes that all of the pesticide in the watershed is applied simultaneously using the application method most likely to produce maximum runoff. Assuming simultaneous application tends to exaggerate residue estimates in drinking water because that means all potentially treated area in the watershed will have pesticide residues (from a maximum application applied with the technique most likely to produce runoff) available when the next rainfall event occurs. Assuming staggered application between growers would be more realistic but data is not currently available that would allow that level of sophistication in the model. All these factors lead to an assessment that PRZM/EXAMS is expected to predict high end or upper bound concentrations. (Ref. 53 at 20-21).

EPA sought SAP review of the PRZM/EXAMS modeling system in 1995 as part of the SAP's review of the report entitled ''Aquatic Dialogue Group Report: Pesticide Risk Assessment and Mitigation''. The SAP was complementary of this overall approach to exposure assessment modeling (See Ref. 19 at 7-9). In addition, the PRZM/EXAMS model has been before the SAP in the context of the issue of the introduction of incorporation of a ''percent cropped area'' [PCA] factor in OPP's drinking water models. In 1999, EPA requested SAP review of the appropriateness of using PCA and presented the results of several modeling exercises using PCA in connection with both PRZM/EXAMS and GENEEC. Comparisons of these modeling exercises to monitoring data showed that in most cases, the models overstated residues by an order of magnitude or greater. In other cases, the models overstated residues by factors less than 10. Finally, in two instances, the models understated values found in vulnerable water bodies.

The SAP generally endorsed the use of the concept of PCA for drinking water models. (See Ref. 16 at 67). Further, the SAP concluded that ''[u]se of the maximum PCA appears to result in an appropriately conservative assessment for most chemicals for major-use compounds.'' Id. The SAP, however, was skeptical of the conservativeness of the use of PCA with regard to minor crops. Id. at 68. This appears to have been due to the fact that the two instances in which PRZM/EXAMS under predicted drinking water concentrations involved minor crops. Accordingly, EPA has used a default PCA value of 87% in conducting PRZM/EXAMS modeling for minor crops for drinking water assessments. Further examination of the two cases of under prediction, however, suggest that not too much weight should be attached to these results. As to one of the cases (methomyl), the comparison was between PRZM/EXAMS modeling for minor crop (lettuce and peaches) and monitoring data on a major crop (corn). Further, the relatively higher concentration value found in monitoring was not from a drinking water reservoir but a stream adjacent to a corn field. In the other case (methidathion), the monitored value was from a river (the San Joaquim River in California) that is largely composed of irrigation return flow from agricultural fields. Such a river is generally not a drinking water source (the portion of the San Joaquim River where the samples were drawn is not used for drinking water) and PRZM/EXAMS is not structured so as to predict levels in such an environment.

Both the PRZM and EXAMS models have been the subject of extensive validations. The FIFRA Environmental Model Validation Task Force recently completed a review of PRZM. (Ref. 28). That study was an industry-sponsored calibration effort, but EPA scientists participated in the design and conduct of the study. The study's report concluded that PRZM ''provides a reasonable estimate of chemical runoff at the edge of the field.'' Id. at 6. The study found that ''[s]imulations based on the best choices for input parameters (no conservatism built into parameters) are generally within an order of magnitude of measured data with better agreement observed both for larger events and for cumulative values over the study period.'' Id. When simulations were run using conservative input parameters such as employed by EPA, according to the study, ''substantial over-prediction of runoff losses occur.'' Id. at 6, 8, 49. This conclusion regarding over-prediction only considered estimated values at the edge of the field and did not take into account the substantial conservatism introduced by EPA's assumptions regarding pesticide application amount, the percentage of the watershed receiving pesticide treatment, and the timing of application on adjacent fields.

EXAMS has also been the subject of extensive validation efforts. Satisfactory validation has been achieved in studies conducted in the Monogahela River, USA, an outdoor pond in Germany, a bay on the each coast of Sweden, Japanese rice paddies, and rivers in the United Kingdom and South Dakota, USA. (Ref. 6).

The most important validation of these models is not the abstract study of these models but how well the models have worked in practice when used by EPA in pesticide risk assessment. To do such an evaluation, EPA compared its surface water estimates from GENEEC, FIRST, and PRZM/EXAMS to data on pesticides in surface water compiled through the U.S. Geological Survey's National Water-Quality Assessment (NAWQA) Program. NAWQA is designed to provide ''consistent and comparable information on water resources in 60 important river basins and aquifers across the Nation.'' (Ref. 68)These river basins and aquifers account for approximately 60 to 70% of the country's water use. Id. EPA found 47 instances in which it had estimated pesticide residues in surface water resulting from the pesticide's use on a particular commodity using either GENEEC (14), FIRST (3), or PRZM/EXAMS (30) and there was also NAWQA data on the pesticide in surface water. (Ref. 41)See Table 6 below. In each instance, the peak modeled value exceeded the maximum value in the NAWQA data. In fact, in 42 of the 47 cases, the modeling value was nearly an order of magnitude or more higher. This further confirms that reliable data support EPA's conclusion that use of these surface water models is not likely to underestimate drinking water exposure. To the contrary, these data confirm that these models produce

conservative (health-protective), and often extremely conservative, results.

TABLE 6.—COMPARISON OF SIMULATION MODEL OUTPUTS WITH UPPER LEVEL NAWQA MONITORING VALUES

Pesticide	Model(s)	Crop	Peak Modeled Value*	NAWQA 95th%ile	NAWQA Maximum
2,4-D	FIRST	Sugarcane	132.00	0.35	15(E)
2,4-D	PRZM/EXAMS	Apples	118.00	0.35	15(E)
Acetochlor	PRZM/EXAMS	Corn	284.00	0.17	25.1(E)
Acifluorfen	PRZM/EXAMS	Soybeans	14.00	<0.04	1.10
Alachlor	GENEEC	Corn/Soybeans	199.00	0.10	10.90
Aldicarb	PRZM/EXAMS	Citrus	2.03	<0.550	0.51(E)
Atrazine	PRZM/EXAMS	Sugarcane	205.00	2.86	201(E)
Azinphos methyl	PRZM/EXAMS	Peaches	16.00	<0.05	0.5(E)
Benfluralin	PRZM/EXAMS	Apples	61.00	<0.01	0.01
Bentazon	PRZM/EXAMS	Not given	122.00	0.15	8.60(E)
Bentazon	GENEEC	Not given	100.20	0.15	8.60(E)
Butylate	GENEEC	Corn	33.10	<0.002	1.40
Carbaryl	PRZM/EXAMS	Citrus	494.00	<0.041(E)	5.2(E)
Carbofuran	PRZM/EXAMS	Grapes	39.40	0.043(E)	7.00(E)
Chlorothalonil	PRZM/EXAMS	Tomatoes	43.80	<0.48(E)	0.29(E)
Chlorpyralid	FIRST	Canola	17.10	<0.230	<0.230
Chlorpyrifos	GENEEC	Sweet corn	56.50	0.01	0.26
Chlorpyrifos	PRZM/EXAMS	Sweet corn	40.60	0.01	0.26
DCPA	PRZM/EXAMS	Cabbage	160.00	0.02	100(E)
Diazinon	PRZM/EXAMS	Citrus	540.00	0.02	2.50
Dichlobenil	GENEEC	Turf	951.00	<1.2(E)	0.01(E)
Disulfoton	PRZM/EXAMS	Potatoes	15.51	<0.021	0.43
Diuron	GENEEC	Orchard	152.00	0.26	14(E)
EPTC	PRZM/EXAMS	Citrus	57.35	0.02	7.30
Ethalfluralin	PRZM/EXAMS	Sunflowers	2.27	<0.009	0.07
Ethoprop	PRZM/EXAMS	Sweet Potato	127.00	<0.005	0.45
Linuron	PRZM/EXAMS	Carrots	1.30	<0.035	1.40
Malathion	PRZM/EXAMS	Citrus	324.00	<0.027	0.52
Methomyl	GENEEC	Lettuce	409.00	<0.020	0.67
Methomyl	PRZM/EXAMS	Corn	60.00	<0.020	0.67
Metolachlor	PRZM/EXAMS	Corn	134.60	1.38	77.6(E)
Metribuzin	GENEEC	Sugarcane	390.00	0.05	6.61
Norflurazon	GENEEC	Cane Berry	72.10	<0.040	1.24
Norflurazon	PRZM/EXAMS	Citrus	396.00	<0.040	1.24

TABLE 6.—COMPARISON OF SIMULATION MODEL OUTPUTS WITH UPPER LEVEL NAWQA MONITORING VALUES—Continued

Pesticide	Model(s)	Crop	Peak Modeled Value*	NAWQA 95th%ile	NAWQA Maximum
Oxamyl	GENEEC	Pineapple	321.80	<0.020	0.16
Parathion	GENEEC	Cotton	166.00	<0.008	0.14
Pebulate	PRZM/EXAMS	Not given	2.90	<0.004	0.08
Propargite	PRZM/EXAMS	Cotton	34.30	<0.023	2.62
Propochlor	GENEEC	Sorghum	202.00	<0.010	0.51
Propochlor	PRZM/EXAMS	Sorghum	64.00	<0.010	0.51
Propyzamide (Pronamide)	FIRST	Ornamentals	390.00	<0.004	0.28
Tebuthiuron	PRZM/EXAMS	Pasture/Range	15.10	0.02	0.95
Terbufos	PRZM/EXAMS	Sorghum	21.70	<0.017	0.56
Thiobencarb	GENEEC	Celery	186.00	<0.005	3.66
Triallate	PRZM/EXAMS	Wheat	5.50	<0.001	0.65
Triclopyr	GENEEC	Pasture	364.00	<0.25	16(E)
Trifluralin	PRZM/EXAMS	Sugarcane	3.44	<0.009	0.17

