

Pesticide Program Dialogue Committee

Session VII - Updates from the Office of Pesticide Programs

May 14, 2015

Comparative Safety Statements – presenter: Marty Monell, OPP

EPA's Design for the Environment (DfE) program has adopted a new name (Safer Choice) and logo for most of the products that are part of the program. OPP is retaining the DfE name and logo for our products. We have extended the pilot for the DfE logo for another year, until May 2016. We also have expanded our guidance to include biopesticide ingredients that go through the DfE screening process.

The pilot that allows certain statements to be included on pesticide labels (dye and fragrance-free, corporate commitment, biodegradability, USDA biobased product certification, USDA BioPreferred Program certification) has also been extended until May 2016.

More information on the DfE and label statement pilot projects for pesticides is available on our website: <http://www.epa.gov/pesticides/regulating/labels/product-labels.htm#projects>

SmartLabels – presenter: Phil Villanueva, EFED

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. This presentation will provide a status update and next steps for the ongoing external pilot with registrants.

More information on the SmartLabel pilot is available on our website: <http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot>

WPS and C&T – presenter: Kevin Keaney, FEAD

EPA's Agricultural Worker Protection Regulation

In 2014, EPA proposed revisions to the Agricultural Worker Protection Standard in order to protect the nation's two million farm workers and their families from pesticide exposure. EPA's revised Worker Protection Standard will afford 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.

EPA proposed significant improvements to worker training regarding the safe usage of pesticides, including how to prevent pesticide exposures. The proposal included increased training and signage to inform farm workers about the protections they are afforded under the law and help them protect

themselves and their families from pesticide exposure. In addition, EPA proposed establishing a minimum age for handling all pesticides, with an exemption for family farms.

Over 2,400 written comments with over 393,000 signatures were submitted by a wide range of stakeholders. Commenters included farmworker advocacy organizations, state pesticide regulatory agencies (states) and organizations, public health organizations, public health agencies, growers and grower organizations, agricultural organizations, applicators and applicator organizations, pesticide manufacturers and organizations, PPE manufacturers, farm bureaus, crop consultants and organizations, and others. The comments received covered a wide range of issues and took diverse positions. Overall, the comments were thoughtful and demonstrated a high level of interest in ensuring the protection of workers and handlers, while minimizing burden on employers and regulatory agencies.

EPA is reviewing the public comments submitted on the proposal and developing a final rule. EPA expects to publish the final rule in 2015.

More information on the worker protection standard is available on our website:

<http://www.epa.gov/pesticides/health/protecting-workers.html>

EPA's Certification of Pesticide Applicators Regulation

In summer 2015, EPA plans to propose 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 for commercial applicators),
- 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.

More information on pesticide applicator certification is available on our website:

<http://www.epa.gov/oppfead1/safety/applicators/applicators.htm>

Spray Drift and Volatilization: Update on Policies – presenter: Jeff Dawson, HED

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.

Each of these will be discussed with a focus on the major scientific and policy issues that were identified. More information on EPA's activities related to spray drift is available on our website:

<http://www2.epa.gov/reducing-pesticide-drift>

Drift Reduction Technology – presenter: Anne Overstreet, FEAD

OPP received an application from an adjuvant manufacturer to review data submitted 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. FEAD and EFED plan to meet with the applicant to finalize the submission package and discuss some technical questions and plans to brief management with a timeline for review and assigning a star rating.

We are developing a template for DRT submission, including guidelines for formatting and analysis of spray drift data needed to assign a rating. We will be posting the template will be posted onto our DRT website to provide guidance to applicants.

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

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

<http://www2.epa.gov/reducing-pesticide-drift>

Repellency Awareness Graphic – presenter: Martha Shimkin

The Repellency Awareness Graphic is an initiative that is part of an ongoing effort to enhance public health information and improve the clarity of pesticide product labeling for consumers. The graphic will enable producers of skin-applied insect repellent products to use a standardized graphic that will clearly communicate to consumers the estimated number of hours mosquitoes and/or ticks are repelled by a product when used as directed. Participation in this initiative is voluntary.

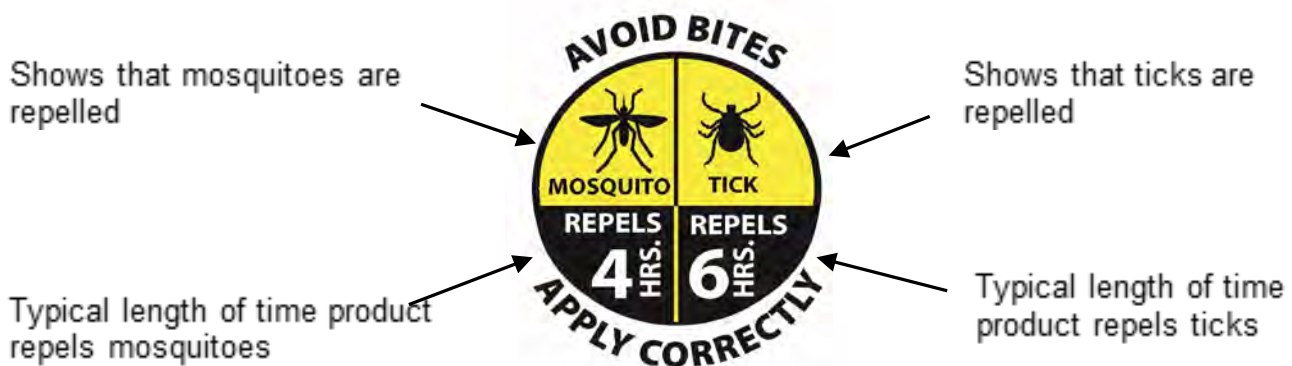
In 2010 and 2011, the EPA conducted focus groups and a national online consumer survey about consumers' perspectives on the clarity of insect repellent product labeling. The consumers indicated that they wanted information about which types of insects are repelled and the number of hours those insects are repelled. Most consumers were aware that mosquitoes and ticks can carry potentially dangerous diseases. Consumers indicated that they wanted to know how long they may be protected from those pests. Consumers also responded that they would like this information to be clear, concise, and in large print on product labels.

