

Written Objections to EPA's Response to
PESTICIDES IN THE AIR – KIDS AT RISK:
Petition to EPA to Protect Children From Pesticide Drift

Submitted on behalf of
United Farmworkers, Pesticide Action Network of North America,
Physicians for Social Responsibility, Pineros y Campesinos Unidos del Noroeste,
Sea Mar Community Health Center, California Rural Legal
Assistance Foundation, and Farm Labor Organizing Committee

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WRITTEN OBJECTIONS TO EPA'S MARCH 31, 2014 RESPONSE TO
"PESTICIDES IN THE AIR—KIDS AT RISK: PETITION TO EPA TO
PROTECT CHILDREN FROM PESTICIDE DRIFT (2009)"

These objections are submitted on behalf of original petitioners Pesticide Action Network of North America ("PANNA"), United Farmworkers, Pinos y Campesinos Unidos del Noroeste, Sea Mar Community Health Center, California Rural Legal Assistance Foundation, Physicians for Social Responsibility, and Farm Labor Organizing Committee (collectively "Petitioners"). These objections are submitted under 21 U.S.C. § 346a(g)(2)(A) and in accordance with 40 C.F.R. §§ 178.20 and .25.

SUMMARY

Petitioners object to the U.S. Environmental Protection Agency's ("EPA") Response to "Pesticides in the Air—Kids at Risk: Petition to EPA to Protect Children from Pesticide Drift (2009)" (the "Kids Petition")¹ based upon the following:

1. EPA's Response leaves in effect the tolerances originally developed under the FQPA with its refusal to timely and quickly correct exposure assessments to include consideration of drift exposures when setting tolerances under the Food Quality Protection Act ("FQPA") by 2006. EPA's Response unreasonably and arbitrarily continues EPA's ongoing violation of the FQPA and leaves children unreasonably at risk for pesticide exposures;

2. In deciding to leave the incomplete and inadequate tolerances in place with no interim protections, EPA is in violation of its obligation under the FQPA to include an additional tenfold safety factor to protect infants and children due to the incompleteness of data for pesticide drift and failure to assess all aggregate exposures for which it had reliable information

¹ The Kids Petition is attached without original exhibits as Exhibit A; exhibits to the Kids Petition were submitted to EPA at the time of filing the Kids Petition. EPA's Response to the Kids Petition is attached as Exhibit B.

in EPA's initial setting of tolerances in 2006.

Petitioners do not seek an evidentiary hearing as the questions presented are legal issues only.

RELIEF

Petitioners ask EPA to immediately correct its failure to consider pesticide drift in setting tolerances. Pending EPA's reconsideration of tolerances to take into account pesticide drift (regardless of whether EPA moves immediately or on a longer timeframe), EPA must at a minimum immediately amend tolerances to include an additional tenfold safety factor to account for incompleteness of data, as provided for and required by the FQPA.

FEE WAIVER

Under 40 C.F.R. § 180.33(i), objections to a tolerance must be accompanied by a filing fee of \$4,050.00. The Administrator may waive or refund the filing fee when doing so will promote the public interest. *Id.* § 180.33(l). Further, while the regulations provide that an additional fee of \$2,025.00 must accompany every request for a fee waiver, that additional fee is not required when the objecting party has no financial interest in the outcome of the objection. *Id.* While Petitioners are providing the initial \$4,050.00 fee with this Objection, Petitioners request the Administrator waive the fee requirement and refund the amount in full. None of the Petitioners has any financial interest in the tolerances at issue or any of the chemicals that may be affected. Petitioners seek to protect the public from health risks associated with pesticide drift. Many of the Petitioners represent and work with persons who have personally been affected by pesticide drift, either through exposure to themselves or members of their families. As noted in the Kids Petition, many of the communities affected by drift are rural communities with higher poverty rates, raising environmental justice issues. Imposition of this large fee is and will be a significant barrier and deterrence to members of the public asserting their rights under

the law by pursuing the objection process to protect their communities. By creating a high barrier to pursuing justice for those directly affected by pesticide drift, such an onerous fee “would work an unreasonable hardship” on Petitioners, and “waiver or refund will promote the public interest.” *See id.* EPA should grant Petitioners’ request for fee waiver in this case.

