



April 25, 2014

Submitted to Federal e-rulemaking Portal

OPP Docket

**Environmental Protection Agency Docket Center (28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001**

Re: Docket ID No. EPA-HQ-OPP-2013-0676-0025. Pesticides; Consideration of Spray Drift in Pesticide Risk Assessment: Notice of Availability and Request for Comment 79 FR 4691. January 29, 2014

To Whom It May Concern:

CropLife America (CLA) is the trade association representing the US crop protection industry which provides virtually all the crop protection products and biotechnology traits used by America's farmers and ranchers. Our industry is continuously innovating in our field of expertise—inventing new crop protection chemistries, discovering and developing crop biotechnology traits, and reinventing existing technologies for continuous improvement of crop yield, quality and environmental outcomes. Our association's membership is 100 companies strong and most of our members have both US and international business operations.

On January 29, 2014, the EPA announced in the Federal Register the availability of two draft guidance documents for public comment. The documents describe how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides. EPA stated that it is "providing an opportunity, through this notice, for the public to provide comments and input on any additional information that may impact the Agency's assessment of spray drift in pesticide risk assessments."

The EPA guidance describes how the Agency intends to use AgDRIFT and other models in Residential Exposure, and Ecological and Drinking Water Assessments. It is CropLife America's opinion that the use of the AgDRIFT model to generate spray drift fractions to assess spray drift exposure for pesticide applications has serious limitations and is unlikely to provide "realistic exposure and risk estimates for both ecological and human health assessments.", as claimed in the Federal Register Notice.

The Spray Drift Task Force (SDTF) data used as the basis of the AgDRIFT model should not be considered to be a definitive data-set as suggested in the EPA guidance, nor should the distribution of data be assumed to represent what might be expected using typical application practices used today.

CropLife America continues to support the development and adoption of new technologies to reduce and manage the potential for off-site movement of pesticides including the development

Representing the Crop Protection Industry

1156 15th St. N.W., Suite 400 Washington, D.C. 20005 • 202.296.1585 phone 202.463.0474 fax www.croplifeamerica.org

of models for the assessment of drift potential for crop protection products. The AgDRIFT model represented a significant advancement at the time it was developed and has been demonstrated to provide reasonable estimates of drift exposure to near-field areas immediately downwind of fields receiving an aerial or ground application of crop protection products. However, the proposed use of the model by EPA will often stretch it beyond its well-characterized limitations and is inconsistent with guidance of the EPA SAP regarding, how it should be used, and how the results should be communicated. It is unclear whether EPA has evaluated any other models to determine whether there are any that are better suited to the needs described. This evaluation should occur before any guidance is adopted. Additionally, AgDRIFT is limited in enabling use of the best available data including SDTF data to estimate the influence of new spray nozzle technology; label restrictions such as wind speed; and other best management practices in reducing potential for off-site movement of pesticides.

The crop protection industry is committed to the continued development and adoption of new technologies to reduce or eliminate the potential for off-site movement of chemicals required for pest control through effective targeting of treated plants and plant pests. Additionally, the industry supports labeling that encourages the application of crop protection products in the most efficient manner possible and by promoting the adoption of measures to minimize potential for exposure without unduly impacting the ability of farmers to productively raise crops. The objective of drift mitigation should be to minimize the potential for off-site movement of pesticide with minimal impact on a farmer's ability to treat his or her field as required for effective pest management. Any recommendations for no-spray buffers that become part of labeling need to consider the implications for effective pest and resistance management and be implemented in the context of an overall pest management plan. Any recommendations for no-spray buffers that reduce a farmer's ability to reap the maximum yield from his acreage should be supported by a cost benefit analysis taking into consideration both potential farmer and consumer economic impact.

The EPA is urged to more thoroughly consider all currently available alternatives to exclusive reliance on AgDRIFT and SDTF data before making a final decision. CropLife America urges EPA to more carefully consider the recommendations of the National Academies of Sciences regarding use of models in risk assessment and the recommendations of the Scientific Advisory Panels that reviewed the spray drift data/models (1997 and 1999). The EPA should make clear their over-arching objectives and make provisions for the use of best available science and information, as well as the use of new models that may be better suited to making estimates of drift potential considering current agricultural technology. EPA needs to also fully consider and document the limitations of the models currently in use for estimating exposure due to spray drift; at a minimum a quantitative estimate of the uncertainty associated with drift estimates based on SDTF data and AgDRIFT should be included with any risk analyses based on the SDTF data where the model has been used.

In other circumstances, courts have found EPA's use of outdated and inaccurate data and models in the context of regulatory decisions to be arbitrary and capricious. *See, e.g., Sierra Club v. Environmental Protection Agency*, 671 F.3d 955 (9th Cir. 2012); *see also Columbia Falls Aluminum Co. v. Environmental Protection Agency*, 139 F.3d 914 (D.C. Cir. 1998). If EPA were to rely on risk assessments based on its proposed guidance, without consideration of new data or

models in future regulatory decisions; those decisions could be subject to similar challenge. CLA and its member companies reserve their right to challenge any future regulatory decision that is arbitrary and capricious or that otherwise violates the registration standard Congress has laid out, “unreasonable adverse effects on the environment.”

CLA welcomes the opportunity to continue to discuss its views on this guidance document with the Agency and to work towards the development of risk assessment guidance that is protective of the environment, allows growers the tools they need to manage pests, promotes the use of DRT (Drift Reduction Technology) and other stewardship, and that meets all applicable scientific and legal standards. CLA appreciates the opportunity to provide comments on the Consideration of Spray Drift in Pesticide Risk Assessment. Questions or concerns regarding these comments may be directed to me via email at mleggett@croplifeamerica.com or at (202) 296-1585.

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'M. Leggett', written over a faint, illegible typed name.

Michael Leggett, Ph.D.
Sr. Director of Environmental Policy
CropLife America

Enclosure: Specific Technical Comments



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Summary

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The Spray Drift Task Force (SDTF) data used as the basis of the AgDRIFT model should not be considered to be a definitive data-set as suggested in the EPA guidance, nor should the distribution of data be assumed to represent what might be expected using typical application practices used today. The data provide an estimate of drift that has a bias to over-predict, by design. The studies were also conducted over 20 years ago, and application technology has advanced significantly since that time. The SDTF data were combined in broad categories to generate curves in AgDRIFT that can be applied to all products in a ‘one-size-fits-all’ approach. This certainly has advantages in terms of simplicity. However, it eliminates numerous options for label mitigation that could reasonably be justified with existing data such as the specification of droplet size to obtain spray stewardship goals. Two examples of this are:

- Droplet Size categories - Where the AgDRIFT model has combined data into categories of very fine to fine, and fine to medium/coarse; these two categories do not represent any nozzle class, and in fact, the fine to medium/coarse class covers droplet sizes of approximately 325 to 750 μm (volume mean diameter), which represent the medium, coarse, very coarse, extremely coarse, and ultra coarse droplet sizes available with current sprayer technologies. The way the data are combined eliminates the possibility to use the model to support drift mitigation based on restrictions of droplet size used in ground applications.
- All wind categories - Approximately 25% of the data generated by the SDTF for ground application were generated under high wind conditions (>20 mph). By combining these studies to get a 50th and 90th percentile deposition load, the ability to demonstrate the efficacy of mitigation by wind speed has also been eliminated.

