



March 5, 2010

Catheryn O'Connell
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: Comments on Federal Register Notices 74 FR 57166 [11/4/2009, Docket No. EPA-HQ-OPP-2009-0628]

Dear Ms. O'Connell,

CropLife America (CLA) is the not-for-profit trade organization representing the nation's developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the U.S. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers. CLA comments on issues that can have broad regulatory implications, which sometimes occur in the context of chemical-specific or product-specific regulatory reviews, decisions, and actions.

On November 4, 2009, EPA issued a Federal Register Notices entitled "Draft Guidance for Pesticide Registrants on Pesticide Drift Labeling" [74 FR 57166, 11/4/2009, Docket No. EPA-HQ-OPP-2009-0628] requesting comments on three drift-related documents: (1) Pesticide Registration Notice (PRN) Draft Pesticide Drift Labeling; (2) Draft Pesticide Drift Labeling Interpretation; and (3) Draft PRN Additional Information and Questions for Commenters. CLA's comments on these documents are attached as follows:

- "CLA Comments and Answers" which include
- General Overview and Major Points;
- Sections A through G;
- Conclusion; and
- Appendices A through I.

CLA appreciates this opportunity to comment and EPA's consideration of our concerns. If you have any questions or need further information, please contact me (dastaats@croplifeamerica.org; (202) 872-3873) or Dr. Barbara Glenn, Vice President, Science and Regulatory Affairs (bglenn@croplifeamerica.org; (202) 833-4474).

Sincerely,

A handwritten signature in blue ink that reads "Dee Ann Staats".

Dee Ann Staats, Ph.D.
Environmental Policy Director

CROPLIFE AMERICA
COMMENTS and ANSWERS ON
“Draft Guidance for Pesticide Registrants on Pesticide Drift Labeling”
[74 FR 57166, 11/4/2009, Docket No. EPA-HQ-OPP-2009-0628]

CropLife America (CLA) appreciates the opportunity to comment on the draft Pesticide Registration Notice (PRN) and related documents provided by the Environmental Protection Agency’s (EPA or the Agency) in the docket cited above. CLA is the not-for-profit trade association representing the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA is vitally interested in this draft PRN because of the potential for significant impacts on our member companies, their customers, America’s growers, and, more importantly for the United States consumer. In addition, the actions being proposed by EPA raise serious questions and concerns for our members regarding the approach to regulating pesticides consistent with its authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Comments provided herein are directly related to and should be considered in conjunction with CLA’s comments on two other EPA Federal Register Notices: “Petition to Protect Children from Pesticide Drift” [74 FR 57168, 11/4/2009, Docket No. EPA-HQ-OPP-2009-0825] and “Policy Paper on Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses” [74 FR 88032, 12/10/2009, Docket No. EPA-HQ-OPP-2009-0889]. In addition, CLA supports the comments submitted by Responsible Industry for a Sound Environment (RISE) on this draft PRN and related documents.

Furthermore, CLA believes that to the extent that EPA has included specific mandatory language for pesticide labeling in the draft PRN (now by its terms or in the future by implementation), then such requirements could only be implemented through rulemaking and amendment to 40 CFR Part 156. The draft PRN as written would obligate registrants to place specific statements in specific positions on product labels, without EPA amending the corresponding regulation, “Labeling Requirements for Pesticides and Devices” (40 CFR Part 156). Such requirements in the draft PRN contradict the legal disclaimer common to all PR Notices: “...this Notice is not binding on EPA personnel, pesticide registrants and applicants, and the public.” (Section X, p. 18) Also, such specific requirements for pesticide label language in the draft PRN bear the look, feel, and effect of regulations. CLA believes that such mandatory regulation beyond the current scope of 40 CFR Part 156 provisions could only be implemented by notice-and-comment rulemaking to amend those regulations.

CLA’s comments begin with the following general overview and a summary of CLA’s major points. Thereafter, the major points are discussed in more detail in appendices organized according to topic, to a specific draft PRN related document, to specific EPA questions, or to specific EPA examples of theoretical drift cases.

GENERAL OVERVIEW AND MAJOR POINTS

In the draft PRN, the Agency has proposed new labeling statements for a wide range of pesticide products and use patterns with the stated purpose of providing guidance on “pesticide labeling instructions concerning spray and dust drift to minimize drift and to protect people, other non-target organisms, and the environment from adverse effects that may be caused by off-target pesticide drift”. A secondary objective of the draft PRN is to improve the consistency and clarity of pesticide labeling”. However, the positive of improving consistency and clarity is vastly overshadowed by the far-reaching and overly restrictive proposed label language which, without some level of quantification of the benefit to be gained from the proposed restrictions, has the potential to severely impact American agriculture by reducing the amount of available cropland. Reduced acreage translates to lower production of food and fiber, which translates into increasing food costs to the American consumer as well as inhibiting the ability of the American farmer to compete worldwide, thus reducing America’s trade surplus.

The full economic impact on agriculture of multiple, intersecting EPA actions and initiatives (such as Clean Water Act (CWA) National Pollution Discharge Elimination System (NPDES) permitting, litigation-driven endangered species (ES) mitigations, as well as this draft drift PRN) has not been evaluated by EPA or the Office of Management and Budget (OMB). In addition, EPA has failed to adequately substantiate and quantify the existence of risk or the likely probability that risk will occur to the level consistent with the meaning of “unreasonable adverse effects” as defined by FIFRA 2(bb) necessary to justify the Agency’s proposed draconian drift label language and policy. CLA recommends that before moving forward EPA work with AAPCO and the regulated community to evaluate the surveys and other reported incidents to determine the significance of the complaints. Since the vast majority of pesticide applications are carried out without adverse effects and without complaints, EPA should be cautious in making major decisions based on a comparatively small number of complaints.

CLA supports efforts to ensure that pesticide use does not cause unreasonable adverse effects to the public and the environment. However, CLA does not agree with the Agency’s allegations regarding the significance of risk associated with pesticide drift, nor with the approaches for mitigation presented in the draft PRN. Our disagreement primarily revolves around:

- 1) EPA’s apparent abandonment of FIFRA’s “unreasonable adverse effects” standard;
- 2) EPA’s implementation of an unrealistic and unworkable drift management policy that is not based on a risk-benefit analysis;
- 3) the potential negative economic impact the draft PRN would have on U.S. agriculture;

CLA contends that the primary approaches to minimizing off-target drift of pesticides should be through education programs, good application practices, and advances in application technology. CLA welcomes the opportunity to work closely with EPA, USDA, and other agricultural stakeholders to further advance effective and efficient drift minimization programs. When the Agency prepares the final PRN, CLA recommends the following steps in addition to the other recommendations contained herein. EPA should:

- (1) maintain and comply with the risk-based FIFRA standard of “no unreasonable adverse effects”;
- (2) propose a drift management policy that recognizes the complementary roles of non-regulatory and regulatory approaches;
- (3) consider the benefits to farmers and the rest of society from pesticide use;
- (4) conduct an economic impact assessment on those label-restriction options determined to be warranted;
- (5) develop a scientifically-valid problem formulation and risk assessment for drift bystander and drift-residue related exposures;
- (6) provide state lead agencies with clear directions for making risk-based enforcement decisions
- (7) allow sufficient implementation time for registrants to comply with any proposed label changes

More detailed comments and answers to EPA’s questions are presented below.

A. INCONSISTENT WITH FIFRA STANDARD OF “WILL NOT GENERALLY CAUSE UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT”

By its express statutory provisions, FIFRA established a standard for label language, including directions for use language. That statutorily-mandated standard is that label language for use of a pesticide will set forth directions for use such that “. . . *when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered . . . or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment*” (emphasis added) (FIFRA Sec. 3(d)(1)(B)), and also set forth in Sec. 3(c)(5) and in the corresponding regulations at 40 CFR 156.10). The term “unreasonable adverse effects on the environment” is defined in FIFRA Section 2(bb), and that section provides, in relevant part, “(1) *any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.*” (emphasis added). This risk-benefit analysis is also undertaken for public health pesticides (such as mosquitocides, etc.) that balance the risks of use vs. the risks of diseases if not reduced by use of pesticides. Contrary to the express mandate given to EPA by FIFRA, the draft PRN and justification documents appear to have deliberately abandoned any notion of regulating to avoid “unreasonable adverse effects” and do not appear to take into account the “economic, social and environmental costs and benefits”.

The FIFRA statutory standard of “generally no unreasonable adverse effects” with respect to label language directions for use must be upheld and consistently applied to spray drift directions for use provisions. This standard is applicable to many aspects of the directions for use, and it is not clear on what basis EPA would purport to apply a different standard only to spray drift label language. EPA has acknowledged that it is not intending to create or operate under a standard not provided under FIFRA by these provisions of the PRN and they must be evaluated under the established FIFRA standard which includes the basic statutory “risk/benefit” analysis. In addition, no new or undefined legal standards, such as “harm” or “could cause an adverse effect”, can be promulgated through a PRN. “Harm” in the PRN is purported to be used in replacement of “generally no unreasonable adverse effect” in the context of the established

FIFRA standard; however, it is not a term that has been legally defined under FIFRA and should neither be used in the PRN nor as a basis for undermining the established regulatory criteria contained in FIFRA. Furthermore, other terms and concepts used in the PRN and especially in many of the examples in the PRN contain vague and unenforceable provisions.

EPA cites findings in the Final Report (April 27, 2007) to the Pesticide Policy Dialogue Committee by the Spray Drift Workgroup (PPDC-SDWG) as impetus for this draft drift label language. However, the final report from this group states “Consensus Findings: The workgroup meaningfully explored differing ideas of what constitutes “harm” from spray drift. However, the group did not agree on a central concept of harm”. Instead of EPA focusing this draft PRN on areas of PPDC-SDWG consensus, such as the use of new technologies to minimize drift, EPA appears to have abandoned the FIFRA risk-based standard and purports to create a new standard of “harm” as put forth by the most extreme, non-consensus perspectives of a few individuals in the workgroup. As is set forth in more detail in the next section, CLA contends that it is inappropriate and not legally supportable for this draft PRN to purport to create a new standard of enforcement and to define as a violation the mere presence of a pesticide off of the application site at any detectable level, even after the grower or applicator has complied with all label language spray drift mitigation requirements.

While CLA believes that the draft PRN as written exceeds EPA’s statutory mandate, CLA does believe that EPA can accomplish the goal of minimizing drift within the confines of FIFRA. As described more fully herein, CLA believes that any label language required by a final PRN should focus on incorporating specific performance standards and technologies that exhibit a measurable reduction in the potential for drift, including drift reduction technologies, droplet size, wind speed, wind direction and other environmental conditions, etc., and should include a general drift statement such as **“Follow label directions to reduce the potential for drift incidents.”**

B. UNREALISTIC DRIFT MANAGEMENT POLICY THAT IS NOT BASED ON RISK-BENEFIT ASSESSMENT

The label language proposed by the draft PR Notice is unrealistic and seriously flawed from the perspective of prudent regulatory decision-making. It replaces the required balancing of the benefits and risks of pesticides under FIFRA with what appears to be a zero-drift, zero-exposure policy. For example:

In the PRN, EPA proposes expanding the Worker Protection Standard (WPS) for products intended for agricultural crop, nursery, forestry, and greenhouse uses from requiring the statement:

“Do not apply this product in a way that will contact workers or other persons, either directly or through drift.”

by the following “general” drift statement:

"In addition, do not apply this product in a manner that results in spray [or dust] drift that could cause [*emphasis added*] an adverse effect to people or any other non-target organism or site".

Also, EPA proposes expanding the application of the original WPS plus this additional language to other areas that EPA now deems "commercial", which includes "applications to rights-of-way, golf courses, athletic fields, residential turf, landscapes, parks, grounds, and other similar sites, commonly performed by hired personnel".

And EPA proposes applying the following general drift label language to products intended solely for non-commercial application, such as residential use on lawns and gardens:

"Do not apply this product in a way that could contact people, or that results in spray [or dust] drift that could cause harm [*emphasis added*] to people, pets, property, aquatic life, wildlife, or wildlife habitat".

Furthermore, EPA states that these general drift statements take precedence over product-specific label directions in the following:

"For products with specified application restrictions that minimize drift, complying with these specified application restrictions may not be sufficient to comply with the general drift labeling statements."

And EPA adds the following language to labels with product-specific language:

"Applicators must meet the standard set by the general drift statement, in addition to complying with following additional application restrictions."

The consequences of requiring such language would be ineffective attempts to manage drift, unwarranted economic losses to agriculture, and inconsistent and arbitrary standards. Label directions and mitigations must be developed based upon the risk assessment during registration such that, if followed by the applicator, generally no unreasonable adverse effect is anticipated. Moreover, proposed language is inconsistent with EPA's own policies and procedures regarding allowable label language. In the process of reviewing pesticide labels, OPP staff screen a "hit list" (3/11/2008) of words and phrases that adversely affect enforcement of label language. The list and accompanying instructions focus on clearing up "vague, unclear, or contradictory labeling text". In this draft PRN on spray drift and related documents, use of "could cause" clearly violates the intent of the "hit list" instruction sheet regarding lack of enforceability of label language.

EPA must incorporate risk and benefits into its drift management policy. A policy based entirely on exposure or the mere presence of a pesticide at any level is technically unachievable and inconsistent with EPA's FIFRA mandate. Furthermore, the benefits of risk mitigation must be balanced with the associated costs and overall economic impacts. Risks must be characterized and quantified, not only to comply with regulatory mandates, but also to assure that effective

mitigation can be formulated and implemented without imposing unnecessary burdens on the agricultural sector.

Contrary to FIFRA's mandate, the proposed general label language appears to circumvent or nullify the product-specific risk assessment process by attempting to cover all products with general language. In practical terms, any attempt to define one set of label language that fits all products is impossible. The proposed label language treats all products and all application techniques as having an equal amount of risk. It does not differentiate between those products that are considered hazardous and can only be applied by trained professionals and those recognized as registered for application by homeowners. The general label statement does not differentiate between, for example, application via aircraft and application by hand sprayer. In short, the language does not include conclusions from the risk assessment.