BACKGROUND

I. PESTICIDE SPRAY DRIFT IS A RECOGNIZED THREAT TO CHILDREN AND FAMILIES THAT IS UNADDRESSED BY CURRENT REGULATORY PROTECTIONS.

A number of epidemiological studies link pesticide drift to specific adverse health effects in humans, including autism spectrum disorders,² Parkinson’s disease,³ and childhood acute lymphoblastic leukemia.⁴ For decades, EPA has required pesticide labels to include general admonitions to avoid spray drift, but EPA has also repeatedly recognized that this generalized label direction is inadequate to protect innocent bystanders, such as children, from drift. For example, the Worker Protection Standard (“WPS”) regulations have included a provision generally requiring pesticide users to “assure that no pesticide is applied so as to contact, either directly or through drift, any worker or other person”⁵ With only this general label direction, EPA found that numerous poisoning incidents were occurring each year and the

² E.g., Roberts, E., et al., *Maternal Residence Near Agricultural Pesticide Applications and Autism Spectrum Disorders Among Children in the California Central Valley*, *Envtl. Health Perspectives*, Vol. 115, No. 10, at 1482 (Oct. 2007), attached to Kids Petition.

³ E.g., Costello, S., et al., *Parkinson’s Disease and Residential Exposure to Maneb and Paraquat From Agricultural Applications in the Central Valley of California*, *Am. Journal of Epidemiology*, Vol. 169, No. 8, at 919 (Jan. 2009), attached to Kids Petition.

⁴ E.g., Rull, R., et al., *Residential Proximity to Agricultural Pesticide Applications and Childhood Acute Lymphoblastic Leukemia*, *Envtl. Research*, Vol. 109, at 891 (July 2009), attached to Kids Petition.

⁵ 40 C.F.R. § 170.210(a).

current drift labeling was “inconsistent or inadequate and for many products unclear to applicators and others.”⁶

In order to provide better protections from drift, EPA initially took two actions. First, it established a “Spray Drift Task Force” (“Task Force”) charged with helping to develop “a generic spray drift database which is expected to be capable of satisfying spray drift data requirements for virtually all pesticide product registrations in the United States and Canada.”⁷ The Task Force ultimately developed an evaluation tool—called “AgDRIFT”—that can help estimate exposure from spray drift for individual pesticides.⁸ Second, EPA published a notice proposing “improved and more consistent product label statements for controlling pesticide drift in order to be protective of human health and the environment.”⁹ EPA explained why it believed new spray drift label language was necessary:

EPA’s position on pesticide drift is that applicators must not allow pesticide spray or dust to drift from the application site and contact people, animals, and certain sensitive sites, including structures people occupy . . . , parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, or rangelands. The Agency believes this is prudent public policy. It sets high but appropriate standards for applicators to protect people and the environment. . . . EPA believes the suggested labeling in this Notice will reduce risks associated with pesticide drift without a significant reduction in product efficacy. Accordingly, EPA believes that these label statements will help ensure that the requirements of FIFRA are met and, specifically, that pesticides are used in a manner that does not result in “unreasonable adverse effects on the environment.”¹⁰

⁶ EPA, *Pesticide Registration (PR) Notice 2001-X Draft: Spray and Dust Drift Label Statements for Pesticide Products*, attached to Kids Petition. See also continuing reported incidents in Washington State since 2001 and most recently, in spring of 2014, *infra* at 4-5.

⁷ EPA, *Pesticide Registration (PR) Notice 90-3: Announcing the Formation of an Industry-Wide Spray Drift Task Force* (Apr. 6, 1990), attached to Kids Petition.

⁸ Task Force, *AgDRIFT Frequency Asked Questions* (July 31, 2003), attached to Kids Petition.

⁹ Draft Spray Drift PR Notice.

¹⁰ *Id.*

EPA's proposal would have placed limits on application equipment, methods, and conditions, such as wind speeds to reduce drift exposures.¹¹ Unfortunately, EPA's efforts stalled at this point with no change to pesticide labels or registrations.