The Repellency Awareness Graphic will address these consumer needs by providing manufacturers of skin-applied insect repellent products the ability to place a graphic on their label depicting how long mosquitoes and/or ticks are repelled. The Repellency Awareness Graphic is intended to be displayed prominently on participating products for quick and easy identification by the consumer.

To assist manufacturers who may be interested in participating in this program, the EPA published a guidance document that provides recommendations on what the agency considers to be the credible information and sound science needed to support the information provided in the Repellency Awareness Graphic. In addition, the EPA has developed a Web page that will inform consumers how to interpret and utilize the graphic effectively, and will, in the future, provide a list of products approved for the graphic.

Updates since the last PPDC presentation:

- We have received some applications for the graphic.
- No products have been approved yet for the graphic.
- Products with the graphic could be available in 2016.
- OPP is continuing with public outreach efforts and engaging interested participants.



More information on the repellency graphic is available on our website: <http://www2.epa.gov/insect-repellents/repellency-awareness-graphic>

Glyphosate – presenter: Neil Anderson, PRD

The agency is currently reassessing glyphosate as part of the scheduled registration review (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 later this year.

- The preliminary ecological 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 monarch butterflies.)
- The preliminary human health 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 resistance management as it relates to glyphosate-resistant weeds.
- The agency is coordinating its re-evaluation with Canada's Pest Management Regulatory Agency. EPA and PMRA collaborated on the data requirements that were required in the respective glyphosate re-evaluations and have also shared information.

More information on glyphosate is available on our website: <http://www2.epa.gov/ingredients-used-pesticide-products/glyphosate>

Monarchs

The science surrounding what is affecting monarch butterfly populations is still evolving. Like commercial honeybee losses, there are multiple factors that may be affecting monarchs including loss of habitat, weather and pesticides. EPA is also engaged in other 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 them. With regard to pesticide exposure, EPA is looking holistically at all herbicides, not only glyphosate, to determine the effects on monarchs and resources critical to butterfly populations. We expect to release a preliminary risk assessment for glyphosate this Spring/Summer 2015 and respond to the petition from NRDC at the same time.

More information on what EPA is doing to protect pollinators is available on our website: <http://www2.epa.gov/pollinator-protection>

Comparative Efficacy Claims – presenter: Kable (Bo) Davis, RD

OPP has received requests to amend existing labels for registered products to include comparative efficacy claims. Examples of comparative efficacy include:

- [Registered product] repels [cited pest] better than leading product of this type;
- [Registered product] is 10x more effective than leading product of this type;
- [Registered product] kills listed pests 50% faster than leading product; and
- [Registered product] protects against twice as many pests as the leading product.

The regulation that applies to these types of claims is 40 CFR 150.10(a)(5), which outlines general labeling requirements and the provision to prevent the use of false and misleading statements on product labels. A pesticide is misbranded if its labeling is false or misleading in terms of pesticidal and non-pesticidal claims. Comparative safety claims such as safe, non-poisonous, harmless and non-toxic are not allowed. Claims including false or misleading comparison with other pesticides or devices are also not allowed. Therefore, when EPA receives comparative claims, the Agency is required to make a determination if the claims are considered false and misleading.

The challenges the Agency is facing include:

- data needed to make a determination on what is false and misleading,
- repercussions of including these types of claims on product labels, and
- the need to include external review to determine acceptability of these claims.

In terms of data, the Agency is concerned that data needs will vary depending on the types of proposed claims and that guidance for registrants would be needed. At this time, no guidance or guidelines exist, and there is a lack of definition and clarity for terms such as “better than” or “leading brand.” The Agency seeks stakeholder input on additional considerations in evaluating these types of claims.

The potential repercussions of including these types of claims on product labels include implications for products that do not include public health claims. There is no process in place to determine the efficacy of products such as herbicides. There are also implications for “me too” product submissions. A determination needs to be made on whether or not comparative efficacy claims will be allowed on products that come in as “me too” applications, and a process will need to be developed to track “me too” products. If we allow these claims, there will be repercussions for registered products if/when another company submits contradictory data. A process to remove claims that are no longer valid will be needed. State partners have identified concerns in determining if claims are misleading, resulting in misbranded products, as well as concerns with the methodology used to make the determinations.

External review may be needed to determine the acceptability of these claims. Third party verification may be needed, including a memorandum of understanding with the Federal Trade Commission.