* = 1-in-10 year peak value; (E) = NAWQA Estimate

A review of drinking water assessments by the pesticide industry reached a similar conclusion. In this study, results from FIRST modeling (conducted for the purpose of the study) and PRZM/EXAMS modeling (from EPA exposure assessments) were compared with data from a USGS/EPA monitoring program.(Ref. 23). The monitoring data was gathered from small drinking water reservoirs in areas with high pesticide use in 12 geographically disparate regions in the United States. The study compared acute prediction values with the maximum value from the monitoring data and the chronic prediction values with 95th percentile of a time weighted average of monitored values. The result was that ''[f]or both acute and chronic exposure the models systematically overestimate measured exposure typically by 10 to 10,000 fold for the majority of cases.'' Id. There was no instance in which a model underestimated exposure. Id. The study concluded that the overestimation occurred due to ''[c]ompounding conservative assumptions, without considering associated probabilities of occurrence/co-occurrence.'' Id. The conservative assumptions identified as most likely leading to this result are (1) maximum label rate application on the highest percent cropped area in the United States; (2) reservoir immediately bordered by treated field; and (3) highest mobility, upper percentile half life, no reservoir dilution effects, and no soil photolysis. Id.

b. Ground water. As mentioned above, EPA uses the SCI-GROW model for estimating residues of pesticides in ground water. SCI-GROW is a regression model that uses chemical-specific data on a pesticide's adsorption (i.e. the soil/water partition coefficient of K_D or K_{oc} value) and the pesticide's persisence (i.e. the soil metabolism half-life) in combination with the assumption that the pesticide is being applied at its maximum application rate. The model is based on data obtained from ten prospective monitoring studies measuring the degree to which various pesticides leached to ground water. These studies were conducted in hydrogeologically-vulnerable sites (i.e., shallow aquifers; sandy, permeable soils; and substantial rainfall or irrigation to maximize leaching). SCI-GROW provides a screening value which is applied to both peak and chronic exposure screening.

In its review of the SCI-GROW model in 1997, a majority of the SAP concluded that it was ''highly conservative.'' (See Ref. 18 at 10) The SAP summarized the reasons for this conservatism as follows:

a. SCI-GROW is based mainly on OPP prospective ground water studies designed to maximize the opportunity for pesticides to leach into ground water:

- Soil site highly vulnerable to leaching (very sandy, little clay, low organic matter).
- Rainfall supplemented with irrigation to ensure higher than average monthly rainfall for each consecutive month of study. Supplementation of rain with irrigation errs on the side of greater opportunity for encountering rainfall amounts in excess of normal patterns.
- Sites with shallow water tables.
- Sites that represent an unknown but very low percentage of the ground water used as drinking water.
- Sites with wells totally surrounded by treatment area; no dilution with clean water.
- Sites with wells directly adjacent to treatment area; short path to well.
- Maximum rate of pesticide application; multiple treatments may be applied as one massive application.

b. Development of SCI-GROW ignored PGW [prospective ground water] studies with no ground water detections; only those that produced concentrations were included in the regression data set. Therefore, SCI-GROW reflects a filtered data set that implies greater frequency of observed concentrations than what actually occurred in the PGWs.
Id. at 12.

As with the surface water models, EPA has examined how well the models have worked in practice when used by EPA in pesticide risk assessment. To do such an evaluation, EPA compared its ground water estimates from SCI-GROW to data on pesticides in ground water compiled through the NAWQA program. Comparisons of the SCI-GROW screening model have been made to various upper bound distributions (99.0,

99.5, and 99.8 percentiles) rather than to the absolute maximum values in the NAWQA data (as was done with the surface water model). No higher percentiles were calculated because such calculation would not be reasonable given the sample size. The reason for not using maximum values, as was done with surface water evaluation above, is the difference in the nature of ground water and most surface water sources sampled in the study. Surface water bodies sampled were generally streams, reservoirs, or lakes which represent a significant amount of mixing of runoff water from a watershed that may be tens or hundreds of square miles in area. Well water often is most representative of pesticides leaching from a much smaller geographic area. Furthermore, there is a significant risk that at least some individual wells in any large sample will be severely impacted by pesticides because of either poor well construction (allowing direct influx of pesticide residues from the surface) or spillage from pesticide mixing/loading activities or leakage from pesticide storage facilities. Contamination levels in individual wells can be much, much higher from these sources than would occur in ground water solely from maximum agricultural applications of pesticides to the surface. The consequence of this is that the highest values of pesticides observed in a large scale survey of ground water cannot be assumed to represent contamination from normal outdoor uses of pesticides.

EPA identified 39 instances in which it had estimated pesticide residues in ground water resulting from the pesticide's use on a particular commodity using SCI-GROW and there was also NAWQA data on the pesticide in ground water. (Ref. 42). In all but three instances, the peak modeled value exceeded the 99.8th percentile value from the NAWQA data. No exceedances occurred for any of the 39 compounds at the 99.5 percentile level or below. Most estimates, even at the 99.8th percentile, were substantially above the NAWQA value. For example, in 24 cases, the modeling value was an order of magnitude or more higher than the 99.8th percentile NAWQA value. Of the three cases in which the monitoring value exceeded the projected value, in each instance the difference was less than a factor of 2x. In two of the three cases both the projected and monitored values were extremely low both absolutely and relative to other exposure values for the pesticide. For example, malathion had SCI-GROW and NAWQA ground water values (99.8th percentile) of 0.006 ppm and 0.007 ppm, respectively, compared to PRZM-EXAMS and maximum NAWQA surface water values of 324 ppm and 0.39 ppm, respectively. Additionally, tolerance values for malathion range from 0.1 ppm to 135 ppm with most values for agricultural crops either 4 ppm or 8 ppm. The other instance where a monitored value exceeded the modeled value involved alachlor. There, SCI-GROW predicted a value of 0.82 ppm and the monitored value was 1.2 ppm or a factor of 1.5x higher. Preliminary results of comparisons with alachlor concentration frequency distributions from other large scale surveys, including those targeted for alachlor or at least for corn use areas (the major crop use for alachlor) are inconclusive with regard to the conservativeness of the SCI-GROW prediction. Id. EPA plans to look more closely at the data on alachlor to determine if any adjustment of SCI-GROW is warranted. Primarily needed for this are the completion of analysis of new monitoring data recently submitted to support the registration of acetochlor (which includes some very useful concentration distribution information for alachlor as well as two other corn herbicides) and the analysis of a large amount of additional ground-water monitoring for multiple pesticides conducted by USGS in more recent phases of the long-term NAWQA project. EPA expects that any adjustment to SCI-GROW would be slight.

iii. *Imidacloprid-specific data*. EPA has received and reviewed two prospective ground water studies for imidacloprid (Refs. 43 and 45). Such studies are designed to measure maximum concentrations of pesticides likely to occur in ground water under geological conditions vulnerable to ground water contamination. The studies were conducted in Montcalm County, Michigan and Monterrey County, California.

At the Michigan study site, imidacloprid parent was consistently detected in one of six monitoring well clusters in the treated field beginning about 500 days after application and continuing through the close of the study some 5 years after application. No degradation products were detected in ground water during this period (there were a very few detections before application that may have been due to previous uses nearby or sample contamination). The maximum concentration of imidacloprid parent detected in ground water in any one sample at the Michigan study site was 0.24 ppb. EPA concluded that the 0.24 ppb level might increase slightly over time as imidacloprid continues to leach into ground water; however, the level was not expected to increase dramatically given that the levels seen at the 3 and 12 foot soil depths was 1.63 ppb and 1.31 ppb, respectively. (Ref. 43)

Data from the California site is less useful due to the fact that there appears to have been very little ground-water recharge occurring during the course of the study as evidenced by the almost complete lack of detection of the bromide tracer (applied concurrently with imidacloprid) in ground water. The maximum combined residue of imidacloprid parent and degradates found in the suction lysimeters was 0.62 ppb at 633 days post application. The maximum combined imidacloprid residue in the ground water at the California site was 0.14 ppb found 149 days post application. EPA concluded that low (sub-ppb) level contamination of potable ground water might occur in this region following application to irrigated vegetable or fruit crops. Id.

Additionally, extensive ground water monitoring data that has recently been submitted from the New York State Department of Environmental Conservation, Division of Solid and Hazardous Materials for Nassau and Suffolk Counties of New York includes data on imidacloprid. Nassau and Suffolk counties have ground water that is exceptionally vulnerable to pesticide contamination and have a long history of a number of pesticides being banned from use in these counties over the years. This exceptional vulnerability to contamination is due to the very rapid infiltration of pesticides that occurs in the sandy soils present in the agricultural areas of Long Island and the tendency for pesticides to persist in the ground water. These conditions have been documented from many years of monitoring ground water in this area (many of early detections for pesticides that were subject to scrutiny for ground-water contamination in the 1960s and 1970s were from Long Island. (Ref. 26).

