



August 18th, 2014

Office of Pesticide Programs
Regulatory Public Docket (EPA-HQ-OPP-2011-0184)
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Sent via Federal eRulemaking Portal: <http://www.regulations.gov>

Re: Public Comment Period Associated with Agricultural Worker Protection Standard Revisions

This comment regarding the proposed revision to the Agricultural Worker Protection Standard (WPS) under 40 CFR 170 is submitted on behalf of CropLife America. Established in 1933, CropLife America (CLA) represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. CropLife America comments on Federal Agency actions that broadly affect agriculture and particularly the crop protection industry.

The proposed WPS does little to improve worker safety beyond the current standard. The significant advances in science, regulatory requirements and technology used to apply pesticides over the last 20 years are not referenced *at all* in the proposed revisions. Any revisions should be made considering agricultural practice today, not 20 years ago. There is no justification for the proposed revisions based on the data for acute or chronic illness, and the benefits that are argued to accrue are simply not there. The significant added cost burden imposed by these revisions could be reduced by focusing on the gaps in the implementation of the current WPS, rather than by adding layers of bureaucracy and prescription. **In light of the deficiencies of the proposal, and the lack of a balanced cost:benefit to the rule, we strongly urge EPA not to proceed on promulgating this rule. Instead the Agency should withdraw the rule and focus on improving the necessary training on the current WPS.**

CLA is dedicated to supporting responsible stewardship of our products to promote the health and well-being of people and the environment, and to promote increasingly responsible, science-driven legislation and regulation of pesticides. CLA supports retention of the current version of the WPS. The current version of the WPS has successfully improved farm worker health and safety over the last 20 years. CLA further supports improved training to reflect the massive changes since 1992 in agricultural practices, in pesticide products, and in pesticide registration requirements, and to continue to ensure



compliance with the pesticide label. The attached comments address the numerous assumptions made to rationalize the proposed changes to the rule. The farm worker demographics are not accurately reflected in the proposed WPS. The data demonstrate a steep and ongoing reduction in incidents of acute poisoning and a lack of evidence in support of elevated levels of chronic disease. The cost burden has also been significantly under estimated and is not justified relative to the assumed benefits. CLA does not support the increased record keeping, the availability of records to an “authorized third party representative”, the use of additional restricted-entry buffers that have no science basis, the specific performance standard requirements for closed systems, the additional posting requirements, and other prescriptive requirements described in the Proposed Rule.

Thank you for the opportunity to comment on this draft guidance.

Sincerely,

A handwritten signature in black ink, appearing to read "Clare Thorpe".

Clare Thorpe
Senior Director of Human Health Policy
CropLife America

ENVIRONMENTAL PROTECTION AGENCY: 40CFR Part 170**EPA-HQ-OPP-2011-0184 PESTICIDES: WORKER PROTECTION STANDARD REVISIONS****EXECUTIVE SUMMARY OF COMMENTS**

CropLife America (CLA) is the crop protection association that represents the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. CLA members are dedicated to supporting responsible stewardship of our products to promote the health and well-being of people and the environment. CLA recognizes the positive impact the existing Worker Protection Standard (WPS or "the Standard") has had on agricultural worker health and safety and commends EPA for its success. Based upon our members' accumulated knowledge of the details and benefits of the existing WPS, CLA is offering comments on the Proposed Rule which proposes updates and revisions to the existing WPS as outlined in 79 FR 15443, March 19, 2014.

CLA has five primary comments on this proposal, which are discussed throughout the rest of this document:

1. The current version of the WPS has successfully improved farm worker health and safety over the last 20 years. CLA supports retention of the current version of the WPS.
2. CLA supports improved training to reflect the massive changes since 1992 in agricultural practices, in pesticide products, and in pesticide registration requirements, and to continue to ensure compliance with the pesticide label.
3. The data demonstrate a steep and ongoing reduction in incidents of acute poisoning and a lack of evidence to support elevated levels of chronic disease in farm workers. The farm worker demographics have also significantly changed since 1992, and since 2005, the most recent data cited in the WPS revision preamble.
4. The cost burden has been significantly under estimated and is not justified relative to the assumed benefits. CLA does not support the increased record keeping, the availability of records to an "authorized third party representative", the use of additional non-scientifically defined buffers, the specific performance standard requirements for closed systems, the additional posting requirements, and other prescriptive requirements described in the Proposed Rule.
5. **In light of the deficiencies of the proposal, and the lack of a balanced cost:benefit to the rule, we strongly urge EPA not to proceed on promulgating this rule. Instead the Agency should withdraw the rule and focus on improving the necessary training on the current WPS.**

Crop protection products are necessary to ensure safe, predictable and adequate supplies of food. They are necessary to control invasive species which can threaten our crops and our ecosystems. They

protect our livestock from harmful pests and disease. They enable efficient production from a finite resource, the land, and thus help reduce the conversion of wildlife habitat into agricultural use.

CLA members support science based regulation, using a comprehensive risk assessment approach to ensure crop protection products can be used without causing unreasonable harm to either human health or the environment. To this end pesticides are required by EPA to undergo rigorous regulatory testing, including extensive studies in product chemistry, toxicology, ecotoxicology and environmental fate as well as residue and exposure testing; potential short term and chronic human health and environmental hazards and risks are carefully evaluated by EPA before granting a product registration. Developing and registering a pesticide for entry into the US market takes on average 10 years after the initial research discovery. The results of the testing culminate in the production of a product label which stipulates the conditions under which the product may be used in order to ensure human health and the environment are not adversely impacted. The product label is a legally binding document, and non-compliance can be prosecuted by the States' regulatory bodies.

CLA members commend EPA for developing the 1992 WPS which underpins the use of crop protection products according to EPA label requirements. Implementation of the existing standards has resulted in increased emphasis on worker safety and adherence to the label, with success readily apparent by the ongoing reduction in incidences of acute poisonings since the WPS came into force. Concurrently, advances in risk assessment methodology and the EPA registration review process have also contributed to increased worker protection through changes to all product labels.

Concurrently, over the past two decades, CLA members and their customers have invested heavily in developing safer active ingredients and formulations, and in developing precision application technologies that reduce exposure to applicator, workers and bystanders. The crop protection industry is also committed to developing training programs, training materials, and stewardship measures around container use and disposal to further protect those who work with our products.

CLA overarching comments

- CLA welcomes a sound examination of the 1992 WPS. After 20 years, it is appropriate to assess both the achievements and shortcomings of the program and determine how the standard can be revised and improved.
- CLA supports meaningful WPS that ensures the safe use of crop protection products according to the label directions.
- The data demonstrate that the EPA has successfully regulated crop protection products to ever improving safety standards, and that the products currently on the market do not pose an unreasonable risk to human health, including farm workers, when used according to the label.
- The positive effect of the existing standard is apparent. The most recent statistics from multiple sources all demonstrate that the 1992 WPS has been successful in reducing the incidence of acute poisonings and illnesses as well as eliminating fatalities associated with the use of pesticides.
- As a whole, the epidemiological data do not indicate that exposure to pesticides cause cancer or chronic illnesses.

Justifications and revisions made in the proposed rule that are problematic -

- The content of the proposed rule is not reflective of best scientific practices: There is a lack of data analysis on acute incidents in absolute terms and over time. The scope of cited publications is incomplete, and the description of the farm worker and their relationship with the grower is out of date.
- We are concerned over the lack of reference to existing EPA requirements and procedures to register a product, as well as those currently in development, for example, the recent proposal to regulate bystander exposure to spray drift. There is no reference to the significant amount of information EPA holds on the relative toxicity, exposure and risk assessment for each registered product. This could undermine the Agency's competency in the eyes of the public, and may negatively impact work other Agency divisions have ongoing.
- The revisions are overly prescriptive and based on process rather than outcome. Many are impractical and will be difficult or impossible to implement, place a disproportionately heavy burden on smaller operators, and in some cases may actually increase exposure risk rather than decrease it.
- The socioeconomic data cited by EPA on farm workers are almost a decade old (2005), and cover only half of the period since WPS implementation. Thus, the WPS fails to reflect the changing status of farm workers, especially in the more recent years.
- The significant advances in science, regulatory requirements and technology used to apply pesticides over the last 20 years are not referenced *at all* in the proposed revisions. These must be incorporated if the revisions are to reflect 'real-life' as it is today, not 20 years ago.
- The cost burden comparison with the existing standard is misrepresented and the added cost significantly underestimated. CLA estimates the cost of all proposed changes will result in an increase of over 340 million dollars without taking into account costs associated with retrofitting existing closed system equipment. This compares with the EPA estimate for the current WPS of **\$92,729,052** and their estimate of **\$196,130,463** to include their proposed revisions.
- Costs to the states, which will be responsible for recordkeeping compliance and enforcement activities, are also not included, nor are estimates for developing and implementing new training materials and procedures.
- The epidemiology literature used to support economic gain assumptions made in the preamble is selective, has not been evaluated according to EPA's own standards¹, and fails to accurately reflect the findings in the epidemiology literature and the totality of the knowledge.
- Assuming reductions in chronic illnesses caused by pesticide exposures resulting from labelled directions implies that EPA's risk assessment and regulatory decision making processes are flawed. This is not the case. The benefits – i.e. the reductions in acute and chronic disease that EPA proposes, are inappropriately and unscientifically determined.
- EPA admits that quantifying disease reduction is impossible. Their method to determine benefit makes it impossible to determine whether or not the revisions have been successful, and thereby determine if the cost was warranted. By using chronic disease as a metric for success, EPA has

¹ Office of Pesticide Programs US Environmental Protection Agency "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" Jan 7 2010.

created an ever moving target and an endless requirement for revisions to the WPS without measurable performance metrics.

The current WPS is a success, and CLA recognizes the EPA for this achievement. As with everything over time, their implementation could be improved, particularly by better training. In keeping with our industry's focus on product safety, CLA members support revisions to standards that address, in a meaningful and practical way, existing gaps in training, use of protective equipment and practices and appropriate record keeping. At the same time any accepted proposed steps in the revised WPS must avoid undue disruption to agricultural practices and demonstrate a measurable and quantifiable benefit that is commensurate with the cost. There is no justification for the proposed revisions based on the data for acute or chronic illness, and the benefits that are argued to accrue are simply not there. The significant added cost burden imposed by these revisions could be reduced by focusing on the gaps in the implementation of the current WPS, rather than by adding layers of bureaucracy and prescription.

The body of CLA comments is in five parts –

PART 1: Addresses the preamble and specifically the acute and chronic disease assumptions

PART 2: Addresses the farm worker demographics.

PART 3: Addresses the cost analysis and Information Collection Request

PART 4: Addresses the specific proposals to revise the current WPS

PART 5: APPENDICES

PART 1

1.1 CLA: OVERARCHING COMMENTS:

Fundamentally, the tone of this proposal implies EPA has been wholly unsuccessful in regulating pesticide products, when in fact the opposite is the case. Within the preamble EPA states that between 2000 and 2009, the number of cases of acute work-related pesticide poisonings reported to poison control centers dropped from 2,827 in 2000 to 2,040 in 2009, and in fact less than 60% of the reported cases actually occurred on establishments where WPS requirements apply. The current WPS have been effective. How is it possible that revisions to the current WPS could impact these cases if they are not covered by the WPS?

CLA overarching comments

- **CropLife rejects the implication that the EPA has been ineffective at regulating pesticide products.**
- **CropLife does not believe the pesticide labels are inadequate.**
- **It is unclear how the recommended training and record keeping will result in a quantifiable and measurable reduction in acute incidents or chronic illness, and in particular how these reductions – on which the cost of these improvements are based – can or will be measured. Without this, EPA will be unable to make a future assessment as to whether these proposed revisions, if implemented, have been effective and the money well spent**
- **Evidence shows that implementation of the current WPS has reduced pesticide exposures and associated work related accidents and illnesses.**
- **CropLife supports improved training to reflect the massive changes since 1992 in agricultural practices, in pesticide products and in pesticide registration requirements and to continue to ensure compliance with the pesticide label**

CropLife America (CLA) supports a thorough evaluation of the existing worker protection standards (WPS) which were developed over 20 years ago, as much has changed in agricultural practices and technologies in the intervening years since 1992. It is therefore appropriate to review the standards, and to determine whether those standards continue to adequately address agricultural worker safety in the light of 20 years of scientific and technological advances in pesticide regulation, new product development and product application. The industry today is markedly different from that which existed in 1992, as are the working conditions and the farm worker demographics. CLA does support revising the existing standards when changes or additions will demonstrably improve worker safety and can be expected to significantly reduce the frequency of pesticide exposures, accidents and non-compliance with the label in and around the establishment.

CLA members commend EPA for developing the 1992 WPS which underpins the use of crop protection products according to EPA label requirements. Implementation of the existing standards has resulted in increased emphasis on worker safety and adherence to the label, with success readily apparent by the ongoing reduction in incidences of acute poisonings since the WPS came into force. Concurrently, advances in risk assessment methodology and the EPA registration review process have also contributed to increased worker protection through changes to all product labels.

Concurrently, over the past two decades, CLA members and their customers have invested heavily in developing safer active ingredients and formulations, and in developing precision application technologies that reduce exposure to applicator, workers and bystanders. The crop protection industry is also committed to developing training programs, training materials, and stewardship measures around container use and disposal to further protect those who work with our products. Worker protection standards help ensure products are used according to the label, and in ways that protect agricultural workers, particularly with respect to the correct use of personal protective equipment, and adherence to restricted entry intervals. The pesticide label is the culmination of a rigorous multidisciplinary regulatory process that enables the EPA to assess human health and ecological risk, inclusive of farm workers. . As part of the regulatory process, EPA conducts conservative exposure and risk assessments for applicators and other agricultural workers before approving any conventional pesticide product label. The final registered label reflects the many different uses and applications, and adherence to the label ensures that the product can be used without causing unreasonable harm to human health and the environment. If, as this proposed rule suggests, farm workers are experiencing frequent acute overexposures or chronic illness arising as a result of pesticide use according to label directions, then the first question is whether the EPA registration process, i.e. the label approval process, is inadequate.

CLA does not believe the registration process is inadequate. The evidence presented in the proposed rule supporting assumptions that frequent acute overexposures or chronic illnesses are occurring due to pesticide use is unbalanced and incomplete. Trend analyses over the past twenty years are one way of determining the extent to which the current WPS are achieving or failing to protect workers – and thereby identify what actions are required–. These trends could speak to whether chronic illness or acute exposure incidences for agricultural workers are increasing or decreasing, how application technology has changed and with it, any impact on exposure levels, or how the incidence of illness and days off work of farm workers compares with that of workers in other employment categories. From this trend analysis, key improvement targets for the revised standards, the evaluation of progress towards achieving these targets, and potential obstacles could be defined. The WPS proposed rule and supporting documents fail to provide a context for the proposed revisions in the light of the significant changes that have occurred since 1992 in regulation, pesticide safety, and the demographics of farm workers.

The GAO report of 2000 notes “the lack of consistency and involvement by EPA in monitoring inspections and the need to have a target number of inspections” ...it also suggested that “EPA improve oversight of state-level WPS enforcement and set standard guidance for inspectors”. It is unclear from the EPA proposal whether or not this has been done over the past decade. For example,, in examining the demographics of the work force, EPA cites data which is almost a decade out of date – coming from 2002

(National Agriculture Worker Survey - NAWS) or 2005 (USDA), despite the availability of NAWS data which is as recent as 2012. In addition to out of date information on the demographics, there is also a dearth of objective and quantitative information within the EPA preamble to the rule on the status of current training based on the existing WPS. In these circumstances it is not possible to determine whether or not the improvements are required and if so, which aspects need to be targeted. Until these can be identified based on more than surveys and anecdotal evidence, the addition of further training requirements is premature.

Absent from the EPA preamble is any indication that the EPA has conducted a gap analysis on the adequacy of on-farm training. One available source is the State Regulatory Authorities (SRAs) that conduct inspections to determine if workers received training and if they remember the material covered. The number and type of violations identified by SRAs, including training violations are reported to EPA on a regular basis. However there is no reference to this material within the proposal to revise the WPS. A thorough, multiyear analysis on the adequacy of on-farm training would provide actual data to support the changes that EPA proposes.

The Agency has not provided any documentation in support of whether improvements in the current WPS training and record keeping would be more or less effective than the status quo. Additionally, it must be considered that pesticide use practice varies by crop, geography and cropping system. The 'one size fits all' approach to training and record keeping in the proposed revisions increases the burden on employers and handlers with little likelihood it would achieve any meaningful improvements in the health and safety of farm workers.

There are serious questions around the accuracy of the EPA cost estimates for training and record keeping. There are serious concerns over the arguments EPA brings to bear to demonstrate that chronic disease is characteristic of farm worker exposure to pesticides.

Again, EPA authors have left out important data on trends, data which demonstrate (i) ongoing reductions in acute poisoning, (ii) that agriculture workers are actually healthier relative than their non-farm worker peers, and (iii) which demonstrate significant improvements in farm worker demographics since 1992.

It is unclear how the recommended training and record keeping will result in a quantifiable and measurable reduction in acute incidents or chronic illness, and in particular how these reductions – on which the cost of these improvements are based – can or will be measured. Without this, EPA will be unable to make a future assessment as to whether these proposed revisions, if implemented, have been effective and the money well spent.

1.2 TRENDS OVER TIME:

There have been three major changes or evolutions in crop protection over the last twenty years that are discussed below.

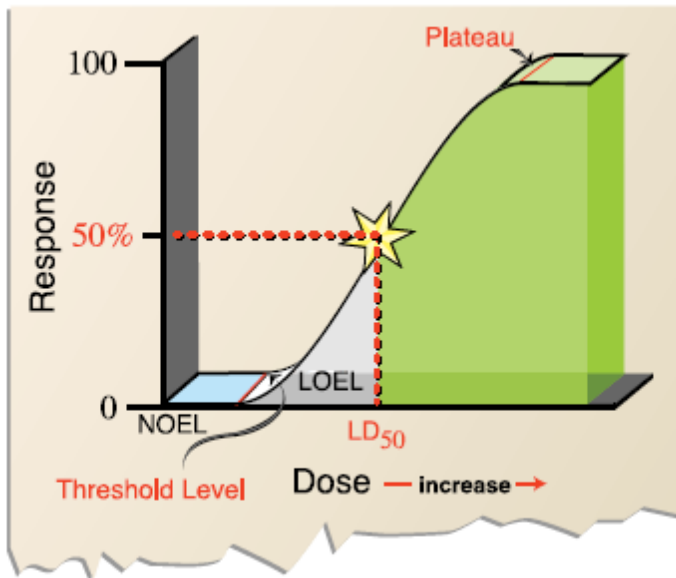
1. Regulatory Changes and Requirements
2. Technological Advances:
3. Stewardship and Education:

Regulatory Changes and Requirements

The regulations and requirements governing the approval and use of pesticides have changed significantly since 1992, and this has significantly impacted the nature of products being brought to the market – both new and those subject to re-registration. It has also impacted on their use authorizations. EPA, through its rigorous requirements and conservative decision making approach, has contributed towards the development of safer compounds, and the safer use of those compounds. The net effect of this on farm worker exposure and safety is very positive, yet is not referenced at all by the EPA in their preamble to their proposed revisions. CropLife America members, as the regulated community, have in depth understanding of how these regulations apply and the significant impact they have had. We believe EPA should be credited for their science based, rigorous and comprehensive approach to ensuring the FIFRA mandate of “no unreasonable harm” has been and continues to be met.

Thus, as the science has developed, EPA has added **new test requirements** to address concerns over chronic illness, including tests to examine developmental neurotoxicological effects on children and long term chronic effects on adults. Testing is also conducted to evaluate, genotoxic effects, immunotoxic effects, endocrine effects and reproductive effects. In terms of the latter, 1998 saw the introduction of the 2 generation reproductive toxicity test which is conducted on the parents, including pregnant and lactating animals, and two generations of offspring. Industry is required by law to conduct these tests at the behest of the EPA, and to provide additional data if EPA requests, that goes beyond the mandatory testing. These tests also have to be conducted in laboratories which follow Good Laboratory Practice (GLP). These data are robust, replicable and take years to develop.

Pesticides are regulated to the dose at which there is “No Observable Adverse Effect”. This is further bounded by the use of “safety factors” which result in pesticides being regulated to orders of magnitude lower (100X) than the toxicological dose at which there are no observable effects level (NOEL) (Fig 1.). In other words pesticides are regulated to levels 100 times lower than the lowest dose in the most sensitive species that causes no adverse effects. These safety factors account for differences which exist between laboratory animals and people, so the animal testing data can be used with confidence; and to account for variability amongst people within a population. For certain compounds, an additional safety factor to account for data gaps or to specifically protect children. - In these instances, the dose at which the compound is regulated could be three orders of magnitude lower than the dose at which no effect is seen in the most sensitive laboratory animal – bearing in mind that these laboratory animals also include fetuses, new born and developing animals.



This diagram articulates the relationship between the NOEL and the LOEL:
 The threshold level is the beginning of the linear response region of the curve and is the demarcation between the “no observed effect level” (NOEL) and the “lowest observed effect level” (LOEL).
 Determining the dose response curve and the upper and lower test concentrations is a pre-requisite for toxicological testing.

Source: PP40 Purdue University Cooperative Extension Service: “PESTICIDE TOXICOLOGY - Evaluating Safety and Risk”

In addition to the toxicological testing requirements, EPA requires substantial testing to evaluate environmental fate and to determine or model exposure scenarios under different use scenarios. This testing is conducted both in the field and in the laboratory. EPA uses models which are highly conservative and often overestimate exposure.

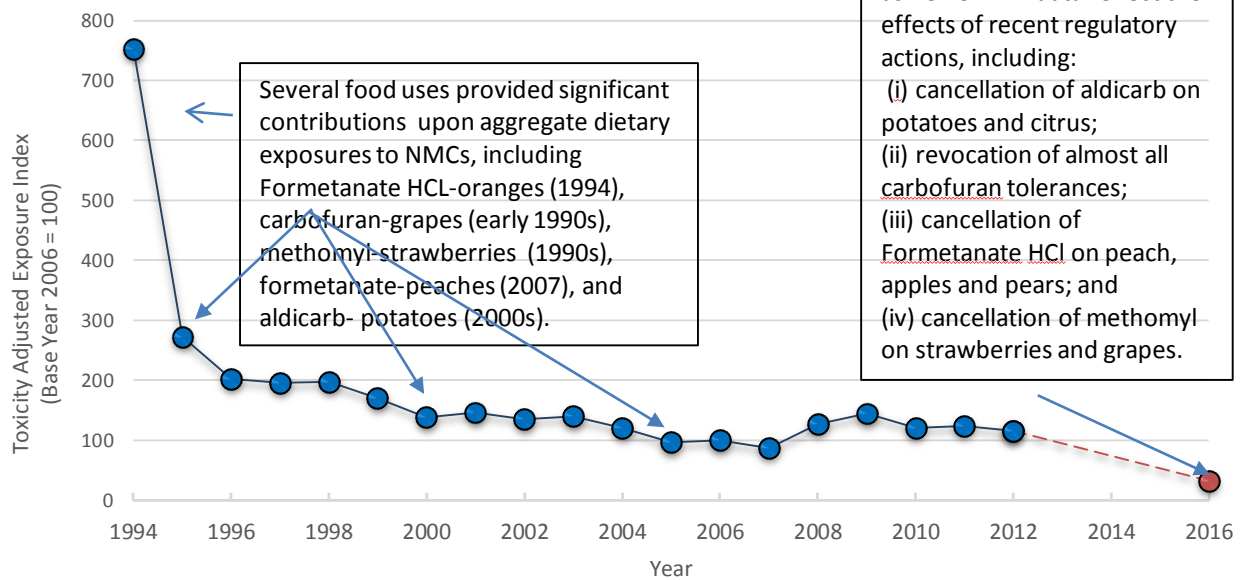
In addition, in 1996 the Food Quality and Protection Act (FQPA) created a single, health-based standard for all pesticides on all foods. FQPA mandates that there must be “...a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” FQPA also required changes to EPA’s pesticide risk assessment process to:

- Address aggregate exposure to a given chemical from non-occupational sources
- Combine risk assessments for groups of chemicals with common mechanisms of toxicity (cumulative risk assessment)
- Provide additional protection for infants and children
- Limit the consideration of benefits

While FQPA does not regulate worker protection it none the less speaks to the advances and requirement required in order to register or re-register a pesticide for use. And FQPA risk assessment processes also improve the non-occupational safety of farm workers. These regulatory changes and increased requirements for the registration of a pesticide product have effectively changed the landscape of products available on the market over the last 20 years, changes which can be evaluated in a number of ways.

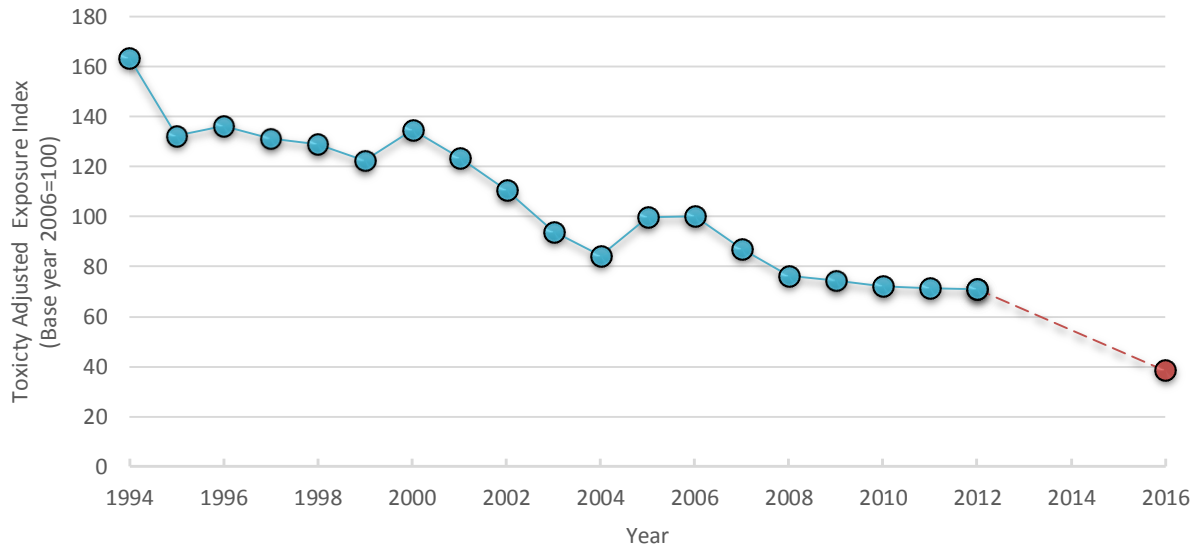
For example, improvements in the safety of pesticide active ingredients on the market today relative to 1994 have resulted in significant reductions in the indices for toxic exposures. The following examples are for dietary exposures to carbamates and organophosphates, but are none-the-less indicative of the changes in exposures that have arisen as a result of changes in both the compounds and their use authorizations on crops produced for human consumption. Specifically, the toxicity adjusted exposure index demonstrates how exposures to toxic pesticides have plummeted since 1994 and subsequently plateaued. This is a result of the implementation of FQPA in 1996, safer products, the removal of some older chemistries and greater restrictions or withdrawals of residential uses.

PDP Trend for N-Methyl Carbamate Cumulative Risk Assessment Toxicity Adjusted Dietary (Food Alone) Exposure Index at the per capita 99.9th percentile for children 1-2 years old (Base year 2006 = 100)



PDP Trend for Organophosphate Cumulative Risk Assessment

Toxicity Adjusted Dietary (Food Alone) Exposure Index at the per capita 99.9th percentile for Children 1-2 years old (Base Year 2006 = 100)



Source: EPA OPP presentation at the 2014 USDA PDP meeting

Thus, and while recognizing that FIFRA is the statute which regulates worker protection, the combined effects of FQPA, the evolution in toxicology and exposure testing, and the comprehensive risk assessment process have had an important impact on the environment in which applicators, handlers and farm workers now find themselves with respect to pesticides. It has had a positive impact on their wellbeing, as articulated by the data on acute and chronic illness. These data requirements and test methodologies are overseen and evaluated by EPA as part of the decision making process, and EPA expends considerable time and resources in evaluating these data in a robust and conservative way. They have had a significant impact on the type of compounds that can be registered, and their use conditions. This, in turn, has made a huge difference to the likelihood of exposure and the nature of possible harm caused by that exposure. This is, from the EPA's perspective, a success story - yet unfortunately EPA does not reference any of this or provide it as context within the revised WPS proposals and preamble.

2. Technological advances:

As previously discussed, over the last 20 years, advances in product chemistry have improved the type and safety profile of compounds brought to the market, and advances in synthetic chemistry have enabled better identification of compound characteristics which lead to the selection and development of a safer end product for the market.

New pesticide application technologies have further reduced exposure, such as the use of microscopically thin seed dressings which confine the product to the area directly around the seed, or precision technologies including GPS, and field mapping, which have reduced exposure through precise and lower application rates. For example, aerial and ground applicators increasingly employ sophisticated equipment for making precision applications, including GPS (Global Positioning Systems), GIS (geographical information systems), flow controls, real time meteorological systems and precisely calibrated spraying equipment. Spray drift reduction technologies (DRTs) incorporated into the set-up of aircraft include carefully designed and located spray booms, adjustable nozzle angles to control droplet wind shear, and valves for in-flight shutoff of specific nozzles to create a sharply-delineated swath edge. Adoption of new technology, precision aerial and ground application and spray drift limitation adds significantly not only to the protection of the environment, but to the protection of agricultural handlers and workers.

New products are applied at much lower rates than in the 1980's when the WPS was first developed. Rates of pounds of active ingredient per acre were replaced with products applied at ounces per acre. The spray jets or nozzles are designed so that the droplet size can be manipulated to reduce drift, and to focus the application on the target organism. This all significantly reduces exposure, all other things being equal, because much less pesticide is now handled by handlers and lower residues are present in the fields where field workers come in contact.

Stewardship and Education:

CLA member companies continue to make substantial commitments to product stewardship and education of pesticide handlers: CLA members have improved stewardship, storage, disposal and inventory of containers, and contributed considerable sums toward the development of appropriate training materials for use by trainers and handlers. **The Pesticide Environmental Stewardship (PES)** is sponsored by the Center for Integrated Pest Management². PES provides convenient access to information on proper pesticide handling. CLA and individual member companies provide support to this organization which is coordinated on a regional basis by Cornell University, North Carolina State University, University of Nebraska, and Washington State University.

In September of 2013, the National Stakeholder Team for Pesticide Safety Education Program (PSEP) Funding created a three-year initiative to enhance the education of pesticide applicators. This team includes representatives from government, extension, industry, professional societies and universities. <http://www.epa.gov/pestwise/about/index.html>

Goals of the PES initiative include:

- Establishing a national website for training materials
- Creating more online distance education classes
- Compiling, updating and producing training materials for the national website
- Focusing appropriate time on pesticide safety in certification and recertification classes

² <http://pesticidestewardship.org/Pages/About.aspx>

- Increasing collaborative efforts among states to fill training material gaps
- Pursuing additional direct and indirect sustainable support for PSEPs at the state level

Container Management

The Ag Container Recycling Council (ACRC) is an industry funded not-for-profit organization that safely collects and recycles agricultural crop protection, animal health and specialty pest control product containers (Jugs and Drums). 135,000,000 pounds of plastic have been recycled since 1992.

<http://www.acrecycle.org/>

Warehouse Inspection/Certification

The **American Agronomic Stewardship Alliance (AASA)** is an organization that has taken the lead in developing a stewardship inspection program for agricultural retail facilities that store bulk, mini bulk, portable refillable containers (PRC's) and packaged crop protection products.

<http://www.aginspect.org/>

Stewardship of the Pesticide Life Cycle

CLA companies are also members of **The Pesticide Stewardship Alliance (TPSA)**, a collaborative partnership of government agencies - federal, state and local, educational and research institutions, public organizations, private corporations and individuals actively involved in stewarding the pesticide life cycle. Founded in 2000, TPSA utilizes education, training, outreach and other activities to accomplish stewardship objectives in local, national and international arenas. <http://www.tpsalliance.org/index.php>

CLA and its member companies have made substantial commitments to product stewardship and education of pesticide handlers. While committed to improvements to the WPS, CLA believes that many of the justifications for the proposed revisions are either misleading or fail to acknowledge the progress that EPA has made in protecting pesticide handlers and workers since 1992. CLA members want to ensure their products are being used according to the label and that the risk of illnesses or disease is mitigated to the fullest extent possible. So while the objectives of the proposed changes are not in question, as listed under Section E page 15446, the specific details on how and why EPA wants these objectives achieved are in question.

Ensuring compliance will require support and understanding for the necessity of any changes made. They will also need to be practically applicable in “real life” situations. However the revised requirements are often overly prescriptive, impractical or difficult to implement, and lack the flexibility needed to address the numerous differences between farms, crops grown, machinery and equipment, pesticide products used and even the workers themselves. In some instances – such as the requirements for closed systems – there is a clear lack of understanding on the part of EPA on how these systems operate in practice. As a result, some of the requirements if implemented could actually give rise to a greater risk of exposure.

Furthermore the prescriptive nature of the requirements increases the potential for technical violations even though the violations could have no bearing on worker safety and exposure. For example, specifying “*running water sufficient to provide 1.5l per minute for 15 minutes for handlers to use for eye flush purposes*” requiring “*at least 3 gallons of water available per worker for decontamination*”. It is not clear if these requirements will be enforced, and thus represent a technical violation if not adhered to, or are they simply for guidance purposes. Is it not clear how these figures were derived and why other recommendations are not appropriate. For example, the requirement to mix pesticide products at a specific pressure regardless of the physical properties of that formulation, and the necessity to rinse a container “three times” is overly prescriptive and may not be sufficient to meet the objective of ensuring the container is clean. In many instances an outcome based approach would be more robust, rather than a process based approach.

CLA recommendations

CLA recommends the rule be withdrawn and re written to reflect the following:

- The costs of additional training should reflect reductions in acute illnesses only, and reference to reducing chronic illness be removed as it is not supported by the scientific evidence, or by the EPA risk assessments that have been conducted on all the pesticide products currently on the market.
- The cost estimates for training and record keeping require significant revision in light of cost estimates from people in the field, such as the farming community, trainers and handlers. Also – with reference to the revised WPS ICR, the costs have been significantly underestimated relative to the ICR of 2013 and overall (See Part 3 of this document)
- EPA should include language to reflect the extensive pesticide testing which takes place as a requirement for pesticides to be registered and label requirements.
- The EPA recommendations should reflect current agricultural technologies, practices and products.
- That EPA replace the 1992 WPS INTERIM acute dermal toxicity hazard based PPE and REI standards with product specific risk based PPE and REI requirements.
- That record keeping should enable worker safety, not enforcement requirements.
- A prescriptive based approach should, in many cases, be replaced with an outcome based approach.

1.3 THE PREAMBLE - JUSTIFYING THE BENEFITS OF THE REVISED WPS PROPOSALS:

1.3.1 Overarching Comments

Section E. Benefits of the Proposal: According to EPA, the benefits of the proposed rule primarily accrue to workers, handlers and, indirectly, to their families. EPA estimates the quantitative value of avoided acute incidents as a result of the proposed rule to be between \$1.2 million to \$2.8 million annually. EPA then states that adjusting the estimate based on the unsupported assumption that only 25% of acute incidents are reported brings the estimated benefits from reducing acute pesticide incidents to \$11.4 million annually. The Agency further states that the exposures to the agricultural workforce can pose both significant long- and short-term health effects.

The health effects are divided in two categories: (i) Acute effects and (ii) Chronic effects. Acute effects occur through exposure to high doses of pesticide. They arise, by definition, as a result of accidents or lack of compliance with the label. Whether this lack of compliance is by accident, due to lack of training, or deliberate is the question.

Furthermore, the acute effects are typically categorized by severity into Low, Medium and High. Low severity poisonings resolve without treatment whereas High severity poisonings may result in hospitalization. The factors related to incidents of Low vs. High severity are not the same. From the perspective of WPS and training, understanding the root causes of the effects and their severity is important to implementing measures which prevent those effects from occurring: Some exposures can be reduced through improved training and use of safety equipment (*e.g.*, non-compliance, and thereby the *probability* of accidents occurring); some exposures may be mitigated but not prevented (accidents will still take place); and some exposures may be outside the control of the individual or his employer, and therefore impossible to predict and unfeasible to address – as some of our later examples demonstrate. In that third case, the response is primarily damage limitation, such as by having proper emergency care available. A decision on how or even whether to address the exposures should reflect the severity of the event.

Chronic disease is presumed to arise from repeated, long-term, low level exposure to pesticides. Because the regulatory toxicological testing specifically addresses the effects of chronic exposure, adhering to the pesticide label **prevents** this level of exposure from taking place.

Unfortunately, the overarching justification presented by the Agency for the proposed revisions to the WPS is that “EPA expects the revisions, once final, to prevent unreasonable adverse effects from exposure to pesticides among agricultural workers and pesticide handlers; vulnerable groups, such as minority and low-income populations, child farmworkers, and farmworker families; and the general public.” (79 FR 15443, at 15444.) All costs and burdens imposed by the proposed revisions therefore rely upon the supposition that current exposures to pesticides are unacceptable and that the proposed revisions will prevent the alleged unreasonable adverse effects from exposures that allegedly result under the current WPS.

CLA Summary:

- **CLA rejects this implicit statement that the EPA has failed in its mandate to protect farm workers.**
- CLA instead contends that a thorough and accurate evaluation of the alleged unreasonable adverse effects, through analysis of morbidity and mortality data, discredits the Agency's underlying assumption that current exposures under the WPS present unacceptable acute and chronic health effects.
- Analysis of the illness data for agricultural workers suggest that the current WPS and other changes in pesticide practices since 1992 have lowered the level of morbidity and mortality, such that the proposed revisions, with their additional imposed burdens and costs to American agricultural, are unlikely to yield additional reductions.
- CLA contends that a "modernization" of the existing WPS and associated training to reflect the reality that exists today is not sufficient to continue this downward trend in morbidity and mortality associated with acute pesticide exposures.

1.4 ACUTE EXPOSURES MORTALITY AND MORBIDITY**1.4.1 CLA Overarching Comments:**

The EPA rightly recognizes that addressing acute exposures and illnesses offers immediate and direct benefits to both the farmer (who pays for the cost of reducing their incidence, and the loss of man hours) and to the worker, as doing so will translate into fewer sick days, and fewer missed workdays which have direct effects on not just the worker but their family. Industry supports actions to reduce acute exposure and make improvements in reporting and treating the effects of such exposures, not least because this is a measurable goal and it speaks directly to the extent to which the pesticide label is being complied with. However, we question EPA's assumption that only 25% of acute poisonings are reported, and that those which are under reported are sufficiently severe to incur a cost. EPA's stated reason for under reporting is given as "many symptoms of pesticide poisoning, such as fatigue, nausea, dizziness and diarrhea may be confused with other illnesses and may not be reported by the workers as related to their occupational exposure." But is this really under reporting, or is this because these symptoms are, in fact, caused by things other than pesticide exposure? Or is the under reporting a reflection of the symptoms not being severe enough to lead a worker to seek treatment, or prevent him from going to work? Without more information on the reasons why 75% of pesticide related illness goes unreported, it is not reasonable to assume – as the EPA does - lost wages and medical costs. In other words, increasing the cost burden associated with acute poisonings, based on an assumption of under reporting alone, is illogical and untenable.

Due to the paucity of data provided by EPA on acute pesticide exposures, CLA examined five databases that provide information on exposure and/or illness and fatalities caused by pesticides. They are:

1. The 2011 California Pesticide Illness Surveillance Program (CA-PISP);
2. The Bureau of Labor 2012 Census of fatal and non-fatal occupational injuries (BoL Census);
3. The 2012 National Poison Data System (NPDS);
4. The Center for Disease Control (CDC) National Institute for Occupational Safety and Health (NIOSH), SENSOR Pesticides Database; and
5. The National Safety Council 2014 (NSC).

The information captured by each database increases in specificity, from the **BoL Census** which relates to all causes of occupational illness, injury or fatalities across all industry sectors, The **NPDS** examines 19 poisoning categories across the general population in all 50 states, of which one category (#11) is pesticide poisonings. The **NIOSH SENSOR database** tracks pesticides poisonings across 12 states, and the **CA PISP** is the most comprehensive state program capturing pesticide illness and fatalities including but not limited to agriculture workers, and provides detailed case study information. From these data we can compare – within and across years - acute pesticide illness / injury and fatalities across industry sectors and against other causes of illness injury and fatalities. We can also segregate the data across age, gender, occupation, and severity, and determine the cause of any particular poisoning and whether or not it is agriculture related.

The data presented in the following graphs and discussion are drawn directly from the databases or annual reports. No attempt has been made to evaluate the data statistically, as the objective is to contextualize the information EPA provides in the Preamble. The rationale for this is to determine the impact of the current WPS on the incidence and absolute number of acute pesticide poisonings, whether those illnesses and fatalities occurred as a result of pesticides, to what extent revising the current WPS is likely to make an impact.

The overall picture the data present across all five databases is one of

- Reduced acute poisoning incidents in absolute terms and in comparative terms,
- Diminishingly small numbers of fatalities, most of which are the result of suicides.
- The majority of poisonings that do occur are not related to agricultural use.
- The few pesticide poisonings are primarily the result of accidents, misunderstandings, poor communications or deliberate misuse. These could all be addressed by evaluating and improving the current training, not by changing the current requirements.

1.4.2 ACUTE MORTALITY / FATALITIES

In order to provide some perspective on where pesticides fall in the spectrum of unintentional acute poisonings in the U.S. from all types of chemicals, it is instructive to examine recent mortality statistics. Certainly, one might argue that there is under-reporting in any of the line items in Table 1. For example, Table 1 lists deaths from non-opioid analgesics, antipyretics and anti-rheumatic drugs as 224, yet there are an estimated 3,200 persons that die annually from bleeding ulcers induced from non-aspirin, non-steroidal anti-inflammatory drugs (Tarone et al., 2004). Similarly, alcohol poisoning is listed but not the thousands of fatal automobile accidents in which it is directly implicated each year. Further, during 2005–2009, overall, an average of 3,880 persons died annually from water toxicity (unintentional drowning including boating incidents) in the United States (1.29 deaths per 100,000 population; National Center for Injury Prevention and Control (NCIPC), 2014). However, death (especially from acute poisoning) is an incontrovertible endpoint with a legal mandate in most States to perform an autopsy, and relative risk amongst causes is readily compared. While one could argue about the absolute numbers, there is generally no argument about cause of death following acute exposure to chemicals making it a useful comparative statistic.

Table 1: Unintentional Poisoning Deaths in the U.S. by Chemical Category in 2010^a

Total poisoning deaths	33,041
Non-opioid analgesics, antipyretics, and anti-rheumatics (X40)	224
Antiepileptic, sedative-hypnotic, anti-parkinsonism, and psychotropic drugs, n.e.c. (X41)	1,916
Narcotics and psychodysleptics (hallucinogens), n.e.c. (X42)	12,280
Other drugs acting on the autonomic nervous system (X43)	21
Other and unspecified drugs, medicaments, and biological substances (X44)	15,565
Alcohol (X45)	2,107
Organic solvents and halogenated hydrocarbons and their vapors (X46)	79
Other gases and vapors (X47)	674
Pesticides (X48)	6
Other and unspecified chemical and noxious substances (X49)	169

^a From NSC (2014)

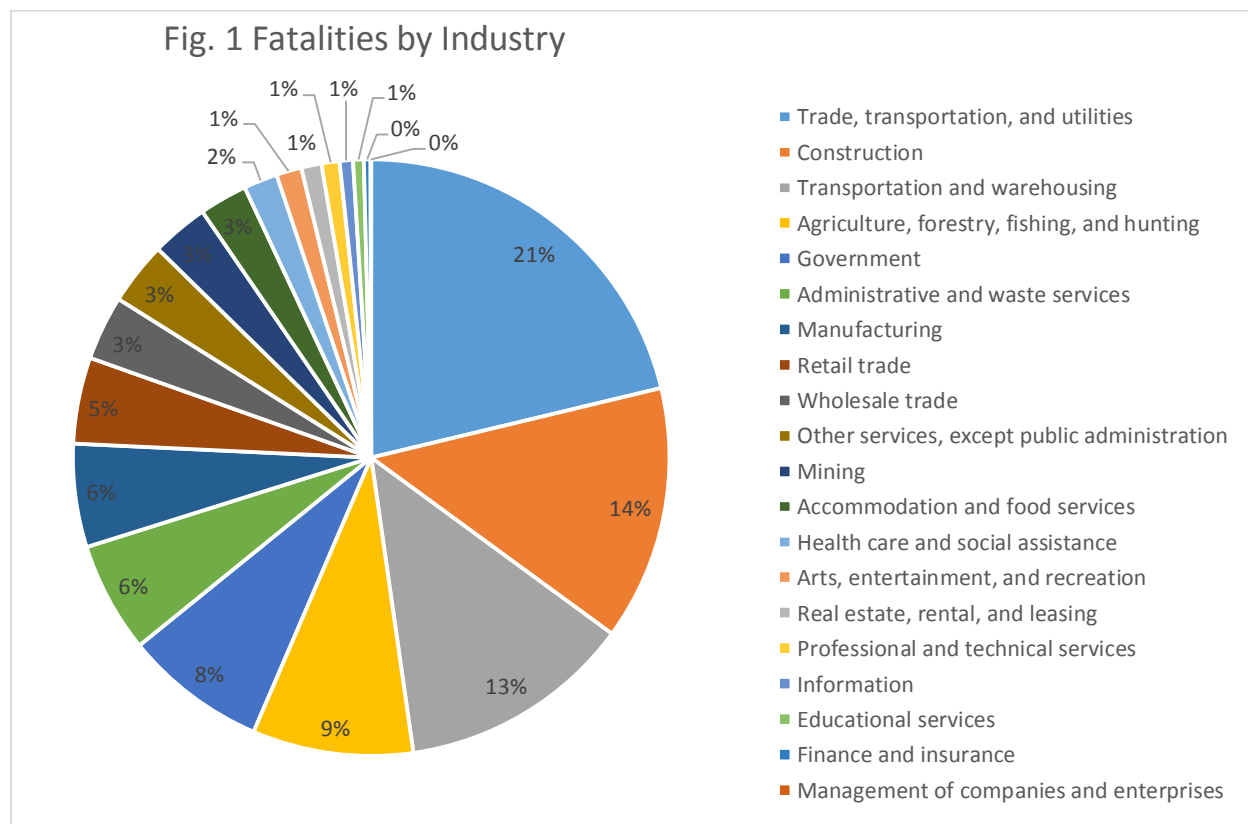
Relative to other chemical causes of death in the general U.S. population, pesticides are the smallest category representing 0.02% of the total as summarized in the second to last row of the table above, and the point is that even if under-reported by 10-fold, it would still be a miniscule cause of death relative to legal pharmaceuticals. Note that this tabulation of poisoning deaths includes worker and non-worker related mortality, and the already low number of pesticide deaths have a significant component of non-workers. The results in this table make clear the relative risk of prescription medications compared to pesticides and is in stark contrast to the level of concern perceived by the public for the two types of chemicals; one designed to kill pests, and the other to provide direct benefit to users.

BUREAU OF LABOR CENSUS OF FATAL OCCUPATIONAL INJURIES 2012

The **BoL Census** uses federal, state, and local data sources to define and verify work fatalities. Data are collected and reviewed by Bureau of Labor Statistics staff. States obtain information on work fatalities through death certificates, workers’ compensation reports, and other state administrative reports. The Occupational Safety and Health Administration (OSHA), Office of Workers’ Compensation Programs (OCWP), and the Mine Safety and Health Administration (MSHA) within the Department of Labor also serve as federal-level data sources. In order to determine if the fatality is work-related, the relationship must be verified by two or more independent source documents and a follow-up questionnaire sent to the employer. The graph below shows fatalities (regardless of cause) for each industry in 2012 as a percentage of total fatalities. Agriculture including forestry, fishing and hunting accounted for 509 work-related fatalities or 9% of the total. The industry sections are based on the 2007 North American Industry Classification System.

Fig 1. Fatalities by Industry

(Source: Bureau of Labor Statistics Census of Fatal Occupational Injuries: Revised 2012 Data)



The graphs below shows the percent of occupational fatalities of subcategories in the agriculture, hunting, fishing, and forestry industries (Source: Bureau of Labor Statistics Census of Fatal Occupational Injuries: Revised 2012 Data).

Fig 2. Agriculture, Hunting and Forestry Fatalities by Category

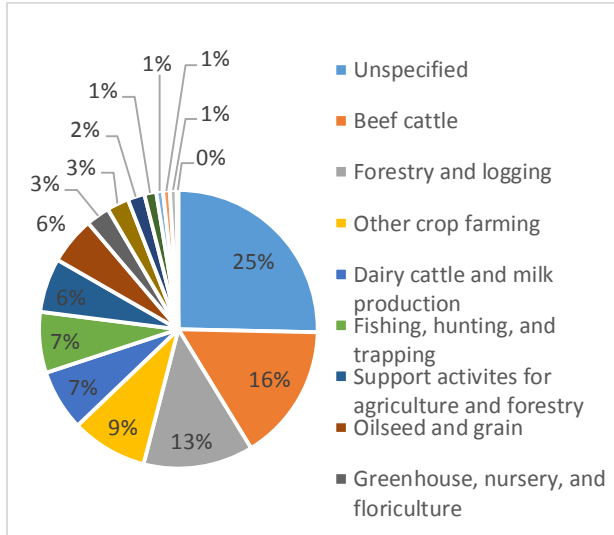


Fig 2. Agriculture, Hunting and Forestry Fatalities by Category.

Within the Agriculture Sector, most (54%) of fatalities occurred in the ‘unspecified’, cattle farming or of forestry and logging sectors.

Crop farming, oilseed and grain and greenhouse nursery and floriculture represented (16%). These sectors are traditionally more pesticide use intense.

Fig. 3 In 2012, 5% of all fatalities were attributed to exposure to harmful substances or environments. This includes, but is not limited to pesticides. For example, they can include exposure to methane gas from the fermentation of manure. In fact, Fig 5 (next page) demonstrates that most of these fatalities occurred in the beef cattle sector. Transportation incidents; contact with objects and equipment; and falls, trips, and slips all caused more deaths than exposure to harmful substances or environments. Violence and Other Injuries by Persons or Animals accounted for the same number of fatalities as pesticides in this year.

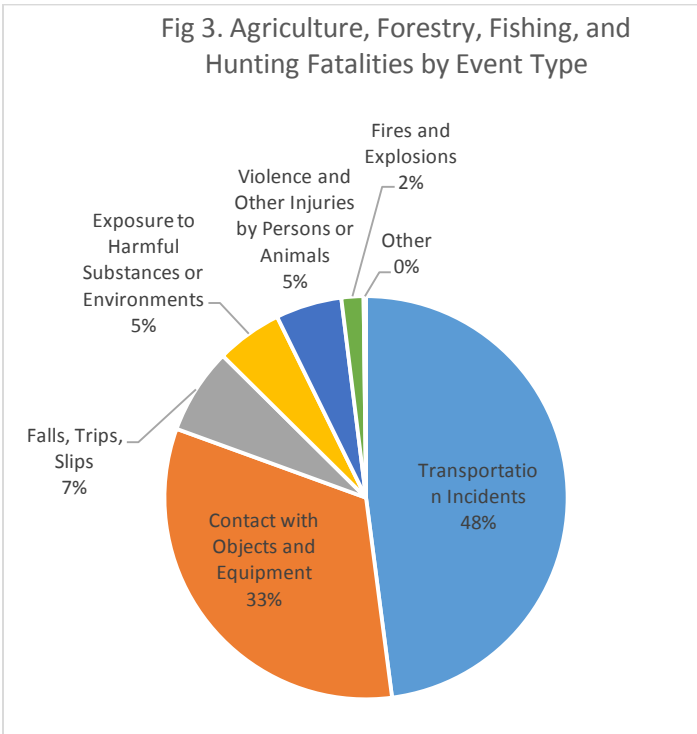
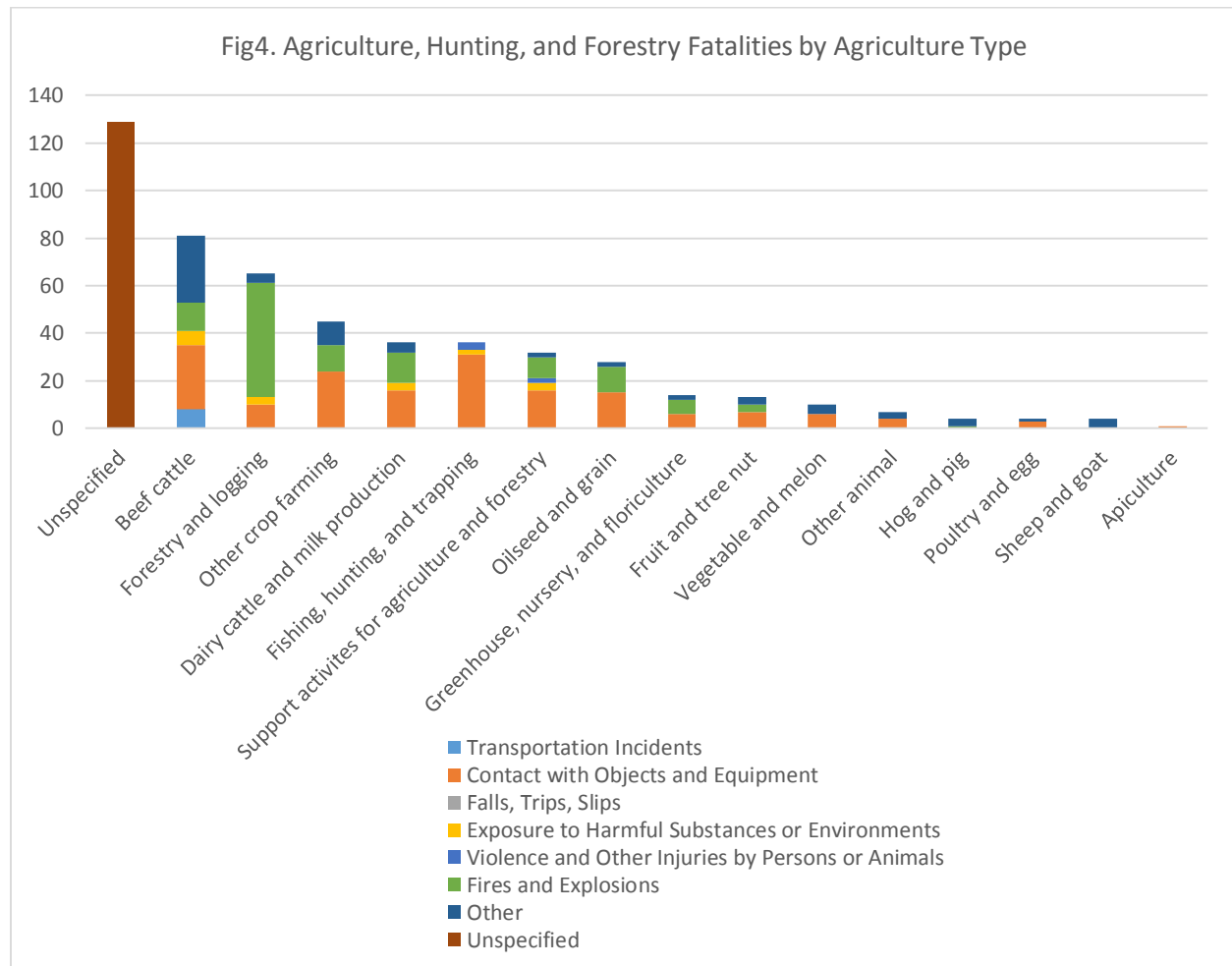


Fig 4. An examination of where the fatalities within the agriculture sector occurred



(Source: Bureau of Labor Statistics Census of Fatal Occupational Injuries: Revised 2012 Data).

