October 2, 2006



Ms. Debbie Edwards, Director Special Review and Reregistration Division (7508P) Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P) Environmental Protection Agency 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001.

Dear Ms. Edwards,

This is a submission to docket number EPA-HQ-OPP-2006-0618.

On behalf of Pesticide Action Network North America (PANNA), Farm Worker Pesticide Project and their members and affiliated organizations, as well as the 18 co-signers of this letter, and in solidarity with the more than four million U.S. farm workers and their families who face the greatest risks from exposure to pesticides, we appreciate the opportunity to provide comments on EPA's Organophosphate Cumulative Risk Assessment (CRA) issued 31 July 2006 in response to the congressional mandate under the Food Quality Protection Act (FQPA). In this assessment, the Agency claims to have evaluated the potential risk associated with more than 30 organophosphate pesticides (OPs).

Much of the August 2006 CRA was based on EPA's June 2002 assessment, with a focus on OP exposure in food, drinking water, and in residential/ non-occupational settings. The key elements of the 2006 update to the hazard and dose-response assessment include evaluation of inter- and intra- species extrapolation and assignment of OP-specific FQPA factors for the protection of infants and children.

We would like to begin by acknowledging the substantial work that EPA has conducted to get to this point in the CRA process and recognize the extensive new science that was developed by Agency staff. We support the risk reductions that have been achieved since 1996, when 49 OP pesticides were registered for use in agriculture and residential settings. Today, 14 of those pesticides have been canceled completely. Considerable risk mitigation actions have been taken for another 28 pesticides. These are good steps.

While recognizing that the Agency has not yet finalized some of the individual OP risk assessments and mitigation actions (e.g. DDVP, dimethoate, azinphos methyl, phosmet), we remain concerned that the CRA as written will not lead to mitigations that would sufficiently protect public health (especially the developing fetus and children) from adverse effects of cumulative exposure to OP pesticides.

Advancing Alternatives to Pesticides Worldwide

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In these comments, we echo the concerns expressed by three unions representing over 9,000 EPA scientists, risk managers and their staff in their May 24, 2006 letter to EPA administrator Stephen Johnson.¹ The scientists expressed serious concern that EPA's pending decision on OPs would violate the precautionary intent of the FQPA in its failure to adequately consider pre- and post-natal exposure to OPs among the susceptible subpopulation of children on farms, in or near farm area homes, and in associated public areas.

We are encouraged by the Agency's promise to evaluate "comments or data that it receives" and to "modify this assessment, as appropriate." With that expectation, we submit the following comments that focus on three issues:

- 1. Uncertainty factors selected by EPA are not protective of the population, especially children
- 2. Important residential exposure pathways (especially inhalation) were not considered
- 3. Highly exposed farm children and farm worker children were not considered

1. Uncertainty factors selected by EPA are not protective of the population, especially children

In its July 31, 2006 CRA document, the Agency announced a reduction in the uncertainty factors for several OPs. We are concerned that EPA considered only one mechanism for neurotoxic effects of OP (and carbamate) pesticides—cholinesterase inhibition—and failed to require pesticide registrants to test for other mechanisms of nervous system toxicity. Developmental neurotoxicity is a particular concern, as indicated by an ample and continuously expanding literature illustrating the scope of non-cholinergic neurotoxic effects.

a) Recent studies indicate damage to the developing fetus through non-cholinergic mechanisms

A brief review of the relevant literature provides sufficient evidence to raise serious doubts about using cholinesterase inhibition as the sole toxicological endpoint for OP pesticide exposure. We highlight a few of the relevant papers below.

- Many recent studies indicate that low-level exposure to chlorpyrifos interferes with the development of the nervous system in the mammalian fetus. Developmental effects of chlorpyrifos involve mechanisms unrelated to cholinesterase inhibition, notably events in cell signaling that are shared by non-neural targets (Meyer *et al.*, 2003).²
- In 1997 and 1998, Song et al. identified several mechanisms of non-cholinergic developmental effects of chlorpyrifos in rats at subtoxic doses.^{3, 4}
- Slotkin *et al.* (2006) document a decade of evidence implicating a host of noncholinergic mechanisms of OP toxicity that depend upon the direct targeting of events specific to the developing brain. Neural cell replication and differentiation are both affected, with a reduction in the number of neural connections observed in exposed rats.⁵ The relative potency of OP pesticides for producing developmental

neurotoxicity via mechanisms unrelated to choline sterase inhibition has not yet been determined. $^{\rm 6}$

- Whyatt *et al.* (2001, 2004) conducted epidemiological studies on pregnant mothers exposed to chlorpyrifos through involuntary home pesticide use and demonstrated a link between *in utero* exposure to chlorpyrifos and low birth weights and/or reduced head circumference of newborns in the study, most significantly for mothers whose genetic makeup is such that they produce low levels of PON1, the enzyme that is responsible for detoxifying chlorpyrifos and its oxon in the body.⁷
- Colborn (2005) shows that chlorpyrifos attacks neurons that appear during the earliest stage of brain and central nervous system development.⁸
- Rawlings *et al.*(1998) documented the endocrine disrupting effects of chlorpyrifos; moderate doses have been shown to alter hormone levels in animal studies.⁹
- Aldrige *et al.* (2003) showed that chlorpyrifos effects on serotonin are likely to contribute to the non-cholinergic component of its developmental neurotoxicity.¹⁰

Each of these studies was conducted by independent scientists who published their work in the peer-reviewed literature. Much of this work has been done since IREDs were published for specific OPs, but these papers should certainly have been given equal (if not preferential) consideration to industry studies in the development of the CRA.

