

**Implementing Chemical Specific Human Health
Spray Drift Analysis for Pesticide Registration Actions**



July 2024

**Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC**

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I. Overview

This document provides a background and description of chemical-specific spray drift analysis in the Agency's Office of Pesticide Programs (OPP) and the changes it is making as of July 15, 2024, in regards to conducting chemical-specific spray drift analysis for pesticide registration decisions. Section II of this document summarizes the change, and Section III provides a brief summary of the spray drift analysis methodology and associated spray drift risk assessment determinations. Section IV provides the Agency's rationale for making this programmatic change, and Section V provides a brief discussion of how chemical-specific spray drift analysis will be implemented under both the Registration Review and Registration Programs of OPP.

II. Summary of Current Action

Pesticide spray drift is the movement of a pesticide through the air at the time of application or soon after to a site other than the area intended (such as residential lawns or recreational areas). A chemical-specific human health spray drift analysis uses chemical-specific use, exposure, and hazard data to estimate potential exposure and risk to bystanders from spray drift. The Agency has routinely incorporated chemical-specific human health spray drift analysis into Registration Review decisions since 2014 and has relied upon the general protections required under the Agricultural Worker Protection Standard (WPS) for registration decisions to protect individuals from pesticide spray drift. On July 15, 2024, the Agency announced that it will begin to conduct chemical-specific human health spray drift analyses to certain decisions made under the registration program. With this action the Agency will:

- Include chemical-specific human health spray drift analysis as part of new active ingredients petitions being evaluated for initial U.S. registration.
- Include chemical-specific human health spray drift analysis as part of FIFRA Section 3 new use or amended use decisions *if* that active ingredient has previously received a chemical-specific spray drift analysis either as part of a new active ingredient initial U.S. registration decision or under Registration Review.

III. Background of Chemical Specific Human Health Spray Drift

Bystander spray drift assessments illustrate the movement of pesticide following application by aircraft, airblast, or ground boom sprayers where droplets may drift and deposit in areas adjacent to the application site. These types of application equipment are generally used when pesticides are applied to areas such as agricultural fields, golf courses, rangeland, or rights-of-way. As a result, people may come into contact with pesticides that are applied and

subsequently drift onto adjacent areas through dermal and/or incidental oral¹ exposure to the deposited pesticide droplets.

The Agency published its chemical-specific human health spray drift assessment methodology² in 2014 to estimate potential risk from this route of exposure (79 FR 4691; FRL-9903-12). The methodology utilizes chemical-specific data (i.e., application rates, equipment, and hazard data) with drift modeling, coupled with peer reviewed standard operating procedures designed to evaluate pesticide exposure from turf. A residential turf assessment is conducted but the residue value inputs are adjusted to account for the amount of pesticide residue deposited as a result of spray drift instead of being based on a direct, intentional application onto turf. The amount of residue which deposits from drift varies with distance from the edge of a treated field. The assessment indicates the distance (i.e., buffer zone) needed from the edge of the treated area to where the estimated risk is not of concern³. The Agency has been incorporating this methodology into draft human health risk assessments (DRA) completed in support of Registration Review. Under Registration Review all uses of a chemical are evaluated, thus making the conclusions of a chemical-specific spray drift analysis applicable to the entire chemical case.

Conducting a chemical-specific spray drift analysis can result in four potential conclusions with regard to exposure and/or risk:

- 1) A qualitative human health spray drift analysis is sufficient. In certain cases, the characteristics of a pesticide registration precludes potential spray drift. For example, a pesticide may only be used indoors, be formulated only as a granular, or only be applied by soil injection. In these cases, while numeric risk estimates are not generated, the Agency has considered the chemical-specific information and determined exposure and/or risk from spray drift is not expected.
- 2) The potential exposure and risk from a direct turf residential use is protective of potential spray drift exposure and risk from other relevant application scenario(s). In cases where an active ingredient is registered for both direct use on residential turf and other use patterns that could result in spray drift exposure (e.g., application to crops), the Agency concluded that if the maximum application rate to crops adjusted by the drift fraction (i.e., 0.26⁴) is less than or equal to the existing turf application rate, then

¹ For children 1-2 years old, the Agency estimates incidental oral exposure that results from hand-to-mouth activities when that activity occurs on grass or turf (such in residential settings, or parks).

² Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift

³ Risk is represented by a Margin of Exposure (MOE) which is a ratio between exposure and hazard, where a larger MOE indicates lower risk. More information on MOEs and pesticide risk assessment can be found at:

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>

⁴ The highest residue expected at the edge of a treated area as a result of drift is the determined by multiplying 0.26 by the application rate for the scenario under review.

the risk assessment for use on turf is considered protective of potential spray drift exposure from the registered crop uses. Therefore, additional human health spray drift analyses would not be necessary.