This graph illustrates the small number of accidents due to exposure to harmful substances or environments. Pesticides are a sub group within the category, which includes a number of situations totally unrelated to intentional use of fuel or chemicals, including silo-fillers’ lung disease (caused by oxides of nitrogen); gases from manure or other waste (hydrogen sulfide); combustion related incidents (carbon monoxide, in building, vehicle, or fire); and the general category of confined space entry/hypoxia.

CALIFORNIA DEPARTMENT OF PESTICIDE REGISTRATION DATA for PESTICIDE FATALITIES:

The **California Health and Safety Report on Pesticide Fatalities 1990-1996** is available at <http://www.cdpr.ca.gov/docs/whs/pdf/hs1821.pdf>. The report states that “Since the 1960s and 1970s, the total rate of unintentional pesticide mortality has decreased tenfold, while the proportion of childhood victims has dropped from more than half to less than one fifth of the total.”

1990-1996: In the seven-year period of this study, two children, a boy and a girl, died of unintentional pesticide ingestion. Both were less than two years old, and both ingested common household insecticides: mothballs in one case, flea dip in the other. The next youngest victim was a 16-year-old suicide. Of 59 total pesticide-related fatalities, 36 were documented as suicides, and another four may have been suicides. Insecticides (18 cases) and rodenticides (9 cases) were the pesticide classes most frequently used to commit suicide.

California continues to report on pesticide mortalities and since 1996 the number of fatalities has continued to decline, and none have been associated with agricultural use:

2005: DPR and CACs investigated eight deaths and pesticides were strongly implicated in four of the deaths and excluded as causes in three. One case could not be evaluated. Of the four pesticide-related deaths, one was a suicide. The other three deaths were caused by fumigants, none of which were related to agricultural use.

2009: The CACs and DPR investigated four deaths in 2009, three of which were reported by CPCS. Three of the fatalities were determined to be pesticide related. One was a suicide, another was exposure to methyl bromide caused by a faulty canister which exploded at the formulation facility, the third was caused by xylene intoxication which may have been related to an insecticide but the source was never confirmed. None of these deaths were related to agricultural use.

NATIONAL POISON DATA SYSTEM DATA 2012 ON PESTICIDE FATALITIES:

The NPDS total number of fatalities due to all exposures across all ages for 2012 was 1,190 – not including indirect effects. Total pesticide fatalities as defined by the NPDS represent 1.3% of the total fatalities.

The number of fatalities reported are different depending on whether NPDS reports them as being the result of a single pesticide exposure, or the result of exposure to several compounds, of which a pesticide may be one. In most cases the fatalities arise as a result of deliberate suicide attempts – which explains why more than one compound is involved. In all other cases it is a result of accidental ingestion. None of the fatalities were to farm workers, or under circumstances which the WPS could have prevented them from happening. And in 2012, despite a reported 82,916 exposures to pesticides, only 12 (0.01% or 1 in every 10,000 exposures) resulted in a direct fatality. They were all suicides. None of them were children.

Table 2. NPDS 2012 Annual Report Table 21 Listing of the 12 Fatal Nonpharmaceutical and Pharmaceutical Exposures

Annual Report ID	Age	Gender	Substances	Substance Rank	Cause Rank	Chronicity	Route	Reason
419	26	M	rodenticide (bromethalin)	1	1	Acute	Ingestion/Unknown	Intentional, Suspected Suicide
			methamphetamine	2	2	Acute		
			amphetamine	3	3	Acute		
420pa	40	M	pyrethroids	1	1	Acute	Inhalation/Dermal	Unintentional, Misuse
[421ph]	42	M	malathion	1	1	Acute	Ingestion	Intentional, Suspected Suicide
422	50	M	glyphosate	1	1	Acute	Ingestion	Intentional, Suspected Suicide
423	60	M	organophosphate	1	1	Acute	Ingestion	Intentional, Suspected Suicide
			pesticide, unknown	2	1	Acute		
[424pha]	60	F	borate	1	1	Acute	Ingestion	Intentional, Suspected Suicide
425h	64	M	aldicarb	1	1	Acute	Ingestion	Intentional, Suspected Suicide
426h	66	M	2,4-D	1	1	Acute	Ingestion	Intentional, Suspected Suicide
			ethanol	2	2	Acute		
427	70	M	moth balls	1	1	Unknown	Ingestion	Unintentional, General
428	71	M	carbamate	1	1	Acute	Ingestion	Intentional, Suspected Suicide
429a	75	M	glyphosate	1	1	Acute	Ingestion	Intentional, Suspected Suicide
430	93	F	rodenticide, unknown	1	1	Acute	Ingestion	Intentional, Suspected Suicide
			drug, unknown	2	2	Acute		

Pediatric fatalities

Of greatest concern is children's exposure to chemicals and pesticides. Children can be disproportionately affected by exposure relative to adults, and it for this reason that EPA specifically regulates with children in mind. EPA takes account of the higher relative skin surface area of children, and their mouthing behavior, for example. Additional uncertainty factors are also applied to the existing 100x uncertainty factor. In 2012 there were no fatalities caused by pesticides in children under the age of 12.

Although children younger than 6 years were involved in the majority of exposures (to all chemicals), they comprised 46 of 2,937 (1.6%) of fatalities including both direct and indirect exposure. The first ranked substances associated with these fatalities included smoke, antifreeze (ethylene glycol), carbon monoxide, disc battery, lithium, morphine, and tramadol, and 15 other substances (1 each). In the age range 6 – 12 years, there were 7 reported fatalities, 4 of which were unintentional environmental, 1 was unintentional therapeutic error. Carbon monoxide, acetaminophen, methadone and salicylate were the leading causes. The table below is excerpted from the NPDS 2012 report in a more readable format. It enumerates the substance categories that were the leading cause of pediatric deaths in 2012.

Table 17E. Substance Categories Most Frequently Involved in Pediatric (≤ 5 years) Deaths.^a

Substance (Major Generic Category)	All substances	% ^b	Single-substance exposures	% ^c
Fumes/Gases/Vapors	16	24.62	4	12.90
Analgesics	10	15.38	5	16.13
Cold and Cough Preparations	4	6.15	4	12.90
Antihistamines	3	4.62	1	3.23
Automotive/Aircraft/Boat Products	3	4.62	0	0.00
Hormones and Hormone Antagonists	3	4.62	0	0.00
Sedative/Hypnotics/Antipsychotics	3	4.62	0	0.00
Stimulants and Street Drugs	3	4.62	1	3.23
Unknown Drug	3	4.62	2	6.45
Antidepressants	2	3.08	2	6.45
Batteries	2	3.08	2	6.45
Cardiovascular Drugs	2	3.08	1	3.23
Cleaning Substances (Household)	2	3.08	1	3.23
Alcohols	1	1.54	0	0.00
Anticonvulsants	1	1.54	1	3.23
Antimicrobials	1	1.54	1	3.23
Dietary Supplements/Herbals/ Homeopathic	1	1.54	1	3.23
Electrolytes and Minerals	1	1.54	1	3.23
Gastrointestinal Preparations	1	1.54	1	3.23
Hydrocarbons	1	1.54	1	3.23
Information Calls	1	1.54	1	3.23
Other/Unknown Nondrug Substances	1	1.54	1	3.23
Total	65	100.00	31	100.00

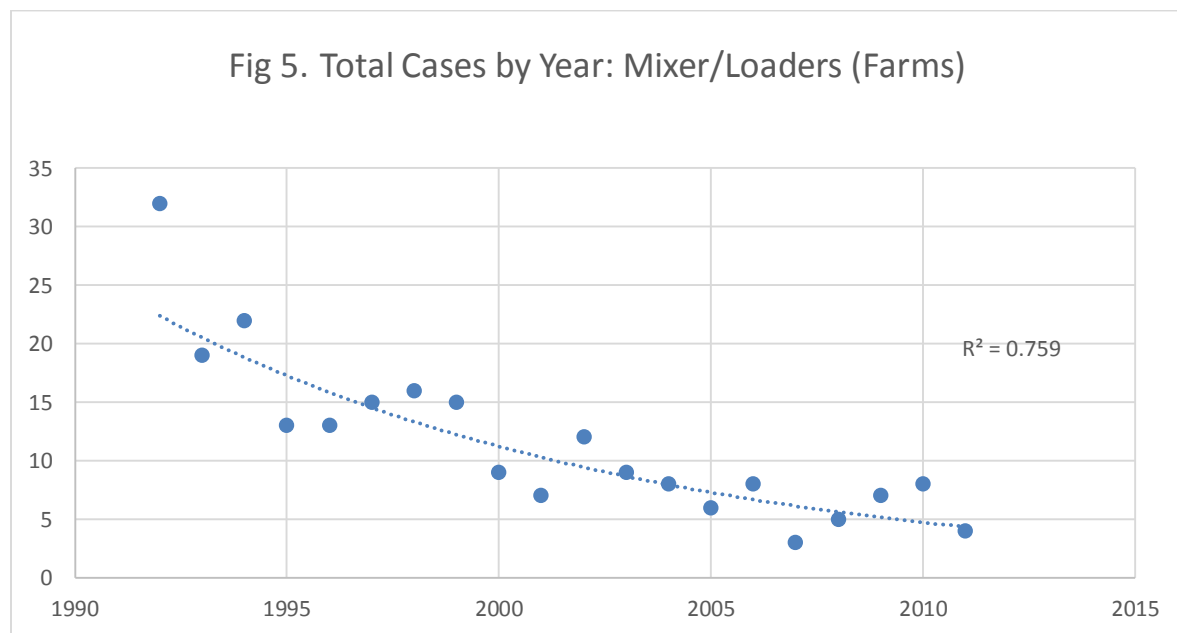
^aIncludes all children with actual or estimated ages ≤ 5 years old. Results do not include "Unknown Child" or "Unknown Age". Includes death and death (indirect) regardless of Relative Contribution to Fatality.

^bPercentages are based on the total number of substances reported in pediatric fatalities (N = 65).

^cPercentages are based on the total number of single-substance pediatric fatalities (N = 31).

1.4.3 ACUTE, NON-FATAL EXPOSURES, ILLNESSES AND INJURIES

The relative importance of pesticides as causes of mortality previously articulated are supported by data from States like California and Washington that have long made pesticide poisoning a legally mandated reportable cause of mortality or morbidity. Since California has the largest number of farmworkers (15% of the nation's total), uses more pesticides than any other State, and has had mandatory illness reporting for pesticides since 1982, its illness statistics provide unique insight into trends over time. Shown in Figure 5 is a summary of illnesses by year for Mixer/Loaders of pesticides in the State of California. Note the general downward trend in number of illnesses annually between 1992 (the year California Department of Pesticide Regulation chose to start providing a publicly available web portal for retrieval of selective mortality and morbidity data) to 2011, the most recent year for which illness data are publicly available.

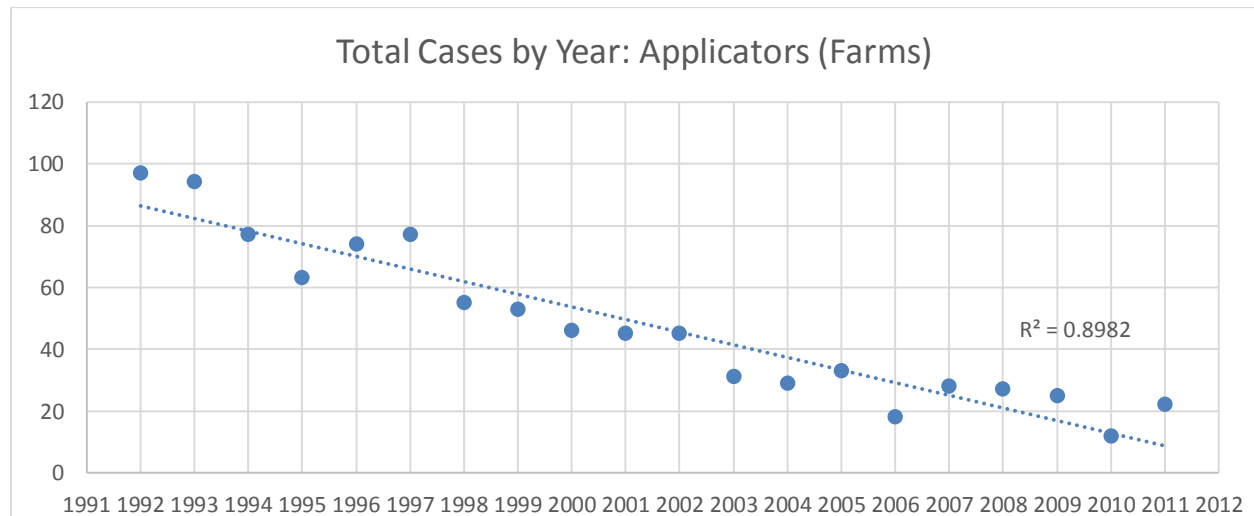


Source: CA Department of Pesticide Registration, Cal PIQ

California illness data was taken from the California Pesticide Illness Query program (CalPIQ). CalPIQ is available at <http://apps.cdpr.ca.gov/calpiq> and was used to retrieve cases evaluated as definitely, probably, or possibly related to pesticides from 1992 through 2011.

The results in Figure 6 for Applicator illnesses are similar to those of Mixer/Loaders with a downward trend in illness incidents that accounted for nearly one-hundred incidents per year in 1992 and plateaued at approximately 20 per year from 2006 onward.

FIGURE 6



Source: Cal PIQ

It appears that there may be a plateau developing in number of illnesses per year reported for mixer/loaders and applicators. A plateau suggests that certain accidents may be difficult to prevent. Accidents involving inappropriate behavior (e.g., reaching into a mix/load tank to retrieve one's hat) result from instinctual reflex. Similarly, broken hose lines under pressure occur no matter how diligent one is in maintaining the hoses. No regulation can prevent poor judgment, lack of thought, or mechanical failure that occurs despite maintenance.

The illness data for fieldworkers (Figure 3) are typically greater than both Mixer/Loaders and Applicators combined in part due to a much larger number of fieldworkers than pesticide handlers. Additionally, fieldworker incidents tend to occur with a whole crew of workers resulting in large numbers for most fieldworker incidents. However, it is clear even with the episodic nature of fieldworker illness that there is a downward trend in illnesses, i.e., over time the higher numbers have come down and are approaching the lower annual illness rates.

An evaluation of pesticide illnesses recorded in the state of California would raise questions regarding the alleged strong evidence that exposure to pesticides in the workplace is producing substantial risks. Ca-PISP is a good barometer of the types of illnesses occurring from occupational exposure to pesticides, because California is the nation's largest agricultural producer with extensive pesticide use, a large farmworker population working in crops that require multiple hand-labor tasks, and the best reporting system in the country. An evaluation of the annual summary reports of CA-PISP that are issued by the Worker Health and Safety Branch of the CA Department of Pesticide Regulation shows that the number of episodes of pesticide illness dropped between 1992 and 1998 and has been steady since then, that only about a quarter of the illnesses investigated were associated with agricultural pesticide use, and that a majority of the agricultural use illnesses resulted from either safety violations, drift, or improper early re-entry into a treated field.

CLA conducted a detailed evaluation of two CA-PISP annual reports (2010 and 2008) to illustrate the nature of worker illnesses in California and by extrapolation to the rest of the country.

CA PISP 2010:

In **2010** there were 1,114 cases that were identified as potential health effects of pesticide exposure. This is a typical number in California since 1998. Between 1992 and 1997 the number of annual cases declined from more than 2,500 in 1992 to approximately 1,500 in 1998. Of the 1,114 cases identified in 2010, DPR scientists determined that in 73% (811) of the cases, it was possible, probable, or definite that pesticide exposure was a contributing factor. Of these cases, 231 (20%) involved agricultural use of pesticides. 80% were non-agricultural cases including residential, intentional ingestion, and other uses not intended to contribute to the production of agricultural commodities, and in 2010 there were 572 such cases. In the remaining 8 cases of the 811 cases where pesticide exposure was a contributing factor it was not possible for DPR to determine if the use was agricultural or not.

Two factors appear to account for the majority of the 811 illnesses reported (agricultural and non-agricultural) that appeared related to pesticide exposure – (i) safety violations (51%) and (ii) drift (14%).

Safety violations appeared to contribute to 417 – or just over half of the cases. There were 45 cases involving exposures to pesticides used in agriculture in 2010 in which the pesticide use appeared to be in full compliance with regulations and labels. The number of cases involving violations of regulations or the label is approximate, because some enforcement actions were still under consideration at the time of the report preparation.

- (i) The second factor is **agricultural related drift**, and these cases primarily involve field workers. Because field workers work in crews, a large number of cases can occur from one episode. Of the 231 agricultural related pesticide illnesses in 2010 a total of 139 involved field workers and of these 115 involved drift in 12 separate episodes. Two of these episodes involved a large number of field workers:

The first involved an insecticide drift: In this episode 32 field workers arrived in a field to harvest strawberries about 1200 feet from an ongoing application to a different field. The workers noticed odors from the application and developed symptoms. The growers were eventually cited for failure to take their employees for medical management, and the handler training records did not include the use of the pesticide that was involved in that particular application.

In the second episode 26 broccoli harvesting fieldworkers unknowingly violated an active inner buffer zone in an adjacent field treated with a fumigant and tarped. The field workers parked their cars within 10 feet of the fumigated field which partially blocked a harvesting machine that then tore a 120 foot section of the tarp and exposed the workers to fumes. The investigation determined human error was the cause of this episode, as the broccoli grower had agreed to allow the buffer zone to extend into his property, since the harvest was not supposed to start until the following day, when the REI for the fumigated field would have expired. However, the farm manager allowed the harvesting to start a day early due to an oversight.

CA PISP DATA 2008

The **California PISP annual report for 2008** was evaluated because of its emphasis on fieldworker illnesses and one large drift related episode. In 2008 a total of 895 cases appeared to be pesticide related and of these 311 (35%) were associated with agricultural pesticide use. Again, approximately half of the cases provided evidence that violations of regulations or labels contributed to the exposure. Of those cases which were associated with agricultural use, there were 194 cases of fieldworker illness associated with pesticide use (21% of the total cases associated with agricultural use). Drift was the apparent cause in 119 of the 194 cases and involved 14 episodes, while 73 cases (15 episodes) involved exposure to pesticide residues. In regards to the 73 cases of exposure to field residues, one episode involved 56 cases. In this case a crew of 70 strawberry harvesters entered a field and began to develop symptoms after entering an area treated three days earlier with two fungicides and two insecticides. The symptoms involved eye, nose and upper respiratory tract irritation but there was no REI violation. The largest drift episode involved an aerial application to an alfalfa field in which drift was determined to occur to crews harvesting broccoli half a mile away. Thirty-three cases were determined to be probably related to the drift and the aerial applicator was fined.

The PISP contains a significant amount of data that can provide an accurate picture regarding the nature of illnesses, their causes, and potential solutions or conversely ineffective proposed solutions. The California PISP data suggest that a significant number of illnesses result not from failures of the WPS or label requirements but rather from noncompliance with either regulations or label requirements. None of these cases resulted in fatalities or permanent injury to the individual. Drift from ongoing adjacent applications toward fieldworker crews also contributes to a significant number of the pesticide related agricultural illnesses investigated by California DPR. However when one considers the number of incidents of drift, (as opposed to the number of cases caused by that drift) and the circumstances under which they occurred, it is unlikely that the proposed changes to the WPS will make a meaningful impact, and certainly not one that justifies the additional requirements that would be imposed.

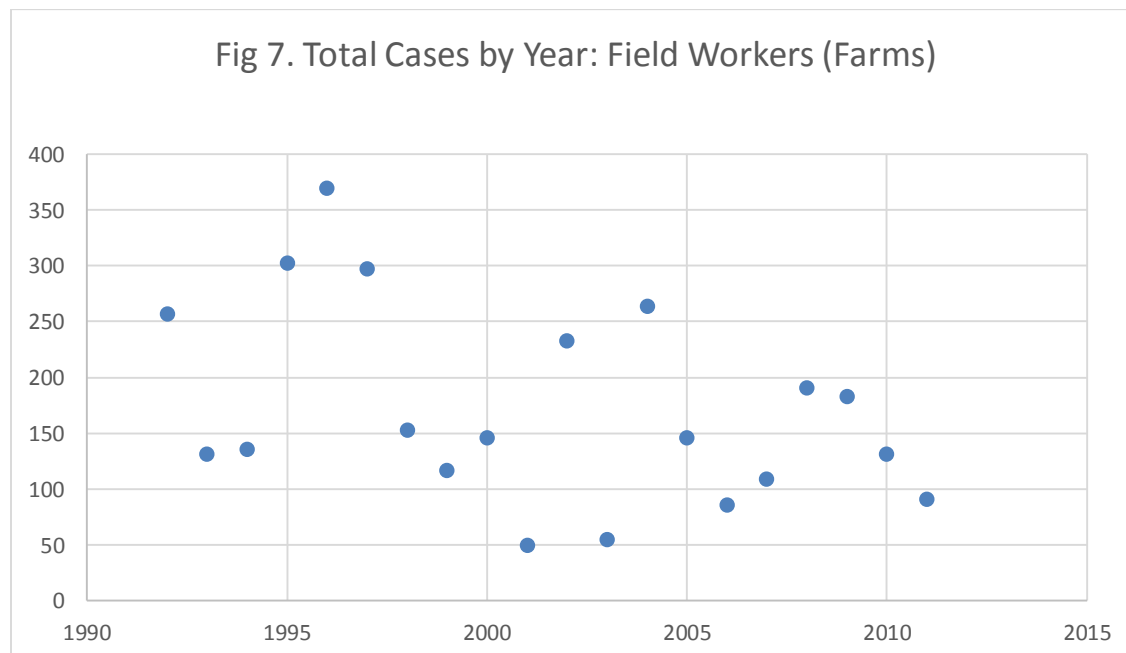
When one examines the circumstances under which the episodes of drift related illness occur –it is clear that human error, or disregard for the requirements of the current WPS have a large part to play. Furthermore, ascribing these incidents to “drift” is not accurate in certain instances. “Odor” plays a large part in the assumption of drift, and in some cases the “drift” was associated with opening a package, not with a pesticide application. Moreover, drift as regulated by DPR has been interpreted as any measureable amount of the pesticide under investigation regardless of concentration. In many cases the worker returned to work, in some cases they returned to work after a few hours / one day of illness at most. None of the case gave rise to permanent injuries or fatalities.

A table, unedited and drawn directly from the CA PISP 2011 database on agriculture related drift incidences is available in ANNEX 4. It describes the cases and circumstances under which the drift incidents occurred.

Here are some unedited examples from this table to illustrate the above points:

- *“A mixer/loader was pouring 25-pound bags of a product into a nurse tank. When he lifted his goggles to mop sweat, rotor turbulence blew dust into his eyes. He rinsed them with eye wash and finished his shift, but became increasingly uncomfortable”*
- *“Three fieldworkers were asked to sit in their cars as a helicopter sprayed an adjacent celery field. Confusion between the farm mgr & crew leader resulted in the workers weeding in the treated field before rei expiration. When the manager realized the women were in the sprayed field, he told them to go home, wash their clothes, and take a shower. They began having symptoms on the way home & called a crew supervisor who took them for care. The farm labor contracting company was issued violations for allowing the women to enter the field before the label allowed and for sending the women home rather than taking them for care when they suspected pesticide exposure”*
- *“As a crew leader worked in an organic strawberry field, she felt ill while an application took place in a nearby field. The interview was months after the incident, but wind reports support a possible exposure. No others reported illness, but noted odor.”*

Fog 7 illustrates the points made regarding the incidences of drift captured by the CA PISP. It speaks to the fact that small numbers of drift incidents may result in larger numbers of illness. From the perspective of the WPS, the action would be to address the incidents of drift, not the number of cases.



Source: CA PISP

These represent cases, but not incidences, and thus the incidence of spray drift is lower than the number of cases because workers are usually sent into fields in groups. Thus one incident (as described in previous examples) can give rise to a number of cases. In fact, in 2011, out of almost 2.5 million pesticide applications there was a total of 76 reported cases arising from 24 incidents (Annex 4). Of these cases, none required hospitalization and almost none resulted in loss of days at work.

Another factor obscured by summary statistics such as those appearing in Figure 7 is that when an entire crew is sent to the hospital, for instance, even the workers that had a transient complaint may be listed as possibly affected.

While there is an overall downward trend, there is also considerable variability from year to year. The most common causes of fieldworker illness are related to accidental reentry to a field before expiry of the REI and pesticide drift from applications in an adjacent field. Both of these causes of fieldworker illness should be preventable under the current WPS. At times drift incidents involve “adjacent” fields that may be up to a mile away, and it is clear that odor plays a role in a number of fieldworker illnesses, i.e., it is not physically possible to obtain sufficient drift at long distances to produce illness from the active ingredient. Odor may produce a transient illness (e.g., nausea and/or vomiting), but regulating foul smells is beyond the scope of the WPS.

Other Causes of Illness and Injury in Farm Workers

EPA has done little to contextualize, or examine the trends in acute pesticide exposures leading to illness within the context of other causes of injury and illness farmworkers may experience. Neither has EPA compared pesticide incidents in the agriculture community against those in other industries. Thus it is impossible to determine whether or not the levels are excessive relative to industry norms, comparable with industry norms or minor in terms of impact and number relative to other causes of illness and injury. As the proposed revisions confer a considerable and significant cost burden on the grower community, it would seem reasonable to determine whether that cost burden results in a considerable or marginal benefit, and whether the resources might be best spent in mitigating what illness and injury does occur. In other words, whether there is, in fact, a case to answer.

Agriculture in the U.S. is a hazardous job relative to some job categories. However, as shown in Table 3, the morbidity (non-lethal illness) rates for agriculture (with exception of pig farming) don't make the top 25. Moreover, the primary cause of worker mortality in crop production (85%) is not pesticides, but rather accidents that occur from being in proximity to heavy equipment, e.g., forklifts, tractors, power take off units, etc. (Table 3). Whether transportation (responsible for approximately half of all mortality), or crush injuries from equipment, the vast majority of mortality in agriculture results from mechanical (physical) injury, and is not due to chemicals (recorded in the column marked “exposure to harmful substances or environments”) including pesticides. Based on the results of Table 4, the mortality incidence rate of all chemicals (including pesticides) used in crop production was $11/224 = 4.9\%$ in 2012. It is noteworthy that there are many chemicals used in the workplace that are toxic (antifreeze, fuel, compressed gasses, water, etc.) in addition to pesticides. That point is well-illustrated by a comparison of mortality on crop

production farms in 2012 (11) with the 261 deaths in the broader category of farming, fishing and forestry (Table 5).

TABLE 3. Highest incidence rates¹ of total nonfatal occupational injury and illness cases in U.S. Workers, 2012 (from NSC, 2014; Table SNR01).

Industry ²	NAICS code ³	Incidence rate	
		2011	2012
Nursing and residential care facilities (State Government)	623	13.1	13.6
Manufactured home (mobile home) manufacturing (Private Industry)	321991	10.9	11.8
Police protection (Local Government)	92212	11.3	11.8
Travel trailer and camper manufacturing (Private Industry)	336214	11.2	11.7
Iron foundries (Private Industry)	331511	10.9	11.5
Fire protection (Local Government)	92216	13.5	411.2
Truck trailer manufacturing (Private Industry)	336212	9.4	10.7
Truss manufacturing (Private Industry)	321214	7.6	10.4
Heavy and civil engineering construction (Local Government)	237	8.8	10.3
Skiing facilities (Private Industry)	71392	11.5	10.2
Iron and steel forging (Private Industry)	332111	7.4	9.8
Veterinary services (Private Industry)	54194	—	9.6
Nursing and residential care facilities (Local Government)	623	10.2	9.6
Hog and pig farming (Private Industry)	1122	7.2	9.5
Beet sugar manufacturing (Private Industry)	311313	9.4	9.3
Prefabricated wood building manufacturing (Private Industry)	321992	8.2	9.3
Hospitals (State Government)	622	9.2	9.2
Ambulance services (Private Industry)	62191	9.7	9.1
Secondary smelting and alloying of aluminum (Private Industry)	331314	6.1	9.0
Materials recovery facilities (Private Industry)	56292	5.4	8.8
Correctional institutions (State Government)	92214	—	8.8
Animal (except poultry) slaughtering (Private Industry)	311611	7.8	48.7
Aluminum foundries (except die-casting) (Private Industry)	331524	9.5	8.7
Aluminum die-casting foundries (Private Industry)	331521	7.8	8.6
Light truck and utility vehicle manufacturing (Private Industry)	336112	9.4	48.5
Crop production⁵	111	—	5.3
All Industries including state and local government⁶		3.8	43.7

¹ The incidence rates represent the number of injuries and illnesses per 100 full-time workers and were calculated as: (N/EH) x 200,000, where
 N = number of injuries and illnesses
 EH = total hours worked by all employees during the calendar year
 200,000 = base for 100 equivalent full-time workers (working 40 hours per week, 50 weeks per year)

² High rate industries were those having the highest incidence rate of total

recordable cases of injuries and illnesses and at least 500 total recordable cases at the most detailed level of publication, based on the *North American Industry Classification System -- United States, 2007*.

³ *North American Industry Classification System -- United States, 2007*

⁴ A statistical significance test indicates that the difference between the 2012 incidence rate and the 2011 rate is statistically significant at the 95 percent confidence level.

⁵ Crop production has been added to this list for comparative purposes.

⁶ Excludes farms with fewer than 11 employees.

NOTE: Dash indicates data do not meet publication guidelines. SOURCE: U.S. Bureau of Labor Statistics, U.S. Department of Labor

Table 4. Fatal occupational injuries by industry and event or exposure, all United States, 2012 from BLS (2014; Table A-1)

Industry ¹	NAICS code ¹	Total fatal injuries (number)	Event or exposure ²					
			Violence and other injuries ³	Transportation incidents ⁴	Fires and explosions	Falls, slips, trips	Exposure to harmful substances or environments	Contact with objects and equipment
Total	111	4,628	803	1,923	122	704	340	723
Private industry	1111	4,175	666	1,706	111	661	318	702
Goods producing	11111	1,823	111	643	68	387	169	443
Natural resources and mining	11115	690	31	322	34	58	39	205
Agriculture, forestry, fishing and hunting	11116	509	27	244	9	35	27	166
<u>Crop production</u>	11119	224	5	119	6	12	11	71
Oilseed and grain farming	111191	28	--	15	--	--	--	11
Soybean farming	1112	5	--	--	--	--	--	3
Wheat farming	11121	5	--	5	--	--	--	--
Corn farming	111211	13	--	6	--	--	--	6
Rice farming	1113	--	--	--	--	--	--	1
Other grain farming	11133	--	--	--	--	--	--	--
Oilseed and grain combination farming	111332	1	--	--	--	--	--	--
<u>Vegetable and melon farming</u>	111334	10	--	6	--	--	--	--
Vegetable and melon farming	1114	10	--	6	--	--	--	--
Potato farming	11141	5	--	4	--	--	--	--
<u>Fruit and tree nut farming</u>	111411	13	--	7	--	--	--	3
Non-citrus fruit and tree nut farming	11142	13	--	7	--	--	--	3
Grape vineyards	111421	1	--	--	--	--	--	1
Berry (except strawberry) farming	111422	--	--	1	--	--	--	--
<u>Greenhouse, nursery, and floriculture production</u>	1119	14	--	6	--	1	--	6
Food crops grown under cover	11191	--	--	--	--	--	--	--
Mushroom production		1	--	--	--	--	--	1
<u>Nursery and floriculture production</u>		11	--	6	--	1	--	3
Nursery and tree production		8	--	4	--	1	--	--
Floriculture production		--	--	--	--	--	--	1
<u>Other crop farming</u>		45	--	24	1	3	5	11
Tobacco farming		5	--	--	--	1	--	--

Table 5: Number of nonfatal occupational injuries and illnesses involving days away from work^a and fatal occupational injuries by selected worker and case characteristics, private industry, United States, 2011 (NSC, 2014; page 86).

Characteristic	Private industry ^{b,c} nonfatal cases	All industries fatalities
Total	908,310	4,693
Sex		
Men	559,740	4,308
Women	344,730	385
Age		
Younger than 16	200	10
16 to 19	20,030	74
20 to 24	85,940	292
25 to 34	198,660	714
35 to 44	202,270	875
45 to 54	225,680	1,222
55 to 64	133,740	936
65 or older	26,670	569
Occupation		
Management, business, and financial	27,700	497
Professional and related	77,740	66
Service	220,080	875
Sales and related	57,220	240
Office and administrative support	72,250	92
Farming, fishing, and forestry	13,910	261
Construction and extractive	73,000	798
Installation, maintenance, and repair	85,570	356
Production	109,960	222
Transportation and material moving	168,980	1,248
Military occupations	-	38
Race or ethnic origin^d		
White, non-Hispanic	377,530	3,305
Black, non-Hispanic	70,290	437
Hispanic	117,210	749
Other, multiple, and not reported	343,280	202
Source of Injury or Illness		
Chemicals or chemical products	12,640	164
Containers	109,310	68
Furniture or fixtures	38,720	21
Machinery	52,310	388
Parts and materials	84,190	196
Worker motion or position	126,740	-
Health care patient	48,210	7
Floors, walkways, or ground surfaces	142,030	152
Handtools	43,250	28
Ladders	19,160	122
Vehicles	86,460	2,041
All other	145,290	1,504

Characteristic	Private industry ^{b,c} nonfatal cases	All industries fatalities
Event or exposure		
Violence and other injuries by persons or animals	33,230	791
<i>Intentional injury by other person</i>	<i>11,760</i>	<i>468</i>
<i>Injury by person unintentional or intent unknown</i>	<i>11,450</i>	<i>36</i>
Transportation incidents	40,230	1,937
<i>Roadway incidents involving motorized land vehicles</i>	<i>25,780</i>	<i>1,103</i>
Fires or explosions	1,700	144
Falls, slips, or trips	225,550	681
<i>Slips or trips without fall</i>	<i>35,350</i>	<i>-</i>
<i>Fall on same level</i>	<i>134,580</i>	<i>111</i>
<i>Fall to lower level</i>	<i>46,560</i>	<i>553</i>
Exposed to harmful substances or environments	39,120	419
Contact with object or equipment	230,290	710
<i>Struck by object</i>	<i>131,490</i>	<i>476</i>
<i>Struck against object</i>	<i>52,960</i>	<i>5</i>
<i>Caught in object, equipment, or material</i>	<i>33,930</i>	<i>145</i>
Overexertion and bodily reaction	329,910	7
<i>Overexertion in lifting or lowering</i>	<i>112,300</i>	<i>5</i>
<i>Repetitive motion involving microtasks</i>	<i>27,690</i>	<i>-</i>
All other	8,270	-

Source: This research was conducted with restricted access to Bureau of Labor Statistics (BLS) data. The views expressed here do not necessarily reflect the views of the BLS.

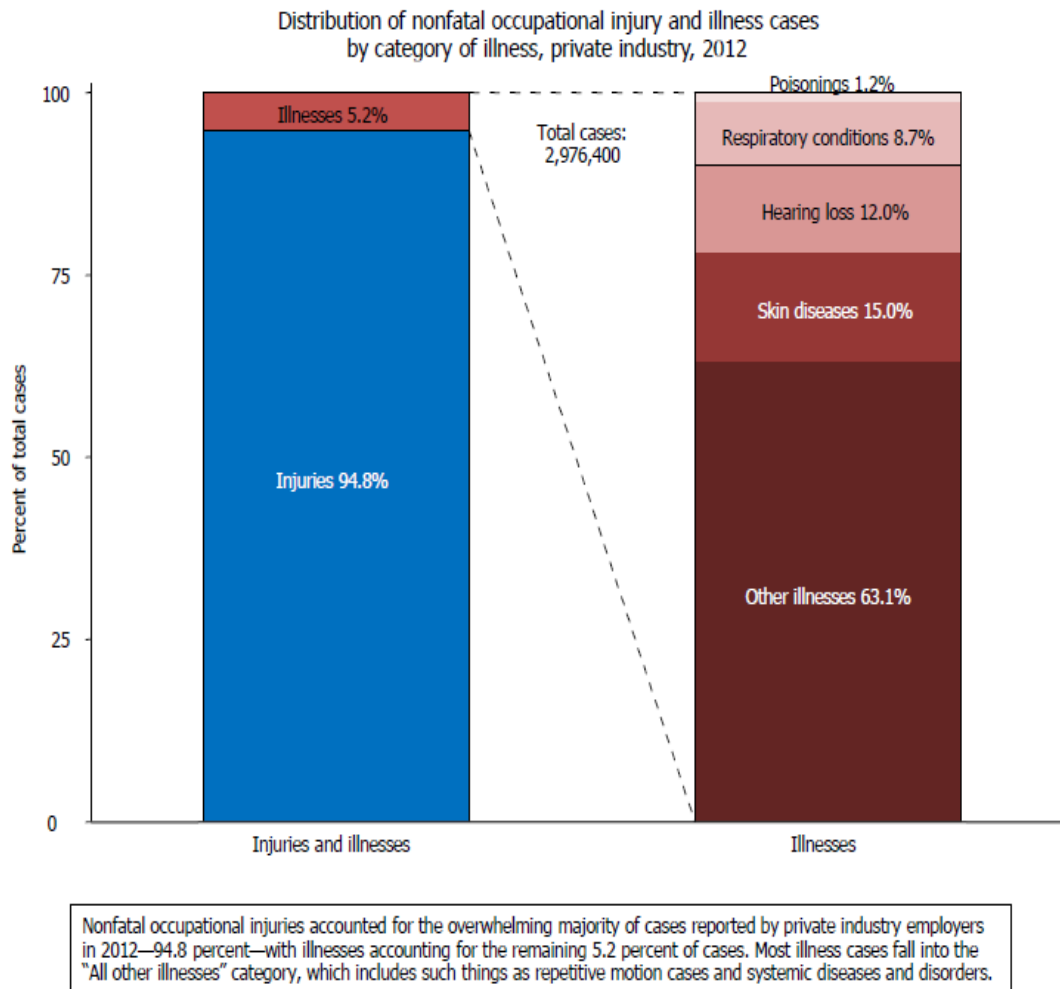
Note: Because of rounding and data exclusion of non-classifiable responses, data may not sum to the totals. Dashes (-) indicate data that do not meet publication guidelines.

^aDays away from work include those that result in days away from work with or without restricted work activity or job transfer.^bExcludes farms with fewer than 11 employees.

^cData for mining operators in coal, metal, and nonmetal mining and for employees in railroad transportation are provided to BLS by the Mine Safety and Health Administration (MSHA), U.S. Department of Labor; and the Federal Railroad Administration (FRA), U.S. Department of Transportation. Independent mining contractors are excluded from the coal, metal, and nonmetal mining industries. MSHA and FRA data do not reflect the changes in OSHA recordkeeping requirements in 2002.^dIn the fatalities column, non-Hispanic categories include cases with Hispanic origin not reported.

In addition to the California data, The **Bureau of Labor Statistics for 2012** also speak to the relative importance of poisoning as a cause of non-fatal illness / injury in the work place across all industry sectors, including agriculture³: Illnesses accounted for 5.2% of occupational injury and illness cases across all industry sectors. 1.2% of that 5.2% were a result of all poisonings, or “exposure to harmful substances or environments”. (Fig. 8.)

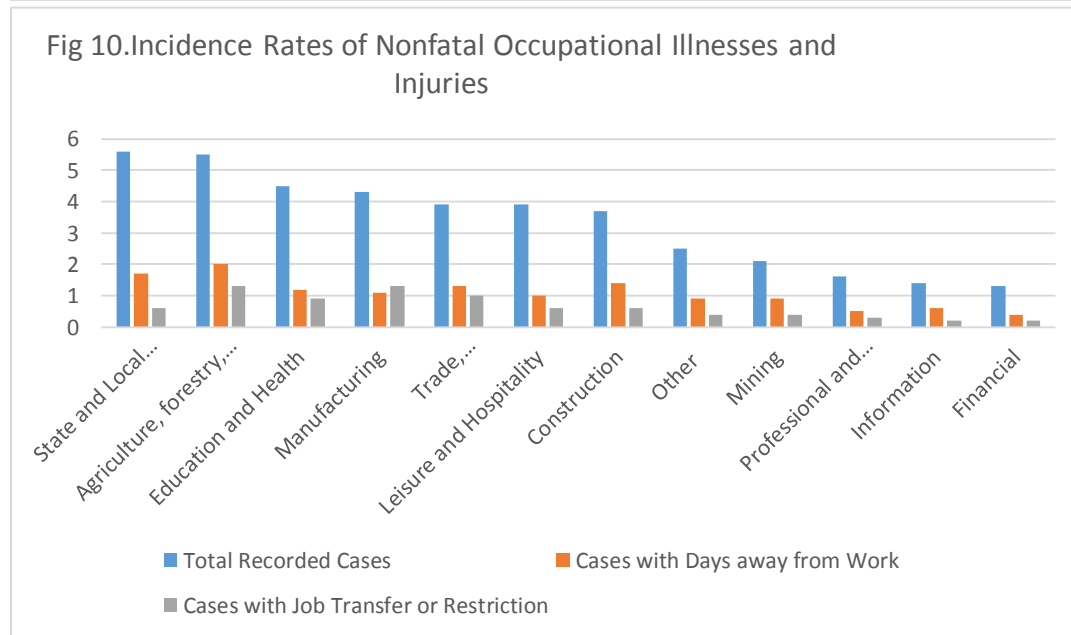
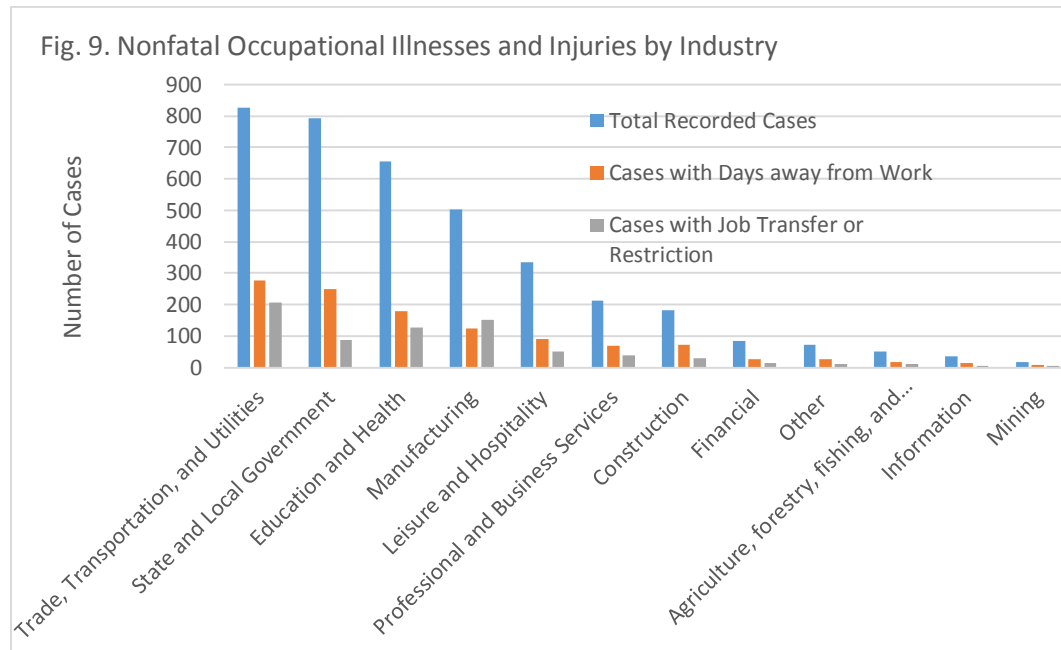
Fig. 8 Distribution of non-fatal occupations injury and illness cases by category of illness, private industry, 2012



Source: U.S. Bureau of Labor Statistics, U.S. Department of Labor, November 2013

³ ‘Agriculture’ is a broad category which includes agriculture, forestry, fisheries and hunting

When these non-fatal illness and injuries (ALL causes) are examined by industry sector, the BoL data demonstrates that the absolute number of agricultural workers impacted is low relative to other industry sectors (Fig 9.), although the incidence rate⁴ (ALL causes, Fig 10) is the second highest.



⁴ The incidence rates represent the number of injuries and illnesses per 100 full time workers and were calculated as: $(N/EH) \times 200,000$, where N=number of injuries and illnesses, EH=total hours worked by all employees during the calendar year, 200,000=base for 100 equivalent full-time workers (working 40 hours per week, 50 weeks per year).

The cause of these non-fatal illness and injuries for all sectors is broken down in Table 6 of the 2012 Bureau of Labor data. This table is an extraction of the top 8 industry sector data for absolute numbers of injury and illness, and overall incidence rate per 10,000 workers. So while the incidence of overall illness and injury rate in the agriculture sector is the second highest, incidence of exposure due to harmful substances /environments ranks fifth. Pesticides are a subset of “harmful substances and environments”.

Table 6: Illness and Injury Incidence Rates by Type of Injury

Industry Sector	Number of illnesses and injuries	Incidence rate	Musculo-skeletal disorders	Exposure to harmful substances / environments ⁵
Local Government:				
Justice, public order and safety	38,380	425	111.8	28.3
Transportation and Warehousing	9,190	391.8	165.6	36.7
State Government				
Health care and social assistance	20,290	366.5	88.9	7.0
Justice, public order and safety	20,420	286.1	74.1	11.8
Private Industry:				
Transportation and Warehousing	89,260	222.9	87.3	5.4
Agriculture, forestry, fishing and hunting	17,620	195.0	38.0	9.5
Construction	71,730	143.4	42.1	5.1
Accommodation and Food Services	74,010	99.1	22.3	10.3

Source: Bureau of Labor Statistics 2012 Industry Injury and Illness Data

⁵ Exposure to hazardous substances or environments also includes a number of situations totally unrelated to intentional use of fuel or chemicals, including silo-fillers lung (oxides of nitrogen), gases from manure or other waste (hydrogen sulfide), combustion related incidents (carbon monoxide, in building, vehicle, or fire), and the general category of confined space entry/hypoxia.

National Poison Data System 30th annual report 2012

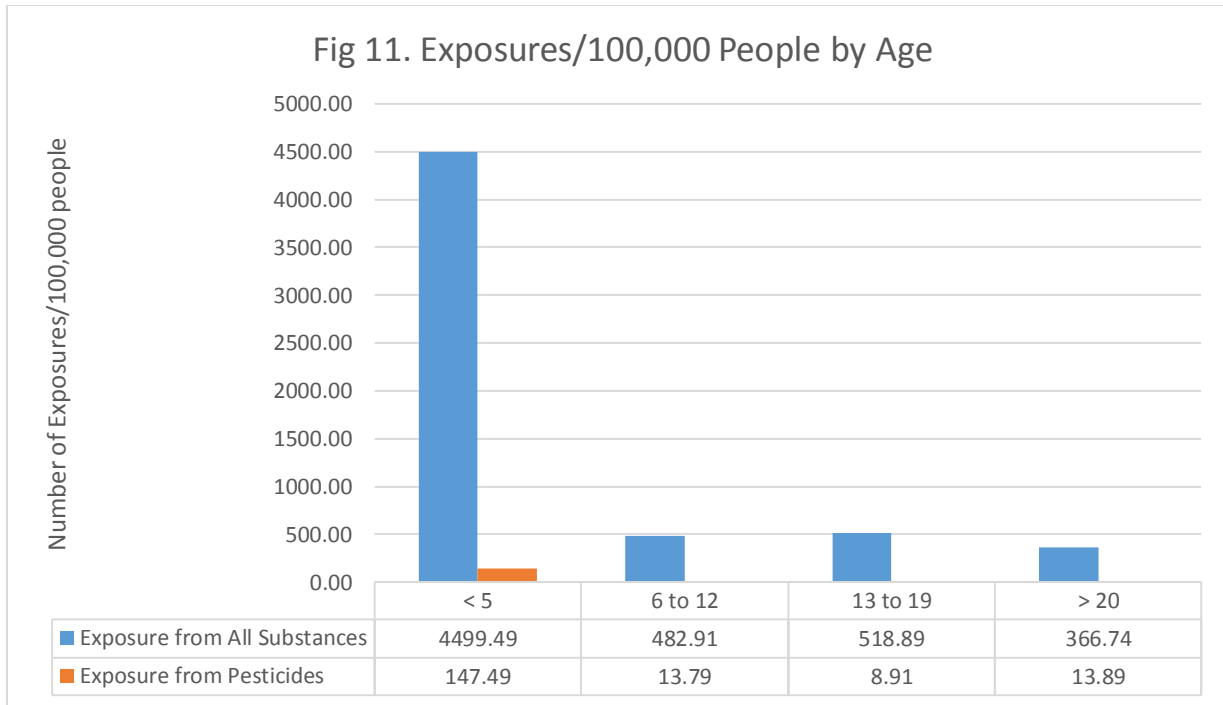
The Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 30th Annual Report⁶ 2012 evaluates exposures, illness and fatalities across a range of exposures to agents that can cause harm. It covers all poisonings reported to the Poison Control Centers, and agriculture workers are therefore a subset of this data. NPDS data provide a context for pesticide poisonings and fatalities relative to poisonings from all other sources.

The 2012 NPDS Annual Report states that *"The top five substance classes most frequently involved in all human exposures were analgesics (11.6%), cosmetics/ personal care products (7.9%), household cleaning substances (7.2%), sedatives/hypnotics/antipsychotics (6.1%), and foreign bodies/toys/miscellaneous (4.1%). Analgesic exposures as a class increased the most rapidly (8,780 calls/year) over the last 12 years. The top five most common exposures in children aged 5 years or less were cosmetics/ personal care products (13.9%), analgesics (9.9%), household cleaning substances (9.7%), foreign bodies/toys/miscellaneous (7.0%), and topical preparations (6.3%)"*.

