

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2015

## Twelfth Annual Report



*March 1, 2016*

## Process Improvements in the Pesticide Program

### Human Health Risk Assessments

**Science Review Committees.** The Residues of Concern Knowledgebase Subcommittee (ROCKS) continues to lead the application of predictive Tox 21 tools for metabolites, residues, and environmental degradation products. In FY'15, the ROCKS held five meetings on five chemicals and completed an e-review of a sixth chemical. The Dose Adequacy Review Team (DART) reviewed study protocols for 3 chemicals. The Cancer Assessment Review Committee (CARC) met four times on different chemicals, and the Toxicology Science Advisory Council (ToxSAC) met 43 times and completed 6 e-reviews to discuss and determine end-points of concern. The Risk Assessment Review Committee (RARC) met 23 times to peer review risk assessments.

**Implementation of 21<sup>st</sup> Century Toxicology and Exposure Assessment: International Collaboration, Integrated Approaches to Testing and Assessment, and Adverse Outcome Pathways.** Consistent with NAS reviews, and in collaboration with national and international bodies, the agency continued to develop and implement 21<sup>st</sup> Century toxicology and exposure methods, including computer-modeling and *in vitro* techniques, to advance more efficient and effective risk assessments that support sound, risk-based, regulatory decision-making. In 2015, OPP continued its implementation of guiding principles for data requirements and waiver guidance for inhalation, dermal, neurotoxicity, and immunotoxicity studies (See <http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/about-test-guidelines-pesticides-and-toxic#harmonization>) and collaborated with NIEHS-NICEATM on a retrospective analysis to evaluate the regulatory value of the acute dermal lethality test in pesticide labelling. In FY'15, OPP expanded a multi-stakeholder project to accelerate the implementation of alternative approaches for data generation of the 'six pack' (acute oral, dermal, and inhalation lethality; eye irritation, skin irritation; and skin sensitization) in support of pesticide formulations. OPP released the draft guidance on the *Process for Establishing & Implementing Alternative Approaches To Traditional In Vivo Acute Toxicity Studies* for public comment. This draft guidance provides a transparent approach to collaboration with industry and academic researchers developing and/or using non-animal approaches such as *in vitro*, *in silico*, integrated testing strategies (ITS) or IATA. This guidance represents an important step towards implementing OPP's strategic plan for new toxicity testing and more immediate initiative of eliminating lethality acute testing for formulations and adopting advanced *in vitro* approaches for eye irritation and skin sensitization.

In 2015, OPP partnered with the ORD on the policy entitled *Proposed Approach to Efficiently Develop Physiologically Based Pharmacokinetic (PBPK) & Physiologically Based Pharmacokinetic-Pharmacodynamic (PBPK-PD) Models for Pesticides* which initiates a paradigm for using new technologies to rapidly replace traditional approaches for chemical exposure estimation, species extrapolation, dose-response extrapolation, and probabilistic risk

estimations. OPP is also coordinating with industry on development of PBPK models for atrazine and some pyrethroids. We are increasing our use of epidemiology data and integrating data from lines of evidence. In 2015, we released the draft document, *Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides* which evaluated numerous epidemiology studies and included a synthesis across large amounts of data from registrants and other sources using advanced risk assessment approaches (adverse outcome pathways, pharmacokinetics).

EPA scientists continue to participate in the OECD Joint [Integrated Approach to Testing and Assessment \(IATA\)](#) Projects. The Report of the Workshop on a Framework for the Development and Use Of Integrated Approaches to Testing and Assessment held in November, 2014 was published (OECD [No. 215](#), <http://www.oecd.org/env/ehs/testing/listsofprojectsontheaopdevelopmentprogrammeworkplan.htm#Section2>). Prompted by the insights provided by OPP at the 2014 workshop, OPP was invited to give a webinar in 2015 on toxicity testing for organophosphates and *N*-methyl carbamates as potential OECD IATA case studies. OECD continues to make progress on the Adverse Outcome Pathways (AOP) Knowledge Base (KB), a web-based platform to facilitate AOP development and dissemination. (<http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm>). OPP scientists participated as peer reviewers in two proposed AOPs through the AOP-KB: PPAR $\gamma$  activation leading to decreased fertility in adult female rodents and PPAR $\alpha$  activation leading to decreased fertility in male rodents. The international community continues to make great strides toward developing an IATA for skin sensitization based on the AOP that does not involve whole animal testing (<http://www.oecd.org/env/ehs/testing/listsofprojectsontheaopdevelopmentprogrammeworkplan.htm>). In 2014, the OECD collected IATA case studies specific to skin sensitization; one of these was developed by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) with active participation and policy direction by OPP scientists. In addition, the OECD published a Guidance Document for Describing Non-Guideline *In Vitro* Test Methods (OECD [No. 211](#), <http://www.oecd.org/env/ehs/testing/listsofprojectsontheaopdevelopmentprogrammeworkplan.htm#Section2>) which will help accelerate the use of non-guideline *in vitro* data in IATA. In 2015, OPP held a meeting of the FIFRA Scientific Advisory Panel to review current progress by industry to develop an IATA for evaluating potential for juvenile sensitivity to pyrethroids.