- 3) The spray drift analysis resulted in exposure and risk estimates at the edge of the field that are not of concern. In cases where the estimated margin of exposure (MOE) at the edge of the field is greater than the chemical-specific and route-specific level of concern (LOC) (MOE > LOC indicates no risk of concern), risk mitigation (e.g., buffer distances from the edge of the treated area) is not recommended in the DRA.
- 4) The spray drift analysis resulted in exposure and risk estimates at the edge of the field that are of concern. In cases where the estimated MOE at, or beyond the edge of field is less than the chemical-specific and route specific LOC (MOE < LOC indicates a risk of concern), risk mitigation (e.g., larger droplet size or a buffer zone) is recommended in the DRA.

Chemical-specific spray drift conclusions are captured in DRAs and integrated with other information to contribute to overall Registration Review decisions. Unlike decisions made under the Registration Review Program, decisions made under the Registration Program relied upon requirements under the WPS⁵ and other mandatory spray drift label language⁶ to protect against potential risk from pesticide drift.

IV. Rationale for This Change

The Registration Review program commenced in 2008 and as the Agency enters a new round of the Registration Review in 2024, it has determined that it is an appropriate time to extend the practice of conducting chemical-specific spray drift analyses to a wider range of regulatory decisions. The Agency is not making any changes to its chemical-specific methodology outlined in the 2014 document but has decided to extend the chemical-specific spray drift methodology to certain registration actions.

With this change, the Agency is furthering protections to bystanders wherever pesticide spray drift may occur, and thereby strengthening environmental justice protections associated with the use of pesticide products. By including chemical-specific human health spray drift analyses into new active ingredient decisions, the Agency ensures that new active ingredients have the same or greater spray drift protections as products that are on the market. By including human health spray drift into certain Section 3 new use/amended use decisions (i.e., those that involve

⁵ The WPS provides for general protections against pesticide drift through requirement of an application exclusion zone (AEZ). The AEZ is an area surrounding the application equipment and which must be generally free of all persons other than appropriately trained and equipped handlers. The WPS, and more information about the AEZ can be found at: <https://www.epa.gov/pesticide-worker-safety/agricultural-worker-protection-standard-wps>

⁶ More information on pesticide labeling can be found in the EPA Pesticide Label Review Manual, <https://www.epa.gov/pesticide-registration/label-review-manual>

an active ingredient that has previously received a chemical-specific spray drift analysis), potential risks from new uses/amended uses can be addressed at the time of the decision, rather than deferring any potential spray drift mitigations until the next time that active ingredient undergoes Registration Review.

The change the Agency is making at this time is consistent with its overarching goal that all pesticide products in the U.S. are registered based on the most up-to-date and accurate science. This change will not result in any change to PRIA codes, fees, or established decision review times. The Agency does not anticipate that this change will result in an increased burden to the regulated community since it does not result in any additional data requirements, and registrants and the grower community have already adapted practices to incorporate the results of spray drift analyses through Registration Review decisions for over a decade. In addition, this change aligns with Agency efforts to comply with the Endangered Species Act (ESA), where EPA is working to improve and optimize how we evaluate risk and mitigations to endangered species. Where spray drift risks are identified to either bystanders or to non-target species, risk managers will work with the human health and ecological risk assessors and registrants to determine efficient and effective mitigation options.

At this time, the Agency will not conduct chemical-specific human health spray drift analysis to Section 3 new use/amended use registrations if that active ingredient has not previously received a chemical-specific spray drift analysis either under Registration Review or as part of an initial U.S. registration action. Incorporating chemical-specific spray drift for new use/amended use registrations that have not previously received an analysis could disincentivize registrants from introducing new tools for growers and could lead to unclear labels and confusion at the user level. In these scenarios, the Agency will continue to rely upon the protections provided under the WPS as well as mandatory label language to protect individuals from pesticide spray drift. The Agency will conduct chemical-specific human health spray drift analyses for these uses and active ingredients when they are evaluated under Registration Review. Then, once an active ingredient receives a chemical-specific human health spray drift analysis as part of the DRA under Registration Review, all Section 3 new use/amended use registrations for that active ingredient thereafter will include a chemical-specific human health spray drift analysis.

V. Implementing Plan

Beginning July 15, 2024, the Agency will conduct chemical-specific spray drift analysis for registration applications as discussed herein. Also, the Agency has decided to apply this change to registration actions that are currently under review with the Agency, when possible. The inclusion of pending actions is impactful since any new active ingredient or new use/amended use that is not assessed for spray drift would not be assessed until that active ingredient undergoes Registration Review.