There are other data sources that should be considered for use in estimating drift potential.

- Research and development continues on the AGDISP model, primarily supported through USDA. Although the original model development team at Continuum Dynamics, Inc. is in the process of moving away from their support of AGDISP, succession plans for continued development and support are currently under way.
- The Pest Management Regulatory Agency in Canada uses data generated by Agriculture and Agri-Food Canada (AAFC) that is more current and subsequently includes use of more

contemporary application equipment compared to the trials conducted by the SDTF which warrants consideration by regulators.

The crop protection industry is committed to the continued development and adoption of new technologies to reduce or eliminate the potential for off-site movement of chemicals required for weed, fungus, and pest control through effective targeting of treated plants and plant pests. Additionally, the industry supports labeling that encourages the application of crop protection products in the most efficient manner possible and by promoting the adoption of measures to minimize potential for exposure without unduly impacting the ability of farmers to productively raise crops. The objective of drift mitigation should be to minimize the potential for off-site movement of pesticide with minimal impact on a farmer's ability to treat his or her field as required for effective pest management. Any recommendations for no-spray buffers that become part of labeling need to consider the implications for effective pest and resistance management and be implemented in the context of an overall pest management plan. Any recommendations for no-spray buffers that reduce a farmer's ability to reap the maximum yield from his acreage should be supported by a cost benefit analysis taking into consideration both potential farmer and consumer economic impact.

The EPA is urged to more thoroughly consider all currently available alternatives to exclusive reliance on AgDRIFT and SDTF data before making a final decision. CropLife America urges EPA to more carefully consider the recommendations of the National Academies of Sciences and the Scientific Advisory Panels that reviewed the spray drift data/models (1997 and 1999), both of which EPA should rely on in the development of guidance. The EPA should make clear their over-arching objectives and make provisions for the use of best available science and information, as well as the use of new models that may be better suited to making estimates of drift potential considering current agricultural technology. EPA needs to also fully consider and document the limitations of the models currently in use for estimating exposure due to spray drift; at a minimum a quantitative estimate of the uncertainty associated with drift estimates based on SDTF data and AgDRIFT should be included with any risk analyses based on the SDTF data where the model has been used. EPA must also define a weight of evidence approach describing the data available and relative weight applied. The potential economic impact of overly conservative buffers should also be considered.

In other circumstances, courts have found EPA's use of outdated and inaccurate data and models in the context of regulatory decisions to be arbitrary and capricious. *See, e.g., Sierra Club v. Environmental Protection Agency*, 671 F.3d 955 (9th Cir. 2012); *see also Columbia Falls Aluminum Co. v. Environmental Protection Agency*, 139 F.3d 914 (D.C. Cir. 1998). If EPA were to rely on risk assessments based on its proposed guidance, without consideration of new data or models in future regulatory decisions; those decisions could be subject to similar challenge. CLA and its member companies reserve their right to challenge any future regulatory decision that is arbitrary and capricious or that otherwise violates the registration standard Congress has laid out, "unreasonable adverse effects on the environment."

CLA welcomes the opportunity to continue to discuss its views on this guidance document with the Agency and to work towards the development of risk assessment guidance that is protective of the environment, allows growers the tools they need to manage pests, promotes the use of DRT (Drift Reduction Technology) and other stewardship, and that meets all applicable scientific and legal standards.

Background

The following guidance documents made available for public comment by EPA describe the Agency's proposed approach with regard to the estimation of spray drift and the communication of risk with implications for labeling restrictions (docket EPA-HQ-OPP-2013-0676 "Consideration of Spray Drift in Pesticide Risk Assessment");

- ***Use of AgDRIFT and AGDISP in OPP Risk Assessments***
- ***Guidance on Modeling Offsite Deposition of Pesticides Via Spray Drift for Ecological and Drinking Water Assessments***
- ***Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift***

In addition to the assessments mentioned in the titles of the documents, it is proposed that AgDRIFT will be used to define an 'Action Area' for Endangered Species Assessments where a species of concern could be exposed at a level exceeding a threshold that would have an effect on one in a million individuals in a population of that species.

There are a number of facets of the guidance for use of AgDRIFT for ecological, drinking water assessments and residential exposure assessments that are of concern to CLA member companies including:

- How the model will be parameterized, the opportunities for refinement of screening level estimates, and the communication of exposure estimates with consideration of the suitability of the model and underlying data for making some of the inferences proposed.
- The continued use of spray drift data based only on dated application technology to support current registrations where use of new innovation may be stipulated.
- The way that SDTF data is combined in AgDRIFT Ground, which inadvertently results in an inability to estimate drift exposure based on parameters typical of current use and with consideration of certain use restrictions.
- The lack of data supporting the default multiplication of 90th centile estimates to account for multiple swaths in drift estimates from ground applications.
- The lack of consideration of near-field habitat improvements.
- The use of best available data and the lack of continuity between US EPA assessments and Canadian evaluations, which rely on newer Agriculture and Agri-Food Canada (AAFC) data.
- How model estimates will be taken into consideration with respect to labeling.

Industry concerns are further detailed in the following sections.

AgDRIFT Status and Weaknesses

AgDRIFT was developed as a proprietary product of the Spray Drift Task Force (SDTF), as described in the EPA document. As also described, the Spray Drift Task Force data were the product of an unprecedented effort to generate a solid scientific foundation for EPA to use in the estimation of drift potential from applications of pesticides. The studies were all conducted under adherence to GLP and were of excellent quality. They continue to provide a valuable source of information regarding potential for exposure from drift, particularly for aerial application where the data generated was most abundant.

At the same time it must be noted and taken into consideration that the SDTF studies were designed in order to examine drift potential, not to identify the level of drift which might be expected as the result of typical use. The EPA Scientific Advisory Panel (SAP) noted that the nozzles/sprayers were selected on the basis of providing a worst case situation for drift, and that there were no applicator surveys done by the SDTF prior to spray trials to identify the application equipment or operating parameters in common use, in order to choose parameters/conditions typical of what was identified as normal practice. The data provide an estimate of drift that has a bias to over-predict, which is what the studies were designed to do. The studies were also conducted over 20 years ago, and application technology has advanced significantly since that time. Older studies providing a biased estimate of drift potential have utility in defining what an upper-bound of exposure might be, largely because of the integrity of the data collected. However, the SDTF data should not be considered to be a definitive data-set as suggested in the EPA guidance, nor should the distribution of data be assumed to represent what might be expected due to typical application practices used today.

