UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 3 1 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

VIA EMAIL AND POST

To Addressees Listed in the Enclosure to this Letter

Subject: EPA Response to "Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift"

Dear Petitioners:

Enclosed please find the Agency's response to your petition, "Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift," submitted in October 2009 on behalf of a number of health and environmental organizations.[1] As you may recall, EPA posted the petition to the public docket (www.regulations.gov, docket ID EPA-HQ-OPP-2009-0825) in November 2009 and opened a comment period that ran 120 days in its entirety. In summary, and as related more specifically in our response, the petition asked EPA to account for children's exposures to pesticide drift and volatilization in its risk assessments and to take certain steps to reduce the risks from these exposures.

On July 24, 2013, you filed a writ of mandamus lawsuit against EPA alleging that EPA had unreasonably delayed responding to the petition. The parties agreed to stay the case as long as EPA promised to issue a final response to the Petition by March 31, 2014.[2] The enclosed response fulfills that promise.

During the several years that passed between the time the petition was submitted and the present, the Agency was actively developing drift and volatilization assessment methodologies, applying those methodologies to both fumigant and conventional pesticides, and finding ways to mitigate the risks to adults and children posed by pesticide drift and volatilization.

Recently the Agency posted to the docket and solicited comments on the methodologies it has developed for assessing the risks from pesticide drift and volatilization. The comment periods

[1] The organizations were Pesticide Action Network of North America (PANNA), United Farmworkers, Pineros y Campesinos Unidos Del Noroeste, MomsRising, Sea Mar Community Health Center, California Rural Legal Assistance Foundation, Farm Labor Organizing Committee, and Physicians for Social Responsibility.

[2] In re: Pesticide Action Network North America, et al. v. EPA, No. 13-72616 (9th Circuit)

for both methodologies are open at this time (at www.regulations.gov; the docket ID for the drift methodology is EPA-HQ-OPP-2013-0676; for the volatilization methodology, EPA-HQ-OPP-2014-0219).

The enclosed response discusses background on the petition, the pending lawsuit, the statutory and regulatory framework for EPA's pesticide programs, how these programs are implemented, and how EPA assesses and manages the risks associated with pesticide use, including risks from spray drift and volatilization. The response also directly addresses the three major changes to current practices that were requested by the petitioners, that the Agency 1) assess the potential risks posed by drift and volatilization for children in places where they live and play, 2) accelerate the assessment of these potential risks, and 3) adopt uniform buffers for pesticides of special concern in the interim while the risk assessments are being conducted.

EPA shares the concerns expressed by the petitioners, and agrees that the risks from drift and volatilization must be accounted for, for both children and adults, and that action must be taken to mitigate any such risks. The Agency believes that the registration review program already in place is a timely, efficient, and effective way to assess and take action on these risks, and does not believe that imposing requirements for uniform, interim buffers is scientifically supportable or defensible. Thus the Agency grants in part and denies in part the petitioners' requests.

We thank you for your interest and for your role in advancing awareness of the risks that pesticide drift and volatilization can pose to children. We hope that you will review and provide constructive comments on the newly published assessment methodologies for addressing those risks. Should you desire further information on the Agency's approach to assessing drift and volatilization, please contact Jill Bloom of my staff, at bloom.jill@epa.gov or (703) 308- 8019, and she will do her best to assist you.

Sincerely,

Martha Monell, Acting Director
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Agency Response to "Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift (2009)"

Table of Contents

I. Executive Summary

This document presents EPA's response to a petition that asked the agency to: 1) evaluate the risks to children exposed to pesticides through drift and volatilization, 2) establish a separate process or modify its pesticide re-evaluation process to expedite assessment and management of these risks, and 3) for certain types of pesticides, require the adoption of "one size fits all" buffer zones between treated areas and places where children congregate. EPA grants in part and denies in part this petition.

EPA agrees with Petitioners that individuals including children may be exposed to pesticides through drift and/or volatilization; that these exposures can occur in places where children live, go to school, play, or are otherwise present; and that, apart from occupational activities, children (depending on certain factors, including age) may experience higher levels of pesticide exposure relative to their size than do adults. Furthermore, the Agency agrees with the petitioners that it should conduct pesticide-specific assessments of the risks that include drift and volatilization exposures, as appropriate, and that if warranted, the Agency will take action to mitigate those risks. The steps the Agency has been taking to address these exposures are discussed later in this document.

Petitioners define the term drift to include "any airborne movement of pesticides away from a target site during and/or after application, including the airborne movement of pesticide droplets, pesticide powders, volatilized vapor-phase pesticides, and pesticide contaminated soil particles." In Sections VI through VIII of this response, EPA defines drift and volatilization as they relate to our risk assessments. The definitions differ mainly because the Agency draws a distinction between the off-site movement of spray droplets or pesticide particles during and shortly after the application process ("pesticide drift") and the movement of pesticide active ingredients as a vapor or gas that can occur for longer time after application is completed ("volatilization"). Both processes describe movement of pesticides through the air. The type of pesticide drift on which this response focuses is "spray" drift, the off-site movement of aerosols originating with pesticides applied as liquids, because spray drift is more likely to occur than the drift of pesticides in solid form, and when it does, it generally poses greater risk. EPA's efforts to assess and manage pesticide drift consequently are concentrated on spray drift.

EPA denies the Petitioners' request that EPA use a process outside of the ongoing pesticide re-evaluation process, as currently scheduled, to assess and manage spray drift and volatilization risks. The Petitioners suggest that the Agency should use alternative approaches that reprioritize pesticides for registration review or speed up risk assessments. The Agency believes that such adjustments to the registration review process are not needed and do not represent an efficient use of limited Agency resources.[1]

[1] If specific and significant concerns arise about an individual pesticide not in registration review at the time, the Agency can utilize other processes as appropriate to assess and mitigate risks (as needed). These processes are described later in this document and are not intended to replace the systematic and regular actions that constitute registration review. See IV.C.iii, which discusses regulatory options for cases in which the Agency has determined that a registered pesticide no longer satisfies the statutory standard.

EPA also denies the petition as it relates to Petitioners' request that EPA immediately adopt interim prohibitions on the use of certain pesticides that they allege are toxic and may be prone to drift or volatilization, near homes, schools, parks, and daycare centers or wherever children congregate. EPA instead believes that case-by-case, chemical-specific risk assessment is a sound, science-based approach, consistent with the Agency's mandate, that yields a more realistic representation of actual risks and facilitates the identification of what, if any, mitigation measures (potentially including no-spray buffers) are needed to protect potentially exposed individuals.

The response to the petition is organized in the following manner. After this executive summary, EPA follows with two sections (II and III) that discuss background on the petition, the pending lawsuit brought by the Petitioners, and the statutory and regulatory framework as it relates to EPA's implementation of its pesticide programs. The next two sections of the response (IV and V) outline the Agency's pesticide regulatory programs and how EPA assesses and manages the risks associated with pesticide use. The following sections (VI through VIII) revisit the Agency's terminology for describing the off-site movement of pesticides through the air via spray drift and volatilization and explain how the risks of each are assessed and managed. The next section (IX) contains EPA's response to the Petitioners' request for three changes to the Agency's current practices. The last section (X) provides EPA's conclusion.

II. Background

A. Petition History and Major Claims by Petitioners

In October 2009, a group of health and environmental organizations[2] ("Petitioners") jointly filed a petition entitled, "Pesticides in the Air- Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift ("Petition"). The Petition alleged that EPA has failed to address children's exposures to and potential risks from pesticide drift and volatilization. More specifically the Petitioners ask EPA to:

1. fully and expeditiously evaluate the exposure of children to pesticide drift or vapors that originate from agricultural applications and travel to areas where children congregate, such as homes, parks, schools, and daycare centers. Furthermore, the Petitioners ask that the Agency act to ensure that children are protected from aggregate pesticide exposures, including exposures to drift;
2. implement an accelerated schedule (relative to the schedule for registration review) for completing drift assessments and modifying registrations that prioritizes assessments based on the suspected degree of risk posed by the pesticide drift and volatilization; and

[2] The organizations include Pesticide Action Network North America (PANNA), United Farm Workers, Pineros Y Campesinos Unidos Del Noroeste, Moms Rising, Sea Mar Community Health Center, California Rural Legal Assistance Foundation, Farm Labor Organizing Committee, and Physicians for Social Responsibility.

3. immediately adopt interim prohibitions on the use of toxic drift-prone pesticides such as organophosphates and n-methyl carbamates and certain other pesticides that are used near homes, schools, parks, and daycare centers or wherever children congregate.[3]

On November 4, 2009, EPA issued a Federal Register Notice requesting public comment on the assertions and requests made in the October 2009 petition. The comment period for the petition closed on January 4, 2010. EPA has reviewed the comments received.[4]

B. Lawsuit

On July 24, 2013, the Petitioners filed a writ of mandamus lawsuit against EPA alleging that EPA had unreasonably delayed responding to their 2009 Petition. EPA and the Petitioners agreed to stay the case. In EPA's unopposed motion to stay the case, the Agency promised to issue a final response to the Petition by March 31, 2014.[5] This response fulfills that promise.

III. Statutory and Regulatory Background/Framework

EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, and the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §346a. FIFRA sets forth a federal licensing scheme for the sale, distribution and use of pesticides; FFDCA establishes the mechanism and standards by which EPA must set tolerances (allowable levels) for pesticide residues in food. As a general matter, under FIFRA section 3, before a pesticide can be distributed or sold in the United States, it must be registered. Petitioners' administrative petition implicates both statutes.

A. The Federal Insecticide, Fungicide, and Rodenticide Act

The principal purpose of FIFRA is to regulate the sale, distribution and use of pesticides (through registrations) while protecting human health and the environment from unreasonable adverse effects associated with pesticides. *See generally* FIFRA section 3. Under FIFRA, EPA registers a pesticide only after conducting a scientific review of the risks, and when appropriate, benefits of that pesticide to determine whether the use of the pesticide causes "unreasonable adverse effects" to human health or the environment.[6] Registration and registration review decisions under section 3, reregistration decisions under section 4, and cancellation decisions under section 6 are governed by the same statutory standard, which generally is referred to as "risk-benefit" balancing, *i.e.*, a pesticide must not pose "any unreasonable risk to man or the

[3] The petitioners believe these interim measures also should apply to "all other pesticides that are (1) registered for application by ground sprayers, broadcast equipment, and/or aerial equipment; and (2) suspected of causing acute poisonings, cancer, endocrine disruption, developmental effects, and/or reproductive effects.

[4] The Petition docket is found at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0825.

[5] In re: Pesticide Action Network North America, et al. v. EPA, No. 13-72616 (9th Circuit)

environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA §§ 3(c)(5) & 2(bb); 7 U.S.C. §§ 136a(c)(5) & 136(bb). If this standard is not satisfied, EPA may not register the pesticide and existing pesticides are subject to modification or cancellation. *See* FIFRA §§ 3(c)(5) & 6(b); 7 U.S.C. §§ 136a(c)(5), & 136d(b).

In order to properly evaluate pesticide applications, FIFRA and its implementing regulations generally require applicants for registration to submit or cite to a significant body of toxicity and exposure data for the pesticides for which they are seeking registration. *See* 7 U.S.C. § 136a(c)(2)(A) (directing EPA to publish guidelines for submissions by applicants); 40 C.F.R. §§ 158.1 *et seq.*161.20 *et seq.* (setting forth information to be provided by applicants).

While EPA must consider a broad range of factors in determining whether a pesticide meets this standard, the balancing of the various risks and benefits of the pesticide, and consideration of inherent policy questions, is left largely to the discretion of EPA: "[W]ithin broad limits, the [A]dministrator has latitude not merely to find facts, but also to set policy in the public interest. Like most regulatory statutes,... FIFRA confers broad discretion on the [Administrator]." *Wellford v. Ruckelshaus*, 439 F.2d 598, 601 (D.C. Cir. 1971); *See also Envtl. Def. Fund v. EPA*, 465 F.2d 528, 538 (D.C. Cir. 1972) (FIFRA empowers EPA to "take account of benefits or their absence as affecting imminency of hazard").

As part of the process of EPA's approval of a pesticide registration, the agency must review and ultimately approve proposed labeling and directions for use for each pesticide. *See* FIFRA § 3(c)(5)(B). The approved pesticide label sets forth the lawful conditions of use for a pesticide, *i.e.*, those mandated by EPA in order to ensure that the pesticide will not cause unreasonable adverse effects to human health or the environment. *See Id.* § 3(d). Indeed, it is a violation of FIFRA for any person to use a pesticide in a manner inconsistent with the EPA-approved labeling. *See Id.* § 12(a)(2)(G).