**Hazard and Science Policy Committee (HASPOC).** As a forum to address science, policy, hazard data waivers, and risk deliberation and coordination issues, the HASPOC was very active this year. HASPOC plays an important role in the implementation of the vision of the 2007 NAS report on toxicity testing in the 21<sup>st</sup> century -- moving toward smarter testing strategies by waiving toxicity studies that do not provide useful information. In FY'15, HASPOC reviewed data waivers for a variety of toxicity studies, primarily for immunotoxicity, acute and subchronic neurotoxicity, and subchronic inhalation toxicity studies. Waivers were granted for 80 requests resulting in the saving of about 15,000 animals and over \$8 million in the cost of conducting the studies.

**Crop Grouping.** Analysis of two new crop groups (Herb Crop Group 25 and the Spice Crop Group 26) were completed and submitted to HED ChemSAC for concurrence. These two groups will replace the current Herb and Spice Group 19 and will include more than 300 commodities. The review of public comments and final regulation for Phase IV Crop Grouping was completed and submitted to FEAD. Phase IV contains five new crop groups including tropical fruits and contains over 400 commodities. The regulation is current waiting for OD signoff.

**Pesticide Use Site Index.** Work continues on further updates to the Pesticide Use Site Index, which helps registration applicants identify the specific requirements needed to register a pesticide product. Now available at <http://www2.epa.gov/pesticide-registration/pesticide-use-site-index>, this index introduces information needed to complete the registration process including pesticide use sites and major pesticide use patterns. For example, after identifying desired pesticide use sites, registrants are directed to one or more major use patterns which, in turn, point to the technical data requirements in 40 CFR part 158.

**Dietary Exposure Assessment.** Work continues on further updates to the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID)/Calendex software which replaced the previous version posted on the EPA website in June 2012. The DEEM-FCID software (current Beta version) can be found and downloaded at: <http://www.epa.gov/pesticides>.

**Updated Transfer Coefficient (TC) Policy.** Since the 2011 policy for evaluating the risks associated with hand labor activities for all major commercial crops (<http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-post-application-exposure>), periodic updates have been added. In 2014 we began to review a proposal from the Agricultural Reentry Task Force (ARTF) that would change transfer coefficients for some activities in grapes and hops. Based on the ARTF data, the transfer coefficient for harvesting hops was reduced in 2015. The proposal for harvesting grapes is still under review and should be completed in FY'16.

**Revised Residential Standard Operating Procedures (SOPs).** The Revised Residential SOPs were first released in January 2012 and billed as a “living document” subject to revision based on new or more contemporary information. In early FY'13, we released the second update to include revisions to the outdoor fogger and insect repellent SOPs. In addition, it included new

versions of the SOP spreadsheet calculators as reflected on the Residential SOP webpage (<http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedure-residential-exposure> ). All of these changes were the result of close work with stakeholders to ensure the SOPs stay up-to-date and reflect the current state of the science. In FY'14 we continued revisions to incorporate calculations that would allow for better incorporation of route-specific inhalation toxicity studies, a new scenario to address aquatic use pesticides, and other miscellaneous edits. Various updates and revisions are currently being used as necessary, but formal incorporation into the Residential SOP document, as appropriate, is planned for FY '16.

**Updated Unit Exposure (UE) Surrogate Table.** Continuing a multi-year effort, OPP is maintaining the unit exposure surrogate table, a quick reference guide that presents the current recommended unit exposures for standard agency occupational pesticide handler exposure scenarios. We will continue to update this surrogate reference table as additional pertinent exposure data become available including data from the Pesticide Handler Exposure Database (PHED), the Outdoor Residential Exposure Task Force (ORETF), the Agricultural Handler Exposure Task Force (AHETF), and other available registrant-submitted exposure monitoring studies. This effort continues to ensure that all of the data sources used in the surrogate table are compliant with applicable ethics requirements pursuant to 40 CFR 26. In FY'14 we began review of new data on backpack and handgun applicators from the AHETF and in FY'15 formally incorporated the new data into the reference table and our risk assessments, superseding any previous datasets. Work continues on related data, including planned reviews of completed studies by the Human Studies Review Board and completion of seed treatment handler data analysis in FY'16.