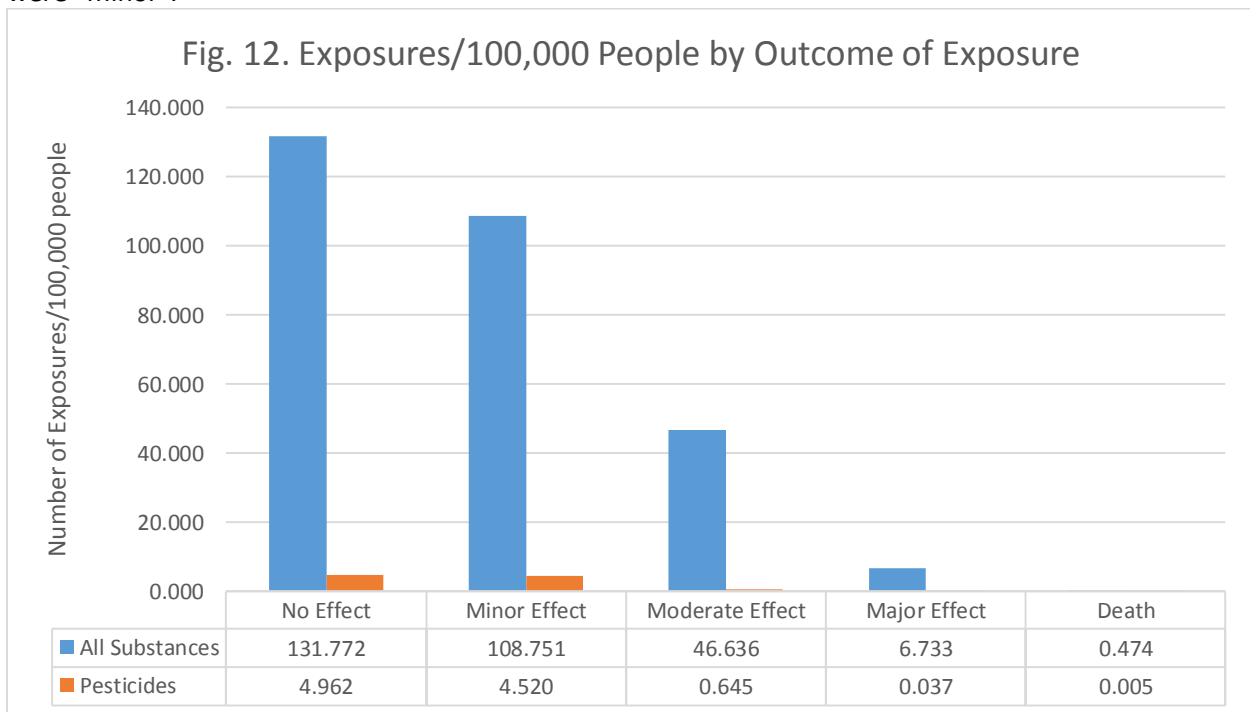
Unlike the CA PISP dataset, the NPDS data provides information on the number of exposures reported to the poisoning centers (Fig. 11.), separate to the consequences of those exposures (Fig. 12). Thus exposure in NPDS is not necessarily associated with an illness or injury. In both cases the data indicate that exposures to pesticides relative to other exposures is extremely low, and that those exposures primarily give rise to either no effect or minor effects.

The graphs below describe the number of exposures incidents per 100,000 people, and the outcome of those exposures. The use of incident rate better contextualizes the number of exposures that occur in each age group, since the ≥ 20 age group contains more people than the other age groups. Children 5 years old and under have the most exposures per 100,000 people, but pesticide exposure accounts for a small portion of the total number of exposures per 100,000 people (Source: National Poison Data System 2012 Annual Report). An examination of the consequences of those exposures reveals that the vast majority of exposures result in either no effect or a minor effect. Again, these numbers are not confined to agricultural use of pesticides, but all exposures to pesticides. Thus to better understand the implications of these data and the role of the WPS in mitigating these effects requires closer scrutiny of the moderate to major effect cases, and the people and circumstances under which they occurred.

⁶ *Clinical Toxicology* (2013), 51, 949–1229 Copyright © 2013 Informa Healthcare USA, Inc. ISSN: 1556-3650 print / 1556-9519 online DOI: 10.3109/15563650.2013.863906



Outcomes of that exposure, by severity: The graph below indicates that the majority of exposures, including pesticide exposures, were “without harm” and the majority of exposures which did cause harm were “minor”.



California PISP data: CA PISP database links exposure to an illness that has been reported as a result of a visit to a physician. It could be argued that these events are underreported, but it is not possible to

determine why. Thus agriculture workers may not visit a physician to report illness because they lack severity, or because they lack of insurance coverage, or because they may fear it might jeopardize their employment. This could apply to the broader community not just ag workers, however. The reasons for underreporting have different implications for the interpretation of the data, and no assumptions can be made about the severity – and therefore the cost burden - of the unreported poisoning event for this reason. None the less an examination of the relative causes and levels of acute exposures is relevant as the under reporting could apply to reports of all cases of illness and injury not just those involving pesticides. From the figure below it is clear that (1) 80% of all exposures are NOT agricultural and (2) only 17% of all exposures and illnesses can be “definitely” ascribed to pesticides.

Sources of confirmed exposure in 2011, CA PISP data.

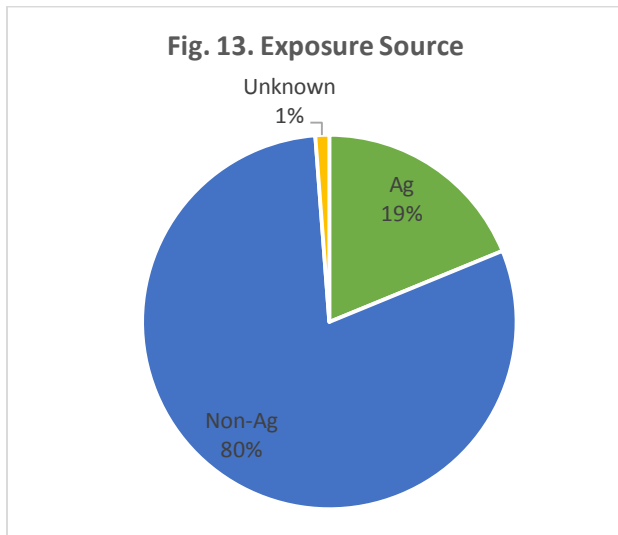


Fig 13. Source of confirmed exposures to pesticides in California in 2011. Cases are sorted by whether or not the pesticide involved was intended to contribute to the production of an agricultural commodity. 80% of all exposures were from non agriculture sources. From 2010, the number of total reported cases increased. This increase mostly came from a 42% increase in non-agricultural situations.

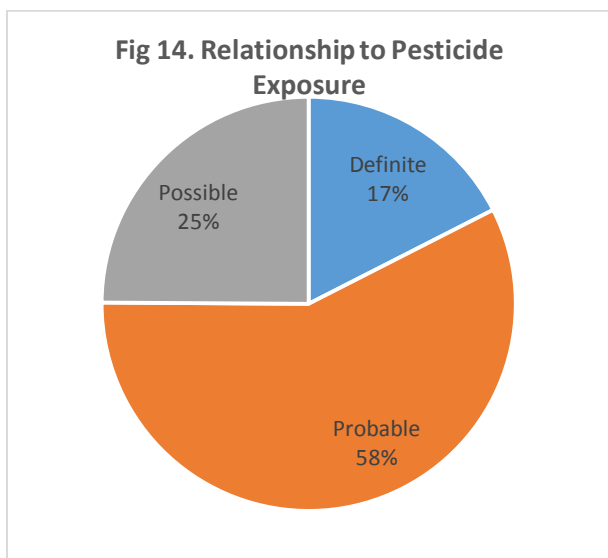


Fig. 14. Percentage of reported California cases in 2011 which were either definitely, possibly or probably related to pesticide exposure. Both the physical and medical evidence document exposure and consequent effects if there is a definite relationship. “Probable” indicates limited or circumstantial evidence for the relationship between exposure and illness. “Possible” indicates that health effects have been recorded which are generally associated with exposure. In this case it should be noted that symptoms of pesticide poisoning are often generic and could be associated with other causes such as skin rashes, diarrhea and so forth. For the purposes of our analysis, all incidents, regardless of relationship, are included.

The following examples are actual CA PISP Case Reports describing the circumstances under which the acute pesticide exposures occurred. Again, noting that approximately 20% of the total are actually

agriculture related (A larger table of these incidences, including case number and the pesticide involved is available in Appendix 3):

“A man reached for his eye drops in the glove compartment of his car. After placing a drop into one of his eyes, he developed symptoms and realized he put ear miticide for cats into his eye by mistake. He sought care and recovered without incident”

“A 3-year-old became ill and was hospitalized after ingesting an unknown herbicide containing diquat stored in a gatorade bottle. His dad got the herbicide from a friend, which the child later found and asked the babysitter to give him a drink. “

“To save money, a woman had her gardener spray an unknown amount of outdoor termiticide in her attic. She was away from home for about two weeks and soon after returning she turned on the heat and began feeling ill. She refused to provide contact for the gardener”

“A worker was spraying a vineyard in an open cab when a vine hit his face knocking his goggles up above his eyes. Spray went into his eyes. He develop symptoms, washed out his eyes and was taken for care”

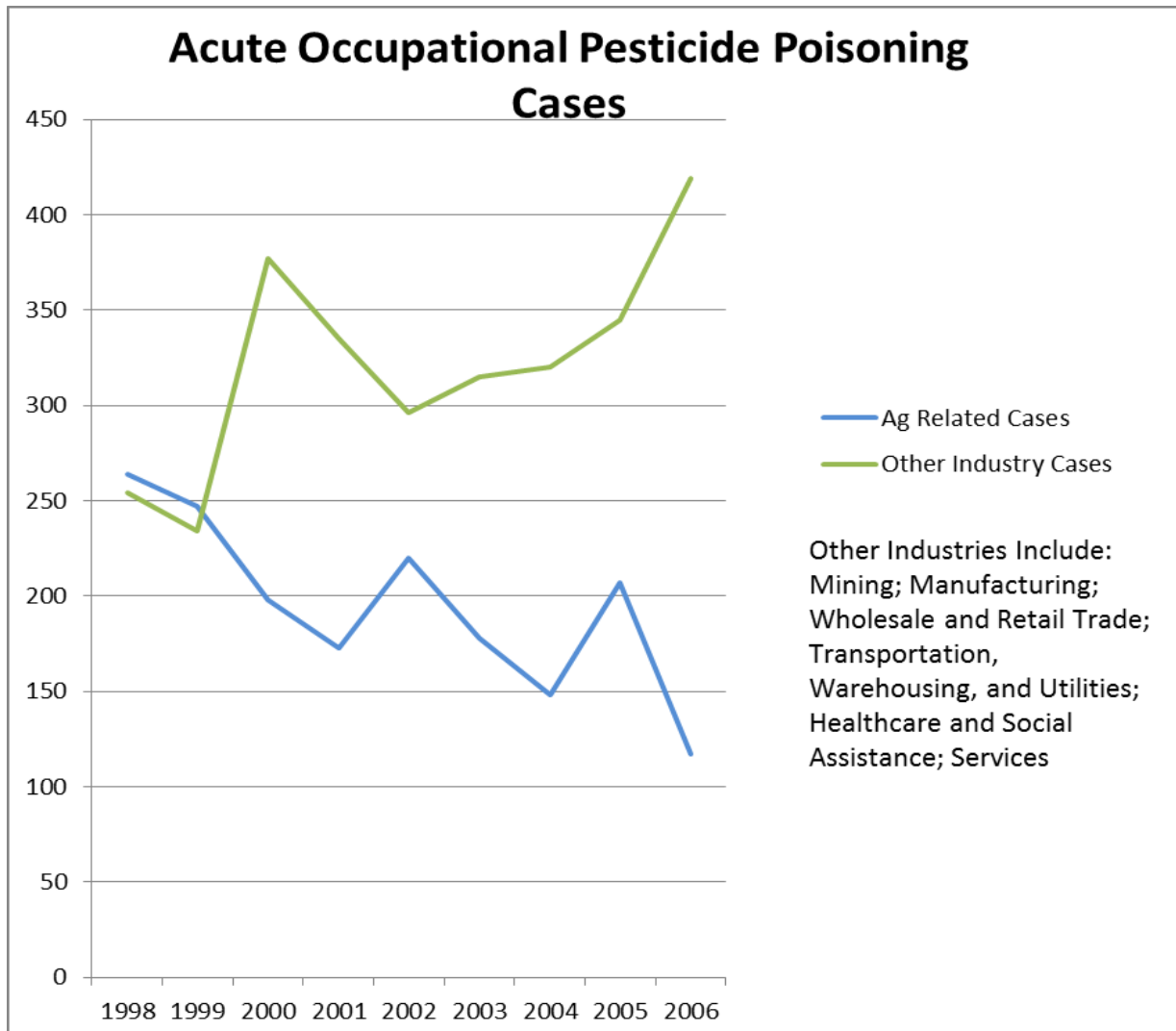
“A resident mixed 1/4 of herbicide with water in a container and pumped the sprayer. The sprayer leaked and sprayed one arm. He experience symptoms and sought care. He was not wearing the proper protective measures as listed on the label”

Some of these accidents are tragic. Some of these accidents are unlucky. However it is hard to see what role the current or the revised WPS could play in preventing such exposures, particularly when so many occur under circumstances where the WPS do not apply.

The **NIOSH SENSOR database** has tracked the number of acute pesticide poisoning cases within agriculture and other industries. As with the CA PISP data, there can be some uncertainty over the relationship between the exposure to the pesticide and the reported outcome.

According to the **1998 – 2006 NIOSH SENSOR data**, acute occupational poisoning cases fell dramatically for agriculture related cases, while continuing to rise for all other industries (Fig 15.)

Fig 15: Acute Occupational Pesticide Poisoning for Agriculture and Other Industries. 1998-2006



The **NIOSH SENSOR Clinical Description for an acute adverse effect** refers to any acute adverse health effect resulting from exposure to a pesticide product (defined under the Federal Insecticide Fungicide and Rodenticide Act [FIFRA]1) including health effects due to an unpleasant odor, injury from explosion of a product, inhalation of smoke from a burning product, and allergic reaction. Because public health agencies seek to limit all adverse effects from regulated pesticides, notification is needed even when the responsible ingredient is not the active ingredient.

A case is characterized by an acute onset of symptoms that are dependent on the formulation of the pesticide product and involve one or more of the following:

- Systemic signs or symptoms (including respiratory, gastrointestinal, allergic and neurological signs/symptoms)
- Dermatologic lesions
- Ocular lesions
- This case definition and classification system is designed to be flexible permitting classification of pesticide-related illnesses from all classes of pesticides. Consensus case definitions for specific classes of chemicals may be developed in the future.

The NIOSH SENSOR website states that a case will be classified as occupational if exposure occurs while at work (this includes: working for compensation; working in a family business, including a family farm; working for pay at home; and, working as a volunteer Emergency Medical Technician (EMT), firefighter, or law enforcement officer). All other cases will be classified as non-occupational. All cases involving suicide or attempted suicide are classified as non-occupational.

A case is reportable to the national surveillance system when there is:

- Documentation of new adverse health effects that are temporally-related to a documented pesticide exposure; AND
- Consistent evidence of a causal relationship between the pesticide and the health effects based on the known toxicology of the pesticide from commonly available toxicology texts, government publications, information supplied by the manufacturer, or two or more case series or positive epidemiologic investigations; OR
- Insufficient toxicologic information available to determine whether a causal relationship exists between the pesticide exposure and the health effects

Fig. 16 Status of Reported Acute Occupational Pesticide Poisoning

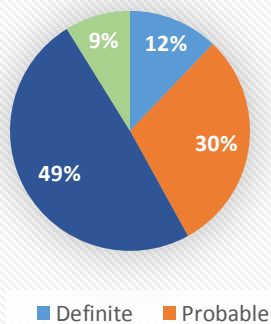


Fig 16. For the NIOSH SENOR reporting, a case of pesticide-related illness or injury is classified into one of the following categories: definite, probable, possible, or suspicious. The specific status applied to a given case depends on the strength of exposure evidence, the health effects that were reported, and whether the health effects were consistent with the known toxicology of the implicated pesticide(s).

Despite all regulatory efforts, there will always be pesticide illnesses. This is NOT because pesticides are inherently more dangerous than prescription pharmaceuticals or even water, because both of those cause orders of magnitude more deaths each year than pesticides, and corresponding higher levels of morbidity. Rather, most pesticide illnesses are due to lapses in judgment or common sense with a fair ration of fear. No amount of increased paper work or posting is going to reduce illnesses or accidents resulting from poor judgement or lack of thought. Illness in agriculture is due more often to transportation and heavy equipment accidents than to pesticides.

Focusing on one cause of illness and injury draws resources away from addressing other causes. As resources are not infinite, care should be taken in determining where resources would be best spent. While the EPA WPS may help protect workers from illness due to pesticides, they do not address the illness and injury arising from other causes which are far more significant to the overall health and wellbeing of farm workers. Neither can they address other causes impacting their well being such as immigration status, economic concerns, literacy and education levels. When one examines the massive cost burden these proposed revisions are likely to incur, and the specific benefits relative to this cost, the proposed revisions seem neither necessary, nor the resources required well placed..

Exposure data:

In the last 20 years, and since the issuance of the WPS in 1992, the quantity and quality of exposure data, including dermal and inhalation exposure data, have improved exponentially. Since 1992 there has been the development of the Pesticide Handlers Exposure Database and the conduct of a multitude of exposure studies by task forces whose purposes have been to develop and provide to EPA the best available mixer/loader, applicator, and fieldworker exposure data. The Farm Family Exposure Study and various biomonitoring equivalent studies have demonstrate that actual systemic exposures are at levels well below the EPA chronic reference dose. One specific example is the series of publications on the biomonitoring equivalent approach and urine data for 2,4-D⁷. Without exception exposure levels detected in urine are well below any concentration of concern. In another study⁸ which examined exposure to glyphosate, urine samples were collected from farmers, their spouses and children. The study evaluated 24-hr composite urine samples for each family member the day before, the day of, and for 3 days after a glyphosate application. The detectable levels were in the parts per billion, therefore none of the systemic doses estimated in this study approached the U.S. Environmental Protection Agency reference dose for glyphosate of 2 mg/kg/day (2ppm).

The EPA has gathered information on exposure data and it is available at <http://www.epa.gov/pesticides/science/handler-exposure-data.html>. These data capture the wide variability of exposures during actual applications and field work, and provide a greater understanding of

⁷ 2,4-D Exposure and risk assessment: Comparison of external dose and biomonitoring based approaches
Sean M. Hays, Lesa L. Aylward, Jeffrey Driver, John Ross, Christopher Kirman Regulatory Toxicology and Pharmacology 64 (2012) 481–489

⁸ Glyphosate Biomonitoring for Farmers and Their Families: Results from the Farm Family Exposure Study. *John F. Acquavella,1 Bruce H. Alexander,2 Jack S. Mandel,3 Christophe Gustin,1 Beth Baker,2 Pamela Chapman,4 and Marian Bleeker1*. Environmental Health Perspectives • VOLUME 112 | NUMBER 3 | March 2004

the relationship between work practices and exposure potential based on the range of exposures to be expected during actual use of the pesticide. Acceptable risk as generally defined by EPA is an exposure that is at least 100 times less than the dose level that did not produce any observable adverse effect in the most sensitive species tested, and even lower than the lowest dose level that did. With this risk assessment procedure in place and now having been used on all pesticides registered in the United States, CLA finds it hard to reconcile this risk assessment procedure with the statement of apparent fact that significant short- and long-term health risks occur because of exposure to pesticides when used under widespread and commonly recognized practice.

CLA Recommendations:

- **Information from a number of sources could assist in determining (i) the real magnitude of the problem to be addressed and (ii) the most appropriate training requirements in order to address it.**
- **Sources include California PISP data, NPDS, NIOSH SENSOR data and often provide detailed accounts of the circumstances under which the incidents took place, thus allowing for better tailoring of WPS training needs.**
- **EPA should examine the nature of pesticide related incidents and illnesses and their causes in greater detail before deciding possible solutions to put forward.**
- **EPA should reference its own data on real life exposures and reference doses as part of its analysis of the WPS.**

PART 1.5 CHRONIC MORBIDITY AND MORTALITY IN AGRICULTURE

1.5.1 CLA Overarching Comments

CLA objects to the Agency position that the evidence is strong for chronic health effects due to occupational exposure to pesticides, in general and particularly with respect to cancer.

- **The break even analysis suggests that the benefits are limited to very few cases and reduced cancer and illness rates will be too small to be measured. This also means it will not be possible to judge whether the revised WPS have worked or not.**
- **The causal evidence between exposure to pesticides and the chronic diseases cited has not been demonstrated. In light of the extensive controlled and laboratory studies available for individual pesticides the Agency should not be including cancer rates in their benefit analyses, even for illustrative purposes.**
- **Of great concern is a tacit admission that the Office of Pesticide Programs has failed in its primary mission under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to only register a pesticide the Agency determines that when used in accordance with the label it will not generally cause unreasonable adverse effects to handlers and workers.**
- **Specifically CLA supports efforts of the WPS to comply with the label.**

The EPA admits that *“the wide range of employment histories and pesticide exposures characteristic of the agricultural workforce generally prevents reliable estimates of the full impact of chronic pesticide exposure”*. Despite this, justification for the costs and benefits of the proposed revisions rely heavily upon the alleged relationship between pesticide exposures and chronic health effects. In order to account for the reduction in chronic diseases expected as a result of the proposed WPS changes, EPA used a “break-even” analysis. Owing to the high costs associated with these chronic illnesses, EPA believes that reduction in the frequency of these illnesses among workers and handlers by less than 1% (53 total cases per year) would result in sufficient benefits to bridge the gap between the estimated costs of the revisions and the anticipated benefits associated with reducing acute pesticide exposures, an estimated \$65m. Specifically EPA estimated a reduction in *“the frequency of chronic illnesses by at least 0.08% for lung cancer and at least 0.8% for the other illnesses considered.”* (Federal Register/Vol. 79, No. 53/Wednesday, March 19, 2014, pg 15450.). It is difficult to understand how EPA plan to measure these infinitesimally small changes in chronic illness, or to differentiate whether the revised WPS, or environmental influences such as smoking and other lifestyle factors, are responsible for future changes incidence in these diseases.

Prior to calculating the benefit analyses, the EPA has not demonstrated – and furthermore, does not claim a causal link between exposure to pesticides and chronic disease. The Agency did not conduct their usual rigorous and balanced approach to evaluating the epidemiology literature. For example, only 3 publications were cited as evidence of an association of pesticides and lung cancer (Alavanja et al., 2004; Beane Freeman et al., 2005; Lee et al., 2004). Further, all 3 are from the same population, the Agricultural Health Study (AHS) applicators. Importantly, lung cancer incidence was much lower in the AHS participants than the population as a whole. Of the 50 pesticides evaluated in the AHS, only 4 (8%) were

statistically significantly associated with lung cancer, only slightly more than the expected 5% by chance alone (consistent with p value of 0.05).

Of great concern is a tacit admission that the Office of Pesticide Programs has failed in its primary mission under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to only register a pesticide the Agency determines that when used in accordance with the label it will not generally cause unreasonable adverse effects to handlers and workers. If the Agency is indeed succeeding in its primary mission to only register pesticides that do not cause unreasonable adverse effects then how can the use of such products pose significant long- and short-term health risks?

In Chapter 6 of the Economic Analysis the Agency suggests that although it is *“not stating that there is a causal link between certain health outcomes and exposure to specific pesticides”* the Agency apparently believes that it is only a matter of time and growing epidemiology study that *“additional causal links between pesticide exposure and adverse health outcomes in the human population will be provided.”* (page 199) In contrast, with continued efforts to reduce exposure, the epidemiology literature is actually supporting the safety of current use pesticides and the regulatory process. An evaluation of every publication cited by EPA within their preamble is available in Appendix 6 at the end of this document. It is clear from this analysis that the literature cited is incomplete, and in some cases not even illustrative of the link between disease and pesticide exposure articulated in the preamble.

Details are provided for cancer and Parkinson’s disease.

Cancer:

The Agency listed three specific cancers, Non-Hodgkin lymphoma (NHL), prostate and lung, in their calculation of qualitative benefits. However, the epidemiology evidence suggests that pesticides are not causally associated with these cancers. (Burns 2005, Koutros et al 2010, Waggoner et al 2011, Weichenthal et al 2010) If a causal relationship does not exist, changes to the WPS will not reduce these cancers. Furthermore, in light of the extensive controlled and laboratory studies available for individual pesticides the Agency should not be including cancer rates in their benefit analyses, even for illustrative purposes.

In regards to NHL, two reviews published in 2007 reached conflicting conclusions. Bassil et al. (2007), which was cited by EPA in their preamble, treated pesticides as a single entity and concluded that the majority of publications on NHL and pesticides found a positive association. Pesticides are not a single entity, and they do not all have the same mode of action. As such it is not clear whether the positive association was real or simply an artifact of bias, confounding or chance. Alexander et al. (2007) concluded that the data were inconsistent and the more methodological robust studies found no causal association between NHL and any specific pesticide. More recently, the Agricultural Health Study (AHS) has reported no statistically significant increased mortality or incidence of NHL in applicators or their spouses. (Koutros et al 2010, Waggoner et al 2011) Organizations such as the American Cancer Society and National Cancer Institute list exposure to phenoxy herbicides as being historically linked with NHL. However, the older studies reporting these associations may be spurious since the growing body of literature is reporting no association of NHL and certain herbicides. (Burns & Swaen 2012, von Stackelberg 2013)

The evidence of a link with pesticides and prostate cancer is similarly poor. Whereas farmers in the AHS have higher incidence rates of prostate cancer, they also have lower mortality rates. (Koutros et al 2010, Waggoner et al 2011) In their comprehensive review, Mink et al. (2008) conclude that the evidence for pesticides and prostate cancer is inconsistent and the quality of studies highly variable. In addition, the associations commonly reported in rural populations may be attributed to other factors (life style and so forth) unique to farmers.

Lastly the evidence for a causal association of lung cancer and pesticides is sporadic at best. Some analyses of the AHS have suggested associations with specific pesticides and lung cancer. (Beane Freeman et al 2005, Lee et al 2004) However, these links have not been supported in other human or animal studies; nor is lung cancer increased overall in the AHS farmers or their spouses. (Koutros et al 2010, Waggoner et al 2011) By comparison, the American Cancer Society estimates that at least 80% of lung cancer cases in the US are attributed to smoking (www.cancer.org). It is unacceptable that EPA referenced only 3 publications, all from the AHS, as sufficient evidence for a benefit analysis for pesticide exposure and lung cancer.

Parkinson's disease

The etiology of Parkinson' Disease is largely unknown. Ecological studies associating rural residents with the disease have triggered studies of pesticides. In their review of both the epidemiology and toxicology evidence for pesticides, Li et al., (2005) concluded that the human data were limited by poor exposure assessment. They further reported that *"In animal studies, no pesticide has yet demonstrated the selective set of clinical and pathologic signs that characterize human PD, particularly at levels relevant to human populations. We conclude that the animal and epidemiologic data reviewed do not provide sufficient evidence to support a causal association between pesticide exposure and PD."* The very large Agriculture Health Study (AHS) was designed to provide better exposure data on specific pesticides. According to Kamel et al., (2007) in their evaluation of PD among the approximately 80,000 AHS participants, neither prevalent or incidence PD was associated with use of any pesticide, personally mixing pesticides, personally applying pesticides or use of personal protective equipment (reduced risk). In fact, fewer than expected pesticides were statistically significant in their extensive analyses of 45 pesticides. Other reviews have also highlighted the inconsistent nature and weak study methods of the epidemiology data. (Brown et al., 2006; Freire et al., 2012; and Van Maele-Fabry et al., 2012) A recent review of studies specific to paraquat highlighted the need for more robustly designed epidemiology studies to address the etiology of PD (Mandel et al., 2012). As this report discusses, evaluating epidemiology studies and PD etiology requires more than just counting the number of "positive" studies. The evidence for exposure to specific pesticides and developing PD is not conclusive. In the context of the extensive animals data required for US registration the evidence is even weaker.

Summary information

There are a number of recent reviews which point to problems in evaluating chronic illness with pesticides exposure. For example, in a recent review conducted at the behest of the European Food Safety Authority (EFSA) scientists at the Ioannina Medical School evaluated more than 6000 publications. They concluded

“Despite the large volume of available data and the large number (>6,000) of analyses available, firm conclusions cannot be made for the majority of the outcomes studied. ... this observation is in line with previous studies on environmental epidemiology and in particular on pesticides which all acknowledge that such epidemiological studies suffer from many limitations and that the heterogeneity of data is such that does not allow firm conclusions to be made. ”

The UK Government Committee on Toxicology’s 2014 review of the literature on the long term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults concluded that *“collectively the evidence reviewed is reassuring. It suggests that exposure to cholinesterase inhibiting organophosphates do not cause important long term neurological toxicity in adults, and if toxic effects on the nervous system do occur, then they are minor and subtle.”*

In 2013 Burns *et al* published their review of the epidemiology and animal studies on Pesticide Exposure and Neurodevelopmental Outcomes. This review analyzed epidemiologic studies testing the hypothesis that exposure to pesticides during pregnancy and/or early childhood is associated with neurodevelopmental outcomes in children. They concluded that *“As a whole, the epidemiologic studies did not strongly implicate any particular pesticide as being causally related to adverse neurodevelopmental outcomes in infants and children.”* And *“the in vivo peer-reviewed published mammalian literature focused on effects of the specific active ingredient of pesticides on functional neurodevelopmental endpoints (i.e., behavior, neuropharmacology and neuropathology). In most cases, effects were noted at dose levels within the same order of magnitude or higher compared to the point of departure used for chronic risk assessments in the United States. Thus, although the published animal studies may have characterized potential neurodevelopmental outcomes using endpoints not required by guideline studies, the effects were generally observed at or above effect levels measured in repeated-dose toxicology studies submitted to the U.S. Environmental Protection Agency (EPA).”*

CLA objects to the implicit assumption that the EPA Office of Pesticide Programs has failed in its mission to protect the general population and the environment from “unreasonable harm” as articulated with the FIFRA statute. The Health Effects Division of the Office of Pesticide Programs (HED/OPP) has established human non-dietary exposure and risk assessments procedures that are generally accepted by the scientific and pesticide industry community to be well founded and protective. The risk assessment procedures used by HED have been evaluated by the National Academy of Sciences and the FIFRA Science Advisory Panel. Under current standards the toxicologists within HED evaluate an extensive and complete battery of mammalian toxicology studies required under 40 CFR Part 158. These studies encompass short-term, subchronic, chronic, developmental and reproductive, carcinogenicity, immunotoxicology, and neurotoxicity studies. The toxicologists determine the most appropriate and sensitive point of departure for the conduct of risk assessments to both handlers and fieldworkers based on use patterns of each pesticide. These points of departure are **no** observable adverse effects dose levels that are several times, to an order of magnitude lower than the lowest dose level that produced an observable adverse effect. The most sensitive and appropriate point of departure is coupled with an extensive evaluation of the exposure potential to both handlers and fieldworkers to determine the potential risk.

Alternative data sources include toxicological studies published in the literature and regulatory toxicological testing data required by EPA for pesticide registration. Yet despite the wealth of reliable, repeatable regulatory toxicological data available to the EPA, it is not referenced when, as the document states - “providing a plausible estimate of the number of chronic illnesses with a plausible association with pesticide exposure”. Because the regulatory toxicological testing specifically addresses the effects of chronic exposure, adhering to the pesticide label **prevents** this level of exposure from taking place. CLA therefore objects to the Agency statement that there is “strong evidence that workers and handlers may be exposed to pesticides at levels that can cause adverse effects”. Specifically CLA supports efforts of the WPS to comply with the label. The epidemiology evidence, in concert with the extensive animal data, does not support a causal association of occupational exposure to pesticides and cancer or specific chronic diseases.

CLA Recommendation

CLA recommends the current proposal be withdrawn and re –written to reflect the following:

- **CLA proposes that costs associated with revisions to the WPS can only be meaningfully balanced by reductions in the incidence of acute poisonings and that reference to chronic disease should be excluded from the cost estimates. The causal role of pesticides in chronic disease is unfounded and reductions in chronic disease due to reductions in chronic exposure are therefore unlikely and un-measurable.**
- **Referencing chronic disease in the preamble becomes unnecessary and should be removed, or at least rebalanced by (i) using a scientific literature review that includes toxicological data as well as epidemiology data, and (ii) which follows recommended best practice including the EPA Office of Pesticide Programs recommendations and guidelines such as their 2010 document “Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment”, <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2009-0851>, or the Weight of Evidence process EPA follows when incorporating other scientifically relevant information into a risk assessment.**

PART 2

2.1 CLA COMMENTS REGARDING EPA UNIT IV. PROTECTION OF PESTICIDE WORKERS

Demographics of the Farmworker Population

The EPA, within Section G, Page 15449 of the FRN give reasons for their proposed actions to protect workers, based on the age of the current WPS, occupational exposure, and demographics of farmworkers. CLA members have significant concerns over the tone and accuracy of this section.

EPA emphasizes “the disproportionate risk carried by this disadvantaged community” and paints a picture of an impoverished, exploited and victimized community. This is unfortunate because the demographic information cited is almost a decade out of date and fails to reflect a number of positive trends in worker demographics. Furthermore, many of the issues cited are beyond the scope of the worker protection standards to address as they speak to literacy, poverty and other socio demographic features beyond the scope of EPA’s remit to directly address.

The revised WPS preamble creates a dichotomy between the workers and the employers, pitting them against each other: Thus the preamble speak to the benefits of pesticide applications only accruing to the employer, while the benefits of the revisions to the WPS accrue primarily to the farm worker. It speaks to farmers who only care about their family, but not their workers. This is not an accurate portrayal and is very unproductive in representing the true relationship between employer and employee –particularly in a farm setting. In fact, the data reveal that workers return to the same farms year after year and, with an increasing demand for farm workers, workers do have choices where they work.

EPA speaks to the concept of “environmental justice” and states that the “agricultural handler and employers are the group that benefit from pesticide application on their establishment”. This statement fails to acknowledge the benefits which may accrue to the farm worker - As none of the farm worker employees are coerced into working on farms, or are prevented from leaving their work should they so wish, and as the farm workers draw a wage from their work, it is neither accurate nor helpful to assign all the benefits of pesticide application only to agricultural and handler employers. This statement fails to recognize the gainful employment provided to the worker, and the opportunity for integration into US society, which has been the trend ever since 1992.

Furthermore, assigning full responsibility of care to the employer is a dangerous precedent, as it could be construed as releasing the farmworker from any obligation to manage their own safety. This does not mean the employer is not fully responsible for providing the safety equipment and training and meeting all other aspects of the WPS but the worker also bears responsibility for, e.g. paying attention to training, following verbal and posted warnings and directions, using the PPE correctly, asking questions if anything is unclear and so forth. Based on the information provided in the previous section it is clear that regardless of training, accidents can happen and personal responsibility is key to implementing the WPS.

EPA states the benefits of the revised standards “accrue to **just** the workers, handlers and their families. This is another dichotomous statement. A healthy workforce benefits the employer as well, because they have a healthy workforce, US society also benefits from having safe, affordable food, thus there are many that benefit from well trained workers. Yet the assumption that the employer must “internalize the effects of their decisions” and thereby “minimize the externalities” seems to imply that employers only care about the health of their workers if made to do so which is simply not the reality. It is in the farmer’s best interest to have a healthy and happy workforce –as it is to any employer. In the BEAD Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions, EPA proposes various market failures that they believe may give rise to avoidable pesticide exposure. In a discussion of externalities EPA states “Another factor that contributes to unnecessary pesticide exposure is that the party making the application decision does not bear all of the negative effects of a pesticide application, including the health effects on others. This is a classic externality that can result in a divergence between the social and private costs of using a pesticide”. It goes on to states “An externality of this type could imply that there are fewer protections for workers and handlers than would be socially desirable. Employers may lack the incentive to seek out or act on the information they have on the negative consequences of pesticides or the possible measures that can be taken to avoid negative outcomes”. This is incorrect, because activities which result in harm to the worker are considered violations under the current WPS and are prosecutable. Of real concern however is the tone of this section, which suggests an exploitative relationship between the farmer and worker. While this may have been a possibility in the 1950 / 60’s, this is hardly the case now as demonstrated by the 21 years of Department of Labor’s National Agricultural Workers Survey (NAWS). Farmers and Farm employers need and want a healthy, happy sustainable work force.

Department of Labor’s National Agricultural Workers Survey (NAWS)

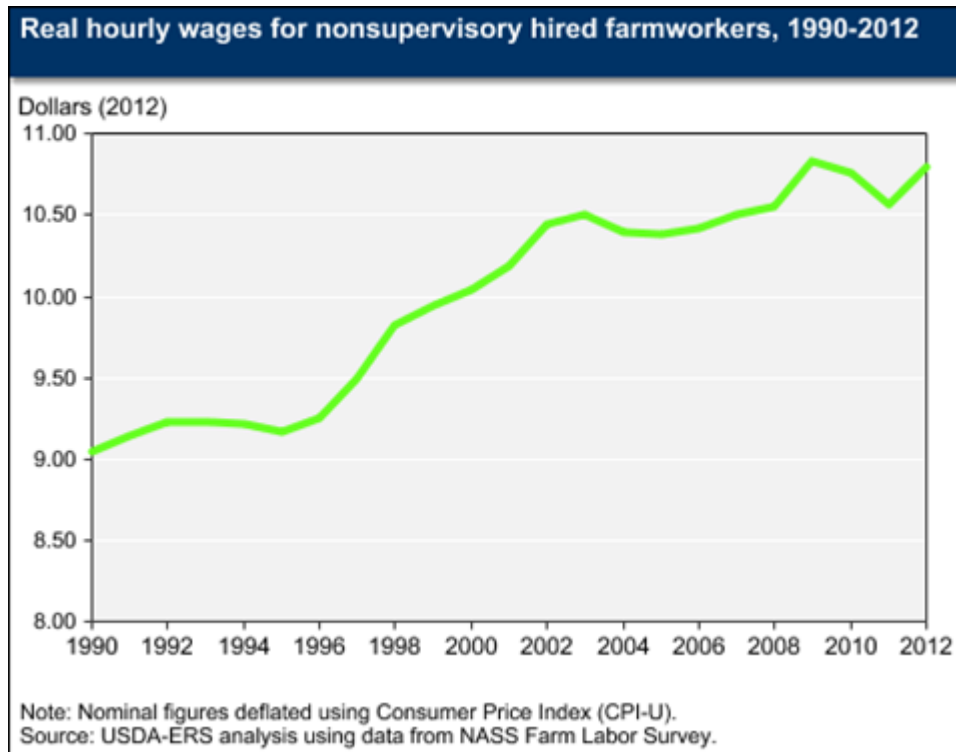
The data presented in the EPA proposal comes from the Department of Labor’s National Agricultural Workers Survey (NAWS) in 2001-2002. The USDA study cited by EPA dates from 2005. Yet the most recent data from NAWS is for 2012, not 2002 as presented by the EPA. The USDA report describes the hired worker status as ‘disadvantaged’ based on their lack of education, impoverished status and lack of access to health care – due to being too costly, lacking health insurance, language barriers and – for undocumented workers – a fear of being deported. More recent data from NAWS (2009) and the USDA 2012 National Agricultural Statistics Survey (NASS) data present the demographics of this group in a far more positive light, with ongoing improvements in all measures over the last decade⁹:

For example, the NAWS 2009 data and USDA demonstrate that average hourly earnings increased both nominally and in real terms (Fig. 17), and the share of workers with total family incomes below poverty decreased significantly from 56% in 1995 to 23% in 2009 – although we acknowledge this was still significantly higher than the average poverty rate of 14.3% for America as a whole. This may partly reflect the education level and language speaking skills of this community, which are generally poor. However, farm employment was less affected by the 2007-2009 recession than was nonfarm employment -

⁹ *Immigration Reform and Agriculture Conference: Implications for Farmers, Farm Workers, and Communities* University of California, D.C. Campus 12 May 2011, “*Changing Characteristics of U.S. Farm Workers: 21 Years of Findings from the National Agricultural Workers Survey*”, Daniel Carroll, U.S. Department of Labor

according to the Bureau of Economic Analysis, farm wage and salary employment fell by 1.5 percent between 2007 and 2009, compared to 4.7 percent for the nonfarm economy. The most recent Farm Labor Survey found that average farm employment in 2012 was above 2007 levels.

Fig 17.



Immigration Status

Clearly some farmworkers face the typical challenges of first generation immigrants and this is compounded by the additional challenges for those farmworkers who are not legally in the United States. But the emotive tone of this section of the WPS prevents an objective, fact based discussion of farm workers' real needs and wants. Addressing education, socio economic status or language barriers may contribute to improved worker protection as much as any revision to existing protection standards might achieve. The latter issues are ones that transcend the WPS and any revisions proposed by the Agency; however, CropLife believes that a thorough understanding of the farmworker demographics is critical to the proper development and focus of training material and record keeping requirements.

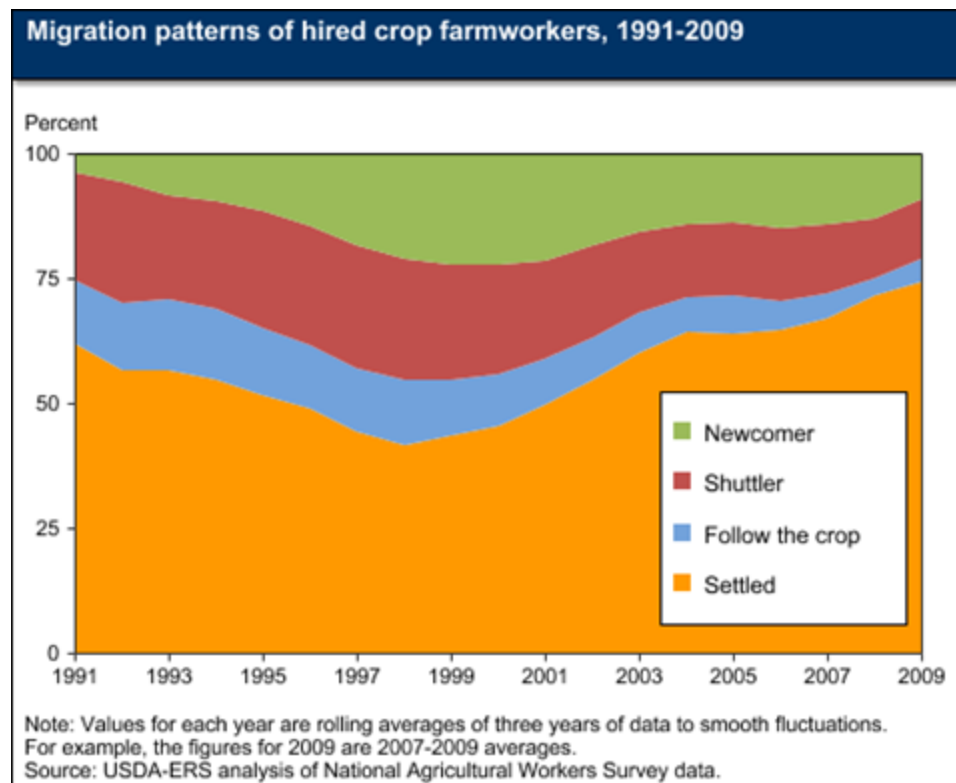
According to the March 2005 NAWS report the majority of the hired crop labor force was foreign born with 78% born outside the United States and primarily from Mexico (this figure fell by 10% by 2009). While most were foreign born the majority (59%) had been in the United States for five or more years when they were interviewed for the NAWS. By 2009 that figure had climbed to 74%, with 29% of the farm workers in the United States for over 20 years.

The 2002 data suggests immigrant status is an issue. Slightly more than half (53%) lacked work authorization which compounds the health, housing, employment, education and other challenges that they face. By 2009 this figure had reduced somewhat to 48%, with the remaining 52% broken down into 33% holding US citizenship, 18% holding a green card and 1% with work authorization.

Migrancy: Migration Patterns (US Department of Agriculture <http://www.ers.usda.gov/topics/farm-economy/farm-labor/background.aspx>)

Understanding the farmworker population is important to developing training and education programs to improve worker safety. Almost three-quarters of hired crop farmworkers are not migrants, but are considered settled, meaning they work at a single location within 75 miles of their home. Among migrant workers, the largest group are "shuttlers," who work at a single farm location more than 75 miles from home, and may cross an international border to get there. They made up about 12 percent of hired crop farmworkers in 2007-09 (Fig 18.). More common in the past, the "follow the crop" migrant farm worker, who moves from state to state working on different crops as the seasons advance, is now a relative rarity. These workers make up just five percent of those surveyed by the NAWS in 2007-09, down from a high of 14 percent in 1992-94. The final category in the figure are the newcomers to farming, whose migration patterns have not yet been established.

Fig 18.

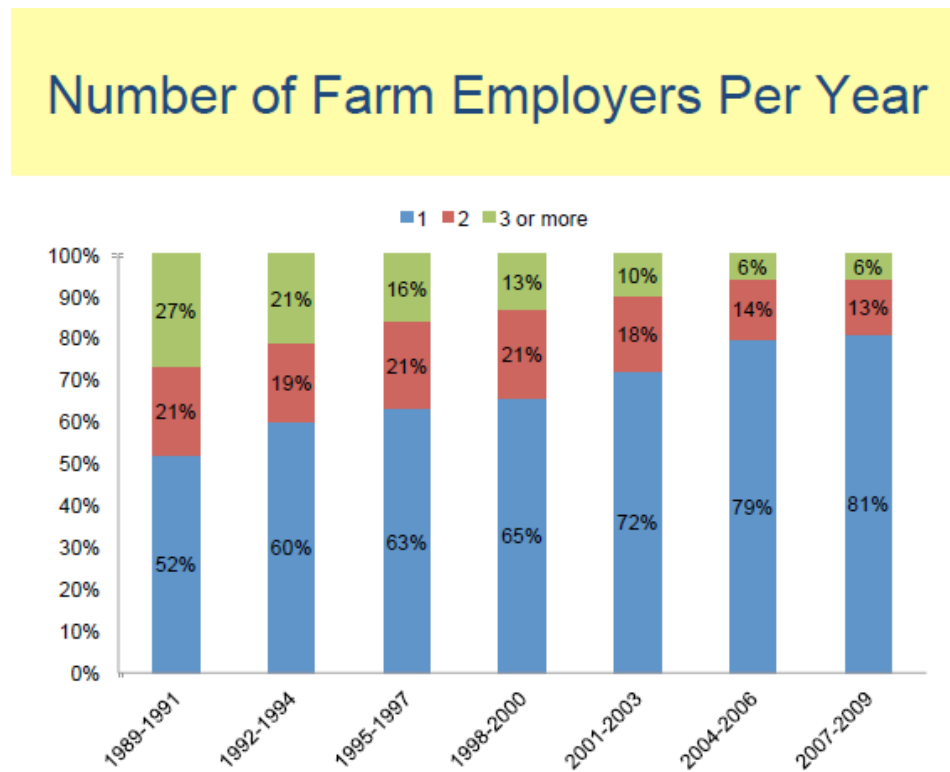


In 2001-2002 migrant farmworkers comprised 42% of the crop worker population; since then the percentage of farmworkers who are migrants has declined. In 2002, the overwhelming majority of

farmworkers reported working for one or two employers during the previous 12 month period as reported in the WPS proposal (72% worked for only one employer and an additional 18% worked for two employers). By 2009 84% of all farm workers reported working for only one employer and 13% worked for 2 employers; only 6% worked for three employers (Fig. 19.).

Taking into account the most recent 2012 NASS data 566,469 farms hired 2,736,417 farm workers in 2012. 148,000 of these farms were less than 50 acres in size. Of the 566,469 farms that hired workers only 18,911 or 3% hired migrant laborers. A total of 217,322 farms (38%) used contract labor of which only 3,360 or 1.5% of those farms used migrant contract labor. Clearly the demographics of migrant workers has changed since the 1992 WPS was written.

Fig. 19



Source: Data drawn from the Department of Labor, NAWS: Immigration Reform and Agriculture Conference: Implications for Farmers, Farm Workers, and Communities 12 May 2011, “Changing Characteristics of U.S. Farm Workers: 21 Years of Findings from the National Agricultural Workers Survey” D Carroll U.S. Department of Labor.

Hired Farm and Migrant Labor

The US Census for Agriculture (USCA, 2012) makes a distinction between hired farm labor and migrant labor. Definitions used to categorize laborers are quoted below from the Census:

“Migrant farm labor on farms reporting only contract labor. Data are for those operations that did not have hired farm workers but reported that they did have migrant contract workers on their operation in 2012.

Migrant farm labor on farms with hired labor. Operators were asked whether any hired or contract workers were migrant workers. A migrant farm worker is a farm worker whose employment required travel that prevented the worker from returning to his/her permanent place of residence the same day.”

The US Census for Agriculture (USCA, 2012; Table 7) addresses hired farm labor in all States. Rather than summarize them from the multi-page table, the number of workers in all States is listed in Table 3 below with the total farm workers in the U.S. broken out as hired or migrant laborers. Note that of all 50 States, only Rhode Island had less than 10,000 farmworkers listed in the 2012 census. On the opposite end of the spectrum, California had 465,422 farmworkers in 2012.

Table 7: Summary of Hired and Migrant Workers on Crop Production Farms in the U.S. in 2012

	Farms	Workers
Hired Farm Labor	312,566	1,910,055
Migrant on farms with hired labor	14,977	91,522 ^b
Migrant on farms with only contract labor	2,528	15,448 ^b
Total	330,071	2,017,025

^a From (USCA, 2012; Table 68).

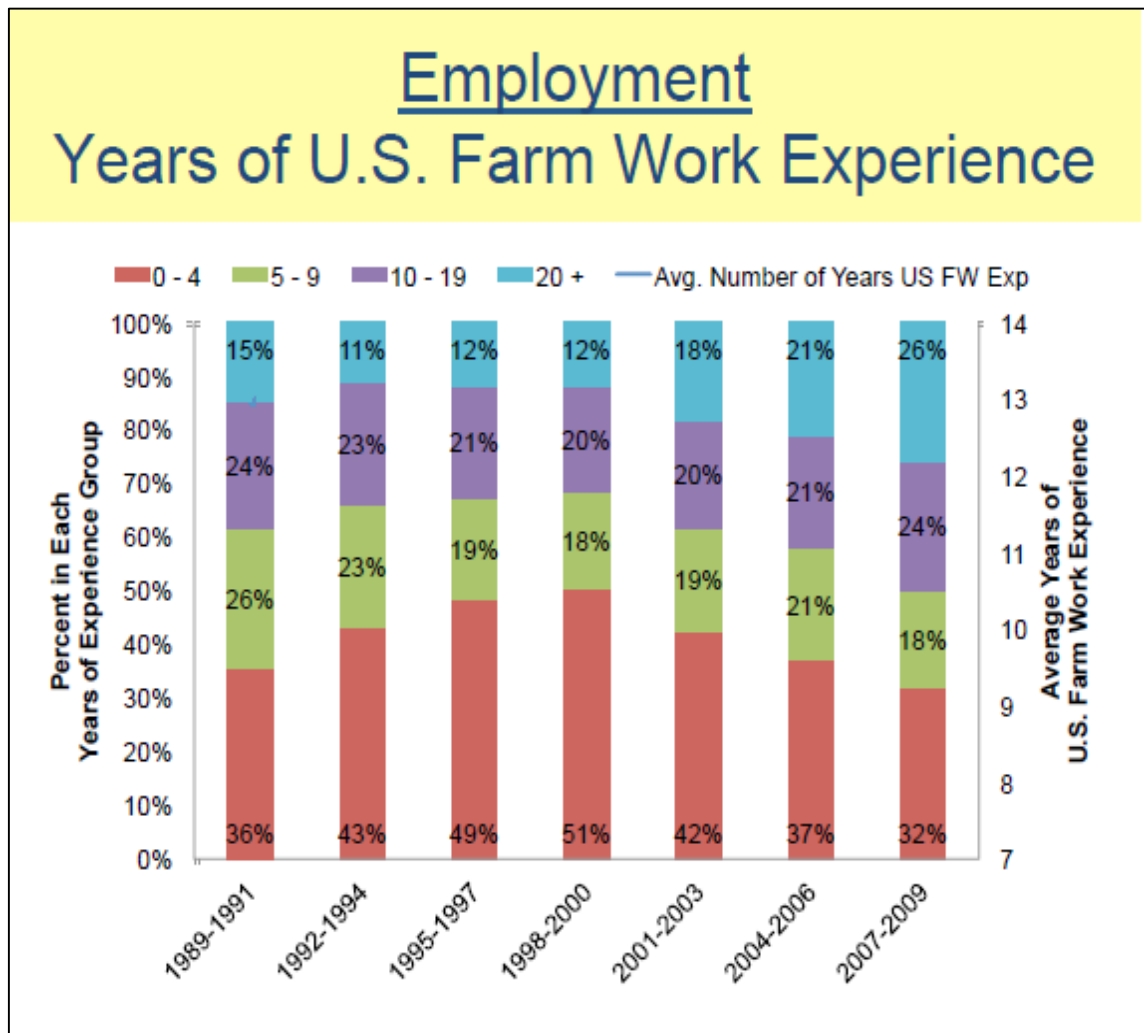
^b Estimated number of migrant workers on farms involved in crop production = (number of farms with migrants/hired labor farms)x(number hired labor workers).

The fraction of paid workers on farms that are migrants is 13.8% based on information summarized in Table 3 above. There appears to be a close correlation between fraction of the labor force that is contracted vs. migrant i.e., 17.1-19.3 vs. 13.8, respectively. The definition of migrant does not address the frequency that a laborer (classified by the farm manager that filled out the census) did not return to their residence the same day. In fact the number of workers of all kinds is “soft” because it is based on payroll count estimates rather than individual social security numbers or some other means of identifying individuals, i.e., the same individual could be reported as a worker on multiple farms. Further complicating any complete accounting are immigration laws variably enforced which may be at cross purposes to the primary reason for existence of a national agricultural census, i.e., taxation.