The general language and the product-specific language appear contradictory and increase the possibility of inappropriate enforcement actions and frivolous litigation through vague allegations of "contact (to) people" and "could cause harm to..." without regard to the manner, volume or frequency of application. By this standard, a single droplet could be interpreted as "contact" or "could cause harm". The result of EPA's required language is that even if an applicator uses all drift reduction technologies required by the label and complies with all label mitigations and directions for use designed to minimize drift, the applicator can still be found liable for drift if there is even a mere detection of a pesticide to an off-target site.

With today's highly sophisticated analytical technologies, pesticides and other chemicals can be detected at very low levels, even at parts per trillion levels, which typically would be well below any toxicologically significant level of risk to human health or the environment. So although it is US EPA's purview to make acceptable exposure determinations via a risk assessment during the registration process, state enforcement officials, who are typically NOT toxicologists or risk assessors, will be left with the overly conservative enforcement position that the mere detection of a pesticide is a violation. EPA's policy position must recognize that some trace level of drift outside the application site is often unavoidable. Spray Drift Task Force (SDTF) studies have shown that there is essentially zero drift upwind such that applicators can use wind direction to prevent drift into environmentally sensitive areas and areas where workers or bystanders could be contacted. The EPA would be better served to implement label changes that give incentive to the use of wind directional buffer zones to protect bystanders and sensitive areas, rather than implementing unobtainable "do not drift" language. The EPA's position should be that applicators must exercise caution during application and follow label directions/requirements so as to mitigate the potential for pesticide spray or dust to drift from the application site in levels that would cause an unreasonable adverse effect on the environment (which includes man in the environment). The mere detection of the presence of a chemical off-target is NOT an unreasonable adverse effect.

EPA should not impose broad, vague, unenforceable drift label language such as "could cause harm" and "could cause an adverse effect", etc., or "do not drift", which is not possible to achieve under all circumstances. Instead, the label language for drift mitigation should focus on specific performance standards and technologies that are known to reduce the potential for drift, including drift reduction technologies, droplet size, wind speed, wind direction and other

environmental conditions, etc. Therefore, EPA should implement a general drift statement such as “**Follow label directions to reduce the potential for drift incidents**”, along with drift mitigation label language incorporating valid standards and technologies to reduce drift potential at application.

C. INADEQUATE RISK CHARACTERIZATION AND QUANTIFICATION

FIFRA is a risk-benefit statute that obligates the Agency to conduct a risk-benefit analysis regarding any use of a pesticide. The proposed PRN on pesticide drift labeling recognizes this requirement under the Authority section of the PRN. Specifically in the second paragraph under Authority the Agency states that “based on its risk assessment, EPA may determine that the applicant-proposed labeling does not prevent unreasonable adverse effects from use of the pesticide. In those circumstances, EPA will, when appropriate, suggest revisions or restrictions for the labeling that will mitigate the pesticide’s adverse effects.” That paragraph concludes with the statement that “Thus pesticide labeling may be the means by which EPA effectuates risk mitigation measures identified through the risk assessment process”.

Notwithstanding this apparent recognition of its statutory obligations, EPA’s draft drift PRN does not provide for a risk assessment as the basis of the risk mitigation measures imposed via the drift label language. Instead, it redefines adverse effects on humans in a way that is inconsistent with the FIFRA definition and contains errors of facts. These issues are discussed in detail below.

Risk assessment is a process in which information is analyzed to determine if an environmental hazard might cause adverse effects to exposed persons and ecosystems.¹

Section 1.1.1 of the EPA evaluation of EPA risk assessment methods(EPA/100/B-04/001, March 2004) states that “EPA uses risk assessment as a tool to integrate exposure and health effects or ecological effects information into a characterization of the potential for health hazards in humans or other hazards to our environment.” This process is highly interdisciplinary, drawing from such diverse fields as biology, toxicology, ecology, engineering, geology, statistics, and the social sciences to create a rational framework for evaluating environmental hazards. Section 2.1.1 states that its general approach is that risk assessments “have been developed to assess risk based on available data and information, and EPA has been at the forefront of much of this development. Risk assessment is a complex process, requiring the integration of data and information across a broad range of activities and disciplines, including source characterization, fate and transport, modeling, exposure assessment, and dose-response assessment. EPA seeks to use the available information (data) in an objective, realistic, and scientifically balanced way. In each specific assessment, the Agency incorporates the relevant data and information to the extent possible (e.g., see chapter 5). Where relevant chemical- and/or

¹ Under FIFRA, EPA must register a pesticide before it can be sold or used in the U.S. (7 U.S.C. § 136a). To register or reregister a pesticide use, the Agency must ensure that the chemical will perform its intended function without generally causing any “unreasonable adverse effects on the environment.” (7 U.S.C. § 136a(c)(5)(C)). FIFRA defines unreasonable adverse effects as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide...” (7 U.S.C. § 136 (b)(1)).

site-specific data are not available, EPA uses specific default assumptions and extrapolations to fill in the data gaps and allow the risk assessment to proceed (see chapter 4) so that the Agency can ultimately make the decisions required under its mandates. This approach is consistent with the NRC's recommendation about EPA's use of defaults (NRC, 1994). In general, EPA's default assumptions are based on peer reviewed studies, empirical observations, extrapolation from related observations, or scientific theory."

The risk assessment is then used to inform the risk manager's decision making process. The risk assessment process therefore is a key source to permit the risk manager to make scientifically sound judgments. Inherent in the risk assessment process is the utilization of toxicity or hazard information and the exposure to the pesticide based on the intended labeled uses.

Thus, risk characterization and quantification, determined in the process of problem formulation, are fundamental, essential components of effective pesticide regulation under FIFRA. The importance of scientifically defensible risk characterization and management was stressed in a policy that EPA put forth in 1992 in the "New Paradigm" memorandum signed by Linda Fisher, Assistant Administrator, Office of Pesticides and Toxic Substances (now EPA Deputy Administrator). The policy stated that "As a regulatory agency, we must have a clear sense of how to use the data which we require." It further states that EPA would focus on risk assessment (characterization), followed by risk management through risk mitigation. Yet in the draft PRN, EPA prescribes label language requirements and restrictions based solely on the potential for exposure due to drift even at the level of mere detectable presence, with no regard for the combined elements of risk, i.e. exposure and hazard.

Both methodology and data exist to permit the Agency to conduct quantitative assessments to determine the exposure and risks resulting from human contact with residues deposited off target following lawful pesticide applications.² The SDTF developed a generic spray drift database that is intended to address spray drift requirements for pesticide products. The AgDRIFT® database evaluation tool was developed from the data to help estimate exposure from spray drift for individual pesticides. Drift data can then be combined with established exposure assessment methodologies such as those detailed in the Agency's Residential Exposure Standard Operating Procedures to estimate exposure resulting from contact with drift residues.³

The Agency must take a consistent approach regarding bystander exposure to pesticides. EPA's proposed approach to spray drift should be consistent with the Agency's approach to regulating volatile pesticides and volatilization from non-volatile pesticides as presented in December 2009. The Agency proposed a risk assessment approach to assess inhalation exposure resulting from field volatilization of conventional pesticides with the goal to develop "user-friendly" methodologies to guide the assessment of bystander exposure resulting from field volatilization of conventional pesticides. For this effort the Agency has taken exposure assessment methodologies developed for the fumigants and adapted them by utilizing soil models to predict field volatilization of conventional pesticides from plant and soil surfaces. A two tiered risk

² Such capabilities are similarly stated in the petition by Farmworker Justice and Earth Justice (Pesticides in the Air – Kids at Risk? Petition to EPA to Protect Children From Pesticide Drift, submitted 13 October 2009).

³ A similar procedure and guideline has been proposed to European Union regulatory agencies (Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application, Martin et al., Journal of Consumer Protection and Food Safety, 3(2008) 272-281.)

assessment approach was developed which appears consistent with the Agency's mandate under FIFRA to conduct a risk/benefit analysis. The proposed spray drift approach must also be consistent with EPA's "Proposed Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses" issued on 9 December 2009. On page 8 of the document the Agency states its intention to expand the risk assessment process from volatiles to also include pesticide spray and dust drift.

CLA has provided a direction for risk assessment for drift that it believes is consistent with FIFRA and the petition by Farmworker Justice and Earth Justice. The proposed path forward is presented in Appendix A and is also included along with CLA's comments on the other two drift-related EPA Federal Register Notices: "Petition to Protect Children from Pesticide Drift" [74 FR 57168, 11/4/2009, Docket No. EPA-HQ-OPP-2009-0825] and "Policy Paper on Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses" [74 FR 88032, 12/10/2009, Docket No. EPA-HQ-OPP-2009-0889].

D. LEGAL RAMIFICATIONS RELATED TO A ZERO THRESHOLD FOR DRIFT

Zero drift is not often achievable in the real world and therefore imposes unrealistic requirements on applicators, farmers and homeowners. EPA's proposed general drift statements (quoted above) that impose a zero-drift policy and vague, unenforceable language including "may cause or could cause harm or adverse effects" will invite unreasonable and/or inconsistent enforcement against farmers, applicators, and homeowners who follow label directions and use best management practices to minimize spray drift. While EPA maintains that enforcement agencies will act reasonably, such assurances provide little protection for regulated applicators who become subject to enforcement on the basis of the individual discretion of state personnel, rather than actual adverse effects. The Agency's proposed zero-drift policy may also encourage other types of potentially meritless litigation. Farmers, applicators, homeowners and other regulated parties may face unwarranted civil liabilities should plaintiffs claim that *de minimus* amounts of pesticide residue constitute a nuisance or *per se* negligence. The prohibition may also have a significant effect on insurance availability for applicators and homeowners since no amount of care can prevent all *de minimus* spray drift. EPA is well aware that some *de minimus* level of drift occurs from most pesticide applications. In short, the proposed policy/language opens the door to frivolous and contentious neighbor-against-neighbor litigation. **CLA reminds EPA of the experiences of its previous zero cross-contamination policy.** Many of the enforcement actions brought pursuant to that policy were based on insignificant (from a risk perspective) and largely unavoidable low level cross-contamination of pesticide products. The numerous complaints from both regulated entities and enforcement agencies caused the Agency to revise the cross-contamination policy to include quantitative criteria and to recognize that "cross-contamination is a reality, and that not all cross-contamination is problematical." (EPA PR-Notice 96-8, 10/31/1996).

CLA also maintains that the proposed language erodes the credibility of the EPA's authority, because it does not take into consideration either the realities of agricultural practices or the real risk. Low levels of drift do not necessarily cause environmental effects and should not be

subject to enforcement unless the predicted levels pose an unreasonable risk to defined non-target areas. Because of the number of pesticide products on the market, such risk assessments can only be determined on a product-by-product basis.

E. UNWARRANTED ECONOMIC IMPACTS ON U.S. AGRICULTURE

Under FIFRA, EPA is required to consider benefits of pesticides, as well as impacts on agriculture, including economic impacts. Under the Endangered Species Act (ESA) as amended in 1988, Congress mandated that ESA compliance for EPA's pesticide regulatory program be designed to "minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators."

The draft drift PRN provides neither substantive analysis nor consideration for the benefits of pesticides use or the impacts on agricultural productivity and economics that these draft drift label statements will incur. The extremely broad restrictions on the use of pesticides that would result from this PRN will have significant negative economic impacts on agricultural productivity and the health of the agricultural industry, in general. The current serious economic conditions in agriculture and in the United States in general, make it even more important that the Agency realistically characterize and quantify the risks associated with pesticide drift, and take regulatory actions that avoid negative economic impacts.

CLA requests that EPA and OMB evaluate the economic impact of this draft PRN on agriculture, and in conjunction with other similar EPA actions such as NPDES permitting and litigation-driven ES mitigations, and that EPA analyze the benefits of the draft PRN in this economic context. CLA believes that should EPA finalize this draft PRN as proposed, a significant amount of agricultural land will be removed from production, growers will lose viable pest management options, and the economic costs will be significant. In 2001 EPA proposed a similar 'zero drift' policy in a draft PRN. At that time the SDTF conservatively estimated that the implementation of such a policy would result in up to seven million acres of farmland removed from production, and lost earnings of \$1.4 billion annually (SDTF comments, Docket #OPP 00730, April 1, 2002). By its own assessment, the U.S. Department of Agriculture (USDA) estimated that, if non-wind-directional buffers were implemented, the U.S. economic loss would be on the order of \$1-2 billion dollars due to the large amount of irreplaceable acreage removed from production (USDA comments, Docket #OPP 00730, April 1, 2002).

F. MAGNITUDE OF RISK: ASSOCIATION OF AMERICAN PEST CONTROL OFFICIALS (AAPCO) SURVEY, and STATES' ROLE IN DRIFT MANAGEMENT PROGRAMS

EPA did not adequately characterize or quantify the existence of risk or the probability that "unreasonable adverse effects" (as defined in FIFRA 2(bb)) warrants further label restrictions on drift. The Agency references the AAPCO Pesticide Drift Enforcement Survey, a compilation of "complaints" of drift from individuals and investigated by roughly 40 states, as justification for the proposed drift label language and basis for its assumptions of risk. However, no detailed

analysis of the incidents is presented, and it appears that EPA's justification for increased regulation is based solely on the number of incidents reported without consideration to their validity or significance. The AAPCO survey covers years 1993-8 and 2002-4 (totaling nine years). Over that time, both the total number of complaints investigated (almost 2,500 in 1993 to roughly 1,700 in 2004) and the number of confirmed drift incidents have trended downward. Drift was confirmed in only about 50% (less than 850 cases) of the cases investigated (2002-4), while the percentage of enforcement actions taken in confirmed drift cases has consistently been approximately 35%. Given the hundreds of thousands of pesticide applications each year, the number of confirmed drift incidents is relatively few. The category of non-target sites in the AAPCO survey varied widely across states, with 'drift to humans' occurring rarely in most states; but of the 90-115 per year (2002-4) cases of 'drift to humans', approximately 60-70% occurred in just two states, California and Washington.

CLA disagrees with the one-size-fits-all national approach that is being proposed for drift management because it imposes unnecessary and burdensome regulation on the entire country, rather than allowing state authorities to address locally-inherent issues. A variety of local factors, such as cropping practices, agricultural landscapes, topography, and climatic conditions, determine the potential for drift from pesticide applications. California's agricultural valleys, for example, have characteristics that render those areas particularly prone to drift. EPA writes "States have increasingly been adopting state-specific drift regulations and prohibitions over the 10 years of the survey period"; in such unusual areas, state-specific drift regulations may be warranted and in fact, best addressed locally. The knowledge and experience of state authorities are best suited to manage effectively the localized factors that affect potential for drift. Drift management has a very significant local component. Drift management cannot be conducted solely and effectively from the federal level. EPA needs to redefine its drift management policy and to identify the most effective and efficient roles of federal and state authorities.