**OECD Activities.** OPP continued to coordinate US Government participation in the OECD Test Guideline Program. The program develops and updates test guidelines and guidance documents that are the most relevant for testing the safety of chemicals. Harmonizing testing across the 34 member countries of the OECD can reduce testing costs for industry since a study conducted under the test guidelines and Good Laboratory Practices will be accepted for review by all member countries. The OECD harmonized Test guidelines are the foundation of the global pesticide review process. Several new and updated test guidelines and guidance documents were approved this year, including *in vitro* tests that avoid testing on animals, studies that can be used to test toxicity of pesticides to bees, and tests that can be used to test the efficacy of antimicrobial products, higher tier tests that support the EDSP, and updated genotoxicity test guidelines. OPP also continued to support OECD programs on integrated testing and assessment (IATA) and adverse outcome pathways (AOP). Although the Office of Pesticide Programs coordinates the OECD Test Guideline efforts, other EPA offices participate, as do representatives of the Food and Drug Administration, Consumer Product Safety Commission, National Institute for Environmental Health Sciences, and the US Army.

**Global Review Work.** OPP is a leader of global joint review activities for new conventional pesticides. In addition to tackling a larger portion of the primary reviews for several large submissions, OPP's Residues of Concern Knowledge-Based Subcommittee (ROCKS) of the RARC supported the international residues-of-concern discussion. For each of the global review decisions, we shared documentation and perspectives with our international partners. Without

this leadership, each country's team would have had to make a chemical-by-chemical decision. In addition to the ROCKs committee, international partners were invited to participate on numerous peer review committees, including ChemSAC, ToxSAC, RARC, and CARC. The agency has taken a leadership role by providing draft documents for review, resulting in better support for proposed decisions, and more consensus from global partners.

**Global Harmonization Work.** OPP supported the completed update of the crop field trial guidance document which encourages the use of proportionality based on adjusting field trial residues by application rate. The RCEG will be drafting new guidance on rotational crop studies in FY15, with approval proposed for FY16. Furthermore, OPP is working with Crop Life America, USDA's IR-4, and Canada's PMRA to evaluate the extent to which geographic zones contribute materially to determining residue levels for a given crop/pesticide combination. We have assembled a large dataset to evaluate this question, and expect to continue to present results to Codex and the JMPR. To the extent that global zones are not contributors to systematic differences in residues between regions, common global MRL's could be seen as appropriate. Additionally, *Global MRL* ([www.globalmrl.com](http://www.globalmrl.com)) is now available for easily extracting tolerances of commodities and is available to the public under funding provided by EPA and USDA. The Global MRL Database is a comprehensive source for international pesticide maximum residue level regulations.

**Human Health Benchmarks for Pesticides (HHBPs).** We updated the HHBPs in water to include cancer quantification values for 40 chemicals and to add non-cancer values for 11 new chemicals and revisions for 11 existing chemicals. HHBPs can be found on the EPA's website at [www.epa.gov/pesticides/hhbp](http://www.epa.gov/pesticides/hhbp). The HHBPs were developed jointly by OPP and EPA's Office of Water (OW) and will be used to assist states, the public and other stakeholders to determine whether the detection of a pesticide in drinking water or source waters for drinking water may indicate a potential health risk. The water benchmarks were derived using peer reviewed Reference Dose values from OPP's human health risk assessments along with typical methods used to develop OW's drinking water health advisories. Stakeholders can use HHBPs when evaluating the significance of detections of pesticides in both surface water and groundwater sources of drinking water.

## Ecological Risk Assessments

The EPA continued to develop and implement new scientific methods, tools, models, and databases for use in pesticide ecological risk and drinking water assessments. Examples of these improvements are described in the sections below.