The AgDRIFT model describes SDTF data using a Gaussian curve that is a weak predictor of the data found at distances farther from the edge of the field. The drift curves tend to over-estimate the amount of drift at farther distances off the field. The model also includes factors to account for multiple passes made by a ground-boom sprayer to cover an entire field which exacerbates the over-prediction at distance.

The EPA-HQ-OPP-2013-0676-0004 EFED document, titled "Use of AgDRIFT and AGDISP in OPP Risk Assessments" contains the following statement (page 3):

"Several updates have occurred in recent years to improve the performance and reliability of AgDRIFT and AGDISP. When updates occur, OPP evaluates the latest versions of these models, and determines if changes are needed to OPP's methodologies for estimating exposure and risk."

These statements are somewhat misleading, with respect to the AgDRIFT modeling shell. The AgDRIFT model, currently at version 2.1, has not been updated for several years, in spite of advances in ground application technology and availability of additional deposition data for analysis. In addition, AgDRIFT was a proprietary product of the Spray Drift Task Force, as indicated above. The Task Force will cease to exist as a legal entity at the end of 2014, and no plans have been announced for further updates to AgDRIFT. Thus, AgDRIFT is essentially an 'orphaned' model, with no support or update path currently envisioned.

The atypical default parameters used in the models produce unrealistic estimates

The 1999 Scientific Advisory panel indicated that the use of empirically based models represents a major advance over assumptions that a fixed proportion of the applied chemical moves off-target as drift, with the caveat that the identified limitations of the model and underlying data were addressed and were adequately described before estimates were used in risk assessment. CropLife America agrees with the SAP in this regard. Estimates based on empirical data generated from studies closely approximating a proposed use, or well-validated models with model inputs that closely reflect the use of chemical being described, provide the best estimate of potential for off-site movement. However, that is not what is being proposed by EPA in the guidance provided for comment. In describing the SDTF data for the SAP, the EPA indicated that the “highest deposition occurred with a nozzle producing the finest spray and the highest boom height, a configuration which is stated to be atypical”. **This ‘atypical’ scenario is the assumed default for modeled estimates from ground applications. Most concerning, is the lack of refinement options of this estimate for ground applications.** Similarly, aerial application defaults are atypical of conventional applications, but some conservative refinements (Tier II/Tier III) are available. Therefore, the use of the AgDRIFT model to generate spray drift fractions to assess spray drift exposure for pesticide applications is unlikely to provide “more realistic risk estimates”, as indicated in the EPA guidance (EPA-HQ-OPP-2013-0676-0004), since the default model parameters will very rarely reflect common agricultural practice for any of the application categories described.

The reliance on Spray Drift Task Force data

As described in the guidance documents; the Spray Drift Task Force (SDTF) data were the product of an unprecedented effort to generate a solid scientific foundation for EPA to use in the estimation of drift potential from applications of pesticides. The studies were all conducted under adherence to GLP and were of excellent quality. These data continue to provide a valuable source of information regarding potential for exposure from drift, particularly for aerial application where the data generated were most abundant. It should be noted and recognized that the studies were designed in order to examine drift potential, not to identify the level of drift which might be expected as the result of typical use. The SAP noted that the nozzles/sprayers were selected to provide a worst case situation for drift and that there were no applicator surveys done by the SDTF prior to spray trials to identify the application equipment or operating parameters in common use, in order to choose parameters/conditions typical of what was identified as normal practice. The data provide an estimate of drift that has a bias to over-predict, which is what the studies were designed to do. The studies were also conducted more than 20 years ago, and application technology has advanced significantly since that time. The studies have utility in defining what an upper-bound of exposure might be, largely because of the integrity of the data collected. However, the SDTF data should not be considered to be a definitive data-set as suggested in the EPA guidance, nor should the distribution of data be assumed to represent what might be expected due to typical application practices used today. This was not the intent of the SDTF, and the SAP reviewers urged the update of data and AgDRIFT, indicating at the time that the model is still at “the development stage” and should be open to revision as more high-quality ground spray drift studies become available. While updates of the model have been made in the 15 years since the SAP commented on it, none have involved an upgrade of the underlying ground-spray data. The SAP report further states that “Flexibility in the models is essential so that they can be updated as new validated data sets become available.” This applies to different application practices that were not tested in the field study (e.g., low-drift venturi nozzles), as well as a range of different formulations/additives (many of which were tested in the atomization study, but not in the field study)”. The SAP also noted that “the deposition curves pertain only to the possible drift of materials into flat areas. In this respect, they can be used in estimating water

and land contamination and in constructing buffer zones and operating limits based on droplet size and boom height". It was further stated that "No dermal exposure or inhalation risk assessments are possible with the current state of the data analysis". One of the guidance documents available for public comment (EPA-HQ-OPP-2013-0676-0003) describes in detail how the Agency intends to use the data to estimate dermal exposure. It should be noted that the exposure estimates for residential settings would only apply to lawns immediately adjacent to a sprayed field. The model estimates do not account for vegetation and topographical barriers which would disrupt the deposition onto flat surfaces. There is no description of SAP identified short-comings in either the model or the available data in the current guidance. At a minimum, model users relying on this guidance need to be aware of these concerns, so that estimates made based on these data are not portrayed as being more robust than they actually are.

The 90th-centile of the SDTF data

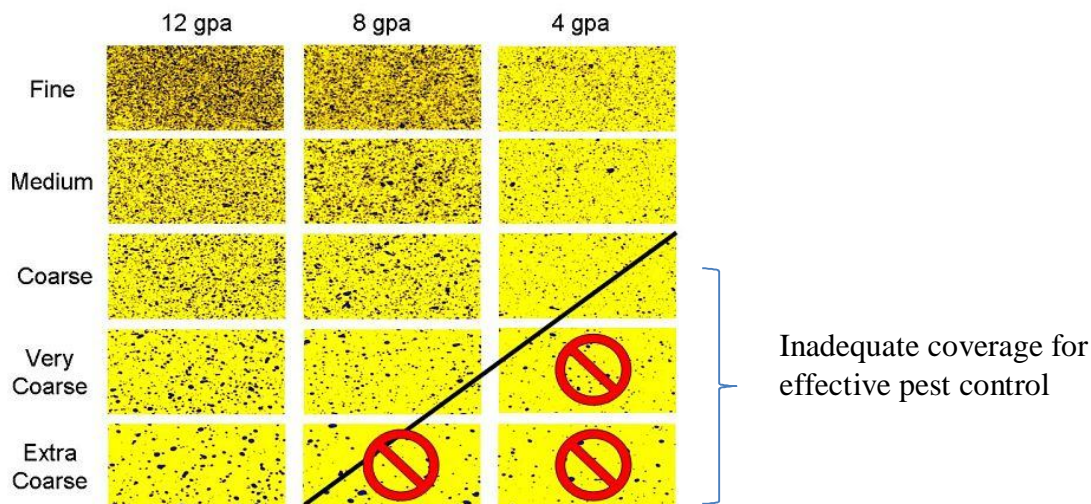
The AgDRIFT ground model provides an estimate of the 90th-centile distribution of the SDTF data that were averaged together arbitrarily for convenience into default categories. The data have a distribution that should be reported in summary statistics and considered in risk assessment. The mathematical model used to describe the 90th-centile curve is also subjective. As noted by the SAP reviewing EPA's interpretation of the SDTF data, there are a number of mathematical curves that are equally valid descriptors of the underlying data. The model chosen by EPA that is used in the AgDRIFT model generates a Gaussian curve that is a weak predictor of the data at distances farther from the edge of the field. This was noted by the SAP. A consequence of choosing this model as a descriptor is that drift estimates never dissipate completely. This is intuitively flawed, as has been pointed out by Thistle and others (Teske and Thistle, 2003). It is possible, in some circumstances, for AgDRIFT to predict movement of more material off-target than the total amount of material applied.