B. The Federal Food, Drug, and Cosmetic Act

In 1996, the Food Quality Protection Act ("FQPA") was enacted, amending FFDCA and FIFRA to require all pesticides the use of which results in residues on food to meet new dietary risk standards. The FQPA amended the FIFRA risk-benefit standard ("any unreasonable risk to man or the environment") to add another element to the definition of that term: "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [FFDCA section 408]." *See* FIFRA § 2(bb); FFDCA § 408(b)(1). In other words, the registration of a pesticide is contingent upon its meeting the food safety standard established under FFDCA section 408, if use of the pesticide results in residues on food. Section 408 also was amended by FQPA to add protections for infants and children and to establish the estrogenic substances screening program.[7]

[7] Public Law 104– 170, 110 Stat. 1489 (1996).

Section 408 of the FFDCA authorizes EPA to establish by regulation "tolerances" setting the maximum permissible levels of pesticide residues in foods.[8] FFDCA §§ 301(a), 408(a). Tolerance setting is discussed in more detail in Section IV.B.

EPA may only promulgate a pesticide tolerance, if the tolerance is "safe." FFDCA § 408(b)(2)(A)(i). "Safe" is defined by the FFDCA section 408 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." *Id.* § *408*(b)(2)(A)(ii) [emphasis added]. Section 408's reasonable certainty of no harm standard is a risk-only standard, which generally does not allow consideration of benefits.[9] Congress also amended the FFDCA to require that EPA re-assess, using the new safety standard, the existing tolerances and exemptions for all pesticide chemical residues that were in effect on August 3, 1996. *Id.* § 408(q)(1). Congress directed EPA to complete the reassessments by August 3, 2006.

Congress instructed EPA, when applying the new safety standard, to assess, among other things, the risks of pesticide chemicals based on available information concerning the special susceptibility of infants and children to pesticide chemical residues. FFDCA § *408*(b)(2)(C). To ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pesticide chemical residues, Congress mandated that EPA apply an additional ten-fold margin of safety (known as the FQPA safety factor) in setting tolerances unless reliable data show that a different margin of safety will be safe for infants and children. *Id.* The additional ten-fold margin of safety can be reduced or removed based on such a finding.

The FQPA amendments to the FFDCA also directed EPA to consider "aggregate exposure" in its decision-making. EPA has interpreted "aggregate exposure" to refer to the combined exposures-to a single chemical across multiple routes (oral, dermal, inhalation) and across multiple pathways (food, drinking water, residential). As amended by FQPA, section 408(b)(2)(ii) of FFDCA requires the Agency to make a finding for each tolerance or tolerance exemption "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"[emphasis added]. Section 408(b)(2)(C)(ii)(I) of FFDCA states that the Agency must find "there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues." Finally, section 408(b)(2)(D)(vi) directs the Agency, when making tolerance decisions, to consider "aggregate exposure levels...to the pesticide chemical residue...including dietary exposure and exposure from other non-occupational sources."

EPA reaffirms its consistent interpretation of FFDCA section 408 as requiring consideration of all exposures to pesticide residues and other related substances other than those exposures

[8] Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce.

[9] Benefits may only be considered under section 408 in one very narrow circumstance not applicable in this case.

occurring in the occupational setting.[10] 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.

It is important to note that Congress has expressly provided that any issue that can be raised through the FFDCA review process can only be reviewed through that process.[11] Accordingly, to the extent a petition to revoke tolerances and cancel registrations raises issues relevant to the establishment or revocation of tolerances, EPA's response to those issues may be challenged only through the administrative and judicial review procedures provided in section 408 of the FFDCA and are not reviewable under FIFRA or any other provision of law.

C. Executive Orders Cited in Petition

EPA includes the following general discussion on two Executive Orders mentioned by Petitioners as support to their claims.[12]

i. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

On February 11, 1994, President Clinton issued Executive Order 12898 on Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.[13] This Order focuses federal attention on the environmental and human health conditions of minority and low-income communities and calls on agencies to make achieving environmental justice ("EJ") part of their mission. Since the issuance of that Executive Order, EPA has been actively working to ensure that EJ issues are considered in its decision-making processes. In September 2011, EPA issued its Plan EJ 2014 strategy.[14] The strategy is the Agency's roadmap for advancing environmental justice. Based on this strategy, the Agency seeks to:

- Protect the environment and health in overburdened communities.

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[10] See Imidacloprid; Order Denying Objections to Issuance of Tolerance 69 Federal Register 30042, 30073 (May 26, 2004).

[11] FFDCA § 408(h)(5); NRDC v. Johnson, 461 F.3d 164, 176 (2d Cir. 2006).

[12] These Executive Orders do not create an independent right of action against the United States.

[13] http://www2.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice

[14] See http://www.epa.gov/compliance/ej/plan-ej/for more information. The plan is not a rule or regulation. It is a strategy to help integrate environmental justice into EPA's day-to-day activities. Plan EJ 2014 has three major sections: Cross-Agency Focus Areas, Tools Development Areas, and Program Initiatives. Within these areas, EPA plans to more effectively protect human health and the environment for overburdened populations by developing and implementing guidance on incorporating environmental justice into EPA's rulemaking process. EPA also plans to enable overburdened communities to have full and meaningful access to the permitting process and to develop permits that address environmental justice issues to the greatest extent practicable under existing environmental laws. Under the two statutes at issue here, FIFRA and the FFDCA, EPA has already begun to incorporate these considerations into its licensing program.

- Empower communities to take action to improve their health and environment.
- Establish partnerships with local, state, tribal, and federal governments and organizations to achieve healthy and sustainable communities.[15]

EPA is committed to addressing risks to population groups with unique exposure pathways, such as children, farm and migrant workers, urban poor populations, rural or isolated populations, and Native Americans and Alaskan Natives [emphasis added].[16] EPA's Office of Pesticide Programs has developed an internal training program for staff that provides an overview of environmental justice issues to be considered in risk assessment. Guidance materials and the templates for risk assessment documents direct risk assessors to address environmental justice concerns specifically as a basic element of pesticide risk assessment and the Agency risk management decision-making process includes consideration of any such concerns identified for the subject pesticide.

ii. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

On April 21, 1997, President Clinton signed Executive Order 13045 on the Protection of Children from Environmental Health Risks and Safety Risks.[17] This Executive Order requires all federal agencies to assign a high priority to addressing health and safety risks to children, coordinate research priorities on children's health, and ensure that their standards take into account special risks to children. While not directly cited in the Petition, it should also be noted that on October 20, 1995, EPA adopted the Policy on Evaluating Health Risks to Children (predating the Executive Order). This policy requires the EPA to consider the risks to infants and children consistently and explicitly as part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment.[18]

In response to Executive Order 13045, EPA established the Office of Children's Health Protection ("OCHP") in May 1997. The focus of this office is to make the protection of children's health a fundamental goal of public health and environmental protection in the United States. The Agency's Office of Pesticide Programs and OCHP are committed to ensuring that the Agency's risk assessments for pesticides are protective of children's health.[19]

IV. EPA's Pesticide Regulatory Programs

[15] Petitioners claim that EPA's pesticide assessments do not adequately address environmental justice issues as directed by the 1994 EJ Executive Order (Exec. Order No. 12,898, 59 Fed. Reg. 7,629 (Feb. 11, 1994)). EPA disagrees. EPA's commitment to EJ issues is clear from its recent pronouncements on these issues.

[16] http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2011.300121

[17] http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

[18] http://yosemite.epa.gov/ochp/ochpweb.nsf/content/policy-eval_risks_children.htm

[19] http://gao.gov/products/GAO-13-254

The following sections discuss how EPA implements its statutory obligations under FIFRA and the FFDCA.

A. EPA's Review of Pesticide Registration Applications

EPA provides an application kit[20] to assist in preparation of an application to register a pesticide. The applicant is responsible for submitting or citing all of the information and data that are required to support the registration, including proposed product labeling, and scientific data that meet the data requirements related to the specific product the applicant intends to register. In addition, the applicant provides a Confidential Statement of Formula that details the composition of the pesticide product, i.e., 1) all active ingredients, 2) all inert ingredients, 3) all impurities of toxicological significance associated with the active ingredient, and 4) all impurities found to be present at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient.[21]

The applicant will also provide EPA with draft labeling. FIFRA section 2(p)(1) defines "label" as "the written, printed or graphic material on, or attached to, the pesticide or device or any of its containers or wrappers." The term "labeling" is defined as "all labels and all other written, printed, or graphic matter –

(A) accompanying the pesticide or device at any time; or
(B) to which reference is made on the label or in literature accompanying the pesticide or device." *See* FIFRA § 2(p)(2)

Labeling includes detailed information such as the ingredients statement, warnings and precautionary statements, and directions for use. It is unlawful to sell or distribute a pesticide if any claims made for it differ from claims made on labeling required for registration. *See* FIFRA § 12(a)(1)(B). Therefore, advertising claims for a pesticide product must not contradict claims made in the product's labeling. Labeling requirements are codified in 40 CFR Part 156. EPA has developed a Label Review Manual[22] as guidance to its staff on reviewing labels.

Applicants are responsible for citing or generating all data to meet data requirements. The purpose of these data requirements is to demonstrate that the product will not cause unreasonable adverse effects on the environment. In general, these data are used to evaluate whether a pesticide has the potential to cause adverse effects on humans, non-target wildlife, and plants, as well as possible contamination of surface water or groundwater from leaching, run-off, and spray drift. For pesticides that will need a tolerance or tolerance exemption to demonstrate a reasonable certainty of no harm, additional data are needed.

Requirements may include, as applicable, data on:

- spray drift,
- residue chemistry,

[20] http://www.epa.gov/pesticides/registrationkit/

[21] http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-sec158-320.pdf

[22] http://www.epa.gov/oppfead1/labeling/lrm/

- environmental fate,
- toxicology,
- applicator exposures
- reentry protection,
- wildlife and aquatic organisms,
- plant protection,
- nontarget insects,
- product performance, and
- product chemistry.

Data requirements in support of applications for registration of a pesticide product are specified in 40 CFR Part 158.[23]

EPA's review of the application includes the assessment of the risks to human health and the environment that may be posed by the pesticide.[24]

B. Tolerance Setting

i. Process overview

A tolerance is the maximum allowable concentration of a pesticide on a particular food item. The tolerance is the residue level that triggers enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure by the government. EPA must consider a number of factors when it establishes, modifies, leaves in effect, or revokes a tolerance for a pesticide chemical residue. FFDCA § 408(b)(2)(D). The process for the establishment, modification, or revocation of tolerances, is described directly below.

A tolerance action may be initiated by EPA of its own accord[25] or in response to an administrative petition. *Id.* § 408(d)(1), (e)(1). "Any person may file with [EPA] a petition proposing the issuance of a regulation . . . establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." *Id.* § 408(d)(1)(A). If EPA determines that an administrative petition meets the statutory and regulatory requirements governing petition contents, EPA publishes a notice of the administrative petition's filing. *Id.* § 408(d)(3). (The Agency will also publish a notice when the action is Agency-initiated.)

After the publication of the notice, EPA must give "due consideration" to the petition and then: i) issue a final regulation establishing, modifying, or revoking a tolerance; ii) issue a proposed regulation under the separate provisions of the FFDCA § 408(e), and thereafter issue a

[23] Data requirements are described at http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-part158.pdf; links to guidelines for the conduct of required studies are located at http://www.epa.gov/pesticides/science/guidelines.htm

[24] For further details on the pesticide registration see http://epa.gov/pesticides/factsheets/registration.htm.

[25] When, for example, the tolerance action follows a cancellation action.

final regulation after additional public notice and comment; or iii) issue an order denying the petition. FFDCA § 408(d)(4)(A). *See NRDC v. Johnson*, 461 F.3d at 173-74.