EPA needs to better articulate its concerns over pesticide drift with substantiated data before proposing new label language. Before concluding that drift incidents justify additional regulation of pesticides, CLA asks that EPA (1) determine whether the incidents are actual violations of existing label requirements; (2) quantify the effects on human health and ecologically valuable resources; and (3) determine whether there were unreasonable adverse effects as defined in FIFRA 2(bb). Otherwise the result may be wasted resources for both the Agency and registrants, with no assurance that the new label language will address the Agency's underlying concerns. If EPA is concerned about lack of compliance with existing spray drift labeling, new label language may not remedy this issue as effectively as non-regulatory approaches, such as stewardship and outreach efforts.

G. INSUFFICIENT IMPLEMENTATION TIMELINE

In the draft PRN, EPA allows only six months from the date of final PRN release for registrants to implement new drift language on labels that currently have no drift statements, and only twelve months for implementation on labels that currently do have such statements. This time allotment is not feasible, particularly for home and garden products that are numbered in the tens-of-thousands for which label amendments must be reviewed and approved in some states,

while other states need time to review and comment. In addition, registrants will need time to comply with provisions for existing stocks of home and garden products in retail and distribution channels. **The registrant community will need at a minimum 24 months to review all product (agricultural and non-agricultural uses) labels and implement new drift label language, regardless of whether product-specific drift language already exists on the label.**

The PRN directs registrants to remove "general drift statements from product labeling". This kind of instruction is extremely vague and will contribute to mass confusion when registrants attempt to comply with the PRN. The Agency will need to provide specific examples of this language. It is important to note that currently general drift statements on product labels provide instructions on how pesticide spray drift can be minimized. If these instructions are removed, and product-specific spray drift tables are not added to labels until years later after the product has been through the registration review process as the PRN suggests, the potential for drift increases in the interim period. Instead, we suggest that all changes to labels relative to spray drift for products that have existing drift labeling be changed during the pesticide's next registration action involving a new use or a new product or at latest during the registration review process. This will allow for an orderly transition.

In addition to the points already addressed, Considerations for Possible Standard Operating Procedure(s) for Conducting Risk Assessments for Spray Drift and Technical Difficulties to Consider may be found in Appendix A.

CONCLUSION

In conclusion,, the Agency's draft PRN proposes far-reaching and overly restrictive proposed label language which, without some level of quantification of the benefit to be gained from the proposed restrictions, has the potential to severely impact American agriculture by reducing the amount of available cropland. Reduced acreage translates to lower production of food and fiber, which translates into increasing food costs to the American consumer as well as inhibiting the ability of the American farmer to compete worldwide, thus reducing America's trade surplus.

The full economic impact on agriculture of multiple, intersecting EPA actions and initiatives (such as Clean Water Act (CWA) National Pollution Discharge Elimination System (NPDES) permitting, litigation-driven endangered species (ES) mitigations, as well as this draft drift PRN) has not been evaluated by EPA or the Office of Management and Budget (OMB). In addition, EPA has failed to adequately substantiate and quantify the existence of risk or the likely probability that risk will occur to the level consistent with the meaning of "unreasonable adverse effects" as defined by FIFRA 2(bb) necessary to justify the Agency's proposed draconian drift label language and policy. CLA recommends that before moving forward EPA work with AAPCO and the regulated community to evaluate the surveys and other reported incidents to determine the significance of the complaints. Since the vast majority of pesticide applications are carried out without adverse effects and without complaints, EPA should be cautious in making major decisions based on a comparatively small number of complaints.

CLA supports efforts to ensure that pesticide use does not cause unreasonable adverse effects to the public and the environment. However, CLA does not agree with the Agency's allegations regarding the significance of risk associated with pesticide drift, nor with the approaches for mitigation presented in the draft PRN. Our disagreement primarily revolves around:

- 1) EPA's apparent abandonment of FIFRA's "unreasonable adverse effects" standard;
- 2) EPA's implementation of an unrealistic and unworkable drift management policy that is not based on a risk-benefit analysis;
- 3) the potential negative economic impact the draft PRN would have on U.S. agriculture;

When the Agency prepares the final PRN, CLA recommends the following steps in addition to the other recommendations contained herein. EPA should:

- (1) maintain and comply with the risk-based FIFRA standard of "no unreasonable adverse effects";
- (2) propose a drift management policy that recognizes the complementary roles of non-regulatory and regulatory approaches;
- (3) consider the benefits to farmers and the rest of society from pesticide use;
- (4) conduct an economic impact assessment on those label-restriction options determined to be warranted;
- (5) develop a scientifically-valid problem formulation and risk assessment for drift bystander and drift-residue related exposures;
- (6) provide state lead agencies with clear directions for making risk-based enforcement decisions; and
- (7) allow sufficient implementation time for registrants to comply with any proposed label changes.

CLA contends that the primary approaches to minimizing off-target drift of pesticides should be through education programs, good application practices, and advances in application technology. CLA welcomes the opportunity to work closely with EPA, USDA, and other agricultural stakeholders to further advance effective and efficient drift minimization programs.

Appendix A. CONSIDERATIONS FOR POSSIBLE STANDARD OPERATING PROCEDURE(S) FOR CONDUCTING RISK ASSESSMENTS FOR SPRAY DRIFT AND ADDITIONAL POINTS TO CONSIDER

Development of Drift Management Parameters and Mitigation for Product Labels

Different models (AGDISP, Ag DRIFT, and others) currently are being used by EPA and state agencies to determine minimum values for boom height, droplet size, wind speed, and buffer zones for applications made by ground and air. The science applied in determining mandatory application parameters for preventing spray drift that "could cause an adverse effect to people or any other non-target organism or site" needs to be sound, transparent, and equitably applied across products. Refinement and further development of such models requires time.

The notice states that the dictated label language must be "sufficiently clear, flexible and practical so that applications can be performed by pesticide applicators". Requiring registrants to include a table on each product label that lists mandatory limits for maximum wind speed and minimum values for boom height, droplet size, and buffer zones for applications made by ground and air is not "flexible" or "practical". State agencies have indicated that they want clear and concise directions on labels, particularly as they relate to spray drift. The new drift tables will not necessarily be "concise" if one takes into account the multiple product rates on labels which could require multiple tables with varying restrictions and even more confusion. It will take the registrant considerable time to develop such tables. Also, time may be required to allow for farmer and applicator training so that they can understand how to interpret and implement these new tables and label directions. Additionally, these minimum mandatory limits may render products ineffective, especially fungicides and insecticides that require thorough plant canopy coverage. The registrant needs time to evaluate whether drift label changes affect efficacy of the product, to discuss this with the Agency, and to develop drift mitigation strategies that do not sacrifice efficacy. EPA has not considered nor allowed for all these additional time requirements. Evaluation of drift potential and movement, associated risks, product efficacy, and mitigation measures and technologies is best accomplished during the registration review process.

Drift mitigation should be tailored to specific application scenarios and conditions. Drift mitigation should be performance driven to allow applicators the discretion to utilize the most appropriate technologies, techniques, and practices dictated by the circumstances of each application and professional judgment. Applicators already take measures that effectively control drift. These measures include spray swath adjustment, equipment modifications, product selection, application timing, wind direction, and many other commonly accepted regional and crop-specific practices.

Excessively Broad Application to All Pesticide Uses

In the draft PRN, EPA proposes labeling statements for agricultural use pesticides as well as for home and garden products and other uses. The potential for havoc created by the draft drift

language such as “could cause” adverse effects, in conjunction with defining human health effects as “any” symptoms that may be “temporary” and does not require medical treatment or confirmation, is an open invitation for frivolous lawsuits and inappropriate enforcement actions, which would impact not only farmers and applicators, but individual homeowners as well. Neighbor will be suing neighbor. Already farmers and applicators in several states are being harassed by individuals who intentionally stand at the edge of property or in a field while applications are occurring.

No-Spray Zones or Buffer Zones

EPA refers to the use of “no spray zones” (buffers) in minimizing drift. CLA recognizes that under certain conditions buffers, or “no spray zones” may be an effective tool in reducing drift to non-target areas. However, it is CLA’s opinion that generic, location specific buffers should be considered to be a last resort after exhausting other Best Management Practices (BMP) techniques and technologies to protect against product or chemistry specific unreasonable adverse effects on human health or the environment. Given the potential for significant cost to the farmer in lost production, EPA should work with the agricultural stakeholder coalition to discuss workable measures to minimize drift without unduly penalizing growers. As discussed above, EPA should implement ‘wind directional’ no spray zones, particularly to sensitive areas when needed.

CLA suggests that EPA take an approach consistent with Canada’s Pest Management Regulatory Agency (PMRA) for determining buffer size and necessity as described in “Agricultural Buffer Zone Strategy Proposal”, November 2005.

Further comments on no-spray zones are provided below in Appendix H “Technical Comments”.

Timeframe for Releasing Products for Shipment With New Drift Labeling

Dates for implementation of the draft PR notice are not feasible. The draft notice states that "Products released for shipment after notification or approval of an amendment must bear the approved statements when new labeling is printed, or 12 months following the label's approval, whichever is earlier." Registrants need clear timelines for label printing, not "when new labeling is printed". This is too vague and is neither feasible nor enforceable. As an example, if a label is approved by EPA on Oct. 31, 2010, and labels for that product are scheduled to be printed on November 20, 2010 for the following year's production, there is no physical way to get the new labels typeset, reviewed, printed, and to the production facility in time for production. Even if this was possible, registrants need time to prepare a printers proof of the market label and submit it to some state agencies (e.g., New York, California) for review and approval **before** the label is ever released for production. This process can take up to a year or more alone, particularly since most of the new drift label language will be reviewed as an amendment by both the EPA and state agencies and not by notification.

Timing for label changes should be handled in the same manner that previous PRNs have been handled, but allow more than the standard 18 month timeframe for products registered in

California and New York. CLA suggests:

- applications for amendment be submitted with sufficient time for EPA to review before a specified date;
- once approved, registrants to have up to 24 months (28 months for products registered in California and/or New York) from the date of the approved label to release product for shipment bearing the newly approved label language.

Appendix B. A PROPOSED METHODOLOGY FOR HUMAN HEALTH RISK ASSESSMENT FROM SPRAY DRIFT

The proposed PRN on drift label language is inconsistent with the requirements of FIFRA because it is not based upon a risk assessment. A risk/benefit approach to spray drift would be consistent with the process EPA has previously used with bystander exposure to the fumigant pesticides and proposes to use to address bystander exposure resulting from the volatilization of conventional pesticides. Instituting a similar, risk-based approach to bystander exposure to spray drift would therefore be consistent with the Agency's approach to other sources of bystander exposure.

Bystander exposure can be differentiated into two categories. The first is when an individual is inadvertently present for a short period of time during the application of a pesticide. They may be directly exposed via the dermal or inhalation routes. Because this type of exposure involves direct contact with the spray during application, it is a violation of the label regardless of the level of exposure and therefore should not be included in the risk assessment during the registration process.

The second category involves exposure to drift residues that have deposited on off-target surfaces. Exposure in this situation involves dermal exposure from the transfer of deposited residues from contact with surfaces; inhalation exposure from vapors or re-suspended particles; and for young children, incidental oral ingestion from hand-to-mouth contact or similar activities. Quantification of the potential exposure to drift residues involves combining the information obtained from drift studies with the EPA Residential Standard Operating Procedures (SOPs). AgDRIFT® and AGDISP models estimate levels of spray drift residue deposited downwind at different distances following various types of applications such as aerial or airblast. The Residential SOPs are a series of scenarios including outdoor lawns that provide algorithms for calculating dermal and oral exposure to turf residues following a lawn application. Conceptually there is no difference in estimating the exposure to residents following a lawn application in which the residues were applied directly to the turf and the exposure to residents from contact to turf in which the residues were deposited on the turf from off-target drift. The residential lawn SOP scenario can reasonably be assumed to be representative of other exposure scenarios including off-target drift.

Appendix I PROPOSED RISK-BASED SPRAY DRIFT ENFORCEMENT

METHODOLOGY discusses, in broad terms, quantitative exposure assessment methods that could be used prospectively for label revision by relying on validated, quantitative models that predict exposure.

The Residential Lawn SOP

Post-application exposure regarding drift residues refers to an exposure scenario in which an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) pathways as a result of being in an environment in which pesticide residues have been deposited on exposed surfaces via drift. Post-application dermal exposure is dependent on surface residues after deposition and surface-to-skin transfer. Post-application inhalation exposure depends on

concentrations in the air after deposition and inhalation rates. Post-application oral exposures are based on the ingestion of residues that can result from transfer of residues from hand-to-mouth or object-to-mouth or via direct ingestion of residues through soil ingestion or dust ingestion.

Post-application dermal and inhalation assessments are typically conducted for adults, teens, youths, toddlers, and infants while non-dietary oral post-application exposure assessments are typically only conducted for toddlers and infants. Unlike occupational exposure assessments, a drift exposure assessment assumes that the individuals are not likely to take actions to avoid or control their exposure and that the clothing worn will be typical for the season of the year and may reasonably involve less than long pants and a long-sleeved shirt. Because there are no administrative controls to prohibit exposure to deposited drift residues, the residential exposure assessment to drift should include an estimated dose based on residue on the day of deposition.

The EPA residential turf post-application SOP provides a standard method for estimating potential dermal doses among adults and/or toddlers from dermal contact with turf that has previously been treated with pesticides. This method is also applicable for estimating the potential dermal exposure from dermal contact with turf on which drift residues have deposited and have been estimated using the AgDRIFT® model. This scenario assumes that pesticide residues are transferred to the skin of adults/toddlers who enter treated lawns for play, recreation, yard work, or other homeowner activities.

Post-application Dermal Exposure Algorithm – Physical Activities on Turf

Exposure resulting from contacting previously treated turf while performing physical activities is calculated as follows:

$$E = TTR_t * CF1 * TC * ET$$

where:

- E = exposure (mg/day);
- TTR_t = turf transferable residue on day t (µg/cm²);
- CF1 = weight unit conversion factor (0.001 mg/µg);
- TC = transfer coefficient (cm²/hr); and
- ET = exposure time (hr/day).