For imidacloprid, there have been about 27 detections of imidacloprid above a detection limit of 0.2 ppb in about 5,000 ground water samples taken by the Suffolk County Department of Health Services, to date, with much of the monitoring targeted to areas with known histories of imidacloprid use and previously documented ground-water contamination issues. Overall, imidacloprid detections are rare in drinking water wells. Three wells had detections above the model-predicted maximum of 1.4 ppb. After closer investigation, however, EPA has concluded that those three wells are not reliable indicators of imidacloprid

values that can be expected in ground water from agricultural use of imidacloprid. The first of these wells is a private well in Mattituck, Long Island in which imidacloprid was found at a level of 6.69 ppb. An investigation by the New York authorities, however, concluded that these high levels were due to misuse of the pesticide in a greenhouse adjacent to the well where imidacloprid contaminated water was drained onto the ground in the immediate vicinity of the well. The second well was one of five shallow monitoring wells installed directly down gradient from imidacloprid use sites for the purpose of monitoring pesticide levels. One of those wells, ''Jamesport B-2'', showed levels of imidacloprid as high as 2.06 ppb. It was discovered, however, that this well was in all likelihood contaminated as a result of a manmade sump nearby that was constructed to alleviate ponding in the field and directly connected surface water to ground water. Imidacloprid was detected in only one of the other five wells, and the level of imidacloprid detected in the other well did not exceed 0.24 ppb. Finally, imidacloprid has been detected in shallow ground water wells directly downgradient from a site investigating use of tree injection treatments of imidacloprid. The highest level of imidacloprid found in these wells was 3.9 ppb. These wells, however, are not representative of wells used to supply ground water for drinking water. The wells were screened at extremely shallow depths (screens beginning only 4 to 10 feet from surface) due to the fact that the depth to ground water averaged about five feet. It was concluded that these wells are ''no more representative of what would likely occur in drinking water supplies than pesticide concentrations in samples taken from a weir draining an agricultural field are representative of what would occur in a community water supply drawing from a river or reservoir downstream.'' (Ref. 43)

iv. *Conclusion*. Based on the above analysis of EPA's drinking water models, EPA concludes that they are based on reliable data and have produced estimates that EPA can reliably conclude will not underestimate exposure to pesticides in drinking water. The model estimates EPA used for assessing the aggregate exposure to imidacloprid (37.6 ppb for acute and 17.52 ppb for chronic from the FIRST surface water model) are substantially higher than any actual data on imidacloprid residues in drinking water including the imidacloprid prospective ground water study and even the extraordinary and unrepresentative values seen in ground water on Long Island as a result of pesticide misuse, a direct connection between ground water and surface water, or extremely shallow ground water.

5. *Missing exposure data - specific*—a. *Information on regional consumption*. NRDC contends that, for imidacloprid, EPA relied on estimates of national consumption of blueberries and not regional or state-specific data for its granting tolerances in connection with the approval of emergency exemptions under FIFRA for use of the pesticide on blueberries in the States of New Jersey and Michigan. NRDC argues that the fresh nature of the food and the potential for heavy local consumption with a strong seasonal component strongly suggests that national consumption data may underestimate consumption in localized areas in New Jersey and Michigan.

EPA is confident that the methodologies used in its estimation of exposure and the percentile of regulation selected do not systematically underestimate exposures to major identifiable subpopulations. This is based, in part, on the extensive food consumption survey data from USDA (its Continuing Survey of Food Intake by Individuals or CSFII) which surveyed more than 20,000 individuals from all States and results in more than 40,000 unique person-days of consumption. EPA notes that, contrary to the assertion by NRDC, consumption is not averaged throughout the year, but instead the CSFII includes each reported consumption amount in the form of a frequency distribution of actual reported single-day consumptions. Each individual consumption event thus can be considered separately when such consideration is appropriate to risk assessment as for risk assessments estimating acute risks.

Accordingly, the CSFII survey is adequate to capture the high-end consumers about which NRDC raises concerns. The survey is statistically designed to be representative of the U.S. population and reflects variability in consumption over all seasons and geographic regions. Due in part to this design and the fact that fresh blueberries are widely available in season in states where they are not grown, EPA does not believe that the high-end consumption estimates present in the USDA CSFII survey materially or systematically underestimate the consumption patterns of consumers in blueberry-producing states (either overall or during harvest and other ''high-availability'' seasons). (Ref. 52).

It should be emphasized that in objecting to EPA's reliance on this scientifically designed consumption survey, NRDC has offered nothing other than speculation to support its claim that EPA is underestimating blueberry consumption. For this reason alone, NRDC's argument lacks merit.

For the reasons detailed above, NRDC's allegations concerning blueberry consumption do not indicate that EPA has underestimated exposure of consumers in Michigan and New Jersey to imidacloprid. NRDC's objection to the children's safety factor decision on this ground, therefore, is without merit.

b. *Residential exposure information*. NRDC claims that EPA failed to include several residential exposure scenarios in its aggregate exposure estimate for imidacloprid based on low toxicity. Imidacloprid Objections at 16. Previously, EPA had concluded that certain residential exposure scenarios did not present any significant risk either because the toxicity data did not reveal any relevant adverse effects for the duration of exposure in question (intermediate-term exposure for all population groups) or because imidacloprid exposure was not expected for a particular population group (short-term adult exposure). See 66 FR at 56229, 56231. On October 8, 2002, however, the Health Effects Division (HED) Hazard Identification Assessment Review Committee (HIARC) re-reviewed the hazard and exposure database for imidacloprid and established additional endpoints. Endpoints were chosen for each of the following exposure scenarios: acute dietary, chronic dietary, short-term oral, intermediate-term oral, short-term dermal, intermediate-term dermal, long-term dermal, short-term inhalation, intermediate-term inhalation, and long-term inhalation. Additionally, it was concluded that short-term exposure was likely for adults by the dermal and inhalation route. Oral exposure for adults is not expected from the residential uses for imidacloprid (e.g., turf, ornamental, pets) because adults do not generally engage in the type of hand-to-mouth behavior that can produce such pesticide exposure in young children. Accordingly, an aggregate risk assessment for short-term dermal and inhalation exposure for adults was conducted. 68 FR 61624, 61632 (October 29, 2003). Intermediate-term risk assessments (i.e. risk assessments that aggregate exposure from food, water, and residential exposures for comparison to intermediate risk endpoints) were not conducted because, based on residential application

practices and the half-lives observed in the turf transferable residue study, residential exposures to imidacloprid are not expected to be continuous for periods of 30 to 90 days. 68 FR at 61632; (see Ref. 44 at 51).

c. *Prospective ground water monitoring studies*. As discussed above, these studies have been received and reviewed. The levels of imidacloprid found in ground water were below the levels from modeling used to calculate aggregate exposure.

6. *Missing risk assessment*. NRDC claims that a short-term residential risk assessment is missing as to imidacloprid. Imidacloprid Objections at 5. EPA would note, however, that such a risk assessment was conducted and is summarized on pages 39,046 and 39,047 of the **Federal Register** notice. 67 FR 39041, 39046-39047 (July 21, 1999). See also 68 FR 61624, 61632 (October 29, 2003).

7. *Conclusion on children's safety factor issues*. In the challenged tolerance action, EPA applied an additional safety factor of 3X to address the missing DNT study. As discussed above, that study has now been received and reviewed. Taking into account the results of that study as well as all of the arguments raised by NRDC, EPA has concluded that there are reliable data supporting removal of the additional safety factor for infants and children for all risk assessments other than the acute risk assessment relying on the acute neurotoxicity study in rats to project a safe dose in humans. As to the acute risk assessment using the acute neurotoxicity study in rats, there are reliable data supporting use of an additional 3X factor instead of 10X. See Unit VII.C.2. The 3X safety factor has been incorporated into the acute risk assessment by dividing the LOAEL from the acute neurotoxicity study by 3 in deriving the acute reference dose.

C. LOAEL/NOAEL

NRDC argues that EPA cannot legally make the reasonable certainty of no harm finding for imidacloprid because EPA has relied on a LOAEL in assessing the safe level of exposure to the pesticide. NRDC claims EPA ''cannot lawfully establish tolerances in the absence of a no-observed-effect-level (NOEL).'' Imidacloprid Objections at 18. Implicit in this argument is that EPA cannot use a no-observed-adverse-effect-level (NOAEL) in making a safety finding. In later objections, NRDC confirmed that in fact it was contending that section 408's safety standard does not permit EPA to rely on a NOAEL in concluding a tolerance is safe. Rather, according to NRDC, EPA may only make a safety finding for a pesticide where EPA has determined the dose in animals at which no effects, adverse or otherwise, are elicited from exposure to the pesticide. Isoxadifen-ethyl Objections at 17-18. Below EPA identifies the flaws in NRDC's generic argument concerning LOAELs and NOAELs and addresses the pesticide-specific concerns NRDC raises with regard to use of a LOAEL as to imidacloprid.

1. *Generic legal argument*. EPA believes that it can make a reasonable certainty of no harm finding based on a LOAEL from an animal study (where no NOAEL was found) in appropriate circumstances. Whether or not a reasonable certainty of no harm finding can be made when only a LOAEL is identified in a study depends on whether EPA has sufficient toxicological evidence to estimate with confidence a projected NOAEL that is unlikely to be higher than the actual NOAEL. Typically, when a LOAEL but not a NOAEL has been identified by a study, EPA will, when the data support it, project a NOAEL for that study by dividing the LOAEL by a factor, usually 3X.

