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EPA Guidance on Pesticide Drift Will Affect Product Registrations

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Background

How to address and manage potential risks posed by pesticide "drift" -- the unintentional movement of some level of pesticide outside of the intended area of application -- has long been a challenging, complex regulatory policy issue. It is difficult to dispute that when applying a pesticide product some small amount may, in some circumstances, move off-site. In other words: "drift happens." The issue quickly becomes whether, from a risk management perspective, the amount of off-site movement matters. That question is, in turn, heavily dependent on factors specific to the pesticide application at issue, such as the nature of the specific pesticide (*e.g.*, its volatility), the application method used (*e.g.*, aerial or ground application), and climatic conditions. Because many such factors must be considered, the U.S. Environmental Protection Agency (EPA) has found it challenging to devise a "drift policy" or define generally what, if any, level of potential drift is acceptable.

As EPA struggled to define a clear policy, in October 2009 health and environmental advocacy groups filed a petition asking that EPA:

- 1. "Expeditiously evaluate the exposure of children to pesticide drift";
- 2. "[I]mpose safeguards to ensure that children are protected from aggregate pesticide exposures, including pesticide drift"; and

3. "Immediately adopt interim prohibitions on the use of toxic drift-prone pesticides . . . near homes, schools, parks, and daycare centers or wherever children congregate." These "no-spray" buffers are requested to be "at least 60 feet for ground applications and 300 feet for aerial applications."

EPA sought public comment on the petition in November 2009. In July 2013, the petitioners filed a court action alleging that EPA had unreasonably delayed its response. EPA agreed to, and did, respond to the petition on March 31, 2014.

EPA's response agreed with the petitioners on key issues regarding the need to address drift. EPA denied, however, petitioners' requests that EPA:

- 1. "Use a process outside of the ongoing pesticide re-evaluation process, as currently scheduled, to assess and manage spray drift and volatilization risks."
- "[I]mmediately adopt interim prohibitions on the use of certain pesticides that they allege are toxic
 and may be prone to drift or volatilization, near homes, schools, parks and daycare centers or
 wherever children congregate."

EPA stated that it "instead believes that case-by-case, chemical-specific risk assessment is a sound science-based approach, consistent with the Agency's mandate" EPA left open the possibility of case-by-case buffer zones and other risk mitigation measures.

EPA also noted it had been "actively developing drift and volatilization assessment methodologies, applying those methodologies to both fumigant and conventional pesticides, and finding ways to mitigate the risks to adults and children posed by pesticide drift and volatilization." Indeed, a few months earlier, EPA had released for public comment, on January 29, 2014, two sets of documents addressing specific drift issues, discussed below. (Although not discussed here, EPA also released for public comment, on March 28, 2014, draft guidance on how it will evaluate pesticide volatilization in its human health risk assessments.) These guidance documents may profoundly affect pesticide assessments, yet raise, some believe, troubling issues.

It appears that EPA plans to articulate a series of specific policies to implement its commitments in response to the petition. When complete and considered together, this series of specific policies may become an operational "drift policy." By developing the general drift policy this way, EPA presumably intends to avoid past pitfalls associated with issuing an abstract, overarching "drift policy." Such a *de facto* drift policy will also have implications for other program activities such as the Worker Protection Standards, since newer, more conservative estimates of possible off target movement might imply the need for larger buffer zones, longer re-entry intervals, and similar measures. EPA has not been able to unfurl such an overarching policy over the past 20 years.

The pathway forward is already not as smooth as EPA might have hoped. The advocacy groups that filed the original court action recently filed, on May 29, 2014, a court challenge to EPA's response to their petition.

This challenge may well influence EPA's policy development. Environmental justice issues also will likely be a significant influence, given other advocacy group court actions in which EPA is embroiled.

New Spray Drift Guidance

EPA published on January 29, 2014, two guidance documents (dated November 1, 2013) on assessing spray drift. The first details methods to assess ecological exposure and risk. The second provides methods to assess post-application exposure and risk for bystanders, particularly children.

Ecological and Drinking Water Assessment Guidance

EPA's Guidance on Modeling Offsite Deposition of Pesticides via Spray Drift for Ecological and Drinking Water Assessments for the Environmental Fate and Effects Division (EDWA Guidance) proposes using the AgDrift model to estimate drift of liquid pesticides from residential and agricultural applications. Three application methods can currently be assessed: groundboom, airblast, and aerial. The limits on assessing liquids and application methods are based on the AgDrift model's limits. The EDWA Guidance provides step-by-step input to the AgDrift model. The model, in conjunction with other ecological models, is then used to:

- Estimate the spray drift fraction for inputs into PRZM/EXAMS (EPA ecological exposure models) for estimating aquatic exposure in drinking water and ecological risk assessments.
- Estimate exposure of plants to spray drift in ecological risk assessments.
- Estimate the fraction of applied pesticide, used in assessing exposure for terrestrial organisms located off the application site, including for applications directly to water.
- Determine the maximum distance from the edge of the area where the pesticide is directly applied (also known as the initial area of concern) to the point where levels of concern (LOC) are no longer exceeded for both terrestrial and aquatic organisms.

The spray drift distances are used to determine any needed mitigation options (e.g., buffer zones, reduced application rates).