Overall, the data speak to a community of workers that are less migrant, more naturalized, and for whom the education levels are slowly climbing. Poverty levels are reducing, and the age of farm workers is also increasing. (Figs 20, 21, 22) In summarizing the 23 years of NAWS data, the Bureau of Labor concluded that:

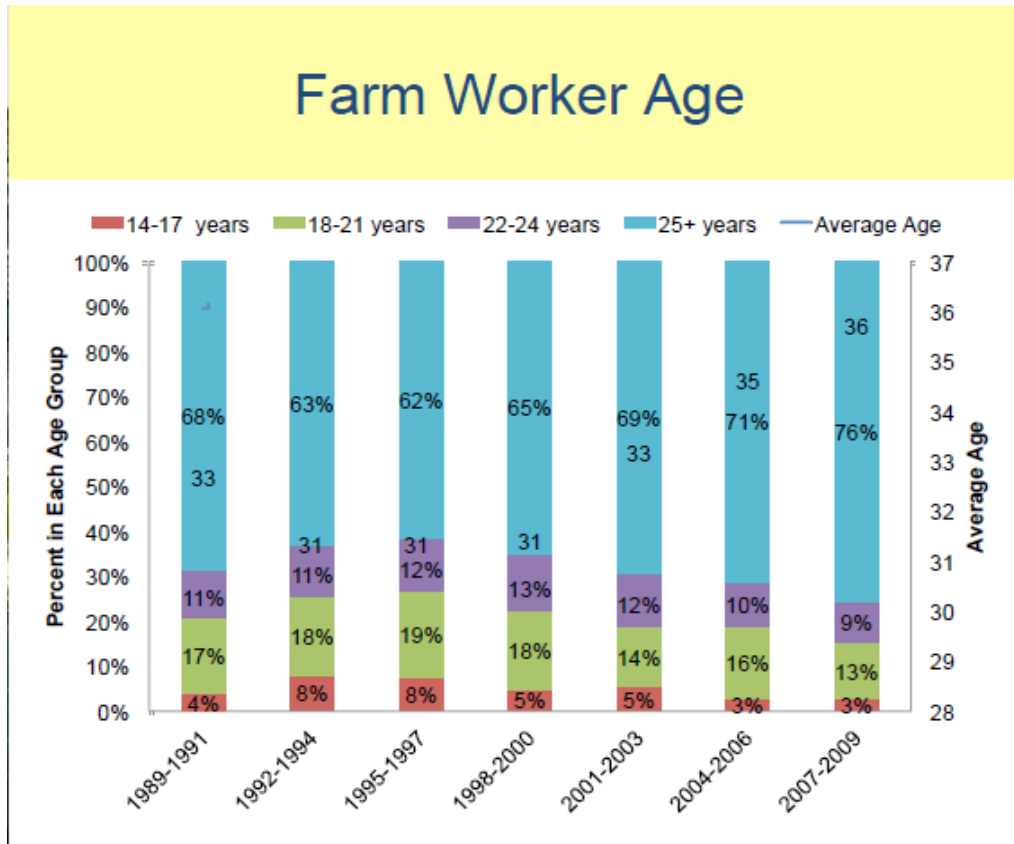
- The average age of crop workers has increased more in recent periods; it is now 36.
- The share of farm workers who migrate has been decreasing.
- An increasing share of immigrant crop workers is naturalizing.
- The share of mixed-status families is increasing.

Fig 20



Source: NAWS

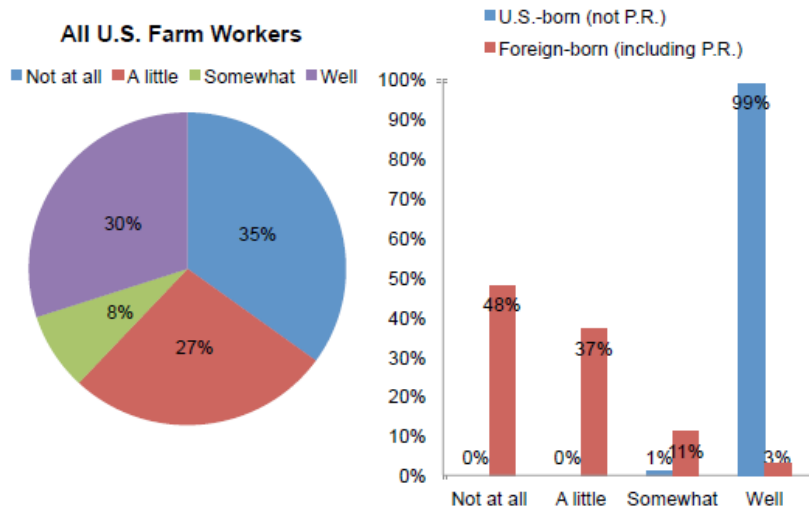
Fig 21.



Source: NAWS

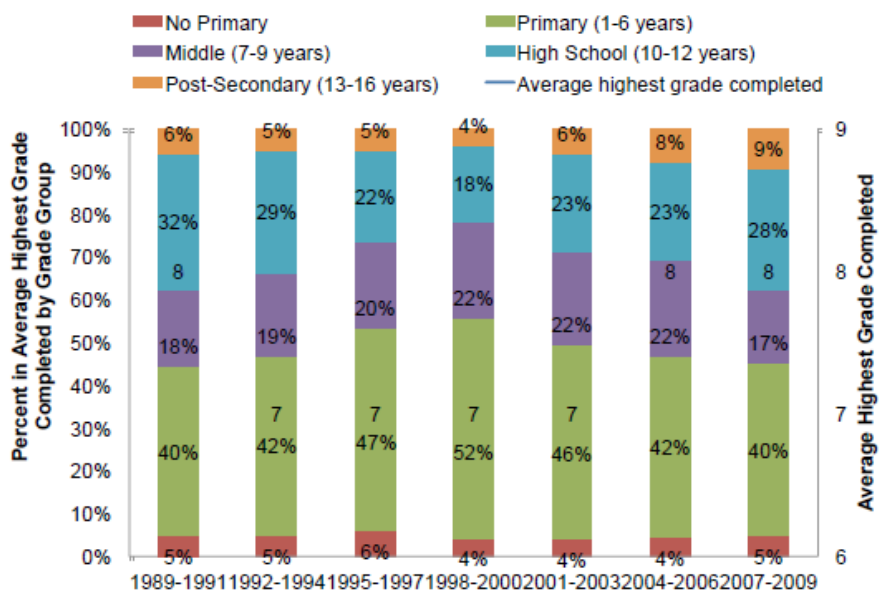
Fig 22

2007 – 2009: English Speaking Ability



Source: NAWS

Fig. 23 Farm Worker Education



Source: NAWS

The education level, native language, and type of tasks performed are also critical in developing the most effective type of training for farmworkers. It is clear from the survey that most farmworkers have not completed high school level education. The mean highest grade completed was seventh and the median grade completed was sixth grade. Only 18% completed high school or higher. Once in the United States 20% reported taking adult education classes such as English or GED classes. Not surprisingly language is an issue. Among all crop workers 44% responded that they could not speak English at all and only 24% felt that they were fluent in English. English ability was also broken down based on whether the farmworkers were immigrants or were born in the United States. Among US born Hispanics 66% stated that they could speak and read English well. The majority of farmworkers born outside the United States reported that they could not read or speak English at all.

Farm workers are not a “one size fits all” category either - The preamble does not adequately separate people who mix, load and apply pesticides from field workers. This is an important distinction in training development and emphasis as the mechanics of exposure and how a worker can reduce their exposure to pesticides is totally different for individuals who mix, load, and apply pesticides compared to those who enter treated fields and may be in contact pesticide residues. The fruit, nut, and vegetable crops account for 65% of the hired farmworkers. Field crops account for only 14% and horticultural accounts for 18%. Within these crop types 16% of the crop workers conduct tasks such as hoeing, thinning, and transplanting, while 30% conduct harvest related tasks. Post-harvest activities such as field packing, sorting and grading accounted for 9% of the tasks that were conducted by farmworkers. Technical production such as pruning, irrigation, and machinery operation accounted for an additional 17% while other tasks accounted for the remaining 27% of primary farmworker tasks. Understanding how farmworkers are employed is also important to the development of training and record retention. Growers and packing firms directly hired 79% of crop workers while farm labor contractors hired the remaining 29%. The NAWS survey indicates that training should be geared primarily at farmworker tasks rather than handler tasks and preferably developed into two cores, one handler focused and the second field worker focused. Language is an issue and the training must be aimed at an approximately sixth grade level.

We are deeply concerned over the lack of data used to support the statements made by EPA with respect to farmworkers and their employers. We note the Agency cites documents provided by farmworker advocacy organizations¹⁰ which refer to violations of “WPS rights”. The discussion in the letter and the related attachment¹¹ appear to deal principally, if not solely, with violations of workers’ rights, not general pesticide or FIFRA/label violations. Indeed, EPA should note that a number of the signatories to the letter have an acknowledged interest in reducing or eliminating the use of pesticides:

¹⁰ “Reference 36”, letter dated December 15th, 2006 on Farmworker Justice letterhead and signed by numerous other organizations.

¹¹ Cf. above-referenced letter, Attachment 1: Specific Recommendations for Improvements in the worker Protection Standard”

- “Beyond Pesticides,” which signed the letter, has in its mission statement “to lead the transition to a world free of toxic pesticides.”¹²
- The “Northwest Coalition for Alternatives to Pesticides” states that their program “aims to safeguard community health by eliminating pesticide uses, and consequently, pesticide exposures.”¹³
- The “Pesticide Action Network North America (PAN North America) works to replace the use of hazardous pesticides with ecologically sound and socially just alternatives.”¹⁴

It is troubling that EPA is willing to take the stance it has, using out of date information on farm worker demographics and letters asserting the existence of violations, without developing their own analysis to determine the extent to which this is true, or the extent to which changes to the WPS can address these meaningfully. It is of concern that an Agency which relies on science and data for decision making, has chosen to cite unsubstantiated claims in the absence of verifying whether such claims are true.

In conclusion:

- CropLife America takes exception to the unnecessary tone of this section within the preamble to the revised WPS, and the inaccurate portrayal of the farmworker population.
- EPA presents an inaccurate picture of the farm worker population: one which is both out of date and which does not reflect the improvement in socio economic and demographic characteristics since 1992.
- EPA describes the relationship between the grower and the worker as exploitative, and of lack of care. This description is not supported by the data or views of farmers and farm employers.
- CropLife recommends that EPA provide a more accurate portrayal of the farm worker population which references the most recent data available, both demographic and socio economic and focus on how those facts might yield improvements to training of workers
- CLA recommend that EPA parse out the areas where the WPS can have a positive impact and those where it cannot – for example the literacy rate, poverty and immigration status of this population are not within the purview of the EPA to address. If they are referenced at all, then it should be within the context of how they may influence the training requirements - for example, translation needs and oral versus written notification, use of signatures and so forth.
- CLA recommend that EPA provide data and distinguish between the different types of farm worker, and avoid over generalization when evaluating the WPS requirements.
- CLA recommend that EPA research the investments farmers and industry make in providing farm worker housing and child care facilities etc. to provide more balance to this section.
- CLA requests revisit the right to access on farm records by an “authorized representative” when it is unclear how the “authorized representatives” will contribute to improving farm worker safety, when in fact no such relationship to an employee or handler is even demonstrable, much less established. The agency’s own proposal¹⁵ defines an “authorized representative” as a “person

¹² <http://www.beyondpesticides.org/about/mission.php>

¹³ <http://www.pesticide.org/Our%20Work/healthy-people-and-communities>

¹⁴ <http://www.panna.org/about/mission>

¹⁵ See 170.5, definition of “authorized representative”, Federal Register page 15516

designated by the worker or handler, orally or in writing...” which effectively enables any individual to claim they have been “orally designated” to receive business sensitive records with absolutely no clarity as to how those records may be used to protect worker safety. It is entirely possible that this could be more detrimental than helpful to the employer and employee relationship. Employee rights have to be protected, but we believe proper enforcement of existing WPS requirements can be protective of workers and their rights. In fact the EPA proposal may infringe growers’ legal rights, subverts EPA’s own system of protective public health and safety through a rigorous registration process, and it undermines the legitimacy of FIFRA.

PART 3

COST ANALYSIS AND INFORMATION COLLECTION REQUEST (ICR)

SUMMARY CONCLUSIONS

- The cost burden comparison with the existing standard is misrepresented
- The added costs are significantly underestimated.
- No direct cost comparison can be made based on the existing documents, since very different, and much lower assumptions in wage rates and certain types of establishment numbers are presented in the proposed ICR compared to the ICR for the continuing WPS approved on September 12, 2013.
- Additional costs for recordkeeping activities specific to the proposed ICR are also underestimated, with a number of record management activities also not included in the assumptions;
- It is likely that smaller entities will be more highly impacted than medium or large facilities, and this impact has not being adequately evaluated or costed.
- Costs to the States, who will be responsible for recordkeeping compliance and enforcement activities, are also not included,
- Estimates for developing and implementing new training materials and procedures are not included.
- CLA estimates that the proposed changes will result in a total cost burden of over 340 million dollars not including the costs of retrofitting existing closed system equipment. Details supporting this estimate follow.
- The cost of retrofitting existing closed loading systems to meet the requirements of the Director's Memo is estimated to be 1.3 Billion dollars.

CLA commissioned an independent review of the ICR contained within the WPS proposal. It was conducted by consultancy firm "Summit" and the full report is available in ANNEX 7 to this document. The estimated annual burden to agricultural employers for the existing WPS which was approved in late 2013 is **1,827,493 hours** at a cost of **\$92,729,052**. The expanded WPS ICR proposal calls for **8,316,993 hours** and **\$196,130,463**. However, since the expanded WPS adds costs for Commercial Pesticide Handler Employers as well as adds handler specific costs for the agricultural employer, it is difficult to directly compare the currently approved burden numbers to the proposed ICR time and cost estimates. Therefore CLA decided to compare the information in the previous two ICRs that OMB approved (2008 and 2013) with the time and cost estimates for similar agricultural employer and worker activities provided in the current proposed ICR to better understand the added burden specific to the grower. Our review included examining the 3 ICR support documents and appendices to understand the number of establishment assumptions, wage assumptions for employers and workers, employer and worker activities and the time assumptions to achieve the activities.

Under Executive Order 12866 (58 FR 51735, October 1993), this action is a "significant regulatory action", and therefore EPA submitted the proposed rulemaking and an economic analysis to OMB for review and comment. In addition, as required under the Paperwork Reduction Act (PRA, 44 U.S.C. 3501), information collection requirements for the proposed rule were submitted to OMB for approval. The ICR entitled

“Agricultural Worker Protection Standard Training and Notification” identified by EPA ICR 2491.01 and OMB Control No. 2070-NEW is meant to replace the existing ICR entitled “Worker Protection Standard Training and Notification”, the most recent version having been approved on September 12, 2013 (EPA ICR No. 1759-06, OMB Control No. 2070-148) as reported in 40 CFR part 170 on October 23, 2013. EPA ICR No. 1759-06 is due to expire on September 30, 2016.

Specifics of the proposed revision to the WPS activities which impact the cost burden:

The proposed rule states that the replacement ICR addresses the information requirements of the current regulations as well as in the proposed regulations. The proposed revision to the WPS introduces a number of new requirements related to recordkeeping, as well as enhanced training requirements. The table below shows a tabulation of these proposed activities.

Proposed Revision to the WPS Activities

Category	Activity
New Entrant Rule Familiarization	Agricultural or CPHE Employer: Learn/refresh requirements annually
Information Exchange	Agricultural Establishment provides information on treated areas under an REI to CPHE CPHE provides application information to agricultural establishment CPHE provides information to CPHE handlers CPHE handler receives information from CPHE
Safe Operation, Cleaning, and Repair of Equipment	Agricultural or CPHE Employer Informs Handlers Agricultural or CPHE Handler Receives information
Information for Emergency	Agricultural or CPHE Employer provides information to medical personnel, worker, or handler
Pesticide Training Safety	Agricultural Employer or CPHE provides training to handlers Agricultural or CPHE Handler attends training Agricultural Employer or CPHE records and maintains handler training records Agricultural Establishment Handlers or CPHE sign acknowledgement of training
Personal Protective Equipment Information	Agricultural Establishment or CPHE handler receives respirator training Agricultural Establishment or CPHE handler undergoes initial respirator survey Agricultural Establishment or CPHE handler undergoes respirator fit-test Health care worker reviews medical evaluation Agricultural Establishment or CPHE handler undergoes follow up evaluation Agricultural or CPHE Employer records and maintains records Agricultural or CPHE Employer informs cleaner/lauderer Agricultural or CPHE Employer maintains closed system repair records

The proposed rule states that the replacement ICR addresses adjustments to the estimated number of respondents, time for activities and wage rates related to the current regulatory requirements as approved under OMB Control No. 2070-0148, but it does not provide a comparison of the previous and proposed ICR assumptions. What is compared is the estimated annual burden in hours, with the 2013 approved reported as 1,776,131 hours and the new proposal 8,316,993 hours, an increase of 6,540,862 hours.

In the economic analysis of the proposed rule change, EPA estimates the incremental cost of all proposed revisions to be between 62.1 and 72.9 million dollars annually, nearly all of which are borne by the farm, nursery or greenhouse owners who hire labor. To try to better understand the details of the incremental cost increase claim, CLA examined the estimated burden of the ongoing WPS by looking up the most recently approved ICR, EPA No. 1759-06. The estimated annual burden to agricultural employers for the existing WPS is actually 1,827,493 hours at a cost of \$92,729,052. The expanded WPS ICR proposal calls for 8,316,993 hours and \$196,130,463, which appears to be a much higher dollar value than the incremental increase put forward in the economic analysis document.

Therefore CLA hired the consulting firm Summit to compare the information in the previous two ICRs that OMB approved (1759.05 approved in 2008 and 1759.06 approved in 2013) and the proposed ICR with particular emphasis on number of establishment assumptions, wage assumptions for employers and workers, employer and worker activities and the time assumptions to achieve the activities. Impacts on small businesses as well as Federal and State Agencies were also considered.

There are gross level differences in key assumptions in the proposed ICR as compared to those in the 2013 ICR such that the cost burden values cannot be directly compared. Examples as follows:

Assumption #1: Wages

The most serious difference is the selection of wage inputs; both the 2013 and 2008 ICRs used fully loaded wages (wage plus benefits plus overhead) for their cost calculations, but the proposed ICR is only using loaded wage values (wage plus benefits); this has significantly reduced the cost burden calculated in the proposed ICR (the previous employer wage is 191% of that used in the proposed ICR, and the previous worker wage 148%).

Wage Assumptions

	Estimated Agricultural Employer Wages			Estimated Worker Wages		
	Unloaded Hourly	Loaded Hourly	Fully Loaded Hourly	Unloaded Hourly	Loaded Hourly	Fully Loaded Hourly
2008 ICR (BLS 2006)	23.47	33.56	50.34	8.10	11.58	17.37
2013 ICR (BLS 2009)	25.03	35.92	53.89	9.23	13.25	19.87
Proposed ICR	19.74 (BLS 2007)	28.21		9.40 NASS 2007 & BLS 2010	13.43	

BLS=Bureau of Labor Statistics

Based on the analysis of recent ICRs published by OCSPP, it appears that there is significant reason to use Fully Loaded Wage Rates in the calculation of burden estimates for the proposed revision to the WPS ICR. Doing so would make the proposed revision to the WPS ICR consistent with other ICRs from the OPP, the 2013 WPS ICR being a most recent example, as well as simplify cost estimations for material used in WPS activities, which are otherwise calculated separately.

Assumption #2: Number of Greenhouses

The proposed revision to the WPS estimates certain activities, specifically those for notifications and postings, which will require more effort by greenhouse owners than by other WPS-affected establishments. The proposed revision to the WPS ICR estimates the number of greenhouses which would be impacted by this proposed revision to the WPS as 519, whereas the current WPS ICR estimates the number of greenhouses as 11,350. Because the number of applicable establishments is an assumption used in determining the burden of a variety of activities, Summit identified the number of greenhouses as a key assumption.

A review of the EPA Economic Analysis did not reveal how EPA has estimated the number of greenhouses to be affected by the proposed revision to the WPS to be 519. CLA engaged an independent consultant "risksciences.net LLC" to review the most recent USDA NASS 2012 agricultural data to confirm the number of greenhouses within the U.S. The number identified through this study (28,147 farms with greenhouse facilities) may be used to substitute the 519 greenhouse assumption currently used in the proposed revision to the WPS ICR. However, it is recognized that this number may well be an underestimation, as farms may contain multiple greenhouses.

If the total number of farms with greenhouse is applied in the burden calculation, assuming that there is only one greenhouse per farm requiring posting, rather than 519, at the assumed 20 minutes per posting, the time to post would be at least (28,147x16x0.33) or 150,117 hours rather than 2768 hours (519x16x0.33). Assuming the wage rate applied in the proposed ICR (\$28.21), the cost for greenhouse posting would be at least \$4,234,810 rather than \$78,058. The cost burden approaches 8.5 million dollars if a fully loaded wage rate is assumed.

Please refer to the Appendix for further details regarding how these were calculated.

Assumption #3: Recordkeeping Activities

The proposed revisions to the WPS identifies six distinct recordkeeping activities required to maintain compliance. Since the recordkeeping requirement did not exist in previous versions of the WPS, this set of activities is one of the primary sources of increased cost and time burden in the ICR for the proposed revision to the WPS. These activities are summarized below.

Summary of Recordkeeping Activities Proposed in WPS ICR

#	Record Type	Description	Recordkeeping Time Burden (per unit)
1	Application-specific information	Pesticide application information, including timeframe of application, duration of REI, product label, and SDS information.	Gather record info = 12 minutes Maintain record = 1 minute Provide record info upon request = 6 minutes
2	Training Records	Record of worker/handler training, including training requirements met and agricultural employer data.	7 minutes per worker 4 minutes per handler
3	Recordkeeping associated with handler medical evaluation, fit testing, and respirator training	Records of completion of handlers' medical evaluation fit testing, and respirator training. Includes results of extensive qualitative and quantitative fit tests and equipment information for the respirator used.	4 minutes per medical evaluation record (per handler) 4 minutes per respirator fit test (per handler) 23% will require follow-up to the medical evaluation (another 4 minutes of recordkeeping for that subpopulation)
4	Records of system maintenance for handler employers of closed systems	Maintenance records of closed systems; maintenance to be completed as specified in written operating instructions and as needed.	3 minutes

#	Record Type	Description	Recordkeeping Time Burden (per unit)
5	Records that employees received oral notice of pesticides (for workers exempt from training in first 2 days)	[Exemption for workers that are performing tasks up to 2 days before the training requirement is enacted.] Worker must be provided a copy of an EPA-approved pesticide information sheet and its contents communicated to the work orally in a language the worker understands prior to conducting any tasks.	10 minutes
6	Early entry notifications records	Records of worker early entry activities - includes acknowledgement of notification by printed name, date of birth, and signature of each early-entry workers who received the information.	4 minutes

According to the proposed revision to the WPS, the EPA's rationale for adding the recordkeeping requirements is due to feedback received from the agency's state regulatory partners, who have indicated "difficulty enforcing some requirements, due primarily to a lack of records." The EPA notes that "proposed recordkeeping is designed to improve enforcement capability as a means of fostering compliance, thereby improving protections." EPA also expects that recordkeeping will enhance enforceability of training and notification requirements. Though EPA's justification for the increased burden is based on the ability of records to improve consistency across information tracking, the proposed revision to the WPS requires that all records are created and maintained within each agricultural establishment. With no central authority from EPA to create and manage the records in the desired format, the third-party recordkeeping requirement may unnecessarily increase the burden on agricultural employers without significant improvement in compliance, enforcement capability or most important worker safety.

According to the Paperwork Reduction Act (PRA), agencies are required to provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. This must include, if applicable, a total capital and start-up cost component, annualized over the expected useful life, as well as a total operation and maintenance. These estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. In cases in which sensitive information containing personally identifiable information (PII) is created, agencies also often include costs related to protecting this information, or disposal costs, including shredding or destruction

of records. Summit's examination of the proposed ICR compared to others involving recordkeeping also found that not all recordkeeping costs are currently accounted for in the proposed ICR; a number of activities should be considered for inclusion:

- Set-up costs to establish a recordkeeping system (if one has not already been established)
- Costs to develop internal record forms
- Printing costs (for paper records)
- Computer software/system costs (for electronic records)
- Storage costs
- Disposal costs of records with sensitive information
- Maintenance costs for records beyond the two-year minimum for longer-term employees

Additionally, the burden estimates for various recordkeeping activities have been adjusted upward to reflect a minimum of 5 minutes per activity. This revised estimate is based on research conducted of similar ICRs, which suggested that a minimum standard of 5 minutes is used to approximate the burden for such recordkeeping activities.

Based on Summit's review of other ICRs, including a 2014 DOL ICR related to mine safety standards and a 2013 EPA ICR for recordkeeping associated with the Clean Water Act, there are inconsistencies regarding the wage rate to be assigned to recordkeeping in a nontraditional business environment, such as farming, mining, or pollution mitigation. The proposed revision to the WPS assigns a wage rate of \$28.21 for recordkeeping, which represents the BLS wage rate for an agricultural employer. Each recordkeeping task calculates the total cost of the activity as the time estimate (i.e. 0.05 hours) multiplied by the \$28.21 wage rate. The EPA Clean Water Act ICR calculates the cost for recordkeeping based on wage rates for data clerks hired for such tasks. Since clerical responsibilities are not a typical job function of an agricultural employer, the wage rate of \$28.21 may not adequately incorporate the added burden of recordkeeping efforts, especially within smaller establishments that likely have less experience in this area.

Assuming the same wage rates applied in the proposed ICR, the Summit estimated cost of recordkeeping is slightly over 15 million dollars compared to 3.5 million dollars presented in the proposed ICR. Applying fully loaded wage rates as used in the most recently approved ICRs will nearly double the estimated cost of recordkeeping.

Assumption #4: Small Business Impacts

The introduction or revision of federal standards often uniquely impacts small businesses, which typically operate with less administrative overhead and may not have sophisticated business systems or infrastructure in place to easily adapt to new regulations. Specifically, the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires special consideration for small entities because such firms often cannot devote staff resources to follow regulatory developments and often are less able to bear the burden of an information collection because of their smaller staff and resources. The proposed revision to the WPS does not account for a potential differential impact on small businesses that may need to spend additional resources to set up a recordkeeping system or employ staff in the required tasks for WPS compliance.

Within the proposed revision to the WPS, EPA notes that "requirements cannot be reduced for small establishments without significantly compromising the protections offered to their workers and handlers"

and that “small entities are required to follow the same requirements as larger establishments” (except in the case of solely family-operated establishments). Costs are estimated on an individual basis (per worker, handler, or employer, for example), which estimates a lower total cost burden for the over 300,000 small farms, nurseries, greenhouses, and other entities affected by the rule. However, the per-unit cost for these activities may actually be greater within smaller establishments due to the lack of business infrastructure found in many larger establishments, noted above.

In the proposed revision to the WPS, EPA does not provide any cost adjustments for small agricultural entities, as the agency estimates that per-person recordkeeping and training costs will be identical, regardless of the size of the establishment. Though these per-unit costs may be similar, it is likely that smaller entities may incur additional costs to establish a recordkeeping system, for example, if one had not been set up previously that would be adequate to handle the new WPS requirements. Furthermore, small businesses may require additional clerical support to comply with the recordkeeping activities that the agricultural employer may be unable to perform, given other demands from day-to-day operational responsibilities.

The Paperwork Reduction Act, in accordance with the RFA, requires that an agency justify any specific impact to small businesses in an ICR and also explain how the agency attempts to minimize that impact. To meet this requirement, other ICRs have included provisions and established programs to assist small businesses in determining what aspects of the federal rule applies to them, and to provide alternative methods of compliance, if applicable. A similar approach could be incorporated in the proposed revision to the WPS, given the necessity for consistency in worker training around pesticide application and protections, but accounting for the differences in accounting and recordkeeping burden, depending on the farm size.

Assumption #5: Agency Burden

The proposed revision to the WPS specifies that there are no costs to the EPA or other governmental agency for standardization of documents or enforcing compliance with the proposed revision to the WPS. However, with the introduction of the new requirements of the proposed revision to the WPS, some level of state agency action will be required to facilitate the implementation and enforcement of the new proposed revision to the WPS requirements.

With the introduction of recordkeeping requirements, some standardization of records is likely to be necessary, especially as it is difficult to estimate recordkeeping burdens without specifications of what information needs to be recorded. Moreover, without guidance from either the EPA or state agencies, agricultural establishments are likely to incur costs of developing the appropriate records on their own. Standardized documentation for recordkeeping will also reduce any enforcement burdens necessary in ensuring that agricultural establishments comply with the proposed revision to the WPS. Therefore, it is likely that individual states or other local authorities will be tasked with developing standardized forms for the recordkeeping activities. In such cases, state and local authorities will incur costs associated with becoming familiar with WPS requirements, developing standardized documents, and providing standardized documents and guidance to agricultural establishments.

In addition, a certain level of enforcement action by local or state authorities is likely to be necessary to ensure that agricultural establishments comply with the requirements of the proposed revision to the WPS. Though agricultural establishments are not required to submit reports to the EPA for review, local

authorities are likely to choose to inspect agricultural establishments periodically to ensure compliance with regard to recordkeeping. This type of review may be undertaken independently, or as part of the review procedures for other state or local actions, such as fulfilling compliance requirements for program participation.

Summit reviewed the sample of ICRs published by EPA previously used in the wage rate assumption analysis and identified those ICRs which had actions associated with State agencies or the EPA. The annual burdens per respondent and type of labor used were determined for the following types of actions:

- Standardized Documentation Costs:
 - Rule familiarization
 - Answer Questions
 - Create Guidance/Information
- Enforcements Costs:
 - Review report

A review of the sample ICRs indicated that typically EPA, state agency, or both institutions were tasked with some level of information collection preparatory activity or result review. The annual average amount of time for each labor category and action is shown below.

Sample ICR Standardization and Enforcement Average Agency Burden

Activity Type	Average Annual per Agency Burden Amount (Hours)		
	Managerial	Technical	Clerical
Rule Familiarization	1	2	0
Answer Questions	7	8.4	0
Create Guidance	3.7	11.9	39
Standardized Documentation Costs	11.7	22.3	39
Enforcement Costs: Review Report	2.7	7.7	0.7

Though the current and proposed revision to the WPS have not included standardization and enforcement costs in the associated ICRs, the need for recordkeeping may substantiate increased efforts on the part of local agencies, in order to ensure compliance with the WPS. It is assumed that each state will have one set of respondents, and so documentation standardization and enforcement tasks will be completed by 50 respondents (one for each state, District of Columbia and territories excluded). Estimated annual enforcement costs under an assumption that states will review all WPS farms once over a three year period are estimated to be nearly 23 million dollars assuming fully loaded wage rates.

Assumption #6: Additional Train the Trainer Costs

The training requirements for the proposed rule specify that all existing and new workers and handlers are generally trained by the start of their third day on an agricultural establishment where a pesticide product bearing a WPS label has been applied, or an REI has been in effect within the last 30 days. Qualified trainers include certified applicators by EPA or a state or tribal agency responsible for pesticide enforcement, or those who have completed a pesticide safety train-the-trainer program approved by

EPA. Per the proposed rule, it is assumed that time and cost estimates to equip these individuals as qualified trainers occur outside of the scope of the WPS. At a minimum, therefore, it could be assumed that trainers-in-training would require materials to a) be trained or b) train others.

EPA notes in their 2011 version of the WPS that EPA and industry leaders have created and distributed approved training materials at no cost to many agricultural establishments. In training new trainers, however, a number of establishments may require additional training materials. To account for this additional cost, Summit conservatively estimates that half of the expected trainings coordinated by these newly qualified trainers (from train-the-trainer programs) would require new training materials from the EPA. As observed in other ICRs, we estimate mailing costs to amount to \$2 per package. The adjusted costs for this activity, therefore, are estimated to increase the overall cost by \$3,768 (50% of 11,305 train-the-trainers, times \$2 per mailing, divided by 3 for annual cost over the 3-year rule). This cost would directly impact costs incurred at the state or federal level, and does not include labor costs associated with preparing packages of training materials.

Finally, training costs in the proposed ICR may be grossly underestimated given the wage rates used for the cost calculations. Training wage rates range from \$28.21 per hour (for certified applicators of RUPs) to \$37.87 per hour (for certified applicators and those who completed train-the-trainer programs). According to the Bureau of Labor Statistics, Training and Development Managers earn an average of \$45.86 per hour. While these employees may largely be staffed outside of the agricultural sector, it is important to consider that a higher wage rate (than that included in the proposed rule) may be necessary to attract and retain effective and skilled training staff.

Assumption #7: Additional Costs to Convert Existing Closed Loading Systems

In a Director's Memo issued by the California Department of Pesticide Regulation and separate from the proposed WPS, the definition of a compliant closed system has been revised in such a way that it will require significant retrofitting of a large percentage of existing closed systems. For example, the new definition would require that the maximum container pressure not exceed 5 PSI, which is difficult to measure on a consistent basis and even more difficult to regulate. CropLife estimates that the cost to convert an existing mid-large system to meet the proposed standard would cost an initial \$25,000 to \$100,000 plus annual maintenance costs of \$5,000 to \$10,000.

Given that the proposed WPS estimates that 96,763 large and large-small agricultural establishments have closed systems, a conservative calculation increases overall cost of the proposed WPS by \$1.3 billion¹⁶ in the first year of implementation of the rule. While Summit has not incorporated this extreme cost in its assumption change calculations, this figure serves to illustrate an additional potential burden that would be placed on agricultural producers through the proposed rule.

¹⁵ \$25,000 initial cost for retrofit divided by 3 years (term of rule) + \$5,000 annual maintenance cost = \$13,333 per retrofit * 96,763 large and large-small establishments = **\$1,290,173,333**.

PART 4

PROPOSED REVISIONS AND ASSOCIATED CHARGE QUESTIONS

4.1 FRN UNIT VII: TRAINING FOR WORKERS AND HANDLERS

CLA Overarching Comments

- **CLA supports the emphasis presented in the proposed WPS revision on the importance of training being provided by capable individuals**
- **We believe the rule should be withdrawn and the requirements for training re-evaluated.**
- The proposed requirements for trainer qualifications and its potential cost and time burden on growers and State Lead Agencies has not been fully discussed in the proposed rule revision, and is not included within the ICR. It is likely to be significant, and EPA should provide estimates on these costs.
- Current training (every five years) has been successful - as demonstrated by the steep decline in acute exposure incidents since 1992.
- The proposed trainer qualifications seem more lenient for handler training vs. worker training (i.e. proposed revision would allow a certified applicator to train handlers but not workers). The rationale for this is not clear, and EPA needs to clarify.
- Although a yearly training interval may present the simplest approach, it is not necessarily the most efficient or beneficial approach across all workers. We prefer and support a training system which recognizes (i) the existing worker experience; (ii) the nature of the work required; and (iii) the nature of the establishment, rather than a “one size fits all” approach. EPA could consider programs that include different types of training, e.g., refresher training for specific activities, which could be more frequent, while more in-depth training could be required less frequently.
- With shorter training intervals, it would be necessary that the worker who obtained the training to carry some transferable demonstration of his/her competencies to other employers should he/she change employers within the period between trainings. This would reduce duplicative training within the training interval period. It would need to address the potential for fraudulent documentation of training.
- With the plethora of electronic communications devices that have mushroomed since 1992, it should be possible to provide information and materials electronically, by video, smart phone and other digital devices.
- EPA should revisit the training requirements in consultation with those who are responsible for the design and implementation of training. Experience, best practice and pragmatism should be fundamental to any changes made.
- We urge EPA to delete in all references to “authorized representatives” in the proposed rule.
- EPA seems to have conflated literacy levels and non-native speakers with frequency of training. The former needs are addressed through the format of the training materials, not through increased frequency.

CLA General Comments:***Distinctions between the different categories of “worker”***

EPA needs to clarify the difference between a worker and a handler, and the types of work they are involved in from the perspective of exposure to pesticides. Too often, EPA refer to both in the same sentence and with the same requirements despite significant differences in their on-farm roles and the nature of the work they do involving pesticides.

Consistency of Criteria:

In order to assure the same level of preparation and effectiveness of trainers, we propose that there be consistency between the criteria for training handlers and the criteria for training workers. The proposed revision states that although certified applicators are not qualified to train workers, they would none the less be allowed to train handlers. Since some certified applicators may hold their license in a category that does not fall under the scope of the WPS, such as structural pest control, or lawn and ornamental, they may not be knowledgeable in WPS. While the certified applicator will have expertise in the safe handling of pesticides, he/she may not be able to effectively explain the regulations stipulated under the WPS. We propose that this should be a requirement to assure that the persons conducting handler training also have good understanding of WPS.

Grace period: See also Unit XVIII C.

CLA supports the retention of the 5 day grace period for the following reasons:

There is a difference between the training workers receive immediately they arrive on the farm, and the more detailed training they receive prior to entering the field (which can take half a day). This is why there is a necessity for a “grace period” – and why a two day grace period, as proposed in the revised standards is impractical: because training everyone to the full extent within two days of their arrival on farm when workers come and go on a daily basis and when that training can take half a day of paid time is impractical, unnecessary and not economically justifiable. The grower needs to be able to gather enough workers together at one time to justify half a day of training costs for those workers. Furthermore the training required should be justified based on jobs those workers will be engaged on - those who are there for a half day or day to harvest a crop may not need comprehensive training to be protected, and the training they receive prior to entering the field could be sufficient.

FRN Section A. Shorten the Retraining Interval:

- The EPA statement that “*the risks from pesticide exposure through agricultural work are similar to the threats posed by hazardous chemicals in other industries*” is used to justify the need for shortening the training interval to the annual training required by the Resource Conservation and Recovery Act (RCRA). The RCRA applies to personnel at hazardous waste treatment, storage and disposal facilities. EPA provides no evidence to support a comparison of farm workers with workers at hazardous waste treatment, storage and disposal facilities, and CLA contends this analogy is not appropriate considering the nature of the products to which farm workers may be exposed to, and the levels of such exposures should they occur.
- Current training (every five years) has been successful - as demonstrated by the steep decline in acute exposure incidents since 1992.
- **Although a yearly training interval may present the simplest approach, it is not necessarily the most efficient or beneficial approach across all workers. We prefer and support a training system which recognizes (i) the existing worker experience; (ii) the nature of the work required; and (iii) the nature of the establishment, rather than a “one size fits all” approach. EPA could consider programs that include different types of training, e.g., refresher training for specific activities, which could be more frequent, while more in-depth training could be required less frequently.**
- With shorter training intervals, it would be necessary that the worker who obtained the training to carry some demonstration of his competencies to other employers should he change employers within the period between trainings. This would reduce duplicative training within the training interval period. It would need to address the potential for fraudulent documentation of training.

This section fails to describe the existing WPS requirements provided to workers, handlers and applicators and how it differs between those three categories. Under the current WPS, all workers receive training prior to entering a field to work. This is in addition to the more in-depth training that is provided every five years. Worker training differs from handler training which differs from the training required to become a certified applicator. Instead EPA justifies shortening the retraining interval by reflecting on the requirements in other industries, industries which are not appropriate models for the environment or exposures which farm workers are subject to.

The training interval should reflect the experience of the applicator / handler / worker. In other words, a worker who has been on the farm or harvesting the same crops for several years may require less repeat training than a worker who moves from farm to farm.

The training interval should also reflect the complexity of the information provided. Thus applicators and handlers have different information needs than workers – who routinely do not handle, mix, load or apply pesticides.

A Federal Training Program would mitigate against being required to meet the different training requirements in different states. However it would be helpful to better define what elements of the

worker training are common across all types of operations and products (generic knowledge) and which training is specific to the operation on which the farm worker is employed (such as specific products used and requirements). In addition, certain aspects of training could be scheduled to take place less frequently, while other aspects which are more site specific could be required on an annual basis, or for newcomers to the operation.

Section A. Charge Questions:

Should EPA consider different pesticide safety training timing? If so, what timeframe and why?

CLA supports training which ensures their products are used according to the label. CLA supports a training scheme which is straight forward and easy to track. For certified applicators and crop advisors the certification cycle of their qualifications should be recognized. Trained workers should be able to bring documented evidence of their training with them should they change employer within the training interval to avoid unnecessary duplication of training and associated costs. Refresher courses should be offered as an alternative to more experienced workers.

Do you have information concerning the relationship between the frequency of training of workers and handlers and the frequency of incidents of pesticide exposure or illness? If so, please provide.

No, and furthermore it would be difficult to relate these two in a meaningful way because of confounding factors such as difference in agricultural operations, and the nature of the pesticide products used etc. Overall the data support the adequacy of the current training except in very few cases.

Are there other ways EPA could ensure that workers and handlers retain the information presented in pesticide safety training so the retraining interval can be longer than one year?

CLA acknowledges that most training is of little value unless it is acted upon repeatedly and frequently – in other words through practice. Training sessions every year may simplify the process and ensure that everyone has the necessary training but this could be overly burdensome relative to the benefits it provides. Thus training should reflect the experience of the worker, the nature of the work and the establishment – in terms of the familiarity of the worker with the establishment as well as the nature of the operation. However in their preamble EPA seems to have conflated literacy levels and non-native speakers with frequency of training. The former needs are addressed through the format of the training materials, not through increased frequency.

Are there other burdens or benefits associated with a 2-year retraining interval that EPA has not considered?

The main cost is associated with the record keeping burden and the level of detail required by EPA. Furthermore, there are no proposals to standardize the forms required for such records. EPA should consider providing software or downloadable materials to ensure training is reported in a consistent and comparable way. These materials should be drawn up in consultation with the growers (who will have to

implement them), trainers and certified applicators, to ensure the records are practical to implement and useful in the information they collect.

What would be the impact of a 1- or 2-year retraining interval on states and tribes?

CLA has no comments.

Should EPA consider retaining the current 5 year retraining interval for workers and handlers and adding a requirement for annual refresher training? Please provide information on the relative benefits to and burdens on employers, workers, and handlers.

EPA currently envisions that, if adopted, the annual refresher training for workers would include the topics proposed at 170.309(e), the grace period training (see Unit XVIII for a full discussion of the proposed points for training workers under the grace period). The annual refresher training for handlers would include a review of information necessary for handlers to protect themselves, their families, workers, and the environment from pesticide exposure. EPA anticipates that the refresher training would be slightly shorter in duration than the proposed full pesticide safety training, but seeks comment on the duration of such refresher training. Retaining the current 5 year retraining interval and adding a requirement for annual refresher training should be contingent on the ability of the worker to demonstrate they received the full training within the previous five year period. The employer would maintain training records for workers and handlers as discussed in Unit VII.B. below, as well as records containing the same information for the refresher training.

We believe that training requirements should reflect the experience of the worker, the nature of the work he will be engaged in, and the farm on which she/he is employed – including whether or not the farm worker has worked on that farm in the past and thus has familiarity with its practices. Thus refresher training on an annual basis coupled with more in depth training every five years could be adequate, particularly as EPA has not demonstrated the benefit of reducing the training interval, and the acute exposure data speak to an existing training system that is protective of farm worker health.

FRN Section B. Establish Record Keeping Requirements To Verify Training For Workers and Handlers:

CLA Comments:

CLA does not support expansive record keeping for training. We support simple and standardized record keeping that enables the grower / contractor to identify what, if any additional training may be required, and allows the worker to demonstrate competency if changing employers. We do not support records being provided to a “third party authorized representative” for a variety of reasons including (i) lack of benefit in terms of additional worker safety and (ii) openness to abuse. Access to any records which goes beyond the employer / grower / worker should be specific, define the circumstances around which it can occur and define the material which can be provided. Thus for incident requiring medical assistance, the treating medic should be provided with information on the pesticide, but not the training records, as they

are not relevant to treatment. Furthermore, any other person authorized to access these records should be able to identify themselves using more than just “oral designation”.

CLA is concerned by the prescriptive nature of the record keeping and the amount of detailed information being requested. We are also concerned over the reference to “authorized representatives” and their access to such information. It is entirely unclear how this serves to improve worker safety. It places an unnecessary burden of cost and time on the employer which would be better utilized for doing the actual training itself. Please see our comments regarding our opposition to the use of this term and the necessity for access to any records which go beyond the employer / grower / worker should be specific, define the circumstances around which it can occur and define the material which can be provided. And furthermore that any other person authorized to access these records should be able to identify themselves using more than just “oral designation”.

Section B. Charge Questions

B. Establish Recordkeeping Requirements to Verify Training for Workers and Handlers

Would a requirement for employers to report worker and handler training information to the state or federal government for compilation in a central repository have benefits? If so, please detail the potential benefits and cost.

We do not support the development of a central repository, and believe the cost of this is not justified. We would have concerns regarding the confidentiality of personal information. If the decision is for an annual training requirement (refresher or otherwise) it would not be worthwhile. The employer – be that the grower or the contractor – should be responsible for maintaining and storing records.

Should the Agency reconsider any of the alternate options presented in developing a final rule? If so, why? Please provide data to support your position.

We support the Agency’s decision in not pursuing any of the alternative proposals – viz. providing a wallet sized card with pertinent information, requiring employers to submit training records to EPA, state, territory or tribal regulatory authorities, having trainers retain the records, or establishing a five year interval for record keeping. We do not believe these options are justified in terms of cost or in terms of the value they bring to protecting workers.

Are there changes that would make the training verification card program more effective and less prone to falsified cards? If so, please provide detailed suggestions for improving the system.

The cost of this approach would more than likely exceed the benefits associated with it. Some people will cheat the system – unless you put an expensive tracking process in place to help with training. This probably will not serve as something to force them into the training. The false cards being produced should be a very small percentage of overall qualified applicators.

Should EPA consider a performance standard to evaluate worker and handler training (asking questions based on the training content) rather than recordkeeping? Are there benefits or drawbacks to this approach that the Agency has not considered?

EPA should consider something like a video training program with a group of valid questions that are randomly drawn and computer scored is acceptable. Examples include current Commercial Driver tests, Flight Instructor Renewals, etc. These obviously must be produced in both English and Spanish – with an emphasis on demonstrations. Trainers could provide an option to correct the answers to “qualify” – but we do not support this. Any program should be used as a tool to identify gaps in knowledge and address them.

Would employers rely on training records provided by the worker or handler as verification that the worker or handler had received pesticide safety training?

EPA should define “employer” to include both the grower and / or the contractor. We believe they would accept worker or handler provided documents on training as authentic. We do not agree with the suggestion that “*The WPS must prohibit an employer from refusing to hire a worker who does not have proof of having been trained*”¹⁷. No employer should be put in the position of having to hire any worker, trained or untrained. If the worker has no proof of training, then she/he can be trained by the employer as required in order to fulfill the work s/he is given in a safe manner. However, there are many reasons why an employer might choose not to hire an untrained worker, e.g., the employer needs immediate help or the task is of limited duration so that the time and cost of training is onerous or the employer does not believe the untrained worker is suited to the task. Choosing not to hire an untrained worker should not be treated as discrimination.

FRN Section C. Require Employers to Provide Establishment-Specific Information for Workers and Handlers

Section C. Charge Questions

To what extent do employers already provide this information to all workers and handlers when they first arrive at the establishment, for example, during the hiring process?

CLA supports the provision of relevant information. Progressive companies already do this. EPA should examine such operations to identify best practices.

¹⁷ Cited as reference #35, ‘David, S et al. letter to the U.S Environmental protection Agency Administrator Stephen Johnson. On behalf of farmworker Justice et al, December 15 2006.

The current rule requires employers to ensure that the workers and handlers receive information in a manner they understand. Are there any issues with the current requirement for employers? If so, please describe and provide data to support this position.

Under the EPA's current requirements, training must be "EPA approved" and must be represented in a manner that the worker can understand, such as through a translator. It is therefore unclear how additions to this provision could provide additional benefit without also incurring additional cost and bureaucracy.

FRN Section D. Establish Trainer Qualifications

CLA Comment:

Within this part of the proposal, EPA eliminates the automatic authorization of certified applicators and handlers to train workers. EPA cannot ascribe any specific benefits to this proposal. We agree, in principle that training for workers should be done by qualified individuals, and we would urge the Agency to ensure that trainers are appropriately trained, while being cogniscent of existing resource constraints. With respect to the role of cooperative state extension agents, who often play a vital role in providing this training, EPA should not make the system so burdensome that it predisposes extension agents not to engage. Again, this could be achieved by a system of less frequent core training, supplemented by refresher training to provide updates on new training materials or products.

Section D. Charge Questions:

Are there other programs that would prepare trainers to convey pesticide safety information to workers and handlers? Please describe the program and the feasibility of its implementation for affected establishments.

Yes - A video training program with a group of valid questions that are randomly drawn and computer scored. Examples include current Commercial Driver tests, Flight Instructor Renewals. Again, this would have to be developed with cost estimates. Short run costs would be high but over the longer term it might be less expensive.

Should EPA consider requiring trainers of workers and handlers to refresh their qualifications periodically, such as requiring attending a train-the-trainer program every 5 years? Please provide data in support or opposition.

Although this proposal appears reasonable at first glance, CLA is concerned by any effort that would place a greater strain on the system that is necessary. Absent data showing that such periodic requirements would enhance worker safety or contribute to a lessening of pesticide exposure, CLA does not believe such a requirement is warranted.

FRN Section E. Expand the Content of Worker and Handler Pesticide Safety Training**CLA Comments:**

EPA proposes to expand the content of information provided to workers and handlers. As previously stated, we support training which provides all appropriate information necessary to ensure the label is correctly followed and to support a safe work environment and limit exposure to pesticides according to label requirements. We have previously stated that we believe training should be reviewed and updated in light of the many advances that have been made in the agricultural industry over the last 20 years. The information must be presented in a manner that is useful to the person who is implementing it and should not go what is beyond necessary to ensure label measures are adhered to.

Thus we have some specific concerns with certain bullet points:

EPA state that handler training should include “environmental concerns such as drift, runoff and wildlife hazards” CLA believe that information on this matter should be specific to FIFRA. CLA also argue it is not necessary from a worker protection perspective. Furthermore, if the label is adhered to, these issues are already addressed by virtue of the EPA extensive environmental fate studies and risk assessments that have been conducted to develop the label in the first place. Understanding *why* the label provisions are necessary is helpful, but this is subtly different to what is being suggested here which could be seen to imply that the environmental concerns are not satisfactorily addressed in the label and the handler somehow needs to know this.

Section E, Sub Section (i) speaks at length about “*protection from pesticide take home exposure*”. However current training already addresses the risks of pesticide residues on clothes, and this awareness could be augmented quite simply by updating current training materials. It does not warrant the attention paid to it within the preamble, and we are concerned that the tone and information provided by EPA to justify this action undermines the great strides that have been made in product safety, labelling and application.

To justify these additional requirements the agency cites a 1995 CDC study¹⁸ on the issue and specifically refers to “pp. vii, 17-19.”¹⁹ The pages cited in the report relate to pesticides and the report itself notes that “*most of the reports are dated 1980 or before*”²⁰ and goes on to say that “*the three reports since 1990 indicate that pesticide exposure may continue to be a risk for families of applicators and farmworkers.*”²¹ Case studies noted in the CDC report date from 1959, 1977, 1978, 1992, 1953, 1964, 1967, 1952, 1965 – all before the WPS was promulgated, and certainly not reflective of current risks. However, and again referring to the data from the various poisoning databases, it is clear that significant reductions in acute

¹⁸ “Report to Congress on Workers’ Home Contamination Study Conducted Under the Workers’ Family Protection Act”, cited as Reference 49, Federal Register, page 15510.

¹⁹ Federal Register, page 15469

²⁰ *Op. cit.*, page 17

²¹ *Ibid.*, pg. 17-18.

illness and injury rates have been achieved since 1992. These reports speak to another era and one which the current WPS has been successful in ensuring it no longer exists. In this, we are in agreement with the comments and detailed analysis of the CDC report provided by the American Farm Bureau Federation.

Furthermore, the Agency specifically states that it *“does not have conclusive data about the impact of a pesticide residue transfer from a worker or handler to his or her home, car and family members”*²², yet the letter EPA cites²³ – without any supporting data - states that *“farmworkers often return home from work with pesticide residues on their skin, clothes and shoes”*. Neither is there any information as to how or whether those residues get transferred, and importantly, whether those residues are sufficient to cause harm. For example, although Curl et al. (2002) demonstrated a statistically significant association between dust levels of pesticides in vehicles and homes of farmworkers, they did not find a significant association between dust levels in those homes and children’s exposure to those pesticides as determined by urine analysis. Further, despite a statistically significant decline in the most dominant pesticide in house dust in both vehicles and homes of farm workers, there was a statistically significant increase in urine metabolite levels of both farm worker adults and children, likely due to diet and not take home residues Thompson et al. (2008). The studies by Curl et. al. and Thompson et. al were supported by EPA grants and thus we are rather surprised they are not referenced in this section.

Section E, SubSection (ii) CLA does not support the proposal by the Agency to require worker and pesticide safety training to include information on how to report suspected pesticide use violations, or include contacts for legal representation. We object to this requirement in part because of the context used to justify this action, and not because of any desire on our part to see pesticide violation or illegal uses go unreported. Again, CLA members have invested considerable resources in developing a label which is protective of human health and specifically farm workers, and therefore we do not support violations of its requirements. However the context supplied by EPA for this requirement speaks to the infringement of “WPS rights”, not general pesticide or FIFRA label violations.