As set forth in the Kids Petition, poisoning incident reports continue to show that pesticide drift poses significant risks to people. For example, in 2006, the Washington State Pesticide Incident Reporting and Tracking Review Panel found that "[e]xposure to pesticide drift is an important cause of documented pesticide-related illness in Washington."¹² The California Department of Pesticide Regulation ("CDPR") documented 3,997 reported pesticide drift incidents in California between 1992 and 2007.¹³ Moreover, it is well-documented that actual reported drift incidents are simply the tip of the iceberg in that many incidents go unreported due to the well-documented disincentives and obstacles to such reporting.¹⁴

Numerous other drift exposure events have occurred in Washington and elsewhere. In Washington State in 2012 and 2013, there were 72 pesticide drift incidents, 35 of which involved direct human exposure.¹⁵ In one of these incidents, six children and two adults were drifted on

¹¹ *Id.*

¹² Washington State Pesticide Incident Reporting and Tracking Review Panel, *Annual Report: 2005*, at 81 (May 2007), attached to Kids Petition.; *see also* Barbara Morrissey, *Washington State Department of Health, Spray Drift and Human Health Incidents*, attached to Kids Petition.

¹³ Cal. Dep't of Pesticide Regulation, *California Pesticide Illness Query*, attached to Kids Petition.

¹⁴ *See* General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children* (Mar. 2000), attached to Kids Petition. *See also*, EPA, *Regulatory Impact Analysis of Worker Protection Standard for Agricultural Pesticides*, at V-11 to V-20 (Aug. 1992), attached to Kids Petition.

¹⁵ Bud Hover, Director Washington State Department of Agriculture Pesticide Management Division, 2013 Annual Report to the Legislature at 11 (Feb. 2014), *available at* <http://goo.gl/h5FFcz>.

by Oxamyl, Pyraclostrobin, and Metriam.¹⁶ In Washington, spray drift “continues to be the most frequent type of complaint involving pesticide applications.”¹⁷ In the spring of 2014, Washington is reporting record-high number of pesticide drift events sickening workers.¹⁸ It is highly likely that pesticides harming workers are drifting to nearby areas and exposing other innocent bystanders as well. At a minimum, the ongoing problems with drift sickening—and at times hospitalizing—workers and bystanders reinforces the inadequacy of generalized cautionary label language regarding drift.

Petitioners have also provided EPA with ongoing evidence of drift exposures suffered by Petitioners’ own members. After EPA’s four-year silence on the Kids Petition, a number of the Petitioners filed a mandamus petition in the Ninth Circuit of the U.S. Circuit Court of Appeals in 2013 in order to compel EPA to respond. With the mandamus filing, a number of declarations from members of the petitioning organizations showed that drift incidents continue to expose families and communities to pesticides drift, well after the 2009 filing of the Kids Petition. For example, Manuel Silveira submitted a declaration describing the ongoing exposure to pesticides he, his family, and his community suffer through spray drift, including acute exposure to chloropicrin.¹⁹ Bonnie Wirtz, another declarant in the mandamus action, suffered a pesticide drift event at her home in rural Minnesota.²⁰ Ms. Wirtz’s infant son was also likely exposed

¹⁶ *Id.* at 12.

¹⁷ *Id.* at 10.

¹⁸ *See*, Washington Dep’t of Health Press Release, enclosed as Exhibit C. *See also* letter from Columbia Legal Services describing earlier drift and chlorpyrifos incidents in Washington State, enclosed as Exhibit D.

¹⁹ Silveira Decl. ¶¶ 6-12, enclosed as Exhibit E.

²⁰ Wirtz Decl. ¶¶ 4-8, enclosed as Exhibit F.

through the drift incident.²¹ Howard Hurst, a teacher at a school in Hawaii, filed a declaration describing how teachers and students have been repeatedly exposed to drifting pesticides at school from test fields adjacent to the school.²² In these incidents, children at the school and other teachers have been directly exposed to pesticides.²³ Copies of the relevant declarations are included with these objections as Exhibits E through G. Finally, as part of comments critiquing EPA's recently-proposed drift assessment guidance (EPA Docket No. EPA-HQ-OPP-2013-0676), Petitioners submitted additional evidence of drift incidents such as a reported incident in California where a school bus was directly drifted on with some kids reporting symptoms of pesticide exposures.²⁴ In that incident, a school bus full of children near Stockdale, California was directly exposed to chlorpyrifos in an aerial application drift incident with some students exhibiting symptoms of exposure.²⁵ Inspectors were able to confirm the presence of chlorpyrifos through swabs and clothing samples.²⁶