After EPA issues a regulation or order establishing, modifying, or revoking a tolerance for a pesticide chemical residue on food, any person may file objections with EPA and request an evidentiary hearing on those objections. FFDCA § 408(g)(2). After consideration of any such objections, EPA must issue a final order separately stating the action taken on each objection and whether any hearing is appropriate. *Id.* § 408(g)(2)(C). Then the Agency can conclude its deliberations and grant, modify, or deny the tolerance, as appropriate.

ii. The Tolerance Petition and Required Documentation

As discussed above, a determination on the proposed tolerance relies on the risk-only standard from FFDCA section 408. EPA must ensure that the use associated with the tolerance will not pose unreasonable risks to human health. Except in certain instances,[26] a tolerance petition request is usually accompanied by an application for registration, an application to amend the registration of a currently registered product, or an experimental use permit for the uses proposed in the petition. As risk assessments are a component of the standards for evaluating both tolerance proposals and registration actions, EPA determines whether any meaningful risks exist for the proposed uses, based on an evaluation of the applicant's petition for a tolerance. The Agency bases its tolerance decision on the aggregate exposures and risks associated with the pesticide and the use to which the petition applies. Aggregate exposure is the combined exposures to a single chemical across multiple routes (oral, dermal, inhalation) and across multiple pathways (food, drinking water, residential).[27]

iii. How the Proposed Tolerance Action is Assessed

The risks of concern that are considered in the setting of tolerances are the human health risks from aggregate exposures, which are the sum of exposures from each relevant pathway--food, drinking water, and/or residential. The assessment of human health risks is described in more detail in Section V. Aggregate risks are calculated based on varying durations of exposure. When no residential uses exist, aggregate risks are based on exposure contributions from food and drinking water for the acute and chronic durations. For residential-use pesticides, residential exposures are combined with food and drinking water exposures for each applicable duration of exposure. As discussed above, a determination on the proposed tolerance will be based on the risk-only standard from FFDCA section 408.

[26] A request for an import tolerance generally would not require an accompanying application for registration.

[27] Residential exposures include exposures associated with homes, home lawns, yards, gardens, apartments and grounds around apartment buildings, schools, schoolyards, daycare facilities, playgrounds, athletic fields, and parks and other public spaces.

In 1997, EPA issued "HED SOP 97.2 Interim Guidance for Conducting Aggregate Exposure and Risk Assessments (11/26/97)."[28] The Agency continued to work on more sophisticated methods for estimating aggregate exposures to pesticides, and in 2001, released "General Principles for Performing Aggregate Exposure and Risk Assessments,"[29] to augment the guidance document.

The aggregate risk assessment process relies on available data, assumptions designed to be protective of public health, standard analytical methods and Agency SOPs to estimate exposures to a pesticide for each potential pathway and route of exposure. EPA combines these separate exposure estimates to calculate potential aggregate exposure and risk; aggregate exposures estimated in this way reflect upper-bound or high-end of exposures for each route/pathway. The most highly exposed group, which generally also has the highest associated risk, is used as the basis for decision-making purposes. Aggregate risk assessments conducted in this manner typically can be refined by the use of additional exposure data and data specifically designed to address the uncertainties within an individual aggregate analysis, as well as more sophisticated analysis techniques.

The assumption implicit in this approach is that individuals can encounter the high-end exposures from the different pathways all at one time. In actuality, co-occurrence of high-end food, drinking water, and residential exposure scenarios is very unlikely. Thus, in using this approach, EPA is confident that aggregate exposure estimates will overstate, sometimes significantly, the amount of a pesticide to which people actually are exposed. The primary advantage to relying on these highly conservative assessments is that they require relatively fewer data and analytical resources and less time to conduct. In addition, an aggregate risk assessment of this type may be enough to indicate that a particular pesticide use satisfies the appropriate regulatory standards.

C. Pesticide Re-evaluation Processes

i. Reregistration

FIFRA requires the periodic re-evaluation of currently registered pesticides. In 1988, Congress amended FIFRA section 4 to include a specific process for the "reregistration" of pesticides containing active ingredients first registered before November 1, 1984. Pub. L. 100-532, title I, § 102(a), 102 Stat. 2655, 2683(1988). To make a Reregistration Eligibility Decision (RED), [30] EPA reviewed all the studies that were submitted by the pesticide registrants for a

[28] U.S. Environmental Protection Agency. 1997e. Memorandum from Margaret Stasikowski, Health Effects Division to Health Effects Division Staff. "HED SOP 97.2 Interim Guidance for Conducting Aggregate Exposure and Risk Assessments (11/26/97);" November 26, 1997. Office of Pesticide Programs, Office of Prevention, Pesticides, and Toxic Substances, Washington, D.C. Available upon request.

[29] http://www.epa.gov/pesticides/trac/science/aggregate.pdf

[30] In particular cases, the Agency issued a variation on the RED, i.e., a Tolerance Reassessment Decision, or, for individual active ingredients identified as belonging to a group of pesticides with a common mechanism of action, an Interim Reregistration Decision may have been issued before the RED.

pesticide active ingredient, as well as other relevant information, developed the appropriate risk assessments, and decided whether or not the pesticide active ingredient satisfied the risk-benefit standard of FIFRA section 3(c)(5). After determining eligibility of the active ingredient, EPA determined whether to reregister products containing the active ingredient.[31] *See* FIFRA § 4(g)(2)(B). In conjunction with most REDs, the Agency "called-in" active ingredient- or product-specific data considered necessary to reduce uncertainty in the RED risk assessments.

Reregistration was an open and transparent process. Before finalizing its decision on the eligibility for reregistration of a pesticide, EPA made the supporting risk assessments available for public comment, although it was not required to do so. Comments were solicited particularly on the factual basis of the risk assessments and also on options for mitigating the risks posed by the subject pesticide. These comments were considered in the Agency's decision-making.

Most of the pesticides specifically named in the Petition went through the reregistration process. Information on the reregistration status and links to the reregistration dockets for any pesticide can be accessed via the Agency's Chemsearch database.[32] And, as explained more fully below, they have also been scheduled for review early in the current re-evaluation process, known as Registration Review. *See* FIFRA § 3(g).

ii. Registration Review

Once the reregistration decisions for all the subject active ingredients were completed, the Agency began the next re-evaluation process under FIFRA, which requires EPA to regularly review pesticides to ensure that they continue to satisfy the statutory standard for registration. The ongoing re-evaluation process is called registration review. Section 3(g) of FIFRA requires EPA to complete its initial registration review cycle by October 1, 2022, for all pesticides registered prior to October 1, 2007, and by 15 years after the date of initial registration for pesticides registered after that date. *Id.*[33] Following the initial review of the pesticide, EPA must conduct subsequent reviews of each registered pesticide every 15 years thereafter.

The registration review program[34] makes sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Through registration review, the Agency is ensuring that registered pesticides do not cause unreasonable risks to human health or the environment when used as directed on product labeling. Changes in science, public policy, and pesticide use practices will occur over time, and the cyclical nature of registration review will enable the

[31] While the Agency has completed its statutory requirement to make eligibility determinations on the subject active ingredients, product reregistration is still ongoing for some reregistration cases.

[32] http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1; search by active ingredient name, PC Code, or CAS number.

[33] See also 40 CFR Part 155 for the implementing regulations. An overview of the process is found at http://www.epa.gov/oppsrrd1/registration_review/highlights.htm.

[34] Unlike earlier re-evaluation programs, registration review operates continuously, and provides for the review of all registered pesticides.

Agency to consider updated information every time a pesticide comes up for registration review.[35]

In conducting the registration review program, EPA generally is reviewing pesticides in chronological order according to their baseline dates;[36] that is, older cases are being reviewed first. In addition, many pesticides that received priority scheduling for reregistration have been scheduled early in registration review. Thus, food-use chemicals[37] that were identified as or suspected of having risk concerns at the outset of reregistration generally are scheduled early in the registration review process. Additionally, within this structure, EPA plans to review certain related pesticides at the same time, particularly pesticides in the same family, with the same general structure and mode of action.

In reregistration, EPA gained experience and benefited from efficiencies in the concurrent review of pesticides in families like the organophosphates (OPs), N-methyl carbamates (NMCs), triazines, and chloroacetanilides. The rodenticides and soil fumigants were also reviewed concurrently. EPA plans to continue the practice of grouping related pesticides during registration review.[38] Potential efficiencies from this practice include:

- Technical and regulatory issues may be resolved more easily looking across an entire chemical class or group;
- Resources can be optimized within EPA, among stakeholders, and within other federal agencies; and
- In developing decisions, a "level playing field" among chemicals in the group may be assured so that EPA's actions do not inadvertently cause increased risks.

EPA completed cumulative risk assessments and reregistration risk management decisions for the OP pesticides in August 2006 and the NMC pesticides in September 2007. In recent years, EPA and stakeholders have invested significant resources in gaining a better understanding of these classes of pesticides. The registration review of the OPs began in 2008, and the N-methyl carbamate review began in 2010. The Petitioners are requesting expedited reviews for both classes of chemicals. These classes of pesticides were among the first pesticides to enter the registration review program, so the assessment of risks associated with their use (including risks to children, and risks from spray drift), and the management of those risks, should be accomplished early in the current registration review cycle, and in subsequent cycles as well. Volatilization will also be addressed based on the results of the screening analysis and the subsequent availability of pertinent data, should they be required for individual pesticides. The scheduling of these classes of pesticides in registration review reflects an understanding of the importance of addressing the toxicity, dietary and aggregate risks, and the

[35] The Agency uses the best, most recent information in any risk assessment, but the cyclical nature of registration review assures that assessments for any one pesticide will be updated at least every 15 years.

[36] The baseline date is the date when a RED was completed, or for a pesticide not subject to reregistration, the date when the pesticide was first registered.

[37] Pesticides used on food crops were given high priority because they have potential to affect the population at-large via dietary exposure.

[38] The overview at http://www.epa.gov/oppsrrd1/registration_review/highlights.htm provides links to information on the pesticide family groupings.

volume of use for these pesticides. *See* Appendix to this response for the registration review schedules for the OPs and NMCs.

EPA initiates a registration review by establishing a docket for a pesticide registration review case and opening the docket for public review and comment. The Agency publishes a Federal Register notice that announces the availability of a Preliminary Work Plan (PWP) and provides a comment period of at least 60 days. Anyone may submit data or information in response. EPA will consider information received during the comment period in conducting a pesticide's registration review. The PWP:

- explains what EPA knows about the pesticide from previous risk assessments including hazard and exposure information related to children, when available, and application of uncertainty factors including the FQPA safety factor;
- tentatively identifies what kind of risk assessments are needed;
- tentatively identifies what data will be needed to conduct the assessments;
- addresses the uncertainties in the database that will impact the risk assessments (particularly missing or unclear use parameters);
- provides basic use and usage information and other background information on the pesticide; and
- provides a proposed schedule that lays out milestones up until the registration review decision is made.

Information from registration review dockets that have opened is readily accessible via Chemical Search on a chemical-by-chemical basis.

Registration review, as set forth in the regulations, is a transparent process in which stakeholders of all types are invited to provide relevant data and comments. At the beginning of registration review, the public is asked to comment on the PWP and its supporting documents; by soliciting these comments, EPA aims to gather additional information that can enhance registration review planning and decision-making. Other registration review documents also are subject to a public comment period, such as when the preliminary risk assessments are posted to the docket later in the process. Similar approaches to public notification and comment were used during reregistration and can be used in decision-making about new active ingredients.

EPA may also, as needed, consult with registrants, the U.S. Department of Agriculture. and other stakeholders to resolve any uncertainties about how the product is used, particularly if use parameters are not clear from product labeling, or if the registrant may have data not already submitted to the Agency that could inform the process. For example, some labels are not specific about retreatment intervals or seasonal maximum application rates. Without actual use parameters, the Agency is forced to make conservative assumptions that can result in overly conservative risk assessment results. The Agency may solicit such information in a "Focus Meeting." These meetings can be held whenever in the registration process they might be helpful. To ensure transparency, materials associated with Focus Meetings are available in the pesticide-specific registration review dockets. If a focus meeting is held prior to the docket

opening, these materials are posted to separate docket.[39] Once the docket opens, a copy of the focus meeting notes will be posted to the case-specific docket.

After the close of the initial comment period, EPA revises its work plan as needed based on public input and any additional information that has become available in the interim. The Final Work Plan is then posted to the docket, and EPA prepares to call-in any data needed for the risk assessments. Once the registrants submit the required data, work on the risk assessments begins. As noted above, EPA makes the draft risk assessments available for public review and comment, and subsequent to review of public comments, the Agency posts the revised assessments. If the revised assessments indicate that there are risks of concern, EPA may invite the public to submit suggestions for mitigating those risks. These suggestions are used in the development of a proposed registration review decision.

EPA will announce the availability of a proposed registration review decision on the docket and will provide a public comment period of at least 60 days. The process culminates with a final registration review decision—EPA's determination on whether the pesticide in question meets or does not meet the standards for registration. The final registration review decision discusses any changes that are needed to the pesticide's registration or labels to address the risks of concern. If a registrant fails to take action to implement these changes, EPA may take appropriate action under FIFRA.