CLA is concerned over the recommendation to include training on *“potential hazards to children and pregnant women from pesticide exposure”*. What are these hazards? EPA regulates all pesticide products to be protective of these vulnerable populations, and has specific measures in place to ensure this is the case. Furthermore, the term “hazard” does not equate to risk, and pesticides are regulated based on a comprehensive and scientific risk assessment. Risk encompasses exposure, but hazard does not and pesticide regulation accounts for both. We would welcome an approach which enables a better understanding of the importance of not taking pesticide containers home and not using food containers to mix pesticides (both of which are illegal according to the label). However the acute poisoning databases on the incidents in children, the published literature on children’s health, and the toxicological data, children are not suffering illness, or fatalities as a result of pesticide use as defined under the WPS. CLA

²² Federal Register, page 15469

²³ “Reference 26” on the docket, Attachment 1 Specific recommendations for improvements in the farm Worker Protection Standard” – letter dated Dec 15 2006 on Farmworker Justice letterhead and signed by other organizations such as PANNA, “Beyond Pesticides” etc

does supports empowering people to avoid accidental exposures at levels that would cause acute illness through common sense behaviors, to prevent exposures such as those described in Annex 3:

“A 3-year-old became ill and was hospitalized after ingesting an unknown herbicide containing diquat stored in a gatorade bottle. His dad got the herbicide from a friend, which the child later found and asked the babysitter to give him a drink”

We agree training should include instructions that children and nonworking family members should be kept away from pesticide treated areas, but we support this for reasons which go beyond the pesticide application to trespass issues and dangers of physical injury due to the terrain or the machinery that may be at work. The risks which children and non-working farmers are exposed to are outlined in part 1 on acute poisoning incidences, and apart from the fact the children and non-working spouses are outside the remit of the WPS, most of the incidences which cause harm to children or non-working spouses are not due to pesticides. Where they are a result of pesticide exposure it is due to activities which are not covered by the WPS.

Section E. Charge Questions:

Are there any training points listed above that EPA should consider not including in the final proposal? If so, which points and why?

In addition to our comments above, we support the EPA’s decision not to include contact information for legal representation as part of worker and handler training.

Are there points that EPA should consider adding to the training content? If so, what points should be added? Please provide a rationale for why the additional content would benefit workers and/or handlers.

No comments.

F. Retain Audiovisual Presentations as Permissible Methods for Pesticide Safety Training

Please provide any additional information on the efficacy of different methods used to conduct worker and handler training.

The DVD process should work well, as long as someone is there to answer questions in the necessary language.

G. Eliminate Exception to Handler Training Requirements

Should the proposed training under 40 CFR part 171 include a requirement for expanded training on the WPS?

Under existing regulations, an employer is not required to provide handler training to an individual performing handler tasks if that person has already met those requirements under the Certification of Pesticide Applicators regulation. However EPA states that this training (40 CFR 171) does not include specific training requirements relevant to the WPS, therefore the exception allows handlers to qualify without learning about Part 170 requirements such as REI's and the prohibition against spraying when anyone is in the treated area. EPA is proposing to eliminate this exception, and specifically, this change would require persons who apply pesticides under the direct supervision of a certified applicator to receive handler training under the WPS. This gap in training could be covered by either modifying 40 CFR 171, or the WPS. Either route is acceptable to CLA providing it does not result in duplication of training, or training that is not relevant to the handler.

How would the benefits to employers from giving a single training that would apply to both WPS handlers and applicators using RUPs under the direct supervision of a certified applicator compare to the costs of requiring agricultural applicator training for all applicators using RUPs under the direct supervision of a certified applicator?

As articulated by EPA, it is unnecessary to train RUP applicators beyond a slight expansion in current training and testing. It is the best for custom applicators to have every one covered as a certified applicator and that is the most verifiable part of the current training. This question is a little confusing, but in the end, it should be emphasized that there are certain segments of applicator training that should not have to be endured by the handlers.

4.2 FRN UNIT VIII: NOTIFICATIONS TO WORKERS AND HANDLERS

Posted Notification Timing and Oral Notification

- (I) Location of Warning Signs (near housing)
- (II) Warning Sign Content

Overview: EPA is proposing several changes in the WPS that relate to Restricted Entry Intervals (REIs) and no entry buffers that would have significant impact on farmworkers, farmers, employers, state regulators and registrants. The proposals are based on the same letter submitted by Farmworker Justice previously referenced (Ref 35 on the docket).

Specifically the proposals would:

- (i) Require Posting (as opposed to just oral notification) for all products with REIs greater than 48 hours for outdoor uses (farms, forests, nurseries) and products with REIs greater than 4 hours for indoor uses (greenhouses)
- (ii) Significantly increase training and recordkeeping requirements for workers

CLA recommend that these requirements NOT be implemented based on the following:

CLA Comments

The preamble and other parts of the proposed rule seem to not be aware of, or discount a great deal of information regarding the many improvements that have taken place with respect to training and protecting workers during the reentry interval time frame since the last WPS rules were promulgated. Many farmworker employers conduct their own training or rely on State and University resources. Further, many sustainability or buyer requirements have dramatically changed and increased training and recordkeeping are now required for growers and other employers, and posting is already required by the current WPS / label requirements. These changes are not reflected in the proposals for the revised WPS. Without recognizing existing practices it is not possible to contextualize the EPA recommendations or draw conclusions on their efficacy. Furthermore, the data on acute and chronic pesticide exposures (Part 1 of this document) do not support these additional requirements, as they demonstrate the current provisions are protective, and have successfully reduced exposures and associated illnesses.

Posting REI's is one of the most expensive activities under the revised WPS. CLA conducted a thorough review of the estimated costs (PART 3) and believe that these costs are also substantially underestimated. Regardless of the benefits, the costs alone are prohibitive both in terms of time and materials. The assumption that posting will only require 20 minutes is highly suspect. There are cheaper and more efficient ways of ensuring the REI is not breached by workers unauthorized workers, or workers not wearing appropriate PPE without having to repeatedly, frequently post field and greenhouse entryways. This posting for an REI is further complicated by the additional requirement to post "no entry" buffers during application.

Most importantly, the documentation requirements lack justification as there is little if any evidence that the proposed changes will have substantial impact in improving farmworker protection. In terms of the benefits which accrue to additional posting, the poisoning data is not indicative of a need – although EPA cite drift and incorrectly entering a restricted area as the leading causes of acute exposures to farm workers, in absolute and proportional terms those exposures are diminishingly small and are a result of either (i) deliberate non – compliance (which would be better addressed through inspections and enforcement activities) or (ii) human error under circumstances where these changes are unlikely to impact. Appendix 4 to this document - "Cases Of Exposure To Drift And Their Associated Incidents Leading To That Drift Incidents California PISP Database, 2011 Data", cite 76 cases of exposure to drift leading to an illness (from 24 incidents). The annual California Pesticide Use Reporting (PUR) reports indicate that in 2011 there were 2,472,672 agricultural applications were made (<http://www.cdpr.ca.gov/docs/pur/pur11rep/chmrpt11.pdf>). This suggests there were approximately 3 cases per 100,000 applications, which is consistent with annual statistics for 11 States reported by NIOSH researchers²⁴ and cited by EPA. Of those 76 cases, many related to more than one worker being impacted – in other words, the number of drift incidents is less than 76. And of those drift incidences,

²⁴ Acute Pesticide Illnesses Associated with Off-Target Pesticide Drift from Agricultural Applications: 11 States, 1998–2006 *Soo-Jeong Lee, Louise Mehler, John Beckman, Brienne Diebolt-Brown, Joanne Prado, Michelle Lackovic, Justin Waltz, Prakash Mulay, Abby Schwartz, Yvette Mitchell, Stephanie Moraga-McHaley, Rita Gergely, and Geoffrey M. Calvert* Environmental Health Perspectives volume 119 number 8 August 2011

some were not a result of drift “A man had symptoms and sought care after he found and opened a container of rodenticide pellets leftover from a harvesting business he operated 20 years ago. He lives on 6 acres of alfalfa, but no longer operates the land or holds an applicator license.” A further review of the 76 report summaries reveals that none of the incidents would have been prevented by implementing the restricted entry buffers proposed by EPA. Furthermore, of those 76 cases, none required hospitalization and there was a total of 8 lost working days indicating that none of these illnesses were severe in nature. Some (based on the category “possible” may not even have been a result of pesticides (Table 8.).

Table 8. Example: Case from CA PISP 2011 drift incidents data

Uncultivated Agricultural Areas (Other or Unspecified)	Nausea, headache, and burning eyes. She said it smelled like burning oil.	57-sb-11. See 2011-1017. The crew saw an idling diesel truck 40 feet away, & thought an odor was coming from it. They later saw a tractor applying herbicide on a field about 200 feet southwest. There was also farm equipment being painted 65 feet away.
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Extract from Annex 4

The substantial documentation / record keeping requirements appear to be for enforcement purposes; however, they could also serve as a target for activists and lawyers and may become the basis for lawsuits. It is entirely unclear how these records will actually serve to protect the workers safety however. Furthermore, establishing requirements which could lead to a litigious outcome will do little to address those growers who routinely infringe the current WPS – if they do not comply now, then they are unlikely to comply if the requirements make them vulnerable to litigation. Plus it could significantly impact those growers who, in good faith, are following the current WPS but become confused or overburdened by the new revisions. The objective should be to improve the consistency and quality of implementation of the current WPS across the board, through improved training and properly resourced State enforcement, not make compliance even harder to achieve.

Research has consistently shown that better training and good supervision do far more to protect farmworkers than creating records and paper trails. In a time of limited resources at the Federal and State agency, more gains may be had by allocating dollars to more frequent and effective training on the current WPS. Deliberate non-compliance leading to accidents and illness is not going to be addressed by increasing the activities required in order to comply – inspections and enforcement will.

Section A: Posted Notification Timing and Oral Notification (REI) (proposed 170.109)

The current WPS requirement is oral or posted warnings unless the label specifies both. The revised proposal is retaining the option of oral and/or posted only for products used outdoors with REIs of any length, but now requires mandatory posting for all products with REIs greater than 48 hours. The rationale EPA gives for changing this is EPA doesn’t believe workers will remember oral notifications for more than 48 hours. Ironically, the Farmworker Justice proposal was to require posting for products with an REI

greater than 72 hours. Why EPA opted instead for 48 hour REI's or greater is not explained. Furthermore, this could be addressed through training and best practice. The posting requirements are a very prescriptive approach to addressing this issue, and prone to errors and confusion (particularly when coupled with the no entry / buffer postings) – whereas empowering workers through training and improved understanding, would enable them to make informed decision on their presence or absence in a field.

There is a lack of clarity on how to notify and post on products with multiple, activity specific reentry times which EPA at the least needs to address before determining a course of action to recommend.

For indoor areas, the proposal is to require posting for any product with an REI greater than 4 hours. Given that many greenhouse applications are made at night or on weekends when workers are not present, can EPA demonstrate any real difference in safety going from 4 hours to 12 hours?

There are significant costs associated with printing, posting and taking down of signs. The cost of signs is not insignificant depending on the size of the operation and number of signs needed –roughly 50 cents per sign. However, the real cost burden with respect to posting signs is the personnel to put them up, take them down and coordinate the timing and placement during busy farm operations. Additionally, signs inadvertently left up too long or taken down too soon could cause confusion. Furthermore, based on the inaccuracy of calculating the number of greenhouses that require posting, this provision is one for which the costs could rapidly spiral out of control and not justify the cost burden in terms of improved health and safety.

The rule assumes there is no supervision of workers. Most agricultural operations today are significant businesses with established rules and procedures to ensure crops can be grown, meet food safety requirements and protect their employees. Crews do not just wander fields. They are foreman and crew supervisors. It might be more beneficial to invest the time in printing, posting and moving signs in training of supervisors and scheduling crews to be sure crews are not in fields when pesticide applications maybe going on or during REIs.

We support EPA's rejection of the alternatives considered but not proposed.

SECTION B: Locations of warning signs 170/109(b)(3)(ii)

There is a lot of discussion about posting signs around fields near worker housing areas. Strategic placement of signs to keep people who aren't working in the fields as part of a supervised crew out of the fields is a good general practice but caution should be exercised in adopting an overzealous application of this practice, which may frighten people unnecessarily. Again, when one examines the acute exposure data and the requirements of the existing WPS, posting of these signs is an excessive burden – in both time and cost – relative to the benefits it would provide.

EPA also proposes posting locations to include locations visible from worker housing areas if the housing area is within 100 feet of a treated area is an additional requirement. In principle, we support the intent of this proposal which is to prevent inappropriate entry into treated fields at times of greatest risk. However there are practical problems with this proposal. For example, visibility could be an issue if there are trees in the way (which can also act as a physical buffer and so negate the need for a warning). Furthermore, the positioning of these signs is not based on a risk assessment, and thus the assumption is that (i) people are going to be exposed and (ii) exposed to an extent sufficient to cause harm. These assumptions are not necessarily correct, which is why EPA HED conduct a risk assessment in the first place. In short, we believe requiring the posting of fields within 100ft of a workers house is an overly prescriptive and unnecessary provision which will not provide additional protection above that already provided by the label and existing WPS.

Section C. Warning Sign Content

When posting signs are needed based on the EPA risk assessment and label requirements, we support the changes proposed to the signage – changing the circle to an octagon (like a stop sign) and changing the wording to “Entry Restricted”. We agree with EPA that having signs with a skull and cross bones will be confusing and unnecessarily alarming. EPA signs have specific meanings. A skull and cross bones implies death – and the data previously provided demonstrates death is not a consequence of unauthorized re-entry.

4.3 FRN UNIT IX: HAZARD COMMUNICATION

Section A. Pesticide-Specific Hazard Communication Materials – General [Proposed §170.11(b)]

CLA Comments:

EPA proposes to require (in addition to existing requirements related to the date, time and location of application, length of REI and identity of pesticide products) that:

- Agricultural and handler employers make available to workers and handlers Safety Data Sheets (SDS) and the labeling for pesticides used on the establishments that require WPS compliance;
- That these employers maintain the SDS and pesticide labeling on the establishment for 2 years from the date of pesticide application;
- That not only employees but authorized representatives of workers or handlers would be permitted access to this information during normal business hours.

Before addressing this section of the proposed rule and associated preamble, it is important to clarify the differences between an OSHA Hazard Communication Standard Safety Data Sheet (SDS) and FIFRA pesticide labels. This is particularly pertinent because EPA is basing their proposals on recommendations made by health care, medical and farmworker organization who may not be aware of the differences in how chemical products (including pesticides) are classified by OSHA compared to how pesticides are classified for labeling under FIFRA.

OSHA requires Safety Data Sheets (SDSs) under its Hazard Communication Standard (HCS) (29 CFR 1910.1200) and has aligned its HCS requirements with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). However, EPA has not yet moved to amend its labeling regulations to reflect the GHS.

There are differences between EPA's labeling requirements and the GHS related to classification criteria, hazard statements, pictograms, and signal words as it relates to acute toxicity and skin and eye effects. FIFRA has 4 categories and three Signal Words, DANGER, WARNING, CAUTION for acute toxicity and skin and eye effects, with no signal word required for products in lowest category (IV) for all effects. Skull and Crossbones appears only on Category I Toxic products (DANGER-POISON).

GHS has 5 acute toxicity categories and two Signal Words, DANGER and WARNING. For acute toxicity Categories 1-3 are DANGER and bear Skull and Crossbones pictogram, 4-5 are WARNING and bear the Exclamation Point pictogram. Very low toxicity products are not classified. For skin and eyes, products may bear the "Corrosive" pictogram for severe effects or the Exclamation Point pictogram for irritation effects.

The two classification systems values do not coincide, thus a toxicity limit test value for FIFRA Category III (CAUTION) will result in a WARNING or even DANGER signal word under GHS.

Thus, there are going to be inconsistencies between EPA-approved labels for pesticides regulated under FIFRA and the SDSs that OSHA requires for these same product under the HCS.

As a result, there is potential for confusion over the information provided in the SDS compared to the label. The attached link is to EPA OPP's "Pesticide Registration Notice 2012-1 Material Safety Data Sheets as pesticide Labelling" (April 20 2012). In this document the EPA provides guidance which describes how registrants can ensure their FIFRA labelling and SDS comply with both EPA and OSHA requirements.

[Pesticide Registration \(PR\) Notice 2012-1: Material Safety Data Sheets as Pesticide Labeling](#).
United States Environmental Protection Agency. April 20, 2012.

Specifically, the attached document states that "EPA has not yet moved to amend its labeling regulations to reflect the GHS. There are differences between EPA's current requirements and the GHS related to classification criteria, hazard statements, pictograms, and signal words. Therefore, EPA is issuing this clarification of its policy in order to avoid potential inconsistencies between EPA-approved labels for pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the SDSs that OSHA requires for these chemicals under the HCS."

Bearing in mind the potential for confusion, it would seem that the pesticide label is the more appropriate document to use, particularly when training workers (as opposed to applicators and handlers) on hazard and safety requirements. Furthermore and from a worker safety perspective, the most relevant part of the label is that which relates to the use of PPE.

The pesticide label provides hazard information and the safety requirements for the formulated product for its intended uses. It includes information on the first aid requirements, emergency care and the personal protective equipment (PPE) required. It also contains information on cleaning PPE, such as keeping and washing PPE separate from other laundry. The label also provides information relating to environmental safety and restrictions, where necessary, whereas a MSDS or SDS does not include information regarding environmental safety as it relates to a pesticides intended crop use.

The label is a legally binding document and lack of adherence is a prosecutable violation. The use conditions on the label are designed to meet two requirements – (i) to ensure the product is used effectively in targeting the pest and (ii) to ensure that the use does not give rise to acute or chronic illness – in other word, with “no unreasonable risk of harm” as specified in the FIFRA statute. The label is the culmination of the regulatory testing requirements for both hazard and exposure; it defines the product use in such a way as to mitigate the risk of harm to the worker, handler and applicator. The use requirements are important in that they are what prevent workers from being exposed to the pesticide at levels which could cause not just acute but also chronic illness. As stated before, the label regulates to the dose at which there is **no** adverse effect, and there are layers of protection inherent in the label – such as conservative exposure modelling and uncertainty factors – to ensure that even this chronic NOAL is not reached in “real life”.

The current WPS *already* requires employers to provide access to pesticide labels during pesticide handling activities, to ensure that the handler has read the labeling, and/or has been informed in a manner the handler understands of all labeling requirements related to safe pesticide use (40 CFR 170.232(a)). In addition to the label, the current WPS require employers to display basic pesticides safety information, including certain information about pesticide applications when the pesticide is applied or when an REI has been in effect within the last 30 days. Both the labels and the SDS are available easily on the internet. Thus there is a plethora of information on the hazards of pesticides so we are not entirely sure why this section (Section XI A) states that “The existing WPS does not require employers to provide workers and handlers with pesticide specific hazard information on the products they are exposed to”. We are also not clear whether EPA has differentiated sufficiently between the types of information handlers require from that required by workers.

EPA should also clarify why this apparent lack of “specific hazard communication materials” is perceived to be a problem for worker safety, and why EPA “believe that providing access to specific hazard information would assist workers and handlers in better protecting themselves and others from pesticide hazards in the workplace – particularly in the light of the existing requirements for PPE, and the data we have provided on acute exposure and illness in our comments, couple with the nature of that acute exposure and illness. Ultimately the hazard posed by the product is a reflection of the type of contact that might occur, and is mitigated by the use of PPE.

In principle, CLA has no problem with the retention of relevant safety information by the employer, or its provision to the worker / handler / applicator nor does CLA have a problem with providing appropriate

information to medical personnel as needed. However, it is not clear what the utility of doing this is. EPA provides no evidence that the current practice of only providing worker's with the label has resulted in workers or handlers not having access to any needed information. EPA has not provided any rationale for why access to pesticide specific information from the SDS is going to provide any additional protection over and above that already provided by complying with the label requirements for PPE, REI and so forth. This section also conflicts with the EPA's repeated statements that farmworkers have limited literacy and often don't have English as their native language and therefore should have oral notification. EPA has included substantial requirements for notifications in writing, maintenance of records, and access to documents for workers, handlers and their "authorized third party representatives". Appendix 6 provides an example of a SDS. It seems unnecessary to provide all of this information to a farm worker who may only have to enter a field to harvest lettuce.

Section B. Pesticide Application Information – Content and Timing

EPA proposes to increase the amount of information to be kept in relation to pesticide applications, requiring employers to record the specific crop or site treated, the start and end dates and times of the application and the end date and duration for the REI. Employers would be required to record the information no later than the end of the day of application, which is a revision to existing requirements.

We believe providing information within 24 hours would be sufficient as opposed to the new stipulation of "by the end of the day." The requirement "by the end of the day" is both unclear and unhelpful. We presume EPA is aware that there are often pesticide applications very late in the day or at night, thus the end of the day could actually be the beginning of the next one. We believe providing the information within 24 hours of the application is specific, reasonable and likely more realistic and enforceable.

Section C. Pesticide Application Information – Location and Accessibility

EPA proposes to eliminate the requirements for displaying pesticide application information at a central location and require employers to maintain pesticide application information on the establishment, while making such information available to workers, handlers or their authorized representatives upon request. CLA supports this change. However, we strongly object to the provisions allowing "authorized representatives" access to this information and urge that this portion of the proposal be eliminated. This is further discussed in response to the charge questions. We do support the change from requiring a central display location to a requirement that merely requires all the information be maintained on the establishment.

Section D. Pesticide Application Information and Pesticide Specific Hazard Communication materials – Retention of records

CLA does not object to the imposition of an appropriate period of record retention. As previously stated, CLA believes that recordkeeping requirements should be minimal and time-sensitive and not solely driven by the needs of enforcement agents, nor should they be so onerous as to burden producer members. The purpose of the WPS is to protect workers therefore we believe the burden is on EPA to show that the new

requirement will indeed protect workers. The Agency cannot quantify benefits²⁵, and in the absence of any ability to justify a change that has the effect of improving worker health or safeguarding employees, any mandate imposed by the Agency should be minimal, non-intrusive and have the demonstrated effect of furthering the purposes of the statute. The two year requirement goes beyond what is reasonable. We believe a one year record retention requirement should be sufficient.

EPA needs to clarify which material must be retained – whether it is the current SDS and label or the one that was in use at time. EPA also needs to clarify which safety information should be provided – the SDS for the active ingredient(s), or the SDS for the formulated product. We recommend the latter, as the two may differ and would create confusion.

Overall, CLA believes existing hazard communication requirements are sufficiently informative and protective. We agree with the Pesticide Program Dialogue Committee Pesticide Safety Trainer representative’s recommendations that “providing simple information on how to prevent potential pesticide exposure is the most effective way to enable workers and handlers to protect themselves.” It is noteworthy that the officials whose job it is to provide the training and who have a lot of interaction with workers did not endorse a specific type of hazard training.

4.4 FRN UNIT IX: CHARGE QUESTIONS:

Q: What would be the burden on employers to maintain the SDS and pesticide label for 2 vs. 5 years?

As outlined earlier, we believe any recordkeeping requirement should be the minimum amount required to achieve the purposes of the Act. It should be noted that this recommendation regarding hazard communication in no way alleviates the employer from the other requirements of WPS: Viz. of not allowing a worker in the area during application or within the REI. This simply addresses the requirement of when to have hazard information available.

We support that each establishment that applies pesticides should have on site the pesticide label and SDS but do not support the proposed requirement for them to keep these for 2 years. We are not persuaded that a 2-year requirement is necessary, and we strongly oppose anything beyond that, specifically a 5-year requirement. There is no conceivable reason from a farmworker health perspective to require employers to maintain records for such a lengthy time. Furthermore, pesticide labels and SDS can change within 2 years, sometimes multiple times. EPA needs to demonstrate who or what this action serves. It is entirely unclear how this action would improve worker protection. Neither is it clear which version an employer would be required to keep in that 2 year period.

We support EPA’s decision not to require crop sheets we agree that they vary too much state by state and product by product used.

²⁵ [Federal Register, page 15477](#)

Providing information in a variety of languages has obvious benefits; however multiple attempts haven't proven very challenging due to different dialects, lack of agreement on translations between EPA and states, etc. Again, we support the opinion of pesticide safety trainers – the best way to protect workers and handlers is to be sure they understand how to prevent exposure and making sure those training materials are clear and understandable.

Q: Do agricultural employers already collect SDSs? If so, how do they obtain them and what burden is associated with retrieving the SDS for one or more products?

SDSs should come with shipments of products sent directly from the manufacturer. Most growers buy from a distributor and the distributor should have the SDS so they would not receive it directly. The reason for this is because the SDS is more appropriate for transportation and storage, whereas the label is more appropriate for mixing, handling and use. It would place a burden on the distributor to provide each grower with an SDS for each purchase. The grower could access the SDS from the internet or call the manufacturer to get an SDS for each product. This would be difficult to keep up with. Again, the pesticide label has the necessary safety information on it.

Q: What are the benefits and drawbacks of requiring employers to maintain and provide access to employees and others the proposed pesticide-specific hazard information?

See our discussion above on this matter.

Q: Are there other approaches for providing workers and handlers with understandable, readily accessible, and relevant information on the symptoms, short-term health effects, and long-term health effects of exposure (including prenatal exposure) to specific pesticides? If so, please describe these approaches, their implementation, and the advantages they provide in comparison to the proposed approach.

CLA requests the Agency to provide a description of the rationale for this question, and how the Agency thinks this information could augment the already comprehensive measures in place to protect workers from incurring these symptoms in the first place – including the actions taken by EPA when determining the conditions under which a pesticide may be registered for use.

In terms of the short term health effects, or acute effects, if one examines the symptoms described in the case reporting under the CA PISP and NIOSH SENSOR requirements, it is clear that (a) workers would be well able to identify any short term symptoms they may have themselves (headache, nausea, rash, stinging eyes etc.), and (b) that the cause of these effects is better addressed by a clinician using a differential diagnosis– particularly as many of these symptoms are common to a variety of causes that also exist on farms (tobacco leaves can cause skin rash, gasoline fumes can cause headaches etc.). The existing WPS and the proposed revisions already mandate emergency treatment, decontamination, and training on what to do in the event of acute exposures.

In terms of addressing long term effects, and specifically pre natal effects, it is entirely unclear how explaining these help. Pesticides are regulated to prevent the incidence of long term chronic disease. Their use is prescribed by law, through the label and is again designed to prevent chronic illness from occurring. Rather surprisingly, EPA falls short on clarifying the difference between a hazard and a risk, and the importance of exposure is determining whether or not harm will occur. To reiterate, pesticides are regulated to ensure that real life exposure is below the dose at which there is NO adverse effect for chronic effects. The USDA Pesticide Data Program²⁶ examines pesticide residue levels on a variety of fruits and vegetables in order to determine dietary risk, and to check that pesticides are being applied according to the label. Numerous years of data collection demonstrate that growers are applying pesticide products according to the label and not at concentrations or frequencies that are greater than that prescribed. The evidence in the literature and from toxicological testing supports the veracity of EPA's risk based regulatory approach and confirms they have been effective in mitigating these long term health effects. The benefits of providing information to workers and handlers on the long term health effects of pesticides is questionable, when one understands that those effects are prevented by virtue of the EPA regulatory requirements for pesticides and by following label requirements.

Q: Are there other data on the benefit to workers and handlers from receiving pesticide-specific information before every entry into a pesticide treated area?

CLA does not believe so.

Q: Does opening access to pesticide-specific information to authorized representatives raise any problems? If so, please describe the potential issues with particularity and provide supporting information where available.

In §170.5 of the proposed rule, "authorized representative" is defined as a "person designated by the worker or handler, orally or in writing, to request and obtain any information that the employer is required to provide upon request to the worker or handler."

We strongly object to the EPA's proposal to open up such records to "authorized representatives" of workers and handlers and urge that the Agency withdraw it. The Agency misuses the term "authorized representative" when, in fact, no such relationship to an employee or handler is even demonstrable, much less established. The Agency's own proposal²⁷ defines an "authorized representative" as a "person designated by the worker or handler, orally or in writing..." In this extensive proposal the Agency laments the inability to enforce existing WPS provisions. In order to remedy these alleged failing, new requirements for recordkeeping, personal protective equipment, health warnings, buffer zones and other matters are proposed. Yet here, the Agency proposes to permit any individual who wishes to walk up to a farm gate, claiming to have been 'orally' designated to receive business-sensitive information.

²⁶ <http://www.ams.usda.gov/AMSV1.0/PDP>

²⁷ See §170.5, definition of 'authorized representative,' Federal Register page 15516

We remind EPA that the Farmworker Justice letter already mentioned is cosigned by organizations that publicly oppose the use of pesticides.²⁸ Under this proposal, any member of an anti-pesticide organization could present him- or herself at a farm claiming to have been ‘orally designated’ by a worker and demand to be given all information on that operation related to RUPs. This is an intolerable violation of a farmer’s legal rights; it subverts EPA’s own system of protecting public health and safety through a rigorous registration process; it undermines the legitimacy of FIFRA; and it has nothing to do with worker safety.

The issue EPA is attempting to address in this case is, in fact, access to the label by health care workers and farmworker organizations, who argue they are not being provided the information. Whether or not the WPS has the authority to extend requirements to meet the needs of these individuals is questionable, and certainly begs the question as to how this would impact farmworker health and safety. Furthermore, as (i) pesticide labels and MSDS are readily available on Federal, state and registrant websites and (ii) the current WPS requires the worker will know what pesticide has been used within the last 30 days. It is not clear how this additional requirement adds anything to the information already available. If a farmworker experiences health issues of which a potential cause could be exposure to pesticides, then their health care provider can instantly download both the label and MSDS for free from multiple websites to evaluate the case. In short, there is no justification for placing this additional requirement on the grower, or legal base that authorizes EPA to mandate provision of such specific information to the health care worker, or additional benefits to the farmworker that would balance the additional costs associated with these additional provisions.

In the strongest terms, we urge EPA to delete in it’s entirely the reference to “authorized representatives” in the proposed rule.

Q: Would the additional pesticide application information proposed by EPA impose undue burden on the applicator or employer?

CLA believes the proposed revisions are already imposing an excessive burden on employers.

Q: Are there benefits or drawbacks to requiring this additional information that EPA has not considered? If so, please describe.

Not applicable.

Q: Should EPA consider a different timeframe for recordkeeping for this requirement? If so, what period and why?

Please see our discussion above on this matter. We believe 1 year record retention is sufficient.

Q: What burdens would be imposed on agricultural employers as a consequence of the proposed two-year record retention requirement?

²⁸ See our discussion of this matter in VII E above.

Please see our discussion above on this matter. We believe 1 year record retention is sufficient. Please refer to the Summit report on the ICR provided in Annex 7 to this document.

Q: How would the burden of the proposal to maintain application records compare with the current requirement to maintain a central display?

For application records, we support the change from requiring a central display location to a requirement that merely requires the information be maintained on the establishment.

4.5 FRN UNIT X: INFORMATION EXCHANGE BETWEEN HANDLERS AND AGRICULTURAL EMPLOYERS.

CLA Comments:

EPA proposes two additional requirements related to the information exchange between handlers and agricultural employers: (1) the Agency would include the location of the proposed “entry-restricted areas;” and (2) the Agency would require the handler employer to include the proposed start and estimated end times for the application; EPA would require handler employers to provide changes to pesticide application plans to agricultural employers within 2 hours of the end of the application (changes to the estimate application end time of less than 1 hour would not require notification).

CLA does not object to ensuring information exchange between handlers and agricultural workers are timely and well-coordinated. However, we feel the new requirement to ensuring changes to information provided in §170.13(i) be provided to agricultural employer within 2 hours after completing the application is unrealistic and impractical. EPA needs to be mindful of the dynamics of farming operations and the need to respond to pest infestations, wind conditions, changing weather patterns, timing of harvest, and the economic impact all of these factors can have on a farmer’s livelihood. Furthermore, many applications are conducted at night. We are uncertain whether the changes proposed by the agency would in fact reduce worker pesticide exposure and are unaware of any documentation in the docket that supports this belief held by the Agency.

FRN UNIT X: CHARGE QUESTIONS:

Q: Is it reasonable to require the handler employer to notify the agricultural employer of changes to scheduled pesticide application within 2 hours of the end of the application?

This is an unrealistic, impractical and over burdensome requirement when considering the dynamics of farming operations. There is a need to respond to pest infestations, wind conditions, changing weather patterns, timing of harvest, and the economic impact of all of these factors can have on a farmer’s livelihood. It remains the handler’s responsibility to ensure that non-handlers are not in the area to be treated or where spray drift can directly contact non-handlers.

Q: What are the benefits to expanding the information to be exchanged between handler and agricultural employers? Are there any drawbacks?

We are uncertain whether the changes proposed by the Agency would in fact reduce worker pesticide exposure and are unaware of any documentation in the docket that supports this belief held by the Agency.

Q: Would this impose additional burden on employers? If so, what burden and how could it be reduced?

See our discussion above on this matter.

4.6 FRN UNIT XI: HANDLER RESTRICTIONS

CLA Comments:

Section A: Suspend Application

This proposal would require handlers to cease application if they “observe” any person other than a trained and properly equipped handler to be in the treated or entry –restricted area. This is already covered by the current WPS provision which requires handlers and applicators to take actions necessary to ensure bystanders and other non-authorized persons are not exposure to spray drift. Furthermore it is entirely unclear how an aerial applicator could identify whether or not the person is authorized from the air, not to mention logistically impractical. Do they have to land in order to check first?

We refer to our previous comments on handler restrictions and spray drift.

Section B. Establish a minimum age of 16 for Handling Pesticides.

We support this restriction recommendation as long as the exemption for immediate family members is maintained.

4.7 FRN UNIT XII: RESTRICTIONS FOR WORKER ENTRY INTO TREATED AREAS

CLA comments:

It is unclear why the existing WPS regulations for early entry are inadequate. Current WPS regulations prohibit employers from sending workers into a treated area during the REI except under specific early entry exceptions (40 CFR 170.112(a)). If an employer sends a worker in under one of the specific early entry exceptions, the employer is required by current WPS regulations to provide workers with PPE, to assure that early entry workers follow precautions on the label and to provide water and decontamination supplies nearby for when the worker exits the treated area. When one examines the circumstances under which violations of the REI occur, and their outcome – using the data EPA provides to justify this activity as the “second leading cause of acute occupational pesticide poisoning cases” – it is clear that the frequency and severity of the outcome in terms of health impacts do not justify the additional requirements (ref. Part 1 of this document).

Under the revisions, EPA is proposing to require employers to

- Inform the workers of the specific exception under which they are being asked to make an early entry
- To describe the tasks permitted and any limitations under the exception
- To explain the PPE required and
- To create a record of the oral notification, to obtain the signature and birth date of each early-entry worker acknowledging the oral notification prior to early entry and to maintain that record for 2 years.

While items 1-3 above seem reasonable item 4 seems unduly burdensome and provides no additional protection for the worker while adding significantly to the employer's time and cost burden. It is not clear why this is therefore required, or how it will be used.

4.8 FRN UNIT XII RESTRICTED ENTRY REQUIREMENTS

CLA has provided comment on FRN Section XII Part E BELOW, as it relates to the previous FRN Section VIII

Section E. Expansion of Entry Restricted Areas Viz. No Entry Buffers During Applications (Proposed 170.05)

EPA is proposing that farmers observe and post adjacent "Buffer Zones" of restricted entry access of 25 ft. for ground applications and 100 feet for aerial applications within the confines of agricultural establishment at the time of application in order to address accidents with drift in a pre-emptive manner. The 170.105 provides a table entitled "Entry-Restricted Areas During Outdoor Production Pesticide Applications" and references the "Treated area plus 100 feet around the treated area within the boundaries of the agricultural establishment". The agricultural establishment is defined as any farm, forest operation, or nursery..... (Definitions 170.05). This definition of "agricultural establishment" appears to be a wider definition than the actual field of application. These restricted entry areas would require additional posting.

CLA opposes these buffers and the posting of these buffers as redundant:

The current proposals would result in multiple different posting all at the same time but for different reasons. However posting is already required for certain pesticide end-use products, and it is typically required adjacent to the treated field or in obvious access routes to the treated fields.

The buffers do not extend beyond the property line. However, it is beyond the property line in nearby adjacent fields that most of the recorded incidents of potential drift exposure cited by EPA occur. The proposed regulation would not prevent those incidents, and furthermore, such incidences are already covered by the current WPS: Handlers are required to "assure that no pesticide is applied so as to contact, directly or through drift, any worker or other person other than an appropriately trained and equipped

handler. This is prosecutable offence. Thus the proposed language to “cease application” is implicit in this requirement and is articulated on the label.

Spray drift is a function of application technology used and meteorological conditions. The proximity of workers to the field is only relevant downwind of the application with respect to potential drift exposure, except in the event of conditions promoting inversions. The proposed WPS states that *“Applicators should not be applying under conditions conducive to inversions that could lead to off-target movement of spray and labels are becoming more explicit in indicating meteorological conditions that must be avoided. Labeling should include reference to best practices for avoiding drift.”*

However, current labels often specify that a no spray buffer is required downwind of an application to a sensitive area, which would most often include a neighboring field. Most if not all labels are likely to include buffer requirements in the future as registered chemicals are evaluated under registration review. No spray buffers are implemented with consideration of effects on non-target organisms and bystanders in nearby schools or residential settings. The application area therefore may not include the entire field and ironically it is therefore feasible that the restricted entry area would be in closer proximity to the application than a no-spray buffer designated on the label.

For the following reasons, CLA believes the proposed entry restriction buffers and associated posting requirements should not be included in the revised WPS.

1. Duplicative and Unnecessary

Current WPS already prohibits the actions the proposed measures are designed to prevent. The proposed measures are likely to be ineffective, providing no benefit. They would require farmers to spend time posting in areas where drift exposure is physically impossible, e.g. 100 ft upwind of application.

2. Confusion and warning fatigue

Labels are likely to include no-spray buffers in addition to the proposed restricted entry buffers. Buffers of multiple distances and multiple purposes increases the potential for confusion and error. The implementation of additional buffers will add a cost and nuisance factor to farm operations without providing any added benefit in terms of protection, particularly as they, too, require posting – in addition to the posting of REI. Between the taking down and putting up of all the different notices associated with different applications, different pesticide products, different crops and so forth the opportunity for human error increases, and with it the chance that inadvertent exposures will take place. Workers may become complacent due to over/multiple posting, which may result in erosion of trust in the need for any posting or PPE in the actual treated area posting. Over warning is a significant issue to avoid, or people will simply ignore the warnings, whether there is a true risk or not. One excellent example of the impact of over warning is the Proposition 65 program in California where the warnings are so ubiquitous that they have lost their impact.

3. Enforcement:

The Buffer Zone posting will be difficult to enforce, not just in terms of ensuring the postings are in place, but that they are also removed immediately after the application has ended. We recommend that State enforcement officials provide feedback on the logical implementation and enforcement of these proposed changes.

4. Fumigants:

Fumigants should be specifically excluded from these posting restrictions. They are addressed individually with more detailed restrictions and this would prove counterproductive in their case.

5. Effectiveness:

The data cited by EPA regarding incidence of drift associated illness is dated. Even so, it suggests that exclusion and posting will be of limited value in preventing drift incidents. With California as an example, NIOSH research indicates that there were 1.6 drift events per 100,000 agricultural applications in California suggesting that drift events are rare occurrences. Applicator error was cited commonly as a cause for incidents. Aerial application was the most frequent application method found in drift events, accounting for 249 events (39%) in an 11 State survey of incidents over 9 years (that represents 28 incidents per year on average across 11 states, or an average of 2.5 per state). Aerial applicators have sought to reduce or eliminate errors through additional and on-going training for their industry. Through careful planning, standard operating procedures (SOPs) for aircraft sprayer set-up and calibration through the Operation S.A.F.E. program, ongoing education programs such as the PAASS program,²⁹ and years of experience, application mistakes or spray drift incidents are even more rare.

In addition, aerial applicators increasingly employ sophisticated equipment for making precision applications, including GPS (Global Positioning Systems), GIS (geographical information systems), flow controls, real time meteorological systems and precisely calibrated spraying equipment. Spray drift reduction technologies (DRTs) incorporated into the set-up of these aircraft include carefully designed and located spray booms, adjustable nozzle angles to control droplet wind shear, and valves for in-flight shutoff of specific nozzles to create a sharply-delineated swath edge. As a result of NAAA-member driven training efforts and adoption of new technology, precision aerial application and spray drift limitation adds significantly not only to the protection of the environment, but to the protection of agricultural handlers and workers. Analogous training is available and promoted for applicators to understand and adopt drift reducing technologies that are available and to ensure pesticide applicators have required certification. These are cost-effective measures that address the root causes of incidents that occur. Had a no-entry buffer system been in place over the past decade there is no indication that it would have reduced or eliminated incidents reported. It cannot be assumed to be effective in reducing future incidents and should be reconsidered since it will add a significant burden to day-to-day farming operations.

²⁹ <http://www.agaviation.org/paassprogram>

Early-Entry into enclosed spaces. Column C of Table 2 under paragraph (b)(4) of this section specifies that ventilation criteria must be met, ventilation must continue until the air concentration is measured to be equal to or less than the inhalation exposure level the labeling requires to be achieved. If no inhalation exposure level is listed on the labeling, ventilation must continue until after one of the following conditions is met:

- (i) Ten air exchanges are completed.
- (ii) Two hours of ventilation using fans or other mechanical ventilating systems.
- (iii) Four hours of ventilation using vents, windows, or other passive ventilation.
- (iv) Eleven hours with no ventilation followed by 1 hour of mechanical ventilation.
- (v) Eleven hours with no ventilation followed by 2 hours of passive ventilation.
- (vi) Twenty-four hours with no ventilation.

It is unclear how EPA determined these requirements. If there is data to demonstrate that these requirements actually confer any real protection then the EPA should supply it.

It is further unclear how these requirements can or will be enforced. Based on the remarkably low level of poisoning incidents that are occurring in the farm worker population, it would seem that this does not represent something which is not already met through the current WPS. Unless EPA can provide evidence from the various poisoning databases that this is, in fact, a real problem, then it is not possible to justify this prescriptive requirement. Even if it were justified, then EPA would be bound to demonstrate that these recommendations are based on sound science, and that they deliver meaningful and cost effective benefits.

4.9 FRN UNIT XIII: DISPLAY OF BASIC PESTICIDE SAFETY INFORMATION

The Agency addresses two issues relevant to the display of safety information

1. Location of basic pesticide safety information displays, and
2. The content of the basic pesticide safety information displays.

Section A. Location of Basic Pesticide Safety Information

CLA Comments:

In regards to the first issue, EPA is requesting comments regarding additional benefits and burdens to employers in adding pesticide safety information at decontamination sites, in addition to the current single site required for posting the safety information and whether data exist regarding whether accessibility to workers of this information leads to improved workers' and handlers' access to the self-protective and decontamination information.

EPA states that it can't quantify the benefits associated with this proposed revision to the WPS. CropLife believes that the burdens of placing this basic information at decontamination sites are not great and that

there exists potential benefits to the additional reminders of basic pesticide safety information. Therefore CLA does not object to this additional requirement for employers.

Section B. Content of Basic Pesticide Safety Information Display

CLA Comments:

In regards to the second issue, EPA proposes to broaden the content of the safety information to include additional emergency medical information and to include contact information for the state or tribal regulatory agency for pesticide enforcement. The Agency is requesting comments regarding whether they should consider other changes to the content of the pesticide safety information and if so what changes and why. Again the Agency has identified no benefits with this proposal.

CLA does not object to updating and providing relevant information to employees. However, CLA is concerned that the proposed requirement to provide contact information for the state or tribal regulatory agency can potentially lead to malicious reporting of alleged violations by employees or their third party representatives. If this provision is adopted, CLA believes that EPA should carefully monitor any reports of alleged violations and work with state and tribal agencies to monitor whether such reports are well-founded and whether this particular initiative is being used to harass employers rather than addressing safety issues. There will be a cost burden associated with this activity which should be reflected in the ICR.

4.10 FRN UNIT XIV: DECONTAMINATION

This section is specific to routine and emergency decontamination for workers and handlers under work situations in which they are not entering treated areas during a REI being in effect. The proposed revisions are intended to address

- A. Clarification of the quantity of water required for decontamination,
- B. Elimination of the substitution of natural waters for decontamination supplies,
- C. Requirements for ocular decontamination for exposed handlers, and
- D. Adding a requirement for showers for handler decontamination.

Section A. Clarification of the quantity of water required for decontamination

CLA Comments:

In regards to the first issue to clarifying the amount of water required to one gallon for routine decontamination washing for workers and three gallons for routine and emergency worker and handler decontamination, CLA considers these quantities to be reasonable although rather prescriptive. Clarification is required on whether or not this is three gallons at all times, or three gallons at the beginning of each day. Clarification is also required on whether or not the 3 gallons is per worker or not. In addition, waterless cleansing agents in lieu of soap, water, and towels are also reasonable for routine washing and

already are acceptable hygienic practice. However, CLA does not believe these agents would be practical for handler decontamination although they would be suitable for routine daily clean up.

Section B. Elimination of the substitution of natural waters for decontamination supplies

CLA Comments:

CropLife objects to the Agency's proposal to remove the exemption that allows employers to use clean, natural bodies of water in lieu of the required decontamination supplies. The Agency contradicts itself regarding the costs and benefits of this proposed elimination by stating "a negligible number, if any employers would be impacted by this proposal" and then, in the next sentence, EPA admits that it "has no data on the number of employers that may use this option." Since EPA admits that it is without any data that would substantiate the cost and benefits of eliminating this provision, CLA disagrees with the proposed withdrawing of an existing provision that is designed to protect workers.

Section C. Requirements for ocular decontamination for exposed handlers

CLA Comments:

CropLife considers the proposal to require that clean, running water be present and flowing at a minimum of 0.4 gallons per minute for 15 minutes at permanent mixing and loading stations to be reasonable with certain understandings. This proposal should NOT be morphed to also require the water to be potable, there should be a specified period of 12 months from the proposal taking force for the employer to provide the eye decontamination station, and record keeping regarding water flow rates should not be required. This proposal is also considered reasonable only in regards to permanent mixing/loading stations that already have running water available. There are alternatives to ocular decontamination which do not require running water – such as the provision of eye wash stations with bottles of sterile saline for example. EPA should consider these options as well.

Section D. Adding a requirement for showers for handler decontamination

CLA Comments:

CropLife concurs with EPA and supports the agency's decision not to impose a requirement to provide showers for handler decontamination. Decontamination in this case is defined as routine washing at the end of the day. At the end of a long work day the handler is going to be focused on getting home. CLA believes that it is more efficient to emphasize during training and in safety information the importance of showering and changing clothes once the handler returns home. In addition, the Agency states that the costs associated with this proposal are \$22.7 billion, not including future costs of maintenance. There is no way that the minimal, if any, benefits of requiring shower facilities can justify this cost and the Agency is justified in not imposing this requirement.

4.11 FRN UNIT XV: EMERGENCY ASSISTANCE

The current WPS requires “prompt” transportation to an emergency medical facility to workers or handlers who have been “poisoned or injured by exposure to pesticides.” As “prompt” is subjective the Agency is proposing to require that emergency medical assistance be provided by employers within 30 minutes of learning that an employee has been poisoned or injured by exposure to a pesticide. In addition to redefining “prompt”, the Agency is proposing that the employer be required to provide to the employee or treating medical personnel information on each pesticide that the employee may have been exposed to. Providing both the label and the safety data sheet (SDS) would satisfy the information requirement. Two alternative options that was considered by the Agency, but not proposed were replacing “prompt” with “immediate” or replacing “prompt” with “one hour”.

The Agency is requesting comments on the following questions:

1. Whether the 30 minutes is a reasonable timeframe,
2. Do medical personnel require more information than what is proposed, and
3. Should the employer also be required to report the estimated time of the incident in addition to the proposed information?

CLA Comments:

CLA understands the Agency’s desire to address the subjective nature of the current “prompt” standard but cautions the agency not to adopt too rigid a position. At first glance the 30 minute requirement appears reasonable. However, agriculture is an industry where arbitrary definitions are not always the most appropriate approach. A severe injury, whether from pesticide poisoning or other accident would clearly require a more immediate response than the 30 minutes to be considered appropriate. On the other hand, there are farming operations, particularly in western U.S. geographies, where operations are sufficiently large that providing a worker or handler or treating medical personnel the appropriate SDS or pesticide label might be difficult or impossible within 30 minutes and an immediate and appropriate response will require more than 30 minutes.

CLA believes that retaining the current standard timeline requirement, “prompt”, remains the most appropriate approach to providing emergency assistance. Flexibility is essential. For example, the most appropriate response may be immediate transport from the field, which can be miles from the operation’s offices, to a medical facility, while other responsible individuals are currently obtaining and providing the necessary pesticide information such as the label and SDS. CLA believes that regardless of any regulation, it would be in the employer’s self-interest to document the incident and include information on the nature of the injury requiring emergency assistance such as the time from knowledge of the event to transport, assistance provided at the injury site, and other relevant information regarding the event.

4.12 FRN UNIT XVI: PERSONAL PROTECTIVE EQUIPMENT, PPE

Section A. Chemical Resistant PPE

CLA Comments

Section 170.207 makes the distinction between chemical-resistant and waterproof equipment with chemical-resistant material requiring a manufacturer's written declaration that the material is chemical-resistant. The distinction properly carries over to protective gloves where a distinction is made through the glove selection charts as to whether the protective gloves should be waterproof (for aqueous or solid formulations) or a specific chemical-resistant material based on the solvents in non-aqueous liquid formulations.

However, this distinction then gets muddled as the regulation defines protective footwear, aprons, and headgear. CLA believes that the handler community would be better served if chemical-resistant was replaced with waterproof in describing protective footwear, aprons, and headgear. Because there is no linkage between the term chemical-resistant and a specific chemical being used the handler has no guidance provided by the label as to whether the footwear, apron, or headgear is truly resistant to the formulation being handled unlike the guidance provided for gloves. The nature of the exposure to the body areas being protected by the footwear, apron, or headgear also differs from that of the hands during the handling of the formulation. In the absence of direct contamination of the footwear or area covered by the apron, the exposure is most likely to be with diluted material for the footwear and the term waterproof footwear is more appropriate. Direct contamination would require immediate removal of either the footwear or apron under the WPS and because of the short duration of exposure under these circumstances the term waterproof would be adequately protective and not produce confusion as to whether the material was resistant to the chemical or chemicals involved. The protective headgear is required only for overhead applications which involve exposures to diluted spray solutions that are primarily aqueous. In addition, the exposure data that the Agency has evaluated regarding overhead exposure to the head involved the use of waterproof rain hats or rain jackets with hoods. For this reason, the protective headgear should be described as waterproof headgear and not chemical-resistant headgear. CLA recognizes that chemical-resistant suits are rarely required by the Agency as opposed to coveralls, which are not claimed to be chemical-resistant.

CLA recognizes that these changes will require concurrent changes of label language and in Chapter 10 of the Label Review Manual. Coordinating these changes with revisions to the WPS is the opportune time to correct what has been the inappropriate use of the term "chemical-resistant" where "waterproof" would be more appropriate and not introduce compliance confusion. Therefore, CLA requests that EPA replace the term chemical-resistant with waterproof in Sections 170,207 (b) (6), (8), and (10).

CLA Recommendation

Replacement of Interim Hazard Based PPE and REI Requirements with Risk Based Requirements

The proposed revisions to the WPS are intended to address issues which have arisen in the 20 years since the promulgation of the WPS in 1992. At the time of the development of the WPS in 1992 the Agency established interim requirements for PPE and REI duration based on the acute dermal toxicity, skin and eye irritation of the formulation for the PPE requirements and of the technical grade active ingredient for the REI.

The PPE hazard-based requirements under the 1992 WPS were put in place because many pesticides did not have comprehensive risk assessments at that time. The Agency considered the hazard-based requirement to be temporary pending a comprehensive risk assessment. Specifically, the preamble to the WPS in 1992 stated the following:

“Ideally, each pesticide product label should list specific PPE reflecting the formulation, anticipated exposure level, and toxicity of the product. These determinations are made or are refined as products are registered or reregistered. However, the Agency acknowledges that many pesticide labels require PPE for handlers that are inadequate by the Agency’s present standards. The Agency proposed to establish PPE requirements until appropriate product-specific requirements can be established.”

In the intervening period since 1992, and consistent with the intent of the Agency when the WPS was issued, CropLife believes that the PPE requirements based on the dermal toxicity or “Lethal Dose 50 (LD50) of the formulations are now superseded by the comprehensive risk assessment based on a complete toxicology data set and the best available exposure data. These risk assessments determine the level of clothing/PPE required to provide acceptable margins of exposure and use appropriate toxicity endpoints much more sensitive and relevant than the dermal LD50 – which is the dose at which 50% of the experimental animals die. However because a risk assessment is not conducted for skin or eye irritation, the hazard based requirements would remain unchanged.

In a similar fashion the Agency also considered the hazard-based minimum REIs to be temporary. The 1992 preamble stated the following:

“The REIs established through this final rule are intended to remain in effect until the re-registration process or other comprehensive EPA review process makes definitive REI determinations....The Agency expects to establish appropriate entry restrictions on the basis of several types of data. These may include, as applicable, data on how residue degradation rate and dislodgeability (amount readily transferable from a surface to persons contacting that surface) are influenced by pesticide formulation type; rainfall, dew, and irrigation practices; sunlight; crop type, height, and density; specific production practices, or worker activity and length of exposure.”

Since 1992 the Agricultural Reentry Task Force (ARTF) was incorporated and in response to a data call-in issued on 18 October 1995 developed an extensive data base of dislodgeable foliar residue data and field worker exposure data in multiple crops for multiple farm labor tasks. These data have been evaluated by

the Agency and the FIFRA Science Advisory Panel and have been incorporated into the Health Effects Division Policy 3 for use in conducting product and crop specific post application exposure assessments. As all pesticides have been thoroughly evaluated through pesticide registration, re-registration, or the current re-evaluation processes, CropLife concludes that the revisions to the WPS should address the interim status of minimum REIs based on the acute dermal toxicity of the technical grade active ingredient. As predicted in the 1992 preamble, the risk assessment process has established longer REIs when necessary based on the risk assessments and have also shown where REIs can be reduced to 12 hours from either 24 hours (acute dermal toxicity category II) or 48 hours (acute dermal toxicity category I) based on a product specific risk assessment. As with the PPE, the minimum REI process established by the acute skin or eye irritation of the technical grade active ingredient would remain unchanged.

