

**State-Federal Issues Research Group**  
**Updates from Office of Pesticide Programs**  
**April 2016**

**Enlist Duo**

EPA discovered, after granting the registration for Enlist Duo, that the registrant, Dow, had made claims of “synergistic herbicidal weed control” in its Provisional and Non-provisional patent applications to the U.S. Patent and Trademark Office for Enlist Duo. After reviewing the patent applications, EPA sent Dow a letter requesting all available information about potential synergistic effects within 30 days of the letter. EPA received the information from Dow on November 9, 2015.

On November 24, 2015, EPA asked the court to vacate and remand the registration of the pesticide Enlist Duo because the Agency had received new information from the Dow on the potential effects of the pesticide on non-target plants. The information was not provided to EPA by Dow prior to EPA issuing the Enlist Duo registration. EPA has not yet completed its review of the information.

Dow is also conducting a new study that will demonstrate the toxic effects of the two active ingredients when used together so that the Agency can determine safe use of the combination herbicide and whether synergism is seen or not. These data are expected to be submitted to EPA in the spring of 2016. EPA will review this data to determine whether changes need to be made to the original registration decision.

EPA felt compelled to seek a remand because this new information could lead EPA to a different decision on the restrictions on use of Enlist Duo and, specifically, could potentially result in changes to the labeling requirements for users and also EPA’s initial ‘no effects’ finding concerning the protection of listed species in the context of the Endangered Species Act.

The Court did not vacate the registration, and instead left the registration in place. Enlist Duo is currently registered for use in 15 states. Questions about whether or not the product is available for sale should be directed to Dow.

**Dicamba on dicamba-tolerant soybean and cotton**

On March 31, the Agency posted a proposed decision on the use of dicamba DGA (Monsanto’s M1691 Herbicide) on dicamba-tolerant cotton and soybeans for public comment. The proposed decision outlines mitigation measures and terms of registration, which are intended to address concerns about drift, volatility, and managing herbicide-resistant weeds. The proposed decision and supporting assessments may be found in the docket EPA-HQ-OPP-2016-0187 on [www.regulations.gov](http://www.regulations.gov). We encourage states to provide comments so that the Agency can consider them as we move toward finalizing this registration decision.

## **WPS and C&T**

### **EPA's Agricultural Worker Protection Regulation**

On September 28, 2015, EPA announced the final revisions to the Agricultural Worker Protection Standard (WPS) in order to protect the nation's two million farm workers and their families from pesticide exposure. EPA's revised WPS affords farm workers similar health protections to those already enjoyed by workers in other jobs. Protecting our nation's farm workers from pesticide exposures is at the core of EPA's work to ensure environmental justice.

The revisions to the WPS cover many different areas. The major revisions include:

- Annual mandatory training to inform farmworkers about the standards in the WPS and how to protect themselves from pesticides.
- Expanded training includes instructions to reduce take-home exposure from pesticides on work clothing and other safety topics.
- Children under the age of 18 are prohibited from handling (mixing, loading or applying) pesticides and from doing early entry work in fields before the restricted-entry interval expires.
- Expanded mandatory posting of no-entry signs for the most hazardous pesticides. The signs prohibit entry into pesticide-treated fields until the restricted-entry interval expires.
- New no-entry application-exclusion zones up to 100 feet surrounding pesticide application equipment to protect workers and others from exposure to pesticide overspray.
- Workers and handlers will have access to pesticide application information and, for the first time, hazard information (in the form of Safety Data Sheets) at a central location. Workers, handlers or their designated representatives can also request access to or copies of that information.
- Mandatory recordkeeping to improve states' ability to follow up on pesticide violations and ensure compliance. Records of pesticide applications and worker/handler training must be kept for two years.
- Anti-retaliation provisions are comparable to the Department of Labor's.
- Changes related to personal protective equipment will be consistent with the Occupational Safety and Health Administration's standards for ensuring respirators are effective and will require medical evaluation, fit testing and training for handlers who have to wear respirators.
- Expanding the definition of immediate family and the exemption from many WPS requirements for farm owners and their immediate families.

