

ESA SME Liaison to EPA OPP Report for May/June 2021

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EPA OPP-ESA Interactions Update

University of Georgia entomology professor Nancy Hinkle will be giving a webinar presentation for EPA OPP staff and regional offices on June 16th. She will present a broad overview of the types of products available for flea and tick control on pets, considerations when selecting a product, and other related issues.

EPA OPP staff will present a “career” information webinar to ESA members that is tentatively scheduled for Wed, July 28 at 11 am ET. Erin Cadwalader is coordinating the webinar with Murphy Coy, the EPA OPP liaison.

EPA Announcements (April/May 2021) of Possible Interest to ESA Members

(The full news stories and all links can be accessed at URL <https://www.epa.gov/pesticides/pesticide-news-stories>)

- **Comment Period Extended for EPA's Analysis of Groundwater Model** (posted June 4, 2021)

EPA is extending the public comment period on its Analysis of Subsurface Metabolism in Groundwater Modeling to give the public and stakeholders more time to review and comment. Comments can be submitted through July 6, 2021, to the docket EPA-HQ-OPP-2021-0241 at www.regulations.gov. This report evaluates assumptions used in Pesticide in Water Calculator groundwater modeling, which EPA developed to estimate pesticide concentrations in vulnerable groundwater sources and is used in human dietary risk assessments. EPA will carefully consider public input when evaluating whether changes in the methodology for estimating pesticides concentrations in groundwater are necessary. The water assessment models used by the EPA can be found at URL <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide#przmgw>.

How EPA conducts its exposure assessment for insecticides in water may be of concern to ESA members with interests in businesses (farms, consulting, sales, etc.) that are associated with commodities growing on soils with high infiltration capacities, such as typical for potato production. Presently, the leaching model used by the EPA (PRZM, Pesticide Root Zone Model) is incorporated in a ‘Pesticides in Water Calculator’ (PWC) model and assumes degradation drops to zero within one meter of the soil surface. The revised methodology that EPA is seeking comments for used literature analysis to refine the zone of degradation to two meters. The results showed that more pesticides were modeled to be within 10-fold of the actual field measurements rather than to exceed this benchmark based on assumptions of insignificant degradation at one meter.

- **EPA Hosts Webinar on Electronic Gold Seal Letter Process for Exporting Pesticides** (posted June 4, 2021)

EPA is hosting a webinar geared towards pesticide registrants on June 14, 2021, at 1:00 PM EST, to provide a walkthrough of the Pesticide Submission Portal (<https://cdx.epa.gov>), the digital platform for requesting Certificates of Registration, commonly known as gold seal letters. These letters serve as proof for pesticide exporters that the product is registered with EPA and meets all necessary registration requirements. Stakeholders interested in attending the presentation can link to the announcement at URL <https://www.epa.gov/pesticides/epa-hosts-webinar-electronic-gold-seal-letter-process-exporting-pesticides> and then click the link for joining the online meeting (registration is not required).

This announcement may be of interest to ESA members involved in biopesticide research and development with interests in export markets for their products. Since launching the ‘Gold Seal’ digital platform in 2020 in response to the COVID-19 public health

emergency, the electronic process has resulted in quicker processing of the letters and more thorough and complete internal tracking.

- **EPA Proposes Registration of Products Containing *Purpureocillium lilacinum* strain PL11, a New Microbial Active Ingredient** (posted June 2, 2021)

EPA is proposing to register several biopesticide products containing *Purpureocillium lilacinum* strain PL11, a new microbial (fungal) active ingredient that controls plant-parasitic nematodes. All the files the EPA released in association with the human and ecological risk assessments and proposed product labels are contained in docket number EPA-HQ-OPP-2016-0079 at www.regulations.gov (in the search line, enter the docket number to access the documents). The risk assessment summaries provide an excellent overview of the types of information that EPA will need to register biopesticides. The docket will be available for comments until June 17, 2021.

- **EPA Releases Updated Occupational Pesticide Handler and Post-application Exposure Calculators** (posted May 26, 2021)

EPA has updated the “Occupational Pesticide Handler Exposure Calculator” and “Occupational Pesticide Post-application Exposure Calculator” with the latest available data and sources to provide the agency with more efficiency in completing risk assessments and ensuring transparency to the public and affected stakeholders.

EPA uses these tools to carry out risk assessments to make informed decisions when approving new pesticides, new uses of registered pesticides, and during regular reviews of existing pesticides. The updated exposure values are more reflective of actual exposures to occupational pesticide handlers and post-application scenarios, which reduces uncertainty in decisions and serves as the basis for labeling decisions.

The calculators also help state and local governments, pesticide manufacturers, academics, and others evaluate the potential for health effects to a person who might be exposed to pesticides as part of their work. They provide exposure information for risk assessments based on exposure scenarios, exposure routes, and applicable personal protective equipment.