Section B. Closed Loading Systems

CLA Comments:

Closed Loading Systems are used to dilute pesticide active ingredients (a.i.) with water and/or mix the active ingredient with other ingredients required for the formulation. Closed systems can significantly reduce exposure to pesticides, providing they are used properly, and therefore their use can also reduce the need for personal protective equipment. Because mixing and loading are two of the areas where significant exposure can occur, and to concentrated solutions of the pesticide, EPA should provide guidance which encourages and facilitates the use of these systems. Unfortunately, the revised proposal is far more likely to discourage their use than encourage it and is also unpractical and overly prescriptive. The revisions require changes which are logistically challenging to implement and involve considerable cost and recordkeeping, which could actually discourage their use, which in turn fails to reduce the risk of exposure. The prescriptive requirements could act to prevent best practice, and yet lack of compliance could be used to claim a grower, handler or applicator is in technical violation of the rule. The revisions are process based not result based. EPA is regulating using a one- size- fits- all approach when there is no 'one size', thus the regulatory risk of non-compliance is high even if the violation is irrelevant to exposure. In addition, the emphasis is specific only to liquid formulations and does not address the adequate engineering controls, such as water soluble packaging and lock and load systems, used for dry formulations of pesticide products.

Closed systems can typically be bought either "off the shelf" or custom built. They are usually used by larger operators who require economies and efficiencies of scale. They can be sophisticated, pressurized pieces of equipment and should not be retrofitted for a variety of reasons, yet this is exactly what EPA are requiring if current pieces of equipment are to meet "California Standards". It should be noted that the additional cost of such retrofitting has not been recognized in the overall estimation of the costs.

The Agency is proposing to replace the existing definition of a closed loading system with the definition referenced in a "Director's Memo" issued by CDPR. However, the definition of a closed system in Section 170.5 is not consistent with the specifications of the "Director's Memo" and will create confusion regarding the definition/requirements of a closed loading system. CLA understands the need to improve the definition of a closed loading system to provide better guidance to state regulators and in addition, to

handlers who must determine if the loading system they are using meets the intended standards of exposure reduction. Such a redefinition should be the Agency's responsibility, in collaboration with stakeholders, rather than taking a definition "off the shelf" for convenience. For the record, CLA believes that the CDPR definition is overly complex and will in and of itself raise difficulties for state regulators in determining such specifics as to whether the Pounds per Square Inch (PSI) or pressure is within specifications, or the gallons of water used for rinsing. In addition, the CDPR definition may be too restrictive to address future innovations in loading system technology. The incorporation of the "Director's Memo" creates conflicts within the proposed revisions. Specifically, Section 170.307 (d)(2) (ix) states that commercially produced closed systems or components must be sold with complete instructions implying that systems manufactured by a grower does not require complete operating instructions. Yet, Section 170.307 (d) (3) (i) states written operating instructions for the closed loading system must be available, which implies all systems whether commercially manufactured or not. Therefore, a grower who has a compliant closed loading system must have written operating instructions regardless of its source and regardless of whether the individual who produced such a system would require written instructions to operate a system that the individual constructed and knows how to operate. Furthermore, the definition does not address engineering controls developed for solid formulations such as water soluble packaging.

The intent of the engineering control exemption for reduced PPE is that the closed loading system provides sufficient reduction in exposure to be equivalent to or superior to the protection afforded by any PPE required by the label above long pants and a long sleeved shirt. The definition should therefore be based on the exposure reduction potential. The Agricultural Handler Exposure Task Force (AHETF) is currently conducting mixer/loader exposure studies involving both the transfer of liquid formulations through mechanical devices and the loading of solid formulations packaged in water soluble packages. The Agency has been engaged with AHETF in the development of the protocols for these studies and will be evaluating the completed study reports for eventual use in handler exposure assessments. CLA believes that these studies will provide valuable insight on the reductions in dermal and inhalation exposure compared to open pouring or loading under actual field conditions. This information, which will include detailed descriptions of the loading systems used, will provide the Agency with the information required to develop a definition with examples of acceptable equipment that adequately defines a closed loading system that is supported by realistic exposure data and can provide the flexibility to meet the variability in loading systems while providing sufficient guidance to state regulators. We are surprised that this work by the EPA is not recognized in the proposed standards, and recommend that it does so.

Some practical issues EPA needs to consider in the requirements it has outlined include

- The cost of retrofitting a closed system to meet the requirements
- The additional cost of maintaining a retrofitted system.
- The availability of compatible parts to enable the retrofit to be successful.
- The likelihood that retrofitting will abdicate the warranty and render the unit non-compliant with the manufacturer specifications for a pressurized unit.

- The practicality of stipulating a mixing pressure of only 25 psi when the average pressure required to mix formulations range between 60/80 psi to about 100 psi. Ninety five percent of all mixes need agitation and therefore require a high pressure pump to prevent ingredients settling or clumping.
- The accuracy of the current scales used to mix large loads – current breaks are at 10 lbs. – and the necessity of measuring loads to the nearest ounce (as would be required for a one acre application) when these loads are typically much larger and mixed for much greater acreages. Accuracy should be specified as a ratio i.e. 1:100 or 1:1000 as this is applicable across a wide range of load sizes.
- Failure to recognize existing commercial standards and best practices that are in operation and which work well– such as alternatives to dry break couplers.

Section B: Charge Questions

Are the proposed standards for closed systems reasonable and achievable?

No they are not, and are in general counterproductive to real efforts by employers to improve efficiency and reduce exposure. They are far too prescriptive and demonstrate a lack of familiarity with their use in terms of practical considerations and field experience.

Are the proposed standards for closed systems too specific? If so, please describe what aspects are too specific, why, and how to achieve sufficient protection while reducing the specificity.

170.307 (D)(1)(iv) “... *Measuring devices must be accurately calibrated to the smallest unit in which the material is being weighed or measured.*” This sounds laudable, but in reality while many products are low use rate per acre they are prepared in very large batches or loads (several hundred acres). On this scale an acceptable accuracy is achievable by measuring to the nearest pound or gallon. There are real limitations to the units of measurement with the weighing scale available on the equipment when reasonable ranges are needed. The accuracy standards should be more open and based on the use of the system and the scale of the load, not the individual unit of product. CLA believes that the extreme prescriptive nature of this requirement exceeds what is necessary to protect handlers.

170.307 (D)(1)(v) “ *The movement of pesticide concentrate beyond a pump by positive pressure must not exceed 25 pounds per square inch (psi) of pressure.*”

This is totally unrealistic. Bulk pesticide pumps must have high pressure and volume capability for recirculation of product in the bulk tanks. Obviously these same pumps are used to transfer product out. To limit it back to 25 PSI would require pressure regulators that would in themselves be high maintenance type fittings, and subject to a large learning curve on compatibility with different products. These are the types of things that are very time consuming, and expensive to put in and maintain. Estimated cost of retrofitting a pressure regulator is \$25,000 - \$50,000, initial plus \$10,000 per year additional maintenance. A much more realistic proposal is that the system should be initially tested for 50% over the system pressure, maintained and allowed to be used and recognized as a closed system.

170.307 (D)(1)(vii) “... *Dry break coupler that will minimize pesticide loss...*”

Dry Breaks are nice when they work. They do have similar maintenance and compatibility issues as pressure reducing valves in concentrated formulations. A very practical and widely used current system is air purging of connection fittings and the proposal should recognize existing industry practices that work very well before imposing additional and costly alternatives.

170.307 (D)(1)(viii) t“ *...the maximum container pressure must not exceed five psi.*”

This is far too explicit, and furthermore, cannot be effectively regulated. It is entirely unclear when anyone would actually measure the psi a rinse operation actually gets too. More correct would be that the operation is adequately vented to prevent excessive pressure for the container actually being rinsed.

170.307 (D)(3)(iii) “ *If the system is not commercially produced it must be maintained on a regular basis,*”

This explanation should be included with similar language on (i) and (ii) . Many of these systems are custom made and the recognition that they may be viable if maintained and understood should be throughout the exceptions.

Do data exist on the number of establishments that use closed systems, the number that do not use closed systems because the current standard is not clear, and/or the number of establishments that use closed systems that meet the California criteria?

There is no data of which we are currently aware. Because the specifications for CA systems are so particular to CA, it is most likely almost the only ones that meet the California standards are the ones that are in California. In addition, we do not believe there is merit in the imposition of CA systems, for the reasons previously articulated, precisely because the CA standards require many unrealistic and unsupported requirements.

What would be the cost to convert an existing system that does not meet the proposed standard to one that does?

It would be a big expense, one which is difficult to estimate as it depends on the size, type, age etc. of each system currently in place. It would be a case-by-case consideration. These costs should be factored into the overall costs estimates described by EPA.

The Agency should also consider the credibility of their request: If workers are familiar and competent at using the existing closed system, and as a result are more efficient which results in less exposure, then this change will offer little improvement, and in some instances act against efficiency and safety (such as by including the complex pressure regulation system previous mentioned).

Would people who currently use closed systems that do not meet the proposed standard upgrade their closed system or opt to use the label-required PPE? What information would impact this decision?

The practical real world answer is that if operations have a well put together system that increases efficiency and increases safety, they will continue to use it regardless of the rule. All this really does is increase unrealistic regulatory burdens with no reduction in exposure. The Agency should consider a grandfather clause or careful rewording of this point would be appropriate.

What would be the cost to convert an existing system that does not meet the proposed standard to one that does?

For a mid to large custom application bulk site the estimate is \$25,000 to \$100,000 initial and \$5,000 to \$10,000 per year additional maintenance.

Should EPA consider eliminating any of the criteria listed in the proposal? If so, which criteria and why?

The criteria should be greatly scaled back. The detail in this is counterproductive from a logistical standpoint and from the perspective of offering additional worker protection. There are huge benefits to using closed systems to increase efficiency and reduce exposure, and their use should be encouraged – over complicating the requirements will act as a deterrent to increased adoption of closed systems for loading and handling.

Specific suggestions are as follows:

170.307 (D)(1)(iv) “... Measuring devices must be accurately calibrate to the smallest unit in which the material is being weighed or measured. Should be deleted

170.307 (D)(1)(v) “ The movement of pesticide concentrate beyond a pump by positive pressure must not exceed 25 pounds per square inch (psi) of pressure.” Should be deleted

170.307 (D)(1)(vii) “... Dry break coupler that will minimize pesticide loss to not more than 2 milliliters per disconnect must be installed at the disconnect point” Should be deleted

170.307 (D)(1)(viii) “ ...the maximum container pressure must not exceed five psi” Should be deleted

170.307 (D)(3)(iii) “ If the system is not commercially produced it must be maintained on a regular basis,” This explanation should be included with similar language on (i) and (ii)

What would be the benefits and draw backs of the requirement for the closed system to triple rinse the container? Is the technology available to provide this element at a reasonable cost?

For the larger containers approximately 30 gallons and above closed systems are viable for rinsing, but only if the previous amendments are implemented. Specifying a “triple rinse” indicates a lack of understanding of how these systems work: It is a poor description for many good rinsing operations to specify “triple rinse.” Because many closed systems will remain in a continuous rinse operation until the discharge water is clean. This should be reflected in the language.

Would it be possible for agricultural and handler employers, handlers, and inspectors to measure the closed system's PSI while the system is in use? If it would not be possible, should EPA consider eliminating this element?

It would be possible to measure pressures. However there would be unintended, practical consequences due to difficulty in adding the ports required in order to do so, keeping all the fittings from leaking, and having the compatible pressure gauges that are durable when used under conditions of concentrated chemical service. It is a genuine issue to get all the materials (hoses, pump seals, valves seals, joint seals, etc.) compatible for continuous chemical service. Experience suggests that this will introduce a greater risk of leaks, accidents and exposure incidences than the risk such measures are meant to remove.

In conclusion, CLA recommends that all references to the "Director's Memo" and its specifications be eliminated from the proposed revisions of the WPS. CLA concludes that the proposed Section 170.5 definition is adequate – *Closed system* means a system for mixing or loading pesticides that encloses the pesticide during removal of the pesticide from its original container and transfer, mixing, or loading of the pesticide product, mixtures or dilutions, and any rinse solution, if applicable, into a new container or application equipment, in such a manner that prevents the pesticide and any pesticide mixture or use dilution from contacting handlers or other persons before, during and after the transfer, except for negligible release (and exposure) associated with normal operation of the system. CLA recommends adding the (and exposure) to the definition. This definition, supplemented with examples of representative equipment from the AHETF studies, covers both liquid and solid formulation closed loading systems and provides sufficient guidance for both handlers and state enforcement on what is an adequate closed loading system.

Section C: Contaminated PPE

CLA Comments

Please refer to our previous comments on this topic.

Section D: Eyewear Protection for Open Cockpits

CLA Comments

CLA supports the comments submitted by the National Association of Agricultural Aviators.

Section E. Respirators: Fit testing, Training and Medical Evaluation

CLA Comments:

CLA supports the proper use and fit of protective equipment, including respirators. However we have serious concerns with the practicality and cost of the proposals put forth by EPA in this regard:

The proposed WPS adopts the Occupational Safety and Health Act (OSHA) requirements for respirator use by handlers, i.e., fit test, medical evaluation, and training. The proposal aims to reduce some burdens on growers by eliminating duplicative respirator requirements. The proposal states that it will harmonize the requirements for agricultural employers that may be required to provide a respirator for their employees using pesticides under the WPS with those issued by OSHA for respirator use in agriculture beyond pesticide use in order to reduce the burden on employers to comply with two separate standards.

The proposed WPS states (page 15526, section 170.207 (b)(9)) that “whenever a respirator other than a dust/mist filtering respirator is required by the pesticide product labeling, the handler employer must ensure that the requirements of paragraphs (b)(9)(i) through (iii) of this section are met before the handler performs any pesticide handler activity where the respirator is required to be worn.” Paragraphs (b)(9)(i) through (iii) of the PPE section require (i) fit-testing, (ii) training, and (iii) medical evaluation that conform to the provisions of 29 CFR 1910.134 (OSHA’s respirator standard). However, OSHA’s respirator standard states that “In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable: (i) Procedures for selecting respirators for use in the workplace; (ii) Medical evaluations of employees required to use respirators; (iii) Fit testing procedures for tight-fitting respirators; (iv) Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; (v) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators; (vi) Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators; (vii) Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations; (viii) Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and (ix) Procedures for regularly evaluating the effectiveness of the program.” The proposed WPS is not in line or consistent with the established OSHA standard and certainly does not reduce the burden on growers by eliminating duplicative requirements. This creates confusing and differing requirements.

Under OSHA respirator standard, a dust/mist filtering respirator that is required for the job would fall under all requirements of the standard. The WPS ignores this and eliminates the requirements for this type of respirator. This is the most commonly used respirator type amongst workers exposed to pesticides. This difference does not achieve the EPA’s goal of harmonizing the requirements. Another issue is that the proposed WPS makes no mention of a written respiratory program. This is a major tenet of the OSHA respirator standard. Again, this reflects the lack of harmonization between the proposed WPS and OSHA respirator standard. CLA has significant concerns that by intending to harmonize with the OSHA regulations and citing the OSHA regulations, yet not fully adhering to the OSHA regulations, will create confusion in regards to compliance and enforcement.

The proposed WPS revisions implements training, fit-testing, and medical evaluation of respirator users. Meeting these requirements will not be a simple task for handler employers. Prior to fit testing or using a respirator, employees will have to obtain written medical clearance. A medical evaluation must be performed by a physician or other licensed health care professional (PLHCP) using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire (this

information is listed in Appendix C of 29 CFR 1910.134). The medical evaluation is required initially and then again under certain circumstances such as the employee reports medical signs or symptoms related to the ability to use respirator; PLHCP, program administrator, or supervisor recommends reevaluation; change occurs in workplace conditions that may substantially increase the physiological burden on an employee, etc. The costs associated with a respirator medical evaluation (pulmonary function test, review questionnaire/history) would be in excess of \$100. These costs have not been accounted for in the ICR.

Employers will need to be familiar with the OSHA respirator standard and able to train employees on the proper selection, use, and care of respirators or hire someone capable of conducting the training. They will also need to be trained in how to properly conduct a fit test as described in the OSHA standard. Materials to perform a fit test will need to be purchased. These items can be costly. A quantitative fit test, which provides the most reliable results, involves instrumentation which can cost upwards of \$12,000 (<http://www.tsi.com/portacount-respirator-fit-tester-8038/> TSI Catalog price is \$12,810 (mask adaptor kits can be between \$200-300)). Qualitative fit tests require fewer materials but will still involve the purchase of test materials and equipment such as an Allegro Bitrex Respirator Fit Test Kit (\$240, Grainger) which includes a test hood, nebulizers, sensitivity and fit test solutions. Fit tests will need to be performed annually or whenever there is a change in physical condition that could affect respirator fit including, but not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight. These costs have not been included in the proposed ICR.

General recommendations:

- CLA recommends that EPA eliminate references to harmonization with the OSHA standard in the preamble and WPS.
- We recommend clarifying which respirator type EPA is referring to throughout the document. The term respirator is used throughout the preamble text (which would include dust/mist filtering respirators), however, the proposed rule is only applicable to respirators other than dust/mist filtering respirators. Specific language as to what respirator types are involved in the proposed rule should be used throughout the preamble and rule.

The proposed WPS as currently written is not harmonized with OSHA's respirator standard. This language and insinuation of harmonization creates confusion and potential enforcement actions.

- Thus we recommend adding more specific language to the proposed regulatory text concerning respirator requirements § 170.207(b)(9) of the proposed rule such as:
 - Whenever a respirator other than dust/mist filtering respirator is required by the pesticide product labeling, the handler employer must ensure that the requirements of paragraphs (b)(9)(i) through (iii) of this section are met before the handler performs any pesticide handler activity where this type of respirator is required to be worn.
 - The handler employer must maintain for 2 years, on the establishment, records documenting the completion of the requirements of paragraphs (b)(9)(i) through (iii) of this section.
 - Handler employers must provide handlers with a medical evaluation by a physician or other licensed health care professional prior to the fit test or required use of a respirator. The

- medical evaluation must conform to the provisions of 29 CFR 1910.134(e)-1910.134e(7)(iv) to ensure the handler's physical ability to safely wear the respirator specified on the pesticide product labeling.
- Handler employers must provide handlers with training using a program that conforms to the requirements specified in 29 CFR 1910.134(k)-1910.134(k)(6).
 - Handler employers must provide handlers with fit-testing if a negative or positive pressure tight-fitting facepiece (other than dust/mist filtering respirator) is specified on the pesticide product labeling in a manner that conforms to the provisions of 29 CFR 1910.134(f)-1910.134(f)(8)(iii).
- CLA also proposes that any label requiring a respirator other than a dust/mist filtering respirator must include the above language on the label within a reasonable timeframe after the proposed revisions become in force.
 - CLA would also like to recommend that the text in the proposed rule under § 170.207(b)(7) be modified. A full-face respirator is listed as a type of "protective eyewear" and this may create confusion and other compliance issues if not clarified. The use of a full-face respirator, even if only for eye protection, can reasonably be construed to trigger the requirements for respiratory protection. We propose the following language:
When "protective eyewear" is specified by the pesticide product labeling to be worn, one of the following types of eyewear must be worn:
 - (i) Goggles.
 - (ii) Face shield
 - (iii) Safety glasses with front, brow, and temple protection
 - (iv) Full-face respirator if respiratory protection is required according to pesticide product labeling.

4.13 FRN UNIT XVII: MONITORING HANDLER EXPOSURE TO CHOLINESTERASE INHIBITING PESTICIDES**CLA Comments:**

CLA supports EPA's decision not to establish a national program to monitor handlers of cholinesterase (ChE)-inhibiting pesticides. The most effective approach in which to prevent handler exposure to any pesticide product is to address the potential for exposure in advance of use, proactively, rather than after exposure has taken place. Therefore we agree with EPA that the product-specific risk assessments supporting the registration of pesticide products combined with robust handler training and effective enforcement of label requirements is the best approach that can be taken to mitigate exposure.

FRN Unit XVII: Charge Questions

Do you believe the costs and burdens of a national ChE monitoring program would be justified by the protections to handler health? If so, please provide justification.

The responsibility for any acetylcholinesterase (ChE) monitoring program most appropriately resides with individual states in conjunction with their responsibilities for label enforcement and pesticide handler certification programs. A properly coordinated local approach is preferred as potential exposure is based on regional pesticide use patterns. A nationwide program will be costly, burdensome, and will address exposures only after they occur rather than in advance of exposure.

Although EPA has provided an estimate of potential costs associated with a national ChE monitoring program, this estimate does not take into account additional costs to develop the infrastructure for implementation and continued support. As EPA notes, the requirements of a national program include training, recordkeeping, clinical testing, field investigations and enforcement; and it also requires knowledgeable physicians and qualified laboratories nationwide. EPA's cost estimates do not include state resources that would be necessary to provide the infrastructure and support for ChE monitoring on a national scale. Therefore, further details regarding the implementation, management, and enforcement are required in order to fully assess resource needs and costs associated with the establishment of such a program.

More importantly, a ChE monitoring program should not be used as a substitute for adherence to pesticide labelling and sound handler safety practices. The proposed enhancements of the WPS include aspects pertaining to training, communications, and PPE that are important protective benefits for all pesticide handlers through increased knowledge of exposure risks and prevention strategies, ultimately leading to reductions in potential exposure.

Do you agree that it is more protective to prevent handler exposure than to address it after it occurs? If so, why? If not, do you have an alternative proposal to address handler exposure?

The most effective approach in which to prevent handler exposure to any pesticide product is to address the potential for exposure in advance of use, proactively, rather than after exposure has taken place.

The Food Quality Protection Act of 1996 requires EPA to review periodically the registration of pesticides currently registered in the United States at least every 15 years to ensure that they continue to meet current safety standards based on up-to-date scientific approaches. Pesticides reviewed under the reregistration program meeting scientific and safety standards are declared “eligible” for registration. Where appropriate, measures to reduce exposure to handlers and workers are addressed through pesticide labeling which includes information on application rates, frequency, timing, and restrictions, classification, PPE, REIs, user safety requirements and use directions. EPA’s reregistration (and new substance registration) reviews assess the specific risks associated with particular chemicals and ensures that no unreasonable adverse effects are anticipated.

As noted in the March 19, 2014 Federal Register, ChE-inhibiting pesticides have completed the reregistration process and as a result revised labeling has been included in many cases with requirements for closed systems for mixing and loading, additional PPE, reduced application rates, and number of annual applications permitted. We agree with the Agency that the product-specific risk assessments conducted by EPA combined with robust handler training and effective enforcement of label requirements is the most effective approach to mitigate exposure.

Does other information exist on the benefits or challenges of ChE monitoring that the Agency has not presented in this proposal? If so, please provide.

The following comments are provided regarding two statements in the March 19, 2014 Federal Register Notice:

ChE is described as “*permitting the transmission of signals across the space between the nerves called the synapse.*” It states that “*ChE-inhibiting pesticides block the transmission of these signals, resulting in adverse symptoms.*” However, a more accurate description of ChE and its function is stated in EPA’s Economic Analysis of the Proposed Agricultural Worker Protection Standard Revisions (RIN 2070-AJ22, Docket: EPA-HQ-OPP-2011-0184) where the following text on page 47 is found:

“Cholinesterase (ChE) is an enzyme that breaks down the chemical acetylcholine, which transmits signals across nerve synapses. When cholinesterase is inhibited, overstimulation and exhaustion of nerves, muscles, and glands can occur and result in illness.”

It is noted that tests for ChE depression exist only for organophosphate (OP) and carbamate pesticides. Cholinesterase is a family of enzymes found in plasma, blood and the nervous system and can be measured with a routine clinical chemistry assay. The evaluation of ChE is not specific to ChE-inhibiting pesticides, although depressions in ChE activity may suggest possible exposure to such a substance.

In addition to the concerns noted above regarding implementation, management, and cost, there are two important biological factors that also suggest a national ChE monitoring program is impractical.

First, the proposed rule recognizes that there is no universal normal range for ChE levels because baseline levels vary widely between individuals. In addition to inter-individual variation in ChE levels, ChE levels fluctuate within an individual. It is well known that changes in human physiology can substantially affect

ChE levels. Factors that can impact ChE levels include the timing of meals, stress, physical activity, and changes in body mass. (³⁰PNAS 5512–5517, PNAS, April 13, 2004, Vol. 101, No. 15). Therefore, it is highly important that an individual's baseline level be established prior exposure to ChE-inhibiting pesticides. Given the degree of intra-individual variability, baseline values should ideally be taken on the day of use prior to handling a ChE-inhibiting product. However, the current ChE monitoring programs in the states of Washington and California (discussed in the Federal Registered Notice) recommend baseline values be established annually and every 2 years, respectively. Therefore, comparison of post-exposure ChE values to a single baseline ChE measurement taken every 1 or 2 years does not provide meaningful information concerning the degree of exposure to a ChE-pesticide product.

Second, N-methyl carbamate (NMC) insecticides are a class of ChE-inhibiting pesticides that cause reversible carbamylation of ChE. The carbamylated enzyme undergoes spontaneous hydrolysis resulting in reactivation of ChE activity. The degree of reactivation is rapid occurring within minutes to hours depending on the severity of ChE depression. Therefore, blood ChE levels after use of a NMC insecticide are not informative unless samples are taken and analyzed immediately following use.

These conclude CropLife America's comments on the proposed revisions to the Worker Protection Standards.

The following sections are the Appendices referenced within the text of our comments.

³⁰ Sklan, et. al. 2004. Acetylcholinesterase paraoxonase genotype and expression predict anxiety scores in health, risk factors, exercise training, and genetics study. PNAS 101 (15): 5512-5517.

PART 5: APPENDICES

5.1 APPENDIX 1: REFERENCE LIST FOR CLA COMMENTS, PART 1

Alexander DD, Mink PJ, Adami HO, Chang ET, Cole P, et al. 2007. The non-Hodgkin lymphomas: a review of the epidemiologic literature. *International journal of cancer. Journal international du cancer* 120 Suppl 12: 1-39

Bassil KL, Vakili C, Sanborn M, Cole DC, Kaur JS, Kerr KJ. 2007. Cancer health effects of pesticides: systematic review. *Canadian family physician Medecin de famille canadien* 53: 1704-11

Beane Freeman LE, Bonner MR, Blair A, Hoppin JA, Sandler DP, et al. 2005. Cancer incidence among male pesticide applicators in the Agricultural Health Study cohort exposed to diazinon. *Am J Epidemiol* 162: 1070-9

Burns CJ. 2005. Cancer among pesticide manufacturers and applicators. *Scandinavian journal of work, environment & health* 31 Suppl 1: 9-17; discussion 5-7

Burns CJ, Swaen GM. 2012. Review of 2,4-dichlorophenoxyacetic acid (2,4-D) biomonitoring and epidemiology. *Critical reviews in toxicology* 42: 768-86

Koutros S, Alavanja MC, Lubin JH, Sandler DP, Hoppin JA, et al. 2010. An update of cancer incidence in the Agricultural Health Study. *Journal of occupational and environmental medicine American College of Occupational and Environmental Medicine* 52: 1098-105

Lee WJ, Blair A, Hoppin JA, Lubin JH, Rusiecki JA, et al. 2004. Cancer incidence among pesticide applicators exposed to chlorpyrifos in the Agricultural Health Study. *Journal of the National Cancer Institute* 96: 1781-9

Mink PJ, Adami HO, Trichopoulos D, Britton NL, Mandel JS. 2008. Pesticides and prostate cancer: a review of epidemiologic studies with specific agricultural exposure information. *European journal of cancer prevention : the official journal of the European Cancer Prevention Organisation* 17: 97-110

von Stackelberg K. 2013. A Systematic Review of Carcinogenic Outcomes and Potential Mechanisms from Exposure to 2,4-D and MCPA in the Environment. *Journal of toxicology* 2013: 371610

Waggoner JK, Kullman GJ, Henneberger PK, Umbach DM, Blair A, et al. 2011. Mortality in the agricultural health study, 1993-2007. *Am J Epidemiol* 173: 71-83

Weichenthal S, Moise C, Chan P. 2010. A review of pesticide exposure and cancer incidence in the Agricultural Health Study cohort. *Environmental health perspectives* 118: 1117-25

Bureau of Labor Statistics 2012. TABLE A-1. Fatal occupational injuries by industry and event or exposure, all United States, 2012. <http://www.bls.gov/iif/oshwc/cfoi/cftb0268.pdf>

Bureau of Labor Statistics 2012. TABLE 1. Incidence rates of nonfatal occupational injuries and illnesses by industry and case types, 2012. <http://www.bls.gov/iif/oshwc/osh/os/ostb3581.pdf>

NCIPC (National Center for Injury Prevention and Control) 2014. <http://www.cdc.gov/ncipc/factsheets/drown>

NSC (National Safety Council) 2014. Injury Facts. Itasca, IL.

Tarone RE, Blot WJ, McLaughlin JK. 2004. Nonselective nonaspirin nonsteroidal anti-inflammatory drugs and gastrointestinal bleeding: relative and absolute risk estimates from recent epidemiologic studies. *Am J Ther.* 11: 17-25.

EPA (U.S. Environmental Protection Agency) 2014. SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR). February 19, 2014.

EPA (U.S. Environmental Protection Agency) 2013. SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR). June 14, 2011.

USCA (United States Census of Agriculture) 2012. Census of Agriculture. United States Summary and State Data Volume 1 • Geographic Area Series • Part 51, Tables 41, 51, 68.

5.2 APPENDIX 2:

DESCRIPTION OF THE VARIOUS PROGRAMS FROM WHICH THE ACUTE EXPOSURE AND POISONING DATA WAS DRAWN AND THEIR WEBSITES

The **Bureau of Labor Statistics** reports on illness and fatalities across all industry sectors and across all causes of fatalities, and it provides information on the incidence of fatalities and illness per 10,000 of the population as well as in absolute numbers.

The **National Poison Data System** (NPDS) is a compilation of poison exposure phone calls received by the poison control centers within the United States. These poison control centers serve the 50 US States and the District of Columbia. NIOSH uses NPDS data to track acute work-related pesticide poisonings, and is one of 19 Occupational Health Indicators of which #11 deals with Acute Work-Related Pesticide Poisonings Reported to Poison Control Centers.

The **SENSOR** program enables occupational illness and injury surveillance capacity within state health departments. Under this program, NIOSH provides cooperative agreement funding and technical support to state health departments to conduct surveillance on one or more occupational illnesses or injuries. One of the illnesses supported under SENSOR is acute occupational pesticide-related illness and injury. A total of 12 states participate in the SENSOR-Pesticides program. The SENSOR-supported surveillance systems perform in-depth investigations for case confirmation. However, a national aggregated database is also available. It consists of acute occupational pesticide-related illness and injury cases submitted by the SENSOR-pesticides states in 1998 to 2006. Websites for the SENSOR Pesticides Database:

<http://wwwn.cdc.gov/niosh-survapps/sensor/Search.aspx>

<http://wwwn.cdc.gov/niosh-survapps/sensor/CaseDefinition.pdf>

<http://www.cdc.gov/niosh/topics/pesticides/pdfs/standardizedVariableDocument.pdf>

Finally, since 1971, California law requires physicians to report any known or suspected illness caused by a pesticide exposure. The staff of the **Pesticide Illness Surveillance Program** (PISP) is tasked with collecting and evaluating these reports before they are assigned to county agricultural commissioners to investigate the exposure circumstances. PISP also provides detailed information on the circumstances under which the pesticide poisoning occurred.

5.3 APPENDIX 3 – EXAMPLES OF AGRICULTURAL AND NON AGRICULTURAL EXPOSURES – CASE DESCRIPTIONS

APPENDIX 3: 2011 Examples of Confirmed California Exposure Cases : Agriculture and Non Agriculture related							
Case	Relationship	Days Lost from Work	Days in Hospital	Ag/Non-Ag	Application Site	Medical Description	Narrative Description
1		0	0	Non-Ag	Not Applicable	Eye pain and excessive watering. Exam found injected sclera but no corneal abrasions	A man reached for his eyedrops in the glove compartment of his car. After placing a drop into one of his eyes, he developed symptoms and realized he put ear miticide for cats into his eye by mistake. He sought care and recovered without incident
39	Probable	Unknown	10	Non-Ag	Not Applicable	2 days after exposure, patient was taken for care and admitted to the hospital for 10 days. Dry/cracked/sore lips, tip of tongue blistered and drooling. A scope performed found oral lesions, white plaque and black tissue, periodic rhythmic breathing	A 3-year-old became ill and was hospitalized after ingesting an unknown herbicide containing diquat stored in a gatorade bottle. His dad got the herbicide from a friend, which the child later found and asked the babysitter to give him a drink.
107	Possible	0	0	Non-Ag	Household or Domestic Dwelling	Dizziness and nausea. She did not detect and odor or taste	To save money, a woman had her gardener spray an unknown amount of outdoor termiticide in her attic. She

					(Other or Unspecified)		was away from home for about two weeks and soon after returning she turned on the heat and began feeling ill. She refused to provide contact for the gardener
122	Probable	0	0	Non-Ag	Inanimate Objects	Within minutes of exposure, he felt like his throat was closing up, brief episode of bronchospasm, scratchy throat, some discomfort swallowing. Upon arrival to ER had only mild throat and airway irritation. Symptoms improved after treatment with nebulizer	A man accidentally kicked over a fogger and was sprayed in the face while setting off four foggers in his bathroom to rid of his mattress of bedbugs. He became ill and his wife called 911. Responding firefighters were briefly exposed, but none reported symptoms
191	Probable	Unknown	0	Non-Ag	Ornamental Plants (Other or Unspecified)	She began feeling dizzy at the end of applying the pesticide. Three days later, sought care for fatigue, dry cough, and watering eyes	A woman sprayed 3/4 of an 18 oz bottle of NEEM product to control white flies on an azalea plant. She did not read directions and admitted inhaling "a lot" of spray mist. She developed symptoms while applying, but waited 3 days and sought care.
194	Probable	0	0	Non-Ag	Surfaces (Other or Unspecified)	Coughing, nausea and bad taste in mouth. Doctor noted "mild discomfort" from the exposure.	A 38-year-old woman "got a whiff" of an EPA exempt organic insecticide when a co-worker was spraying "a lot" of the product in the kitchen area of their office. She immediately developed symptoms and sought care.

219	Probable	0	0	Non-Ag	Unknown	Redness, slight burning, itching, numbness, and irritation to fingers	A resident mixed 1/4 of herbicide with water in a container and pumped the sprayer. The sprayer leaked and sprayed one arm. He experience symptoms and sought care. He was not wearing the proper protective measures as listed on the label
221	Possible	0	0	Non-Ag	Not Applicable	Mother washed him head to foot after she realized the exposure. At the ED, his grandmother stated he was rubbing his eyes, indicating irritation, but his mom said on the interview that he had no symptoms. His eyes were irrigated at the ED	A four-year-old sprayed his 18-month-old brother with insecticide when the mother left the room for a moment. He was sprayed from head to food, and enough to wet his hair. Mom said she would now keep products out of reach. Symptoms quickly resolved
290	Probable	Unknown	0	Non-Ag	Dogs	"Swollen" and itchy eye. Dermal edema. Per MD's advice, his eye and affected skin areas were rinsed with water by his father	A 5-year-old boy developed symptoms after hugging the family dog who was treated with insecticide one hour prior to exposure. Fater called MD and symptoms resolved

316	Probable	0	0	Ag	Grapes	Rash and hives. At an unknown time after the exposure, a rash developed over the body. The patient became concerned when the rash reached his hands and face and did not dissipate. He sought care ten days after the incident	As a worker mixed fungicides, a leaky valve caused a hose to break free and soak him. He changed his clothes but did not wash, and continued with the application. He notified his supervisor at the end of the day, and sought care ten days later
383	Probable	0	0	Ag	Grapes	On exposure, burning eyes. He rinsed his eyes out with saline before seeking care. He noted that he did not smell or taste anything. He said his eyes felt irritated and sensitive to the sun for about two days	A worker was spraying a vineyard in an open cab when a vine hit his face knocking his goggles up above his eyes. Spray went into his eyes. He develop symptoms, washed out his eyes and was taken for care
422	Probable	Unknown	0	Non-Ag	Surfaces (Other or Unspecified)	Feeling flushed, sweating, lightheadedness, racing heart, anxiety, chest tightness on inspiration, blurred vision. The effect on vision could have been a direct result of spray in the eye (none noted) or a consequence of cholinesterase inhibition	Spraying the outside of his home, a man used up an insecticide and refilled his sprayer with an old one, undiluted, from his garage. Wind blew the material onto his bare arms and legs. The label required long pants and sleeves, avoiding wind, and 1:256 dilution

448	Probable	Unknown	0	Ag	Not Applicable	A doctor's report noted that the patient complained of stomach ache, dizziness, slight nausea, throat irritation, and red face/chest	While working in the fields, a worker stopped and mixed gatorade powder with water. He drank it and realized the powder was an insecticide. He sought care for his symptoms. The investigator was unable to reach him due to a lack of contact information
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5.4 APPENDIX 4: CASES OF EXPOSURE TO DRIFT (TOTAL = 76) AND THEIR ASSOCIATED INCIDENTS LEADING TO THAT DRIFT INCIDENTS CALIFORNIA PISP DATABASE, 2011 DATA

Year Case Identified	Case Number (a)	County	Relationship (b)	Days Lost from Work (c)	Days Hospitalized (c)	Application Site	Medical description	Narrative description
2011	24	FRESNO	Probable	0	0	Soil	He smelled an odor, then began sweating, having shortness of breath, numbness in hands & arms, and redness in hands. He became anxious, felt worse and was taken for care that evening where he was observed overnight on a gurney in the hallway.	A young applicator inserted fumigant tabs to soil in a pistachio orchard. On the third day he noted a "garlic type" odor and felt ill. On the way to the ED later that evening, an ambulance met and took him for care. He recovered fully after several days.
2011	82	GLENN	Definite	4	0	Almonds	Worsening eye pain, by next morning unable to open eyes. He was examined the day after exposure. Injection was noted in both eyes, and fluorescein uptake covered 80% of the right eye and 40% of the left. One eye (presumably the right) was patched.	A mixer/loader was pouring 25-pound bags of ziram into a nurse tank. When he lifted his goggles to mop sweat, rotor turbulence blew dust into his eyes. He rinsed them with eye wash and finished his shift, but became increasingly uncomfortable.
2011	129	SANTA BARBARA	Probable	0	0	Celery	Took a shower & changed before going for care. Headache, tingling to tongue/lips & facial itching. Cbc, chem and che tests were wnl. On f/u had stomach upset, headache & numb tongue. She	Ref2011-129. See 2011-130 & 131. Three fieldworkers were asked to sit in their cars as a helicopter sprayed an adjacent celery field. Confusion between the farm mgr & crew leader

							stated her pants were very wet; she was not wearing rubber pants.	resulted in the workers weeding in the treated field before rei expiration.
2011	130	SANTA BARBARA	Probable	0	0	Celery	Modest global headache and tingling around the mouth and tongue. She washed exposed skin and changed clothing prior to exam. On follow up, she felt better.	Ref. 2011-129. When the manager realized the women were in the sprayed field, he told them to go home, wash their clothes, and take a shower. They began having symptoms on the way home & called a crew supervisor who took them for care.
2011	131	SANTA BARBARA	Probable	0	0	Celery	Dizziness, headache, nausea, vomited twice. She changed clothes & washed exposed skin before arriving for care. She felt better on follow up exam 3 days post exposure.	2011-131. Ref. 2011-129. The farm labor contracting company was issued violations for allowing the women to enter the field before the label allowed and for sending the women home rather than taking them for care when they suspected pesticide exposure.

2011	178	MONTEREY	Possible	0	0	Strawberries	Weakness, shivering, irritated nose, stomach ache, headache, dizziness, nausea, vomiting, and lip numbness. A neighbor gave her an olive oil and orange juice mix to induce further vomiting.	As a crew leader worked in an organic strawberry field, she felt ill while an application took place in a nearby field. The interview was months after the incident, but wind reports support a possible exposure. No others reported illness, but noted odor.
2011	180	MONTEREY	Definite	0	0	Fruit (Other or Unspecified)	Sweating, dizziness, nausea, vomiting and headache. He vomited once in the ED and doctor noted he was in mild distress.	A trained applicator was drifted on when he sprayed insecticides into the wind that was blowing at 11 mph. He stated he was able to smell an odor through his respirator. He immediately developed symptoms, notified his supervisor and was taken for care.
2011	418	FRESNO	Possible	1	0	Pistachios	Itching and burning of the face. Exam found erythema of the face and around the eyes with no abrasion.	As a man sprayed a pesticide & fertilizer mix from a tractor, he felt spray mist & began feeling facial irritation. After the application he felt sunburned, then saw in a mirror that his face was red with a bumpy rash. He called his boss and sought care.

2011	428	KERN	Possible	0	0	Oranges	Coughing, irritated throat, mucosal burning, and difficulty breathing. 2 weeks later: difficulty breathing, irritation, and chest pains. He said that the pulmonary specialist who saw him 2 weeks from the exposure diagnosed him with pleurisy.	A security guard developed symptoms while patrolling the ranch premises during a pesticide application half a mile away. He sought care but his symptoms persisted two weeks after exposure. The farm supervisor had informed him of the application.
2011	438	SANTA BARBARA	Possible	0	0	Lettuce	Headache, dry mouth, nausea, dizziness, and irritation of eye, nose, and throat, shortness of breath. "vomited in the field." felt better when she left the field.	An hour after a lettuce transplanting crew, and a tractor operation crew began work, this worker reported feeling ill. Workers saw a helicopter 1000 ft. Away. A supervisor was sent to check out what was being sprayed. See cases 2011-438-444.
2011	440	SANTA BARBARA	Possible	0	0	Lettuce	Headache, nausea, vomiting, irritated nose and throat, and dry mouth. She felt better around noontime at the doctor's office	Ref. 2011-438. Of the 16 workers interviewed, 3 other transplanters who worked on the other side of the field noted odors, but did not develop symptoms. 3 machine operators were sent for precautionary care.

2011	441	SANTA BARBARA	Possible	0	0	Lettuce	Headache, nausea, and upset stomach. She complained of illness while a field manager was talking to 3 ill co-workers in a car. At the doctor's office, the only symptom was headache.	Ref. 2011-438. On interview, the applicator said he sprayed south in a west to east direction. Both crews were north, more than 1/2 mile away, and there was a raised road between the application sites and the fieldworkers.
2011	442	SANTA BARBARA	Possible	0	0	Lettuce	Nausea, headache, dry mouth, "swollen eyes, and tearing." felt better while waiting at the doctor's office.	Ref. 2011-438. The pilot sprayed close to the ground. He said the helicopter could only be seen during turnarounds. After a field supervisor asked what was sprayed, both applicator, & a mix/loader decided to leave & finish treating when crews have gone.
2011	471	MONTEREY	Probable	Unknown	0	Unknown	Slight irritation to eyes, itching and burning sensation to eyes and nose. Areas washed 7 hours later. Upon examination, doctor observed eye redness with no corneal involvement and area of contact on face has minor redness with no peeling or blistering.	A fieldworker was spraying exempt herbicide & mist drifted above his safety glasses & dripped onto his nose & cheeks, & into his eyes. He developed symptoms & sought care. He could not be contacted for interview. Information was provided by supervisors.

2011	554	MONTEREY	Probable	0	0	Strawberries	Headache, dizziness, chest tightness, difficulty breathing, burning sensation in eyes, weakness and nausea. Most of the symptoms began to resolve in the ed. Headache and nausea continued for 3 to 4 days post exposure.	21-mon-12. A strawberry harvesting crew reported smelling an odor from a pesticide being applied to an adjacent block on the same farm. 7 workers developed symptoms. 1 worker was taken to ED. See 2011-1469-1472 and 2012-534-537.
2011	605	STANISLAUS	Probable	0	0	Not Applicable	Dizziness, lightheadedness. Oxygen saturation 94% and bp was elevated - patient has history of hypertension.	A man had symptoms and sought care after he found and opened a container of rodenticide pellets leftover from a harvesting business he operated 20 years ago. He lives on 6 acres of alfalfa, but no longer operates the land or holds an applicator license.
2011	632	MONTEREY	Probable	1	0	Leafy/Stem Vegetables (Other or Unspecified)	Stomach ache, headache, dizziness, tachycardia and vomiting. He informed his supervisor and was taken to ED.	43-mon-11. Fieldworkers harvesting cauliflower smelled an odor when pesticides drifted from an application made to an adjacent farm. 7 workers developed symptoms. 1 worker was taken to ED and 1 declined to go to ED. See 2011-828-832, 1467-1468.

2011	678	IMPERIAL	Possible	0	0	Alfalfa	Itchy nose.	5-imp-11. A crew of lettuce harvesters smelled a strong odor, apparently from an aerial application nearly a mile away. Foliage samples demonstrated presence of the aerially applied pesticides, which had not been used on the lettuce. See 2011-679 to 700.
2011	680	IMPERIAL	Probable	0	0	Alfalfa	Headache, upset stomach.	5-imp-11. See 2011-678. The episode was reported anonymously via a legal assistance organization. At least two crew members expressed concern about retaliation.
2011	682	IMPERIAL	Probable	0	0	Alfalfa	Vomiting.	5-imp-11. See 2011-678. The aerial applicator applied the same pesticides to two fields, both upwind of the lettuce field. He treated the nearer field after the lettuce harvesters had left. Consequently, drift is certain but human exposure is not proved.
2011	685	IMPERIAL	Possible	0	0	Alfalfa	Eye irritation.	5-imp-11. See 2011-678. Tests found less malathion between the 2 treated fields than in the lettuce field. This suggests the second field, treated after the

								harvesters left, may have been the major source of the contamination found in the lettuce field.
2011	686	IMPERIAL	Probable	0	0	Alfalfa	Upset stomach.	5-imp-11. See 2011-678. The foreman said he removed the crew from the field for about fifteen minutes when they complained about the odor. He said he offered to take the crew to the hospital, but they all refused. They all resumed work.
2011	691	IMPERIAL	Probable	0	0	Alfalfa	Throat irritation.	5-imp-11. See 2011-678. The field supervisor tried to contact the aerial applicator, but the application ended as he arrived. He estimated the distance between the fields as half a mile. The investigator found it to be 0.85 miles.
2011	692	IMPERIAL	Probable	0	0	Alfalfa	Throat irritation.	5-imp-11. See 2011-678.
2011	693	IMPERIAL	Probable	0	0	Alfalfa	Headache, stomach ache.	5-ind-11. See 2011-678.
2011	694	IMPERIAL	Probable	0	0	Alfalfa	Eye and throat irritation.	5-imp-11. See 2011-678.
2011	696	IMPERIAL	Possible	0	0	Alfalfa	Difficulty breathing.	5-imp-11. See 2011-678.
2011	697	IMPERIAL	Probable	0	0	Alfalfa	Nausea.	5-imp-11. See 2011-678.
2011	698	IMPERIAL	Probable	0	0	Alfalfa	Difficulty breathing, eye irritation.	5-imp-11. See 2011-678.

2011	699	IMPERIAL	Probable	0	0	Alfalfa	Upset stomach, vomiting, throat irritation.	5-imp-11. See 2011-678.
2011	700	IMPERIAL	Possible	0	0	Alfalfa	Runny nose.	5-imp-11. See 2011-678.
2011	706	NAPA	Probable	0	0	Grapes	Coughing, skin irritation, nausea and dizziness. Vomited once in vineyard and once in the ed. Stated her clothes were not previously used for field work. Decontaminated upon arrival in ED.	Ref. 2011-705. Field supervisor did not relocate the crew after seeing the tractors. Spray supervisor said the applicators were in the wrong block. A few of the workers stated they smelled an odor and 1 said she saw some spray coming out of the block.
2011	724	MONTEREY	Probable	0	0	Celery	Shortness of breath, chest pain, dizzy, headache, nausea, vomiting. Decontaminated at clinic and then transferred to ED for further evaluation. Doctors observed normal respiratory rate with no distress.	39-mon-11. Shortly after arriving on the field to weed strawberries, 22 field workers saw a helicopter spraying a nearby field. 14 smelled an odor, 6 experienced symptoms and 3 were taken for care. See 2011-725, 726, 780, 781, 1465, 1466, 1473-1487.
2011	725	MONTEREY	Probable	0	0	Celery	Lightheaded, dizzy, nausea, cough, short of breath and headache. Decontaminated at clinic and then transferred to ER for further evaluation. Doctors observed normal respiratory rate with no distress.	39-mon-11. Ref 2011-724. The field workers were 228 ft south of application site & began to experience symptoms 2 hours after smelling the odor. The applicator stated he noticed the field workers in the strawberry field at the end of his application.

2011	726	MONTEREY	Probable	0	0	Celery	Eye irritation, headache, dizziness, dry mouth, nausea and vomiting. ?The odor burned the inside of my nose?. Decontaminated at clinic and then transferred to er for further evaluation. Doctors observed normal respiratory rate with no distress.	39-mon-11. Ref 2011-724. Some of the field workers described the odor as ?insecticide spray raid?, ?Dust in the garden?, ?Light rotten odor?, ?Anti-microbial soap?, ?Fertilizer? & ?Mint-like?. 8 field workers said they could not describe the odor.
2011	780	MONTEREY	Probable	0	0	Celery	Headache that resolved within a couple of hours. He did not inform his supervisor.	39-mon-11. Ref 2011-724. The field workers were immediately relocated to another site after notifying their supervisors of the odor. This worker stated he did not smell an odor.
2011	781	MONTEREY	Probable	0	0	Celery	Nausea that resolved within 30 minutes and he did not notify supervisor.	39-mon-11. Ref 2011-724. Wind was blowing at 3.4-3.6 mph in a ssw to nne direction at time of application, according to gis. However, some field workers and the applicator said the wind was blowing towards the strawberry field during the application.
2011	812	KERN	Possible	0	0	Corn	Muscle ache, burning sensation in nose, shortness of breath, sore throat, dizziness, nausea, feverish. Noted in e.d: fever, and positive strep test. He was referred to a	Aware of upcoming applications, a worker quickly checked pumps & moved to check irrigation in other fields. A helicopter sprayed ? Mile away as he drove an

							medical provider for tonsillitis.	open cab. He noted an odor, got ill that night, went to work ill next day & was taken for care.
2011	828	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Lightheadedness that quickly resolved. She did not inform her supervisor of her symptom.	43-mon-11. Ref 2011-0632. The odor was described as ?rubber?, ?Strong chemical?, ?Burnt oil?, `fuel, ?soap?, and ?manure?. Application site was 1000 ft north of fieldworkers. The cauliflower field was last sprayed with pesticide 21 days prior exposure.
2011	829	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Stomach ache. Resolved within several hours.	43-mon-11. Ref 2011-0632. The workers were removed from the field and they returned to same field 1 hour later where a ?slight odor? Was still noticeable. This worker did not report his symptom to his supervisor.
2011	830	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Dizziness that resolved within a few hours. She informed her supervisor but declined medical attention.	43-mon-11. Ref 2011-0632. The applicator stopped spraying bensulide after notified of odor but continued to spray dicloran. That day wind blew nnw to sse at speed 11.6?13.7 mph.

								Dicloran label states not to apply when wind speeds are greater than 10 mph.
2011	831	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Slight headache. Resolved within a few hours.	43-mon-11. Ref 2011-0632. None of the field workers reported to see or feel any drift. They did not see any posting of pesticide application for that day. This worker did not report his symptom to his supervisor.
2011	832	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Nausea that lasted for 30 minutes. She did not report her symptoms to her supervisor.	43-mon-11. Ref 2013-0632. The investigator was not able to obtain foliage samples as exact location of the field workers was not provided until 5 days post exposure. At which time the cauliflower had been harvested and field plowed.
2011	886	MERCED	Possible	0	0	Corn	Burning eyes, difficulty breathing which lasted for about 3.5 hours.	47-mer-11. Two families live near a corn field. One on the eastside, and another on the northside of the field. This mother from the eastside family was indoors when she noted an odor. See 2011-

								887-893, and 2011- 1445-1447.
2011	887	MERCED	Possible	Unknown	0	Corn	Burning eyes, and difficulty breathing.	47-mer-11. Ref. 2011-886. She thought there was a spill on their porch. She opened windows & turned on the fans. The windows were about 12 feet from the corn field.
2011	888	MERCED	Possible	0	0	Corn	Difficulty breathing	47-mer-11. Ref. 2011-886. The 5 members of the eastside family, and a daughter?s friend were either inside or outside their home during the application. They all developed symptoms, but did not seek care.
2011	889	MERCED	Possible	Unknown	0	Corn	Burning eyes, and difficulty breathing	47-mer-11. Ref. 2011-886. The northside family were indoors, and could taste & smell an odor. They sealed doors with duct tape to keep the odor out. The father (2011-892) went outside & saw an application ? Mile away. Their home is 50 ft to the north.
2011	890	MERCED	Possible	0	0	Corn	Burning eyes, and difficulty breathing.	47-mer-11. Ref. 2011-886. All 5 members of the northside family

								developed symptoms, but did not seek care.
2011	891	MERCED	Possible	Unknown	0	Corn	Burning eyes, and difficulty breathing.	47-mer-11. See ref. 2011-886.
2011	892	MERCED	Possible	0	0	Corn	Burning eyes, burning and blotchy skin, headache, and difficulty breathing.	47-mer-11. Ref. 2011-886. This father from the northside family spoke to the applicator who told him that all laws were followed in regard to the spraying.
2011	893	MERCED	Possible	Unknown	0	Corn	Burning eyes, burning and blotchy skin, headache, and difficulty breathing.	47-mer-11. Ref. 2011-886. Three days later, the pco told investigators wind was blowing east to west during application. The applicator said the wind speed was below 3 mph, and confirmed that a man from the northside came to speak with him.
2011	992	RIVERSIDE	Possible	2	0	Citrus (Other or Unspecified)	Chest pain, shortness of breath. She was asymptomatic in the emergency room. On examination 1 hour later, a doctor noted normal findings and noted no evidence of toxicity.	While spraying, a worker removed her dust mask, inhaled herbicide & felt ill. She was taken for care. 4 months later, she said she was trained but did not mention taking off her PPE at work. The employer had no written medical evaluation & PPE program.