EPA published the final WPS rule in the *Federal Register* on November 2, 2015. The new requirements have a delayed compliance date to give growers and states time to become familiar with the new requirements and prepare for implementation. Compliance for most of the new requirements is required by January 2, 2017. Compliance with several other requirements (new training content, new pesticide safety information display content and handlers having to suspend applications) is required by January 2, 2018.

### **EPA's Certification of Pesticide Applicators Regulation**

On August 24, 2015, EPA issued a proposed rule with revisions to the 1974 regulation that establishes requirements for the certification of applicators of restricted use pesticides. The proposed changes are in response to extensive stakeholder engagement and are needed to ensure the federal certification standards

adequately protect applicators, the public and the environment from potential risks associated with use of restricted use pesticides.

EPA believes the proposed changes to the rule will improve the competency of certified applicators by establishing:

- new standards for certification (such as minimum age and exam standards),
- more specific requirements for evaluating competency of private applicators,
- minimum requirements for recertification programs, and
- new certification categories to address specific high-risk application methods.

The proposed changes will increase protection for noncertified applicators of restricted use pesticides operating under the direct supervision of a certified applicator:

- through enhanced pesticide safety training and standards for supervision of noncertified applicators, and
- by establishing a minimum age requirement for such noncertified applicators.

In keeping with EPA's commitment to work more closely with tribal governments to strengthen environmental protection in Indian Country, EPA is also proposing changes that would provide more practical options for establishing certification programs in Indian Country.

The comment period on the proposed rule closed in January 2016, after two extensions. We are currently reviewing the more than 700 unique comments received from a range of stakeholders and regulators, including state lead agencies, pesticide safety education programs, farm bureaus, associations, nonprofit organizations, certified applicators and growers. Many comments from state and pesticide safety programs provide details describing intricacies of their certification programs and how the proposal would impact them. Based on the information and concerns expressed in the comments, EPA is considering more flexible options for the final rule in areas where different approaches accomplish the goals of the proposal.

More information on pesticide applicator certification is available on our website:  
<http://www2.epa.gov/pesticide-worker-safety/how-get-certified-pesticide-applicator>

## **Spray Drift and Volatilization: Update on Policies**

EPA has been working on issues related to spray drift and how to better evaluate drift and volatilization in our risk assessments for several years. In March 2014, we provided two draft guidance documents for public comment. These documents describe how off-site spray drift will be evaluated for ecological and human health risk assessments for pesticides. Recent activities associated with implementation of the policies for consideration of spray drift and volatilization in risk assessment include:

- a public comment period,
- review of the submitted comments,
- ongoing development of response to comment documents,
- submission of pertinent scientific data which could refine the policies, revisions and refinements to each policy as applicable, and

- development of a final implementation plan.

More information on EPA's activities related to spray drift is available on our website:

<http://www.epa.gov/reducing-pesticide-drift>

## **Drift Reduction Technology**

OPP has recently received nozzle and adjuvant data to obtain a DRT rating for specific formulations of multiple active ingredients. This manufacturer is the first of several interested in developing and submitting data to participate in the DRT star-rated program since the program officially launched in late 2014. EPA plans to complete the review of this data in early 2016 and finalized the first star-rated product.

To facilitate submissions from interested companies, EPA posted a template for DRT submissions, including the necessary analysis of spray drift data needed to assign a rating.

In an effort to increase outreach and participation, presentations will continue with states, local extension services and industry groups that have requested additional guidance and information regarding the program. Questions raised include specific guidance for testing, implementation, enforceability and timing of DRT technologies appearing on labels.

More information on Drift Reduction Technology is available on our website:

<http://www.epa.gov/reducing-pesticide-drift>

## **Glyphosate**

The agency is currently reassessing glyphosate as part of the registration review process (the periodic reevaluation required by FIFRA every 15 years) and will release for public comment the preliminary ecological and human health risk assessments for glyphosate in several months.