If chemical specific TTR data from drift deposition are available, then measured surface residues should be used. However, if data are not available, then TTR_t can be calculated using the following formula:

$$TTR_t = AR * F * CF2 * CF3$$

where:

- TTR_t = turf transferable residue on day t (µg/cm²);
- AR = application rate (kg a.i./m² or kg ai/ha and expressed as µg/cm²);
- F = fraction of ai as transferable residue following application (unitless);

Absorbed dermal doses are calculated as:

$$D = E * AF \div BW$$

where:

D = dose rate (mg/kg-day);

AF = absorption factor (dermal); and

BW = body weight (kg).

Post-application Inhalation Exposure Assessment

The residential SOPs do not include the potential for inhalation exposure resulting from the deposition of agricultural drift. Systemic inhalation exposure can be calculated based on the airborne concentration derived from the active ingredient's vapor pressure, the breathing rate, and duration of exposure. The inhalation exposure algorithm is expressed below:

$$E = (AC_V \times IR \times IA)$$

Where:

E_R = Exposure via the Inhalation Route (mg/day)

AC_V = Airborne Concentration of Vapour (mg/m^3)

IR = Inhalation Rate (m^3/day)

IA = Inhalation Absorption (%)

And the dose normalized by the body weight is expressed as:

$$D = E/BW$$

where:

D = dose (mg/kg/day);

E = exposure (mg/day); and

BW = body weight (kg).

Post-application Non-Dietary Ingestion Exposure Assessment: Hand-to-Mouth

This discussion provides a standard method for estimating the dose from incidental ingestion of pesticide residues resulting from drift deposition. It assumes that pesticide residues are transferred to the skin of toddlers playing on treated turf and are subsequently ingested as a result of hand-to-mouth transfer. It does not include residues ingested as a result of mouthing an object or via soil ingestion

Exposure from hand-to-mouth activity is calculated as follows (based on algorithm utilized in EPA's Stochastic Human Exposure and Dose Simulation (SHEDS)-Multimedia model:

$$E = [HR * (FM * SAH) * (ET * N_Replen) * (1 - (1 - SE)^{(Freq_Replen/N_Replen)})]$$

where:

E = exposure (mg/day);
 HR = hand residue loading (mg/cm²);
 FM = fraction hand surface area mouthed / event (fraction/event);
 SA_H = typical surface area of one hand (cm²);
 ET = exposure time (hr/day);
 N_Replen = number of replenishment intervals per hour (intervals/hour);
 SE = saliva extraction factor (ie, mouthing removal efficiency); and
 Freq_Replen = number of hand-to-mouth contacts events per hour (events/hour).

and

$$HRH = (Fai_{hands} * DE)/(SA_H * 2)$$

where:

HR = hand residue loading (mg/cm²);
 Fai_{hands} = fraction ai on hands compared to total surface residue from dermal transfer coefficient study (unitless);
 DE = dermal exposure (mg); and
 SA_H = typical surface area of one hand (cm²).

and

Dose, normalized to body weight, is calculated as:

$$D = E/BW$$

where:

D = dose (mg/kg-day);
 E = exposure (mg/day); and
 BW = body weight (kg).

Post-application Non-Dietary Ingestion Exposure Assessment: Object-to-Mouth This algorithm provides a standard method for estimating the dose from incidental ingestion of pesticide residues from turf to which drift residues have deposited. Considering the strengths and limitations of available data and behavioral characteristics of potentially exposed populations, exposure for toddlers is calculated in this scenario. It assumes that pesticide drift residues are transferred to a child's toy and are subsequently ingested as a result of object-to-mouth transfer. It does not include residues ingested as a result of soil ingestion.

Exposure from object-to-mouth activity is calculated as follows:

$$E = [OR * CF1 * SAM_O * (ET * N_Replen) * (1 - (1 - SE_O)^{(Freq_Replen/N_Replen)})]$$

where:

E = exposure (mg/day);
 OR = chemical residue loading on the object on day "t" (ug/cm²);
 CF1 = weight unit conversion factor (0.001 mg/μg);

SAM_O = area of the object surface that is mouthed (cm²/event);
ET = exposure time (hr/day);
N_Replen = number of replenishment intervals per hour (intervals/hour);
SE = saliva extraction factor (ie, mouthing removal efficiency); and
Freq_Replen = number of object-to-mouth contact events per hour (events/hour).

and

$$OR = AR * F_O * CF2 * CF3$$

where

OR = chemical residue loading on the object (µg/cm²);
AR = application rate (kg ai/m² or kg ai/ha and expressed in µg/cm²);
F_O = fraction of residue available on the object (unitless);

and

Dose, normalized to body weight, is calculated as:

$$D = E/BW$$

where:

D = dose (mg/kg-day);
E = exposure (mg/day); and
BW = body weight (kg).

Post-application Incidental Soil Ingestion Exposure Algorithm

Exposure from incidental soil ingestion is calculated as follows:

$$E = SR_t * SIgR * CF1$$

where:

E = exposure (mg/day);
SR_t = soil residue on day "t" (µg/g);
SIgR = ingestion rate of soil (mg/day); and
CF1 = weight unit conversion factor (1 x 10⁻⁶ g/µg).

and

$$SR_t = AR * FS * (1-FD)^t * CF2 * CF3 * CF4$$

SR_t = soil residue on day "t" (µg/g);
AR = application rate (lbs ai/ft² or lb ai/acre);
FS = fraction of ai available in uppermost cm of soil (fraction/cm);
FD = fraction of residue that dissipates daily (unitless);

t = post-application day on which exposure is being assessed;
CF2 = weight unit conversion factor ($4.54 \times 10^8 \mu\text{g}/\text{lb}$);
CF3 = area unit conversion factor ($1.08 \times 10^{-3} \text{ ft}^2/\text{cm}^2$ or $2.47 \times 10^{-8} \text{ acre}/\text{cm}^2$); and
CF4 = soil volume to weight unit conversion factor ($0.67 \text{ cm}^3/\text{g soil}$).

Dose, normalized to body weight, are calculated as:

$$D = E \div BW$$

Where

D = dose (mg/kg/day);

E = exposure (mg/day); and

BW = body weight (kg),

Appendix C. PESTICIDE PROGRAM DIALOGUE COMMITTEE (PPDC) SPRAY DRIFT WORKGROUP REPORT

EPA cites findings of the PPDC-SDWG as impetus for this draft drift PRN. Some of the areas of “Consensus Findings” arrived at by the PPDC-SDWG are discussed below.

“Workgroup members decided to focus on: 1) labeling to mitigate spray drift; 2) the role of education, training, and stewardship; and 3) practices and equipment to mitigate drift and adverse effects from drift.”

The Workgroup identified as problems: “labeling statements that are unenforceable” and “labeling statements that are confusing, impractical, and/or contradictory”. CLA contends that label statements such as “could cause harm or adverse effects” are vague, confusing, and impractical from an enforcement standpoint.

“The Workgroup meaningfully explored differing ideas of what constitutes “harm” from spray drift. However, the group did not agree on a central concept of harm”. Instead of EPA listening to the group and focusing this draft PRN on areas of consensus, such as the use of new technologies to minimize drift, EPA neglected the FIFRA risk-based standard and purports to institute in this PRN a new standard of “harm” not defined under FIFRA and its regulations (and indeed, in conflict with FIFRA mandates) based on the most extreme, non-consensus, perspectives of a few individuals in the workgroup.

With regard to Drift Reduction Technologies (DRT), in consensus the Workgroup regarded “advances in DRT as being a promising way to reduce spray drift over the long run. The Workgroup gained the understanding that a variety of DRTs exist and are commercially available. EPA’s DRT project is intended to increase the adoption of DRTs by developing a standardized evaluation process so that incentives can be developed through government programs and through acknowledgement on pesticide labels. The Workgroup recognizes that adoption of new technologies will occur more rapidly if there are appropriate incentives. The Workgroup also recognized that efforts to encourage adoption of new technologies should be part of a larger program that includes appropriate training.” The Workgroup “encourages EPA to continue its support for the DRT project and initiate testing of several technologies, including an assessment of the efficacy of those technologies and the economic impacts of their adoption, as a demonstration of the technology verification protocol under development. The workgroup recommends that EPA should: 1) explore with appropriate experts and practitioners establishing performance standards for pesticide application equipment and practices designed to minimize drift, and 2) encourage the use of such equipment and practices.”

The Workgroup found that “Applicator attention to geography, local weather conditions, cropping patterns, and the presence of people and sensitive areas is essential to prevent harm from spray drift” and recommended that “EPA work with States and applicators to explore mechanisms that tailor regulatory requirements to local conditions. These mechanisms could impose additional, more stringent controls on pesticide use that are appropriate for the specific geographic area where the pesticide would be applied”. Given that the confirmed drift incident data from the AAPCO survey discussed above in Section H indicates that the type of drift

incidents vary widely among the states and bystander exposure to humans is relatively rare in most states and appears to cluster in two states; rather than EPA imposing an unnecessary one-size-fits-all approach to drift label language, EPA should work with States to assist them in determining the roots of their drift incidents and how best to address the problem given local conditions and recent advances in drift reduction technologies.

Appendix D. SPECIFIC COMMENTS ON “PESTICIDE DRIFT LABELING”

The following are comments on specific statements contained in the “Pesticide Drift Labeling” document contained in the docket for the draft drift PRN.

Original Text, Page 3: **“2. Application method: The product bears application instructions for a method that may result in spray or dust drift, including but not limited to, ground boom, airblast, aerial, spray chemigation, right-of-way sprayer, and handheld or backpack/knapsack equipment.”** Does the EPA intend to regulate “spray drift” without regard to total spray volumes or the magnitude of the areas covered? The total volume output, and surface area covered by a hand-held sprayer is vastly different from a ground boom or aerial application. By not distinguishing between the different application methods and the amount of land area covered, the EPA appears to treat all methods as equally hazardous and open to enforcement or litigation.

Original Text, page 4: **“For the purposes of this Notice, EPA considers “pesticide spray and dust drift” to be the physical movement of pesticide droplets or particles through the air from the target site to any non-target site. Pesticide spray and dust drift occurs during application or soon thereafter. Under stable atmospheric conditions (such as a near-ground temperature inversion), drift can also occur after the application has been completed.”** What time-frame is included by “soon thereafter”? Since volatilization of a product at any time after the initial application is not considered in this FR notice, how does the EPA intend to distinguish between “drift” immediately after application and off-site movement hours or days after the application. A spray applicator is unable to predict environmental conditions that may occur days after the application and environmental conditions that may lead to volatilization. How does the EPA plan to regulate or enforce any drift label language when the environmental conditions that may lead to off site movement occurs at a future time?

Original Text, page 5: **“In addition, do not apply this product in a manner that results in spray [or dust] drift that could cause an adverse effect to people or any other non-target organism or site.”** Use of the term “any other non-target organism or site” is extremely vague and can conceptually include anything outside of a treated area. Such vague language has led to litigation including allegations that animals removed from agriculture by hundreds or thousands of miles have been “adversely” affected by spray applications. The areas of concern should be identified and stated through a proper problem formulation as part of the overall risk assessment process rather than through vague and general label language.

Original Text, page 5: **“EPA believes that the general statement required by the WPS regulations – “Do not apply this product in a way that will contact workers or other persons, either directly or through drift.”... should also bear labeling statements to protect against potential adverse effects on people, other non-target organisms, and sites caused by pesticide drift.”** The proposed label changes as worded would state “do not allow to contact” as well as to “protect against potential adverse effects”. Whereas “no contact” would avoid “potential adverse effects” (excluding those attributable to odor), the converse is not true, i.e. it is

possible to have contact without adverse effects. The association between “contact” and “potential effects” should be established through a proper risk assessment, with the results included in the proper label statements. The proposed language appears to extend the protection (i.e. no contact) relegated to individuals not directly associated with the application (workers) to everything not associated with the application. As worded, the proposed changes would extend the WPS language to all others. Protection of applicators and other workers is usually done by way of personal protective equipment or engineering controls. Such methods cannot be applied to everything else. How then does the EPA intend to regulate the rest of the environment based on the premise of no contact or no exposure?

Original Text, page 6: **“...agency believes that additional drift labeling referring to specific application parameters may be necessary to minimize pesticide drift and to protect against potential adverse effects.”** The statement appears to contradict the label language proposed, specifically the “do not allow to contact” portion of the language. We agree that it is important to minimize the potential adverse effects of drift and that product specific application parameters may be needed to accomplish this goal.

Original Text, page 6: **“Additional labeling statements are appropriate for, and may be required for, any pesticide product, based upon EPA’s assessment of the pesticide’s risks.”** It is not clear how the EPA’s assessment of the pesticide risk is connected to the proposed label language. The language states a clear do not allow contact standard that voids any conclusions of the risk assessment. The risk assessment should be used to determine any specific application parameters that may be needed to minimize risk to people and the environment.

Original Text, page 6: **“For products with specified application restrictions that minimize drift, complying with these specified application restrictions may not be sufficient to comply with the general drift labeling statement.”** The label language appears to impose a do not allow contact standard regardless of any risk assessment conclusions rather than a minimize drift standard, or a minimize risk standard. The ‘do not allow contact’ standard would impose the same standards for highly toxic materials as for generally recognized as safe products that may be used for pest control in home gardens. Complying with specified application restrictions should satisfy spray drift management requirements.

Original Text, page 7: **“Pesticide registrants will then be able to choose to recommend or require through pesticide product labels the use of validated DRTs for product application as a drift mitigation measure, and EPA would consider such use in its risk assessment and risk management decisions for the registration of these products.”** The text cited above projects a future scenario when drift reduction technologies have been developed, reviewed and approved for use as a drift mitigation measure. It also says that the measures would be considered in registration decisions. However, the use of DRT and the registration decisions appear to be at odds with the proposed drift label language that does not include options for drift reduction mitigations and still imposes liability even if all recommended DRTs are used. The proposed label language calls for no contact to any area outside of the treated area. This is not rational, since even if the wind is blowing away from a sensitive site, it will be blowing toward some other site, i.e., no application of any kind can be made with zero drift outside the treated area.