The SAP expressed concern that EPA's proposed "use of 95% confidence limits on a 95th percentile seems very conservative", indicating that "some confidence intervals, that are not just upper confidence intervals, are needed". The SAP further stated that "because the bounds are upper 95th percentiles, they are designed to overestimate "real world" levels most of the time. This is fine for a screening level assessment where the goal is to determine whether a potential risk exists. However, to quantify risks in a higher tier assessment requires information on the entire deposition distribution at different distances from field edge". CLA contends that this is also true of 90th centile curves from the distribution of studies combined. Again the SAP suggested that in order "to make the deposition curves more useful for risk assessment, it would be useful to present both upper and lower tolerance bounds". The National Academies of Sciences (NAS) has similarly recommended in multiple reports that "risk assessments should provide a quantitative, or at least qualitative, description of uncertainty and variability consistent with available data". With regard to drift estimates based on empirical data, a quantitative estimate of uncertainty should be plausible. The NAS has further suggested that "EPA should develop guidelines that define key terms of reference used in the presentation of uncertainty and variability, such as *central tendency*, *average*, *expected*, *upper bound*, and *plausible upper bound*".

Influence of Dispersal

There is extensive literature regarding the influence of spray coverage on efficacy (Derkson et al, 2012; 2014). Spray deposit quality on target surfaces is as important of a factor in the efficacy of a pesticide application as the total amount of pesticide on the target (Ramalingam, N. et. al., 2003). The volume of

liquid applied, the nozzle size and flow rate are all critical factors in obtaining optimal coverage, and minimizing fine droplets with drift potential.



The spray quality and volume of liquid applied factor into the level of coverage that can be expected (Wolf, 2012).

AgDrift, AGDISP and models based on empirical data estimate how far a droplet of applied chemical could potentially move off-site. As you move farther downwind from the area receiving a direct application there is more scatter with spray droplets. A collector in a drift study at distance “y” may capture one or two droplets that show up as a detection averaged over the area of the collector to derive a concentration for exposure estimation. For the purpose of risk assessment it is assumed that any organism found at distance “y” is exposed uniformly to the chemical at a concentration of “x”. In reality, the potential for encounter becomes more limited the farther you get from the field edge. Similar to a situation where the chemical’s efficacy is limited due to inadequate coverage in the field (per the figure above), the effect of a sporadic drift exposure will be chemical specific and is unlikely to be identical to an effect observed on organisms exposed to a thorough application at a ‘drift rate’ or ‘Estimated Environmental Concentration’ in a laboratory or semi-field setting. The influence of dispersal is a source of uncertainty that should also be considered.

Communicating Exposure Estimates

In guidance section 2.4 *Reporting on Modeling Procedures, Results, and Uncertainties* there is some example language that EPA suggests would be used to discuss both aquatic and terrestrial spray drift distances. “Table X shows the spray drift distances estimated using LOCs divided by risk quotients (calculated based on multiple applications) as the “Fraction of Applied” in AgDRIFT to estimate the spray drift distance for terrestrial animals. **Based on AgDRIFT2.1, potential direct effects from exposure to spray drift may occur at greater than 997 feet from the use site for multiple applications” (emphasis added).** The paragraph following this sentence descends into a description of how risk might be underestimated if multiple applications are made to the same field with wind blowing in exactly the same direction each time, or if the theoretical animal is circling the field following the wind as repeated applications are being made. There is no estimate as to how often this is expected to occur. The guidance should include more extensive analysis and reporting of uncertainties. The SAP reviewing the SDTF Ground Application data noted that “uncertainties should be estimated that are based on the

physical evidence of contamination, tank mix variability, and weathering”, and that “these uncertainty estimates should always accompany exposure levels calculated based on the curves”. For the multiple application scenario described in the guidance provided for comment, it would be ideal to cite any studies where monitoring adjacent multiple fields/applications resulted in exposure levels exceeding AgDRIFT estimates at 997 feet from the field edge, with reference to how often this might be expected to occur. What might also be included as a relevant uncertainty is the potential for the spray to be intercepted by near-field vegetation. In addition, there is typically measured variability in the chemical degradation kinetics. While it is understood that care is taken to use values in modeling that do not produce underestimates of exposure, it makes sense to report ranges that can provide context to the estimates and assist in developing bounds as suggested by the NAS.

If the EPA Scientific Advisory Panel and the National Academies of Science recommendations were more fully considered, EPA’s proposed risk discussion language provided in Section 2.4 *Reporting on Modeling Procedures, Results, and Uncertainties* might be written differently. The example text:

*“Table X shows the spray drift distances estimated using LOCs divided by risk quotients (calculated based on multiple applications) as the “Fraction of Applied” in AgDRIFT to estimate the spray drift distance for terrestrial animals. **Based on AgDRIFT2.1, potential direct effects from exposure to spray drift may occur at greater than 997 feet from the use site for multiple applications” (emphasis added)***

would be better written as:

Using AgDRIFT2.1 to estimate spray drift potential, the expected concentration (based on central tendency of the data available) is unlikely to pose a risk of direct effects at x feet ... an upper bound estimate suggests a risk may occur at a distance greater than 997 feet from the use site”. The concentration at 997 feet is estimated to be y in a range of zero to z based on AgDRIFT – the probability of exposure at this level is... factors influencing the uncertainty in this estimate include....

This approach is unlikely to provide simple single point values such as those tabulated in the proposed guidance that can then be plugged into an Ubertool™ to provide an RQ value. However, it would be more amenable to providing a much more realistic interpretation of the information that the model provides.

The Categorization of Ground Application Data in AgDRIFT

The SDTF data were combined in broad categories to generate curves in AgDRIFT that can be applied to all products in a ‘one-size-fits-all’ approach. This has advantages in terms of simplicity and predictability. However, it eliminates numerous options for label mitigation that could reasonably be justified with existing data, such as the specification of droplet size to obtain spray stewardship goals. Lumping of wind speeds into two separate percentile categories has also eliminated the ability to use the model to show how prescribed wind speeds on product labeling can be effective to obtain spray stewardship goals. The guidance document provides no mechanism for Tier II evaluation with existing models for ground applications. If a registrant chooses to add label restrictions to reduce the potential for drift, other than a buffer prescribed by Tier I AgDRIFT, it cannot be considered in risk assessment without a supporting field study. That is a regressive outcome of adoption of the guidance provided for comment. The use of improved modeling tools would support the use of a broader variety of mitigation options by

taking full advantage of all data currently available, including the SDTF data, without the unnecessary expense of additional field studies.