### National Strategy to Improve Pollinator Health

In response to the June 2014 Presidential Memorandum<sup>1</sup> to promote the health of honey bees and other pollinators, EPA and the USDA have served as co-chairs of the Pollinator Health Task Force, which consists of multiple other federal agencies. In May 2015, the Task Force released the

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<sup>1</sup> White House. 2014. Presidential Memorandum Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators. Memorandum for Heads of Executive Departments and Agencies. June 20, 2014. <http://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b>

*National Strategy to Promote the Health of Honey Bees and Other Pollinators*<sup>2</sup>. The Strategy outlines a comprehensive approach to reducing the impact of multiple stressors (e.g., pests, pathogens, pesticides, poor nutrition) on pollinator health. The strategy identifies actions by multiple federal agencies and departments to improve pollinator health and includes a Pollinator Research Action Plan (PRAP<sup>3</sup>) and a public education plan that highlights existing and recommended new public-private partnerships. Additional efforts are now underway to develop an overview of public-private partnerships. This overview will be made public in FY'16. As part of the strategy EPA has identified plans to advance its ability to assess the effects of pesticides, including systemic pesticides such as neonicotinoid insecticides, on bee and other pollinator health; to engage state and tribal environmental, agricultural, and wildlife agencies in the development of state and tribal managed pollinator protection plans (MP3s); to encourage the incorporation of pollinator protection and habitat planting activities into green infrastructure and Superfund projects; and to expedite the review of registration applications for new products targeting pests harmful to pollinators.

As part of research efforts associated with the PRAP, EPA committed to continuing to develop proper assessment tools for evaluating the lethal and sublethal effects of pesticides on managed and native pollinators both using laboratory and field-based measures of exposure and effects. EPA highlighted research in which it is engaged, including its collaborative efforts with the USDA Agricultural Research Service to modify the honey bee colony simulation model VarroaPop developed by USDA to include a module for evaluating the effects of pesticides on colony performance with and without the Varroa mite (*Varroa destructor*). The development of colony simulation models is responsive to recommendations from the 2012 FIFRA Scientific Advisory Panel (SAP<sup>4</sup>) on assessing risks to bees and is aligned with recommendations from the National Academy of Sciences on Toxicity Testing in the 21<sup>st</sup> Century to make greater use of predictive tools in assessing risks to better allocate resources to those chemicals where they are most needed.

EPA is working with the U.S. Geological Survey to examine pesticide residues in pollen originating from Conservation Reserve Program (CRP) lands in the Upper Midwest and with researchers at Land Grant Universities (e.g., University of Maryland and Ohio State University) to examine pesticide residues in pollen collected from agricultural areas. This research is providing information on potential exposure of bees to pesticides. The research is also providing a means of assessing effects of pesticides on honey bee colonies which can in turn be used to validate the VarroaPop model.

In response to the research needs identified in the PRAP and to compliment OPP efforts to advance methods for assessing exposure to and effects from pesticides on insect pollinators, a Pollinator Community of Practice (CoP) has been initiated with the EPA Office of Research and Development (ORD) to explore ways in which ORD can lend its expertise to advancing the science of assessing risks to bees at various scales (e.g., laboratory, field, and landscape). In 2015, for example, ORD research was initiated to examine the effects of pesticides on immune response in

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<sup>2</sup> White House. 2015. National Strategy to Promote the Health of Honey Bees and other Pollinators. Pollinator Health Task Force, May 19, 2015. <https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf>

<sup>3</sup> White House. 2015. Pollinator Research Action Plan. Report of the Pollinator Health Task Force. May 19, 2015. Available on-line at: <https://www.whitehouse.gov/sites/default/files/microsites/ostp/Pollinator%20Research%20Action%20Plan%202015.pdf>

<sup>4</sup> USEPA 2012. Final FIFRA SAP Pollinator Meeting Report. SAP Minutes No. 2012-06. A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Pollinator Risk Assessment Framework. September 11 – 14, 2012, FIFRA Scientific Advisory Panel Meeting. <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0047>

both *Apis* and non-*Apis* bees. The CoP will provide a forum to discuss such research and ensure that the objectives of the PRAP are being addressed.

### **Harmonized Risk Assessment Guidance for Pollinators.**

In 2015, in support of the harmonized risk assessment guidance for pollinators<sup>5</sup> released in June 2014, OPP embarked on a rule-making effort to codify additional exposure and effect studies in Title 40 of the Code of Federal Regulations Part 158 as a new subpart (Subpart H) focusing exclusively on insect pollinator data. Pending the outcome of the review process, the rule-making is anticipated to be implemented in FY'17. OPP has continued its efforts to develop guidance for risk assessors on utilizing the new data. This additional guidance will be available in FY'16.