There is nothing in the statutory safety standard explicitly addressing the use of NOAELs or LOAELs. Moreover, nothing in the phrase ''reasonable certainty of no harm'' legally precludes use of LOAELs to make a finding regarding the likelihood that harm will occur at a given dose. Whether a LOAEL provides a sufficient basis for a reasonable certainty of no harm finding is a question of scientific fact.

NRDC correctly notes that the House Commerce Committee indicated that its ''expect[ation]'' was that EPA would be able to make a reasonable certainty of no harm finding where there was an ample margin of safety between exposure levels and -

> the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined ''no observable effect'' level when data are extrapolated from animal studies.

H. Rep.104-669, pt. 2 , 41 (1996). Congress' expectation, however, that a reasonable certainty of no harm finding could be made under one set of circumstances (100-fold safety factor applied to the ''no observable effect'' level), certainly does not preclude the finding being made in a different set (e.g., 300-fold safety factor applied to the lowest observable effect level). Moreover, Congress made clear that it was adopting the reasonable certainty of no harm standard based on EPA's ''current application of the standard.'' Since the passage of FFDCA section 409 in 1958, both FDA and EPA have a long history of applying that standard. In no instance, has either agency indicated that reliance on LOAELs, although it has been an accepted practice generally, (See Ref. 12) was barred by the reasonable certainty of no harm standard. To the contrary, EPA has relied on LOAELs to make reasonable certainty of no harm findings under section 409. (See 61 FR 33041 , 33042 (June 26, 1996) (establishing food additive regulation for flutolanil); 55 FR 23736 (June 12, 1990) (establishing food additive regulation for pirimphos methyl). In fact, FDA and EPA interpreted the reasonable certainty of no harm standard to permit a safety finding to be made in circumstances where a NOAEL cannot be identified - that is, when a substance is believed not to have a threshold below which no adverse affect will result - and the House Commerce Committee in its Report on the FQPA specifically recognized and approved that approach. Id. Thus, the legislative history, if anything, supports the proposition that a LOAEL may provide a sufficient basis for a reasonable certainty of no harm finding.

EPA also rejects NRDC's argument that a safety finding for a threshold effect can only be made based on a ''no observed effect level'' (NOEL) as opposed to a ''no observed adverse effect level'' (NOAEL). EPA's Office of Pesticide Programs (''OPP'') in a response to comment document has explained the Agency's reasoning. Although noting the House Commerce Committee Report uses the term ''NOEL'', OPP concluded that:

> the legislative history does not indicate that Congress intentionally used the term NOEL because it did not think it appropriate for OPP to consider the NOAEL. H. Rept. 104-669, 104th Cong., 2d Sess. 41 (1996). In fact, Congress appears to have assumed NOELs are NOAELs. For example, in defining ''threshold effect'' Congress stated that this ''is an effect for which the Administrator is able to identify a level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health.'' Id. (emphasis added). If Congress had intended that threshold effects be based on NOELs rather than NOAELs, it would not have used the word ''harm'' in defining the effect.
>
> Congress seems to have used the term NOEL because it was common usage for OPP at the time FQPA was passed. However, prior to 1998, in OPP's discussion of the hazard identification process of evaluating pesticide toxicity, the term NOEL was used to describe

the dose level at which no significant adverse effects were noted. OPP's terminology was not consistent with the rest of the Agency, as illustrated in EPA's Integrated Risk Information System (IRIS). This system included more hazard terms than OPP generally employed, including NOAEL, LOAEL, and FEL (Frank Effect Level). On September 2, 1998, this apparent semantic inconsistency was eliminated by HED Standard Operating Procedure (SOP) 98.3 which indicated that OPP would commence using the terms NOAEL and LOAEL in their scientific reviews and documents. It also stated, ''In a practical sense, the terms NOEL and NOAEL have been used interchangeably in OPP. As a general rule, OPP would consider as appropriate for hazard identification and risk assessment only those effects which are adverse or potentially adverse. This inclusion of the term NOAEL should not change any of our hazard endpoints for regulation but add to the quality of the risk assessment.'' (Ref.47 at 165-166)

NRDC claims that only by relying on a NOEL can the Agency legally make the required reasonable certainty of no harm finding. Isoxadifen-ethyl Objections at 17-18. Yet, NRDC's legal argument here both ignores the language of the statute and relies on unsupported factual generalities. NRDC asserts use of a NOEL is required because only by use of a NOEL is ''the risk assessor [] assured that regulatory decisions are based on a dose at which no effect is elicited.'' Isoxadifen-ethyl Objections at 17 (emphasis added). The statute, however, defines the safety standard in terms of protecting against ''harm,'' not ''effects.'' NRDC also argues that the ''adverse'' effects used to define NOAELs are ''crude toxicological endpoints,'' and that ''a NOAEL may represent a dose high enough to elicit significant unpleasant and harmful effects . . . .'' Id. NRDC, however, provides no data or explanation to support such assertions. EPA believes it applies the NOAEL standard in a way that takes into account sensitive indicators of adverse effects. EPA's use of cholinesterase inhibition as an adverse effect is only one example of this. (Ref. 50). In any event, general claims about the non-protectiveness of NOAELs are insufficient to contest a specific finding of safety by EPA. An objector must explain why the specific safety finding, taking into account its component parts (e.g., the NOAEL or LOAEL identified, the safety factors used), does not provide a reasonable certainty of no harm. NRDC has not even attempted to make this case with regard to the NOAELs used in making the safety finding for imidacloprid.

2. *Use of LOAELs to assess imidacloprid risk.* NRDC asserts that EPA relied upon a LOAEL in assessing both acute and chronic toxicity to imidacloprid. Imidacloprid Objections at 18. NRDC is mistaken as to chronic toxicity. In assessing chronic risk, EPA set the RfD using the NOAEL of 5.7 mg/kg/day based upon thyroid effects at the next highest dose of 16.9 mg/kg/day in the imidacloprid combined chronic/carcinogenicity study in rats. 64 FR 39041, 39044 (July 21, 1999); see Imidacloprid Risk Assessment at 26, Table 4. The acute toxicity endpoint was based upon a LOAEL of 42 mg/kg/day from an acute neurotoxicity study in rats. This value was adjusted with a safety factor of 3X to approximate the value of a NOAEL. EPA has high confidence that this value of 3X is sufficient for several reasons. First, the LOAEL (42 mg/kg) from the acute neurotoxicity study is comparable to the LOAELs seen in adults in the developmental rat study (30 mg/kg/d) and the two-generation reproduction study (47/52 mg/kg/d (male/female)) and in the offspring in the DNT study (55 mg/kg/d). Second, the extrapolated NOAEL of 14 mg/kg (42/3 = 14) is comparable to the NOAEL of 20 mg/kg/d established in the offspring in the DNT. Importantly, the LOAEL in DNT study like the acute neurotoxicity study was based on decreased motor activity, and the DNT established a clear NOAEL for that effect. Finally, the neurotoxic effects on motor activity in the acute neurotoxicity study showed a good dose response which resulted in minimal effects on motor activity and locomotor activity at the LOAEL.

D. Aggregate Exposure

1. *Worker exposure.* EPA has interpreted ''aggregate exposure'' to pesticide residues not to extend to pesticide exposure occurring at the workplace based on the language in section 408(b)(2)(D) explaining what exposures are included in the term ''aggregate exposure:''

> [T]he Administrator shall consider, among other relevant factors . . . 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 the dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources . . . .

This language quite plainly directs EPA to limit consideration of aggregate exposure of pesticide residues and other related substances to those exposures arising from non-occupational sources. NRDC's claim that EPA erred by not considering worker risks in making tolerance decisions under section 408 runs afoul of Congress' explicit mandate that such exposures not be included. Although there is some ambiguity as to precisely how the factors listed in section 408(b)(2)(D) relate to the safety finding described in section 408(b)(2)(A)(ii), for the reasons set forth below, NRDC's interpretation of the statutory language is unreasonable.

NRDC argues occupational exposures must be considered because the general safety standard as set forth in section 408(b)(2)(A)(ii) describes ''aggregate exposure'' broadly without any exclusion for occupational exposures. This reading, however, renders section 408(b)(2)(D)'s limitation of aggregate exposure to ''non-occupational'' exposures without effect. Three important principles of statutory construction suggest that such an approach is insupportable. First, the language in the statute should be construed in a manner that accords meaning to all provisions. *United States* v. *Menasche*, 348 U.S. 528, 538-539 (1955) (''It is our duty to give effect, if possible, to every word, clause and sentence of a statute.'') It is not lightly presumed that Congress enacted a meaningless or superfluous provision. *Asiana Airlines* v. *FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998) (''A cardinal principle of interpretation requires us to construe a statute 'so that no provision is rendered inoperative or superfluous, void or insignificant.'''). EPA's interpretation gives meaning to the occupational exposure exclusion in section 408(b)(2)(D). Second, and similarly, statutory language should be construed in a harmonious fashion to the greatest extent possible. *Citizens to Save Spencer County* v. *EPA*, 600 F.2d 844, 871 (D.C. Cir. 1979) (''[T]he maximum possible effect should be afforded to all statutory provisions, and, whenever possible, none of those provisions rendered null or void.'') ''The cardinal principle of statutory construction is to save and not to destroy.'' *Menasche*, 348 U.S. at 538. Although EPA's interpretation does not relieve all potential tension between section 408(b)(2)(A)(ii) and section 408(b)(2)(D), NRDC's approach treats the two sections as directly contradictory, negating the specific language in subsection (b)(2)(D)(vi) pertaining to occupational exposure. Third, specific language should control over general. *Ohio Power Co.* v. *FERC*, 954 F.2d 779, 784 (D.C. Cir. 1992) (''Of course, it is black letter law that when a conflict arises between specific and general provisions of the same legislation, the courts should give voice to Congress's specific articulation of its policies and preferences.'') Hence, the more detailed

explanation in section 408(b)(2)(D) concerning the scope of aggregate exposure should be relied upon to help to provide a harmonious construction of the two sections.