To meet its statutory obligations for registration review, EPA is opening 70 or more dockets annually continuing through 2017, and almost all of the pesticides registered at the start of the program will have dockets opened by 2017. The Agency is directed to complete the first round of registration reviews by October 1, 2022; during that time the Agency will complete the registration reviews of at least 744 pesticide cases comprising 1,165 active ingredients. Pesticides registered after 2007 will be folded in each year.[40]

iii. Regulatory Responses to Unacceptable Risks

If EPA determines that a pesticide product does not meet the statutory standard, the Agency may take "appropriate regulatory action." Such regulatory actions can include, but are not limited to, restricting pesticide uses or canceling the pesticide's registration. *See* FIFRA §§ 3(d) & 6(b). If EPA chooses to cancel a pesticide registration, EPA must first issue a Notice of Intent to Cancel and hold a formal administrative hearing, if one is requested by a person adversely affected by the notice. *See* FIFRA § 6(b).

If the Agency determines that an "imminent hazard" exists from the use of a pesticide (including a pesticide that was not eligible for reregistration), EPA may commence proceedings

[39] General information about focus meetings is at http://www.epa.gov/oppsrrd1/registration_review/focus-meetings.html; the docket itself is at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2012-0778.

[40] The status of all completed and ongoing registration reviews can be found at http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm.

to suspend the registration of a pesticide during the time needed to complete cancellation proceedings. *See* FIFRA § 6(c). Section 2(l) of FIFRA defines imminent hazard as:

> [a] situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act....

If the EPA determines that an emergency exists such that the imminent hazard will occur during the period necessary to complete normal suspension proceedings, the EPA may issue an immediately-effective emergency suspension order in advance of completing suspension proceedings. *Id.* § 6(c)(3).

Courts addressing the suspension provisions have held that an imminent hazard exists if there is "a substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative process." *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988) (quoting *Environmental Defense Fund v. EPA*, 465 F.2d 528, 540 (D.C. Cir. 1972). In the case of an emergency suspension, one court has found by analogy that suspension is appropriate if there is a "substantial likelihood that serious harm will be experienced during the three or four months required in any realistic projection of the administrative suspension process." *Dow v. Blum*, 469 F.Supp. 892, 901 (E.D. Mich. 1979). Thus, courts interpreting the FIFRA suspension standard have made clear that an imminent hazard finding requires a greater degree of likelihood, immediacy, and severity of harm than is otherwise required to take a cancellation action under FIFRA. And in evaluating the nature and extent of information before EPA, the courts have instructed the Agency to consider (1) the seriousness of the threatened harm, (2) the immediacy of the threatened harm, (3) the probability that the threatened harm will occur, and (4) the benefits to the public of the continued use of the pesticide *Id.* at 902.

EPA's review and re-evaluation processes for pesticides have been developed to account for advancements in science so that risks can be identified and managed before a pesticide is registered and at regular intervals thereafter. Through these processes, the Agency can anticipate and correct problems with the use of pesticides as time goes on, and, ideally, reduce the chances that a pesticide would pose risks of an immediacy and magnitude like those associated with an imminent harm finding.

V. How Pesticide Risks Are Assessed

The type of assessment pertinent to this Petition is the human health risk assessment[41] (ecological risk assessments are not discussed in the Petition). EPA uses a science-based risk assessment approach. Risk is a function of both the hazard associated with a pesticide and how much exposure occurs to that pesticide. Hazard is the innate ability of a pesticide or other stressor to cause an adverse effect (its toxicity). At EPA, hazards are typically identified from the results of testing on several animal species and typically the most sensitive effect is used as

[41] See http://www.epa.gov/pesticides/about/overview_risk_assess.htm

the basis for risk assessment. Exposure is the amount or concentration of a stressor with which an affected individual or group interacts. Risk is a function of both hazard and exposure and represents the likelihood that an individual or group will be adversely affected by that stressor. Both hazard and exposure can differ according to a person's age, thus EPA uses age-appropriate behaviors to determine exposures and also looks at any special sensitivity to pesticides associated with the age of the exposed parties. EPA uses the National Research Council's four-step process[42] for its human health risk assessments. The four steps include: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization. Each of these steps is summarized below.

It is important to note that risk assessment and risk management are separate activities. Risk management relates to the ways in which the risks characterized in the assessment may be reduced or eliminated. Risk management measures can include tolerance revocation or the cancellation of registrations, termination of some uses of a pesticide, changes to a pesticide's use parameters, and risk reduction training for people who are occupationally exposed, such as pesticide applicators.

A. Hazard identification

The first step in the risk assessment is to identify potential health effects that may occur from different types of pesticide exposure. EPA considers the full spectrum of a pesticide's potential health effects.

Typically, a pesticide active ingredient is subjected to many toxicity studies, and the data from these studies (if determined to be acceptable) are used in risk assessment. Requirements for the relevant data are typically imposed on the pesticide applicant or registrant, and the studies are typically conducted by independent laboratories, with strict standards for data surety.[43] The data are evaluated for acceptability by EPA scientists. The toxicity studies primarily are performed on laboratory animals or *in vitro*, although some of the required studies are conducted in the field. The Agency will also review human toxicity studies, with qualifications, as discussed below, but does not require them. EPA evaluates pesticides for a wide range of potential toxic effects including eye and skin irritation, neurological effects, cancer, and birth defects. In addition to reviewing the required studies, EPA also consults the public literature or other sources of supporting information.

The required tests are used in the assessment of potential health effects in infants, children, and adults. They are conducted for exposures of different durations, as appropriate to represent the durations of exposure anticipated for various lifestages and behaviors. Exposures may be of single day or longer durations, up to and including durations spanning a lifetime. Additionally, EPA considers the route by which these exposures may occur—orally, e.g., through the diet or via children's mouthing behaviors; through the skin; or by inhalation.

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[42] The National Research Council produces reports for the National Academy of Sciences. The process is explained at http://epa.gov/riskassessment/health-risk.htm.

[43] Required laboratory practices for studies used to support pesticide registration are detailed at http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/xml/CFR-2011-title40-vol24-part160.xml

To address risks to infants, children, and adults, EPA typically requires animal testing at multiple life stages, including during gestation and shortly after. The effects that are observed in this type of testing are fetal development (including birth defects) and reproductive success. The results of these studies are particularly applicable to the assessment of risks to the fetus and young children and, when compared to studies with adult animals, provide a basis for evaluating the relative sensitivity of the young to adults.

In order to develop a risk assessment that is protective of human health, the Agency will select the "most sensitive" endpoints and the corresponding point of departure (POD) from among these different studies for the relevant populations, taking into account the durations and routes of exposure. The endpoint can be described as the toxic effect itself. The POD is typically the dose level below the lowest dose at which the adverse effect is manifested.

As an example, consider an endpoint that was selected from a shorter-term animal study in which the animals were exposed via the dermal route, for a pesticide that is registered for use on lawns. In this example, the POD based on this endpoint would be used to estimate risks to adults and to children aged 1 to 2 years old. Children in this age group typically are the most highly exposed relative to children of all ages for pesticide residues on turf by weight and because of their behavior on lawns, as they are exposed to residues through contact with their skin when they play in their yards or in parks and playgrounds, and are also exposed orally, predominantly via hand-to-mouth behaviors.

As noted previously, the Agency also will consider relevant data from sources other than required studies, including data from prospective and retrospective epidemiologic studies, incident reports,[44] and studies in which human subjects have been exposed intentionally to a pesticide (although the latter must undergo an specialized review to ensure that the Agency does not rely on data from studies that violate established ethical standards).[45] EPA uses its draft "Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments" when considering those types of data.[46]

B. Dose-response

The second step in the risk assessment process is to consider the dose levels at which adverse effects were observed in test animals and to extrapolate those dose levels to an equivalent dose in humans. For animal studies, the uncertainty around the extrapolation from test animals to humans and the variability of sensitivity in the human population are accounted for by uncertainty factors. The default factors assume there could be up to a ten-fold difference between animals and humans and up to a ten-fold difference between the average person and the most sensitive people in the population. That is, humans generally are assumed to be 10 times more sensitive than animals, and the most sensitive individuals generally are assumed to be 10 times more sensitive than that. These uncertainty factors create a margin of safety for protecting

[44] For example, per analysis of pesticide acute illnesses based on 1998-2006 NIOSH SENSOR data, see http://ehp03.niehs.nih.gov/article/info%3Adoi%2F10.1289%2Fehp.1002843, referenced in the Petition.

[45] http://www.epa.gov/oppfead1/guidance/human-test.htm

[46] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0851-0004

people who may be exposed to the pesticides. The FFDCA requires EPA to use an extra 10-fold safety factor to protect infants and children from effects of the pesticide, unless reliable data show that a different (larger or smaller) factor would protect the safety of infants and children.[47]

C. Exposure

The third step in the risk assessment process is to address how long, and at what level people are exposed to a pesticide, a critical consideration when selecting endpoints and also for calculating risks. For spray drift, exposures are assessed for contact with previously contaminated surfaces such as lawns adjacent to treatment areas. More specifically, the Agency assesses exposures from dermal contact (e.g., children playing on lawns) and also non-dietary ingestion from mouthing behaviors of young children. Adults also are expected to have exposures from dermal contact. For volatilization exposure, the primary exposures result from inhalation since exposure is to the gas or vapor form of a pesticide.

In general, pesticide residues deposited on surfaces (such as grass or the leaves of treated crop plants) remain available for exposure to people entering treated areas, or areas in which spray drift residues have settled, for more than a single day, so subchronic studies are used to derive endpoints and PODs. Single day (acute toxicity) studies also may be considered in order to evaluate risks on the day of application (when the greatest exposures are likely). Impacts on fetuses due to the exposure of pregnant women are included in the risk assessments when information on reproductive and developmental toxicities is available. If information on reproductive and developmental toxicities is not available, an uncertainty factor may be used to account for the possibility of the special sensitivity of children not apparent from available data.

More details are provided in Sections VII and VIII below on how exposures to spray drift and volatilization are determined.

D. Risk characterization

The last step in the risk assessment process is to combine the hazard and exposure assessments to describe the overall risk from a pesticide. Risk characterization explains the assumptions used in assessing exposure as well as the uncertainties[48] that are built into the dose-response assessment, and whether or not the assumptions and uncertainties used are likely to overstate or understate potential risks. The strength of the overall database is considered, and broad conclusions are made.

In summary, the risks to human health from a pesticide depend on both the toxicity of the pesticide and the likelihood of people coming into contact with it. At least *some* exposure and *some* toxicity are required to result in a risk. For example, if the pesticide is very toxic, but no people are exposed, there is no risk. Likewise, if there is ample exposure but the chemical is non-toxic, there is no risk.

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[47] EPA may modify these uncertainty factors on a case-by-case basis when supported by chemical-specific behavior.

[48] These are uncertainties not covered by FQPA or other uncertainty factors, e.g. deriving from an incomplete database.

E. Children and pesticides

EPA has developed methods for estimating pesticide exposures to children through the diet and via non-dietary sources such as residential exposures. These methods rely on the best available scientific sources, such as EPA's "Exposure Factor's Handbook."[49] Dietary exposures are based on consumption data for children, and residential exposures are based on methods outlined in the "Standard Operating Procedures (or SOPs) for Residential Exposure Assessment."[50] The SOPs address exposures for various lifestages, and allow for the identification of the most highly exposed lifestage. The SOPs, including the concept of lifestage, have been discussed extensively by the FIFRA Scientific Advisory Panel (SAP).[51] The 2012 revision of the SOPs reflect the input of the SAP.[52]

Young children may have unique exposures that adults do not have because of age-specific behaviors, for example, picking things up from the ground and mouthing them, or putting their hands (potentially contaminated with pesticide residues) in their mouths. They may also come into contact with pesticides when crawling or at play on treated or contaminated surfaces. Children up to adolescence have a higher surface to weight ratio than adults, so they may also be proportionately more highly exposed via the dermal route. Children can also be more highly exposed via the dietary route because they consume more food and water in proportion to body size than adults, and the types of food they eat a lot of tend to contain more pesticide residues.

Available data pertinent to children's health risks are evaluated along with data on adults and the most sensitive, appropriate POD is defined (e.g., NOAEL or no observed adverse effect level) for the most sensitive critical effect(s) based on consideration of all health effects. By doing this, protection of the health of children will be considered along with that of other potentially sensitive populations. In most cases, it is appropriate to evaluate the potential hazard to children separately from the assessment for the general population or other population subgroups.