Original Text, page 8: **“In the case of a currently pending application, an applicant may, at any time, submit revised labeling to address labeling recommendations contained in this PR Notice.”** If the language as stated is to appear on labels, then no risk assessment of any kind is needed. Does this then make it default language that should be on all labels? If any application specific parameters are to be included in the label language, would this require a new risk assessment and review within the EPA and would the additional review required require an additional PRIA fee? In the absence of any other guidance, how would product specific language be crafted that considers the risk assessment conclusions?

Original Text, page 9: **“EPA recommends that applicants for registration of new products...may propose values for the specified application parameters. In reviewing the application, EPA may determine that different product-specific drift parameters and/or values are needed. In such cases, the Agency would not register the product until the appropriate statements are added to the labeling.”** It is unclear which portion of the drift label language should be considered when determining specific application parameters. The general statement says to not allow contact to individuals or could cause harm to non-target areas. How will be application parameters be evaluated against this no contact standard? If an applicant does a risk assessment and submits application specific parameters that the EPA does not agree with, how is the disagreement to be resolved and will additional PRIA fees be assessed for any additional work required?

Original Text, page 10: Under the section “Registered products with no existing drift labeling statements”: **“add the appropriate general drift statements in Unit IV to the labeling for their products within six (6) months from the date of release of this Notice”.** If an existing product had no drift label language, doesn’t this mean that the EPA had no concerns for drift for that specific product? If there was a pre-existing concern, then why wasn’t there drift language? Does this mean that a revised risk assessment must be done, risk to individuals and other non-target areas from drift assessed, and then the general drift statement added? If the label language is added without risk having been identified during the registration of the product, then which action takes precedent, the initial review and evaluation during product registration, or adding label language to address a concern that was not identified in the initial review?

Original Text, page 11: **“In addition to adding the general drift statement in the specified 6-month timeframe,... EPA recommends that registrants submit amendments proposing to add product-specific drift statements to product labeling”.** Six months does not give sufficient time for development of the data needed to assess risk from drift; to conduct the risk assessment; to develop proposed mitigations; to submit the information to EPA; for EPA to review the submitted information; for question and answer meetings between EPA and the registrants; and for issuance of final approval.

Appendix E. SPECIFIC COMMENTS ON “DRAFT PESTICIDE DRIFT LABELING INTERPRETATION”

The following are comments on specific statements contained in the “Draft Pesticide Drift Labeling Interpretation” document contained in the docket for the draft drift PRN.

Original Text, page 7: **“could cause an adverse effect”, “could contact people”, “could cause harm”**: These are very vague statements that are subject to wide variation in interpretation and provide no clear, enforceable standards to state regulators or the regulated community. The potential to cause an adverse effect or cause harm does not constitute an “unreasonable adverse effect”.

Original Text, page 7 PR Notice 2009-X Last paragraph: **Compliance with specific application restrictions** on the label should be sufficient to comply with the general drift labeling statement. The product-specific label should contain all the information necessary to allow the applicator to make a lawful application.

Original Text, page 8 Examples of “Adverse Effects” or “Harm” to Humans: **“Any negative physical impact, health symptom, or illness ...”** A causal link must be established between the symptom or illness and the known properties of the product sprayed. Symptoms claimed after exposure to trace amounts do not establish a causal link if effects of the pesticide are only observed at concentrations orders of magnitude higher than the trace amounts measured. Investigations of many drift incidents do not support claims that were made. The proposed language validates any claims of effect regardless of whether drift was verified by sampling/analysis. Thus mere allegations of drift are upheld above scientific measurement, rendering quantitative investigation superfluous.

Original Text, page 8 Examples of “Adverse Effects” or “Harm” to Wildlife: The term **“viability”** is vague and subject to wide variation in interpretation. More specific terminology should be used to define effects other than death that are considered unreasonably adverse.

Original Text, page 8 Examples of Pesticide Drift that “Could Cause” an Adverse Effect **“EPA intends this prohibition to extend to situations in which an adverse effect from pesticide drift may not have occurred at the time of application, but the quantity or type of drift was reasonably capable of causing an adverse effect or could still cause an adverse effect through exposure to drift residues.”** If the quantity or type of drift was reasonably capable of causing an adverse effect, but did not do so because of steps that the applicator took to avoid exposure, this should not be considered a violation. This is implied in the examples, but should be clearly stated in the text. The terms “reasonably capable” or “could cause” referring to drift require a quantitative risk assessment. It also requires some judgment regarding where exposure is likely to occur. Inappropriately interpreted, drift onto one’s own property could be regarded as “reasonably capable” of causing an adverse effect. Thus, both the concentration and where that concentration occurs must be evaluated quantitatively. However, EPA provides no clear recommendation in that regard.

Original Text, page 9 – 10 Examples of Pesticide Drift that “Could Cause” an Adverse Effect
Bulleted points on these pages: Drift and the potential for effects caused by drift decline with distance from the application site. When determining whether drift of a pesticide which the label indicates has the potential to cause harm to humans or plants or wildlife might reach areas occupied by humans or wildlife or plants, the distance between the application site and the organism should be considered.

Original Text, page 12 Enforcing the General Drift Statement “**Do not allow drift that could cause an adverse effect**”: “Could cause” is a very vague statement that could be subject to wide variation in interpretation and provides no clear and enforceable standards to regulators and the regulated community. The potential to cause an adverse effect or cause harm does not constitute an “unreasonable adverse effect”.

Original Text, page 13 Flowchart Paragraphs 2 & 3 under flowchart: **Could the drift cause an adverse effect? Yes → Violation** A violation should only occur if an adverse effect has been caused. Without a clear quantitative risk assessment, this conclusion is meaningless and lacks credibility.

Original Text, page 13 Paragraph 2 under flowchart: “**Human exposure cases do not have to show direct contact ...Case file evidence showing that humans were directly exposed to a product is sufficient**” This statement needs further explanation, does it mean, for example, that skin contact does not need to be demonstrated if residues can be found on clothing? What about exposure to residues remaining on an agricultural product that are below established tolerances? EPA expressly allows such exposure in the context of residues on food products, for example, but there is no similar allowance in the context of application.

Original Text, page 15 Evidence Gathering Adverse effects occurred “**finding of dead pets, livestock, non-target wildlife or plants**”: To attribute an adverse effect to spray drift, a causal link must be established between the toxicity properties of the product sprayed, the concentration found in residues, and the adverse effect that occurred.

Original Text, page 19 IV. C. Paragraph 1: “**The Agency thinks, as a general matter, that exposure of humans – other than pesticide handlers- to a pesticide either directly (at the application site) or from contact with off-target drift is potentially dangerous.**” The risk to pesticide handlers is evaluated for each pesticide during the registration process, and personal protective equipment is specified based on risk. This same assessment process should allow the assessment of risk to humans other than pesticide handlers. It is inappropriate to apply the same hazard standard to all pesticides. This approach imposes unnecessary restrictions on applicators. Product-specific labeling should provide a clear indication of risk to humans and other non-target organisms to assist applicators in making appropriate application decisions. Applicators should not be required to assume equal hazard for all pesticides. Product-specific risk assessment is the appropriate way to balance the relative risk and benefits of a pesticide.

Original Text, page 19 IV. C. Paragraph 1: “**The Agency is concerned about situations where immediate adverse effects may not have occurred, been discovered, or determined, but where there is a potential for adverse effects to occur (for example, if pesticide drifts onto a**

school yard when children are not present).” It is inappropriate to apply the same hazard standard to all pesticides. This approach imposes unnecessary restrictions on applicators. Product-specific labeling should provide a clear indication of risk to humans and other non-target organisms to assist applicators in making appropriate application decisions. Applicators should not be required to assume equal hazard for all pesticides. Product-specific risk assessment is the appropriate way to balance the relative risk and benefits of a pesticide. Given that within the same chemical class toxicity can vary by orders of magnitude, it is not appropriate to assume that drift of any chemical from that class (e.g., organophosphates) may cause adverse effects without doing a quantitative risk assessment.

Original Text, page 21 IV.C.1.a. Examples of Adverse Effects Adverse effects on humans “**Any negative physical impact, health symptom, or illness ...**”: A causal link must be established between the symptom or illness and the known properties of the product sprayed. Symptoms claimed after exposure to trace amounts do not establish a causal link if effects of the pesticide are only observed at concentrations orders of magnitude higher than the trace amounts measured. Additionally, “negative physical impact” is vague and incredibly broad, and could be as any level of contact, even if no symptoms are exhibited. The nature of the physical impact, health symptom or illness must be consistent with measured concentrations, meteorologic conditions, type of pesticide used and its known effects. EPA’s proposed language allows any effect, no matter how improbable, to be attributed to a particular application.

Original Text, page 21 IV.C.1.a.Examples of Adverse Effects Adverse effects on wildlife: The term “**viability**” is vague and subject to wide variation in interpretation. More specific terminology should be used to define effects other than death that are considered unreasonably adverse.

Original Text, page 22 IV.C.1.a. Examples of Adverse Effects Adverse effects on property **Damage to agricultural commodities:** Effects should only be considered adverse if there is damage that negatively affects commodity quality or yield. Minor injury or discoloration at early plant growth stages in many cases does not impact commodity quality or yield, and may in fact increase yield.

Original Text, page 22 IV.C.1.a. Examples of Adverse Effects Adverse effects on property: The term “**viability**” is vague and subject to wide variation in interpretation. More specific terminology should be used to define effects other than death that are considered unreasonably adverse.

Original Text, page 23 IV.C.1.b.Examples of Pesticide Drift that “Could Cause” an Adverse Effect “**the potential for adverse effects could be high when children subsequently return to the schoolyard**”: It is inappropriate to apply the same hazard standard to all pesticides. This approach imposes unnecessary restrictions on applicators. Product-specific labeling should provide a clear indication of risk to humans and other non-target organisms to assist applicators in making appropriate application decisions. Applicators should not be required to assume equal hazard for all pesticides. Product-specific risk assessment is the appropriate way to balance the relative risk and benefits of a pesticide.

Appendix F. EXAMPLES OF TYPICAL CASES IN “DRAFT PESTICIDE DRIFT LABELING INTERPRETATION”

The approaches to investigating hypothetical drift incidents and the conclusions from those investigations described in most of the examples are reasonable, and these approaches should be captured in general guidance for determination of compliance rather than merely as examples only. Several of the case study examples contain errors regarding exposure and how the Agency conducts its own risk assessments. Additionally, in many instances the facts may be modified slightly from the scenarios presented, but those slight modifications may be significant. If the Agency cannot accurately provide examples of how exposure occurs or how it conducts its own risk assessments, it is unclear how this notice would simplify enforcement by the State Lead Agency (SLA). Even though many of these case examples seem reasonable, they do not consider risks, long term economic impacts, and recovery of plants/animals. Plants often recover from discoloration, and may even grow back hardier after an initial insult of an herbicide.

Again, although EPA’s examples seem reasonable, the potential for havoc created by the draft drift language such as “could cause” adverse effects, in conjunction with defining human health effects as “any” symptoms that may be “temporary” and do not require medical treatment or confirmation, is an open invitation for frivolous lawsuits and inappropriate enforcement actions which would impact not only farmers and applicators, but individual homeowners as well. Neighbor will be suing neighbor, with the SLA caught in the middle. Currently in several states, farmers and applicators are being harassed by individuals who purposely expose themselves by standing at the edge of the property with a drift collection device or even in the field during a ground or aerial application, and then report drift to the SLA.

Other comments/questions regarding several of the 14 case studies are discussed below.

Example 1: No drift violation was determined because no pesticide was found on the homeowners clothing or yard vegetation, and she had no symptoms. What would have been the determination had she had a headache and pesticide was found on her yard vegetation but not her clothing? (see example 6 also)

Example 4: A drift violation was determined to have caused damage to plants in a neighboring garden; however, the extent of economic impact or possibility of the plants to recover was not considered. Also, the example does not indicate if this is a vegetable garden, which is extremely pertinent because the adverse effects of “drift residues on a food commodity for which there is no established tolerance” is an important consideration.

Example 8: A drift violation was determined due to the presence of an organophosphate with a 5-day restricted entry interval, on neighboring schoolyard playground equipment because of “high potential of adverse human exposure”. The assessment of the five-day interval is inappropriate considering this is the time determined with respect to a direct spray to crop. The amount of drift would only be a fraction of the amount from a direct spray, and therefore the re-entry interval would be considerably shorter.

A 5-day re-entry interval is based on residues resulting from direct application to the orchard. Residues in the orchard would be much higher than residues resulting from drift. Conclusions about adverse effects from residues in the school yard should be made based on residue levels in the school yard and toxicity studies for the product.

Example 8 describes a situation where the application of an agricultural pesticide drifted onto a school yard. This example revolves around the assumption that drift could cause an adverse effect. The applicable evidence was that there was a high potential of adverse human exposure to the pesticide because according to its labeling and MSDS, the insecticide was toxic to humans. There was no direct contact of the drift with any person so that the issue is contact with deposited drift residues in the school yard. The example then states that because of the label's 5-day restricted entry interval or REI for tree fruit that one can reasonably presume that the residues present in the school yard could cause an adverse effect.

Example 9: The toxicity classification for birds is often based on gavage studies, but studies with dietary exposures often indicate much lower toxicity. When potential exposure is based on food consumption, it would be appropriate to compare the residues to effect concentrations from dietary studies rather than gavage studies.

Example 10: No drift violation was determined because no presence was found, no symptoms were identified, and a strong smell was the only evidence. What would the determination have been if the neighbor(s) had a headache?

Example 10 describes a situation where the drift from an agricultural application was alleged to have occurred but could not cause or have the potential to cause an adverse effect because it was a pesticide odor. This fungicide is described as moderately toxic via dermal contact but of low inhalation toxicity. The complainant did not allege direct contact, only a horrible odor. The absence of a violation in this case partially rests on the determination that direct contact with drift did not occur. The absence of drift residues may have resulted from a high detection limit. Most fungicides have very low vapor pressures such that volatilization at an odor threshold is unlikely. Odor from a pesticide application may not be from the pesticide active ingredient. Many fungicides (and insecticides) contain sulfur, which has a strong odor, and impurities (even at less than 0.1%) can have very low odor thresholds.