NRDC, pointing to the ''among other relevant factors'' language in section 408(b)(2)(D), objects that this section should not be viewed as controlling because this section is intended to be ''illustrative'' and not ''exhaustive.'' EPA fully agrees that section 408(b)(2)(D) was not intended to list exhaustively all of the considerations appropriate to making safety determinations under section 408, but cannot accept the proposition that the ''other relevant factors'' language somehow undoes the express limitation in subsection (b)(2)(D)(vi) concerning occupational exposure. Not only does NRDC's approach once again fail to give meaning to the occupational exposure exclusion in subsection (b)(2)(D)(vi) but it fails to take into account Congress' directive that EPA could consider ''other relevant factors.'' When used in this fashion, the word ''relevant'' restricts EPA to considering factors that are relevant to the safety determination under section 408(b) - that is, relevant to whether a pesticide's aggregate exposure meets the reasonable certainty of no harm test. Presumably, Congress provided an important reference point for determining relevance by the long list of factors it required that EPA consider. Relevance, moreover, is indicated not only by the factors that Congress included but by the aspects of those factors that Congress expressly directed were not to be considered. Thus, EPA believes that Congress, by excluding occupational exposures from the term ''aggregate exposure'' in subsection (b)(2)(D)(vi) was, in effect, determining the relevance of occupational exposure to aggregate exposure and the safety determination under section 408.

Finally, NRDC has argued, in a Petition which it has appended to its objections, that even if worker exposure generally is excluded from aggregate exposure, ''*in utero*'' exposures resulting from the presence of pregnant women in the workplace should not be excluded from consideration. NRDC, Petition for a Directive that the Agency Designate Farm Children as a Major Identifiable Subgroup and Population (1998). NRDC points to the statutory language directing EPA to consider ''*in utero*'' exposures and cases under state worker compensation statutes that have held that children who are injured ''in utero'' as a result of their mother's employment are not barred by worker compensation schemes from bringing an action against the employer. These cases have held that the bar to seeking a tort remedy against the employer applies only to ''employees'' and an *in utero* fetus is not an employee. See, e.g., *Snyder* v. *Michael's Stores, Inc.,* 945 P.2d 781 (Calif S.Ct. 1997).

Although the statutory language on this issue may permit multiple readings here, EPA believes it is reasonable to exclude workplace exposures to the in utero fetus from aggregate exposure. EPA is not suggesting that the fetus is an employee - the issue involved in the worker compensation cases cited by NRDC. The language of section 408 is significantly different than worker compensation statutes. Section 408 does not bar consideration of exposure to ''employees'' but rather exposure from ''occupational sources.'' Given this statutory language EPA believes it is reasonable to focus upon whether the exposure is principally due to exposure in an occupational setting or not. An exposure to a fetus that results from the fetus' mother's presence in an occupational setting would fall well within this approach. This interpretation also makes sense in terms of the overall statutory scheme. Presumably, Congress excluded occupational exposures from section 408 because it determined that acceptable levels in food for the general public should not be set using the discrete, and highly regulated (including regulation by EPA under FIFRA), exposures occurring in the workplace as an assumed underlying exposure. If occupational exposure to pregnant women is included in aggregate exposure under section 408, however, occupational exposure will invariably be an aspect of the section 408 safety finding for pesticides involved in agriculture or other commercial enterprises because EPA would generally have to assume that pregnant women may be in the workforce.

2. *Classification of farm children as a major identifiable population subgroup.* NRDC points out that FFDCA section 408 directs EPA to consider not just the general population in assessing aggregate exposure but also ''major identifiable subgroups of consumers.'' 21 U.S.C. 346a(b)(2)(D)(vi). In this regard, NRDC argues that children living in agricultural communities should be treated as such a major identifiable subgroup. These children are an identifiable subgroup, according to NRDC, because of the allegedly heightened exposure to pesticides that they receive due to their proximity to farm operations and farm land and, for some, due to their contact with parents involved in agriculture. Isoxadifen-ethyl Objections at 11-12. NRDC claims these children comprise a ''major'' subgroup citing statistics showing that ''320,000 children under the age of six live on farms in the United States[], . . . many hundreds of thousands of children play or attend schools on or near agricultural land, . . . [and] [t]he nation's 2.5 million farm workers have approximately one million children living in the United States.'' Id.

Whether or not EPA attaches the label ''major identifiable subgroup'' to farm children, EPA's risk assessment approach to children, including the major identifiable subgroups of children used in its risk assessments, adequately takes into account any pesticide exposures to children - whether as a result of living close to agricultural areas or otherwise. For some time, EPA has treated infants and children grouped by ages (e.g., infants younger than 1 year, children 1 - 2 years) as major identifiable subgroups. These age groupings have been chosen to reflect different eating patterns of the age groups. In evaluating exposure to these or any other subgroup, however, EPA considers the range of exposures across the subgroup not just as a result of pesticide residues in food but from all non-occupational exposures. If a significant number of any of the population subgroups of children have higher exposures due to a non-food source (e.g., residential uses of a pesticide, proximity to agricultural areas), EPA believes that that exposure is appropriate to consider in evaluating the range of exposures for the subgroup. The fact that the children in the subgroup receiving the higher exposures are not themselves labeled a major identifiable subgroup in no way lessens EPA's consideration of their exposures. This approach is nicely illustrated by the imidacloprid risk assessment.

In the imidacloprid risk assessment, EPA not only considered imidacloprid exposure from food but also exposures resulting from use of imidacloprid on lawns and pets. The residential use scenario that produced the highest estimate of exposure was a toddler hugging the pet right after imidacloprid treatment. In evaluating aggregate exposure to toddlers (children 1-2 years-old), EPA aggregated imidacloprid exposure from the pet hug scenario with imidacloprid exposure from food and water. This was done even though (1) children living with pets capable of receiving a full body hug are not designated a major identifiable subgroup; (2) it is likely that only a minority of the children in the age subgroup of 1-2 years-old live with pets

of this size; and (3) the number of 1-2 year-old children that may actually experience the exposures estimated by the pet hug scenario is likely to be exceeding small. Similar to the manner in which residential exposure was incorporated in the aggregate exposure assessment, if EPA had information showing meaningful exposure to children as a result of living close to agricultural areas, those exposures would receive full consideration in assessing aggregate exposure to the existing children's subgroups. Thus, the fact that EPA has not labeled farm children as a major identifiable subgroup has not in any way affected EPA's consideration of exposures that are unique to farm children. For the reasons discussed in the Units VII.A. and VII.D.4, however, EPA concludes that its exposure assessment has adequately considered any potentially greater exposures to children in agricultural areas.

That being said, EPA does not believe that NRDC has made an adequate case that the group of children NRDC designates as ''farm children'' are an identifiable group. Many of the commenters protested NRDC's designation of ''farm children'' as a major identifiable subgroup, noting the heterogeneous nature of the group and NRDC's lack of precision in defining the group. To be sure, NRDC's suggested subgroup is constructed differently than EPA's historical practice with regard to population subgroups. That practice has focused on categorizing individuals by age, ethnicity, and region of the country. Similarly, NRDC is, in fact, far from precise in defining the limits of the suggested subgroup. For example, NRDC does not clarify whether urban or suburban children on the borders of areas that exist side-by-side with agricultural areas should be included in the alleged subgroup, or whether it would include in the subgroup children in agricultural areas who might live no closer to application sites than some urban or suburban children.

Moreover, several of the reports submitted by NRDC undermined its contention that farm children are an identifiable subgroup based on exposure. The CFPR Report, for example, in a number of places highlights the degree to which, not only farm-area residents, but also urban and suburban residents are exposed to pesticides. The asserted exposures suffered by urban dwellers, moreover, include spray drift not only from urban area applications (e.g., from home and garden applications, as well as other structural applications), but long-range spray drift from agricultural area applications. These aspects of the report run counter to NRDC's suggestions that: (1) farm children are a major subgroup that receives greater exposure than non-farm children; and (2) farm children are a major identifiable subgroup, in that the lines in the report between farm area children and non-farm-area children exposed to agricultural spray drift are blurred.

In addition, although in places the CFPR Report cites to studies purportedly showing that farm children suffer more exposure to pesticides than other children, on account of spray drift, it largely relies on the Washington State studies discussed above. For reasons already mentioned, the Agency does not believe that those studies support the designation of farm children as a major identifiable subgroup.

The Ranking Study, for its part, also emphasized that ''an increasing number of children live along the nation's agricultural-urban edge.'' As discussed above, this phenomenon clouds the potential for a distinction between farm and non-farm children. Moreover, the authors of the study identified ''[n]otable uncertainties'' in their risk assessment, and would go only so far as to suggest that ''farmworker/farm children'' constitute a subgroup ''potentially at higher risk.'' Thus, it, too, fails to support the identification of farm children as a major identifiable subgroup, as distinguished from children generally.