The approach used by EPA to account for pesticide exposures in children is consistent with EPA's general risk assessment methods[53] and follows the Agency's age grouping guidance.[54] The approach is also consistent with recommendations from the National Academy of Science

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[49] http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.

[50] http://www.epa.gov/pesticides/science/residential-exposure-sop.html

[51] The SAP is a federal advisory committee consisting of independent, external scientific experts that advises the Agency's Office of Pesticide Programs (OPP) on technical issues.

[52] The SAP meeting report is at http://www.epa.gov/scipoly/sap/meetings/2009/100609meeting.html.

[53] EPA's risk assessment methods can be found at http://www.epa.gov/risk/guidance.htm; An overview of EPA's approach to assessing and managing these risks is provided in the 2010 report "Protecting Children's Health," found at http://www.epa.gov/pesticides/health/protecting-children.pdf.

[54] An overview of EPA's approach to assessing and managing these risks is provided in the 2010 report "Protecting Children's Health," found at http://www.epa.gov/pesticides/health/protecting-children.pdf: the 2005 paper "Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants, at http://www.epa.gov/raf/publications/pdfs/AGEGROUPS.PDF, advises risk assessors on selecting appropriate age ranges for use in implementing the Agency's initiatives on pr

1993 report, "Pesticides in the Diets of Infants and Children,"[55] cited extensively by the Petitioners. EPA has adopted many of the recommendations from that report into its current risk assessment procedures.

VI. Nomenclature Associated with Spray Drift and Volatilization

EPA uses an informative nomenclature that allows for a clear delineation between the possible forms and/or sources of pesticide movement through the air and away from treated fields. This approach provides for a means of avoiding confusion when describing the unique processes and factors that can contribute to pesticide movement. Whether or not pesticide drift occurs during or after application is an important factor, as is whether or not pesticides are applied in liquid form or as solid material.

As indicated previously, for this response, the Agency focuses on "spray" drift, the off-site movement of aerosols originating with pesticides applied as liquids, rather than dust drift, because spray drift is more likely to occur and generally poses greater risk. Also as noted previously, the Petitioners do not appear to differentiate between drift and volatilization.

Although there are similarities in the mode of transport (through the air) associated with volatilization and spray drift, EPA assesses spray drift and volatilization separately, for several reasons:

- They are two distinctly different processes. Spray drift is dependent on how applications are made and on the form in which the pesticide is applied, while volatilization is driven by the physical and chemical characteristics of the pesticide active ingredient (especially its vapor pressure).
- Spray drift occurs at the time of application and shortly thereafter, for as long as droplets remain aloft. Volatilization, on the other hand, can occur during the application process and also over longer periods of time depending upon the physical and chemical characteristics of the pesticide and how it was applied.
- The route of exposure that the Agency assesses for volatilization is inhalation. The Agency's assessment of spray drift focuses on dermal exposures and exposures from non-dietary oral ingestion (predominantly from hand-to-mouth behaviors in young children). Inhalation exposures are not included in the Agency's spray drift assessments for the following reasons:
    - Most, but not all, of the droplets in spray drift are too large to be respirable.
    - For agricultural pesticides, the Worker Protection Standard (WPS) prohibits the application of a pesticide such that it contacts, either directly or through drift, any worker or other person.[56] This WPS prohibition mitigates the potential for bystander exposure to active drift, but not the residues of drift that are deposited on surfaces to which bystanders may be exposed.

  The Agency at present lacks an assessment methodology for drift inhalation exposures.
- The ways that the risk from volatilization and spray drift can be mitigated are different.

[55] http://www.nap.edu/openbook.php?record_id=2126&page=1.
[56] http://www.epa.gov/pesticides/health/worker.htm

The operating definitions of "spray drift" and "volatilization" are discussed in detail in Sections VII and VIII, respectively.

VII. Assessing and Managing Risks from Spray Drift

EPA has been working with a broad range of public and private stakeholders to address concerns related to spray drift and the potential for adverse effects related to drift exposure.[57] EPA's goal is to assess, and if necessary, to mitigate spray drift via a science-based approach relying on case-specific information.

Spray drift is influenced primarily by environmental conditions (such as wind speed) and application parameters (such as formulation type, application method, application rate, droplet/particle size, application release height). Some degree of pesticide drift is an inevitable result of nearly all types of pesticide application. Even under the best of circumstances, a minute amount of pesticide can move out of the treatment area for a short distance. When the amount of drift is such that it poses risks of concern, the Agency will take action to mitigate those risks.[58]

Quantifying the potential risks of spray drift is a complex process that involves predicting the amount of drift associated with various types of application equipment, estimating potential exposures, and considering the potential health effects from such exposures. Managing the risks associated with spray drift can be complex as well and there are a variety of potential approaches that can be used, as discussed more thoroughly below.

A. Estimating Spray Drift and Potential Exposures to Bystanders[59]

Since the early 1980's, EPA has been working to better understand spray drift. Information key to this effort was developed by a group of pesticide registrants working collaboratively to create a database that addressed spray drift data requirements under 40 CFR 158.440.[60] This group is referred to as the Spray Drift Task Force (SDTF).[61] Since its formation in 1990, the SDTF has generated standardized data on spray drift levels associated with a variety of application methods under varying field and meteorological conditions. The database was reviewed by EPA internally, through external peer review workshops, and by the SAP.[62] Using the database, the SDTF began working with EPA's Office of Research and Development and the USDA's Agricultural Research Service and Forest Service in 2000 to develop and validate a

[57] The Pesticide Program Committee (PPDC) is a federal advisory committee that includes representatives from a broad variety of stakeholders interested in pesticide regulation. See http://www.epa.gov/oppfead1/cb/ppdc/.The PPDC's Spray Drift Workgroup has provided valuable input on the Agency's approach to assessing and mitigating spray drift. Membership of the Workgroup includes environmental advocacy groups, grower associations, registrants, and state officials. See http://www.epa.gov/oppfead1/cb/ppdc/spraydrift/members.htm.

[58] http://www.epa.gov/pesticides/factsheets/spraydrift.htm.

[59] For purposes of this response, bystanders are defined as people who, live, play, or work in areas at proximity to pesticide-treated areas.

[60] See http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series840.htm

[61] The Task Force's website is at http://www.agdrift.com/

[62] See http://www.epa.gov/scipoly/sap/meetings/1997/december/spraydrift.htm.

model for predicting the magnitude of off-target movement of pesticides via spray drift, called the "AgDrift" model.

The AgDrift model was developed to assess spray drift under a variety of different conditions for aerial, ground, and orchard air-blast applications. Input features provide the capability to alter over 30 parameters related to the aerial application method including types and numbers of nozzles, weather conditions, and terrain features. AgDRIFT also can provide empirically based predictions for ground and airblast applications made under various conditions, and can accommodate differences in use patterns that relate to crop-specific pest management needs. In addition, users can run the AgDrift model to estimate the amount of spray drift at specified distances from the application site.

Spray drift associated with aerial application has been evaluated extensively by the U.S. Army and the USDA Forest Service, so the drift database is more extensive for aerial applications compared to ground applications. For orchard airblast and groundboom sprayer estimates, AgDrift is more limited; unlike estimates for aerial applications, there is no mechanistic option for these ground applications. Rather, an empirical approach based on the available data is used, and users are more limited in the number of factors that can be considered (e.g., orchard canopy type for airblast sprayers). Even so, AgDrift is a powerful tool for quantifying spray drift for these application methods.

For aerial applications, EPA uses AgDrift to predict conservative estimates of the amount of spray drift given the conditions specified on pesticide labels (when such conditions are not specified on the proposed label, the Agency uses conservative assumptions). AgDRIFT has more limited capabilities to reflect label specifications for ground applications. AgDrift can be used to estimate the risk reduction attributable to buffer zones of specified widths (essentially by estimating the differences in the amount of spray drift at different distances from the application site). In addition to its use in assessing bystander risks, AgDrift can be used in environmental assessments to estimate the potential spray drift exposures to non-target animals and plants. It also is used to estimate the potential contribution of spray drift to pesticide residues in drinking water.

Results from the use of AgDrift represent a range of possible outcomes that are reflective of cultural practices tied to how the target crops are produced and the nature of the pesticide being applied. For example, a contact insecticide application to dense-canopy field crops may be most efficacious when the spray is composed of finer aerosols, while a systemic herbicide applied to a field crop canopy of lesser density, where complete spray coverage is not needed to achieve the desired degree of efficacy, can contain droplets of a larger size (as an aside, larger size or coarse droplets tend to drift less, all other factors being equal).

EPA acknowledges that there is some potential for drift exposures to occur indoors, but believes that the amount of drift entering enclosed structures is very small relative to the amount present out-of-doors. The Agency's efforts to understand the human health risks posed by drift are focused on outdoor exposures.

B. Assessment of Risk to Bystanders from Spray Drift

EPA has been working to refine and standardize the way it assesses the risks to bystanders from spray drift. On December 5, 2013, EPA presented its approach to assessing spray drift to the PPDC. EPA made this new methodology for assessing spray drift available for public comment on January 29, 2014. The announcement and directions on how to submit comments on the proposal can be accessed on the public docket.[63] EPA will continue to conduct spray drift risk assessments under its current process while it reviews and analyzes comments received during the public comment period, which originally was scheduled to end on March 31, 2014, but is being extended by 30 days. After reviewing public comments, EPA plans to finalize its methodology and consider it in cases that warrant spray drift risk assessment.

The methodology for assessing spray drift exposures is based in part on the methodology for assessing residential exposures to pesticides on turf, as explained below,[64] coupled with estimates of the amount of spray drift reaching the area in question, which are derived as described in Section A., above. EPA has developed methods for estimating risks for residential scenarios in which people may be exposed through their use of a pesticide or because they live, work, or play in places where pesticide use occurs. As noted previously, EPA uses its SOPs for residential exposure assessment as the basis for estimating exposures in these situations. These SOPs have undergone extensive external peer review by the SAP.[65] SOPs exist for a wide range of possible exposure scenarios.

The Agency assesses bystander risks from spray drift based on the residential turf scenario, in which people (including children) are exposed to pesticide residues on lawns.[66] If an agricultural pesticide is also registered for use on residential turf, EPA has determined that an additional drift assessment is not necessary beyond that of the residential turf. For an agricultural pesticide not also registered for use on turf, the Agency can use the screening methodology that is included in the new drift methodology, and may be able to conclude, qualitatively, that drift does not pose risks of concern for bystanders, so a quantitative assessment is not needed. When a quantitative assessment is needed, the methodology calls for the use of the AgDrift model to estimate the amount of pesticide residue available on turf for the exposures of adult and child bystanders. The estimated amount of residue and the exposure factors for adults' and childrens' time and activities on lawns are used to calculate exposures through the skin and from the mouthing behaviors (predominantly hand-to-mouth) of children of appropriate developmental age. These exposures are compared to the appropriate endpoint and POD, as discussed in V.B. "Hazard Identification" above.

The development of the SOPs for evaluating lawn pesticides considered a number of factors related to how residues should be quantified, the appropriate behavioral considerations for adults

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[63] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676

[64] http://www.epa.gov/pesticides/science/residential-exposure-sop.html

[65] http://www.epa.gov/scipoly/sap/tools/atozindex/residentexp.htm and http://www.epa.gov/scipoly/sap/meetings/2009/100609meeting.html

[66] See particularly the Lawns/Turf SOP at http://www.epa.gov/pesticides/science/residential-exposure-sop.html. The SOP identifies default values for exposure parameters e.g., time that a child spends on the lawn, how often children will put their hands in their mouths, etc. These values have been selected so that exposure estimates overall will be conservative.

and children, development of appropriate exposure metrics, how exposures should be combined, and what age groups should be considered as the basis for risk management. EPA considers adults involved in heavy yardwork and children ages 1 to 2 (based on both body weight and play behavior) as the two groups most highly exposed to turf–applied pesticides. EPA has extensively considered children of varying ages in order to ascertain which lifestage (referred to as index lifestage in the SOPs) has the highest relative exposure given behaviors that occur at various stages of development. Children between 1 and 2 years old routinely and very actively engage in outdoor play, and they exhibit mouthing behaviors (predominantly hand-to-mouth) which contribute to the overall exposure levels.