Example 11: This case involves the application of a residential use herbicide onto a soccer field where the herbicide is also registered for use. No violation was determined to have occurred because the herbicide did not cause or have the potential to cause an adverse effect. The herbicide permits reentry into treated areas when the sprays have dried. The sprays have dried statement is standard on residential use products because a REI is not enforceable. The Agency determined that the post application risk to the herbicide on the treated lawn was acceptable based on a risk assessment that compared anticipated exposure with the toxicology profile based on label mandated application rates. While this example likely would not have led to adverse effects the assumption is made in the absence of any knowledge regarding the magnitude of the residues on the soccer field and assumes that a proper application occurred. That may have been an incorrect assumption with a passerby being able to observe the drift moving onto the soccer field.

The purpose of highlighting issues with these examples is intended to illustrate the difficulties that the EPA is imposing on the SLA in enforcing the proposed drift label statements. The key issue again is that enforcement will be arbitrary and often subjective with no clear guidance provided to the SLA.

Appendix G. ANSWERS TO “...QUESTIONS FOR COMMENTS”

1. Are there other products or classes of products that draft Pesticide Registration Notice (PRN) 2009-X should cover or specifically exclude? (page 18)

EPA should exclude from PRN 2009-X products registered exclusively for the following types of uses, for reasons including but not limited to their extremely low potential for exposure and toxicity via the drift pathway. Where drift is an unlikely or impossible result of application of a particular product, drift statements would only serve to confuse the applicator and lead him to question the credibility of the instructions.

- Ready-to-use spot treatments;
- Home and garden products, applied by the home owner or resident;
- Granular formulations applied as granules; [to distinguish from dispersible granule (DG) formulations]
- Drench treatments,
- Pheromone products (regardless of the formulation and application method, wind dispersal is the chief means for pheromone products to achieve pest control);
- Seed treatments, which are applied directly to seed (in a seed treatment facility, before seed is planted) or in the furrow at time of planting;
- Tree injections
- Termiticide treatments for commercial and residential buildings and structures.

EPA has not provided sufficient justification that the proposed drift language is needed on these products. The implementation of such broad and vague language on labels for these products will simply encourage frivolous law suits.

RISE believes pesticide products marketed for non-occupational residential (homeowner) use should be exempted from this draft Pesticide Registration Notice because such products are already required to comply with Pesticide Registration Notice 2008-1 which mandated new label language for environmental hazard statements.

This new language already addresses "drift" or "off target application" of pesticides intended for non-occupational residential use.

The environmental hazard statement for liquid concentrate products that addresses drift is "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product when rain is not predicted for the next 24 hours will help ensure that wind or rain does not blow or wash pesticide off the treatment area...."

The environmental hazard statement for broadcast granular products is "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treated

area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help prevent run off to water bodies or drainage systems."

The environmental hazard statement for dust products is "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not expected for the next 24 hours will help ensure that wind or rain does not blow or wash pesticide off the treatment area."

The environmental hazard statement for liquid ready-to-use (RTU) products is "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help ensure that wind or rain does not blow or wash pesticide off the treatment area."

Pesticide Registration Notice 2008-1 already address "drift" or "off target application" of non-occupational residential (homeowner) use pesticide products. These products are required to remain in the "treatment area" and outdoor application of these products can only be made in "calm weather."

Environmental hazard language is already on the label and is sufficient to minimize pesticide drift from such products. Adding additional "drift" related language to the label would be redundant and confusing for consumers. For these reasons non-occupational residential (homeowner) use pesticide products should be exempted from the draft PRN.

2. The draft PRN describes pesticide drift as the physical movement of pesticide droplets or particles through the air from the target site to any non-target site, "during application or soon thereafter". Please comment on the Agency's use of the phrase, "or soon thereafter", and whether it clearly covers spray and dust drift resulting from application during stable atmospheric conditions, such as a near-ground inversion. If not, what alternate wording would be more appropriate? (page 18)

EPA should define spray or dust drift as the physical movement of pesticide droplets or particles through the air that occurs during initial application resulting in deposition onto non-target sites. Spray drift shall not include movement of pesticides to non-target sites caused by erosion, migration, volatility, or windblown soil particles that occurs after application. Drift due to thermal inversion may occur many hours after application; "or soon thereafter" is too vague to cover this circumstance. EPA should include on labels statements to address the potential for thermal inversion such as those examples provided by CLA in Appendix H Technical Comments.

3. The draft PRN divides affected pesticide products into several categories of use. Has the Agency adequately described the range of products such that registrants can determine whether this Notice covers their products? If not, what aspect of the description is unclear? What alternative description would clarify differences in categories? (page 26)

We would recommend that granules and pellets be removed from the list of formulations. It is difficult to conceive of the application situation where such formulations applied dry would be subject to significant drift. In fact, a common use of such formulations is for the express purpose of avoiding the potential for drift.

EPA should provide a means of easily amending or updating PRN 2010-X to specifically exclude innovative new pesticide formulations and application methods for which drift cautions and instructions would not be appropriate. This might be accomplished through OPP's "Pesticide Labeling Consistency" web page, in which case PRN 2010-X and the answers or updates appearing on that web site should be appropriately cross-referenced.

The description of covered application methods in Section II.A.2 includes the qualifying phrase, "including, but not limited to ..." The covered application methods should have a more comprehensive definition and description, as well as a more comprehensive list of examples, so that the qualifying phrase is omitted. Otherwise, the registrant may be uncertain how to handle labeling of a product and use that do not quite fit the abbreviated description.

4. Please comment on whether the terms "commercial" and "non-commercial" clearly distinguish products that can be applied to non-Worker Protection Standards (WPS) sites, often (though not always) by commercial applicators, from products intended solely for residential use by general consumers? (page 26)

In a number of recent forums and registration actions, EPA has challenged registrants' use of product names that might imply that the product is "professional" or for commercial use only. Using that designation and terminology in this context creates confusion. If continued efforts by the Agency in that regard further blur or remove the distinction between "commercial" and "non-commercial" products, it could increase confusion about label language for drift minimization as well as worker protection. The Agency needs to improve the clarity, specificity, and intent of the commercial/non-commercial distinction and which products are affected.

The draft PRN as written would obligate registrants to place specific statements in specific positions on product labels, without EPA amending the corresponding regulation "Labeling Requirements for Pesticides and Devices" (40 CFR Part 156). Such requirements in the draft PRN contradict the legal disclaimer common to all PR Notices: "...this Notice is not binding on EPA personnel, pesticide registrants and applicants, and the public." (Section X, p. 18) The draft PRN couches all such requirements for label statements in terms such as, "products ... should add the following statements to the labeling ...", "applicants ... are encouraged to resubmit labeling," and "recommended implementation dates." At the end of Section IX, the PRN makes the direct statement that products "...must bear revised labeling when released for shipment after July 1, 2011." (emphasis added). CLA believes that to the extent EPA has included mandatory specific language for pesticide labeling in the draft PRN (now by its terms or in the future by implementation), then such requirements could only be implemented through rulemaking and amendment to 40 CFR Part 156. That type of mandatory language, requiring a general change in the terms of registration under an implicit threat of sanctions for non-compliance, is the type of agency action that can only be imposed through the use of notice-and-comment rulemaking procedures pursuant to the Administrative Procedure Act. It is, for all

intent and purposes, a rule and therefore cannot be implemented through a Pesticide Registration Notice.

5. Please comment on the portion of the general drift statement prohibiting drift that “could cause” adverse effects. (page 26)

See General Overview, Sections A, B, C, and D, and Appendices D, E, and F. The “could cause” approach that EPA has taken is too vague and subject to a wide range of interpretations. This is not the “clear and enforceable” pesticide product label language that state regulators have requested. This part of the general drift language has the potential to generate frivolous or malicious claims. Effects on humans should require medical confirmation.

6. The Pesticide Policy Dialogue Committee’s (PPDC) Spray Drift Work Group discussed at length, but did not reach general consensus on, what constitutes “harm” or “adverse effects” from spray drift. The views of various members of the PPDC Work Group appear in their final spray drift report. The Agency has explained in this Notice how it intends to interpret “harm” and “adverse effects” in the context of the general drift statement. Please comment on EPA’s proposed approach and alternative approaches suggested by the PPDC Work Group. (page 26)

See General Overview, Sections A, B, C, and D, and Appendices D, E, and F.

7. The draft PRN suggests and provides examples of a table presentation of product-specific drift statements as a concise and clear means of conveying critical information to users. Is a table the preferable format to convey this information to users? Are there other formats in which product-specific drift information could be presented on labels that would be more readily-understood by users? (page 28)

See Appendix H Technical Comments.

A table is one appropriate workable format.

A software application containing a product-specific decision tree might be helpful for the applicator. If the applicator could enter the product name, application rate, wind speed, nozzle to be used, and application height, the program could provide a required buffer distance to various sensitive organism (humans, animals, plants).

Tables providing buffer distances also need to include application rate as a parameter to minimize buffer zones and avoid excessive impact on agriculture.

8. The draft PRN establishes the need to protect sensitive sites from adverse effects that could be caused by drift. Is the concept of “sensitive site” clear? If not, what alternative descriptions could be considered to describe sensitive sites? (page 28)

EPA’s definition of “sensitive areas” is vague and does not adequately define what needs to be protected from pesticide drift or what is at risk. As defined, “sensitive areas” are difficult to relate to the agricultural landscape. Areas that need to be protected from drift must be clearly

and realistically defined to ensure that what truly needs protection is protected, and that protection can be accomplished in ways that do not result in unwarranted barriers or negative impacts to growers.

Agricultural systems where pesticides are used are not pristine, undisturbed ecosystems. Rather, these areas have evolved with farming practices including pesticide use over an extended period of time. In general, sensitive areas to be protected should exclude the field planted to the crop, the boundary area that surrounds the crop, areas repeatedly exposed to runoff exiting from a treated field, and any other area within the agricultural system that could be treated with a pesticide registered for non-crop use (Shaw and Gagne, 2000, Terrestrial Non-Target Plant Risk Assessment for Pesticides: A Generic Problem Formulation and Proposed Protection Goals).

The draft PR Notice does not adequately define “sensitive areas,” i.e., what needs to be protected. Sites needing protection must be reasonably defined to ensure protection of appropriate areas without unwarranted loss of agricultural lands. In addressing nature preserves and wildlife refuges, special attention needs to be given to the fact that these areas very often rely on the direct use of pesticides for habitat restoration, protection, and maintenance and for the production of food and cover crops for native and migratory wildlife. Prohibition of spray drift to wildlife management areas when direct application is permitted there is inconsistent and poor regulatory policy.

9. Please comment on how the Agency should identify or describe sensitive sites, and under what circumstances EPA should include additional restrictions in labeling to protect sensitive sites? (page 28)

The draft PR Notice does not adequately define “sensitive areas,” i.e., what needs to be protected. Sites needing protection must be reasonably defined to ensure protection of appropriate areas without unwarranted loss of agricultural lands. In addressing nature preserves and wildlife refuges, special attention needs to be given to the fact that these areas very often rely on the direct use of pesticides for habitat restoration, protection, and maintenance and for the production of food and cover crops for native and migratory wildlife.

10. Are the timeframes outlined above adequate? Are there time considerations that EPA should take into account in determining when new labeling should be submitted, or when products bearing new labeling should be released for shipment? (page 30)

See Section G.

11. The Agency is particularly concerned that language, criteria, examples, and recommendations contained within the draft PRN are compatible with and not in contradiction to, to the fullest extent possible, existing state statutes, regulations, rules and policies in regard to prohibitions or lawful standards involving pesticide drift. The Agency requests that individual state lead pesticide regulatory agencies offer comments in this regard? (page 31)

EPA should clearly state that the Agency is not granting states or tribes *de facto* authority to add or modify the spray drift labeling statements presented in the PRN.

12. *What is the right balance among the tools available to the Agency to motivate pesticide applicators to use all reasonable measures to reduce drift: product labeling, incentives to use drift-reducing technologies, self-implemented educational materials on best management practices, certification training, or other? Why? (page 31)*

The emphasis should be on DRTs, provision of educational and training materials, certification through training, best management practices, and standards for the quality of spray equipment and DRT calibration and validation. EPA should work with USDA to implement incentives for the purchase and use of DRTs. EPA's drift label language and guidance should remain flexible enough to allow for the development and implementation of new technologies and should not be so rigid as to stifle innovation. Positive motivation works better than draconian, punitive measures, particularly if EPA desires to promote the use of new technologies that require training and costs to the applicator and farmer.

13. *EPA has limited spray drift labeling statements to those the Agency regards as enforceable. What are the pros and cons of including advisory statements on labels that may provide useful information to users about how to prevent or minimize drift? Would the pros and cons of advisory statements differ for agricultural or commercially-applied products, versus products intended for small-area, residential use by the general public? (page 31)*

Advisory statements are a good way to convey educational, training, and best management practices. Although this information is vital, it may extend an already lengthy label. Thus, it may be prudent for EPA to include a simplified statement that directs applicators to websites or a central repository website where the latest approved technologies and methods are available. Also, such information can be incorporated into the label by reference similar to Worker Protection Standard requirements or Endangered Species County Bulletin System. These websites provide an opportunity for EPA to link authoritative, current advice and information on drift and other topics such as chemigation, container disposal, etc.

CLA encourages EPA to collaborate with USDA, state extension services, and stewardship partnerships. State-specific advice is needed to support quality recommendations on reducing off-target exposures and appropriate container disposal. References to requirements available on-line can be cited as a driver to provide modern, science-based advice to growers and applicators. All parties will benefit from the access to current recommendations designed for the locality and will provide the best protection and the best agriculture. See USDA Extension and State Extension Institutions website as examples: <http://www.extension.org/> as well as: <http://pesticidestewardship.org/Pages/default.aspx>

However if EPA incorporates advisory language directly on the label, this language should be clearly indicated as such. Currently, it is difficult at times to determine whether label language is advisory or a legal requirement.

Appendix H. TECHNICAL COMMENTS ON “APPENDIX A. EXAMPLES OF PRODUCT-SPECIFIC STATEMENTS/TABLES”

EPA solicited comments on specific application conditions for use in the label statements for drift. CLA responds to the questions posed by EPA on application conditions for controlling drift, but cautions that no specific condition is applicable to all potential scenarios of drift. Effective drift control measures must be tailored to the local factors that influence drift potentials. Finally, CLA reminds EPA that mitigations should be product specific based upon a scientifically sound and rational real-world risk assessment.