NRDC also alleges that farm children have ''unique . . .sensitivities to exposure'' that must be considered by EPA. Imidacloprid Objections at 11-12. NRDC, however, cites no unique toxicological sensitivities of farm children but rather focuses on the allegedly unique exposure patterns of farm children. At most, NRDC points to the fact that children generally may be more toxicologically sensitive than adults because their internal organs and bodily processes are still developing. Id. at 13. But the fact that children may have different toxicological sensitivities than adults does not support any claim regarding differences in sensitivities between children generally and farm children.

In sum, the above studies and information, whether concerning children in agricultural areas and non-agricultural areas or children in agricultural areas alone, and whether concerning environmental levels, biological levels, or both, provide no sufficient basis for designating ''farm children'' as a major identifiable subgroup. It thus was reasonable for EPA to assess aggregate exposure to the challenged pesticide tolerances without identifying farm children as an additional major identifiable subgroup of consumers. EPA's approach, described above, of examining the range of exposures in each of the age-based subgroups of children is adequately protective of children to the extent they experience higher exposures from proximity to agricultural areas.

3. *NRDC's 1998 petition on farm children.* As previously mentioned, NRDC petitioned EPA in 1998 to designate farm children as a major identifiable subgroup under section 408 and take several other various steps regarding farm children's exposure to pesticides. For the reasons stated above, EPA does not believe it is appropriate to designate farm children as a major identifiable subgroup although, as indicated, EPA will consider reliable data on the range of pesticide exposures received by children, including data pertaining to such issues as spray drift, volatilization, and farmworker take-home exposures that were raised by the 1998 petition.

The 1998 petition also requested that EPA: (1) retain the additional 10X safety factor for the protection of children where EPA lacks data on farm children exposure; (2) make specific determinations as to the exposure of farm children from all pathways; (3) require data from registrants where data is lacking on farm children's exposure and not issue a tolerance until such data is submitted; (4) refuse to register a new pesticide unless a validated scientific method is available to detect residues of the pesticide in food; (5) increase research into exposures and health status of farm children; and (6) honor the Executive Order on environmental justice.

As explained above, EPA has initiated a myriad of different research and outreach programs concerned with pesticide exposure to farmworkers and their families. The most important of these include, on the research front, EPA work with the National Agricultural Workers Survey (NAWS), and the Agricultural Health Survey (AHS). In terms of outreach, EPA has many ongoing programs, but would like to highlight two projects in particular. The Agency's work with the Association of Farmworker Opportunity Programs (AFOP), and its work on the National Strategies for Health Care Providers: Pesticide Initiative.

Through the Agency's cooperative agreement with the Association of Farmworker Opportunity Programs (AFOP), EPA funds the National Pesticide Safety Education Program for agricultural workers and farm worker children. Working with Americorps

members, AFOP trains 25,000 farm workers and farm worker children every year about pesticide safety using Americorps members in over 50 sites in 16 states. AFOP conducts pesticide safety training for children at childcare centers, schools, churches, and community centers, and has developed a handbook in Spanish. The National Strategies for Health Care Providers: Pesticide Initiative is an initiative created by the EPA and the National Environmental Education and Training Foundation (NEETF) in collaboration with the U.S. Departments of Health and Human Services, Agriculture and Labor. It is aimed at incorporating pesticide information into the education and practice of health care providers. The goal is to improve the recognition, diagnosis, management, and prevention of adverse health effects from pesticide exposures. This initiative also serves as a model for broader efforts to educate health care providers about the spectrum of environmental health issues. Seven federal agencies and 16 professional associations of health care providers were involved in launching this initiative. These actions address the Petition's request regarding increased research and fidelity to the Executive Order on Environmental Justice.

EPA agrees that where additional data are needed to characterize farm children's exposure to a specific pesticide it will retain the additional 10X safety factor unless reliable data exist that support selection of a different safety factor. Further, EPA will seek additional data on farm children exposure where necessary. Any decision on whether to approve a tolerance where additional data has been required will have to be a case-by-case determination considering other data that is available on the pesticide and the ability of use of additional safety factors to address any uncertainty raised by the requested data. As to making specific findings on all possible pathways of exposure to farm children, EPA will follow a pesticide-specific approach which considers both the generic information and pesticide-specific information in regards to whether a particular pathway has the potential for significant exposure. Finally, EPA agrees that it should not register a new pesticide for use on food unless it has approved an analytical method for detecting the level of pesticide residues in food or found that such a method is unnecessary.

4. *Adequacy of EPA's assessment of the aggregate exposure of children, including children in agricultural areas.* EPA believes that it has adequately assessed the aggregate exposure of children to imidacloprid generally (including both farm children and non-farm children), through its assessment of exposure through food, drinking water and residential use pathways. In support of its objection to this assessment, NRDC cites numerous studies for the proposition that other pathways (e.g., track-in) increase farm children's exposures, and it also cites information purportedly suggesting that volatilization and spray drift lead to higher exposures among farm children. For reasons discussed above, however (see Unit VII.A.), EPA does not believe that this information demonstrates that the pathways asserted, to the extent they exist, lead to farm children experiencing imidacloprid exposure levels higher than those experienced by other children. Rather, these studies are inconclusive, and suggest that farm children and non-farm children generally receive similar levels of exposure. Nor does the information bearing on volatilization and spray drift demonstrate that farm children receive greater imidacloprid exposures through these two additional pathways. For example, as stressed above, imidacloprid exposures due to residential and pet uses common to farm and non-farm areas would dwarf any exposures that might be attributable to either volatilization or spray drift in agricultural areas.

5. *Residential exposure as a result of use requiring a tolerance.* NRDC also argues that EPA has erred in not including the added residential exposure that occurs in the home when an additional agricultural use is added. The reasons explained above as to why any additional exposure to children as a result of their proximity to farming operations is expected to be insignificant as regards imidacloprid apply with equal or more force as to this contention.

6. *Population percentile used in aggregate exposure estimates*—a. *In general.* NRDC contends that EPA in making the reasonable certainty of no harm finding must make such a finding as to ''all children'' - that is, EPA must find that ''no children will be harmed'' by exposure to the pesticide. Although EPA is somewhat uncertain as to precisely what approach to risk assessment and safety findings NRDC is advocating, EPA believes that its approach to implementing the reasonable certainty of no harm standard is consistent with the statutory framework. As specified in the statute, EPA focuses its risk assessment and safety findings on major identifiable population subgroups. 21 U.S.C. 346a(b)(2)(D)(vi). For children EPA has identified the following subgroups: nursing infants (0-6 months); non-nursing infants (6 months - year); 1-2 year-olds; etc. EPA evaluates each of these subgroups to determine if it can be determined that there is a reasonable certainty of no harm for individuals in these subgroups. (See Ref. 48 at 46 and Ref. 51 at 14)

b. *Choice of population percentile.* NRDC asserts that EPA erred by allegedly making its safety decision as to the acute risk posed by imidacloprid based on only a portion of the population, leaving the rest of the population unprotected. According to NRDC, EPA only considered 95% of the affected population. EPA admits using the population percentage cited by NRDC in estimating acute exposure for imidacloprid. EPA most definitely was not, however, acting in a manner designed to only protect 95% of the population. To the contrary, EPA's exposure estimates were designed to capture the full range of exposures in each population subgroup.

As explained in its science policy paper on this subject, EPA, in estimating acute exposure for population subgroups, generally considers various population percentiles of exposure between 95 and 99.9, depending on the extent of overestimation in the residue data used in the assessment.(See Ref. 52) In each exposure assessment EPA is attempting to reasonably estimate the full range of exposures in a subgroup. The use of a particular percentile of exposure is a tool to estimate exposures for the entire population and population subgroups and not a means to eliminate protection for a certain segment of a subgroup. When inputs for pesticide residue values in the exposure estimate are high end (e.g., assuming all food contains tolerance level residues), a lower percentile of exposure (e.g., 95%) is thought to be representative of exposure to the overall population as well as subgroups. As increasingly realistic residue values are used (e.g., information from pesticide residue monitoring), a higher percentile of exposure (e.g., 99.9%) is generally necessary to be protective of the overall population and its subgroups.

This issue was the subject of some attention when EPA began performing probabilistic acute exposure (risk) assessments using monitoring data for residue values and increasingly used a population percentile of 99.9 to estimate exposure. Some affected parties became concerned that EPA was determining that only 99.9% of the population were entitled to protection from potentially unsafe pesticide residues. EPA

addressed this issue in a policy paper, noting that:

> just as when OPP uses the 95th percentile with non-probabilistic exposure assessments OPP is not suggesting that OPP is leaving 5% of the population unprotected, OPP is not by choosing the 99.9th percentile for probabilistic exposure assessments concluding that only 99.9% of the population deserves protection. Rather, it is OPP's view that, with probabilistic assessments, the use of the 99.9th percentile generally produces a reasonable high-end exposure such that if that exposure does not exceed the safe level, OPP can conclude there is a reasonable certainty of no harm to the general population and all significant population groups.

Id. at 31.

