ESA SME Liaison to EPA OPP Report for January 15 - March 09, 2022

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On Feb 4, 2022, Erin Cadwalader and I met via ZOOM with EPA OPP staff liaison Dr. Murphy Coy. The main topics covered in the meeting were notification of planned webinars that Society members would be interested in and updates on the EPA's perspective for doing risk assessments related to the Endangered Species Act (ESA, see EPA announcement regarding the ESA below).

On March 23, 2022, EPA is sponsoring another webinar. The webinar subject is mosquitoes and vector control that will be presented by Dr. Ary Faraji. Dr. Faraji is the current Executive Director and Entomologist for the Salt Lake City Mosquito Abatement District in Salt Lake City, Utah, USA. He also holds Adjunct Faculty positions at the University of Utah and Rutgers University.

On February 24, 2022 I attended (via ZOOM) a "Codling Moth Summit" with over 200 attendees from around the major apple growing regions of the U.S. The summit covered multiple topics to update attendees of our current biological knowledge about codling moths, control using biopesticides and mating disruption, progress in applications of the sterile insect release technique, pesticide resistance, and appropriate insecticide spray programs. I was asked to speak about basic principles of insecticide resistance development and mitigation. I used USDA pesticide use surveys (National Agricultural Statistics Service) to report on current insecticide uses in apple/pear production in the western U.S. and indicated that at least 15 modes of action were being used on at least 10% of the pome fruit acreage and therefore options existed for insecticide rotation schemes as a resistance mitigation strategy.

EPA has issued new policy initiatives as well as announcements of draft and finalized risk assessments and/or pesticide registration decisions. Summary and links to the EPA issued 'news' stories follow (for an archive of all news stories for the past couple of years see URL https://www.epa.gov/pesticides/pesticide-news-stories).

EPA Takes Steps to Protect Endangered and Threatened Species from Insecticide (March 8, 2022; https://www.epa.gov/pesticides/epa-takes-steps-protect-endangered-and-threatened-species-insecticide)

This news release represents the outcome of policy changes that started from lawsuits following the listing of Pacific Northwest salmon species as endangered over 20 years ago. EPA was sued by a coalition of several advocacy groups over violations of Section 7 provisions of the Endangered Species Act on the basis of failure to consult with the National Marine Fisheries Service (now called NOAA Fisheries) regarding potential harm of pesticide registration decisions to salmon runs (a.k.a., "evolutionary significant units"). Because salmon are anadromous, NOAA Fisheries would be the agency overseeing endangered and threatened listings under the ESA. Federal Courts ruled that EPA must consult with NOAA Fisheries as well as the US Fish & Wildlife Service (FWS, for terrestrial bound species) about hazards to listed species before making any final registration decisions. Over 50 specific pesticide active ingredients were initially listed in the court order that would require further risk analysis for possible "take" of listed salmon species (as well as any other listed species). In the consultation process, NOAA Fisheries and/or FWS would issue its own opinion regarding risk to listed species of the pesticides listed in the court order. The report, generically called a BiOP (Biological Opinion) would then be sent to the EPA and some mitigation would be proposed for the continued registration of affected products. This lengthy process and negotiation regarding potentially adverse effects of pesticide use on listed species has slowed the pesticide registration decision process. Nevertheless, EPA announced a few months ago

that all new pesticide registration decision going forward would be automatically subjected to the consultation process. Pertinently, EPA has always considered potential risk to listed species but had not automatically consulted with any agency overseeing protection until they were ordered to do so by the Federal court decisions.

This latest news story regards mitigation measures being proposed specifically for the insecticide malathion, one of three organophosphorus (OP) insecticides most recently subjected to the consultation process. Because EPA had found possible risk above 'levels of concern' for listed terrestrial species, the agency had to initiate a consultation with the US Fish & Wildlife Service. The FWS issued a draft BiOP for malathion that EPA had to analyze and comment on.

The current EPA news release discusses the release of a finalized BiOP that involved a collaborative interagency effort as well as consultation with malathion product registrants. All parties "identified mitigation measures to protect listed species. Registrants involved in the consultation agreed to implement these measures by modifying their product labels." FWS agreed that mitigation measures would resolve their concerns about effects on listed endangered species. Examples of mitigation measures included among other practices "no spray zones, reductions in application rates and number of applications, and other changes to the labels that, once approved, pesticide users must follow". Product registrants will receive notification that product labels will need to be amended 60 days after April 29, 2022. EPA will review and approve the labels and then develop Endangered Species Protection Bulletins.

EPA's 2017 biological evaluation of malathion with regards to endangered species can be accessed at URL https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment. EPA comments on the FWS draft BiOP as well as other BiOPs can be accessed at URL https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.

Notably, AP (Associated Press) issued a news story about the finalized BiOP that is being picked up by other news outlets (see original AP story at URL https://apnews.com/article/science-business-animals-wildlife-billings-e3443e0a0ff76211d1e1bb0275f9385b). The headline being copied among media outlets is "US officials reverse course on pesticide's harm to wildlife" with US News using as subtitle the first line of the AP article, "U.S. wildlife officials have reversed their previous finding that a widely used and highly toxic pesticide could jeopardize dozens of plants and animals with extinction".