- The preliminary ecological risk assessment will include a comprehensive analysis of the potential impacts on all taxa, but will not include an endangered species risk assessment. (EPA's preliminary analysis will include a brief discussion on the direct effects of glyphosate on pollinators, including honeybees and monarch butterflies.)
- The preliminary human health risk assessment review will include a full evaluation of the toxicity, exposure and risk profile of glyphosate.
- In addition to the ecological and human health assessments, the agency will release for public comment a document discussing proposed measures for weed resistance management as it relates to glyphosate.
- The agency is coordinating its re-evaluation of glyphosate with Canada's Pest Management Regulatory Agency. EPA and PMRA collaborated in reviewing certain glyphosate data and have also shared information.

More information on glyphosate is available on our website: <http://www.epa.gov/ingredients-used-pesticide-products/glyphosate>

## **Monarch Butterflies**

The science surrounding what is affecting monarch butterfly populations is still evolving. Like commercial honeybee losses, there are multiple factors that may be affecting monarch butterflies including loss of habitat, weather and pesticides.

EPA is engaged in a number of activities to protect monarch butterflies and other pollinators, including participating in an effort that the Department of Interior is leading with Canada and Mexico to protect pollinators. With regard to pesticide exposure, EPA is looking holistically at all herbicides, not only glyphosate, to determine the potential effects on monarchs and plant resources critical to monarch butterfly populations. In response to concerns raised from the public and in recognition that pesticides may be one factor affecting the monarch butterfly, EPA published for public comment a *Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly*. The comment period recently closed and EPA received approximately 41,000 comments, which we are currently reviewing. EPA will continue to evaluate potential steps forward and will engage with affected stakeholders if necessary.

More information on what EPA is doing to protect pollinators is available on our website: <http://www.epa.gov/pollinator-protection>

## **Pollinator Protection Proposal**

In May 2015, EPA issued a proposal to protect bees used for pollination services from harmful pesticide exposure. Large numbers of bees may be exposed to pesticide spray when growers contract with beekeepers to provide pollination services. EPA believes that strong regulatory measures should be in place to protect bees used for pollination services.

EPA is proposing to prohibit the applications of pesticides that are highly toxic to bees when crops are in bloom and bees are under contract for pollination services. These restrictions would prohibit application of most insecticides and some herbicides during bloom.

The proposed restrictions would apply to all products that have:

- Liquid or dust formulations as applied;
- Foliar use (applying pesticides directly to crop leaves) directions for use on crops; and
- Active ingredients that have been determined via testing to have high toxicity for bees (less than 11 micrograms per bee).

The proposed restrictions would not replace more restrictive, chemical-specific, bee-protective provisions that may already be on a product label. Additionally, the proposed label restrictions would not apply to applications made in support of a government-declared public health response, such as use for wide area mosquito control. There would be no other exceptions to these proposed restrictions.

At this time, EPA is not proposing changes to product labels for managed bees not being used for pollination services.

EPA is also working with state and tribal agencies to develop and implement local pollinator protection plans, known as Managed Pollinator Protection Plans (MP3s). EPA is promoting MP3s to address the use of highly toxic pesticides in areas other than where bees are brought onsite to provide contract pollination services. However, states and tribes have the flexibility to determine the scope of an MP3 that best responds to pollinator issues in their regions. For example, state and tribal MP3s may address pesticide-related risks to all pollinators, including managed bees and wild pollinators. EPA believes these plans can articulate means through which growers, applicators, and beekeepers can quickly and effectively communicate to one another about pesticide applications in close proximity to managed colonies.