Spray Droplet Classes

The Spray Drift Task Force generated ground data in the fine, coarse, very coarse, and ultra coarse droplet classes. However the AgDRIFT model has combined the categories into very fine/fine and fine to medium/coarse. These two categories do not represent any nozzle class, and in fact, the fine to medium/coarse class covers droplet sizes of approximately 325 to 750 μm (volume mean diameter), which represent the medium, coarse, very coarse, extremely coarse, and ultra coarse droplet sizes available with current sprayer technologies. Thus, the combination of data into only two categories eliminates the possibility to use model estimates to support the need for a smaller buffer if application is restricted to use of a coarse nozzle (for example). Combining data with numerous dissimilar variables is scientifically inappropriate. It may be argued that the SDTF data has an insufficient number of replications to avoid combining data into broad categories. However, the scientific validity of this argument is questionable, due to the fact that there are really no replicates for off-site movement in spray deposition studies. Wind vectoring and velocity as well as temperature and humidity are constantly changing, thus precluding the notion of a true replicate (i.e. it is not possible to conduct two trials with identical velocities and vectoring). It is possible to use F-test methodologies to determine which data sets from the same droplet size (spectra) may be combined. This has not been done in AgDRIFT to generate appropriate categories available for use in the model, and thus, much of the utility in the data is lost.

50/90th percentile data and wind speed

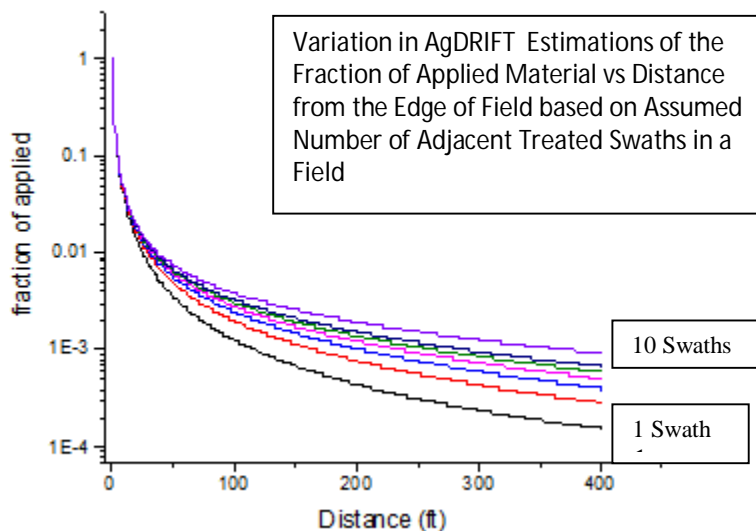
There appears to be some misunderstanding regarding 50/90th percentile deposition results provided by AgDRIFT. The determinant in this variable is wind speed, again mistakenly under the guise of replication. Deposition data were set out with different wind conditions. The SAP indicated that 25% of the data generated by the SDTF for ground application were generated under high wind conditions (>20 mph). By lumping these studies to obtain a 50th and 90th percentile deposition load, the ability to demonstrate the efficacy of mitigation by wind speed has also been eliminated. For example, a label may contain a restriction indicating a maximum wind speed for applications. The SDTF data generated using wind speeds consistent with label restrictions may indicate that this restriction is adequate and the potential for drift exposure to a species of concern is negligible. However, combining the data obscures the effect of the best practices required. The use of AgDRIFT, as indicated in the EPA guidance, will over-estimate drift and may suggest that a level of concern is exceeded. As with droplet size, it is possible to use F-test methodologies to combine similar data sets from the similar wind speeds, but this has not been done in AgDRIFT.

Atmospheric stability category

Stability issues advise the applicator to avoid inversion (strongly stable) conditions and periods when the wind speed is less than 2 or 3 mph. Wind has an effect to create vertical mixing and thus disturb the stability. Currently, AgDRIFT is based on "neutral" stability. As aforementioned, STDF data were generated under various wind conditions that are highly associated with atmospheric stabilities. These atmospheric stabilities significantly affect drift movement off the field. The way the various stabilities are lumped into a "neutral" category eliminates the capability of the model to support drift mitigation by wind speed.

The Treatment of Multiple Passes in AgDRIFT

The SDTF ground application studies were based on the assumption that a typical application would be defined as a 1200-foot wide, 20-swath field, assuming a boom length of 45 feet. A four-swath (180 feet wide) application area was used in the field studies. In AgDRIFT it is assumed that the contribution from successive passes is additive, up to 20 swaths. As described in earlier comments in this document, the drift curves tend to over-estimate the amount of drift at farther distances off the field and this exacerbates the overestimated drift with multiple passes. For example, at 50 feet from the edge of the field it is assumed that that an application made over half a 'standard' field (10 swaths) results in roughly 2X the residue that would result from a single pass near the edge of the field. At 200 feet from the field edge the model indicates that 4.5X of the single pass residue is found, while at 400 feet, the residue is 6X the single pass. This is a mathematical artifact of the drift curves, it is intuitively flawed and available data does not support the notion that residues proportionally increase the farther you move away from the edge of a field. In fact, recent studies have shown that there is a residue increase only up to the first 5 adjacent swaths in collections made at the edge of the field (AAFC, 2011). At 200 feet from the field edge, there is no discernable added contribution to measured residue, regardless of the number of adjacent swaths treated. The current assumption that there is a significant additive contribution of residues to near-field areas over the measured drift from applications made near the edge of the field in order to account for application being made to an entire field is flawed, and needs to be re-examined.