Other parties had the opposite concern - namely, that by using the 99.9 percentile EPA was grossly overstating exposure to the population. Interestingly for the purpose of the NRDC's claims regarding imidacloprid, EPA's analysis of the reasonableness of its exposure assessments demonstrated that exposure estimates using high end residue values and the 95th percentile of exposure were significantly greater than exposure estimates for the same pesticide relying on monitoring data and 99.9th percentile. Id. at 16-17 (citing an example showing exposure estimates over an order of magnitude lower when using 99.9th percentile with monitoring data rather than 95th percentile assuming tolerance level residues).

For imidacloprid, EPA estimated acute exposure using the gross overestimate of all crops covered by the tolerance containing residues at tolerance levels. Thus, EPA believes it acted reasonably in using the 95th percentile of exposure in estimating imidacloprid exposure to the overall population and major identifiable subgroups in making its reasonable certainty of no harm finding as to the acute risks posed by imidacloprid.

7. *Lack of residential exposure assessment for adults.* NRDC objects to EPA's decision not to conduct residential exposure assessments for adults despite the fact that imidacloprid has numerous residential uses. Imidacloprid Objections at 16. As explained in Unit VII.B.5. above, EPA has now determined that residential exposure assessments are appropriate as to short-term dermal and inhalation exposures but that other types of residential exposure are unlikely to occur (e.g., short-term adult oral exposure and intermediate-term exposure).

8. *Percent crop treated.* NRDC asserts that EPA's use of percent crop treated data pertaining to blueberries in calculating aggregate exposure for imidacloprid is in violation of the requirements specified in section 408(b)(2)(F). That section imposes certain conditions upon EPA's use of percent crop treated data when assessing chronic dietary risk. Among the specified conditions are the requirements that EPA find that ''the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue . . . [and] the exposure estimate does not understate exposure for any significant subpopulation group . . . .'' 21 U.S.C. 346a(b)(2)(F). NRDC claims that, because EPA used national percent crop treated data on blueberries even though imidacloprid use on blueberries is only permitted in Michigan and New Jersey, EPA had no ''valid basis'' for projecting the percent crop treated in those two states. Additionally, NRDC argues that use of national percent crop treated data on blueberries will ''understate exposure'' for the significant population group of blueberry consumers in Michigan and New Jersey.

NRDC's argument here is without merit because EPA assumed that 100% of the blueberries consumed in the United States would be treated with imidacloprid in conducting the imidacloprid risk assessment. Although the **Federal Register** notice explaining the basis for the imidacloprid blueberry tolerance does note that ''percent crop treated data [was] used of selected commodities,'' 64 FR 56225, 56228 (November 7, 2001), those commodities did not include blueberries. (Ref. 58; see also Ref. 44 at 43-44)

E. Lack of Emergency

In comments filed on its own objections, NRDC advances a new challenge to the imidacloprid tolerance on blueberries. This challenge is unrelated to the safety issues raised in its objections; rather, it is instead tied to the fact that this imidacloprid tolerance was established in conjunction with EPA's approval of the use of imidacloprid under section 18 of FIFRA to address an emergency situation in the state of Michigan. Section 18 of FIFRA gives EPA the authority to exempt States and Federal agencies from the requirements of FIFRA in emergencies. NRDC claims that the ''alleged'' emergency justifying the approval of imidacloprid on blueberries, and correspondingly the blueberry tolerance, does not meet the criteria for an emergency in EPA regulations.

Under EPA regulations, EPA may authorize an emergency exemption if it determines, among other things, that an ''emergency condition exists.'' 40 CFR 166.25(b)(1)(i). An ''emergency condition'' is defined as ''an urgent, non-routine situation . . . .'' 40 CFR 166.3(d). The regulations deem an emergency condition to exist when (1) no effective, registered pesticides are available to address the conditions; (2) ''no economically or environmentally feasible alternative practices which provide adequate control are available;'' and (3) the situation will cause ''significant economic loss . . . .'' Id. Applicants for emergency exemptions are required to submit information to EPA addressing these issues. 40 CFR 166.20. EPA may ''discontinue processing'' of incomplete applications, 40 CFR 166.30(a)(1), and deny an application for a information gap but must reconsider the application when the information gap is filled. 40 CFR 166.30(a)(2).

EPA first approved the State of Michigan's request for an emergency exemption for the use of imidacloprid on blueberries in July, 2001. The problem faced by growers in Michigan was that the Japanese beetle (an invasive pest introduced to the United States in 1916) was increasingly contaminating shipments of harvested blueberries. Although the beetle does not reduce the production of blueberries in the field, the presence of the beetle mixed in with harvested blueberries has resulted in wholesale rejection by fruit buyers of shipped blueberries. Purchasers, according to Michigan, follow a ''one beetle is too many'' approach. Michigan cited one instance in the prior year (2000) in which two shipments of blueberries totaling 1.7 million pounds of blueberries were rejected at the point of delivery. Looking to the future, Michigan noted that ''the three largest buyers of Michigan blueberries for yogurt production have chosen not to purchase blueberries from Michigan in 2002, because of Japanese beetle contamination in previous years.'' These buyers alone purchased 5 million pounds of the 65 million pound Michigan blueberry crop. Michigan stated that this contamination had occurred despite the addition of more workers on packing lines and investment in expensive color sorting technologies. No pesticides were then registered for control of Japanese beetle grubs in blueberries and the two products registered for control of adult Japanese beetles in blueberries are of limited effectiveness.

The basis for NRDC's challenge to EPA's conclusion that an emergency condition existed in Michigan is (1) that Michigan did not demonstrate that the ''alternative solutions [of using

additional workers or color sorting technologies] are economically or environmentally infeasible;'' and (2) that Michigan has failed to provide economic data on estimated net and gross revenues with and without the pesticide. As to whether Michigan adequately demonstrated the infeasibility of addressing the Japanese beetle problem by using additional workers or sorting technology, EPA believes that Michigan's reliance on the fact that use of these practices has in the past failed to solve the problem is an adequate demonstration. Regarding data on potential economic losses, Michigan's data was not as detailed as EPA would have preferred, but in the context of an emergency situation, providing information indicating that close to 10% of the Michigan blueberry crop had already been threatened by the lack of control of Japanese beetles (the loss of purchasers for 5 million pounds out of Michigan's 65 million pound crop) is sufficient to show a ''significant economic loss.''

In any event, this issue has no relevance to the action being taken today to establish a permanent tolerance for imidacloprid on blueberries because it is not being done in connection with an emergency exemption under FIFRA.

VIII. Response to Comments on NRDC's Objections

EPA has responded to the comments submitted that pertained specifically to imidacloprid to the extent the comments were relevant above. The only remaining comments that EPA believes are appropriate to address are the comments filed by the IWG raising legal objections to EPA's consideration of data bearing on exposure to pesticides other than through pesticide residues in food. EPA has also included a short response to the comments received from citizens and IR-4.

A. IWG Comments

To recap, the IWG's argument is based on the presence of the defined term ''pesticide chemical residue'' in the critical statutory injunctive that a pesticide tolerance is safe only if ''there is reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposures for which there is reliable information.'' 21 U.S.C. 346a(b)(2)(A)(ii). The term ''pesticide chemical residue'' is defined to mean a residue of the pesticide, or any substance present as a result of metabolism or degradation of the pesticide, ''in or on raw agricultural commodities or processed food.'' 21 U.S.C. 321(q)(2). The IWG argues that, because aggregate exposure is described only in terms of exposure to the ''pesticide chemical residue'' and a pesticide chemical residue is defined as only including residues in food, aggregate exposure must be limited to exposure to pesticide residues in food. Under this interpretation, EPA may not consider exposures from non-food sources such as residues in drinking water, or residues in or around the home from residential uses of a pesticide in making the safety determination under section 408.

In its initial construction of the FQPA, and consistently thereafter, EPA has taken a distinctly different approach to section 408's safety finding. EPA's interpretation has been that the statute requires EPA, in making a section 408 safety finding, to consider all exposures to the pesticide and related substances, whether the exposure is from food, water, or other sources, with the exception that occupational exposures are excluded. See, e.g., 61 FR 48843, 48844 (September 17, 1996) (Aggregate exposure ''includes exposure through drinking water, but does not include occupational exposure.''); 62 FR 17096, 17097 (April 9, 1997) (''In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from pesticide residue in food, including water, and all other non-occupational exposures. The aggregate sources of exposure the Agency looks at includes food, drinking water or ground water, and exposure from pesticide use in gardens, lawns, or buildings (residential and other indoor uses).''); (Ref. 62) (''EPA must now consider other non-occupational sources of pesticide exposure when performing risk assessments and setting tolerances. This includes dietary exposure from drinking water, non-occupational exposure, exposure from like pesticides that share a common mechanism of toxicity as well as other exposure scenarios.''). (Ref. 48 at 36 and Ref. 49 at 8). Since August 3, 1996, the date of the passage of the FQPA, EPA has promulgated hundreds of tolerance rulemakings and conducted thousands of tolerance reassessments based on this interpretation of the statute.