Below is a summary of how chemical-specific spray drift analysis will be implemented in the Pesticide Program and for particular registration actions. In general, chemical-specific human health spray drift analysis will be applied to registration actions that are subject to human health science review. An overview of registration actions that are and are not subject to science review, the decision time review periods, and registration service fee requirements can be found at: <https://www.epa.gov/pria-fees>.

A. Registration Program

- **New Chemical Registrations**
All new active ingredient applications for initial U.S. registration will include a human health spray drift assessment. Based upon chemical-specific information, the Agency will evaluate potential spray drift exposure and risk from the proposed use(s) of a new active ingredient. Human health spray drift analyses will not be conducted for new active ingredient applications requesting import tolerances only, as the pesticide under that scenario is not being considered as an initial U.S. registration. The Agency will conduct human health spray drift assessment if an active ingredient with only import tolerances is later considered for U.S. registration.
- **FIFRA Section 3 New Use/Amended Use Registrations**
The Agency will include chemical-specific human health spray drift assessments for Section 3 new use/amended use registrations if the chemical has previously received a chemical specific spray drift analysis either in a finalized DRA during Registration Review or as part of a new active ingredient initial U.S. registration decision. The Agency is identifying the finalized DRA as the determining stage since the DRA reflects updated science policy and methodology for a particular chemical case.
- **FIFRA Section 24(c) Registrations**
FIFRA section 24(c) allows states to register “additional uses of federally registered pesticides” to meet special local needs within the state. In general, the Agency does not conduct human health risk assessments on a Section 24(c) application because they are state registrations. However, the Agency systematically evaluates registered 24(c) uses during Registration Review. Further, the FIFRA Section 24(c) application process includes a 90-day review period by the Agency and states must demonstrate that no unreasonable adverse effects will occur from the proposed new use/amended use. As part of EPA’s review of a 24(c) application, the Agency may request additional information from the requesting state if there are concerns that unreasonable adverse effects may occur, including to bystanders. In rare instances, the Agency may conduct a risk assessment if the circumstances warrant. Since most 24(c) registrations expand the use(s) of a registered Section 3 product, relevant labeling requirements on the existing Section 3 label(s), including spray drift labeling requirements, would apply to the 24(c) label.

- FIFRA Section 18 Emergency Exemptions
Under FIFRA Section 18, states or federal agencies may request an exemption from FIFRA provisions to allow unregistered uses of pesticides in order to address emergency conditions for a limited period. In general, the Agency will conduct chemical-specific spray drift analyses, as part of the human health risk assessment for a Section 18 request so the Agency can confirm that a pesticide use will meet safety standards. For initial Section 18 requests the Agency will, when feasible, implement spray drift mitigation measures. Repeat Section 18 requests that rely upon previously conducted human health risk analyses, including spray drift, will include and require all human health protections, including spray drift protections.
- Applications Involving a Co-formulated Product
As standard practice, the Agency conducts human health risk assessments on individual active ingredients. For applications involving co-formulated products where one or more of the active ingredients has previously received a chemical-specific analysis, the Agency will consider spray drift exposures for that chemical as part of that application.

If the new use/amended use does not apply to a constituent of the co-formulated product, then, in general, the Agency will not update the risk assessment, including human health spray drift, for that chemical. For example, if a Section 3 new use application with a co-formulated product is received, and the requested new use only applies to one of the two active ingredients in the co-formulated product, then the Agency will only assess potential human health risk, including spray drift risk, to the one active ingredient for which that use would be a new component of its registration. In scenarios involving co-formulated products, potential exposure and risk, including potential spray drift risks, is generally driven by the most protective risk estimates amongst the different active ingredients of the co-formulated product.

B. Registration Review Program

Registration Review is intended to ensure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Therefore, the Agency will continue to include chemical-specific human health spray drift analyses as a part of the DRAs in support of Registration Review. Based upon chemical-specific information, the Agency will evaluate the potential spray drift exposure and risk from the registered use(s) of an active ingredient.

Any new use that has been added to the registration of an active ingredient but was not assessed for potential human health spray drift exposure and risk will be assessed under Registration Review. Examples of this might include uses that were approved for an active ingredient in the time between the completion of a DRA for that active ingredient compound

and the implementation of this Program change, or FIFRA Section 24(c) uses added to an active ingredient after this Program change.

Going forward, the number of pesticide products in the market that reflect up-to-date chemical-specific spray drift analysis will continue to increase each year. Active ingredients granted initial U.S. registrations just prior to this change did not include chemical-specific spray drift analysis. These chemicals will be subject to a chemical-specific spray drift analysis at the time the active ingredient undergoes Registration Review.

VI. For Further Information

For more information about pesticide spray drift see the EPA webpage:

<https://www.epa.gov/reducing-pesticide-drift>. For further questions or inquiries, contact the Office of Pesticide Programs Ombudsman at: pesticidequestions@epa.gov.