The EDWA Guidance recommends Tier I modeling for screening assessments and provides default input factors. Tier II and Tier III modeling, typically done for geographic-specific areas or uses, provides more refined outputs, but can only be conducted with refined input values and only for aerial applications.

EPA is developing with the Fish and Wildlife Service and National Marine Fisheries Service (the Services) a common approach for the ecological risk assessment process for threatened and endangered species. EPA has recommended using the results of this modeling in that process and plans to adjust the EDWA Guidance once a final common approach is determined. This, in turn, will likely affect Endangered Species Act (ESA)

compliance considerations, as the model results might imply the need for EPA consultation with the Services for products undergoing registration review.

Residential Exposure Addenda

EPA's Residential Exposure Assessment Standard Operating Procedures (SOPs), Addenda 1: Consideration of Spray Drift (Addenda) provides procedures for assessing potential exposure and risk to human health associated with spray drift. It is based on the current SOP for assessing exposure and risk from use of pesticides on turf. The Addenda defines when quantitative assessments are needed and provides input factors to be used in the assessment.

The exposure and risk assessment focuses on pesticide movement from an applied field to a neighboring lawn where children might play. Dermal and hand-to-mouth exposure and risk are key. The standard SOPs for dermal and hand-to-mouth exposure to children playing on lawns are modified by including a factor for the percentage of applied pesticide that drifts onto the neighboring lawn. These factors or "drift fraction values" are estimated using AgDrift for different application methods (*i.e.*, groundboom, airblast, and aerial, as with the ecological assessment) and for differing distances from the field to the lawn. Three tables provide the drift fraction values for the three different application methods.

The resulting potential risk estimates from dermal and hand-to-mouth exposure incorporating the drift fraction values in the SOP equations are used to determine mitigation options (*e.g.*, buffer zones, reduced application rates). These "bystander risk" estimates may lead to issues for registrants, as critics of pesticide use will likely cite conservative EPA estimates suggesting possible harm even if EPA decisions about appropriate label requirements allow for continued use.

Comments on the New Guidance

Registrants have commented that the current default assumptions are overly conservative and calculations will imply a need for unnecessarily large buffer zones. In addition, some believe that the AgDrift model itself is inappropriate for use, and that drift reduction strategies currently used are not included in the default assessments.

The AgDrift model has not been updated to include newer application methods that include drift reduction strategies now considered best management practice. For example, aerial applicators use larger droplet sizes than are used in the default assumptions, and adjust both nozzle and boom directions to minimize drift. These technologies are not included in the studies used to develop AgDrift. Tiers II and III of AgDrift are not available for assessing groundboom and airblast applications, due to limitations in the data included in AgDrift. This limits pesticide registrants to use of Tier I inputs except for products that are applied aerially. Finally, the AgDrift model is not used by Canada's Pesticide Management Regulatory Authority (PMRA). PMRA uses the AgDisp model and has developed a buffer zone calculator that allows determination of buffer size based on site-specific operating parameters, with recordkeeping requirements intended to verify that applications are made consistently with the restrictions. The AgDisp model includes more recent studies

and is expected to be updated as new drift reduction technologies become available. There is concern that PMRA and EPA are not conducting assessments in the same manner and with the same dataset.

Additionally, AgDrift model results are combined with the already very conservative fraction of applied outputs from T-REX, T-HERPS, and PRZM/EXAMS in ecological assessments, resulting in "cascading conservatisms" -- multiple conservative assumptions -- that produce even more restrictive and overly large buffer zones, particularly based on ecological endpoints. Moreover, conservative ecological exposure estimates may trigger ESA concerns as part of a product's registration review.

Finally, the Addenda discuss briefly the use of "Drift Reduction Technologies." These technologies are not included in the Addenda. The EPA Spray Drift fact sheet states:

OPP and the Agency's Office of Research and Development are currently developing a new voluntary program, the Drift Reduction Technology (DRT) Program, which encourages the development, marketing, and use of application technologies verified to significantly reduce spray drift. The Agency expects the DRT Program to be operative by 2010. The DRT Program will enable manufacturers of pesticide application technologies (e.g., spray nozzles) to voluntarily test their technologies to verify drift reduction potential. EPA intends to encourage pesticide registrants to include use of these technologies, along with standard drift reduction techniques, in product label use directions.

The program, which was to be operative in 2010, is still being developed. Technologies already exist that have been shown to reduce drift up to 75 percent. Yet, the impact of these technologies cannot currently be included in assessing risk and establishing buffer zones.

Conclusion

EPA guidance on specific issues appears destined, when considered as a whole, to become EPA's functional "drift policy," despite years of controversy and difficulty in past attempts to propose a clear and "simple" definition of drift. Implementing offsite deposition modeling and mitigating estimated bystander exposure risks will likely lead to significantly enhanced restrictions on current products and use patterns. As EPA's policies evolve in this arena, and as exposure models mature, registrants may face demands for greater restrictions on products, unless they fully understand and address the elements of EPA models. Concerns from advocacy groups that EPA is not doing enough to address alleged harms posed by drift, especially harms alleged to raise environmental justice issues, and resulting appeals for court intervention, will undoubtedly complicate the matrix of considerations influencing EPA's policy. It is an issue that registrants should monitor closely.