Also in support of the harmonized risk assessment process, EPA worked in close collaboration with the U.S. Department of Agriculture and Michigan State University to develop the guidance entitled *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*<sup>6</sup>. Posted by USDA to the web in June 2015, this document offers information on the extent to which agricultural crops are attractive sources of pollen and/or nectar to honey bees, bumble bees and other non-*Apis* bees, whether the crops require pollination by managed pollinators, and estimates of the acreages of these crops.

**OECD Pollinator Activities.** OPP has continued its efforts as a member and co-chair of the international Organization for Economic Cooperation and Development (OECD) Pesticide Effects on Insect Pollinators (PEIP) sub-group of the Pollinator Expert Group. This sub-group was formed to develop portals for communicating information on pollinator incidents and risk mitigation tools among OECD member countries. The sub-group was formed to review study designs for pollinator toxicity tests to determine if they can be enhanced or if new tests are needed to better assess acute, chronic, and sub-lethal effects on pollinators and to develop such guidelines.

As part of the effort to develop standardized testing methods, EPA participated in the OECD Expert Meeting on Honey Bee Toxicity Testing in April 2015 to review draft protocols under consideration for either OECD test guidelines or guidance documents examining sublethal and chronic effects of pesticides in bees. The protocols included draft OECD guidance for a 21-day (repeat dose) toxicity test with honey bee larvae that extends through emergence of the adult bee. In August 2015, EPA participated in a workshop at the University of Florida to discuss

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<sup>5</sup> USEPA. 2014. Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. [http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf) (last accessed 08/08/2014).

<sup>6</sup> USDA. 2015. Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen. Available on-line at: [http://www.ree.usda.gov/ree/news/Attractiveness\\_of\\_Agriculture\\_crops\\_to\\_pollinating\\_bees\\_Report-FINAL.pdf](http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf)

modifications to the OECD draft guidance; in the fall of 2015, these modifications completed ring testing in both the U.S. and Europe.

The OECD Expert Meeting also reviewed a draft OECD test guideline for a 10-day repeat dose test with adult honey bees, which is going through final ring testing. Several modifications were also evaluated for a proposed revision to OECD Guidance 75<sup>7</sup> examining the effects of pesticides on honey bee colonies with an emphasis on bee brood (*i.e.*, developing larvae and pupae) under semi-field conditions. OECD was briefed on efforts to develop a honey bee homing study protocol examining sublethal effects of pesticides.

EPA acknowledges the uncertainty regarding the extent to which honey bees may be a reasonable surrogate for native insect pollinators, and we are continuing to work with our regulatory counterparts through the OECD to ensure the development of standardized testing methods that will enable EPA to address this uncertainty. Protocols for acute toxicity tests with bumble bees (*Bombus terrestris*; *B. impatiens*) have been developed and will be considered by OECD member countries as formal guidelines in FY 2016. Work is also underway through the International Commission on Plant-Pollinator Relationships (ICP-PR) to develop additional tests with solitary bees (*e.g.*, *Osmia lignaria*), both of which are important in providing managed pollinator services for certain crops. EPA is participating in these efforts as a Steering Committee member of the International Commission on Pollinator - Plant Relationships (ICP-PR) Managed Pollinator Protection and Health Working Group (Bee Protection Group) which is helping to coordinate international research efforts. EPA is also a member of the Colony Loss (COLOSS) Network and continues to monitor the international research efforts coordinated by this group.

**More Pollinator Activities.** Consistent with the Presidential Memorandum and the more recent National Strategy, EPA has continued to engage with multiple stakeholder groups toward advancing our understanding of factors associated with pollinator declines and potential tools for mitigating those factors.

OPP is a member of the USDA-led Colony Collapse Disorder (CCD) and Honey Bee Health Coalition (HBHC) Steering Committee and has assisted in the organization of multiple stakeholder workshops including the Varroa Mite Summit and the Honey Bee Forage and Nutrition Summit, the proceedings<sup>8 9</sup> of which were posted to the web in 2015. As a member of the CCD and HBHC

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<sup>7</sup> OECD. 2007. Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. Series on Testing and Assessment No. 75. ENV/JM/MONO(2007)22.