Pesticide drift is and continues to be a significant route of exposure for many children who live or go to school near agricultural fields. In light of the heightened vulnerabilities of children to pesticides, EPA cannot ensure that children will be protected from harm unless it accounts fully for such exposures and, in cases of missing data, applies an additional tenfold safety factor. Each year that EPA delays addressing its failure to consider pesticide drift

²¹ *Id.*

²² Hurst Decl. ¶¶ 6-18, enclosed as Exhibit G (without attachments. *See* court file for attachments).

²³ *Id.*

²⁴ *See* incident reports, enclosed as Exhibit H.

²⁵ *Id.*

²⁶ *Id.*

exposures in setting pesticide tolerances under the FQPA, more children and families are exposed to unsafe levels of risk.

II. EPA FAILED TO INCLUDE PESTICIDE DRIFT EXPOSURES IN SETTING TOLERANCES FOR PESTICIDES.

In 1996, Congress unanimously adopted the FQPA, amending the Federal Food, Drug and Cosmetic Act (“FFDCA”) to incorporate the National Academy of Science’s 1993 recommendations for EPA to ensure that children are protected from pesticide exposures.²⁷ Under the FQPA, before EPA can allow a pesticide residue on a food, the agency must “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure” to the pesticide.²⁸ The FQPA defines “aggregate exposure” to include “all anticipated dietary exposures and all other exposures for which there is reliable information.”²⁹ The FQPA gave EPA 10 years—until 2006—to bring all uses of pesticides on food into compliance with the new standards.

To implement these statutory mandates, EPA has developed a “risk cup” approach that first quantifies the exposure level for a pesticide that would exceed the safety standard for specific population groups, including fetuses, infants, and children in different age ranges. EPA then adds up exposures from various sources, such as consumption of each food on which the pesticide is used, residues in drinking water, and exposure to the pesticide through residential uses. If aggregate exposures to the pesticide from non-occupational sources “overflow” the risk cup for a particular subpopulation, the pesticide does not meet the FQPA safety standard. EPA

²⁷ H.R. Rep. No. 104-669, Pt. 2, at 43.

²⁸ 21 U.S.C. §§ 346a(b)(2)(C)(ii)(I), (II).

²⁹ 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added); *see also* 21 U.S.C. § 346a(b)(2)(C)(vi) (In setting tolerances, EPA “shall consider . . . available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical and to other related substances, including dietary exposure . . . and exposure from other non-occupational sources . . .”).

will then look for ways to reduce exposure by, for example, eliminating some uses to reduce total exposure to levels that meet the safety standard.

The FQPA also amended FIFRA's "unreasonable adverse effects" definition to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard."³⁰ Accordingly, EPA can register a pesticide only if there is reasonable certainty of no harm from aggregate exposure to the pesticide under the FQPA standard.³¹ EPA can impose use restrictions as necessary to meet this standard, which are included on the legally enforceable pesticide label. Early on in its implementation of the FQPA's aggregate exposure mandate, EPA acknowledged that non-food exposures to children had to be assessed and could lead to use restriction and tolerance revocation. For example, in 2000 and 2001, EPA negotiated a phase-out of almost all home and garden uses of the organophosphates chlorpyrifos and diazinon after determining that residential uses of these pesticides cause the child risk cup for each of these pesticides to overflow.³² The August 2006 deadline for bringing food-use pesticides into compliance with the FQPA extends to both tolerances under the FFDCa and registrations under FIFRA.³³

³⁰ 7 U.S.C. § 136(bb)(2).

³¹ *E.g.*, EPA, *General Principles for Performing Aggregate Exposure and Risk Assessments*, at 9 (Nov. 28, 2001), Attachment 28 ("[T]he [FIFRA] standard for making decisions whether to register or continue registration of a pesticide for food-use must satisfy the standards in the FFDCa.").

³² EPA, *Occupational/Residential Handler and Postapplication Residential Risk Assessment for Chlorpyrifos*, at 6 (Oct. 1999), attached to the Kids Petition 26; EPA, *Diazinon Revised Risk Assessment and Agreement with Registrants*, at 2-3 (Jan. 2001), attached to the Kids Petition.