EPA relies on a number of assumptions when using the SOPs in the calculation of risks from spray drift. Risks are based on residue levels present on the day of application when they are at their highest levels because they have not had a chance to dissipate. Risks are also estimated based on a standardized lawn width of 50 feet. The standardized lawn was derived from U.S. Census information for single- and multi-unit dwellings—it is the mean lot width for multi-unit housing and also is a reasonable representation for single-unit housing with smaller lots. A low-end lot size is used because the concentration of spray drift residues is assumed to be inversely correlated to lot size due to the effects of residue dilution in larger lot sizes.[67] Use of "day of application" residues and the standardized lawn size contribute to a data-informed conservative estimate of risk.

C. How EPA Mitigates Potential Risks Associated with Spray Drift

Unacceptable risks associated with spray drift can be mitigated in a number of ways, including changes to application parameters, use of drift reduction technologies,[68] changes to formulations, and no-spray buffer zones, either in combination or by themselves.[69] While the use of buffer zones is one of the key issues raised by the petitioners, other measures also can be used to manage potential risks associated with spray drift. Changes to application parameters and pesticide labels that may mitigate drift risks include reduced application rates; prohibition of certain application methods; soil-incorporation of pesticides at the time of application; and prescriptive, product-specific labeling that requires a particular spray quality (i.e., droplet sizes) or climatic conditions. The Agency may also undertake cancellation of specific uses, in those rare cases where spray drift causes unreasonable risks that cannot otherwise be mitigated.

There is a significant level of effort within the agricultural engineering community to develop both drift reduction technologies and best management practices to reduce spray drift. Useful drift reduction technologies include different forms of spray nozzles and other sophisticated application equipment (e.g., sensors for canopy identification that turn off nozzles

[67] More information on the standardized lawn is found in the proposed methodology at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2013-0676.

[68] http://www.epa.gov/etop/etc_at_psdt.html and http://www.epa.gov/etop/etc_at_proppsdt.html . An instructive presentation on the Drift Reduction Technology Program is located at http://www.epa.gov/oppfead1/cb/ppdc/2012/may/session-7-drift-reduction.pdf

[69] When appropriate, EPA considers the potential consequences of mitigation measures in light of the impact on producers and on the potential for undesirable risk trade-offs.

at ends of rows), and the use of adjuvants.[70] EPA, working with academia and industry, has developed a program to rate drift reduction technologies, and plans to identify on its website tested technologies and the risk reduction potential attributable to them.[71] Other potential means of reducing exposures to spray drift are already commonly accepted,[72] for example, the adjustment of release height in ground applications. Some formulation types are less prone to drift than others; for example, switching to a dry (soil-incorporated) formulation from one that is applied as a liquid may reduce drift potential. A series of possible drift reduction measures are already included in the proposed EPA method for calculating risks from spray drift as a starting point for considering mitigation options should they be required. This element of the method will facilitate consistency in the Agency's decision-making process for managing spray drift risks.

The Agency has used the proposed assessment approach to support pesticide drift risk mitigation in past decision-making. The Agency completed its Preliminary Human Health Risk Assessment for chlorpyrifos (an organophosphate pesticide) under the registration review process in July 2011.[73] That assessment identified risk concerns for bystanders from exposure to spray drift from agricultural applications of chlorpyrifos and provided estimates of the potential risk reductions associated with various drift mitigation options.

In the Spray Drift Mitigation Decision for Chlorpyrifos (July 2012),[74] EPA announced an agreement with the chlorpyrifos registrants for implementing use restrictions intended to reduce spray drift risks to bystanders. In accordance with the agreement, risk mitigation was accomplished through amendments to chlorpyrifos product labels, which were put in place by the end of the same year. Mitigation measures were: buffer zones for groundboom, airblast, and aerial applications of chlorpyrifos around sites such as homes, sidewalks, and recreational areas; and a reduced application rate for aerial applications of chlorpyrifos (from 6 to 2 pounds active ingredient per acre).

VIII. Assessing and Managing the Risks Due to Pesticide Volatilization

Pesticide volatilization can be defined as the change of a pesticide in solid or liquid form to a gas or vapor after application has occurred.[75] Volatilized pesticides can move off-site resulting in the potential for exposure outside the treatment area. The volatilization process is complex and depends on many factors that include the innate physical and chemical properties of the pesticide, the innate characteristics of the site where it is applied, and the atmospheric conditions at the time of application. Other factors that impact volatilization, particularly those associated with application parameters, directions for use, and best management practices are under the

[70] An adjuvant is broadly defined as any non-pesticide material added to a pesticide product or pesticide spray mixture to enhance the pesticide's performance and/or the physical properties of the spray mixture.

[71] http://www.epa.gov/pesticides/factsheets/spraydrift.htm#other

[72] For example, http://pesticidestewardship.org/drift/Pages/default.aspx provides a general overview of existing technologies.

[73] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0025.

[74] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0103

[75] See http://www.epa.gov/opp00001/about/intheworks/volatilization.htm

control of the user and can be manipulated to reduce off-site movement.[76] For example, soil incorporation of the pesticide, compaction of the soil, and (particularly in the case of fumigant pesticides) tarping and tenting can reduce volatilization from soil- applied pesticides. The use of certain adjuvants may reduce volatilization from pesticides applied to foliage.

Fumigant pesticides are highly volatile.[77] Once applied, they will change into a gaseous form that works by filling the application space or by permeating the soil to kill a wide array of pests. Efficacy is achieved by ensuring that the appropriate air concentration is maintained for the necessary time in order to control the pest of concern.[78] Practices that are used to reduce exposure to (while also improving the efficacy of) fumigant applications include the use of tarps, field conditions management (e.g., soil moisture levels), and the use of specialized application implements (e.g., specially designed shanks for closing up and compacting the soil disturbances to retain the fumigant in soil).

Conventional pesticides (pesticides other than fumigants) tend to be much less volatile than fumigants because of differences in their physical-chemical properties, although some conventional pesticides volatilize under some circumstances. Conventional pesticides also are designed to achieve efficacy via different mechanisms so volatility is not a key required characteristic. When conventional pesticides do volatilize in the field, they too can move outside of the treatment area.

A. Quantifying Volatilization For Conventional Pesticides

EPA has developed a good understanding of the volatilization of fumigant pesticides, as noted above and discussed by the SAP,[79] including an understanding of how use site conditions can impact volatilization. The volatilization of conventional pesticides has not been studied to the same extent. A number of entities are now focusing on the volatilization of conventional pesticides. Research to enhance our understanding of the volatilization of conventional pesticides could include work on the impact of a crop canopy or leaf type on the volatilization process. Air monitoring data are also important in efforts to characterize how much of a pesticide will volatilize and travel out of the treatment area.

The approach used in the past fumigant risk assessments and EPA's proposed approach for conducting volatilization exposure assessments for conventional pesticides consider both single application events and the contamination of ambient air within a local community, region, or the

[76] As in controlling drift, practices that limit the off-site movement of volatilized pesticides can improve the efficacy of an application by keeping more pesticide where it is needed to control the target pests.

[77] Background and status of the Agency's re-evaluation of the fumigants is found at http://www.epa.gov/pesticides/reregistration/soil_fumigants/soil-fum-reg-backgrnd.html

[78] The interaction of concentration and time to achieve efficacy is commonly referred to as the required concentration x time schedule (CxT).

[79] Supporting documents and the final report from the December 1-4, 2009 SAP meeting on "Scientific Issues Associated with Field Volatilization of Conventional Pesticides are located in the docket at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0687.

airshed (the air supply for a defined geographical region) from multiple applications within the same area.

Potential impacts associated with individual application events can be managed more directly through pesticide labels than potential exposures to ambient air. Also, more information can be collected to quantify the volatilization associated with a single pesticide application event than the concentrations expected in ambient air. "Flux" is the term used to describe how much volatilization (or emission) of a pesticide can occur across a given area for specific period of time. Field data can be collected for empirical use in risk assessment and also as the basis for empirically based dispersion modeling. There are a number of recognized flux methods in the peer-reviewed literature.[80] Along with air concentration measurements each method requires that detailed meteorological data be collected and that the conditions of the application are also well- documented.

A large number of flux studies have been completed for fumigants, so their behavior under various field conditions is relatively well understood. Flux data have been also generated for a limited number of conventional pesticides including chlorpyrifos,[81] but in general, they are not available for conventional pesticides. This lack of flux data for conventional pesticides was a primary focus of the 2009 SAP review. EPA presented a number of options for predicting flux in lieu of data which would allow EPA to screen conventional pesticides for potential risk concerns. Building on advice from the SAP,[82] the Agency developed a screening methodology using a preferred approach known as the Woodrow equation.[83]

EPA has recently announced the availability of this screening methodology[84] and is soliciting public input on the new methodology and the proposed approach for assessing volatilization for conventional pesticides. EPA will finalize the approach after considering public comment.

Along with distinct application events, EPA also considers potential exposures to ambient air that may represent those within a community, region, or widespread airshed depending upon where, when, and how such monitoring data were collected. Such data have been used empirically and EPA characterizes such data to the extent possible given available resources. The 2009 EPA SAP analysis provides an example of how an air monitoring result could be characterized by risk assessors based on use information and knowledge of the application site relative to where monitors are placed. To date, EPA has not attempted a modeling approach for

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[80] Relevant citations can be found in the bibliography to "Scientific Issues Associated with Field Volatilization of Conventional Pesticides Presented Jointly to the FIFRA Scientific Advisory Panel, USEPA, 2009" at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0006. They include: USEPA, 2008; Majewski and Capel, 1995; Lenoir *et al.*, 1999; Majewski and Baston, 2002; McConnell *et al.*, 1998; Zamora *et al.*, 2003; Glotfelty *et al.*, 1990; Schomburg *et al.*, 1991.

[81] The preliminary volatilization evaluation for chlorpyrifos is found at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0114; supporting documents posted in the same docket discuss the modeling of flux rates.

[82] The final report of the SAP is found at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037.

[83] See Woodrow *et al.*, 1997 and 2001. Citations found at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0006.

[84] http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219

predicting ambient exposures to pesticides for these types of circumstances, but plans on exploring such approaches in the future.

Air monitoring data for conventional pesticides are limited and the quality is generally lacking compared to current protocols. The data that do exist mostly come from California; data collection under authority of California's Toxic Air Contaminant statute[85] began in the mid-1980s and continues in the present time. The Washington Department of Health has collected air monitoring data with a focus on organophosphates involved in agricultural production.[86] PANNA (one of the Petitioners) has also collected air monitoring data for a number of pesticides in various locations throughout the United States.[87] The Agency does consider these "Drift Catcher" data for risk characterization, despite certain limitations, and has concluded that the data thus far are not suggestive of concentrations of pesticides in the air that pose significant risks to human health. Other sources of air monitoring data are found in the scientific literature.

B. Estimation of Risks Associated with Pesticide Volatilization

At this time, EPA has conducted at least one volatilization assessment for a conventional pesticide using the fumigant methodology approach.[88] Volatilization risk assessments for the fumigants and conventional pesticides consider distinct, individual pesticide applications as well as ambient air contamination from multiple applications of the same pesticide in the same general area. While single application event risk estimates are based on modeled values, ambient air analyses are based on empirical values; for ambient risk estimation the most representative exposure statistic is selected and compared to the appropriate toxicological value. Additionally, risk assessments for both ambient air and single application events are informed by incident information. Looking for commonalities in the incident information and the predictive risk estimates is a critical consideration for regulatory decision-making.

The Agency's approach to assessing risks associated with single application events is multi-faceted. It includes the use of information on how the pesticide is used; flux data, which are needed for use of the Woodrow equation[89] (or, if flux data are not available, information on physical and chemical properties of the pesticide); and information on the toxicology of the pesticide from the inhalation route of administration (if inhalation toxicity data are not available, other toxicity data may be used). An air dispersion model is used to estimate air concentrations

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[85] http://www.cdpr.ca.gov/docs/emon/pubs/tacmenu.htm, and http://www.cdpr.ca.gov/docs/emon/pubs/tac/tacstdys.htm

[86] http://www.doh.wa.gov/ehp/Pest/drift.htm

[87] See http://www.panna.org/science/drift; the Agency considers Drift Catcher data when available and uses them in risk characterization. Unfortunately, the raw data that EPA prefers are not always available and the timing intervals for air samples under the PANNA protocol tend not to permit association with particular applications of the pesticides detected.