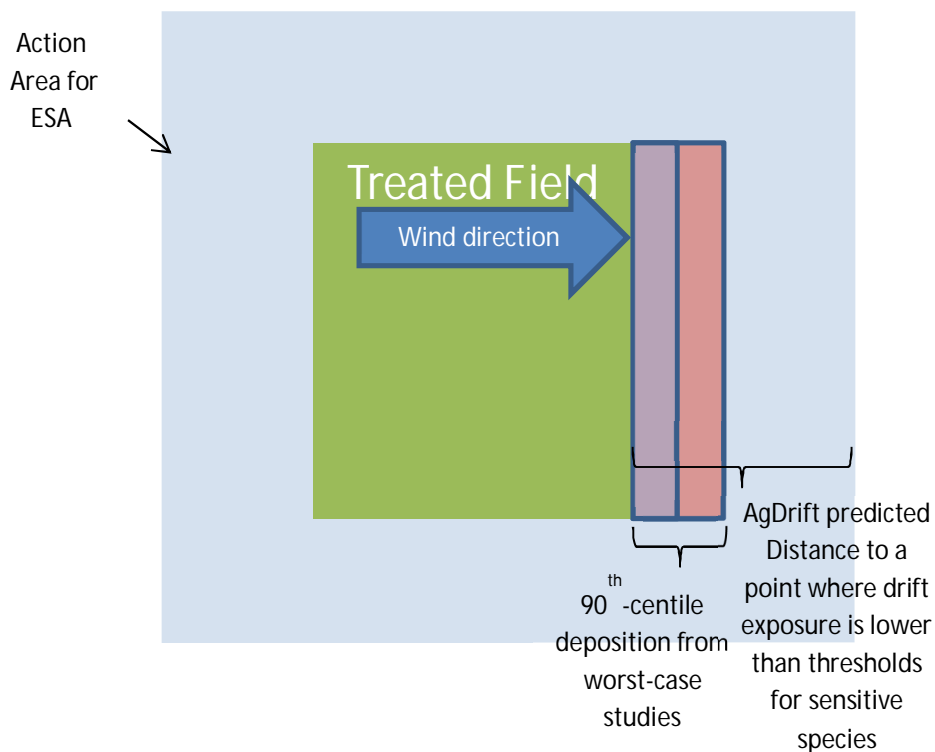


Expanded Use of AgDRIFT

The use of drift models by EPA has expanded beyond what was envisioned when developing the models and well beyond the recommendations of the SAP reviews cited in the guidance documents. When the models were first developed there was a great deal of consideration directed at ensuring that models did not under-predict drift potential from any application. Many of the SDTF studies which are used to

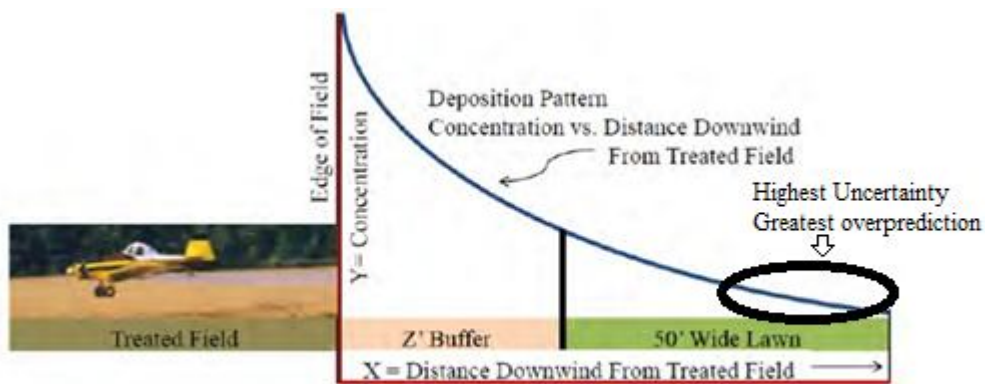
validate the models were conducted under conditions well outside of what is currently accepted as best practices, eg. applications in 20 mph winds.

In the "Interagency Approach for Implementation of National Academy of Sciences Report: Assessing Risks to Endangered and Threatened Species from Pesticides", the EPA, Fish and Wildlife Service, National Marine Fisheries Service and USDA outlined a process where AgDRIFT would be used to define an 'Action Area' where it would be assumed that a species of concern would be exposed at a level exceeding a threshold that would have an effect on 1 in a million individuals in a population of that species. This will define the area to be considered and the number of chemical/species interactions to be considered. Since it cannot be known with any certainty which direction the wind might be blowing when an application is made to a particular field, it is assumed that the action area extends in a 360° radius surrounding a treated field (see following figure). As described above, the models over-predict exposure at greater distances from the field edge. Therefore, it will be very common that low levels of exposure corresponding to very low effects threshold will be predicted to occur at great distances from the edge of a treated field. At the periphery of the Action Area, the actual probability for exposure at a level of concern is certainly near zero. Further, the models predict that downwind exposure is uniform, also a fallacy, which is now extended to a broad area surrounding the entire field. These assumptions are not protective or precautionary, they are simply wrong, and they have large programmatic implications for the EPA and the Services. The use of the models parameterized in the manner described will unnecessarily increase the burden of assessment by assuming there is exposure to species at levels that can have a potential effect, across millions of acres. When in fact the potential for exposure, even at very low threshold levels, can be shown to be unlikely to occur by using more effective tools than what EPA is proposing to adopt as standard. A much narrower peripheral zone of potential influence supported by available data should be used to define the region of potential exposure. What has been the status quo of worst-case assessments for estimating where downwind drift could potentially occur does not serve the programmatic aims of identifying species/chemical interactions of concern, nor is it consistent with a more probabilistic approach to assessment that the National Academies of Science have directed EPA to move toward.



Use of AgDRIFT for Human Health Risk Assessment

Since AgDRIFT was developed there are numerous articles that describe the utility and limitations of the model for predicting drift from aerial and ground applications (Teske and Thistle, 2002; Woodward et al., 2008; Bird et al., 2002). The authors and model developers have repeatedly described the model's tendency to overpredict relative to field data at far-field distances. Developers have further cautioned against extrapolation of results beyond distances where validation data has been generated "except in cases where only relative effects are considered" (Teske and Thistle, 2002). The EPA scheme for assessing risk to bystanders will rely exclusively on modeled estimates of deposition using the portion of a modeled 'drift curve' that has the greatest uncertainty, where the model has been demonstrated to over-predict exposure by as much as 100 X (Woodward et al., 2008). The guidance does not indicate that these estimates would be generated with a caveat that they are upper-bound estimates only and that should be viewed with healthy skepticism. It is likely that these results will be problematic, suggesting that people living in relatively close proximity to agricultural fields have much higher potential for exposure to pesticides from agricultural applications than is actually the case.



Alternative data

Agriculture and Agri-Food Canada (AAFC), a Canadian Federal Government Agency, have generated high quality deposition sets similar to those of the SDTF. The Health Canada, Pest Management Regulatory Agency (PMRA) uses these data as the basis for their decision making. Data from trials conducted in 2000, 2004 and 2006 were recently reviewed by EPA and found to be scientifically valid with the caveat that Quality Assurance data were not submitted with the raw data for review. Data from the 2011 study are currently being compiled for submission to EPA following publication of the study results. The AAFC data (49 ground application data-sets) augments the SDTF data (48 ground application data-sets), roughly doubling the number of trials available for estimation of potential for off-site movement of pesticides due to drift. The AAFC data are more current and include use of more contemporary application equipment when compared to the trials conducted by SDTF, specifically drift-reducing nozzle technologies. The AAFC data are also to some extent, a 'living' data-set, with additional data being generated and reported that could be included for future use. The inclusion of additional, more current, information in EPA decision-making is consistent with EPA use of best-available data which is encouraged by CLA. The EPA has chosen not to use the AAFC data in decision-making due to the current lack of a QA/QC report supporting the data analyses. CLA agrees that there needs to be a standard of