2011	1013	FRESNO	Definite	0	0	Tomatoes	<p>Bilateral rash on arms, burning eyes, sore throat, dry mouth, and headache. Exam found positive macular papular lesions and breathing sounds decreased and tight. Cholinesterase tests run, though no inhibitors were involved - within normal limits.</p>	<p>53-fre-11. On a hot afternoon, six fieldworkers and a supervisor were weeding a honeydew melon field when they noticed a large tractor spraying in a neighboring tomato field. Winds drifted pesticides onto them. See 2011-1014 to 1015 & 2011-1442 to 1444.</p>
2011	1014	FRESNO	Definite	0	0	Tomatoes	<p>Headache, dizziness, nausea, vomiting, shortness of breath, rash on torso. Reported no sensation of itching or eye burning. Exam found positive macular, papular rash to torso and decreased breath sounds.</p>	<p>53-fre-11. Ref 2011-1013. Five workers smelled spray and at least one felt mist on his face. A number of workers mentioned symptoms & concerns about the spray to a supervisor. The crew was moved across the field, but was not offered medical care.</p>
2011	1015	FRESNO	Definite	0	0	Tomatoes	<p>Headache, burning in both eyes, and rash on bilateral arms and chest. Eyes were irrigated and exam found macular, papular lesions to chest and arms.</p>	<p>53-fre-11. Ref 2011-1013. The next day, a worker called the farm labor office & reported her symptoms. She was notified that all would be taken for care. The supervisor, who told investigators he was not in charge, had no symptoms & was not examined.</p>

2011	1017	SANTA BARBARA	Possible	0	0	Uncultivated Agricultural Areas (Other or Unspecified)	Nausea, vomiting, and headache.	57-sb-11. An hour after a flc crew began harvesting, 3 workers experienced symptoms at the same time & were taken for care. 2 others initially reported no symptoms but on interview said they felt ill. See cases 2011-1018-1019, 1489-1490 and 2012-45 & 46.
2011	1018	SANTA BARBARA	Possible	0	0	Uncultivated Agricultural Areas (Other or Unspecified)	Nausea, headache, and burning eyes. She said it smelled like burning oil.	57-sb-11. See 2011-1017. The crew saw an idling diesel truck 40 feet away, & thought an odor was coming from it. They later saw a tractor applying herbicide on a field about 200 feet southwest. There was also farm equipment being painted 65 feet away.
2011	1019	SANTA BARBARA	Possible	0	0	Uncultivated Agricultural Areas (Other or Unspecified)	Nausea, headache	57-sb-11. See 2011-1017. The crew was later moved out & taken to a grower?s office 1/2 mile away from the treated site. A grower said he smelled an odor, & had symptoms that easily went away. 2 others interviewed noted odors but had no symptoms.

2011	1061	SAN LUIS OBISPO	Possible	0	0	Celery	Per medical document: felt dizzy, lightheaded, and nauseated. Vomited. Vital signs were within normal limits. This worker was not interviewed but the labor contractor's investigation report also indicated "she felt itching on her skin."	Two fieldworkers of a crew of nine had symptoms and were taken for care when the broccoli field in which they were working was allegedly oversprayed by a helicopter application to an adjacent celery crop. See 2011-1062.
2011	1062	SAN LUIS OBISPO	Possible	0	0	Celery	Per medical document: felt dizzy, lightheaded, and nauseated. On interview, said she could smell and feel the pesticides, then began to "feel sick", had irritated eyes and a dry mouth.	Ref 2011-1061. A foreman saw the application taking place ~1/4 mile away. He moved the crew, & asked if everyone was okay. One additional worker felt ill but refused care. Reports of wind conditions conflicted among applicator, weather center, and crew.
2011	1151	SISKIYOU	Possible	Unknown	0	Soil	Itchy eyes, nausea and difficulty breathing. In the ed, shortness of breath observed & wheezing heard on lung exam. He told md he inhaled some pesticide as he was downwind of application site & also a chronic smoker. No other workers reported symptoms.	A forklift operator working 470ft outside of an application area developed symptoms same day and sought care 7 days post-exposure. His supervisor said he had called in sick several days prior. Investigator was unable to contact him for interview.

2011	1170	MADERA	Probable	Unknown	0	Not Applicable	Wheezing, difficulty breathing, nausea, vomiting. In the ED., the doctor noted expiratory wheezes, and o2 sat of 99%.	A worker went to ED after inhaling aluminum phosphide. 5 days later, he stressed that he was not applying, only moving a container into storage, but the med records say otherwise. The farm was cited previously for applying without notification.
2011	1297	FRESNO	Probable	0	0	Pistachios	Dizziness, throbbing headache, coughing, neck pain, sweating, blurry vision, and eye irritation.	A worker applying herbicide for 2 hrs felt ill & was taken for care. The wind blew some spray on him. He wore appropriate ppe & applied according to label directions. A training sheet did not show his signature. He could not be reached for an interview.
2011	1312	MONTEREY	Probable	0	0	Lettuce	Mild burning sensation on hands and face immediately after contact. He proceeded to wash hands & face with soap & water to stop the skin irritation. His symptoms resolved by the time he arrived in the ED & was observed to be asymptomatic by doctor.	2 strawberry farm workers were sprayed with fungicide from an aerial application made to an adjacent farm. 1 developed symptoms & both sought care. Samples taken from this worker & the strawberry field were positive for the fungicide. See 2012-153.

2011	1442	FRESNO	Definite	0	0	Tomatoes	Headaches, dizziness, burning eyes, nausea, vomiting, rashes on arms, and general malaise. Exam noted a lot of watering of the eyes and obvious discharge in the back of the throat. Eye exam was within normal limits.	53-fre-11. Ref 2011-1013. A representative from the farm labor company retrieved msds from the tomato farm. The workers were situated directly south of the application. The mixer/loader and applicator said they never saw them, but did notice a work van.
2011	1443	FRESNO	Definite	0	0	Tomatoes	Slight headache. Cough. Exam found slight redness of mucosal membranes of nose and throat. Some discharge in throat.	53-fre-11. Ref 2011-1013. Weather data confirmed that winds may have drifted the pesticide. Four samples of foliage taken from the site of exposure and one from the application site all detected the pesticides sprayed in the adjacent field.
2011	1444	FRESNO	Definite	0	0	Tomatoes	Headache, rash on wrist and abdomen that had diminished by the time of exam a day later. Reported having no pain at time of exam.	53-fre-11. Ref 2011-1013. Searches of pesticide use reports for neighboring applications found no other source for the drift. Several violations were revealed in the investigative process, both involving the applicator and labor contractor.

2011	1445	MERCED	Possible	Unknown	0	Corn	Burning eyes, burning and blotchy skin, headache, and difficulty breathing.	47-mer-11. Ref. 2011-886. The investigators took swab samples 3 days later. They noted that the label directions were followed during application, but cited the PCO for failure to submit a pesticide use report within 7 days of application.
2011	1446	MERCED	Possible	0	0	Corn	Burning eyes, burning and blotchy skin, headache, and difficulty breathing.	47-mer-11. See ref. 2011-886
2011	1447	MERCED	Possible	Unknown	0	Corn	Burning eyes, burning and blotchy skin, headache, and difficulty breathing.	47-mer-11. See ref 2011-886.
2011	1465	MONTEREY	Probable	0	0	Celery	Stomach ache that resolved within a few hours and she did not inform supervisor.	39-mon-11. Ref 2011-724. Samples taken by investigators day after exposure did not show insecticide residue on the strawberry field. Residue was detected on samples taken from the application site, and field between application site and strawberry field.
2011	1466	MONTEREY	Possible	0	0	Celery	No symptoms in the morning but felt dizzy later in the day. She thought symptom could possibly be due to her medication. She did not inform her supervisor.	39-mon-11. Ref 2011-724. No insecticide residue was detected on clothing samples collected at the clinic from workers who were taken for care. This worker did not state if she smelled an odor.

2011	1467	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Eye irritation. Symptom resolved by evening after applying over-the-counter eye drops.	43-mon-11. Ref 2013-0632. This worker did not report his symptom to his supervisor. The adjacent farm was cited for not following label instructions and failing to submit pesticide use report by the 10th day of the following month after application.
2011	1468	MONTEREY	Probable	0	0	Leafy/Stem Vegetables (Other or Unspecified)	Headache that resolved by evening.	43-mon-11. Ref 2011-0632. This worker did not report her symptom to her supervisor.
2011	1471	MONTEREY	Probable	0	0	Strawberries	Headache that resolved shortly after application stopped. He did not inform his supervisor of symptom and he did not seek care.	21-mon-12. Ref 2011-554. The fieldworkers were moved to another block on the farm. They resumed working after the application was stopped and tractors removed from the field. This worker described odor as ?paint thinner.?
2011	1472	MONTEREY	Probable	0	0	Strawberries	Headache that resolved shortly after application stopped. He informed his supervisor of symptom but did not seek care.	21-mon-12. Ref 2011-554. The applicators stated they posted warning signs but did not give verbal notification to the fieldworkers. The pesticide has a 48 hour re-entry period. This worker described odor as ?burnt gasoline.?

5.5 APPENDIX 5: GREENHOUSE STATISTICS

Greenhouses represent some of the most intensive and productive use of land area in agriculture. The ability to control photo-periods, temperature and other environmental factors, allows for the production of multiple crop cycles each year. To gain perspective on the most current data regarding greenhouse posting, an examination of the publicly available historical information is useful. The U.S. Census of Agriculture for the years 2007 and 2012 indicates that the total farms with protected areas (e.g., greenhouse) under glass or plastic in the US was 22,994, and 28,147, respectively (Table 1). It is important to recognize that these figures include neither mushroom houses nor nurseries which are routinely treated with pesticides year round. The only exemption from the posting requirement under the WPS in greenhouses is for operations where the only workers are the greenhouse owners and their immediate family members. Because of the complexity of greenhouse operation, only the smallest sized operations are likely to not have any employees. Table 1 below provides the figures for greenhouse farms by crop type.

Table 1: Summary of Number of Farms with Greenhouses and Crop Types^a

Crop Type	Farms with Greenhouses in the U.S. by Year	
	2007	2012
Fruits and berries	249	673
Vegetables	4,075	8,750
Floriculture	18,670	18,724
Total	22,994	28,147

^a From USCA (2012)

It appears that there was a significant increase (22%) in total greenhouse farms in the U.S. based on the most recent (2012) census, yet EPA (2014) is assuming substantially less time and cost to post these greenhouses under WPS compared to previously approved ICRs. These figures draw into question the statement by EPA (2014) that “Based on USDA, NASS data there are 394,658 agricultural establishments that hire labor, and 304,348 that hire labor and use pesticides (303,829 farms and 519 greenhouses).” EPA’s greenhouse count must be an error given the number of farms with one or more greenhouse(s) on each farm even taking into account that WPS applies only for greenhouses that hire labor and use pesticides. There are very few commercial greenhouses that do not use pesticides given monoculture crop production, high foliage density, ideal temperature and extended photoperiod. Vegetables, fruits and cut flowers routinely require pesticide applications including fungicides and insecticides. Thus, perhaps these farms listed in Table 1 predominately employ only family members and are therefore exempt from WPS notice of application requirements. However, EPA provides no basis for such an assumption, and in fact in the most recently approved ICR for the current WPS program (EPA, 2013) EPA assumed 11,350 greenhouses. Therefore to propose in 2014 that there are only 519 greenhouses to which

WPS applies would seem both inconsistent and implausible. Moreover, out of 52,777 farms categorized as greenhouse, nursery and floriculture production (USCA, 2012; Table 51), there were 7,922 to 25,432 farms with contract labor expenditures (depending on whether one uses data from Table 68 page 180 or 192 of USCA, 2012) suggesting they were not family.

Additionally, the statistics for square footage suggest that about half of the fruit and vegetable farms have more than 10,000 square feet under glass or plastic requiring a substantial work force. Further if one assumes the average size greenhouse is 10,000 square feet, there are more than 10,600 greenhouses dedicated to just fruits and vegetables, and with 18,724 farms involved in floriculture with 873,290,590 square feet under glass, there are many more greenhouses associated with producing flowers, potted plants and foliage. Again assuming an average greenhouse for floriculture is 10,000 square feet would yield over 87,000 greenhouses. Additionally, any type of commercial plant care requires extensive hand labor (i.e., in flowers bud pinching, training and in vegetables thinning) and generic care (watering, fertilizing and harvesting) can occur year round, and frequently requires reentry at a minimum of every other day; therefore the majority of pesticide applications will likely require posting.

Posting will be required several times each growing cycle, with 2 or more cycles per year common in many vegetable and flower crops. "Agency assumes that an average of 20 pesticide applications per year will be made" in greenhouses (EPA, 2014). However EPA (2014) assumes that only 16 of those applications will require posting, but "greenhouses of all sizes are assumed to each have 4 decontamination posters". Even "small" operations have multiple greenhouses that may not be adjacent to one another, and each treated house must be posted at every point of entry individually. The signs must be visible from all reasonably expected points of worker entry to the treated area, including each aisle or walking route that enters the treated area. The time EPA (2014) allocated for posting a greenhouse (20 minutes per posting) may, depending on the size of the greenhouse facility, underestimate the time needed to gather the materials required (posters, adhesives, indelible pen, etc.), fill in dates of restricted entry, walk from the office to the greenhouse to post the signs and subsequently remove them at the termination of the REI.

The 2012 Ag Census makes clear that there were a total of 9,423 *farms* with greenhouses, not just 9,423 greenhouses involved in fruit and vegetable production with another 18,724 *farms* involved in floriculture. If the total number of farms with greenhouse is applied in the burden calculation, assuming that there is only one greenhouse per farm requiring posting, rather than 519, at the assumed 20 minutes per posting the time to post would be at least $(28,147 \times 16 \times 0.33)$ or 150,117 hours rather than 2,768 hours $(519 \times 16 \times 0.33)$. Assuming the wage rate applied in the proposed ICR (\$28.21), the cost for greenhouse posting would be at least \$4,244,800 rather than \$78,058. Given the significant difference in burden estimates and the fact EPA only last year assumed 11,350 greenhouse facilities in the recently approved WPS ICR, EPA needs to re-examine the basis for its greenhouse number and either explain how it arrived at a total greenhouse number of 519 or, if 519 is an error, provide a new greenhouse number with the assumptions made to arrive at the new number.

5.6 APPENDIX 6:

Chronic Benefits section references to the Economic Analysis of the EPA proposed WPS (WPS) organized by chronic health area. The Brief Description and the Citations are provided by EPA. Brief Comments are provided by CLA.

Note: Statistically significant at $p < 0.05$ means that 1 of 20 analyses will be statistically significant. The Agricultural Health Study (AHS) queried 50 pesticides from their questionnaire. That means that any given publication will be expected to show 2 – 3 pesticides are associated with cancer, by chance alone. This doesn't include additional analyses by gender, location, applicator type, and exposure level, for example.

Section	Brief Description (From EPA)	Citation	Brief Comments
	General Epidemiological Research		
6.6	There are several ongoing cohort studies in the US and abroad, analyses within these cohorts suggest plausible hypotheses to link pesticide exposure to chronic health effects.	Kristensen <i>et al.</i> , 1996	Data linkage of Norwegian subjects (born 1925 – 1971) and ag census (1969 – 1989), this paper includes linkage with incident cancer (1969 – 1991). Note the study reported <u>lower rates of overall cancer</u> in farmers
6.6		Nordby <i>et al.</i> , 2005	Data linkage of Norwegian subjects (born 1925 – 1971) and ag census (1969 – 1989), this paper focuses on fungicide use on potatoes (presumed mancozeb). The authors reported a moderate association of mancozeb exposure and a type of birth defect but <u>no association</u> with thyroid cancer.
6.6		Lebailly <i>et al.</i> , 2006	This abstract describes the enrollment via questionnaire of recruitment of more than 50,000 French farmers and farm workers. No results are reported.
6.6		Yoo <i>et al.</i> , 2002	Description of Korean Multi-center cancer Cohort (KMCC), underway since 1993. This does not have an agricultural focus. No results are reported.
6.6		Leon , <i>et al.</i> , 2011	AGRICOH is a consortium of agricultural cohort studies involving 22 cohorts from 9 countries. No results are reported.
6.6	This study shows that pesticide misuse does occur among pesticide applicators.	Bell <i>et al.</i> , 2006	The AHS has several publications on participants who answered “yes” to the question, “ <i>did you have any incidents with fertilizers, herbicides, or other pesticides that caused you an unusually high personal exposure?</i> ” Bell et al., note that the rate of HPEE (High pesticide exposure events) was 8.8/1000 applicators. Only 13% of the applicators sought medical care. Whether this is an indication of under-reporting in the poison control systems is unclear since perception of exposure may vary widely among AHS participants.

6.6.1	There is a wide range of literature demonstrating statistical associations between pesticide exposure and cancer, with biological plausibility illustrated in experimental toxicology studies. The IARC has only identified 2 classes of pesticide to be human carcinogens (arsenical insecticides and those with dioxin contaminants) but classifies non-arsenical pesticides as probably human carcinogens.	WHO IARC, 1999	In 1999 the IARC evaluated cancer and pesticides as a group. Available for review were several case control and cohort studies. Conclusion was “ <i>limited evidence</i> ” that occupational exposures in spraying and application of non-arsenical insecticides entail a carcinogenic risk. The definition of “ <i>limited evidence</i> ” for IARC is as follows: <i>A positive association has been observed between exposure to the agent, mixture or exposure circumstance and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence</i>
6.6.1	Review articles and meta-analyses indicate evidence of an association between various pesticide exposure and lymphohematopoietic cancers (non-Hodgkin’s lymphoma (NHL) and leukemia specifically); among solid tumors (brain and prostate cancers); and some evidence of pediatric cancer risk on association with either in utero exposure or parental pesticide occupation exposure.	Bassil <i>et al.</i> , 2007;	This is a published summary of the highly controversial 2004 review by the Ontario College of Family Physicians. A number of stakeholders, including the Canada PMRA released statements about the weaknesses of the review, not the least of which was an arbitrary study inclusion criterion, and excluding all industry funded publications.
6.6.1	This section is just a listing of some reviews (and one study of pesticides and cancer)	Blair and Beane-Freeman 2009;	The authors summarize the findings of several meta-analyses of cancer and farmers from the 1990’s. They point out the different patterns in farmer applicators and farmworkers, which suggest that pesticides <i>per se</i> are not the sole explanation. They conclude that there are a wide range of exposures possible in agriculture and that future studies should focus on identifying specific exposures.
6.6.1		Koutros <i>et al.</i> , 2010a;	An overall cancer analysis of the AHS participants (applicators and spouses). Note the study reported <u>lower rates of overall cancer</u> in farmers. Of the 39 cancer sites evaluated in Table 2 (for private applicators, commercial applicators, and spouses), prostate cancer and ovary cancer were the only sites statistically higher than the general population.
6.6.1		Van Maele <i>et al.</i> , 2011,	Review and meta-analysis of studies of home use pesticides and childhood leukemia (similar to Turner 2010). The authors concluded an increased risk based on 13 case-control studies but were cautionary about causality and pesticides.
6.6.1		Wigle <i>et al.</i> , 2009,	Companion review of Turner (2010) with focus on parental occupational pesticide exposure and leukemia in children. The association was stronger with maternal exposure than for paternal exposure. Recommended improved exposure indices and continued research on childhood leukemia initiation and progression.
6.6.1		Turner <i>et al.</i> , 2010,	Review and meta-analysis of studies of home use pesticides and childhood leukemia (similar to Van Maele-Fabry 2011). The authors reported positive associations from 15 studies but were cautionary about self-reported exposure data.

6.6.1		Alavanja and Bonner, 2012	Narrative review of pesticides and cancer, with focus on IARC. See next.
6.6.1		Alavanja et al., 2013	Very similar to Alavanja 2012. The authors “strongly suggest that the public health problem is real.” A letter to the editor commented on this review with perspective of EPA assessment, mechanism of toxicity and societal value of pesticides. (Gray et al., 2013)
6.6.1	Example: Lung Cancer	Alavanja et al., 2004	Example of an AHS study on lung cancer. Evaluating AHS applicators with lung cancer, the authors identified only 4 of 50 pesticides evaluated to be associated with lung cancer. Overall, lung cancer incidence was much lower than the population as a whole.
6.6.1	Example: Colon Cancer	Lee et al., 2007	Example of an AHS study on colorectal cancer. Evaluating AHS applicators with colon or rectal cancer, the authors identified only 2 of 50 pesticides evaluated to be associated with colorectal cancer increase. 2,4-D was significantly related to a deficit.
6.6.1	Example: Pancreatic Cancer	Andreotti et al., 2009	Example of an AHS study on pancreatic cancer. Evaluating AHS applicators with pancreatic cancer, the authors identified only 2 pesticides to be associated with pancreatic cancer.
	Lymphohematopoietic Cancers (LHP)		
6.6.1	Over time, evidence of a link between pesticide exposure and blood cancers has increased. Since the 1980's several studies have shown a link between pesticide exposure and lymphohematopoietic cancers.	Zahm and Ward, 1998	Zahm and Ward is a review of epidemiology studies of children and pesticides. The authors recommend improved exposure assessment, evaluation of risk by age at exposure and possible genetic-environment interaction. Note this is > 15 years old and a better reference is the updated review (Infante-Rivard and Weichenthal, 2007). Note: A similar un-cited review by Daniels et al. (1997) was less decisive and concluded that the etiologic relationship was “far from proven”
6.6.1		DICH et al., 1997	This is a review of the epidemiology studies of cancers in adults and pesticides and concludes that “few , if any, of these association can be considered established and causal.” Note this is > 15 years old.
6.6.1	LHP cancers increased coincident with pesticide use increase (1973 – 1990)	Hardell et al., 2003	This Swedish commentary correlates time trends in <u>declining</u> uses of certain pesticides and <u>leveling</u> rates of cancer.
6.6.1	The biological mechanisms are uncertain but some investigators have implicated chromosomal translocation.	Chiu and Blair 2009	The authors speculate that a specific translocation might contribute to development of NHL. However, another study found no increased risk with the t(14;18) subtype (Schroeder et al., 2001)

6.6.1	The AHS found higher incident rates for multiple myeloma and lymphoma among applicators.	Koutros , <i>et al.</i> (2010a)	The EPA writes that the AHS reported “ <i>higher incidence rates for multiple myeloma (MM) and lymphoma.</i> ” Note that higher incidence rates in MM were observed in private applicators from North Carolina, but not commercial or private applicators from Iowa.
6.6.1	A Swedish study reported NHL rates higher among herbicide users, and specifically for glyphosate users.	Eriksson <i>et al.</i> , 2008	The EPA uses this as an example of a increased risk for glyphosate. Of note, this study did <i>not</i> show an increased risk for 2,4-D use. This study is an example where citing a few studies, and not pesticide specific literature reviews can introduce bias.
6.6.1	A review reported 14 of 16 papers were positive for leukemia and pesticides. Not all were statistically significant. Some of the studies were of parents using insecticides on the home/garden and from mothers exposed while pregnant. The authors reported 23 of 27 studies found an association (not all statistically significant) of NHL and pesticides. Elevated risks were found over several classes of pesticides.	Bassil <i>et al.</i> (2007)	This is a published summary of the highly controversial 2004 review by the Ontario College of Family Physicians. A number of stakeholders, including the Canada PMRA released statements about the weaknesses of the review, not the least of which was an arbitrary study inclusion criterion, and excluding all industry funded publications.
6.6.1	A review of studies of occupational pesticides exposure and leukemia in the children. No evidence found between leukemia and all parents’ occupation exposure. The report an association of mother’s exposure and child leukemia	Wigle <i>et al.</i> (2008)	This review concluded an association of maternal occupational pesticide exposure and childhood leukemia, but no association with paternal exposure.
	Prostate Cancer		
6.6.1	Farmers are healthier than the overall population but farmers have an increased risk of prostate cancer which may be explained by pesticide exposure, or possibly by other farm- or non-farm related exposures.	Blair <i>et al.</i> , 2005	The AHS reported 48 deaths due to prostate cancer (second only to lung cancer in number) for a significant reduced risk (SMR = 0.7, 95% CI 0.5 – 0.8). The difference in mortality (reduced) and incidence (increased) is puzzling and could be related stage at diagnosis (see Koutros <i>et al.</i> , next).
6.6.1	Farmers have a roughly 20% increased risk of prostate cancer	Koutros <i>et al.</i> , 2010a	Private and commercial applicators in the AHS have about 20% higher incidence (new cases) of prostate cancer
6.6.1	AHS analyses suggest several OPs related to prostate cancer but only among men with a family history of prostate cancer.	Alavanja <i>et al.</i> , 2003	Evaluating AHS men with prostate cancer, the authors found associations with a few pesticides AND a family history of prostate cancer but not among those with no family history. Note a recent analysis identified that only 4 out of 48 pesticides

			evaluated were associated with prostate cancer risk, of which only fonofos was suggested in the 2003 analysis (Koutros et al., 2013).
6.6.1	Additional follow up within the AHS cohort corroborates this initial finding (see above).	Mahajan <i>et al.</i> , 2006	Evaluating AHS men who used fonofos, the authors reported the associations as reported in Alavanja (2003) and Koutros (2013), note in the same AHS participants.
6.6.1		Mahajan <i>et al.</i> , 2007	Evaluating AHS men who used carbaryl, the authors reported that “carbaryl was not associated with cancer risk overall.” With respect to prostate cancer the authors reported a nonsignificant “trend of <u>decreasing</u> prostate cancer risk with increasing level of exposure.”
6.6.1		Christensen <i>et al.</i> , 2010	Evaluating AHS men who used coumaphos, “ <i>coumaphos was not associated with any cancer</i> ”. The association with coumaphos and prostate cancer in men with a family history of disease was not confirmed in the AHS analysis by Koutros et al., (2013)
6.6.1	The association of prostate cancer with certain pesticide exposure varies by family history of prostate cancer. Genetic variation may explain this.	Koutros <i>et al.</i> , 2010b	The authors observed an interaction among variants on chromosome 8q24, pesticide use and risk of prostate cancer. Of the 49 pesticides evaluated, the strongest association was reported for fonofos use.
6.6.1	Prostate cancer risk has been found among farmworkers	Mills and Yang (2003)	This study of farmworkers is based on union records and pesticide use reports to link workers with applications for presumed exposure. Risk was not associated with patterns of employment. The specific pesticides associated with prostate cancer are different than those suggested in the AHS (Koutros et al., 2010a). This study is another example where citing a few studies, and not pesticide specific literature reviews can introduce bias.
6.6.1	The AHS investigated aggressive prostate cancer and pesticide exposure. This work supports previous analyses (link of specific OPs) and extends an understanding since aggressive form of the disease may have a difference set of causal factors than slow-growing tumors.	Koutros <i>et al.</i> 2012	Evaluating AHS men with prostate cancer, the authors have updated the analysis by Alavanja et al., (2003) with additional years of follow up, more than 350 new prostate cancer cases, and additional interview information. As noted above, only 4 of 48 pesticides evaluated were found to be associated with prostate cancer. Ironically if pesticides led to more aggressive forms of cancer, prostate cancer mortality would be higher (but as shown by Blair et al., (2005), mortality rates in the AHS are lower than the general population.
	Lung Cancer		
6.6.1	There have been studies on the link between pesticide exposure and lung cancer. Alavanja et al. (2004), reported a positive association	Alavanja <i>et al.</i> (2004)	Evaluating AHS applicators with lung cancer, the authors identified only 4 of 50 pesticides evaluated to be associated with lung cancer. Overall, lung cancer incidence was much lower than the population as a whole.

6.6.1	between four pesticides and pesticide exposure among the AHS cohort. In this study, exposure to these pesticides was associated with lung cancer risk in the cohort, despite the fact that, in general the lung cancer risk for the cohort is lower than the population as a whole. Other studies have also shown an association between pesticides and lung cancer in the AHS cohort (Beane-Freeman et al., 2005; Lee et al., 2004).	Beane - Freeman <i>et al.</i> , 2005	Evaluating AHS applicators who used diazinon, the authors identified increase risk for lung cancer (as also identified in the lung cancer paper by Alavanja et al., (2004)).
6.6.1		Lee <i>et al.</i> , 2004	Evaluating AHS applicators who used chlorpyrifos, the authors identified increase risk for lung cancer (as also identified in the lung cancer paper by Alavanja et al., (2004)).
6.6.2	Non-cancer Neurological Effects		
6.6.2	The AHS reported a positive association of PD in those who reported ever using pesticides and a “strong association” with PD for those who personally applied pesticides.	Kamel <i>et al.</i> , (2007),	Evaluating AHS applicators with self reported Parkinson’s disease (PD) at the start of study (prevalent cases) and at follow-up (incident cases), the authors identified mixed results for prevalent and incident cases. Although the EPA writes there was a “strong association” with PD for applicators who personally applied pesticides, the odds ratio of 1.9 was not statistically significant (95% CI: 0.7 – 4.7):
6.6.2	The updated AHS study using physician-diagnosed cases of PD reported a 2.5 fold increase odds of PD in participants used either paraquat or rotenone.	Tanner <i>et al.</i> , 2011	Evaluating AHS applicators with physician diagnosed PD, the authors focused on 15 pesticides, for which only paraquat and rotenone were significantly associated with PD.
6.6.2	A review study of non-cancer and pesticides reported a positive association in 15 of 26 studies reviewed. The authors found 39 of 41 studies displayed a positive increase in one or more neurological abnormality in association with pesticide exposure.	Sanborn <i>et al.</i> (2007)	The EPA highlights this review reported a relationship of PD and pesticide exposure in 15 of 26 studies. Note: The non cancer aspect of Bassil et al., (2007), this is a published summary of the highly controversial 2004 review by the Ontario College of Family Physicians. A number of stakeholders, including the Canada PMRA released statements about the weaknesses of the review, not the least of which was an arbitrary study inclusion criterion, and excluding all industry funded publications.
6.6.2	Residues of OPs were found in a substantial portion of agricultural workers’ homes. A significant correlation was observed between urinary metabolite eves and house dust levels. Poor performance on 5 neurobehavioral tests was associated with higher levels of metabolites. This demonstrates the take-home pathway of pesticide exposure and the need for better home hygiene practices.	Rothlein <i>et al.</i> , (2006)	The authors found a statistically significant association of pesticide metabolite in urine and household dust. Better home hygiene practices were suggested.

6.6.2	Three recent studies investigated the relationship between prenatal exposure to OP pesticides and neurological effects in children through the age of 7 years.	Rauh <i>et al.</i> , 2011	These three studies evaluated prenatal exposure to organophosphate pesticides and subsequent IQ scores at ages 6–9 years. Note: These data were based upon spot samples of blood or urine at delivery and IQ scores many years later. Comments on specific pesticides were reviewed in Burns <i>et al.</i> , (2013).
6.6.2		Engel <i>et al.</i> , 2011	
6.6.2		Bouchard <i>et al.</i> , 2011	
6.6.2	A recent study reviews the possible relationship between adult occupational exposure to pesticide and adverse neurological symptoms.	Rohlman <i>et al.</i> , 2011	This is a review paper, not a study, of neurobehavior and occupational exposure to organophosphates.
Respiratory Function			
6.6.2	The authors reported an association between pesticide exposure and asthma in farm women, despite the fact that growing up on a farm reduced the likelihood of asthma attacks. This study focuses on the spouses of pesticide applicators and may show an important effect from generalized agricultural pesticide exposure to families and farmworkers, rather than exposure as a pesticide applicator.	Hoppin <i>et al.</i> , (2008)	Evaluating all AHS women, the authors compared women with self reported asthma to women without asthma. Several specific pesticides were associated with atopic asthma, but not nonatopic asthma.
6.6.2	As association was reported for childhood asthma and a range of risk factors, including pesticides and other farm exposures.	Salam <i>et al.</i> , (2004)	The authors compared school children with asthma to their classmates. A range of risk factors reported in a telephone interview (exposure to smoke, herbicides, pesticides <i>assume to be limited to insecticides</i> , farm crops, farm dust, or farm animals) were related to childhood asthma.
6.6.2	An international study also reports a relationship between exposure and respiratory symptoms.	Salameh <i>et al.</i> , 2003	Lebanese school children were studied. A questionnaire was completed by their parent. Respiratory symptoms and risk factors were evaluated. Some broad pesticide indicators were significantly associated with symptoms.
6.6.2	The authors report a significant association between 11 pesticides and chronic bronchitis.	Hoppin <i>et al.</i> (2007)	This AHS study of the applicators reported a statistically significant associated between eleven pesticides and chronic bronchitis.
Page 206: The EPA summarizes: <i>“Overall, epidemiological or human study data do not suggest a clear cause-effect relation between specific pesticide exposure and certain chronic health outcomes. However, the totality of national and international research efforts and initial research results in conjunction with plausible hypotheses, taken together, suggest that pesticide exposure may result in chronic adverse health effects beyond those mitigated as a result of chemical-specific label requirements and standards”</i>			

	Benefit Calculations		
	General Considerations		
6.8	Epidemiological research is particularly difficult when the subjects are farmworkers and their families. Relative to other studies of the effects of occupational exposure to chemicals, studies based on farmworkers are more difficult because it is harder to estimate exposure to specific pesticides, because they were not applied by the worker, and may not have been applied by the handler (page 208)	Zahm <i>et al.</i> , 2001	
6.8	Estimate that 10 – 15% of lung cancer is in non-smokers (page 211)	Zahm and Blair 1993	
6.8	Page 217 – EPA uses SIR of 1.14 for prostate cancer to apply 14% excess prostate cancer in farmworkers.	Thun <i>et al.</i> , 2008	“The incidence of lung cancer among lifelong nonsmokers falls within the National Cancer Institute’s (NCI) definition of a “rare” cancer (fewer than 40,000 cases per year, age standardized incidence rate 15 per 100,000).”
6.8	Page 218 – EPA uses SIR of 1.17 for NHL to apply 17% excess NHL in farmworkers	Alavanja <i>et al.</i> , 2003	The AHS observed 566 incident prostate cancers “between enrollment and December 31, 1999. Based on age-adjusted state incidence rates, 494.5 prostate cancer cases were expected, yielding a standardized incidence ratio of 1.14 (95 percent confidence interval (CI): 1.05, 1.24).”
6.8	Page 218 – EPA uses rate ratio of 1.46 for asthma to apply 46% excess of asthma cases in farmworkers.	Koutros <i>et al.</i> , 2010a	The 1.17 used is the <u>relative</u> SIR. Note the <u>observed</u> SIR were 0.95 (IA) and 1.06 (NC) applicators, not associated. Since there was a deficit of all cancers, the authors calculated a ratio of the SIR for each site to the SIR of all cancer sites. This assumes “that the factors responsible for the observed deficit of all cancers apply across the individual cancer sites in the absence of applicator related factors.”
6.8	Page 218 – EPA uses Meta analysis (incorrectly cited as from the AHS) of 1.62 for PD to apply 62% excess PD (31.5 cases per 100,000 farmworkers compared to 19.5 per 100,00 in the general population) in farmworkers.	Hoppin <i>et al.</i> , 2008	“Any use of pesticides on the farm was associated only with atopic asthma (OR, 1.46; 95% CI, 1.14–1.87). Note: Women who grew up on farms and did not apply pesticides had the lowest overall risk of atopic asthma (OR, 0.41;95% CI, 0.27–0.62) compared with women who neither grew up on farms nor applied pesticides.
6.8	Page 218 – EPA uses 60% higher prevalence of chronic bronchitis in non-smoking farm women in the AHS.	van der Mark <i>et al.</i> (2011)	“Thirty-nine case–control studies, four cohort studies, and three cross-sectional studies were identified. An sRR of 1.62 [95% confidence interval (CI): 1.40, 1.88] for pesticide exposure (ever vs. never) was found.”
6.8	Page 218 – EPA uses 60% higher prevalence of chronic bronchitis in non-smoking farm women in the AHS.	Valcin <i>et al.</i> , (2007)	“Women who used three or more agricultural pesticides in addition to the most commonly used pesticides (glyphosate, 2,4-D, malathion, diazinon, carbaryl) had an increased risk of chronic bronchitis, OR= 1.58 (95% CI= 1.19, 2.09);” <u>Note:</u>

			“those who used fewer agricultural pesticides showed no elevated risk. There was no association between overall use of pesticides and chronic bronchitis.”
6.8	Page 218 – EPA uses odds ratio of 1.83 for chronic bronchitis for AHS with a high pesticides exposure event.	Hoppin <i>et al.</i> (2007)	“Increased prevalence for chronic bronchitis was also seen for individuals who had a history of a high pesticide exposure event (OR=1.85, 95% CI=1.51, 2.25)”

SIR: Standardized Incidence Ratio.

Full Reference list For Appendix 6

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APPENDIX 7: SAMPLE of an OSHA Safety Data Sheet (MSDS or SDS)



OSHA3514.pdf

DRAFT

OSHA[®] BRIEF

Hazard Communication Standard: Safety Data Sheets

The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) (formerly MSDSs or Material Safety Data Sheets) for each hazardous chemical to downstream users to communicate information on these hazards. The information contained in the SDS is largely the same as the MSDS, except now the SDSs are required to be presented in a consistent user-friendly, 16-section format. This brief provides guidance to help workers who handle hazardous chemicals to become familiar with the format and understand the contents of the SDSs.

The SDS includes information such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The information contained in the SDS must be in English (although it may be in other languages as well). In addition, OSHA requires that SDS preparers provide specific minimum information as detailed in Appendix D of 29 CFR 1910.1200. The SDS preparers may also include additional information in various section(s).

Sections 1 through 8 contain general information about the chemical, identification, hazards, composition, safe handling practices, and emergency control measures (e.g., fire fighting). This information should be helpful to those that need to get the information quickly. Sections 9 through 11 and 16 contain other technical and scientific information, such as physical and chemical properties, stability and reactivity information, toxicological information, exposure control information, and other information including the date of preparation or last revision. The SDS must also state that no applicable information was found when the preparer does not find relevant information for any required element.

The SDS must also contain Sections 12 through 15, to be consistent with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS), but OSHA will not enforce the content of these sections because they concern matters handled by other agencies.

A description of all 16 sections of the SDS, along with their contents, is presented below:

Section 1: Identification

This section identifies the chemical on the SDS as well as the recommended uses. It also provides the essential contact information of the supplier. The required information consists of:

- Product identifier used on the label and any other common names or synonyms by which the substance is known.
- Name, address, phone number of the manufacturer, importer, or other responsible party, and emergency phone number.
- Recommended use of the chemical (e.g., a brief description of what it actually does, such as flame retardant) and any restrictions on use (including recommendations given by the supplier).

Section 2: Hazard(s) Identification

This section identifies the hazards of the chemical presented on the SDS and the appropriate warning information associated with those hazards. The required information consists of:

- The hazard classification of the chemical (e.g., flammable liquid, category¹).
- Signal word.
- Hazard statement(s).
- Pictograms (the pictograms or hazard symbols may be presented as graphical reproductions of the symbols in black and white or be a description of the name of the symbol (e.g., skull and crossbones, flame).
- Precautionary statement(s).
- Description of any hazards not otherwise classified.
- For a mixture that contains an ingredient(s) with unknown toxicity, a statement describing how much (percentage) of the mixture consists of ingredient(s) with unknown acute toxicity. Please note that this is a total percentage of the mixture and not tied to the individual ingredient(s).

Section 3: Composition/Information on Ingredients

This section identifies the ingredient(s) contained in the product indicated on the SDS, including impurities and stabilizing additives. This section includes information on substances, mixtures, and all chemicals where a trade secret is claimed. The required information consists of:

Substances

- Chemical name.
- Common name and synonyms.
- Chemical Abstracts Service (CAS) number and other unique identifiers.
- Impurities and stabilizing additives, which are themselves classified and which contribute to the classification of the chemical.

Mixtures

- Same information required for substances.
- The chemical name and concentration (i.e., exact percentage) of all ingredients which are classified as health hazards and are:
 - Present above their cut-off/concentration limits or
 - Present a health risk below the cut-off/concentration limits.
- The concentration (exact percentages) of each ingredient must be specified except concentration ranges may be used in the following situations:
 - A trade secret claim is made,
 - There is batch-to-batch variation, or
 - The SDS is used for a group of substantially similar mixtures.

Chemicals where a trade secret is claimed

- A statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.

Section 4: First-Aid Measures

This section describes the initial care that should be given by untrained responders to an individual who has been exposed to the chemical. The required information consists of:

- Necessary first-aid instructions by relevant routes of exposure (inhalation, skin and eye contact, and ingestion).
- Description of the most important symptoms or effects, and any symptoms that are acute or delayed.
- Recommendations for immediate medical care and special treatment needed, when necessary.

Section 5: Fire-Fighting Measures

This section provides recommendations for fighting a fire caused by the chemical. The required information consists of:

- Recommendations of suitable extinguishing equipment, and information about extinguishing equipment that is not appropriate for a particular situation.
- Advice on specific hazards that develop from the chemical during the fire, such as any hazardous combustion products created when the chemical burns.
- Recommendations on special protective equipment or precautions for firefighters.

Section 6: Accidental Release Measures

This section provides recommendations on the appropriate response to spills, leaks, or releases, including containment and cleanup practices to prevent or minimize exposure to people, properties, or the environment. It may also include recommendations distinguishing between responses for large and small spills where the spill volume has a significant impact on the hazard. The required information may consist of recommendations for:

- Use of personal precautions (such as removal of ignition sources or providing sufficient ventilation) and protective equipment to prevent the contamination of skin, eyes, and clothing.
- Emergency procedures, including instructions for evacuations, consulting experts when needed, and appropriate protective clothing.
- Methods and materials used for containment (e.g., covering the drains and capping procedures).
- Cleanup procedures (e.g., appropriate techniques for neutralization, decontamination, cleaning or vacuuming; adsorbent materials; and/or equipment required for containment/clean up).

Section 7: Handling and Storage

This section provides guidance on the safe handling practices and conditions for safe storage of chemicals. The required information consists of:

- Precautions for safe handling, including recommendations for handling incompatible chemicals, minimizing the release of the chemical into the environment, and providing advice on general hygiene practices (e.g., eating, drinking, and smoking in work areas is prohibited).
- Recommendations on the conditions for safe storage, including any incompatibilities. Provide advice on specific storage requirements (e.g., ventilation requirements).

Section 8: Exposure Controls/Personal Protection

This section indicates the exposure limits, engineering controls, and personal protective measures that can be used to minimize worker exposure. The required information consists of:

- OSHA Permissible Exposure Limits (PELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.
- Appropriate engineering controls (e.g., use local exhaust ventilation, or use only in an enclosed system).
- Recommendations for personal protective measures to prevent illness or injury from exposure to chemicals, such as personal protective equipment (PPE) (e.g., appropriate types of eye, face, skin or respiratory protection needed based on hazards and potential exposure).
- Any special requirements for PPE, protective clothing or respirators (e.g., type of glove material, such as PVC or nitrile rubber gloves; and breakthrough time of the glove material).

Section 9: Physical and Chemical Properties

This section identifies physical and chemical properties associated with the substance or mixture. The minimum required information consists of:

- Appearance (physical state, color, etc.);
- Odor;
- Odor threshold;
- pH;
- Melting point/freezing point;
- Initial boiling point and boiling range;
- Flash point;
- Evaporation rate;
- Flammability (solid, gas);
- Upper/lower flammability or explosive limits;
- Vapor pressure;
- Vapor density;
- Relative density;
- Solubility(ies);
- Partition coefficient: n-octanol/water;
- Auto-ignition temperature;
- Decomposition temperature; and
- Viscosity.

The SDS may not contain every item on the above list because information may not be relevant or is not available. When this occurs, a notation to that effect must be made for that chemical property. Manufacturers may also add other relevant properties, such as the dust deflagration index (Kst) for combustible dust, used to evaluate a dust's explosive potential.

Section 10: Stability and Reactivity

This section describes the reactivity hazards of the chemical and the chemical stability information. This section is broken into three parts: reactivity, chemical stability, and other. The required information consists of:

Reactivity

- Description of the specific test data for the chemical(s). This data can be for a class or family of the chemical if such data adequately represent the anticipated hazard of the chemical(s), where available.

Chemical stability

- Indication of whether the chemical is stable or unstable under normal ambient temperature and conditions while in storage and being handled.
- Description of any stabilizers that may be needed to maintain chemical stability.
- Indication of any safety issues that may arise should the product change in physical appearance.

Other

- Indication of the possibility of hazardous reactions, including a statement whether the chemical will react or polymerize, which could release excess pressure or heat, or create other hazardous conditions. Also, a description of the conditions under which hazardous reactions may occur.
- List of all conditions that should be avoided (e.g., static discharge, shock, vibrations, or environmental conditions that may lead to hazardous conditions).
- List of all classes of incompatible materials (e.g., classes of chemicals or specific substances) with which the chemical could react to produce a hazardous situation.
- List of any known or anticipated hazardous decomposition products that could be produced because of use, storage, or heating. (Hazardous combustion products should also be included in Section 5 (Fire-Fighting Measures) of the SDS.)

DRAFT

Section 11: Toxicological Information

This section identifies toxicological and health effects information or indicates that such data are not available. The required information consists of:

- Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact). The SDS should indicate if the information is unknown.
- Description of the delayed, immediate, or chronic effects from short- and long-term exposure.
- The numerical measures of toxicity (e.g., acute toxicity estimates such as the LD50 (median lethal dose)) - the estimated amount [of a substance] expected to kill 50% of test animals in a single dose.
- Description of the symptoms. This description includes the symptoms associated with exposure to the chemical including symptoms from the lowest to the most severe exposure.
- Indication of whether the chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions) or found to be a potential carcinogen by OSHA.

Section 12: Ecological Information (non-mandatory)

This section provides information to evaluate the environmental impact of the chemical(s) if it were released to the environment. The information may include:

- Data from toxicity tests performed on aquatic and/or terrestrial organisms, where available (e.g., acute or chronic aquatic toxicity data for fish, algae, crustaceans, and other plants; toxicity data on birds, bees, plants).
- Whether there is a potential for the chemical to persist and degrade in the environment either through biodegradation or other processes, such as oxidation or hydrolysis.
- Results of tests of bioaccumulation potential, making reference to the octanol-water partition coefficient (K_{ow}) and the bioconcentration factor (BCF), where available.
- The potential for a substance to move from the soil to the groundwater (indicate results from adsorption studies or leaching studies).
- Other adverse effects (e.g., environmental fate, ozone layer depletion potential, photochemical ozone creation potential, endocrine disrupting potential, and/or global warming potential).

DR

Section 13: Disposal Considerations (non-mandatory)

This section provides guidance on proper disposal practices, recycling or reclamation of the chemical(s) or its container, and safe handling practices. To minimize exposure, this section should also refer the reader to Section 8 (Exposure Controls/Personal Protection) of the SDS. The information may include:

- Description of appropriate disposal containers to use.
- Recommendations of appropriate disposal methods to employ.
- Description of the physical and chemical properties that may affect disposal activities.
- Language discouraging sewage disposal.
- Any special precautions for landfills or incineration activities.

Section 14: Transport Information (non-mandatory)

This section provides guidance on classification information for shipping and transporting of hazardous chemical(s) by road, air, rail, or sea. The information may include:

- UN number (i.e., four-figure identification number of the substance)².
- UN proper shipping name².
- Transport hazard class(es)².
- Packing group number, if applicable, based on the degree of hazard².
- Environmental hazards (e.g., identify if it is a marine pollutant according to the International Maritime Dangerous Goods Code (IMDG Code)).
- Guidance on transport in bulk (according to Annex II of MARPOL 73/78³ and the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (International Bulk Chemical Code (IBC Code))).
- Any special precautions which an employee should be aware of or needs to comply with, in connection with transport or conveyance either within or outside their premises (indicate when information is not available).

² Found in the most recent edition of the United Nations Recommendations on the Transport of Dangerous Goods.

³ MARPOL 73/78 means the International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto, as amended.

Section 15: Regulatory Information (non-mandatory)

This section identifies the safety, health, and environmental regulations specific for the product that is not indicated anywhere else on the SDS. The information may include:

- Any national and/or regional regulatory information of the chemical or mixtures (including any OSHA, Department of Transportation, Environmental Protection Agency, or Consumer Product Safety Commission regulations).

Section 16: Other Information

This section indicates when the SDS was prepared or when the last known revision was made. The SDS may also state where the changes have been made to the previous version. You may wish to contact the supplier for an explanation of the changes. Other useful information also may be included here.

Employer Responsibilities

Employers must ensure that the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. This may be done in many ways. For example, employers may keep the SDSs in a binder or on computers as long as the employees have immediate access to the information without leaving their work area when needed and a back-up is available for rapid access to the SDS in the case of a power outage or other emergency. Furthermore, employers may want to designate a person(s) responsible for obtaining and maintaining the SDSs. If the employer does not have an SDS, the employer or designated person(s) should contact the manufacturer to obtain one.

References

OSHA, 29 CFR 1910.1200(g) and Appendix D.
United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), third revised edition, United Nations, 2009.
These references and other information related to the revised Hazard Communication

Standard can be found on OSHA's Hazard Communication Safety and Health Topics page, located at:
<http://www.osha.gov/dsg/hazcom/index.html>.

Disclaimer: This brief provides a general overview of the safety data sheet requirements in the Hazard Communication Standard (see 29 CFR 1910.1200(g) and Appendix D of 29 CFR 1910.1200). It does not alter or determine compliance responsibilities in the standard or the Occupational Safety and Health Act of 1970. Since interpretations and enforcement policy may change over time, the reader should consult current OSHA interpretations and decisions by the Occupational Safety and Health Review Commission and the courts for additional guidance on OSHA compliance requirements. Please note that states with OSHA-approved state plans may have additional requirements for chemical safety data sheets, outside of those outlined above. For more information on those standards, please visit:
<http://www.osha.gov/dcsp/osp/statestandards.html>.

This is one in a series of informational briefs highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; teletypewriter (TTY) number: (877) 889-5627.

For assistance, contact us. We can help. It's confidential.



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**Analysis of the Information Collection Requirements for Agricultural
Workers Protection Standards**

August 6, 2014

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Executive Summary

CropLife America (CropLife) has engaged Summit Consulting, LLC (Summit) to analyze the assumptions underlying the estimate of information collection burden as described in the Information Collection Request (ICR) for the proposed updates to the Agricultural Worker Protection Standards published by the Environmental Protection Agency on February 19, 2014. This analysis was conducted for the purpose of supplementing CropLife's response to the ICR as part of the public comment period.

The major findings of this analysis are as follows:

- **Discrepancies in Cost of Increased Burden:** The proposed update to the WPS include increased recordkeeping, training, and posting requirements, which represent an overall increase in burden hours to approximately four-and-a half times that of the existing 2011 WPS, based on EPA estimates. However, due to differences in how wage rates are calculated across the two ICRs, the dollar estimate of the burden less than doubles between the 2011 WPS ICR and the ICR for the proposed WPS. The calculation in the ICR for the proposed WPS does not accurately reflect the difference in burden reflected by the proposed change to the current WPS.
- **Use of "Loaded" Wage Rates:** The use of "Loaded" wage rates appears inconsistent with recent EPA practice in other ICRs, and inappropriate to the type of activities described. The above-noted discrepancy is due to the use of "Loaded" wage rates in the ICR for the proposed standard, whereas "Fully Loaded" wage rates were used in the ICR for the 2011 WPS. Loaded wage rates are sometimes used to estimate burden in cases in which no capital or operating and maintenance costs are incurred by respondent firms; however, that is not the case in this instance. The use of Fully Loaded rates would increase the cost burden estimate of the proposed WPS by approximately 50%.
- **Costs of Recordkeeping Set up and Maintenance:** The burden estimate in the proposed WPS does not include any recordkeeping costs associated with set-up costs for a recordkeeping system, storage costs, or disposal costs for records that may hold sensitive information. Given the use of "Loaded," as opposed to "Fully Loaded" rates, these overhead costs are not reflected anywhere within the burden estimate proposed in the ICR.
- **Estimation of Greenhouse Numbers:** The ICR assumes only 519 greenhouses will be subject to the proposed WPS. Based on the 2012 data from the National Agricultural Statistics Service, CropLife estimates the number of greenhouses that would be subject to the proposed WPS is actually over 28,000. This difference in the number of greenhouses would lead to an approximately 15% increase in the total burden estimate, all other assumptions held constant.
- **Burden of Recordkeeping Activities:** Several key recordkeeping activities are estimated to take between one and four minutes per worker. Generally, the minimum recordkeeping time for individual recordkeeping activities in similar, recent ICRs from EPA is not less than five minutes per task.
- **Burden of Enforcement:** No consideration is provided in the ICR for rule enforcement costs. WPS agricultural inspections are conducted by state, territorial and tribal pesticide regulatory agencies that will include these updated rules in their inspection protocols. The additional recordkeeping requirements may add to the inspection time, as well as require development of additional training and guidelines for inspectors.