[88] Refer to the fumigant risk assessment documents for a detailed overview of the risk assessment process available: http://www.epa.gov/pesticides/reregistration/soil_fumigants/soil-fum-reg-backgrnd.html#information

[89] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0006

of volatilized pesticides surrounding treated fields.[90] Model inputs include standard assumptions about field sizes and the surrounding terrain, and weather data for representative locations. Dispersion modeling is a two-step process. First, flux information is used to characterize how much applied pesticide will volatilize from a treatment area, and then the dispersion of the volatilized pesticide around the treatment area is characterized. Changing weather patterns over time are considered. The mathematical approach to compute how volatilized residues will dissipate is based on a construct known as a Gaussian plume.[91]

EPA has data requirements for information needed to support registrations of pesticides that may result in inhalation exposures.[92] Such data are strongly preferred for use in volatilization risk assessments, but if necessary oral toxicity data can be used. Issues related to the use of oral data for inhalation exposures were discussed by the SAP in 2009.

As noted previously, EPA has recently released a screening methodology for characterizing the potential risks associated with volatilization of conventional pesticides. The Agency has used the methodology to conduct a screening level assessment of all currently-registered conventional pesticides, and found that only about 20 percent of conventional pesticides need to be evaluated further so that the Agency can better understand the potential risks associated with their volatilization and off-site movement. The results of this screening exercise will be released along with the methodology. The Agency may need additional information to perform more detailed assessments, such as data that are needed to model flux, inhalation toxicity data, and information on the pesticide's use parameters. Comments submitted by the public on the screening analysis and its conclusions will be considered as the Agency determines how to proceed. Also as noted previously, the Agency has already conducted at least one volatilization risk assessment for a conventional pesticide, and it can be viewed on the public docket.[93]

C. How EPA Mitigates Potential Risks Associated with Volatilization

After chemical risk assessments are completed, EPA must determine whether there are risks to be mitigated, and if so, how that should be accomplished. EPA has used this process to address risks posed by the volatilization of a pesticide and its off-site movement. Options that can be effective include: buffer zones, reduced application rates, low volatility formulations or adjuvants, tarping and tenting of treated fields, and crop management practices.

The fumigants assessment and mitigation measures provide a framework for considering how to manage potential volatility risks associated with conventional pesticides. For the fumigants, EPA required a suite of complementary mitigation measures to protect handlers, workers, and bystanders from risks resulting from exposure to the soil fumigant pesticides. The measures were designed to work together to address the full range of risks, but were focused on the risks of volatilization to people (workers and bystanders), and included restricted-use status,

[90] http://www.epa.gov/scipoly/sap/meetings/2004/082404_mtg.htm and http://www.exponent.com/perfum/.

[91] Distribution based on the standard bell-shaped curve.

[92] See 40 CFR §158.500.

[93] Chlorpyrifos: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0130

use site limitations, application rate reductions, and buffer zones with chemical-specific widths.[94] Other risk management measures implemented for the fumigants are not relevant to conventional pesticides, such as the use of tarps over treated fields, which is employed in conjunction with fumigant applications to reduce the off-gassing from soil applications. Risk mitigation measures differ among pesticides because the individual risk assessments were based on chemical-specific information.

IX. Responses to Requests Made by Petitioners

EPA reads the petition to make three specific requests for programmatic changes: 1) that EPA evaluate the risks to children exposed to pesticide drift and volatilization for all pesticides, 2) that EPA modify its pesticide re-evaluation process to expedite assessment of these risks, and 3) that, for certain types of pesticides, the Agency require the adoption of generic buffer zones between treated areas and places where children could congregate.[95] The Agency's responses to each of these elements follow.

Although this petition addresses how EPA assesses risk under the FFDCA, it does not specifically request to cancel registrations or modify or revoke specific tolerances. The Petitioners also are requesting that EPA require interim buffers for all "drift-prone" pesticides during the time EPA makes the programmatic changes they have requested. Because the Petitioners are suggesting specific changes to use practices but not requesting cancellation of registrations, we also have interpreted the petition to request that EPA attempt to procure voluntary label amendments from the registrants. However if the registrants did not agree, Agency-initiated cancellation actions would likely be needed to achieve the requested relief.

A. EPA Will Evaluate the Risks to Children Associated with Spray Drift and Volatilization Exposures.

While it is true that EPA has not always assessed the risks to children from spray drift and volatilization, the need for consistent and refined methods have led to the development of appropriate methodologies for doing so. The development of these methods is described in detail in Sections VII and VIII of this response.

The Petitioners are requesting that pesticide drift and volatilization risk assessments be conducted for all pesticides. We agree. The first step in EPA's new spray drift assessment methodology is a screening process to facilitate the identification of conventional pesticides that could pose risks of concern to bystanders through spray drift. As previously noted, the Agency released the draft spray drift assessment methodology earlier this year. Elements of the "needs

[94] http://www.epa.gov/pesticides/reregistration/soil_fumigants/implementing-new-safety-measures.html#risk

[95] As noted earlier, the Agency considers residential exposures to include exposures associated with homes, home lawns, yards, gardens, apartments and grounds around apartment buildings, schools, schoolyards, daycare facilities, playgrounds, athletic fields, and parks and other public spaces.

screening" process are detailed in materials posted to the docket on "Consideration of Spray Drift in Pesticide Risk Assessment."[96] The new volatilization methodology is designed to serve as a stand-alone screening methodology for any and all conventional pesticides. As noted above, the Agency has already used the volatilization methodology to screen all currently-registered pesticides. The screening processes include consideration of factors such as methods of application and use patterns of the subject pesticide. Using the screening procedures for both spray drift and volatilization, EPA considers the potential for exposure in a qualitative way. In the case of spray drift, pesticides for which the screen indicates there are potential risk concerns will undergo a quantitative assessment. Thus, we grant the Petitioners' request to conduct spray drift and volatilization assessments for all pesticides, while noting that some of these assessments will not provide quantitative results.

In the last several years, EPA has conducted a number of spray drift and volatilization risk assessments, even while the proposed assessment methodologies were being developed and refined. EPA conducted volatilization assessments for the fumigant pesticides during reregistration.[97] Chlorpyrifos also recently underwent a spray drift evaluation,[98] while the recently released proposed drift assessment methodology[99] was still in development (see Section VII B). The preliminary human health risk assessment for chlorpyrifos was completed in July 2011[100] and attendant risk reduction measures for spray drift exposures were implemented in July 2012.[101] EPA also recently published a draft volatilization risk assessment for chlorpyrifos[102] and is working to finalize the assessment even as work continues on the volatilization methodology. The methodologies set out standardized procedures so that the way spray drift and volatilization are assessed will be consistent between pesticides in general, but they are not substantively different from the approaches that were used to assess spray drift and volatilization for pesticides in the recent past.

Further evidence of EPA's commitment to reducing the risks to children exposed to pesticides is demonstrated by actions taken during pesticide reregistration process to terminate residential uses, as was done with many organophosphate insecticides. EPA now has better-developed tools for determining when spray drift poses risks to bystanders, and is committed to taking action on risks to bystanders, including children, during registration review.

The Petitioners also are requesting that EPA include the drift and volatilization exposures of children in its aggregate assessments. Including spray drift and volatilization in EPA's aggregate risk assessments would involve the following steps. First, EPA would look at exposures from drift and volatilization under the new policies to determine whether any non-negligible exposure

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[96] Process described at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0676-0003.

[97] Based on the findings from these assessments, EPA required the implementation of risk mitigation measures, including measures intended to protect bystanders. The risk mitigation measures are detailed at http://www.epa.gov/pesticides/reregistration/soil_fumigants/implementing-new-safety-measures.html.

[98] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0105

[99] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0676-0001

[100] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0025

[101] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0103

[102] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0114

due to drift or volatilization could occur. If non-negligible exposure could occur, EPA would quantitatively assess that exposure under the new policies and then aggregate that exposure with other sources of exposure consistent with existing policies on aggregate exposure. However, aggregation of drift and volatilization exposure with other sources of exposure is not specifically addressed in existing aggregate exposure policies, and thus EPA's approach may need to be modified to account for the factors involved in drift and volatilization exposure. Finally, if initial aggregate exposure estimates using conservative methodologies indicate there could be a risk of concern, EPA would need to develop efficient approaches to refining those assessments.

EPA fully agrees with the Petitioners that exposures to spray drift and volatilized pesticides should be considered in our risk assessments, and that the risks to children, with their unique biology and behaviors, must be considered separately from risks to adults. The Agency has developed the methodologies for assessing drift and volatilization and is committed to considering the comments of the public on them so that we may employ the best possible science in assessing these risks and taking action to mitigate risks as needed.

B. Expediting Assessments of Spray Drift and Volatilization Outside of the Registration Review Schedule is not Necessary

Petitioners state that EPA should accelerate its schedule for completing drift and volatilization risk assessments and prioritize pesticide reviews based on the suspected degree of risks posed to children. Petitioners suggest that this acceleration should be accomplished through modifications to the registration review process or by utilizing other authorities. Petitioners believe that registration review is too slow to be protective of drift and volatilization risks to children.[103] EPA's response to this request covers aspects of public health policy and the Agency's obligations under FIFRA and the FFDCA, and issues of efficiency.

The Agency is denying the Petitioners' request to the extent that they ask EPA to perform bystander risk assessments of the chemicals highlighted in the Petition before considering other exposures and risks. The registration review program is an appropriate and risk-protective approach for evaluating and managing the risks associated with spray drift and volatilization (and other types of risk as well). Utilizing a process outside of registration review to assess these risks to children separately from other types of risk would bypass and defer the comprehensive evaluations that allow the Agency to rely on the best and newest developments in science and to address the full complement of potential risks. The consideration of all potential risks at one time for a single active ingredient can lead to the adoption of a package of risk mitigation measures that works for all the risks of concern, or at the very least, that do not work in opposition to each other.

[103] The Petitioners also assert that because the registration review process is designed to update the reregistration risk assessments, and since the Agency did not address the risks to bystanders from drift and volatilization during reregistration, registration review will not include such assessments. In reality, the Agency updates risk assessments on the basis of available data and scientific developments, so drift and volatilization will be included in registration review, even if they were not considered during reregistration.

To set the schedule for registration review, EPA relied primarily on the baseline date for each pesticide case (usually its RED date or the date the first product containing the active ingredient was registered). Additionally, some registration review cases were grouped for program efficiency. The OPs and NMCs were among those cases.[104] For the most part, food- use pesticides subject to reregistration were given priority scheduling in reregistration, and thus, they have the earliest baseline dates. The OPs and NMCs, on which the Petitioners focus, have been scheduled at the front-end of registration review and many individual pesticides from those families are currently undergoing risk assessment. EPA believes that, insofar as the Petition requests EPA to give high priority to certain chemicals in its registration review program, the petition asks for an action that has already occurred.

The OPs and NMCs account for more than 40 *individual* active ingredients. All of these pesticides have entered registration review (or were canceled prior to entering registration review).The preliminary risk assessments for 12 of the pesticides in these two families are scheduled to be completed before October 2014.The schedule for OP and NMC registration reviews[105] is summarized in the Appendix to this response.[106] The Appendix also identifies the pesticides in these groups that were cancelled subsequent to tolerance reassessment or during the beginning stages of registration review.

With respect to conducting separate bystander exposure assessments of individual pesticides, if the Agency granted Petitioners' proposal, it would significantly reduce the efficiency of the overall registration review program. Separating the bystander drift risk assessment for children from the ongoing comprehensive evaluations for these same chemicals would require Agency resources to be redirected to the evaluation of one type of potential risk, and management of the full complement of potential risks associated with a pesticide would be deferred. In addition, the overall demand for resources and the time needed to assess first spray drift and then all other potential risks for a given pesticide would be greater in total than the time and resources needed to conduct a comprehensive assessment of that pesticide, and thus would slow Agency action on risk management. Registration review, as currently planned, is the most efficient way to achieve the Petitioners' and EPA's common goal of protecting human health, including the health of children, and the environment. Adopting the approach proposed by the Petitioners also would significantly reduce EPA's ability to meet its statutory obligation to complete registration review by 2022 or the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered. *See* FIFRA § 3(g)(1)(A)(iii).

The same logic applies to the idea of assessing chemical-specific volatilization risks separately from the comprehensive registration review assessment. Significantly, preliminary application of the volatilization screening methodology currently under development led the Agency to conclude that only 20% or so of all pesticide active ingredients have characteristics that suggest that they potentially could pose any meaningful level of volatilization risk. Thus, including the volatilization risk assessment in the registration review process as a matter of

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[104] Described in a Federal Register Notice: http://www.gpo.gov/fdsys/pkg/FR-2006-10-11/html/E6-16483.htm.