verifiable quality that should be applied to any data used in regulatory decision-making. The standards being applied to the AAFC data should be applied evenly to all data from all sources and not solely to the products of Government of Canada researchers when determining what is best available. CLA is committed to providing EPA with the QA/QC verification necessary to enable EPA to use the AAFC data in their decision-making. However, the EPA decision not to use the data suggests a need for EPA to adopt a well-defined weight-of-evidence (WoE) approach, describing both the data available and relative weight applied. It seems somewhat incongruous to be making assessments of potential for species exposure by excluding AAFC data generated for a pesticide regulatory authority on the basis of lack of verification of quality when species location information used in the same assessment may necessarily be based on anecdotal accounts from field offices with little verification. It is beneficial to fully document the rationale for the choice of models and data used in assessment relative to available alternatives in the context of regulatory decisions. EPA decisions have been successfully challenged in the past as arbitrary and capricious based on the data or models used in assessment, *eg.*, *Sierra Club v. Environmental Protection Agency*, 671 F.3d 955 (9th Cir. 2012); *see also Columbia Falls Aluminum Co. v. Environmental Protection Agency*, 139 F.3d 914 (D.C. Cir. 1998). The use of best available data with robust criteria will support robust decisions.

Use of AgDRIFT® Tier I Orchard/Airblast (Agricultural)

A difficulty noted by EPA is the relative lack of Orchard/Airblast data supporting the drift curves in AgDRIFT. The AgDRIFT Tier I orchard air-blast model is based on empirical curve fits of data from the very few orchard field trial data generated in the early 1990's by the SDTF. This means that the risk assessment is based on 1990's air-blast nozzle, sprayer and application technology. More contemporary drift reducing technologies, such as low drift nozzles and tunnel sprayers for use in orchard spray applications, are not considered in the assessment without a field trial specifically measuring the potential for drift using that technology. The Orchard/Airblast module in AgDRIFT relies on data that were collected from field trials that were conducted in six orchard crops only (grapes, apples, almonds, oranges, grapefruit and pecans). The EPA guidance document notes that the orchard/air-blast data provided in the AgDRIFT model, are used to provide an estimate of drift based on the 50th percentile and that a 90th percentile estimate is not available at this time. CLA agrees that the use of the 50th percentile deposition data is a logical alternative to use of a 90th centile approximation, since the latter estimate cannot currently be scientifically justified as a valid approximation supported by the underlying data. The guidance document states that the use of "other air-blast modules should be used carefully". CLA would like to have clarification of which other air-blast modules this comment refers to. If this refers to Tier I extended settings we would like to have this stated explicitly in the guidance document.

Similar to ground applications, the guidance documents provided for comment indicate that the ability to conduct risk assessments to evaluate orchard air-blast applications is currently restricted to AgDRIFT Tier I. The SDTF studies may have utility that is underutilized by relying on average estimates based on data-sets with many inconsistent variables. Restricting the orchard air-blast assessments to this basic and empirical data model, means that there is no opportunity to run more refined risk assessment at higher tiers, as is available for Aerial risk assessments, for example. EPA's guidance document indicates that for Tier I Orchard/Airblast the "Sparse (Young/Dormant)" setting should be used and extended settings may not be accessed. If extended settings are not accessed, the data sets from field trials in several of these crops are either grouped as "combination orchards", or different growth stages of the same crop may be lumped together. There are five of these combination orchards; (1) normal (stone and pome fruit, vineyard); (2) dense (citrus, tall trees); (3) sparse (young, dormant); (4) vineyard; and (5) orchard. There is no indication of the very important parameters that would be required for assessing

spray drift such as, canopy height, canopy depth, canopy density, tree spacing, sprayer type, spray droplet size, wind speed and direction etc. for these combination orchards. The only way to access more information about such parameters is to access the extended settings which, for individual orchard cropping situations, provide the following information: crop type, average height, row spacing, leaf area index, sprayer type, swath range, approximate spray droplet size (VMD), and application efficiency.

The guidance document notes that “any changes made to initial input parameters should be based on enforceable statements on labels”. It should be noted that even if the Tier I extended settings were to be accessed, it is unclear how risk assessments conducted using such label statements could realistically be converted into enforceable statements written on labels, due to the very specific nature of the orchards application equipment used in the individual data sets. For example if the “Pecans” extended setting is accessed, these data are relevant for an application made using an FMC Axial Fan Orchard Airblast Sprayer spraying droplets with a VMD of 146 μm in an orchard in which the average height of the trees is 68 feet. The general applicability is questionable, which is an issue that needs to be addressed if models are to be used in the manner described. The development of a fully mechanistic orchard air-blast model would resolve many of the identified issues. CLA is committed to identifying more robust means of estimating drift potential from horticultural applications.

AgDRIFT Aerial

The SDTF generated a relatively large database of aerial application data as a foundation for AgDRIFT Aerial. The aerial component of AgDRIFT contains a mechanistic model with relatively good predictive capability for prediction of drift downwind of an aerial application when the model is used in a Tier III setting consistent with operating conditions for typical applications.

Aerial application of pesticides is very often essential (e.g. when ground equipment cannot enter field due to wet conditions or crop size) and can be accomplished with exceptional precision due to the technology that aerial operators have available for use as part of their drift management plans.

Applicators often use:

- Smokers which provide a visual integration of many factors that can influence pesticide drift.
- Aircraft Integrated Meteorological Measurement System (AIMMS) has the ability to measure and record meteorological information, relevant at the time of application. AIMMS can measure what the pilot sees using a Smoker.
- GPS based precision application equipment. The use of GPS enables multiple swaths to be applied aurally with negligible overlap. The precise identification of areas deemed to be sensitive and the ability to control a spray boom in sections enables segments to be shut off to avoid spraying near those areas.

Stipulating operating conditions consistent with a Tier III analyses can produce an unwieldy prescriptive label. This has potential to stifle innovation, since there is little incentive to adopt/develop new technology for drift control if label recommendations preclude their use or require that larger buffers be observed. A complex variety of factors can be influential in drift mitigation for aerial applications which might be difficult to stipulate. For example, in actual practice, a straight stream nozzle orientated

straight back and operating at high pressures might provide adequate coverage for efficacy with the lowest drift potential. However, it is highly unlikely that a label would include this type of set-up. The best system for labeling would provide flexibility for operator adoption of best practices specific to the conditions on a particular day at a particular site. That is technologically feasible. The buffer zone calculator concept adopted by PMRA in Canada provides an option for growers to determine what buffer should be used, based on site specific operating parameters, with requirements for record keeping, verifying that the application was made consistent with the restrictions in place. The extension of this concept should be explored since it has potential to foster adoption of best management practices, and identify restrictions without adoption of unwieldy one-size-fits-all label language. The system has been demonstrated to be manageable in the context of Canadian regulatory decisions; the EPA should examine its utility for USA registrations and potential benefit in disseminating DRT information.