In addition to EPA issuing a press release about the interagency cooperation to finalize mitigation measures for malathion, the agency issued a press release on March 02, 2022 to publicize release of NOAA Fisheries draft revised BiOP for the insecticides malathion, chlorpyrifos, and diazinon. This revised BiOP can be accessed at the link noted above for all pesticide BiOPs. Public comments are open for 60 days after March 1 and can be submitted to the docket (https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0172/document).

Following Review of Available Data and Public Comments, EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations (March 7, 2022; https://www.epa.gov/pesticides/following-review-available-data-and-public-comments-epa-expands-and-extends-testing)

During May 2020, EPA had issued an Experimental Use Permit (EUP) to Oxitec Ltd to release genetically engineered *Aedes aegypti* males (named OX5034) to reduce native populations in certain localities of Florida and Texas. Upon analyzing data from the releases in Monroe County, Florida (the Florida Keys) under the original EUP, EPA determined no unexpected risks above their levels of concern (meaning, a "reasonable certainty of no harm") regarding ecological receptors (i.e., non-target organisms). Now the EUP has been amended to be effective through April 30, 2024 in Monroe County. Also, the EUP was expanded to include four California counties (Stanislaus, Fresno, Tulare, and San Bernardino). Harris County, TX was removed from the EUP because no releases were made. California and Florida regulatory agencies must assess and approve any new releases on the amended EUP.

The Oxitec *A. aegypti* males registered as a pesticide (OX5034) is an example of a gene drive containing organism. When the males mate with wildtype females, female offspring will not survive unless they consume a tetracycline antidote. Under the EUP, Oxitec must monitor for survival of any female mosquitoes that survive and immediately cease releases if any are found. Also, mosquitoes cannot be released within 500 to 1000 feet of a tetracycline source. The amended EUP can be accessed as docket EPA-HQ-OPP-2019-0274-0001 from registrations.gov (direct link: https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0274/document). A 40-minute EPA webinar video posted on YouTube discusses the original EUP details and can be accessed at https://www.youtube.com/watch?v=V2_ChfKcZ1E.

Other EPA News Releases of Interest:

EPA Takes Next Step to Keep Chlorpyrifos Out of Food, Protecting Farmworkers and Children's Health (Feb 25, 2022; https://www.epa.gov/newsreleases/epa-takes-next-step-keep-chlorpyrifos-out-food-protecting-farmworkers-and-childrens). EPA announced that the Agency is "taking the next step to discontinue use of the pesticide chlorpyrifos on food by denying objections to EPA's rule revoking all chlorpyrifos tolerances". All chlorpyrifos tolerances were revoked in August 2021.

EPA Improves Online Application to Protect Endangered Species (Feb 17, 2022; https://www.epa.gov/pesticides/epa-improves-online-application-protect-endangered-species) EPA announced that it revised its endangered species geographic mapping website, Bulletins Live! Two (BLT). "BLT describes geographically specific pesticide use limitations to protect threatened and endangered species and their designated critical habitat."

EPA Issues Notice of Proposed Rulemaking to Further Extend Certification of Pesticide Applicators Rule Deadline (Feb 7, 2022; https://www.epa.gov/pesticides/epa-issues-notice-proposed-rulemaking-further-extend-certification-pesticide-applicators). "EPA is requesting comments on the potential need to further extend the expiration date of existing certification plans which would allow for certifying authorities that need more time to respond to EPA comments and prepare approvable certification plans."

EPA Expands Pesticide Outreach and Education to Better Meet the Needs of Pesticide Applicators, including Farmworkers, and Consumers (Feb 1, 2022; https://www.epa.gov/newsreleases/epa-expands-pesticide-outreach-and-education-better-meet-needs-pesticide-applicators). This press release corresponds to EPA's pubic commitment for risk communication in conjunction with National Pesticide Safety Education Month.

EPA Transitions to Using Updated Dietary Exposure Model (January 20, 2022; https://www.epa.gov/pesticides/epa-transitions-using-updated-dietary-exposure-model). EPA announced the agency is "using an updated version of the agency's Dietary Exposure Evaluation Model (DEEM) that contains newer consumption data to provide more up-to-date exposure information in human health risk assessments and to ensure transparency to the public and affected stakeholders."

All models for pesticide risk assessments can be found at URL https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment). Most of the executable software for these models can be downloaded from this page.

EPA Releases New Calculator and Updated Data for Occupational Pesticide Seed Treatment Exposure (January 18, 2022; https://www.epa.gov/pesticides/epa-releases-new-calculator-and-updated-data-occupational-pesticide-seed-treatment). "The new calculator provides an estimate of exposure and risk based on seed treatment exposure scenarios, exposure routes, and applicable personal protective equipment (PPE)." Information about the

calculator can be accessed from URL https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-exposure-seed-treatment).