In light of the substantial amount of evidence of developmental neurotoxicity as a result of noncholinergic effects at doses *lower* than those causing cholinesterase inhibition, the entire concept of basing the CRA on a cholinesterase inhibition endpoint alone is called into question, in terms of protecting children's health. Without data on the relative potency of OPs to cause developmental neurotoxicity via mechanisms unrelated to cholinesterase inhibition, EPA cannot ensure that the current use of OPs does not adversely affect infants and children.

b) Reduction in FQPA uncertainty factors is inappropriate

We are concerned that the FQPA uncertainty factor that was intended to protect children was eliminated altogether for: acephate, chlorpyrifos, DDVP, dimethoate, omethoate (oxon of dimethoate) and reduced for: azinphos-methyl, dicrotophos, disulfoton, fosthiazate, methamidophos, and terbufos. The elimination of the FQPA uncertainty factor for chlorpyrifos is especially problematic, considering the existing data showing developmental neurotoxicity and EPA's own conclusion about the FQPA factor in the IRED for chlorpyrifos: ¹¹

"The FQPA 10X Safety Factor has been retained due to increased susceptibility and sensitivity to chlorpyrifos among neonates when compared with adults, and for the qualitative increased susceptibility occurring at the high dose in the developmental neurotoxicity (DNT) study (cholinesterase inhibition in dams versus structural effects on developing brain of the offspring). In addition, recent data in the literature suggest that the inhibition of cholinesterase may not be essential for adverse effects on brain development. Further uncertainty arises from the lack of an offspring No Observed Adverse Effect Level (NOAEL) in the DNT. In that study, structural alterations in brain development were the toxicity endpoint of concern and were seen at the lowest dose tested."

The CRA contains no justification for changing the the FQPA factor from 10 to one, especially given EPA's own justification for its retention in the IRED. The additional developmental neurotoxicity data that have been published since the IRED was released (see section above) indicates that an FQPA uncertainty factor greater than 10 is called for in the case of chlorpyrifos.

In addition to developmental neurotoxicity effects outlined above, the work by Furlong *et al.* demonstrated that activity of the PON1 enzyme responsible for detoxifying chlorpyrifos varied by a factor of 164 between the most robust adult and the most sensitive child in their study population.¹² This result indicates that even an FQPA factor of 10 together with an intraspecies uncertainty factor of 10 is not be sufficiently protective of infants.

In the absence of data that would permit a complete comparative CRA based on non-cholinergic mechanisms of developmental neurotoxicity, EPA must not reduce the FQPA factor below 10 for any OP pesticide and should use uncertainty factors substantially greater than 10 for those pesticides known to have non-cholinergic mechanisms of action, including chlorpyrifos and diazinon.

c) Crucial data regarding intraspecies effects are overlooked

Regarding the intraspecies safety factor, EPA incompletely describes the findings of Furlong *et al.*¹² The Agency lists only the range in sensitivity to diazoxon of up to 26-fold and 14-fold in a group of newborns and Latina mothers, respectively.¹³ The Agency fails to mention the range for chlorpyrifos sensitivity of as much as 35-fold among mothers, and as much as 65-fold among newborns. EPA dismisses the importance of this variability by reporting an earlier suggestion "that other esterase detoxification pathways may adequately compensate for lower chlorpyrifos-oxonase activity; hence an increased sensitivity to low chlorpyrifos-oxonase is not observable until other detoxification pathways or esterases have been appreciably depleted or overwhelmed." But the Agency gives no evidence to support this suggestion and concludes that, "as such, there are no data on most of the OPs to further inform the intraspecies extrapolation factor." Furthermore, "the Agency believes that the standard 10X factor for intraspecies extrapolation in conjunction with 10X interspecies factor as well as the FQPA 10X safety factor incorporated in many RPFs is protective of human health for the OP CRA."

This conclusion does not follow from the available data. Given the information from Furlong *et al.*¹² one cannot reasonably conclude that the combination of safety factors is sufficiently protective, since this one element of variability alone justifies a cumulative factor of more than 100 for intraspecies variability. EPA must use these documented sources of variability to calculate, and employ, uncertainty factors in addition to the 10x intra and 10x interspecies variability uncertainty factors.

2. EPA Failed To Assess Risks of Significant Exposures via All Residential Pathways

For residential exposure, the CRA fails to consider OPs currently registered for agricultural uses Rural communities, often with high farm worker populations, are the most exposed. With the expansion of suburbs into farmland, the number of rural residents living on the ag-urban interface is increasing rapidly. Thus it is critical for EPA to consider exposures to residential populations from agricultural applications of OP pesticides in order to protect children's health.

The primary, unassessed source of pesticide exposure for rural and suburban populations is airborne pesticide drift. There are several types of drift that can affect bystanders:

- 1) **Spray drift** occurs during the application and consists of droplets or dust particles from the application equipment.
- 2) **Post-application drift** occurs after application is complete and can result from either volatilization of applied pesticides from plant or soil surfaces or from wind-driven transport of pesticide-contaminated dust particles away from the application site.

People are exposed to pesticide drift through one of several mechanisms, including by breathing air containing pesticide vapors, particles, or droplets; through dermal or ocular exposure to drift; or by contacting surfaces onto which pesticide drift has deposited or condensed. Spray drift and post-application drift can both be sources of these types of exposures. Examples from Washington State and California illustrate part of the problem.

Wenatchee, WA

A middle school student was taken to the emergency room twice in 2001 with severe OP poisoning symptoms ultimately linked to Guthion that had drifted to her school yard from a nearby orchard. The Washington State Department of Health declared pesticides to be the probable cause of the student's health effects based on residues found on grass and weeds at the school. Spraying was done one to nine days prior to the exposure.

Ventura, CA

In November of 2000, a cloud of chlorpyrifos (Lorsban), drifted onto the school grounds from a lemon orchard across the street. Dozens of students and teachers complained of dizziness, headaches and nausea following the early Wednesday morning application of the insecticide. The grower made a second application on Saturday which also drifted on the school. Various samples taken throughout the campus proved positive for organophosphates, including the kindergarten room (located only 45 feet from the lemon grove) and desks and play areas that are hundreds of yards from the grove.

a) Drift exposures affect hundreds of thousands of people in California alone

In California, more than 15 years of data on worker poisonings show that most reported cases of pesticide-related illnesses result from pesticides drifting off the application site and onto workers in neighboring fields (Fields of Poison).¹⁴ From 1998 to 2004 (a period encompassing some decline in OP use), the California data show that about 60% of worker poisonings related to OP exposure resulted from pesticide drift.¹⁵ Similarly, residents of rural communities and suburban communities bordering farmland are frequently exposed to drift from agricultural pesticides

through these two exposure routes. Urban residents are also exposed to drift from nonagricultural use of pesticides applied to roadsides, lawns, gardens, and homes.