EPA's interpretation that it must consider all non-occupational exposures to pesticides and related substances under section 408 rests on the plain language of the FQPA, its statutory structure, and its legislative history. Section 408, by its very terms, in some places dictates that pesticide chemical residues being referred to are residues ''in or on food'', see, e.g., 21 U.S.C. 346a(a)(1), and yet, in other places omits this ''in or on food'' modifying language. Most notably, the ''in or on food'' qualification is omitted from the aggregate exposure provisions. See 21 U.S.C. 346a(b)(2)(A)(ii); 346a(b)(2)(C)(ii)(I); 346a(b)(2)(D)(vi). Because Congress at times paired the term ''pesticide chemical residue'' with the phrase ''in or on food'' and other times (such as in describing aggregate exposure) did not, EPA believes that Congress' usage of the term ''pesticide chemical residue'' should not be interpreted as restricted to residues in or on food unless Congress explicitly directed in its specific usage of the term ''pesticide chemical residue'' that the residue must be in or on food. Admittedly, the definition in section 201 of ''pesticide chemical residue'' as being a residue in or on food creates ambiguity as to Congress' precise intent with regard to its use of the term ''pesticide chemical residue'' in section 408. As explained below, however, EPA's interpretation is the only reasonable interpretation considering the language, structure, and history of section 408.

First, other plain language in the statute confirms the reasonableness of EPA's interpretation. On two occasions, Congress explicitly referenced other ''sources'' of exposure as being relevant to section 408's safety standard. First, in the provision addressing aggregate exposure, Congress directed that EPA consider aggregate exposure ''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)(vi) 346a(b)(2)(C) (emphasis added). Second, in expanding the protection for infants and children, Congress specified that, for the purposes of making a safety finding as to infants and children, ''an additional tenfold margin of safety for the pesticide chemical residue and other *sources* of exposures shall be applied . . . .'' 21 U.S.C. 346a(b)(2)(C)(emphasis added). Thus, Congress could not have intended that residues in food would be the only ''source'' considered in calculating aggregate exposure. The legislative history is quite clear on this point, explicitly noting that aggregate exposure includes both exposure under all tolerances for the pesticide and exposure from other sources:

> The Committee understands ''aggregate exposure'' to the pesticide chemical residue to include dietary exposures under all tolerances for the pesticide chemical residue, and exposure from other non-occupational sources.

H. Rept.104-669, Part 2, 40 (July 23, 1996)

Second, the structure of the statute confirms that considering other ''sources'' of pesticide exposure in section 408's safety determination is the only reasonable interpretation of this section. Congress required consideration of aggregate exposure not just to pesticide chemical residues but also to ''other related substances.'' 21 U.S.C. 346a(b)(2)(D)(vi). In including ''other related substances,'' however, Congress imposed no limitation that aggregate exposure to these ''other related substances'' was confined only to aggregate exposure to these substances in food. It would be unusual indeed to suggest that Congress intended that the section 408 safety determination on a pesticide tolerance be constrained in the type of pesticide exposures that could be considered (i.e., only pesticide exposures in food but not exposures from other sources such as drinking water or residential uses) but that no such limitations applied to exposures to substances related to pesticides (i.e., consider exposures to related substances from all sources including food, drinking water, and residential uses).

In contrast to the reasonable coherence between EPA's approach to interpreting what pesticide residues should be considered in making the section 408 safety determination and the language, structure, and history of the FQPA, the IWG's construction is frequently at odds with these guides to interpretation and, in the end, even if accepted fails to achieve the IWG's goal of excluding EPA's consideration of pesticide residue sources other than food.

The IWG's narrow approach to aggregate exposure cannot explain both the statute's and legislative history's references to other ''sources'' of exposure. The IWG's position is that Congress' reference to ''other non-occupational sources'' is a reference to dermal exposure to pesticides from handling of food containing pesticide residues during food preparation. Yet, exposure to pesticides from food handling does not constitute a different source of pesticide exposure than consumption of food bearing pesticide residues. In either case, the source is the food. Further, strictly following the definition of the term ''pesticide chemical residue'' introduces numerous redundancies, see, e.g., 21 U.S.C. 346a(a) (defining when a ''pesticide chemical residue in or on a food'' is unsafe); 21 U.S.C. 321(s) (where the definition of the term ''food additive'' states that it excludes ''a pesticide chemical residue in or on a raw agricultural commodity or processed food''); 21 U.S.C. 346a(o)(2) (requiring EPA to provide information to retail grocers concerning actions taken ''that may result in pesticide chemical residues in or on food . . . .''), and even anomalies into the statute. For example, if each reference in the FFDCA to ''pesticide chemical residue'' must be to a pesticide residue in a food, then under section 402(a)(2)(B), a food is only rendered adulterated by the presence of a pesticide if it is a pesticide residue that is already in a food, since to be adulterated a food must ''bear[] or contain[] a pesticide chemical residue [in or on a raw agricultural commodity or processed food] . . . .'' 21 U.S.C. 342(a)(2)(B) (bracketed language inserted from the definition of pesticides chemical residues in 21 U.S.C. 321(q)(2)). Although such an approach might be understandable as concerns prepared foods which are a mixture of different commodities, it makes no sense as to raw agricultural commodities which are, and have been, the focus of FDA monitoring efforts regarding pesticide residues in food (Ref. 20 at 3 and Appendices A and B) (''Emphasis is on the raw agricultural product, which is analyzed unwashed and whole (unpeeled).'').

Finally, the reasonableness of the IWG argument is called into question because, even if followed, it seems to make no difference in what substances are to be considered in making section 408 safety determinations. In other words, IWG's construction does not accomplish the IWG objective of limiting the safety determination under section 408 to consideration of pesticide residues in food. This is due to the fact that EPA is required to consider both exposures to ''pesticide chemical residues'' and exposures to ''other related substances.'' If pesticide residues in water, in the air, and on surfaces in and around the home or public spaces are not ''pesticide chemical residues'', they certainly would qualify under the plain meaning of the term ''other related substances.'' For if the IWG position is accepted that every substance that would qualify under the dictionary definition of a pesticide chemical residue does not actually fall within the FFDCA definition of pesticide chemical residue, it follows necessarily that non-FFDCA-qualifying pesticide chemical residues have to be some other type of substance. Further, such other substances are clearly related to FFDCA-defined pesticide chemical residues given that it is only the limiting nature of the statutory definition that keeps them from being considered the same substance. Notably, there is no language in the statute suggesting that ''other related substances'' only pertains to such substances in or on food.

EPA cannot accept the argument that, because the term ''related substances'' appears in the pre-FQPA version of FFDCA section 408 and EPA allegedly has never stated that ''related substances'' extends to substances residing in exposure sources other than food, Congress's repetition of the term ''related substances'' in the FQPA enacted EPA's supposed sub silentio interpretation of the term ''related substances'' as meaning ''related substances in food.'' Courts have found reenactment of administratively-interpreted language to be a ratification of the administrative interpretation but only in circumstances where a longstanding administrative interpretation has been affirmatively brought to Congress' attention and Congress has clearly expressed its approval. *AFL-CIO* v. *Brock*, 835 F.2d 912, 915 (D.C. Cir. 1987); accord, *Micron Technology, Inc.* v. U.S., 243 F.3d 1301, 1310-1311 (Fed. Cir. 2001). These circumstances are completely absent here. EPA had not affirmatively interpreted ''related substances'' in the manner suggested by IWG in an administrative proceeding prior to FQPA's enactment, and Congress never explicitly addressed the issue of interpretation of the term.

For all of these reasons, EPA reaffirms its contemporaneous and consistent interpretation of FFDCA section 408 as requiring consideration of all exposures to pesticide residues and other related substances other than those exposures occurring in the occupational setting. Relevant exposures include pesticide residues in food and water and exposures to pesticides around the home or in public from sources other than food and water.

Alternatively, the IWG argues that the requirement that data on ''all other exposures'' be based on ''reliable data'' precludes the consideration of exposure information regarding pesticides in drinking water and pesticides used around the home or in public spaces. EPA has repeatedly rejected this argument in the past in issuing policy statements regarding implementation of the FQPA. (See Ref. 47 at 135-155). After reviewing the IWG's latest reiteration of the argument, EPA finds no reason to differ from its earlier conclusions.

B. Citizen Comments

As mentioned above, EPA received several thousand comments from private citizens in support of NRDC's

objections. These comments, for the most part, use identical language. NRDC has urged EPA not to dismiss the citizen comments because they ''raise a wide range of issues reflecting the different ways that people are personally affected by EPA's tolerance decisions.'' (Ref. 37 at 4). EPA has considered the citizen comments but finds their significance to be limited because they contain only unsubstantiated claims regarding the harms of pesticides or general policy arguments as to why fewer pesticides should be used instead of providing reliable information pertaining to the safety standard in section 408(b)(2).

C. IR-4 Comments

EPA appreciates that, as IR-4 mentioned, imidacloprid is critical for minor crop growers and has an important role as an organophosphate replacement. Consideration of information on pesticidal benefits, however, that is often relevant under FIFRA, see 7 U.S.C. 136(bb), plays a very limited role under section 408, see 21 U.S.C. 346a(b)(2)(B), and is not applicable to pesticides such as imidacloprid which only poses threshold-type risks. 21 U.S.C. 346a(b)(2)(B)(i)(I).

IX. Regulatory Assessment Requirements

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

X. Congressional Review Act

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

XI. Time and Date of Entry of Order

For the purposes of 28 U.S.C. 2112(a), the date of issuance of this order shall be May 26, 2004.

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List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recordkeeping and requirements.

Dated: May 14, 2004.

James Jones,

Director, Office of Pesticide Programs.

[FR Doc. 04–11779 Filed 5–25–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0090; FRL–7348–1]

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of imidacloprid, and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent in or on blueberry. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 26, 2004. Objections and requests for hearings must be received on or before July 26, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0090. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 provides a guide