³³ Use restrictions are set out on the EPA-approved label affixed to the product. A pesticide may not be used in a manner inconsistent with the label. If EPA determines that a pesticide registration does not comply with FIFRA, it may commence administrative proceedings to cancel the pesticide's registration or amend the registration to require additional safeguards. 7 U.S.C. § 136d(b).

As EPA has admitted,³⁴ it failed to consider and include pesticide drift exposures when compiling and analyzing children's exposures in its risk cup analysis for its initial setting of tolerances under the FQPA directive by 2006.³⁵ It is only after the filing of the Kids Petition that EPA has done some assessment of spray drift of chlorpyrifos and set interim (very small) spray buffers pending completion of the registration review.³⁶ EPA agrees that it is required to consider drift as it has acknowledged repeatedly for years,³⁷ but EPA disagrees that it must correct its earlier failure to do so in a timely fashion despite its original 2006 deadline.³⁸ EPA has in effect admitted a major gap in its data and health protections, but it has made no effort to provide full protection to children by expediting corrected analysis, or by taking interim protective steps. Acknowledging risk does not, on its own, reduce risk.

III. EPA'S RESPONSE TO THE KIDS PETITION DENIES A TIMELY CORRECTION TO ITS ACKNOWLEDGED FAILURE TO ADDRESS DRIFT IN SETTING TOLERANCES AND DENIES NECESSARY INTERIM PROTECTIVE MEASURES WHILE IT COMPLETES ITS LENGTHY PROCESS TO CORRECT THIS LEGAL ERROR.

Petitioners filed the Kids Petition in October of 2009. EPA sought public comment on the Kids Petition, extending the comment period to March 5, 2010. EPA gave no other response

³⁴ Prior to filing the Kids Petition, EPA's reregistrations of pesticides were challenged in lawsuits that raised exactly this issue. *See, e.g., United Farm Workers v. Adm'r, Env'tl. Prot. Agency*, 592 F.3d 1080 (9th Cir. 2010). That case was ultimately dismissed for lack of jurisdiction, precipitating the filing of a petition challenging chlorpyrifos tolerances under the FQPA and leading Petitioners to request the modification of tolerances in the Kids Petition.

³⁵ *See* EPA Response at 32-33.

³⁶ *Id.* at 33. EPA also has recently done some assessment of volatilization risk of chlorpyrifos and some other fumigant pesticides. Petitioners concern themselves here primarily with spray drift and in either case, none of this recent assessment occurred in compliance with EPA's initial FQPA obligations nor has it led to completion of work on whether revised or revoked tolerances may be necessary when taking into account drift exposures.

³⁷ *See* EPA Response at 32-34.

³⁸ *Id.* at 34-36.

on the Kids Petition until, having received no response, a subset of Petitioners filed suit to compel a response in the summer of 2013. Petitioners initiated the lawsuit almost four years after filing the Kids Petition and seven years after EPA was required to complete consideration of all exposures to pesticides, including drift (as EPA now admits), and to set tolerances in its FQPA processes. EPA finally responded to the Kids Petition on March 31, 2014 (“EPA Response”). EPA effectively denied the relief requested promising only to comply with the law in the future by considering only some avenues of exposure to pesticide spray drift as it moved through its lengthy registration review process.

The Kids Petition sought two basic forms of relief. First, it sought immediate compliance with the FQPA obligation to set tolerances that are protective based upon children’s aggregate exposures to pesticides, including drift. Recognizing that EPA’s registration review process was on an extremely lengthy timeline (completion in 2022), Petitioners asked that EPA act more quickly to correct the acknowledged failure to include drift than the extended registration review process timeline.³⁹

Second, the Kids Petition sought interim protections for children from exposures to pesticide spray drift while EPA’s process of correcting its earlier failure was pending (regardless of whether EPA moved quickly, or, especially if EPA refused to move more quickly than its registration review process). The Kids Petition offered spray application buffers as a strong alternative for interim protections, particularly for those pesticides such as organophosphates and