Scientists at the California Department of Health Services have evaluated the results of comprehensive air monitoring of agricultural pesticides in high use areas in California. They have concluded that very high percentages of the general population are inhaling these pesticides in dangerous levels.¹⁶ Short-term chlorpyrifos exposure estimates exceeded the acute reference value for 50% of the children in the general population, for example. The authors note in their peer-reviewed article about the air monitoring results that "[p]esticide exposures and risks are characterized for the communities around the air monitoring locations. However, the potential for exposures in other residential areas clearly exists....." The authors state that census data suggest "a potential for exposures and risks, similar to those calculated in this risk assessment, for hundreds of thousands of people in California."

To our knowledge, government agencies do not engage in comprehensive air monitoring for agricultural pesticides in other states, despite public demands for the same in some states such as Washington. However, it is likely that similar widespread exposures are occurring elsewhere as well in areas of high OP use. In fact, the California scientists specifically encourage other states to heed their results, as they may be relevant to many other areas with similar crop and pesticide applications. They point out that stricter California pesticide regulations may result in lower exposures there than in other states. Finally, the scientists also note that farm workers and their children are at potentially higher risk than the general population.

Extensive documentation of drift and resulting exposures also is provided by numerous studies measuring OPs and their metabolites in house dust and urine. Rates and severity of contamination generally increase with proximity to farmlands where the pesticides are used. A summary of some of these studies is attached to this letter.

b) Exposure from the volatilization pathway is substantial for rural residents

Available monitoring data show that, for volatile and semi-volatile pesticides (vapor pressure > 10^{-7} mm Hg at 20-25°C), post-application drift typically accounts for 80 to 95% of the total offsite airborne movement. For non-volatile pesticides, spray drift and wind-driven transport of pesticide-contaminated dust particles are the major mechanisms of airborne transport.

Air monitoring studies conducted by the California Air Resources Board (ARB) indicate that post-application volatilization typically peaks between 4 and 24 hours after the start of an application for volatile and semi-volatile pesticides and may persist for days above levels of concern.¹⁷ The ARB has been publishing these air monitoring studies since 1986.

Analysis of comprehensive air monitoring in high use pesticide areas by California state agencies also document the importance of post-application volatilization in terms of high exposures to people.¹⁸ According to the authors who conducted the analyses, "Agricultural use within a 3-mile radius on the monitoring day and use on the 2-4 prior days were significantly associated with air concentrations (p<0.01) for all analytes except malathion: chlorpyrifos oxon showed the strongest association. (p<0.0001)." The authors note that "Agricultural applications of

organophosphates and their oxon products may have substantial volatilization and off-field movement and are a probable source of exposures of public health concern."

With the exception of pesticides used as fumigants and fogging agents, EPA presently does not assess exposures due to spray drift and post-application drift in its risk assessment process. Inhalation exposures for bystanders were thus falsely considered to be zero.

PANNA has evaluated available near-field air monitoring data from the CA ARB and compared measured air concentrations of post-application drift to published EPA reference doses for several pesticides, including the OPs diazinon and chlorpyrifos.¹⁹ The data show that pesticide concentrations in air near application sites commonly exceed reference concentrations for volatile pesticides. For example, the peak concentration of diazinon in air near a legal application in the winter exceeded EPA's inhalation reference concentration determined for short term, intermediate and long-term exposure (determined without using a tenfold FQPA factor) for a one-year-old child by a factor of 39 at a distance of 72 feet from the field boundary (Figure 1). Over a three-day monitoring period, concentrations exceeded the acute reference concentration for 82% of all samples taken and 100% of samples collected downwind from the field.



Diazinon Concentration in Air Near Kings County Peach Orchard, February 1998

Figure 1: Concentrations of diazinon in air as a function of time near an application to a peach orchard. Calculation of the REL is shown in reference 21. For diazinon, EPA uses a single RfC for short-term, intermediate and long-term exposure (see IRED for diazinon).

PANNA has provided EPA with the results of this work for multiple pesticides on several occasions, including in several formal comment letters to EPA on molinate (Docket ID # OPP-34232, included here by reference), several legal petitions²⁰ and in a presentation to EPA staff in May 2002.

c) Ambient air monitoring data collected by non-governmental organizations and communities demonstrate exposures above levels of concern

In the last three years, PANNA has been working with rural communities to conduct air monitoring at people's homes, schools and workplaces. In order to ensure high quality data,

operators of the air monitoring equipment undergo a rigorous training and certification process that has been reviewed by an external Scientific Advisory Committee comprised of scientists from EPA, CA Department of Pesticide Regulation, US Geological Survey, and the CA Department of Health Services. All necessary quality assurance/quality control procedures are utilized and are detailed in reports on the sampling projects.²¹ As an additional check on internal laboratory results, PANNA also sends out selected samples to commercial laboratories (see Washington data below).

Data collected in Lindsay, CA in June and July of 2004, 2005, and 2006, and in Washington state in 2006 demonstrate that daily exposure to chlorpyrifos can be substantial, and regularly exceeds the "acceptable" 24-hour acute dose established by the EPA.

Chlorpyrifos in Lindsay, CA

Pesticide Action Network, in partnership with El Quinto Sol, Californians for Pesticide Reform, and Commonweal, undertook an air monitoring study in the town of Lindsay, California to determine the levels of chlorpyrifos in the air in populated areas.²¹ Residents of the town have experienced adverse health effects in the past at times of high pesticide use.