The remainder of this document is as follows:

- In the first section of this document, we provide an overview of the proposed rule.

- In the second section, we provide a review of the key assumptions that form the basis for the estimate of burden for the revised rule, as well as a critique of some of the inconsistencies, and potential inaccuracies within those assumptions that substantively affect the estimate of employer burden.
- In the third section of this document, we provide a set of revised burden cost estimates using revisions in the EPA assumptions based on a review of similar, recent ICRs from EPA, a review of EPA’s own internal policies regarding estimating burden, and input from CropLife regarding other inputs of interest. With these revised assumptions, we provide several estimates of costs based on different sets of revised assumptions.

About the Proposed Agricultural Worker Protection Standard (WPS)

The Agricultural Worker Protection Standard (WPS) (OMB No. 2070-0148; EPA No. 1759.06) is a rule published by the Environmental Protection Agency (EPA) aimed at reducing the risk of pesticide poisoning and injury among agricultural workers and pesticide handlers. The WPS applies to over two million agricultural workers and handlers and requires that owners and employers on agricultural establishments provide protections to prevent pesticide exposure, trainings on pesticide safety, and mitigation efforts in case of exposures.

EPA has recently proposed changes to the 2011 WPS, and has submitted an ICR for public comment regarding those changes under Docket #EPA-HQ-OPP-2011-0184. Prior to the 2011 update, the WPS was implemented through a 2008 version of the rule. The proposed 2014 revision to the WPS introduces a number of new requirements related to recordkeeping, as well as enhanced training requirements. Table 1 shows a tabulation of these proposed activities.

Table 1: Proposed Revision to the 2011 WPS – New Proposed Activities

Category	Activity
New Entrant Rule Familiarization	<ul style="list-style-type: none"> • Agricultural or CPHE Employer: Learn/refresh requirements annually
Information Exchange	<ul style="list-style-type: none"> • Agricultural Establishment provides information on treated areas under an REI to CPHE • CPHE provides application information to agricultural establishment • CPHE provides information to CPHE handlers • CPHE handler receives information from CPHE
Safe Operation, Cleaning, and Repair of Equipment	<ul style="list-style-type: none"> • Agricultural or CPHE Employer Informs Handlers • Agricultural or CPHE Handler Receives information
Information for Emergency	<ul style="list-style-type: none"> • Agricultural or CPHE Employer provides information to medical personnel, worker, or handler

Category	Activity
Pesticide Safety Training	<ul style="list-style-type: none"> • Agricultural Employer or CPHE provides training to handlers • Agricultural or CPHE Handler attends training • Agricultural Employer or CPHE records and maintains handler training records • Agricultural Establishment Handlers or CPHE sign acknowledgement of training
Personal Protective Equipment Information	<ul style="list-style-type: none"> • Agricultural Establishment or CPHE handler receives respirator training • Agricultural Establishment or CPHE handler undergoes initial respirator survey • Agricultural Establishment or CPHE handler undergoes respirator fit-test • Health care worker reviews medical evaluation • Agricultural Establishment or CPHE handler undergoes follow up evaluation • Agricultural or CPHE Employer records and maintains records • Agricultural or CPHE Employer informs cleaner/lauderer • Agricultural or CPHE Employer maintains closed system repair records

The estimated annual burden to agricultural employers for the existing WPS as described in the accompanying ICR is 1,827,493 hours at a cost of \$92,729,052. The ICR for the proposed rule estimates the burden at 8,316,993 hours at a cost of \$196,130,463, which represents a total increase of nearly 6.5 million hours and over \$100 million with the implementation of the proposed rule.

In addition to the changes in the worker protection, training, and recordkeeping activities included under the proposed rule, the assumptions used to generate the burden estimates provided within the ICR for the proposed rule differ significantly from the assumptions used in the ICR for the current rule. In this document, we provide a review of the key assumptions that form the basis for the estimate of burden for the revised rule, as well as a critique of some of the inconsistencies, and potential inaccuracies within those assumptions that substantively affect the estimate of employer burden.

Review of EPA Assumptions Regarding the Burden Estimate in the proposed WPS Revision ICR

A large number of assumptions are used to generate the burden estimates presented in the ICR for the proposed revision to the WPS.

This section describes the methodology and findings associated with analysis of the previously mentioned key assumptions. This section also suggests potential adjustments to the key assumptions in order to more accurately estimate the cost burden of the proposed revision to the WPS ICR.

We focus on three types of burden that are required with an ICR:

1. Estimates of the Respondent Burden for Collection of Information
2. Capital and Operation and Maintenance Costs for Recordkeeping
3. Estimates of the Agency Burden for Collection of Information

Estimates of the Respondent Burden for Collection of Information

A large number of assumptions are used to generate the burden estimates presented in the ICR for the proposed revision to the WPS. A limited number of key assumptions contributed largely to the overall burden estimate. These key assumptions include:

- Wage Rate Calculations
- Recordkeeping Costs
- Number of Greenhouses
- Burden on Small Businesses

This section describes the methodology and findings associated with analysis of the previously mentioned key assumptions. This section also suggests potential adjustments to the key assumptions in order to more accurately estimate the cost burden of the proposed revision to the WPS ICR.

Wage Rate Calculations

Wage rates represent the hourly cost of a worker's time, and are used to measure labor burden for various types of labor for activities in the ICR. The wage rate used in the 2011 WPS ICR is calculated as follows in Table 2. Calculations for wage rates used in the cost estimates appear in the cost estimation section in Table 7 and Table 11.

Table 2: Components of a Fully Loaded Wage Rate Calculation (Attachment D, 2011 WPS ICR)

Component	Notes	Calculated Amount (Agricultural Workers) ¹
Base Wage Rate	Hourly Salary Amount	\$ 9.23
Fringe Benefits	Equals 43% of the Base Wage Rate, or 30% of the Loaded Wage Rate ²	\$ 4.02
Loaded Wage Rate	Base Wage Rate + Fringe Benefits	\$ 13.25
Overhead Costs	50% of Loaded Wage Rate	\$ 6.62
Fully Loaded Wage Rate	Base Wage Rate + Fringe Benefits + Overhead Costs	\$19.87

Fully loaded wage rates include fringe benefits (paid leave, supplemental pay, health insurance, other insurance, retirement and savings, other fringe benefits), as well as overhead costs (rent, computer support, phones facilities). Loaded wage rates include fringe benefits but do not include overhead costs.

¹ Attachment D: Wage Rate Tables for Agricultural Employers and Agricultural Workers, Supporting Statement for an Information Collection Request (ICR). EPA-HQ-OPP-2010-0896 and OMB Control No. 2070-0148. (January 31, 2011).

² The loading factor of 43% is applied to the hourly salary to calculate the amount of fringe benefits. This loading factor is calculated as the 30/70, or approximately 42.9%. Fringe benefits are assumed to make up 30% of the loaded wage rate, based on data from the Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation (ECEC) for civilian and private industry workers.

The ICR for the current WPS used a fully loaded wage rate in the calculation of the burden estimate. However, the ICR for the proposed revision to the WPS uses a loaded wage rate instead, preventing a direct comparison of the two ICRs.

Review Method

Summit selected a sample of recent EPA ICRs from to the Office of Pesticide Programs (OPP) and Office of Pollution, Prevention, and Toxics (OPPT) as part of this analysis. ICRs from these two offices were selected as both the OPP and OPPT are located within the Office of Chemical Safety and Pollution Prevention (OCSPP), and presumably share similar standards for estimation. Recent ICRs from 2013 and 2014 were selected for review in order to reflect the most recent standards.

Findings

From the sample of ICRs recently published by OCSPP, it appears that the ICRs typically account for some amount of overhead. However, terminology for loaded rates and fully loaded rates are not completely consistent. The three equally used rates include:

- Fully Loaded Rates: Overhead as 50% of Loaded Rates
- Loaded Rates 1: Overhead as 17% of Loaded Rates
- Loaded Rates 2: Overhead not accounted for or explicitly mentioned

Table 3 shows the sample of selected ICRs and the associated wage rate calculations used.

Table 3: Recent EPA Information Collection Request Comparisons

Year	EPA ICR No.	Office	ICR Name	Rate Used ³	Notes
2014	1249.10	OPP	Requirements for Certified Applicators Using 1080 Collars for Livestock Protection	Fully loaded wage rates	Rate calculations are identical to those used in the 2011 and 2008 WPS ICR.
2013	2330.02	OPP	Pesticide Registration Fees Program	Fully loaded wage rates	Rate calculations are identical to those used in the 2011 and 2008 WPS ICR.
2013	2479.01	OPPT	Tier 2 Data Collection for Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)	Fully loaded wage rates	Rate calculations are identical to those used in the 2011 and 2008 WPS ICR.

³ The terms “Loaded wage rates 1” and “Loaded wage rates 2” are named for differentiation. They are both referred to simply as loaded wages within each associated ICR.

Year	EPA ICR No.	Office	ICR Name	Rate Used ³	Notes
2013	2302.02	OPPT	EPA's Design for the Environment (DfE) Formulator Product Recognition Program	Loaded wage rates 1	Wage rates and fringe benefits are taken from the BLS Employer Costs for Employee Compensation (ECEC) data. An additional loading factor of 17 percent is applied to wages to account for overhead for a loaded wage rate.
2013	1741.07	OPPT	Correction of Misreported Chemical Substances on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory	Loaded wage rates 1	Wage rates and fringe benefits are taken from the BLS Employer Costs for Employee Compensation (ECEC) data. An additional loading factor of 17 percent is applied to wages to account for overhead for a loaded wage rate.
2014	2261.03	OPPT	Safer Detergent Stewardship Initiative (SDSI) Program	Loaded wage rates 1	Loaded rates are taken from the BLS Employer Costs for Employee Compensation (ECEC) data. An additional loading factor of 17 percent is applied to wages to account for overhead.
2014	1246.12	OPPT	Reporting and Recordkeeping for Asbestos Abatement Worker Protection	Loaded wage rates 2	Hourly labor rates reflect wage and non-wage benefits. Information on overhead costs is not explicitly mentioned.
2014	1365.10	OPPT	Asbestos-Containing Materials in Schools and Asbestos Model Accreditation Plans	Loaded wage rates 2	Loaded wages including fringe benefits are used. Information on overhead costs is not explicitly mentioned.
2013	2487.01	OPPT	EPA's Design for the Environment (DfE) Logo Redesign Consultations	Loaded wage rates 2	Indicated that no capital or operating and maintenance costs are incurred by respondents under this ICR.

Fully Loaded Wage Rates

The two other ICRs from OPP that Summit reviewed used the fully loaded wage rate. This fully loaded wage rate used calculations that were identical to those used in the current WPS ICR. The source document describing the calculation of fully loaded wage rates is an EPA memo prepared by the Office of Prevention, Pesticides, and Toxic Substances (now the OSCPP), which indicates the methodology for estimating OPP ICR wage rates for industry, state, and EPA labor costs. This document is meant to standardize the calculation of wage rates for ICRs published within OPP, including the following:

- **Sectors:** Industry, State Government, EPA
- **Labor Types:** Management, Technical, Clerical

- **Wages:** Unloaded (basic wages), Loaded (wages + benefits), and Fully Loaded (wages + benefits + overhead)

Summit was not able to locate a more recent version of this memo, and so assumed that the 2006 version is the current version.

Loaded Wage Rates 1 (Limited Overhead Costs)

Three ICRs in the sample used Loaded Wage Rates 1, which used loaded wage rates from the Bureau of Labor Statistics (BLS) and applied an additional loading factor of 17% as overhead. The use of 17% as a loading factor for overhead is substantiated by two source documents published in 2002⁴. Like the wage rates in Fully Loaded Wage rates, the Loaded Wage Rates 1 are divided into standard categories for Management, Technical/Professional, and Clerical labor categories.

Loaded Wage Rates 2 (No Overhead Costs)

Three ICRs in the sample used Loaded Wage Rates 2, which are just the reported loaded wage rates from BLS. These wage rates do not account for any overhead, and the associated ICRs do not make mention of overhead costs. Likewise, the EPA Economic Analysis associated with the proposed revision to the WPS ICR does not specifically mention accounting for overhead costs.

Potential Adjustments

Based on the analysis of recent ICRs published by OCSPP, it appears that there is significant reason to use Fully Loaded Wage Rates in the calculation of burden estimates for the proposed revision to the WPS ICR. Using Loaded Wages Rates with no overhead costs is only appropriate when there are no capital or operating and maintenance costs are incurred by respondents under an ICR. However, there are capital and operating and maintenance costs associated with the type of recordkeeping required by the proposed ICR. Doing so would make the proposed revision to the WPS ICR consistent with other ICRs from the OPP, as well as simplify cost estimations for material used in WPS activities, which are otherwise calculated separately.

Recordkeeping Costs

Proposed revision to the WPS identifies six distinct recordkeeping activities required to maintain compliance. Since the recordkeeping requirement did not exist in previous versions of the WPS, this set of activities is one of the primary sources of increased cost and time burden in the ICR for the proposed revision to the WPS. These activities are summarized in Table 4 below.

⁴ Wage Rates for Economic Analyses of the Toxics Release Inventory Program (EPA, 2002), and Revised Economic Analysis for the Amended Inventory Update Rule: Final Report (EPA, 2002)

Table 4: Summary of Recordkeeping Activities Proposed in WPS ICR

#	Record Type	Description	Recordkeeping Time Burden (per unit)
1	Application-specific information	Pesticide application information, including timeframe of application, duration of REI, product label, and SDS information.	<ul style="list-style-type: none"> Gather record info = 12 minutes Maintain record = 1 minute Provide record info upon request = 6 minutes
2	Training Records	Record of worker/handler training, including training requirements met and agricultural employer data.	<ul style="list-style-type: none"> 7 minutes per worker 4 minutes per handler
3	Recordkeeping associated with handler medical evaluation, fit testing, and respirator training	Records of completion of handlers' medical evaluation, fit testing, and respirator training. Includes results of extensive qualitative and quantitative fit tests and equipment information for the respirator used.	<ul style="list-style-type: none"> 4 minutes per medical evaluation record (per handler) 4 minutes per respirator fit test (per handler) 23% will require follow-up to the medical evaluation (another 4 minutes of recordkeeping for that subpopulation)
4	Records of system maintenance for handler employers of closed systems	Maintenance records of closed systems; maintenance to be completed as specified in written operating instructions and as needed.	<ul style="list-style-type: none"> 3 minutes
5	Records that employees received oral notice of pesticides (for workers exempt from training in first 2 days)	[Exemption for workers that are performing tasks up to 2 days before the training requirement is enacted.] Worker must be provided a copy of an EPA-approved pesticide information sheet and its contents communicated to the work orally in a language the worker understands prior to conducting any tasks.	<ul style="list-style-type: none"> 10 minutes

#	Record Type	Description	Recordkeeping Time Burden (per unit)
6	Early entry notifications records	Records of worker early entry activities - includes acknowledgement of notification by printed name, date of birth, and signature of each early-entry workers who received the information.	<ul style="list-style-type: none"> 4 minutes

According to the proposed revision to the WPS, the EPA’s rationale for adding the recordkeeping requirements is due to feedback received from the agency’s state regulatory partners, who have indicated “difficulty enforcing some requirements, due primarily to a lack of records.”⁵ The EPA notes that “proposed recordkeeping is designed to improve enforcement capability as a means of fostering compliance, thereby improving protections.” EPA also expects that recordkeeping will enhance enforceability of training and notification requirements.⁶

Though EPA’s justification for the increased burden is based on the ability of records to improve consistency across information tracking, the proposed revision to the WPS requires that all records are created and maintained within each agricultural establishment. With no central authority from EPA to create and manage the records in the desired format, the third-party recordkeeping requirement may unnecessarily increase the burden on agricultural employers without comparable improvement in compliance, enforcement capability, or worker safety. This concept is further explored below.

Review Method

To evaluate the estimated burden of recordkeeping in the proposed revision to the WPS, Summit reviewed various existing ICRs from EPA and the Department of Labor (DOL) to compare recordkeeping costs and time burdens associated with these activities. Summit also reviewed EPA’s *Economic Analysis of Proposed Revisions to the Worker Protection Standards*, which informed the development of cost estimations in the ICR, to examine the calculation methodology in more detail. Since recordkeeping was not included in previous versions of the WPS, the added costs of recordkeeping events in the proposed ICR cannot be compared to any earlier baseline cost estimate.

⁵ Agricultural Worker Protection Standard Training and Notification (Proposed Rule) OMB Control No.: 2070-[new]; EPA ICR No.: 2491.01

⁶ Agricultural Worker Protection Standard Training and Notification (Proposed Rule) OMB Control No.: 2070-[new]; EPA ICR No.: 2491.01

Findings

Recordkeeping Wage Rate Considerations

Based on Summit's review of other ICRs, including a 2014 DOL ICR related to mine safety standards⁷ and a 2013 EPA ICR for recordkeeping associated with the Clean Water Act⁸, there are inconsistencies regarding the wage rate to be assigned to recordkeeping in a nontraditional business environment, such as farming, mining, or pollution mitigation. The proposed revision to the WPS assigns a wage rate of \$28.21 for recordkeeping, which represents the BLS wage rate for an agricultural employer. Each recordkeeping task calculates the total cost of the activity as the time estimate (i.e. 0.05 hours) multiplied by the \$28.21 wage rate. While the DOL mine safety ICR uses this same wage rate to account for creating and maintaining training records, the EPA Clean Water Act ICR calculates the cost for recordkeeping based on wage rates for data clerks hired for such tasks. Since clerical responsibilities are not a typical job function of an agricultural employer, the wage rate of \$28.21 may not adequately incorporate the added burden of recordkeeping efforts, especially within smaller establishments that likely have less experience in this area.

Lack of Standard Forms

As noted above, the EPA does not require the use of any standard reporting forms for the recordkeeping activities in the proposed revision to the WPS. Though this allows the employers some flexibility, the lack of standard agency forms may increase reporting burden and costs and could decrease compliance as well as cause difficulties for enforcement personnel. Most other ICRs examined during Summit's review utilized standard forms for recordkeeping.

Potential Adjustments

Overall, Summit found that the following recordkeeping costs are not currently accounted for in the proposed ICR and should be considered for inclusion:

- Set-up costs to establish a recordkeeping system (if one has not already been established)
- Costs to develop internal record forms
- Printing costs (for paper records)
- Computer software/system costs (for electronic records)
- Storage costs
- Disposal costs of records with sensitive information
- Maintenance costs for records beyond the two-year minimum for longer-term employees

Additionally, the time burden for some recordkeeping activities appear to be underestimated, with some activities, like signature-recording, estimated to take only 30 seconds. For example, the time-burden estimate of four minutes for recording the respirator fit test may be low, given the in-depth quantitative and qualitative testing required for this activity.

⁷ DOL Mine Accident ICR 1219-0007 (2014)

⁸ EPA-HQ-OECA-2009-0274-0191 (2013)

Number of Greenhouses

The proposed revision to the WPS estimates certain activities, specifically those for notifications and postings, which will require more effort by greenhouse owners than by other WPS-affected establishments. The proposed revision to the WPS ICR estimates the number of greenhouses which would be impacted by this proposed revision to the WPS as 519, which CropLife believes to be too low a number, especially as the current WPS ICR estimates the number of greenhouses as 11,350. Because the number of applicable establishments is an assumption used in determining the burden of a variety of activities, CropLife identified the number of greenhouses as a key assumption.

Review Method

Summit reviewed the EPA Economic Analysis in order to identify how EPA determined the number of greenhouses for the proposed revision to the WPS ICR.

Findings

A review of the EPA Economic Analysis did not reveal how EPA has estimated the number of greenhouses to be affected by the proposed revision to the WPS to be 519. The EPA Economic Analysis does instead clarify that the number of WPS farms, defined as agricultural establishments that produce crops and also hire workers, includes nurseries and greenhouses, as well as livestock operations that also produce crops. The EPA Economic Analysis also identifies the number of WPS farms estimated to use pesticides. However, the EPA Economic Analysis makes no mention on the specific number of greenhouses.

Moreover, without a specific definition for WPS-affected greenhouses, Summit finds the proposed ICR calculation for greenhouse posting requirements to be potentially inaccurate. The proposed ICR subtracts the assumed number of greenhouses (519) from the number of WPS farms, and calculates the posting requirements for each establishment separately. This calculation assumes that WPS farms have at most one greenhouse, though it is possible that a single farm encompasses multiple greenhouses.

Both the small assumed number of greenhouses, as well as the assumption that a WPS farm has a single greenhouse, may lead to an underestimation of proposed revision to the WPS costs for greenhouses.

Potential Adjustments

CropLife has engaged outside consultants to review agricultural data (National Agricultural Statistics Service 2012) to confirm the number of greenhouses within the U.S. The number identified through this study (28,147) may be used to substitute the 519 greenhouse assumption currently used in the proposed revision to the WPS ICR, retaining the conservative assumption that a WPS farm has at most a single greenhouse.

Impact on Small Businesses

The introduction or revision of federal standards often uniquely impacts small businesses, which typically operate with less administrative overhead and may not have sophisticated business systems or infrastructure in place to easily adapt to new regulations. Specifically, the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires special consideration for small entities because such firms often cannot devote staff resources to follow regulatory developments and often are less able to bear the burden of an information collection because of their smaller staff and resources. The

proposed revision to the WPS does not account for a potential differential impact on small businesses that may need to spend additional resources to set up a recordkeeping system or employ staff in the required tasks for WPS compliance.

Within the proposed revision to the WPS, EPA notes that “requirements cannot be reduced for small establishments without significantly compromising the protections offered to their workers and handlers” and that “small entities are required to follow the same requirements as larger establishments” (except in the case of solely family-operated establishments).⁹ Costs are estimated on an individual basis (per worker, handler, or employer, for example), which estimates a lower total cost burden for the over 300,000 small farms, nurseries, greenhouses, and other entities affected by the rule. However, the per-unit cost for these activities may actually be greater within smaller establishments due to the lack of business infrastructure found in many larger establishments, noted above.

Findings

In the proposed revision to the WPS, EPA does not provide any cost adjustments for small agricultural entities, as the agency estimates that per-person recordkeeping and training costs will be identical, regardless of the size of the establishment. Though these per-unit costs may be similar, it is likely that smaller entities may incur additional costs to establish a recordkeeping system, for example, if one had not been set up previously that would be adequate to handle the new WPS requirements. Furthermore, small businesses may require additional clerical support to comply with the recordkeeping activities that the agricultural employer may be unable to perform, given other demands from day-to-day operational responsibilities.

The Paperwork Reduction Act, in accordance with the RFA, requires that an agency justify any specific impact to small businesses in an ICR and also explain how the agency attempts to minimize that impact. To meet this requirement, other ICRs have included provisions and established programs to assist small businesses in determining what aspects of the federal rule applies to them, and to provide alternative methods of compliance, if applicable.

In an EPA ICR revising regulations related to the effect of particulate matter on air pollution¹⁰, the EPA noted that while regulatory flexibility could not be allowed for small businesses, the agency would assist smaller businesses in navigating the requirements of the rule and determining non-applicable components of the rule to limit unnecessary burden. A similar approach could be incorporated in the proposed revision to the WPS, given the necessity for consistency in worker training around pesticide application and protections, but accounting for the differences in accounting and recordkeeping burden, depending on the farm size.

⁹ Agricultural Worker Protection Standard Training and Notification (Proposed Rule) OMB Control No.: 2070-[new]; EPA ICR No.: 2491.01

¹⁰ Information Collection Request for Changes to 40 CFR Parts 51 and 52: Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers (PM_{2.5}) – Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC). (OMB Control Number: 2060-0609)

Capital and Operations and Maintenance Costs for Recordkeeping

According to the Paperwork Reduction Act (PRA), agencies are required to provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. This must include, if applicable, a total capital and start-up cost component, annualized over the expected useful life, as well as a total operation and maintenance. These estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. In cases in which sensitive information containing personally identifiable information (PII) is created, agencies also often include costs related to protecting this information, or disposal costs, including shredding or destruction of records.

Paper vs. Electronic Records

In the proposed ICR, it is assumed that paper records will be kept. In EPA's *Economic Analysis of Proposed Revisions to the Worker Protection Standards*, the agency includes extremely specific costs for some items such as folders and storage boxes. However, key costs associated with security and disposal of sensitive records are not included.

Other similar ICRs, such as the DOL mine safety ICR noted above, include specific time differentials for standard (paper) compared to e-responses. The DOL ICR also provided evidence that electronic reporting introduced through that ICR would reduce the burden by lowering estimated response times from previous versions. It is also likely that electronic recordkeeping would increase data protection, reliability, and security. Since the agricultural employers have freedom in selecting their method of recordkeeping, the estimated costs should identify the cost variations that account for paper versus electronic systems.

Finally, the proposed revision to the WPS requires that records must be maintained for two years. However, it does not specify whether records must be maintained past the standard two years if an individual worker remains at the establishment as a current employee past this time period. For example, a DOL mine training ICR¹¹ examined by the Summit team requires this extended record maintenance, which would increase the recordkeeping cost burden in such cases. Disposal costs for outdated records are also excluded from the proposed revision to the WPS.

Potential Adjustments

To account for the introduction of electronic records, costs associated with computer and software set-up and maintenance should be considered for inclusion. Furthermore, data security and disposal costs of records with sensitive information should be incorporated in the burden calculations.

Estimates of the Agency Burden for Collection of Information

The proposed revision to the WPS specifies that there are no costs to the EPA or other governmental agency for standardization of documents or enforcing compliance with the proposed revision to the WPS. However, with the introduction of the new requirements of the proposed revision to the WPS, some level of state agency action will be required to facilitate the implementation and enforcement of the new proposed revision to the WPS requirements.

¹¹ DOL Mine Training ICR 1219-0009 (2014)

With the introduction of recordkeeping requirements, some standardization of records is likely to be necessary, especially as it is difficult to estimate recordkeeping burdens without specifications of what information needs to be recorded. Moreover, without guidance from either the EPA or state agencies, agricultural establishments are likely to incur costs of developing the appropriate records on their own. Standardized documentation for recordkeeping will also reduce any enforcement burdens necessary in ensuring that agricultural establishments comply with the proposed revision to the WPS. Therefore, it is likely that individual states or other local authorities will be tasked with developing standardized forms for the recordkeeping activities. In such cases, state and local authorities will incur costs associated with becoming familiar with WPS requirements, developing standardized documents, and providing standardized documents and guidance to agricultural establishments.

In addition, a certain level of enforcement action by local or state authorities is likely to be necessary to ensure that agricultural establishments comply with the requirements of the proposed revision to the WPS. Though agricultural establishments are not required to submit reports to the EPA for review, local authorities are likely to choose to inspect agricultural establishments periodically to ensure compliance with regard to recordkeeping. This type of review may be undertaken independently, or as part of the review procedures for other state or local actions, such as fulfilling compliance requirements for program participation.

Review Method

Summit reviewed the sample of ICR published by EPA previously used in the wage rate assumption analysis and identified those ICRs which had actions associated with State agencies or the EPA. The annual burdens per respondent and type of labor used were determined for the following types of actions:

- Standardized Documentation Costs:
 - Rule familiarization
 - Answer Questions
 - Create Guidance/Information
- Enforcements Costs:
 - Review report

Findings

A review of the sample ICRs indicated that typically EPA, state agency, or both institutions were tasked with some level of information collection preparatory activity or result review. Actions performed by a state agency were sorted into the previously identified task categories based on the following crosswalk in Table 5.

Table 5: Crosswalk of State Agency Standardization and Enforcement Tasks

Prospective WPS ICR Task	Crosswalked Tasks	Notes
Rule Familiarization	<ul style="list-style-type: none"> • Read/Hear rule or any collection instrument • Reading and interpreting regulation 	Refers to agency efforts to become familiar with rule.

Prospective WPS ICR Task	Crosswalked Tasks	Notes
Answer Questions	<ul style="list-style-type: none"> Develop correspondence Answer/respond to questions 	Refers to agency efforts to clarify rule to public.
Create Guidance/Information	<ul style="list-style-type: none"> Create information Develop written guidance for implementing rule Implement program that is not less stringent than regulation Prepare instructions/questionnaires/surveys Distribute forms 	Refers to agency efforts to provide standardized guidance, forms, or information for the public
Review Report	<ul style="list-style-type: none"> Process information/data submissions/initial responses Receive/review submissions Review results 	Refers to agency efforts to collect and review data

Based on the crosswalk, the average time burden per activity was determined for the managerial, technical, and clerical labor categories. The cost of developing standardized documentation is the sum of costs for rule familiarization, question response, and guidance creation. The annual average amount of time for each labor category and action is shown below in Table 6.

Table 6: Sample ICR Standardization and Enforcement Average Agency Burden

Activity Type	Average Annual per Agency Burden Amount		
	Managerial	Technical	Clerical
Rule Familiarization (per agency)	1	2	0
Answer Questions (per agency)	7	8.4	0
Create Guidance (per agency)	3.7	11.9	39
Standardized Documentation Costs (per agency)	11.7	22.3	39
Enforcement Costs: Review Report (per review)	2.7	7.7	0.7

Potential Adjustments

Though the current and proposed revision to the WPS have not included standardization and enforcement costs in the associated ICRs, the need for recordkeeping may substantiate increased efforts on the part of local agencies, in order to ensure compliance with the WPS.

Documentation standardization costs are likely to be incurred once the proposed revision to the WPS is issued, with costs annualized over the time the WPS is in place. Enforcement costs are likely to be incurred for each review action, the frequency of which may vary across localities.

Cost Estimate Scenarios

In order to isolate the quantifiable effect of adjustments to the proposed revision to the WPS, three distinct cost estimate scenarios were developed as a comparison to the base case presented by the EPA developed proposed revision to the WPS ICR. The three scenarios are described as follows:

- **Scenario 1:** The first scenario presents the cost burden of the revision to the WPS using the same time burden estimates as the EPA provided cost burden estimates. However, instead of using a loaded wage rate, a fully loaded wage rate, including costs of overhead, is used for all respondents.
- **Scenario 2:** The second scenario presents the cost burden of the revision to the WPS using the same loaded wage rates as the EPA provided cost burden estimates. However, time burden and respondent assumptions for identified activities are updated, and time burdens and respondent assumptions for additional potentially required tasks are also included.
- **Scenario 3:** The third scenario presents the cost burden of the revision to the WPS using fully loaded wage rates as well as the updated time burden and respondent assumptions used in Scenario 2.

The following sections will explore the assumptions and cost estimates of each section in additional detail, and offer comparisons with the original estimate prepared by EPA.

Scenario 1 Estimate: Wage Rates Adjustment Only

Scenario 1 presents the cost estimate of the proposed revisions to the WPS using fully loaded wage rates instead of loaded wage rates. The time burden estimates, as well as the number of respondents, remain the same between Scenario 1 and the cost estimate originally provided by EPA.

Wage Rate Changes

The loaded wage rates used by the EPA provided estimates for the proposed revisions to the ICR are used to generate the fully loaded wage rates. In Table 7 below, the row labeled Loaded Wage Rate represents the wage rates used by the proposed ICR estimate.

Overhead costs, representing 50% of the loaded wage rate are added to the loaded wage rate to calculate the fully loaded wage rate. This methodology for calculating the fully loaded wage rate is consistent with EPA guidance and wage rate estimation described previously in this report. The fully loaded wage rate is shown for existing labor categories in Table 7 and will be used instead of the loaded wage rate.

Table 7: Wage Rate Calculations – Existing Respondent Categories

Component	CPHE Employer	CPHE Handler	Handler Trainer	Ag. Employer	Ag. Handler	Ag. Worker	Healthcare Worker
Base Wage Rate	\$21.21	\$14.07	\$26.51	\$19.75	\$19.75	\$9.40	\$30.04
Loaded Wage Rate	\$30.30	\$20.10	\$37.87	\$28.21	\$28.21	\$13.43	\$42.91

Component	CPHE Employer	CPHE Handler	Handler Trainer	Ag. Employer	Ag. Handler	Ag. Worker	Healthcare Worker
Overhead Costs	\$15.15	\$10.05	\$18.94	\$14.11	\$14.11	\$6.72	\$21.46
Fully Loaded Wage Rate	\$45.45	\$30.15	\$56.81	\$42.32	\$42.32	\$20.15	\$64.37

Cost Estimate Change by Section

By keeping the time burden and respondent number values the same for Scenario 1, the overall percentage change in Scenario 1 costs are the same as the percentage change in wage rate (50%) from loaded wage rates to fully loaded wage rates. Table 8 displays the changes in cost for each activity category from the EPA proposed estimate to Scenario 1.

Table 8: Scenario1 Cost Comparison by Activity Category

Activity Category	Total Time Burden	ICR Estimated Total Cost	Scenario 1 Total Cost
New Entrant Rule Familiarization	233,554	\$ 6,664,253	\$ 9,996,380
Basic Pesticide Safety Information	73,044	\$ 2,060,571	\$ 3,090,857
Pesticide Specific Information	1,472,514	\$ 41,539,611	\$ 62,309,416
Notification of Restricted Entry	2,166,445	\$ 44,256,901	\$ 66,385,352
Establishment Specific Information	47,004	\$ 825,700	\$ 1,238,550
Exchange Information between Agricultural Employer and CPHE	1,472,229	\$ 43,198,278	\$ 64,797,417
Safe Operation, Cleaning, Repair of Equipment	39,990	\$ 982,482	\$ 1,473,724
Emergency Assistance Information	200	\$ 5,645	\$ 8,468
Pesticide Safety Training – Workers	2,101,714	\$ 40,097,930	\$ 60,146,894
Pesticide Safety Training – Handlers	389,121	\$ 9,395,073	\$ 14,092,610
Pesticide Safety Training – CPHE Handlers	21,095	\$ 470,116	\$ 705,174
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	207,868	\$ 4,867,402	\$ 7,301,103
Personal Protective Equipment - Respirator Uses (CPHE Handler)	20,616	\$ 454,101	\$ 681,151
Exemptions - 2 Day Waiting Period	30,445	\$ 603,314	\$ 904,971
Exemptions - Early Entry	41,183	\$ 795,885	\$ 1,193,828
Total	8,317,021	\$ 196,217,264	\$ 294,325,895

Scenario 2 Estimate: Burden Adjustment Only

Scenario 2 presents the cost estimate of the proposed revisions to the WPS using updated time burden and respondent assumptions. Scenario 2 also includes the time burdens associated with additional tasks that are not included in the proposed ICR estimate provided by EPA. Scenario 2 uses the same loaded wage rates as the EPA proposed estimate provided by EPA.

The following sections describe the assumption changes that were made, as well as the resulting change in cost estimates.

Time Burden Changes

This section describes the time burden changes that were made in Scenario 2. The majority of these changes fall in the realm of the proposed revisions to the WPS' recordkeeping burden. The tasks that have been changed are listed in Table 9 below.

Table 9: Adjustments to Burden Estimates for Recordkeeping Activities (Scenario 2)

Category	Activity	Labor Category	ICR Time Estimate (minutes)	Adjusted Time Estimate (minutes)	Burden Additions
Pesticide Specific Information	Maintain Records	Agricultural Employer	1	5	+ 4 mins.
Pesticide Safety Training - CPHE Handlers	Maintain Record of Training	CPHE Employer	4	5	+ 1 min.
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	Record and Maintain Medical Records	Agricultural Employer	4	5	+ 1 min.
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	Maintenance of Closed System Recordkeeping	Agricultural Employer	3	5	+ 2 mins.
Personal Protective Equipment - Respirator Uses (CPHE Handler)	Record and Maintain Medical Records	CPHE Employer	4	5	+ 1 min.
Personal Protective Equipment - Respirator Uses (CPHE Handler)	Maintenance of Closed System Recordkeeping	CPHE Employer	3	5	+ 2 mins.
Exemptions - Early Entry	Record and Maintain Records	Agricultural Employer	4	5	+ 1 min.

As described in Table 9 above, the burden estimates for the recordkeeping activities have been adjusted upward to reflect a minimum of 5 minutes per activity. This revised estimate is based on research conducted of similar ICRs, which suggested that a minimum standard of 5 minutes is used to approximate the burden for such recordkeeping activities. For example, of the sampled ICRs referenced earlier in this report, the 2014 EPA Asbestos Abatement Worker Protection ICR¹², the 2014 DOL Mine Safety Standards ICR¹³, and the 2013 EPA ICR associated with the Clean Water Act¹⁴ all utilize a minimum of 0.08 hours (5 minutes) to estimate the burden of comparable recordkeeping activities.

The increases in recordkeeping time burden estimates can also be justified due to EPA's exclusion of key aspects of any recordkeeping requirement, as noted earlier in this report. For example, set-up costs to establish a compliant recordkeeping system, storage costs, and disposal costs of records containing sensitive information are not included in the proposed rule. Furthermore, these specific costs, plus the overall burden estimates for recordkeeping, could be more accurately calculated if EPA factored in the use of electronic records to replace paper records.

Incorporating this time adjustment across all recordkeeping activities listed above, the total cost associated with implementation of the proposed rule would increase approximately 16%, from \$196.2 million to \$227.3 million. It should also be noted that applying the 5-minute minimum to only some of the recordkeeping activities would incur a lower overall cost increase, and that using the 5-minute burden minimum for all activities may represent a more extreme scenario for illustrative purposes.

Respondent Changes

This section describes the respondent changes that were made in Scenario 2. These changes are limited to the greenhouse number assumptions described previously in this report, which in turn affects the respondent level of a number of other items. The following represents the respondent number changes which are included in Scenario 2:

- **Number of Greenhouses:** The proposed ICR estimate uses an estimate of 519 greenhouses as respondents. For Scenario 2, the number of greenhouses has been increased to 28,147, as informed by NASS data.
- **Number of WPS Farms without Greenhouses (Non-Greenhouse):** This number represents the number of WPS farms that do not have a greenhouse, and is calculated as the number of WPS Farms that use pesticides (304,348) less the number of greenhouses. It is assumed for this estimation that a WPS Farm will only have one greenhouse.
- **Breakdown of Greenhouses and Non-Greenhouses by Size:** A detailed breakdown of greenhouses by WPS farm size is determined by applying the pro-rata percentage of greenhouse size from the proposed ICR estimate to the updated number of greenhouses. The breakdown of greenhouses by size is shown below in Table 10.
- **Workers in Greenhouses:** For the proposed ICR estimate, a total of 18,388 workers are assumed to work in greenhouses. For Scenario 2, the cost estimate assumes the same number of workers per greenhouse (35.43) for a total of 997,239 greenhouse workers.

¹² EPA Reporting and Recordkeeping for Asbestos Abatement Worker Protection 1246.12 (2014)

¹³ DOL Mine Accident ICR 1219-0007 (2014)

¹⁴ EPA-HQ-OECA-2009-0274-0191 (2013)

Table 10: Breakdown of Non-Greenhouses and Greenhouses by Size

Size	ICR Number of Greenhouses ¹⁵	Percentage of Total	Number of Greenhouses (2012 NASS)	Number of Non-Greenhouses (Calculated from 2012 NASS)
Small-Small	29	5.59%	1,573	39,307
Medium-Small	191	36.80%	10,359	79,200
Large-Small	169	32.56%	9,165	115,795
Large	130	25.05%	7,050	41,899
Total	519	100.00%	28,147	276,201

This change in respondents affects the calculation of the following tasks:

- Basic Pesticide Safety Information
- Notification of Restricted Entry

New Task Burdens

This section describes the new tasks that may be necessary additions to the revisions to the WPS. These tasks that have been added are the following:

- Documentation Standardization and Enforcement by Agencies
- Additional Training the Trainer Costs

Documentation Standardization and Enforcement by Agencies

- Developing Standardized Reporting
- Enforcement and Review Actions

The time burdens for the aforementioned tasks are stated in Table 6 in the assumptions section above, and reflect average value of similar tasks from other ICRs. These new tasks will be performed state agency actors, which are not previously identified in the proposed WPS. The wage rates that are used for local agencies are taken from Bureau of Labor Statistics, and represent loaded wages, which include fringe and benefits, but not overhead. The loaded wage rates for the state actors are shown in the line labeled “Loaded Wage Rate” in Table 11 .

Table 11: Wage Rate Calculations – Additional Wage Categories

Component	State Managerial	State Technical	State Clerical
Base Wage Rate	\$38.36	\$26.78	\$18.20
Loaded Wage Rate	\$54.27	\$54.85	\$38.30

¹⁵ Supporting Statement for an Information Collection Request (ICR) for the Proposed Rule to the Agricultural Worker Protection Standard Training and Notification, February 19, 2014.

Component	State Managerial	State Technical	State Clerical
Overhead Costs	\$27.43	\$19.15	\$13.01
Fully Loaded Wage Rate	\$82.28	\$57.44	\$39.04

It is assumed that each state will have one set of respondents, and so documentation standardization and enforcement tasks will be completed by 50 respondents (one for each state, District of Columbia and territories excluded). Costs of developing standardized documentation are annualized over three years. For Scenario 2, it is assumed that states will review all WPS farms once over a three year period.

Additional Train-the-Trainer Costs

The training requirements for the proposed rule specify that all existing and new workers and handlers are generally trained by the start of their third day on an agricultural establishment where a pesticide product bearing a WPS label has been applied, or an REI has been in effect within the last 30 days. Qualified trainers include certified applicators by EPA or a state or tribal agency responsible for pesticide enforcement, or those who have completed a pesticide safety train-the-trainer program approved by EPA. Per the proposed rule, it is assumed that time and cost estimates to equip these individuals as qualified trainers occur outside of the scope of the WPS. At a minimum, therefore, it could be assumed that trainers-in-training would require materials to a) be trained or b) train others.

EPA notes in their 2011 version of the WPS that EPA and industry leaders have created and distributed approved training materials at no cost to many agricultural establishments. In training new trainers, however, a number of establishments may require additional training materials. To account for this additional cost, Summit conservatively estimates that half of the expected trainings coordinated by these newly qualified trainers (from train-the-trainer programs) would require new training materials from the EPA. As observed in other ICRs, we estimate mailing costs to amount to \$2 per package. The adjusted costs for this activity, therefore, are estimated to increase the overall cost by \$3,768 (50% of 11,305 train-the-trainers, times \$2 per mailing, divided by 3 for annual cost over the 3-year rule). This cost would directly impact costs incurred at the state or federal level, and does not include labor costs associated with preparing packages of training materials.

Finally, training costs in the proposed ICR may be grossly underestimated given the wage rates used for the cost calculations. Training wage rates range from \$28.21 per hour (for certified applicators of RUPs) to \$37.87 per hour (for certified applicators and those who completed train-the-trainer programs). According to the Bureau of Labor Statistics, Training and Development Managers earn an average of \$45.86 per hour. While these employees may largely be staffed outside of the agricultural sector, it is important to consider that a higher wage rate (than that included in the proposed rule) may be necessary to attract and retain effective and skilled training staff.

Additional Costs to Convert Existing Closed Loading Systems

In a Director’s Memo issued by DPR and separate from the proposed WPS, the definition of a compliant closed system has been revised in such a way that it will require significant retrofitting of a large percentage of existing closed systems, according to CropLife. For example, the new definition would require that the maximum container pressure not exceed 5 PSI, which is difficult to measure on a consistent basis and even more difficult to regulate. CropLife estimates that the cost to convert an

existing mid-large system to meet the proposed standard would cost an initial \$25,000 to \$100,000 plus annual maintenance costs of \$5,000 to \$10,000.

Given that the proposed WPS estimates that 96,763 large and large-small agricultural establishments have closed systems, a conservative calculation increases overall cost of the proposed WPS by \$1.3 billion¹⁶ in the first year of implementation of the rule. While Summit has not incorporated this extreme cost in its assumption change calculations, this figure serves to illustrate an additional potential burden that would be placed on agricultural producers through the proposed rule.

Cost Estimate Change by Section

The percentage change in costs from the proposed ICR estimate in Scenario 2 varies by activity. Tasks that are not explicitly mentioned in this section did not change from the proposed ICR estimate.

Recordkeeping

Table 12 shows the comparative costs between the proposed ICR estimate and Scenario 2 costs of recordkeeping.

Table 12: Revised Cost Estimates by Activity (Scenario 2)

Category	Activity	Labor Category	ICR Cost per Activity	Scenario 2 Cost per Activity	Percentage Difference in Cost
Pesticide Specific Information	Maintain Records	Agricultural Employer	\$2,864,801	\$14,324,004	400%
Pesticide Safety Training - CPHE Handlers	Maintain Record of Training	CPHE Employer	\$7,334	\$9,168	25%
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	Record and Maintain Medical Records	Agricultural Employer	\$277,237	\$346,546	25%
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	Maintenance of Closed System Recordkeeping	Agricultural Employer	\$25,141	\$41,901	67%
Personal Protective Equipment - Respirator Uses (CPHE Handler)	Record and Maintain Medical Records	CPHE Employer	\$5,642	\$7,052	25%

¹⁶ \$25,000 initial cost for retrofit divided by 3 years (term of rule) + \$5,000 annual maintenance cost = \$13,333 per retrofit * 96,763 large and large-small establishments = **\$1,290,173,333**.

Category	Activity	Labor Category	ICR Cost per Activity	Scenario 2 Cost per Activity	Percentage Difference in Cost
Personal Protective Equipment - Respirator Uses (CPHE Handler)	Maintenance of Closed System Recordkeeping	CPHE Employer	\$8,872	\$14,786	67%
Exemptions - Early Entry	Record and Maintain Records	Agricultural Employer	\$247,159	\$308,949	25%
TOTAL			\$3,436,186	\$15,052,406	338%

Basic Pesticide Safety Information

Changing the number of greenhouse and non-greenhouse respondents affects the cost of tasks under providing basic pesticide information via postings. The changes for the specific tasks are included in Table 13.

Table 13: Cost Changes for Basic Pesticide Safety Information

Task	ICR Total Respondents	ICR Total Cost	Scenario 2 Total Respondent Number	Scenario 2 Total Cost	Percentage Difference in Cost
Display Main Poster ¹⁷	304,348	\$ 429,283	304,348	\$ 429,283	0%
Display Decontamination Posters (Non-greenhouses)	789,236	\$ 1,113,217	712,687	\$ 1,005,245	-10%
Display Decontamination Posters (Greenhouses)	2,076	\$ 2,928	112,588	\$ 158,805	5324%
Poster Update Changes	365,220	\$ 515,143	376,541	\$ 531,111	3%
Total	1,460,880	\$ 2,060,571	1,506,164	\$ 2,124,444	3%

Notification of Restricted Entry

Changing the number of greenhouses and non-greenhouse respondents affects the costs of notification of restricted entry. The changes for the specific tasks are included in Table 14.

¹⁷ Respondent number does not change, as the respondents are not greenhouse/non-greenhouse specific.

Table 14: Cost Estimation for Notification of Restricted Entry

Task	ICR Total Respondents	ICR Total Cost	Scenario 2 Total Respondent Number	Scenario 2 Total Cost	Percentage Difference in Cost
Provide Oral Notification (Non-greenhouses)	4,253,606	\$ 5,999,711	3,866,814	\$ 5,454,141	-9%
Provide Oral Notification (Greenhouses)	3,114	\$ 4,392	168,882	\$238,208	5324%
Receive Oral Notification (non-Greenhouses)	22,746,416	\$ 15,274,218	22,746,416	\$15,274,218	0%
Receive Oral Notification (Greenhouses)	66,197	\$ 44,451	3,590,060	\$ 2,410,726	5323%
Post Indoor/Outdoor (Non-Greenhouse)	2,430,632	\$ 22,856,043	2,209,608	\$ 20,777,681	-9%
Post Indoor/Outdoor (Greenhouse)	8,304	\$ 78,085	450,352	\$ 4,234,810	5323%
Total	29,508,269	\$ 44,256,900	33,032,132	\$ 48,389,784	9%

Additional State Actions

Task	Respondents	State Managerial Time Burden per Response	State Technical Time Burden per Response	State Clerical Time Burden per Response	State Clerical Material Costs	Estimated Total Costs
Developing Standardized Reporting	17	11.7	22.3	39		\$41,847
Enforcement and Review Actions	32,888	2.7	7.7	0.7		\$15,168,047
Train the Trainer Costs	11,305				\$3,768	\$3,768
Total	44,243	14.4	30	39.7	\$3,768	\$15,213,662

Summary of Changes

Table 15 summarizes the cost changes from the proposed ICR estimate in Scenario 2.

Table 15: Scenario 2 Cost Estimation Changes by Activity Category

Activity Category	ICR Estimated Cost	Scenario 2 Estimated Cost	Difference in Cost	Percentage Difference Cost ¹⁸
New Entrant Rule Familiarization	\$6,664,253	\$6,664,253	\$0	0%
Basic Pesticide Safety Information	\$ 2,060,571	\$2,124,444	\$63,873	3%
Pesticide Specific Information	\$41,539,611	\$52,998,813	\$11,459,203	28%
Notification of Restricted Entry	\$ 44,256,900	\$48,389,784	\$4,132,882	9%
Establishment Specific Information	\$825,700	\$825,700	\$0	0%
Exchange Information between Agricultural Employer and CPHE	\$43,198,278	\$43,198,278	\$0	0%
Safe Operation, Cleaning, Repair of Equipment	\$982,482	\$982,482	\$0	0%
Emergency Assistance Information	\$5,645	\$5,645	\$0	0%
Pesticide Safety Training - Workers	\$40,097,930	\$40,097,930	\$0	0%
Pesticide Safety Training - Handlers	\$9,395,073	\$9,395,073	\$0	0%
Pesticide Safety Training - CPHE Handlers	\$470,116	\$471,950	\$1,834	0%
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	\$4,867,402	\$4,953,472	\$86,070	2%
Personal Protective Equipment - Respirator Uses (CPHE Handler)	\$454,101	\$461,426	\$7,325	2%
Exemptions - 2 Day Waiting Period	\$603,314	\$603,314	\$0	0%

¹⁸ Calculated values may differ due to rounding.

Activity Category	ICR Estimated Cost	Scenario 2 Estimated Cost	Difference in Cost	Percentage Difference Cost ¹⁸
Exemptions - Early Entry	\$795,885	\$857,675	\$61,790	8%
Additional State Actions	\$0	\$15,293,587	\$15,209,894	N/A
Additional Train-the-Trainer (material costs)	\$0	\$3,768	\$3,768	N/A
Total	196,217,261	\$227,327,595	\$31,110,331	16%

Scenario 3 Estimate: Wage Rate and Burden Adjustments

Scenario 3 presents the cost estimate of the proposed revisions to the WPS using the fully loaded wage rate, as well the updated time burden and respondent assumptions and additional tasks included in Scenario 2.

The input assumptions for Scenario 3 include those assumption changes for wages made in Scenario 1 and Scenario 2. Fully loaded wage rates of state agency labor categories are shown in the row labeled “Fully Loaded Wage Rate” in Table 11.

Cost Estimate Change by Section

The percentage change in costs from the proposed ICR estimate in Scenario 3 varies by activity and is as follows.

Table 16: Scenario 3 Cost Estimation Changes by Activity Category

Activity Category	ICR Estimated Cost	Scenario 3 Cost	Difference in Cost	Percentage Difference Cost
New Entrant Rule Familiarization	\$6,664,253	\$ 9,996,380	\$ 3,332,127	50%
Basic Pesticide Safety Information	\$ 2,060,571	\$ 3,186,666	\$ 1,126,095	55%
Pesticide Specific Information	\$41,539,611	\$ 79,498,220	\$ 37,958,610	91%
Notification of Restricted Entry	\$ 44,256,900	\$ 72,584,675	\$ 28,327,774	64%
Establishment Specific Information	\$825,700	\$ 1,238,550	\$ 412,850	50%
Exchange Information between Agricultural Employer and CPHE	\$43,198,278	\$ 64,797,417	\$ 21,599,139	50%
Safe Operation, Cleaning, Repair of Equipment	\$982,482	\$ 1,473,724	\$ 491,241	50%

Activity Category	ICR Estimated Cost	Scenario 3 Cost	Difference in Cost	Percentage Difference Cost
Emergency Assistance Information	\$5,645	\$ 8,468	\$ 2,823	50%
Pesticide Safety Training - Workers	\$40,097,930	\$ 60,146,894	\$ 20,048,965	50%
Pesticide Safety Training - Handlers	\$9,395,073	\$ 14,092,610	\$ 4,697,537	50%
Pesticide Safety Training - CPHE Handlers	\$470,116	\$ 707,925	\$ 237,809	51%
Personal Protective Equipment - Respirator Uses (Agricultural Handler)	\$4,867,402	\$ 7,430,208	\$ 2,562,806	53%
Personal Protective Equipment - Respirator Uses (CPHE Handler)	\$454,101	\$ 692,138	\$ 238,038	52%
Exemptions - 2 Day Waiting Period	\$603,314	\$ 904,971	\$ 301,657	50%
Exemptions - Early Entry	\$795,885	\$ 1,286,513	\$ 490,627	62%
Additional State Actions	\$0	\$ 22,814,840	\$ 22,814,840	N/A
Additional Train-the-Trainer (material costs)	\$0	\$ 3,768	\$3,768	N/A
Total	196,217,261	\$340,863,967	\$144,646,706	74%