[105] http://www.epa.gov/pesticides/cumulative/ identifies the organophosphate and n-methyl carbamate pesticides by name.

[106] The full schedule is at http://www.epa.gov/oppsrrd1/registration_review/schedule.htm.

course will not appreciably affect the resources needed or timing for the vast majority of registration review decisions.

Petitioners suggest that EPA could accelerate the reviews of drift risks for children by utilizing other authorities, such as rulemaking[107] or the special review process.[108] Rulemaking is a long, resource-intensive process that can take many years to complete, and EPA believes its limited resources are better spent assessing and developing risk mitigation measures for pesticides individually than developing a regulation that could take many years to finalize. As an example, the Petitioners suggest that the WPS Rule is an appropriate model for implementing broad changes for a large number of pesticides at once. Although the WPS is an important and effective tool for reducing worker risk, it took approximately eight years to develop and promulgate the initial 1992 rule and as many years to develop a set of proposed amendments to the 1992 rule.[109]

And while Special Review served its purpose in the past, individual Special Reviews typically took many years to conclude and used Agency resources to address a narrow set of risk concerns at a time when there was no systematic re-evaluation process for pesticide registrations. Indeed, in 2009, the Agency announced that "[t]he pesticide program is moving toward closing out both the Special Review and the reregistration programs" in favor of new re-evaluations of previously registered pesticides to be conducted under registration review.[110] That is not to say that potential risk concerns that rise to the highest levels, including "emergency" or "imminent hazard" status, must wait to be addressed in registration review—the processes for such situations include those described in Section IV of this response.

Based on these considerations, for existing registrations, EPA has concluded that registration review, as currently planned, is the most appropriate, timely, and efficient way to achieve the Petitioners' and EPA's common goal of protecting human health, including the health of children, and the environment.

C. Immediate Adoption of Interim No-Spray Buffers Around Homes, Schools, Daycare Centers, and Parks to Protect Children from Drift Is Not Appropriate

Petitioners request that EPA impose interim no-spray buffers around locations where children congregate and that these measures should apply to OPs, NMCs, and all other pesticides that are: "(1) registered for application by ground sprayers, broadcast equipment, and/or aerial equipment; and (2) suspected of causing acute poisonings, cancer, endocrine disruption,

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[107] Although Petitioners mention EPA's general rulemaking authority under FIFRA, EPA is not treating this petition as a specific request for rulemaking. Instead EPA understands Petitioners' statements being made as actions that could be taken by EPA. The Agency's general rulemaking authority is provided at 7 U.S.C. § 136w(a)(1).

[108] 40 C.F.R. § 154.7

[109] The revisions to the WPS were just released for public comment on February 20, 2014--http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0184-0002.

[110] http://epa.gov/oppfead1/cb/csb_page/updates/2009/namechange-prd.html

developmental effects, and/or reproductive effects."[111] Petitioners further state that the interim buffers should be at least 60 feet in width for ground applications and 300 feet in width for aerial applications regardless of the pesticide being applied, and that these buffer requirements should remain in place at least until case-specific drift risk assessments can be undertaken. To accomplish this request, Petitioners further suggest that the Agency could use administrative procedures rather than chemical-specific risk assessment and management to effect the generic buffers i.e., rulemaking or a Pesticide Registration (PR) Notice. The Agency's response to this request covers the usefulness of the alternate approaches, the scientific basis for pesticide decision-making, and issues of efficiency.

The Agency denies the Petitioners' request to impose a requirement for interim buffers of either 60 or 300 feet on these pesticides before EPA completes the registration reviews for these pesticides. EPA contends that drift and volatilization are not posing risks of concern for all pesticides, and that interim buffers, as suggested by the Petitioners, are not the most efficient or scientifically appropriate way to mitigate such risks for any particular pesticide or group of pesticides.[112] It is the Agency's practice to assess pesticide risks based on chemical-specific data. The Agency acknowledges that the OPs and NMCs are generally among the more acutely toxic pesticides, but risk is a function of both toxicity and exposure, so toxicity alone is not sufficient to characterize the risks these pesticides may cause to bystanders via drift or volatilization, or to determine if risk mitigation is needed. Additionally, the OPs and the NMCs were reevaluated both in reregistration and in the tolerance reassessment process and, at that time found to meet the applicable statutory safety standards. These pesticides will be reassessed again in the next few years under registration review. Because pesticides vary in environmental fate characteristics, and use sites and parameters, potential exposures also differ, not just between different active ingredients, but also between different uses of the same active ingredient.

The pesticides other than the OPs and NMCs that the Petitioners believe warrant the use of 60 and 300 foot buffers are a very large and diverse group. Without considering pesticide-specific data, it is impossible to know the risks posed by each. Again, the manner in which the Petition proposes to manage the drift and volatilization risks associated with these pesticides ignores the interaction of exposure and hazard. When these pesticides underwent reregistration, the Agency found that (with certain conditions) they met the statutory standards of FIFRA and FFDCA. In order to make the same type of determinations when spray drift and volatilization exposures are appropriately considered for each individual case, the Agency must satisfy the same standards.

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[111] While an exact count of pesticides that fit in this second category cannot be made, the effects listed are a large subset of the complete set of adverse effects the Agency takes into consideration. Furthermore, EPA notes that the Petition describes the referenced pesticides and groups of pesticides as "drift prone." The Agency rejects this notion. Because drift is influenced by factors other than the characteristics of the pesticide active ingredient, primarily the physical form of the product as applied, the application method, climate, and wind, no one active ingredient or pesticide family can be considered to be drift-prone. There are particular formulations and application methods that may make certain applications of a pesticide product prone to drift. Volatilization, on the other hand, is a direct function of the physical and chemical properties of an active ingredient, and the Agency is able to identify pesticides that tend to volatilize.

[112] EPA does not believe the Petitioners have presented adequate justification for interim, across-the-board buffers for all the pesticides they have identified as being of special concern.

Even if buffer restrictions may be appropriate to mitigate the risks to children from spray drift and volatilization for some pesticides, the EPA contends that the same buffer width will not be appropriate for each of them. Despite the Petitioners' request for across-the-board, interim buffers, the Petition itself makes the point that case-specific assessments have shown that buffers of varying widths are needed to mitigate risks associated with different pesticides. They cite examples of the different buffer widths that EPA determined were necessary for products contain different active ingredients—e.g., for the fumigants, widths ranging from 25 ft to one-half mile. EPA believes that the more scientifically defensible approach involves determining whether no-spray buffers are necessary to protect children on a pesticide-by-pesticide basis. This is the approach the Agency has taken and intends to include in consideration of bystander exposure in future risk assessments.

Finally, the Agency believes that the requests made by the Petitioners with regard to interim buffers would divert limited Agency resources from important risk assessment and risk management activities and would diminish the overall level of protection EPA is able to achieve in its pesticide re-evaluations. The alternate means that the Petitioners suggest to implement the buffer requirement are also resource-intensive, time-consuming, and not likely to result in the broad protections the Petitioners desire. The resource and time requirements of rulemaking are discussed above.

The Petitioners suggest that EPA could use a Pesticide Registration (PR) Notice[113] to inform registrants that label amendments are necessary to address drift and volatilization, and, that failure to make these changes could result in cancellation or the finding that their products are misbranded. Although EPA agrees that a PR Notice is a useful tool to communicate new policies to pesticide registrants, compliance with a PR Notice is voluntary, and the Agency believes that registrants are not likely to implement changes that lack a risk-based rationale. If EPA took action to require the amendment of pesticide registrations to mitigate spray drift via buffers of uniform width, pesticide applicants and registrants could challenge the validity and applicability of the science behind the Agency-prescribed regulatory actions. Additionally, the resources needed to pursue a cancellation proceeding are extensive, and in the absence pesticide-specific assessments, would not be an effective use of EPA's limited resources.

X. Conclusion

The Agency appreciates the concern the petitioners express for bystanders, particularly children, who may be harmed by exposure to spray drift and the off-site movement of volatilized pesticides. We share this concern. The Agency has assessed spray drift and volatilization for particular pesticides in the past and is now taking steps to formalize the assessment methodologies for future assessments. These methodologies include screening-level assessment processes for use in determining if there is a need to take a more in-depth look at any given pesticide. Thus, all pesticides will be assessed either qualitatively or quantitatively. The Agency also believes that we are addressing pesticide risks on a schedule that gives the most potentially

[113] PR Notices are issued by EPA's Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies, procedures and regulatory decisions. The Agency's PR Notice webpage is at http://www.epa.gov/PR_Notices/.

risky pesticides precedence. We will continue to use approved approaches to account for the differences between children and adults in their exposures and sensitivity to pesticides.

The Agency believes that its current program of registration review is the most comprehensive and effective way to assess and mitigate pesticide risks and to take advantage of new and emerging science. The Agency believes that looking at a particular pesticide and all the potential risks associated with its use in a comprehensive fashion provides the best opportunity to effectuate necessary protections for human health and the environment. Other means of managing the risks posed by spray drift and volatilization as suggested by the Petitioners, such as conducting drift and volatilization-only assessments or re-ordering the pesticides in registration review, are either not needed, not likely to be successful, require more resources than are available, and/or take more time than registration review.

While we understand the thinking behind the proposal to mandate generic, uniform buffer requirements on pesticides of particular concern, we do not agree that a "one size fits all" solution is appropriate or scientifically defensible. Without case-specific assessments and risk mitigation, we believe it is unlikely that registrants will voluntarily adopt generic buffers. Pesticide registrants are by law afforded specific rights and opportunities to oppose decisions by the Agency that affect their registrations. Because the evidence needed to support the cancellation or amendment of registrations within this context must be scientifically defensible and specific to the subject pesticide, we believe that Agency resources are better spent in registration review.

APPENDIX

Registration Review Timelines for Pesticide Families Specifically Cited in the Petition

Table 1. Anticipated Organophosphate Registration Review Milestones[114]

Active Ingredient	Docket Opening	Draft Human Health Risk Assessment	Final Decision
Acephate	3/18/09	2014	2015
Azinphos-methyl	All registrations cancelled 2012		
Bensulide	6/25/08	2015	2015
Chlorethoxyfos	12/17/08	2014	2015
Chlorpyrifos	3/18/09	July 6, 2011	2016
Chlorpyrifos-methyl	3/13/10	2015	2016
Coumaphos	6/25/08	2014	2015
Diazinon	6/25/08	2014	2016
Dichlorvos	6/24/09	2015	2016
Dicrotophos	6/25/08	2014	2015
Dimethoate	3/18/09	2014	2015
Disulfoton	3/18/09	All registrations subsequently cancelled	
Ethoprop	12/17/08	2014	2015
Fenamiphos	All registrations cancelled 2007		
Fenitrothion	3/18/09	2015	2015
Fenthion	All registrations cancelled 2004		
Fosthiazate	6/24/09	2013	2014
Malathion	6/24/09	2014	2016
Methamidophos	12/17/08	All registrations subsequently cancelled	
Methidathion	3/18/09	All registrations subsequently cancelled	
Methyl parathion	6/24/09	All registrations subsequently cancelled	
Naled	3/18/09	2015	2016
Oxydemeton-methyl	6/25/08	All registrations subsequently cancelled	
Phorate	3/18/09	2015	2015
Phosmet	6/24/09	2015	2015
Phostebupirim	6/24/09	2016	2017
Pirimiphos-methyl	3/18/09	2015	2016
Profenofos	6/25/08	2015	2016
Propetamphos	6/25/08	All registrations subsequently cancelled	
Phosalone	2/19/08	All registrations cancelled effective 12/30/15	
Temephos	6/25/08	All registrations subsequently cancelled	
Terbufos	6/25/08	2014	2015
Tetrachlorvinphos	6/25/08	2014	2015
Tribufos	3/18/09	2015	2016
Trichlorfon	3/18/09	2015	2016

[114] Dates in the future should be considered tentative.

Table 2. Anticipated N-Methyl Carbamates Registration Review Milestones[115]

Active Ingredient	Docket Opening	Draft Human Health Risk Assessment	Final Decision
Aldicarb	6/20/12	2015	2017
Carbaryl	9/22/10	2016	2018
Carbofuran	All registrations cancelled 2009		
Formetanate HCl	12/22/10	2016	2017
Methiocarb	6/22/10	2015	2016
Methomyl	9/22/10	2015	2016
Oxamyl	9/22/10	Early 2015	2016
Pirimicarb	All registrations cancelled 2010		
Propoxur	12/16/09	2014	2016
Thiodicarb	12/16/09	2015	2016

[115] Dates in the future should be considered tentative.