Historic use patterns for chlorpyrifos around Lindsay indicated that the maximum number of chlorpyrifos applications typically occurs in June, July and August, when orange growers apply the pesticide to control lepidopterous pests and scale. Many homes, schools, and public places in Lindsay are located adjacent to orange groves with high pesticide use. Sampling was planned to match the high-use season, with monitoring conducted from July 13–August 2, 2004 and from June 13–July 22, 2005.

Of the 104 samples collected (spikes and blanks excluded) in Lindsay, CA between July 13 and August 2 in 2004, 76% were found to be above the limit of quantitation (LOQ) of 30 nanograms (ng) of chlorpyrifos per sample (equivalent to an air concentration of 6 ng/m³ for a 24-hour sample). Eleven percent of the samples were above the 24-hour acute and sub-chronic child Reference Exposure Level (REL) of 170 ng/m³, calculated from the US Environmental Protection Agency's inhalation No Observed Adverse Effect Level (NOAEL). The highest concentration observed for a 24-hour period was 1,340 ng/m³ (7.9 times the 24-hour acute child REL) at one of the sampling locations on July 16, 2004.

Of the 108 samples collected (spikes and blanks excluded) in Lindsay, CA between June 13 and July 22 in 2005, 80% were found to be above the LOQ of 30 ng chlorpyrifos per sample (equivalent to an air concentration of 6 ng/m³ for a 24-hour sample). Twenty-three percent of the samples were above the 24-hour acute and sub-chronic child REL. The highest concentration observed for a 24-hour period in 2005 was 1,120 ng/m³ (6.6 times the 24-hour acute child REL) at one site on July 14, 2005. Figures 2–3 show average daily concentrations for the five sites in 2004 and 2005, respectively. Monitoring was also conducted in summer 2006, and while the data are not yet finalized, preliminary results show air concentrations slightly higher than those observed in 2004 and 2005.



Figure 2: Chlorpyrifos concentrations in air in Lindsay, CA in Summer 2004 (PANNA). (REL = Reference Exposure Level;²² ND = no data; MV = minimum value; <MDL = less than method detection limit.)



Figure 3: Chlorpyrifos concentrations in air in Lindsay, CA in Summer 2005 (PANNA). (REL = Reference Exposure Level; ND = no data; MV = minimum value; <MDL = less than method detection limit.)

These data are consistent with results obtained by the ARB for ambient air monitoring conducted in 1996 (Figure 4).



Figure 4: Chlorpyrifos concentrations in air in Lindsay, CA in Summer 1996 (CA ARB). Averages are for 4 days per week of sampling over the 4-week period.

Chlorpyrifos in Air in the Yakima Valley

Farm Worker Pesticide Project worked with farm worker community members in Washington State to conduct air monitoring projects at two locations in the Yakima Valley during April of 2006. In Location 1, a former farm worker with three children who all live next to an apple orchard, conducted air monitoring in his yard, taking 24-hour samples for approximately three weeks. Samples were analyzed both by Pesticide Action Network's laboratory and by a private laboratory as well. Chlorpyrifos was present in the air on each of the 21 days on which monitoring was done (Figure 5). On nine days chlorpyrifos was present in levels exceeding the 24-hour acute and sub-chronic REL for small children.



Chlorpyrifos in Air, Location 1, Yakima Valley April 3–23, 2006



Location 2 was the home of a current farm worker who has three children and whose wife is pregnant. It is surrounded by apple orchards. The air was monitored on a daily basis for three weeks, with one 24-hour sample taken per day. Testing revealed the presence of chlorpyrifos in the air inhaled by these children and their parents on each of the 21 days of testing (Figure 6). The 24-hour acute and sub-chronic REL for one-year-olds was exceeded on 10 of the 21 days.



Chlorpyrifos in Air, Location 2, Yakima Valley, WA April 1–21, 2006



EPA Pesticide Director Jim Gulliford met with individuals involved in the testing at these two locations while in Washington last month, including Manuel Perez, one of the co-signers of this letter. These individuals and countless others in agricultural areas are deeply concerned about the levels of chlorpyrifos in the air, particularly with respect to impacts on their children.

The results found at these two Yakima Valley homes are likely representative of what is happening at countless other homes in agricultural areas in Washington and elsewhere in the United States. In 2003 (the most recent data available) 269,000 pounds of chlorpyrifos were applied to apples, cherries and pears in Washington State.²⁴ Sixty-three percent, 57 % and 42 % of the acres for each of those crops respectively were treated with chlorpyrifos (Table 1). Countless families with small children live next to or even within orchards. Many of these children also attend daycares or schools next to or within orchards.

Сгор	% treated acres	Total active ingredient applied, 1000 lb/year
Apples	63	217
Cherries	57	31
Pears	42	21

Source: National Agricultural Statistics Service (NASS) database on 8/22/06: http://www.pestmanagement.info/nass/act_dsp_usage_multiple.cfm The Washington State results supplement the compelling results of exposure assessment in California cited elsewhere in these comments, in which researchers noted that farm worker community members probably experience greater exposures than the general population. As noted, an astounding 50% of children in the general population were estimated by California state scientists to be inhaling chlorpyrifos at rates exceeding RELs. Clearly, the Washington testing results are not anomalies or isolated incidences. Exposures to high levels of chlorpyrifos are widespread and common. The CRA for OPs does not acknowledge and assess documented exposures which are highly likely to be responsible for adverse health outcomes in poor and minority populations. By failing to do so, EPA's own CRA is both deficient and perpetuates environmental injustice.