³⁹ While EPA has voluntarily set earlier deadlines for some pesticides, EPA’s history of pesticide reregistration and/or reconsideration of tolerances is dismal in terms of timeliness, with EPA rarely conforming to promised deadlines, even when those promises are made to, and relied upon by, U.S. Circuit Courts. *See, Order, In re: Pesticide Action Network of N. Am. and Natural Res. Def. Council*, Court File No. 12-71125 (9th Cir. July 10, 2013) (finding that EPA “set forth a concrete timeline for final agency action that would resolve the Petition by February 2014”). EPA has not met the February 2014 deadline and has refused to commit to an enforceable new deadline.

carbamates where EPA's earlier risk cup analysis left little room for error. During the comment period on the Kids Petition, PANNA even offered calculated buffers for EPA's ease of application.⁴⁰ While other alternatives for interim protection exist and could also have served the purpose (e.g. control of spray drift through technical methods such as droplet size and spray nozzle adjustment, also based upon work of the Task Force, or through other protection measures such as additional safety factors—*see* EPA Response at 27), buffers are simply-applied and proven-effective.

EPA has rejected both requests. EPA purports to “accept” the Kids Petition by committing to include drift exposures as part of its plodding and never-ending registration review process, but EPA's commitment is nothing more than what it has always been legally required to do. Essentially, EPA is “committing” to obey the law at some time in the future when it gets around to correcting its earlier mistakes—that originally should have been corrected by 2006—and, in the meantime, exposure to pesticide drift continues to be unaccounted for in EPA risk analysis.⁴¹ EPA otherwise completely denies the Kids Petition, leaving in place the inadequate and/or incomplete tolerances initially set under FQPA with no consideration of drift as part of the required risk assessment and obligation to protect infants and children.

⁴⁰ Letter from Karl Tupper, PANNA, dated March 5, 2010, EPA Docket EPA-HQ-OPP-0825 (and 0628).

⁴¹ EPA has also stated its intent not to consider direct exposure to pesticide spray drift in its recent draft guidance, Residential Exposure Assessment Standard Operating Procedures (SOPs), Addenda 1: Consideration of Spray Drift (“Spray Drift Assessment Guidance”), EPA Docket No. EPA-HQ-OPP-2-13-0676. Petitioners commented on the Spray Drift Assessment Guidance and pointed out that in omitting a known avenue of exposure, direct exposure to pesticides, EPA will be acting contrary to the obligation under FQPA for EPA to consider all avenues of exposure to pesticides. PANNA et al. Comments on Spray Drift Assessment Guidance at 3-6. Agencies may not assume compliance with the law when evaluating proposed courses of action where violations are known to occur regularly. *See, e.g., Found. for N. Am. Wild Sheep v. U.S. Dep't of Agric.*, 681 F.2d 1172, 1178-79 (9th Cir. 1982).

EPA denies that it has any obligation to modify tolerances now or that the record supports moving more quickly than its standard registration review process (the only deadline for which is 2022—a full 16 years after the FQPA deadline and 13 years after the date of the Kids Petition—almost a generation of kids later). EPA has decided that its process is wholly immutable regardless of admitted errors and its mandate to protect children.⁴²

Moreover, EPA denies any need for or obligation to impose interim protections. Again, EPA appears to take the position that it must plod through its registration review process to completion before it can take any steps to protect kids from pesticide drift, despite ample evidence that children continue to be exposed to pesticide drift and despite its earlier, admitted failure to comply with its obligations to complete tolerances by 2006 that take into account *all* exposures, including drift, when setting tolerances. EPA Response at 2-3, 13, 32-35. EPA's insistence on leaving inadequate tolerances in place with no additional safety factor or interim protections while simultaneously insisting on a long, slow process that will years-hence include consideration of children's drift exposures is unsupported by the law or the record.

OBJECTION

These objections challenge EPA's refusal to quickly and timely act to correct its failure to include pesticide drift in its risk assessments for setting FQPA tolerances for pesticides by 2006 and to impose required additional tenfold safety factors during the period of time that EPA's reassessment of tolerances including drift is pending during its registration review process.

⁴² In fact, EPA's response to the Kids Petition includes a curious statement about its perceived mandate. EPA claims its "mandate" is to unflinchingly apply a lengthy *process*, EPA Response at 3, but in fact, EPA's *mandate* under the FQPA is to proactively *protect* infants and children from the negative health impacts of pesticides.