CLA encourages EPA to incorporate flexibility in regulatory language to allow for advancements in application and formulation technologies, education, training, and the latest science. For example, several relevant new studies in drift modeling and mitigation were presented at the Association of Applied Biologists “Aspects of Applied Biology 99, International Advances in Pesticide Application , Robinson College Cambridge, UK 5-7 January 2010 (<http://www.aab.org.uk/images/IAPA%20TITLE,%20INTRO%20&%20CONTENTS.pdf>); and will be presented at the American Chemistry Society’s symposium entitled “Efficient Application of Pesticides for Sustainable and Effective Crop Protection” in San Francisco in March 2010.

Drift Reduction Technologies (DRTs) and ‘Star Rating’:

CLA recognizes that the percentages of deposition reduction per star-rating provided by EPA are for “illustration purposes only”. When finalizing DRT guidance, CLA encourages EPA to clarify the DRT rating system for specific technologies, such as nozzles; to set such ratings within achievable goals; to allow credit for all DRTs, not just nozzles; and to consider cost for validation testing. A star rating may be an appropriate system for nozzles; however, the star rating must be specific to nozzles and not the same for other DRTs. Also, the current limits of science must be considered. For example, a star rating of 95% drift reduction when only a nozzle is used is too aggressive and is currently technically unachievable for aerial applications. Currently drift reductions of up to 25% are achievable using only nozzle technologies and higher reductions are only now possible if multiple technologies are used concurrently for aerial applications. Therefore, EPA should recognize these other technologies as DRTs and provide buffer-reduction credit for them either when used individually or in combination. Some of these technologies include: shielded sprayers, wind row trees, riparian buffers, landscape features and mitigations, release height, wind speed and direction, formulation improvements, and adjuvants. Also, validation testing of DRTs should not be so expensive as to be cost prohibitive. EPA should recognize that most nozzles cost less than fifty dollars, and if the cost to validate a nozzle as a DRT is in the thousands or tens-of-thousands of dollars, this is cost prohibitive to the nozzle manufacturer. CLA encourages EPA to consider peer-review, testing by other government protocols (such as in Europe) or other evidence of DRT effectiveness. Additionally, CLA encourages EPA to allow flexibility in the regulations to allow for innovation and creativity to foster the invention of future DRTs. Growers should be given credit for the use of multiple DRTs, for landscape features, such as hedge rows, and for DRTs, for other mitigations and for BMPs that they have already implemented. EPA should harmonize with PMRA’s approach

(“Agricultural Buffer Zone Strategy Proposal”, November 2005) to incorporating buffer reduction factors of all DRTs into the risk assessment.

Also, CLA urges EPA to promote the use of drift reducing adjuvants as DRTs. These products are readily available in the marketplace and many applicators, especially commercial applicators, are already using them. Some adjuvants have been shown to reduce downwind drift with most spray tips. Combinations of a drift reduction spray tip and a drift reduction agent are better than either alone. A test method for Drift Reduction Agents (i.e., adjuvants) has been submitted to the American Society of Testing Materials by the Chemical Producers and Distributors Association. The use of all available drift reduction technologies and credit for them in reducing buffer zone is essential.

Currently, there is no one facility in the U.S. that can test and validate the simultaneous use of multiple DRTs or at both high and low wind speeds or test for both aerial and ground applications. EPA’s testing and validation facility in Research Triangle Park (RTP), North Carolina, can only test nozzles using blanks; adjuvants, formulations, and active ingredients can not be used in this facility. Government testing and validation facilities are primarily established for conducting research and are not managerially set up to function as routine batch testing entities for industry. EPA should work with industry and other stakeholders to establish DRT testing and validation facilities in the U.S.

CLA encourages harmonization of DRT acceptance with Canada, Europe and other countries, and refers EPA to the final report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, “Landscape And Mitigation Factors In Aquatic Ecological Risk Assessment, Volume 1. Extended Summary and Recommendations”. This report states, “There are a number of approaches to spray drift mitigation (buffer zones, application technology and windbreaks) that could be included immediately to mitigate exposure where needed. It is proposed that a maximum cap of 95% reduction in exposure via spray drift is applied at Annex I, although several methodologies allow mitigation up to a maximum of 99%.” The final report is presented in two volumes. There is a detailed discussion of drift mitigation in Volume 2, Section 1.3 starting on Page 17. The link to this report is <http://focus.jrc.ec.europa.eu/lm/> .

No Spray Zones or Buffer Zones

EPA refers to the use of “no spray zones” (buffers) in minimizing drift. CLA recognizes that under certain conditions buffers (no spray zones) may be an effective tool in reducing drift to non-target areas. However, it is CLA’s opinion that buffers should be considered to be a last resort after exhausting other BMP techniques and technologies to protect against product or chemistry specific unreasonable adverse effects on human health or the environment. Given the potential for significant cost to the farmer in lost production, EPA should work with the agricultural stakeholder coalition to discuss workable measures to minimize drift without unduly penalizing growers.

EPA should define “no-spray zone” as an area in which direct application of the pesticide is prohibited; this area is the distance downwind between the edge of the target spray area and the nearest boundary of a site to be protected, unless otherwise specified on a product label. No spray zones should be ‘wind directional’; the SDTF has shown that there is zero drift upwind (i.e., in opposition to the wind direction).

CLA suggests that EPA take an approach consistent with Canada’s Pest Management Regulatory Agency (PMRA) for determining buffer size and necessity as described in “Agricultural Buffer Zone Strategy Proposal”, November 2005.

If the Agency determines that a no-spray zone is necessary for a product, the following label statement should be used:

“Do not apply this product within a no spray zone of X feet between the treated area and the sensitive area. When the sustained wind direction is away from the sensitive area and toward the treated area, a no-spray zone is not required.”

[Note: The distance of a no-spray zone (X) and the sensitive areas are determined by EPA based upon the product specific risk assessment. The following factors will be specified by EPA within a table on the label (similar to the example below in section IV. C): no-spray zone; wind speed; application rate; spray droplet spectra; and DRTs.]

Application Rate

Application rate, a critical parameter, is missing from EPA’s example tables. Buffer distance is dependent on application rate.

Wind Speed Limits and Wind Direction

An arbitrary upper wind speed limit is not appropriate for all geographical areas and/or application types. For example, certain application methods use a mechanical shield or air shield that is effective at controlling drift at higher wind speeds. Studies by the SDTF and others have shown that ground applications usually have lower drift potential; therefore, a higher wind speed limit should be permissible.

EPA’s policy position should be that some low level of drift outside the application site is unavoidable. It is extremely important to recognize that, although wind direction may change, there is zero drift upwind (i.e., in opposition to the wind direction). This intuitively obvious fact was definitively proven by the SDTF in Good Laboratory Practice (GLP) studies, approved and accepted by the EPA. The result is that applicators can use wind direction to completely eliminate drift into environmentally sensitive areas, and areas where workers or bystanders could be contacted. The EPA would be better served to implement label changes that give incentive to the use of wind directional buffer zones, if possible, to protect bystanders and sensitive areas, rather than implementing unobtainable “do not drift” language.

Drift Models

The version of the AgDRIFT® model that EPA is currently using has not been validated for longer distance transport such as those now being estimated for endangered species and this version should be updated with corrections as described to EPA by U.S. Forest Service. The current version of the AGDISP model is being updated by U.S. Forest Service to allow for easier user input interface and to incorporate a revised evaporation algorithm. Also, it is being expanded with PMRA Wolf datasets. CLA supports the establishment of a modeling center at U.S. Forest Service that would house and update drift models. CLA also supports the development of a mechanistic ground model as a long term goal to better simulate longer distance ground drift transport. Such a model is currently under development in the United Kingdom, and CLA encourages EPA to participate in this effort as well the U.S. Forest Service modeling center. Development, refinement, and validation of such drift models are vital to the development of bystander exposure scenarios for risk assessment.

Recommendations and Information Regarding Pesticide Droplet Size Spectrum (DSS)

- Generally, a more coarse DSS reduces drift potential. Several factors, such as DSS, application height, wind speed, temperature, and release height, affect drift potential.
- DSS also can affect efficacy. The effects of DSS on efficacy depend on many factors including degree of systemic activity, spray volume, adjuvants, application type (ground, aerial, airblast), and other application-related factors. Generally, systemic and soil applied products can be applied with more coarse droplet spectra than plant applied products with only contact activity. Many, but not all pesticides can be applied effectively with medium or coarser droplet spectra. However, because the effect of DSS on efficacy is dependent on so many factors, many of which are product specific, a universally applicable DSS for all pesticide labels is not feasible.
- Determination of the DSS must be specifically related to the product/pest/host/spray volume. For example, when ultra low volume (ULV) applications are made, a finer DSS is required in order to ensure proper coverage and efficacy. As spray volumes decrease, more fine droplets are needed for coverage, which increases the tendency for drift. Therefore, determination of the DSS appropriate for the application should be done on a case-by-case basis.
- Currently a ‘fine to medium’ DSS is the default value within the AgDRIFT® aerial model that EPA uses to evaluate drift potential in the environmental risk assessment process, while ‘very fine to fine’ is the default for the ground model. EPA and the Services often use droplet parameter values of ‘very fine to fine’ for aerial as well as ground applications. The ‘very fine to fine’ spray quality category is not reflective of the vast majority of pesticide applications. CLA recommends that a ‘medium’ spray quality would better represent typical practices that are applicable to many applications of crop protection chemicals. The default AgDRIFT® model settings should be changed to ‘medium’ for aerial applications and ‘fine to medium/coarse’ for ground applications. These default spray quality values are based on the drop size distributions of standard

nozzles as described in American Society of Agricultural and Biological Engineers (ASABE) S572.1 standard. Not only are these values more reflective of pesticide applications in the U.S than EPA's current defaults, they provide a conservative risk estimate because the drop size distributions reflect the boundary between categories, i.e. 'medium' is the boundary between fine and medium, while for ground applications the 'fine to medium/coarse' category reflects the drift curves from a wide range of DSSs. If the specific product/application requires an alternative DSS to maintain efficacy, such as very fine/fine, or if the product may be applied with a coarse DSS, then the spray quality requirements would be incorporated into EPA's risk assessment and the pesticide product label.

- The optimal method for selecting mitigations, such as buffer size, while maintaining efficacy, is to use an iterative modeling approach in the risk assessment that incorporates application conditions (including DSS) and chemical/formulation-specific characteristics such as ecotoxicology and fate/transport properties.
- Benefits of the pesticide application must be considered when determining buffer size, whether the risk assessment is based on anecdotal evidence or a highly refined iterative risk assessment approach.
- Additional testing may be needed in the future to assure that the DSS is efficacious.
- For aerial application, an important factor that can affect DSS is speed of the aircraft. In general the DSS becomes finer as airspeed increases. Speed is a variable that must be taken into account in configuring the aircraft to produce the necessary DSS. For ground applications, application speed does not affect DSS to the same extent. However, it can affect drift potential due to increased turbulence at higher speeds.
- A balance is needed between maintaining efficacy, reducing drift by increasing droplet size, adjusting buffer size, ensuring agricultural productivity, and protecting the environment.

Application Parameter Tables and Text:

EPA states that "a separate table and text will be used for each application method on a product label". CLA agrees with this, but also suggests that EPA consider separate tables/text for the application "type" as well; for example, forestry application directions may differ from agricultural applications.

CLA suggests the following label language for the application types identified in the PRN. Note that "(www.____.org/spray drift)" is a blank web address and used below to indicate a theoretical website that EPA would establish.

Ground Applications:

- 1) "Follow label directions to reduce the potential for drift incidents."

2) “Additional information regarding best management practices for application is described on the spray drift website ([www.____.org/spray drift](http://www.____.org/spray%20drift)).”

3) “Do not make ground applications within a surface temperature inversion when applying near an area requiring protection to avoid an unreasonable adverse effect. Applicators may determine presence of an inversion by noting the presence of ground fog, light variable wind, or layering of smoke and dust. Be particularly alert to the potential for a surface temperature inversion near sunrise, sunset, and throughout the night when winds are calm (i.e., below 3 miles/hour).”

4) “Applicators must estimate the prevailing wind speed and direction in the vicinity of the application site prior to and during the application.”

[Note: Measuring wind speed with an anemometer, observing wind speed and direction using a wind sock or wind vane, or obtaining a report from a local meteorological station are acceptable methods of estimating wind speed and direction. Wind speed estimates should reflect the height where the application will occur.]

5) “Apply at the minimum nozzle height that produces uniform coverage.”

6) “Do not apply with a nozzle height more than 4 feet above the ground or point of canopy closure.”

7) “Do not apply when prevailing wind speed is 15 miles/hour or more, unless verified DRT or other mitigation (see DRT Table) is employed that prevents the increase in drift expected at higher wind speeds.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects. The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

8) “Use X or coarser spray quality (droplet size spectrum) at application according to nozzle manufacturer, ASABE, or USDA classification.”

Forestry Ground Applications:

1) “Follow label directions to reduce the potential for drift incidents.”

2) “Additional information regarding best management practices for application is described on the spray drift website ([www.____.org/spray drift](http://www.____.org/spray%20drift)). Refer to and follow individual State best management practice guidelines and forest practice regulations that pertain to silvicultural chemical application.”

3) “Do not make ground applications within a surface temperature inversion when applying near an area requiring protection to avoid an unreasonable adverse effect. Applicators may determine

presence of an inversion by noting the presence of ground fog, light variable wind, or layering of smoke and dust. Be particularly alert to the potential for a surface temperature inversion near sunrise, sunset, and throughout the night when winds are calm (i.e., below 3 miles/hour).”

4) “Applicators must estimate the prevailing wind speed and direction in the vicinity of the application site prior to and during the application.”

[Note: Measuring wind speed with an anemometer, observing wind speed and direction using a wind sock or wind vane, or obtaining a report from a local meteorological station are acceptable methods of estimating wind speed and direction. Wind speed estimates should reflect the height where the application will occur.]

5) “Apply at the minimum nozzle height that produces uniform coverage and accommodates slash or residual vegetation.”

6) “Do not apply with a nozzle height more than 8 feet above the ground.”