Inhalation Exposure to Chlorpyrifos Far Exceeds Dietary Exposure

In areas of high chlorpyrifos use, inhalation is the primary source of exposure, dwarfing all other sources. A comparison of dietary exposure estimated by EPA for the 99.9th percentile child to inhalation exposure measured by CA ARB, PANNA and FWPP in several different locations and seasons is illuminating (Figure 7). The highest (99.9th percentile) acute dietary exposures for infants are estimated by EPA to result in a dose that is 50% of the acute Population Adjusted Dose (PAD). In contrast, inhalation exposures estimated from air monitoring data indicate that infants living very close to an application site during the day the application takes place are exposed to a dose that is over 7,500% of the acute PAD (ARB application site monitoring). The ambient air monitoring conducted in Lindsay, CA and the Yakima Valley in Washington State indicate that the highest 24-hour exposures (somewhat comparable to the 99.9th percentile acute dietary exposure) would result in a dose that ranges from 404–793% of the acute PAD. These data very clearly show that EPA is failing to account for the vast majority of exposure when it assumes inhalation exposure is zero for rural residents in areas of high chlorpyrifos use.



Chlorpyrifos from Different Exposure Sources as a Percent of the Acute Population Adjusted Dose (PAD) for Infants Less than One Year Old

Figure 7: Comparison of EPA's estimated dietary exposure to inhalation exposure for chlorpyrifos.

These data also indicate a serious problem with EPA's use of a 21-day rolling average to assess the severity of the inhalation exposure problem. It is clear from the air monitoring data that a rolling average will not adequately assess the impact of a very high 24-hour exposure (or six exposures above the 24-hour acute REL on sequential days, as was observed at one site in Lindsay in 2005).

Inhalation exposures in agricultural communities recur annually and sometimes span multiple sequential months. For example, pesticide use data from California show that considerable use of chlorpyrifos continues for approximately four months or more every year (Figure 8).



Figure 8: Chlorpyrifos use on oranges in Tulare County, CA, 2001-2003 (CA DPR PUR data).

d) Exposures from canceled OP pesticides must be included in the CRA

Risk mitigation measures have historically resulted in voluntary cancellations of specific tolerances or even all uses of the active ingredient (AI). However, when a manufacturer voluntarily agrees to phase out a pesticide or some of its uses, the phase-out is frequently over an extended time period, often many years. An issue arises in that, once a use or AI is on its way to phase-out, EPA does not include exposures from this pesticide in the revised risk assessment, even if the product remains on the market or is legal to use for years to come. We are concerned that phase-out periods may be extended, resulting in continued exposure to cancelled OPs excluded from the risk assessment. Even if all affected parties strictly follow manufacturer agreements, many legal uses omitted from the revised risk assessment will continue for years to come. In addition, private stocks will likely be used illegally, regardless of the phase-out agreement. EPA must take these continued exposures to cancelled OP pesticides into account in the CRA.

e) US EPA's Mandate Requires Assessment of Aggregate Exposure

The FQPA explicitly states that EPA-OPP is required to consider aggregate exposure to a chemical and that any tolerances deemed "safe" for children meet the following definition as stated in Section 408, which was revised to read:

"DETERMINATION OF SAFETY.—As used in this section, the term 'safe', with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined 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.*" (italics added)

Inhalation exposure data are available for many OP pesticides through the CA ARB monitoring program and community monitoring conducted by PANNA and FWPP. US EPA must do a comprehensive exposure assessment for all OPs. Because the exposures are so high for some OP pesticides, we recommend that EPA require no-spray protection zones of at least 1,000 feet around use sites for all OP pesticides to increase the likelihood that children will not be exposed to OPs.

f) EPA's failure to assess inhalation exposure is a violation of EPA's Environmental Justice Mandate

Ignoring inhalation as a route of exposure that particularly impacts farmworker residents, rural residents and farm children appears to be a gross violation of the 1994 Executive Order on Environmental Justice. The vast majority of U.S. farmworkers are from minority, immigrant and low-income communities. As documented in the latest data compiled via the National Agricultural Workers Survey, ²⁵

- "Foreign-born workers comprised a large share of the hired crop labor force in fiscal years 2001-2002. Among all crop workers, 78 percent were born outside the United States: seventy-five percent were born in Mexico, two percent were from Central American countries, and one percent of the workers were from elsewhere."
- "In 2001-2002, 83 percent of the crop workers identified themselves as members of a Hispanic group: 72 percent as Mexican, seven percent as Mexican-American, one percent as Chicano, and three percent as other Hispanic. Only 16 percent of U.S. crop workers self identified as belonging to an ethnic group that was not Hispanic or Latino."

Executive Order 12898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations (February 11, 1994), requires that federal agencies make achieving environmental justice part of their mission. EPA further clarifies this mandate on its own website: *"Environmental Justice is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has this goal for all communities and persons across this Nation. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work."²⁶*

3. Highly exposed farm children and farm worker children were not considered²⁷

Children living in agricultural communities are heavily exposed to pesticides, both *in utero* and post-natally. Children often play in the fields as well. As such, these children are an identifiable subgroup of the population with unique exposure patterns and sensitivities to pesticides.

Farm children, especially the children of farm workers, also come in contact with pesticides through residues from their parents' skin and clothing, soil and dust tracked into their homes, vehicles, contaminated soil and other surfaces in areas where they play, food eaten directly from the fields, drift from agricultural pesticide applications, contaminated well water, and breastmilk. Furthermore, farm and farm worker children often accompany their parents to work in the fields, raising their potential for pesticide exposures even higher. Moreover, farmworker children often are exposed to pesticides *in utero*, when their pregnant mothers work in the fields. Thus, they face pesticide exposure at the most vulnerable life stage of all.

The Federal Food Drug and Cosmetic Act (FFDCA) requires that EPA consider exposure not just to consumers as a whole, but also to "major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D). In reassessing tolerances, EPA must consider, among other relevant factors, "available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers); . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers);" and "available information concerning the variability of the sensitivities of major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii). The 1993 NAS report *Pesticides in the Diets of Infants and Children* found – and Congress recognized in enacting the FQPA – that there are certain subpopulations of people who are likely to be far more heavily exposed or far more susceptible to pesticide toxicity than are average people.

The children of farm workers and those that live on or near farms ("farm children") are a major identifiable subgroup of consumers under these statutory provisions. In reassessing tolerances, EPA is required to consider the unique dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure of farm children.