In support of this effort, EPA, USDA, the National Association of State Departments of Agriculture and the Honey Bee Health Coalition hosted a Managed Pollinator Protection Plan (MP3) Symposium in March 2016. The Symposium was designed to bring together stakeholders in order to share the tools, insights and relationships necessary for states, tribal and other stakeholders to pursue the development of MP3 plans effectively and efficiently. Approximately 130 participants attended, including representatives from EPA, USDA, states, tribes, pesticide manufacturers, beekeeping organizations, and agricultural organizations.

EPA's Proposal to Mitigate Bee Exposure to Acutely Toxic Pesticides is available at [www.regulations.gov](http://www.regulations.gov) in docket EPA-HQ-OPP-2014-0818. EPA accepted public comments on the proposal until August 28, 2015 and is currently reviewing the more than 113,000 comments we received to determine if changes are to be made to the proposed restrictions. A final determination on these pollinator restrictions is expected to be made later in 2016.

In January 2016, we released a preliminary pollinator risk assessment for imidacloprid. The imidacloprid assessment is the first of four preliminary pollinator risk assessments for the neonicotinoid insecticides. Preliminary pollinator risk assessments for three other neonicotinoids, clothianidin, thiamethoxam, and dinotefuran, are scheduled to be released for public comment in December 2016. The complete preliminary risk assessment for all ecological effects for imidacloprid, including a revised pollinator assessment, is also schedule for release in December 2016. The comment period on the preliminary pollinator assessment closes on April 14, 2016.

Additional information on EPA's actions to protect pollinators is available online at: <http://www.epa.gov/pollinator-protection>.

## **Environmental Hazard Statement**

OPP has reviewed the issue paper SFIREG submitted in June 2014: "Pollinator protection language conflicts between "Environmental Hazards" statements and "Directions for Use" instructions found on new neonicotinoid pesticide product labels". As we mentioned at a previous meeting, we are considering this issue as we work through the comments on the pollinator acute mitigation proposal. The team is still reviewing comments and considering path forward.

## **Cannabis**

We have established a team to evaluate pesticides we expect that states may submit as section 24(c) registrations. Currently, we are reviewing pesticides on a list submitted by Nevada for active ingredients that could pose risk issues or need to have specific issues addressed in the 24(c) registration package. The national workgroup (OPP, regions, states) has held two scoping meetings and plans to meet quarterly. Followup items include the PRMA registration process on seven products used on cannabis and the Mississippi facility/National Institute on Drug Abuse. We urge states to work closely with us on 24(c) candidates. EPA regions 8 and 10 are the sub-leads on cannabis.

## **SmartLabel Pilot**

SmartLabel is an ongoing effort to modernize pesticide labeling for all EPA products by developing a standardized, searchable, structured format for label information. We will receive, archive and retrieve these labels electronically.

More information on the SmartLabel pilot is available on our website: <http://www.epa.gov/pesticide-registration/pesticide-smartlabel-pilot>.

## **Cancellation of Sulfoxaflor Products**

On November 12, 2015, EPA issued a cancellation order for all previously registered sulfoxaflor products. This cancellation order is in response to the September 10, 2015, order of the Ninth Circuit Court of Appeals finding that EPA improperly approved the Federal Insecticide, Fungicide, and Rodenticide Act registrations of the pesticide sulfoxaflor; the court's order became effective on November 12.

Pursuant to EPA's cancellation order, and beginning November 12, 2015, distribution or sale by the registrant of canceled sulfoxaflor products is prohibited, unless such distribution or sale is for the purpose of disposal or export. Also, stocks of canceled products held by persons other than the registrant may not be commercially distributed in the United States, but instead may be distributed only to facilitate return to the manufacturer or for proper disposal or lawful export. Use of existing stocks by end users is permitted provided such use is consistent in all respects with the previously-approved labeling for the product.

The Federal Food, Drug, and Cosmetic Act tolerances, also known as maximum pesticide residue levels, for sulfoxaflor are not affected by either the court's decision or EPA's cancellation order, so crops that have been properly treated with sulfoxaflor or that may be treated with existing stocks as described in the final cancellation order can still be sold legally.