7) “Do not apply when prevailing wind speed is 15 miles/hour or more unless verified DRT or other mitigation (see DRT Table) is employed that prevents the increase in drift expected at higher wind speeds, or apply as specified in State forest practice regulations.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects. The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

8) “Use X or coarser spray quality (droplet size spectrum) at application according to nozzle manufacturer, ASABE, or USDA.”

Aerial Applications:

1) “Follow label directions to reduce the potential for drift incidents.”

2) “Additional information regarding best management practices for application is described on the spray drift website ([www.____.org/spray drift](http://www.____.org/spray%20drift)).”

3) “Do not make aerial applications within or above a surface temperature inversion when applying near an area requiring protection to avoid unreasonable adverse effects. Applicators may determine presence of an inversion by noting the presence of ground fog, light variable wind, or layering of smoke and dust. Be particularly alert to the potential for a surface temperature inversion near sunrise, sunset, and throughout the night when winds are calm (i.e., below 3 miles/hour).”

4) “Applicators must estimate the prevailing wind speed and direction in the vicinity of the application site prior to and during the application.”

[Note: Measuring wind speed with an anemometer, observing wind speed and direction using an aircraft smoke release system or wind sock or wind vane, or obtaining a report from a local meteorological station are acceptable methods of estimating wind speed and direction. Wind speed estimates should reflect the height where the application will occur.]

5) “Do not apply when prevailing wind speed is 15 miles/hour or more, unless verified DRT or other mitigation (see DRT Table) is employed that prevents the increase in drift expected at higher wind speeds.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects. The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

6) “For fixed wing aircraft the boom length must not exceed 75% of the fixed wing span and must be located at least 8 -10 inches below the trailing edge of the wing; for helicopters, use a boom length and position so that spray droplets do not become entrained in the rotor tip vortices.”

7) “The spray should be released at the optimum height from the aircraft for minimizing drift and maximizing deposition in the canopy. This height should be no more than 15 feet above the point of canopy closure unless necessary to assure flight safety.”

8) “The boom must be shut off before the aircraft begins to climb at the edge of a field.”

9) “Use X or coarser spray quality (droplet size spectrum) at application according to nozzle manufacturer, ASABE, or USDA classification. Angle of the spray pattern from the horizontal should be adjusted to produce the desired droplet size spectrum. Position on the boom and angle of the nozzle, spray pressure, and flight speed must be considered to meet spray quality requirements.”

10) “The applicator must move upwind to compensate for downwind swath displacement.”

Forestry Aerial Applications:

1) “Follow label directions to reduce the potential for drift incidents.”

2) “Additional information regarding best management practices for application is described on the spray drift website ([www.____.org/spray drift](http://www.____.org/spray%20drift)). Refer to and follow individual State best management practice guidelines and forest practice regulations that pertain to silvicultural chemical application.”

3) “Do not make aerial applications within or above a surface temperature inversion when applying near an area requiring protection to avoid an unreasonable adverse effect. Applicators may determine presence of an inversion by noting the presence of ground fog, light variable wind, or layering of smoke and dust. Be particularly alert to the potential for a surface

temperature inversion near sunrise, sunset, and throughout the night when winds are calm (i.e., below 3 miles/hour).”

4) “Applicators must estimate the prevailing wind speed and direction in the vicinity of the application site prior to and during the application.”

[Note: Measuring wind speed with an anemometer, observing wind speed and direction using an aircraft smoke release system or wind sock or wind vane, or obtaining a report from a local meteorological station are acceptable methods of estimating wind speed and direction. Wind speed estimates should reflect the height where the application will occur.]

5) “Do not apply when wind speed is 15 miles/hour or more unless verified DRT or other mitigation (see DRT Table) is employed that prevents the increase in drift expected at higher wind speeds, or apply as specified in State forest practice regulations.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects. The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

6) “For fixed wing aircraft the boom length must not exceed 75% of the fixed wing span and must be located at least 8 -10 inches below the trailing edge of the wing; for helicopters, use a boom length and position so that spray droplets do not become entrained in the rotor tip vortices.”

7) “The spray release height is determined by the pilot to ensure flight safety, maximize deposition in the canopy and to minimize the potential for drift.”

8) “For forestry insecticide applications, use a spray quality (droplet size spectrum) at application that allows penetration of the forest canopy. This generally will be a very fine to fine spray quality ($D_{v,5}$ of 80-120 μ m) as defined by the nozzle manufacturer, ASABE, or USDA.”

9) “For forestry herbicide applications, use X or coarser spray quality (droplet size spectrum) at application according to nozzle manufacturer, ASABE, or USDA classification. Deflection angle of the spray pattern from the horizontal should be adjusted to produce the desired droplet size spectrum. Position on the boom and deflection angle of the nozzle, spray pressure, and flight speed must be considered to meet spray quality requirements.”

[Note: Coarse spray droplets (~9% of spray-droplet volume < 150 μ m) or ultra coarse spray droplets (~1% of spray-droplet volume < 150 μ m) can be used depending on the conditions (wind speed, application height, etc.) to reduce off-target drift for herbicide applications.]

Orchard and vineyard airblast applications:

1) “Follow label directions to reduce the potential for drift incidents.”

2) “Additional information regarding best management practices for application is described on the spray drift website ([www.____.org/spray drift](http://www.____.org/spray%20drift)).”

3) “Do not make airblast applications within a surface temperature inversion when applying near an area requiring protection to avoid an unreasonable adverse effect. Applicators may determine presence of an inversion by noting the presence of ground fog, light variable wind, or layering of smoke and dust. Be particularly alert to the potential for a surface temperature inversion near sunrise, sunset, and throughout the night when winds are calm (i.e., below 3 miles/hour).”

4) “Applicators must estimate the prevailing wind speed and direction in the vicinity of the application site prior to and during the application.”

[Note: Measuring wind speed with an anemometer, observing wind speed and direction using a wind sock or wind vane, or obtaining a report from a local meteorological station are acceptable methods of estimating wind speed and direction. Wind speed estimates should reflect the height where the application will occur.]

5) “Do not apply when prevailing wind speed is 15 miles/hour or more, unless verified DRT or other mitigation (see DRT Table) is employed that prevents the increase in drift expected at higher wind speeds.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects. The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

6) “Shut off nozzles when turning at the end of rows.”

7) “Apply so that the spray is only directed into the canopy.”

8) “Spray the outside rows only from the outside and spray inwards. Turn off outward pointing nozzles at row ends and outer rows.”

9) “Adjust the air volume to the minimum necessary to fill the volume of the canopy at selected application speed.”

Household Use Products - Broadcast Spray or Dust Applications:

1) “Follow label directions to reduce potential for drift.”

2) “Apply at the minimum height that provides uniform coverage.”

3) “Do not apply when prevailing wind speed exceeds 15 miles/hour. Wind speed can be obtained from your local meteorological station.”

[Note: The Agency may dictate a maximum wind speed different from the default of 15 miles/hour based upon a product specific risk assessment and the potential for adverse effects.]

The registrant may propose a lower maximum wind speed, recognizing potential liabilities that they wish to avoid.]

Appendix I. PROPOSED RISK-BASED SPRAY DRIFT ENFORCEMENT METHODOLOGY

The potential for some degree of drift (i.e., offsite residue dispersion and deposition) occurs with any pesticide application. The definitions of drift are typically not quantitative and interpretations vary from one county to another in the same state, and is not consistent between states. The concentration of the pesticide in air typically decreases with distance from the application regardless of physical form. Normally concentrations moving offsite are below the biologically effective dose, but there have been notable exceptions.

A risk/benefit approach to spray drift would be consistent with the process EPA has previously used with bystander exposure to the fumigant pesticides and proposes to use to address bystander exposure resulting from the volatilization of conventional pesticides (EPA 2009). Instituting a similar, risk-based approach to bystander exposure to spray drift would therefore be consistent with the Agency's approach to other sources of bystander exposure.

This attachment discusses, in broad terms, quantitative exposure assessment methods that could be used prospectively for label revision by relying on validated, quantitative models that predict exposure. See **Appendix B (A PROPOSED METHODOLOGY FOR HUMAN HEALTH RISK ASSESSMENT FROM SPRAY DRIFT)** in these comments for more detailed discussion regarding proposed exposure and risk assessment methods. Ideally, the assessment method would allow use of best management practices to reduce drift including wind speed and direction, nozzle diameter and pressure, pesticide formulation, etc. with due consideration of the need for buffer zones. Any proposed approach must be broadly applicable using scientifically valid methods. Most importantly, those methods must be developed in a transparent fashion by a group of interested parties that include manufacturers of pesticides and application equipment, users/applicators of the pesticides and those concerned about excessive drift, including state and local regulatory officials.

Exposure to drift involves dermal exposure from the transfer of deposited residues from contact with surfaces, inhalation exposure from vapors or re-suspended particles, and for young children, incidental oral ingestion from hand-to-mouth contact or similar activities. There are several methods that could be adopted for quantifying drift exposure. One quantification method involves combining the information obtained from drift studies with the EPA Residential Standard Operating Procedures (SOPs). AgDRIFT and AGDISP models estimate levels of spray drift residue deposited downwind at different distances following various types of applications, such as aerial or airblast. The Residential SOPs are a series of scenarios (including outdoor lawns) that provide algorithms for calculating dermal and oral exposure following application. Conceptually there is no difference in estimating the exposure to residents following an intentional lawn application in which the residues were applied directly to the turf and the exposure to residents from contact with turf in which the residues were deposited on the turf from off-target drift. The residential lawn SOP scenario can reasonably be assumed to be representative of other exposure scenarios including off-target drift. This is also consistent with rationale provided by EPA (2009a): "no scientific justification exists for distinguishing between otherwise identical exposures" (such as the lawn care example above).

Rarely is air monitoring conducted soon enough after a reported drift event that allegedly produced illnesses to capture even a fraction of what was in the air shortly after the application, so from an enforcement perspective, air monitoring is not viable for accurately characterizing these exposures. This is because the particulates from an application settle to the ground, foliage or structures typically within minutes of application leaving only vapors in the air to be monitored. Since most pesticides have very low vapor pressures (typically 10^{-4} mm Hg or less), vapor concentration will be at or below detection limits for many active ingredients, although as analytical capability continues to improve it will be possible to measure ever lower air concentrations. The Agency recently brought the topic of assessing risks from field volatilization of conventional pesticides to the FIFRA Science Advisory Panel (EPA 2009). Further, by analogy with what is known of exposure following fogger use indoors, inhalation does not typically represent the primary source of exposure even from a drift event, because so little is in the air for such a short period of time.

Calculated air and surface levels from spray drift modeling can be used to establish buffer zones, but the presumption with buffer zones is that the wind is always blowing in one direction (toward the sensitive site). This is a common method of setting buffer zones for fumigants, but there is a key difference between fumigant and conventional pesticides sprayed from the ground or air. That difference is that fumigants vaporize and move offsite in the prevailing wind for many hours after application, sometimes with peak concentrations measured 12-36 hours post-application. However, non-fumigant applications can be made when sustained winds are blowing from the sensitive site(s) towards the application, because spray drift is over within minutes of application.

The greatest potential for exposure from spray drift may actually be from the dermal route, not the inhalation route. Post-application surface residues represent the primary source of exposure following drift, and these residue levels do not dissipate nearly as rapidly as air levels. If EPA wishes to implement legitimate enforcement of rules related to drift, there must be uniform methods for measuring and defining drift. Since the state regulatory authorities actually enforce the label at the local level, the label must be uniformly interpreted to eliminate arbitrary and capricious differences across the U.S. There are several standardized methods for measuring surface residue levels, and from them to quantitatively estimate human exposure, some requiring special equipment (e.g., leaf punches, rollers), and others that require minimal equipment, such as surface wipes. The wipe method is commonly used by state enforcement agencies investigating drift incidents; however, surface sampling methodologies are not uniform amongst states. Currently there is no single uniform method specified by each state regulatory agency for conducting wipe or swab measurements. Further, the EPA's proposed PR Notice does not recommend a uniform methodology, nor do the state's agencies proposals provide any. This lack of uniformity represents a very significant problem with EPA's suggested drift PRN enforcement.

CLA is recommending that EPA initiate a public, stakeholder-driven process to develop non-subjective methods to guide state enforcement personnel in investigating drift complaints and potential violations. Two possible methods are proposed and are considered complimentary. Both rely upon the aforementioned risk assessment process. Once the Agency has conducted a drift risk assessment based on label specified methods of applications, the predicted deposition of

pesticide residues by drift to a residence adjacent to the application site or necessary buffer zone will have been calculated. This estimated deposition will have been determined to be unlikely to produce unreasonable adverse effects under FIFRA. Under this approach, if an applicator can document that the label application instructions were properly followed and that the proper spray drift reduction techniques were employed, it would be reasonable for a state enforcement investigator to conclude that any pesticide deposition that may have occurred would have been addressed by the risk assessment conducted as part of the registration/re-evaluation process, and therefore not pose a violation. To support or refute this conclusion, the state regulators could sample residues in a manner that would permit direct comparison of the sampled residues to those residues deemed to be “safe” based on the risk assessment.

Since EPA has no enforcement capability of its own regarding drift, it is incumbent upon the Agency to adopt valid quantification methods that allow uniform enforcement of drift regulations by the states that do enforce the labels. Standardizing surface residue sampling methods and recommending appropriate methods of analysis are important first steps the EPA could take to help ensure reporting consistency across states. The definition of what constitutes illegal drift is a topic that requires the involvement of all agricultural industry stakeholders and enforcement bodies. Any proposal for identifying illegal drift needs to be analytically quantifiable and risk-based to address legitimate concerns about over-exposure to pesticides.

References:

EPA (U.S. Environmental Protection Agency). (2009). Scientific Issues Associated with Field Volatilization of Conventional Pesticides. Presented Jointly to the FIFRA Scientific Advisory Panel By: U.S. Environmental Protection Agency Office of Pesticide Programs, Health Effects Division and Environmental Fate and Effects Division. Presented On: December 1-4, 2009.

EPA (U.S. Environmental Protection Agency). (2009a). Revised Risk Assessment Methods for Workers, Children of Workers in Agricultural Fields, and Pesticides with No Food Uses. By: U.S. Environmental Protection Agency Office of Pesticide Programs. Released On: December 7, 2009. Available online at: <http://www.epa.gov/pesticides/health/revisedRAMethods.pdf>