Natural Resources Defense Council (NRDC), The Breast Cancer Fund (TBCF), PANNA, Physicians for Social Responsibility (PSR), Farm Worker Justice (FWJ) and several dozen other organizations filed a legal petition in October 1998 (hereafter "NRDC, *Farm Children Petition*"), requesting that EPA designate farm children as a major identifiable subgroup and population at special risk under the FQPA.²⁸ EPA denied this petition, and has not yet taken this especially vulnerable sub-group into account in risk assessments.

More than 320,000 children under the age of six live on farms in the United States. In addition, many hundreds of thousands of children play or attend schools or daycare on or near agricultural land, and others have family members who work on farms or handle pesticides as part of their jobs. The nation's two and a half million farm workers have approximately one million children living in the United States.²⁸ Examples of studies documenting pesticide exposure among farm workers and their families are appended as an attachment to this letter.

Citing data from the Department of Labor, the U.S. General Accounting Office (GAO) has reported that seven percent of farm workers with children five years old or younger took their children with them, at least sometimes, when they worked in the fields.²⁹

Children age ten or older legally may and do work on large farms, and children of any age may and do work on their parents' farms or on small farms. There are an estimated 400,000 to 800,000 children farm workers in the United States.³⁰ In a recent survey of 88 Colorado farm workers, 40 began working before they were 18 years old, including several younger than 10.³¹

Farm children are likely to have the highest exposure to pesticides of any group of people in the country. Many of the children with the greatest pesticide exposures are from migrant farm worker families. Seventy-eight percent of farm workers are Hispanic, and sixty-eight percent of farm worker children live below the poverty line.²⁸ Children have unique exposure patterns and sensitivities to pesticides. Per pound of body weight, children eat, drink, and breathe more than adults. Children also engage in more frequent hand-to-mouth contact, and therefore have higher rates of oral exposure from objects, dust, or soil.

Infants and children can be exposed through unusual routes not normally encountered by adults, such as ingestion of turf and soils outside the house and dust on floors and toys inside. The GAO has found that crawling, sitting, and lying on contaminated surfaces may also increase exposure rates of farm children to pesticides.²⁹ The GAO has concluded that, "[b]ecause young children's internal organs and bodily processes are still developing and maturing, their enzymatic, metabolic, and immune systems may provide less natural protection than those of an adult."

Farm children are also exposed to pesticides *in utero*, when pregnant farm worker women are exposed at work or when pregnant residents of rural areas are exposed via contaminated ground water and/or drift and/or contamination of the home by family members who work with pesticides. The FFDCA requires EPA to consider available information concerning "effects of in utero exposure to pesticide chemicals" when conducting tolerance reassessments. 21 U.S.C. § 346a(b)(2)(C)(i)(II). Maternal exposures between conception and birth are relevant to both reproductive and developmental toxicity. Any prenatal exposure to the fetuses of farm workers must be considered in reassessing tolerances.

Because farm children are a population at special risk, their exposures and health status serve as an indicator of potential problems for other population groups. Results from recent studies comparing the neurobehavioral performance in preschool children from agricultural and non-agricultural areas showed that the children from agricultural areas "performed poorer on measures of response speed (Finger tapping) and latency (Match-to-Sample) compared to the Non-AG children. These results demonstrate modest differences in AG children compared to Non-AG children that are consistent with functional effects seen in adults exposed to low concentrations of OP pesticides."³² Similarly, Rothlein *et al.* found "the neurobehavioral performance of Hispanic immigrant farmworkers to be lower than that observed in a nonagricultural Hispanic immigrant population, and within the sample of agricultural workers there was a positive correlation between urinary organophosphate metabolite levels and poorer performance on some neurobehavioral tests."³³

Protection of farm children would ensure a greater level of confidence in protection for the rest of the population. NRDC, TBCF, PANNA, PSR and others have presented EPA with reliable data regarding farm children's exposure to pesticides from house dust, indoor air, pesticide drift from agricultural pesticide applications, and soil around homes, schools, and parks. NRDC, TBCF, PANNA, and PSR have also presented EPA with reliable data regarding the increased susceptibility of farm children to pesticide exposure.

In its 1998 legal petition to EPA, and in a series of comments filed on proposed EPA actions with respect to specific pesticides, NRDC, TBCF, PANNA, PSR and other organizations repeatedly urged the agency to consider extensive scientific data showing that children whose parents are farm workers, and other children who live on or near farms, are far more heavily exposed to pesticides than average consumers. Yet EPA has denied this petition and refused to protect these children from their heavy exposure when reassessing tolerances, even where specific data for a specific pesticide indicating that farm children are more exposed than most consumers.

EPA must consider data regarding farm children's dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure in conducting tolerance reassessment. 21 U.S.C. § 346a(b)(2)(D). If reliable data are lacking, EPA must apply the statutory 10-fold safety factor and require the pesticide chemical registrants to secure the necessary data.

Requirements for an Adequate OP Cumulative Risk Assessment

- 1. In light of the growing number of studies documenting the developmental neurotoxicity of chlorpyrifos and the substantial exposure potential from agricultural use, US EPA must put chlorpyrifos on the fast track for phase-out. In the interim period, a combined FQPA/intraspecies uncertainty factor of 200 should be adopted to account for known adult-child and intraspecies variability in PON1 enzyme levels.
- 2. Where the body of peer-reviewed data is insufficient to support a decision based on "reasonable certainty of no harm" from exposure to OP pesticides, appropriate uncertainty factors must be applied in order to protect human health in conformity with the FQPA. Specifically, where data on neurotoxicity (developmental or behavioral) are absent or incomplete, the Agency must use at least a 10-fold uncertainty factor when making final reregistration decisions. If data suggest that a greater uncertainty factor may be warranted, the Agency must then, in the name of precaution, increase the uncertainty factor unless or until additional peer-reviewed data warrant its removal.
- 3. To meet its mandates under the FQPA and Executive Order 12898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, EPA must consider residential inhalation exposure to agricultural OP pesticides when assessing pesticide risks. This includes exposure from pesticide drift during and immediately following application, post-application volatilization of pesticides, residues from drift, and exposure to pesticides carried into homes on dust and soil particles.
- 4. EPA should use physicochemical properties to determine potential for volatilization and require no-spray protection zones of at least 1,000 feet between application sites and homes,

schools, daycare centers, fields where farm workers labor or other workplaces for all OP pesticides.³⁴

5. The Agency must include farm children and farm worker children as a highly exposed subpopulation in all risk assessments, including the CRA, and develop mitigations that will protect this highly exposed group from occupational take-home exposures to pesticide residues and pesticide drift.