Drift Reduction Technologies (DRT)

The guidance document references the use of a Drift Reduction Technology (DRT) and inclusion of consideration of DRTs in risk assessment. However, the long-awaited EPA DRT program is, as of yet, unavailable. The proposed plan would provide for a reduction in the buffer requirements based on adoption of a DRT or choice of DRTs stipulated on the product label. Currently, the only way to validate the benefit of a DRT is through a field deposition study. There is little indication in the guidance how DRT would be factored into an assessment; this needs to be made much clearer. Options in addition to a field deposition study need to be incorporated into the DRT program. For example, the use of low drift nozzles, tunnel sprayers, or devices to modify air flow such as "donuts" or air volume to canopy matching techniques, cannot be assessed by the Tier I Orchard/Airblast module. If a registrant decided to restrict the use of a product such that only TVI low drift hollow cone nozzles could be used for orchard air-blast applications of a product, there is no guidance on the way to assess the drift risk for this clearly enforceable label statement. Further, the proposed use of AgDRIFT according to the guidance documents provided for comment, does not allow any assessment to be made using crop adapted spraying techniques, such as Tree Row Volume (TRV) spraying, the Unit Canopy Row (UCR) technique or the Leaf Wall Area (LWA) method using available data. It appears likely that this guidance will need significant revision when the details of the DRT program become available. It may be prudent for EPA to delay finalization and adoption of this guidance until details of a DRT program can be incorporated.

Drift buffers and runoff buffers and near field aquatic mitigation

In the guidance document, EPA presents an approach to estimating the aquatic spray drift distance (section 2.3.b) for aquatic risk management. In this approach, an assessment is made by comparing Risk Quotients (RQs) to Levels of Concern (LOCs) (Figure 3 of guidance document). In cases of exceedance due to runoff, a spray drift distance is estimated, although the risk resulting from runoff exposure cannot be mitigated using a spray drift buffer. If the exceedance is due to both runoff and drift, two spray drift distances are estimated: one for mitigating acute risk from drift only, and the other for mitigating chronic risk from both runoff and drift.

Using a spray drift buffer to reduce risk from runoff and drift without recognizing the influence on runoff reduction is not good science and is not supported by basic surface hydrology. The "trial and error" approach described in the document reduces the mass loading to the EPA standard pond through spray drift, and therefore reduces the total loading through both runoff and drift. However, the assumed level

of runoff exposure is not accurately estimated by the models, and therefore runoff exposure should be addressed at a field level, not through imposition of spray buffers. Vegetative filter strips (VFS) have been demonstrated to be effective in removing nutrient and pesticides from runoff. The EPA has expressed concerns regarding maintenance of filter strips and potential for runoff via channelized flow through poorly maintained buffers. Filter strips are often put in place under the direction of NRCS, with requirements for maintenance stipulated as a condition of program participation. Further, vegetative filter strip runoff models can be used to estimate the reduction of off-site chemical movement due to the filter strip being put in place. A model capable of doing this is the VFSSMOD model (VFSSMOD, 2014). This model has been very well validated (Sabbagh, 2009; Sabbagh, 2010; Winchell, 2010), and is considered for risk mitigation by regulators in Europe. EPA expressed interest in VFSSMOD during a buffer strip workshop hosted by the Soil and Water Conservation Society in April 2013; =CLA strongly encourages EPA to further evaluate the model, and expedite the process of incorporating this science-based approach into regulations. The EPA needs to trust that if a vegetative filter strip is required on the label, that it will be put in place by farmers and maintained as a condition of product use, similar to other conditions for product use put on the label. A risk assessment for a product stipulating use of a vegetative filter strip should attempt to quantify what that filter strip does to mitigate off site movement of chemical.

Similarly, the guidance does not address the intercept of drift from a product application by wind-breaks or near field vegetation, though this is understood to be extensive. There has been a large amount of research conducted since the SDTF data were generated, evaluating the efficiency of removal and behavior of applied material near wind-breaks and hedgerows. There is also increasing feasibility of generating site specific recommendations for use with increased ability to verify how and when an application was made. This can provide benefits for all stakeholders if it provides applicators the flexibility to minimize restriction through operation under best management practices.

Resistance Management and No Spray Buffers

Any recommendations for no-spray buffers that become part of labeling need to consider the implications for effective pest management and be implemented in the context of an overall pest management plan. Integrated Pest Management involves the use of a range of control techniques, embracing physical, chemical, and biological methods in an integrated fashion. Chemical control methods employed in a rotational and integrated approach, will help to reduce the selection pressure on any pest species and significantly reduce the potential for development of resistance. The objective of drift mitigation should be to minimize the potential for off-site movement of pesticides, with minimal impact on farmers' ability to treat their fields as required for effective pest management. There needs to be attention given to appropriate rates, timing, and combination of pest control options for the situation under consideration. Leaving areas of a field untreated is not often a viable option, as this could have the unintended consequence of providing a refuge for pests that are able to reinfest a treated crop, creating a need for additional applications, with alternative chemicals, at less optimal timing, and with additional cost. It is normally assumed, and might be stipulated, that a no spray buffer intended to mitigate the potential for exposure of an area deemed as sensitive to spray drift refers to an area downwind of an application. An applicator might choose to treat an area previously left untreated by returning to spray on a day when the wind is blowing away from the area to be protected. A no spray buffer may include a well-placed, well maintained vegetative filter strip or a tillage strip that can provide a measure of pest control without chemical treatment. This has a cost to producers in terms of land taken out of production. Farmers should have the opportunity to put into place the measures that afford the necessary levels of environmental protection that are right for their situation. It is to the

benefit of all stakeholders to seek creative means of adopting management practices that meet multiple objectives.

Conclusions

CropLife America continues to support the development and adoption of new technologies to reduce and manage the potential for off-site movement of pesticides including the development of models for the assessment of drift potential for crop protection products. The AgDRIFT model represented a significant advancement at the time it was developed and has been demonstrated to provide reasonable estimates of drift exposure to near-field areas immediately downwind of fields receiving an aerial or ground application of crop protection products. However, the proposed use of the model by EPA will often stretch it beyond its well-characterized limitations. The use of AgDRIFT with the default parameters described in the guidance document is unlikely to provide “realistic exposure and risk estimates for both ecological and human health assessments.”, as claimed in the Federal Register Notice. Further, the proposed use of the AgDRIFT model is inconsistent with guidance of the EPA SAP regarding limitations of the model, how it should be used, and how the results should be communicated. It is unclear whether EPA has evaluated any other models to determine whether there are any that are better suited to the needs described. This evaluation should occur before any guidance is adopted. Additionally, AgDRIFT is limited in enabling use of the best available data including SDTF data to estimate the influence of new spray nozzle technology; label restrictions such as wind speed; and other best management practices in reducing potential for off-site movement of pesticides.

The implications of using AgDRIFT, as proposed in guidance, are significant with respect to potential impacts on agricultural production, resistance management, communication of risk, and resource management decisions. The use of the model as proposed should be reconsidered.

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