I. EPA MUST IMMEDIATELY MODIFY TOLERANCES TO INCLUDE AT MINIMUM A TENFOLD SAFETY FACTOR TO ACCOUNT FOR ITS FAILURE TO INCLUDE PESTICIDE DRIFT.

Under the FQPA, EPA was required to set tolerances for pesticides that were protective of infants and children, taking into account total aggregate exposures to all pesticides, including drift. 21 U.S.C. § 346a(b)(2)(C)(ii)(I), (II). EPA was required to complete those tolerances no later than 2006. *Id.* at 346a(q). EPA admits that it failed in this obligation because it did not take drift into account in setting those initial FQPA tolerances. EPA Response at 20-3, 6, 32-33. EPA has not completed any tolerance assessments in its registration review process, or otherwise, that include analysis of drift exposures and necessary reductions or mitigation to meet FQPA's safety standard.

EPA's response that it will eventually follow the law, on an extended and apparently inalterable pesticide-by-pesticide schedule, is inadequate given that it has already missed the 2006 FQPA deadline to set protective tolerances, it admits that was an error, and the record makes clear that children are being exposed to pesticide drift on a regular basis. EPA has an obligation to follow the law and correct its mistake quickly on an accelerated schedule that reflects the risk posed to children by pesticide drift.

More importantly, regardless of whether EPA acts to correct its mistake now, in the near future, or over an extended period, for the period of time during which EPA is reassessing tolerances, it must immediately impose modified tolerances that are required under FQPA. The FQPA requires EPA to apply an additional tenfold margin of safety for pesticide chemical residue and other sources of exposure when necessary to account for incompleteness of data with respect to exposure and toxicity. 21 U.S.C. § 346a(b)(2)(C). *See also Natural Res. Def. Council v. U.S. Env't'l Prot. Agency*, 658 F.2d 200, 216-17 (9th Cir. 2008). Indeed, the FQPA states that EPA "shall" apply the additional tenfold margin of safety, which may be reduced only on the

basis of reliable data. *Id.* Because here, EPA has effectively admitted incomplete data, a tenfold safety factor is required by statute.

As EPA recognizes in its response to the Kids Petition, the FQPA requires it to consider all “reliable information” in setting tolerances, and where it lacks reliable information or there is incompleteness or uncertainty, it is required to impose the safety factor. 21 U.S.C.


§ 346a(b)(2)(C). Here, EPA has reliable information on drift exposures (as presented in the Kids Petition itself and as supplemented with the 2013 declarations) and from its own work since 2000 to use in assessing drift exposures and risk for children and infants. *See, e.g.,* EPA Response at 23-24, Kids Petition, and Exhibits to this Objection. Because EPA did not consider pesticide drift, EPA has a data gap in the tolerances it set in 2006, and that gap must be addressed by immediately adding a tenfold safety factor to the existing tolerances until EPA sets other sufficiently protective tolerances. Given its acknowledged failure to consider pesticide drift, EPA cannot credibly argue that it has the requisite “reliable data” to omit the additional safety factor under 21 U.S.C. § 346a(a)(2)(C).

Alternatively, if EPA takes the position that it did not or does not have reliable information on drift—a surprising conclusion given the regular reporting of pesticide drift incidents and EPA’s own work on the issue—EPA’s obligation to include the tenfold safety factor is even stronger. In that instance, EPA’s claimed inability to develop a method for assessing drift exposures dictates, under the plain language of the FQPA, immediate addition of a tenfold safety factor to existing tolerances while EPA’s reassessment is pending. EPA’s mandate to include the additional factor is plain and applies regardless of EPA’s timeline. EPA’s decision to leave tolerances it has effectively acknowledged to be inadequate tolerances in place pending lengthy registration review is unsupported by the law or the record.

CONCLUSION

EPA's mandate under the FQPA is to protect infants and children from pesticides and to do so in a manner that is thorough, timely, and incorporates adequate safety factors to ensure that incomplete data or uncertainty does not leave any gaps in that protection. EPA has failed in its mandate when it did not consider pesticide drift in aggregate exposures in the initial setting of tolerances under the FQPA 2006 deadlines.

Respectfully submitted this 28th day of May, 2014.



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