Sincerely yours,

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Erika Schreder Director, Pesticide Reform Project Washington Toxics Coalition

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 $Acute REL (ng/m^{3}) = \frac{Inhalation NOEL (mg/kg - day) \times 10^{6} \text{ ng/mg} \times \text{body wt. (kg)}}{(UF_{inter} \times UF_{inter} \times UF_{FQPA}) \times \text{breathing rate } (m^{3}/day)} = \frac{0.1 \text{ mg/kg} - \text{day} \times 10^{6} \text{ ng/mg} \times 7.6 \text{ kg}}{(10 \times 10 \times 10) \times 4.5 \text{ m}^{3}/\text{day}} = 170 \text{ ng/m}^{3}$

²³ EMA Labs used a 10:90 mixture of acetone:toluene, while PANNA used pure ethyl acetate, which is the probable cause of the discrepancy.

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http://www.pestmanagement.info/nass/act_dsp_usage_multiple.cfm. Viewed on on 8/22/06.

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³² Rohlman et al, "Neurobehavioral Performance in Preschool Children from Agricultural and Non-Agricultural Communities in Oregon and North Carolina", *Neurotoxicology* 26 (2005) 589-598.

³³ "Organophosphate Pesticide Exposure and Neurobehavioral Performance in Agricultural and Nonagricultural Hispanic Workers", *Environmental Health Perspectives* 2006 114:5, 691-696.

³⁴ A pesticide's potential for post-application drift can be correlated with its physicochemical properties and atmospheric conditions. Researchers have used publicly available air-monitoring data and the known physicochemical properties of pesticides to develop an algorithm to estimate the rate of pesticide volatilization from

treated fields (J.E. Woodrow *et al.*, Correlation Techniques for Estimating Pesticide Volatilization Flux and Downwind Concentrations, 1997, *Environ. Sci. Technol.* 31: 523.) This model provides an estimate of peak concentrations downwind from an application site.

Attachment:

Examples of Studies Documenting Pesticide Exposures Among Farm Workers and Their Families

Examples of Studies Documenting Pesticide Exposures Among Farm Workers and Their Families

All articles published in Environmental Health Perspectives are available for free on-line at the EHP website: <u>http://ehp.niehs.nih.gov/</u> If you have trouble obtaining a study, FWPP may be able to help.

Washington Studies

1) Coronado et al, "Agricultural Task and Exposure to Organophosphate Pesticides Among Farmworkers", Environmental Health Perspectives, 112(2), 142-147 (Feb. 2004). While all pesticide handlers had organophosphate (OP) metabolites in their urine, exposures were not limited to handlers. A high percentage of workers in every job task category had OP metabolites in their urine. For example, 93.3% of harvesters had the metabolite DMTP in their urine. For thinners, the number was 94%. A greater proportion of the children of thinners had dimethyl metabolites in their urine than did the children of non-thinners.

2) Thompson, et al, "Pesticide Take-Home Pathway Among Children of Agricultural Workers: Study Design, Methods, and Baseline Findings," Journal of Occupational and Environmental Medicine, 45:1 pp 42-53, (2003):

Organophosphate metabolites found in the urine of 92% of 213 workers tested.

Over 96 % of 571 farm workers studied reported exposures to pesticides at work.

- 63.4% said pesticides touched their clothes: 33 % daily, 30.4% once in a while
- 53.3% said pesticides touched their skin: 28.6% daily, 24.7% once in a while
- 51.6% said they breathed in pesticide dust: 19.7% daily, 31.9% once in a while
- 17.3% said they were dusted or sprayed: 2.5% daily, 14.8% once in a while

3) Simcox et al, "Farmworker Exposure to Organosphosphorus Pesticide Residues During Apple Thinning in Central Washington State", American Industrial Hygiene Association Journal 60:752-761 (1999):

- * Twenty workers thinning apples at 3 sites in Chelan and Douglas counties were studied.
- * Guthion residues were found on foliage at all sites throughout the 6 week sampling period.
- * Organophosphate metabolites were found in virtually all urine samples taken from the workers.

* "These findings support the conclusion that workers absorbed Guthion daily due to their contact with pesticide-treated foliage during apple thinning."

4) Curl et al, "Evaluation of Take-Home Organophosphorus Pesticide Exposure among Agricultural Workers and Their Children", Environmental Health Perspectives 110(12):787-792, December 2002:

* Guthion was quantified in 85% of the house dust samples from 218 farm worker households and in 87% of dust samples from farm workers' vehicles. Malathion, chlorpyrifos, phosmet, parathion and diazinon were also present in significant percentages of dust samples.

* Of 211 children tested, 88% had organophosphate metabolites in their urine. Children's levels were associated with those of farm worker adults in the household which are discussed in the Thompson article above.)

5) Loewenherz et al, "Biological Monitoring of Organophosphorus Pesticide Exposure among Children of Agricultural Workers in Central Washington State", Environmental Health Perspectives 105(12): 1344-1353 (December 1997) :

* Organophosphate metabolites were detected in 47% of the urine samples of young children living in 48 pesticide applicators' households as compared with 27% of samples for children in reference families. (These percentages do not include samples where traces could not be quantified.)

* The median concentration of metabolites in applicator children was four times that of the other children. * Frequency of detection was higher for applicator family children living within 200 feet of an orchard.