URL for the “Occupational Pesticide Handler Exposure Calculator”: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data>

URL for the “Occupational Pesticide Post-application Exposure Calculator”: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure>

- **EPA Releases Draft Risk Assessments and Proposes Mitigation for Residential Fumigation Using Sulfuryl Fluoride** (posted May 25, 2021)

EPA released for public comment draft risk assessments for the structural fumigant sulfuryl fluoride (approved by use of certified applicators for control of termites, powder post beetles, old house borers, bedbugs, carpet beetles, moths, cockroaches, rats, and mice). For the registration review of sulfuryl fluoride, which includes all the uses of the pesticide, EPA is releasing sulfuryl fluoride draft risk assessments (DRAs), including the combined ecological draft risk assessment and drinking water assessment, and the occupational and residential risk assessment.

The DRAs are part of a multi-step process to identify risks as well as actions that can mitigate risks. After considering public comments, EPA will proceed with registration review by issuing the proposed interim decision, which will propose measures to reduce human health and ecological risks. EPA released the interim re-entry mitigation measures that can be accessed directly from the [regulations.gov](http://www.regulations.gov) docket at URL <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0136-0105>. The docket number for all the sulfuryl fluoride documents is EPA-HQ-OPP-2009-0136 (direct URL link is <https://www.regulations.gov/search?>

[filter=EPA-HQ-OPP-2009-0136](#)). The comment period is open for 60 days from the posting of this announcement.

- **EPA Opens Application Period for Grants Dedicated to Sustainable Pest Control in Agriculture** (posted May 25, 2021)

EPA is accepting applications for a \$1 million dollar grant initiative through the Pesticide Environmental Stewardship Program (PESP) that encourages smart, sensible, and sustainable pest control in agriculture. Through these grants, EPA will support projects that explore innovative practices, technologies, education, and non-regulatory solutions that adopt integrated pest management (IPM) strategies. EPA anticipates awarding approximately \$1 million in total federal funding to support 10 projects – one from each EPA region.

EPA specifically seeks to build IPM capacities or to evaluate the feasibility of new IPM approaches (i.e., innovative approaches and methodologies that reduce the unnecessary pest/pesticide risks). Two issues of concern in decisions about funding a PESP grant that are relevant to ESA members are ‘citrus greening’ and ‘pollinator protection’. Any IPM research that can enhance control of citrus greening or conserve pollinators while meeting environmental stewardship objectives should be competitive for funding.

Interested groups can apply at <https://www.grants.gov/web/grants/view-opportunity.html?oppId=333775>. Applications must be submitted by July 9, 2021, to be considered. Awarded projects will start in the fourth quarter of 2021. More information about PESP grants is located at URL <https://www.epa.gov/peps/pesticide-environmental-stewardship-program-grants>.

- **Update on Previous Changes in USDA APHIS Regulation of Crops Bred using “Genetic Engineering” Biotechnology** (posted April 23, 2021)

Over a year ago, I reported on proposed rule changes by USDA APHIS for determination of whether crops bred using genetic engineering tools that are similar to other crops already deregulated for commercialization could be fast tracked for approval without doing completely new independent studies. APHIS upon petition from a plant breeder would prepare a Plant Pest Risk Similarity Assessment (PPRSA) and preliminary determination of nonregulated status. Now an example of how this policy change works is shown by an April 23, 2021 release of an announcement that Simplot, which has a potato cultivar called ‘Innate’, had petitioned to place under deregulated status a similar cultivar called ‘Snowden’. The Innate cultivar was derived using RNAi technology to silence polyphenol oxidase enzyme specifically in the tuber for reduction of black spot disease and reduce arginine synthesis to reduce acrolein (“carcinogenic neurotoxin”) synthesis during cooking. APHIS determined the two potato cultivars are similar and the new one does not pose a new plant pest risk. APHIS had sought public comments on its review last year and based on the comments decided to formally extend deregulation status to the new Snowden cultivar. The APHIS memorandum and document links can be accessed via the Federal Registrar notification located at URL <https://www.federalregister.gov/documents/2021/04/26/2021-08625/jr-simplot-co-determination-of-nonregulated-status-for-z6-potatoes-with-late-blight-protection-low>.

When the new rules for determining non-regulated status of new cultivars was announced, concern was expressed by advocacy groups that new cultivars would be deregulated based just on a company’s vouching for its safety owing to similarity to cultivars already on the market. However, USDA APHIS still will seek public comment on any petitions for “similarity” approvals. Furthermore, USDA APHIS will closely monitor public comments and then make decisions on new analyses. An example of this conservative but transparent approach to biotechnology-derived crops (aka GMOs) was illustrated in an April 27th announcement that the USDA issued a notice of intent to prepare a formal environmental impact on Bayer’s petition for deregulation of cultivar MON 87429. This cultivar has resistance to five different herbicides, which extends herbicide tolerance previously bred into single

cultivars under deregulation into a new cultivar. USDA APHIS determined that an environmental impact statement would be necessary before approval to non-regulated status.