Nearly 2/3 of the applicator parents had sprayed within 200 feet of their homes at least once during the season.

6) Fenske et al, "Children's Exposure to Chlorpyrifos and Parathion in an Agricultural Community in Central Washington State", Environmental Health Perspectives 110(5): 549-553 (May 2002): (NOTE: Chlorpyrifos has been banned in household products primarily due to concerns about children's health.)

* The study looked at 49 applicator homes, 12 farm worker homes and 14 nonagricultural homes.

* Chlorpyrifos was measured in the house dust of all homes tested, parathion in 41%. Median concentrations were highest for applicator homes, followed by farm-worker homes, followed by nonagricultural homes. Median house dust concentrations of chlorpyrifos were four times higher in agricultural home than in nonagricultural homes.

* Chlorpyrifos was found in measurable levels on the hands of 11% of the agricultural children.

* Despite the inability to use normal analytical procedures better able to detect pesticides, chlorpyrifos

metabolites were found in 24% of urine samples from study children. Parathion metabolites were found in 7%. * Parathion concentrations in house dust decreased 10-fold from 1992 to 1995 consistent with discontinued use of this product in the region in the early 1990s.

7) Lu et al, "Pesticide Exposure of Children in an Agricultural Community: Evidence of Household Proximity to Farmland and Take Home Exposure Pathways", Environmental Research Section A 84, 290-302 (2000):

* In a study of 109 children, median house dust concentrations for organophosphates (Guthion, phosmet) in house dust were 7 times higher for agricultural family children than others.

* Median concentrations of pesticide metabolites in agricultural children's urine were 5 times higher than for other children.

* Proximity to farmland increased exposures. "In some cases the distinction between farmland and residence is blurred, as when a home is in the midst or on the boundary of an orchard..."

8) Fenske et al, "Biologically Based Pesticide Dose Estimates for Children in an Agricultural Community", Environmental Health Perspectives 108(6): 515-520 (June 2000):

* Researchers estimated exposure doses for 109 children based on organophosphate metabolites in the childrens' urine.

* For children whose parents were orchard applicators or fieldworkers, 56% of the estimated doses for the spray season exceeded EPA's "chronic dietary reference doses" (RfDs) for Guthion.

* Twenty-six percent of the single-day dose estimates for these children exceeded EPA's acute reference dose for Guthion.

* Nine percent of the children's estimated doses exceeded EPA's RfD for phosmet.

9) Simcox et al, "Pesticides in Household Dust and Soil: Exposure Pathways for Children of Agricultural Families", Environmental Health Perspectives 103(12): 1126-1134 (December 1995):

* Guthion, chlorpyrifos, parathion, and phosmet were tested in soil and housedust for agricultural (farmers' and farmworkers') homes and for nonagricultural homes.

* All four pesticides were found in 62% of house dust samples for agricultural homes. Two thirds of agricultural homes contained at least one of these pesticides in concentrations above 1000 ng/g. Pesticides in nonagricultural homes were found less frequently and all levels were below 1000 ng/g.

* Soil levels of Guthion were significantly higher for agricultural homes. (Differences were not significant in soil for the other pesticides, and the authors note that Guthion was used in many orchards 1-3 weeks before the sampling period.)

10) Ramaprasad, Jaya et al, "The Washington aerial spray drift study: assessment of off-target organophosphorus insecticide atmospheric movement by plant surface volatilization", Atmospheric Environment 38 (2004) 5703-5713. Methamidophos sprayed on potato fields in Central Washington drifted to nearby residential areas. Based on their research, the authors conclude that volatilization (pesticides rising from plants and soil) after the application was complete may present a significant pathway for human exposure.

Studies in Other States

Oregon researchers have conducted studies similar to those done in Washington with similar results. California researchers have made use of data collected in California which is not collected in Washington State. Their studies shed light on what might be found here if we looked using these additional methods.

1. California Cholinesterase Monitoring.

* A 1993 study reporting the results of 103 worker years of monitoring found that 24% of monitored workers had to be removed from their workplaces because cholinesterase plasma levels were below 60% of baseline. Five percent had to be removed twice. (Fillmore et al, "A Cholinesterase Testing Program for Pesticide Applicators," Journal of Occupational Medicine 35:61-70 (1993)

* In another study, 127 (23%) of 542 employees studied had 20% or greater midseason cholinesterase depressions. (Ames et al, "Cholinesterase Activity Depression Among California Pesticide Applicators: Results from the 1985 Cholinesterase Monitoring Program," CA Dept of Health Services (1987)

2. California Air Monitoring. State agencies collect data on pesticide levels from the roofs of schools and other public buildings in agricultural areas. Looking only at risks from inhaling pesticides, the California Department of Health Services (DHS) has found that:

* So-called safe levels for risks of non-cancer health effects are exceeded for 50% of the exposed populations for subchronic and/or chronic exposures for MITC (breakdown product of metam sodium), 3-dichloropropene and methyl bromide.

* Short-term chlorpyrifos exposure estimates exceed the so-called safe level for acute exposures for 50% of children in the exposed populations.

* Lifetime cancer risks of 1-in-a-million or greater were estimated for 50% of the exposed population for 1,3dichloropropene (based on 1990 data) and 25% of the exposed populations for methidathion and molinate.

"Exposed populations" are people who live and work in agricultural areas where the air monitors are placed. DHS notes that hundreds of thousands of Californians may face risks like those calculated around the air monitors. The Department notes that:

* "There is also a large subpopulation at potentially higher risk: farmworker/farm children."

* Other states use the monitored pesticides nearly as extensively as California. It cites Washington State's massive use of metam sodium as one example.

* "California has the most restrictive pesticide permit conditions of any state, aimed largely at reducing airborne emissions, particularly for fumigants. This may result in lower exposures and risks under California use conditions"...as compared to other states.

See Lee et al, "Community Exposures to Airborne Agricultural Pesticides in California: Ranking of Inhalation Risks," Environmental Health Perspectives 110(12): 1175-1184 (December 2002).