<sup>8</sup> USDA. 2015. USDA Varroa Mite Summit, February 18 – 19, 2014. Summit Held at the USDA Animal and Plant Health Inspection Service, Riverdale, MD. Available on-line at: [http://www.ree.usda.gov/ree/news/Varroa\\_Summit-05-19-15\\_DATED-FINAL.pdf](http://www.ree.usda.gov/ree/news/Varroa_Summit-05-19-15_DATED-FINAL.pdf)

<sup>9</sup> USDA. 2015. USDA Honey Bee Forage and Nutrition Summit, October 21 – 21, 2014, Sheraton Suites Old Town, Alexandria, VA [http://www.ree.usda.gov/ree/news/2014\\_USDA\\_HB\\_Forage\\_Nutrition\\_Summit\\_Report-FINAL.pdf](http://www.ree.usda.gov/ree/news/2014_USDA_HB_Forage_Nutrition_Summit_Report-FINAL.pdf)

Steering Committee, EPA assisted in the compilation of an Action Plan<sup>10</sup> posted by USDA to the web in May 2015, which identified research intended to address uncertainties related to pollinator health and in response to stakeholder input provided during the 2012 National Stakeholder Conference and through follow-up summits on Varroa mites and on honey bee nutrition. As a member of the HBHC, EPA has provided technical input on recent guidance documents developed by the coalition such as the *Tools for Varroa Management A Guide to Effective Varroa Sampling & Control*<sup>11</sup> and an *Incident Reporting Quick Guide to Reporting a Pesticide-Related Bee Kill Incident*<sup>12</sup>.

In 2015, as part of the North American Free Trade Act (NAFTA) project initiated in 2014 to develop guidance for assessing risks to pollinators from use of pesticides in agricultural and urban environments, EPA translated the harmonized risk assessment guidance document into Spanish. The Spanish version of the guidance document has been used to facilitate discussions with Mexico toward development of a NAFTA-harmonized guidance for risk assessors and risk managers for evaluating the potential risk of pesticides to pollinators, particularly honey bees.

The EPA Pesticide Program continued to reach out and to meet with its state, federal, and global regulatory partners and its federal advisory committee (the Pesticide Program Dialogue Committee), as well as other stakeholders, including beekeeping organizations (American Beekeeping Association and the American Honey Producers Association), pesticide registrants, academic researchers, industry, and environmental groups, on pollinator protection efforts that focus on (1) advancing tools for risk assessment, (2) advancing tools for risk management, and (3) communication and outreach. EPA staff also co-chaired platform sessions and presented posters and symposium papers at conferences and scientific meetings on pollinator issues this year. OPP staff have also presented a series of webinars to EPA regional offices and to stakeholder groups on agency pollinator protection efforts.

EPA has also provided technical assistance on the pollinator risk assessment process to regulatory counterparts in other countries. In 2015, EPA participated in a two-day videoconference with the Brazilian Institute of Environment and Renewable Natural Resources (Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis; IBAMA) and continued interactions with IBAMA are planned for FY'16.

**OPP/OW Harmonization of Aquatic Life Assessments.** In FY'15 OPP and EPA's Office of Water (OW) expanded on efforts initiated in 2012 when OPP and OW, with support from the

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<sup>10</sup> USDA. Colony Collapse Disorder and Honey Bee Health Action Plan, CCD and Honey Bee Health Steering Committee, May 21<sup>st</sup>, 2015. Available on-line at: [http://www.ree.usda.gov/ree/news/CCD-HBH\\_Action\\_Plan\\_05-19-2015-Dated-FINAL.pdf](http://www.ree.usda.gov/ree/news/CCD-HBH_Action_Plan_05-19-2015-Dated-FINAL.pdf)

<sup>11</sup> HBHC. 2015. Tools for Varroa Management A Guide to Effective Varroa Sampling & Control Honey Bee Health Coalition. Available on-line at: <http://honeybeehealthcoalition.org/varroa/>

<sup>12</sup> HBHC. 2015. Quick Guide to Reporting a Pesticide-Related Bee Kill Incident. Available on-line at: <http://honeybeehealthcoalition.org/wp-content/uploads/2015/05/Quick-Guide-to-Reporting-a-Bee-Kill-Incident-Final-03062015.pdf>

Office of Research and Development (ORD), presented a Common Effects Methodology, showing possible methods to harmonize the analysis and characterization of aquatic ecotoxicity data, to the FIFRA Scientific Advisory Panel (SAP). The methods and subsequent analysis included examples of approaches that could be used to leverage OPP data to meet OW's minimum data requirements for Aquatic Life Criteria derivation. In the SAP meeting, the EPA evaluated several possible approaches for analyzing available data to estimate effects on aquatic organisms.

Feedback from this external peer review is a key step in establishing new approaches and methods. The SAP's written response gave positive feedback on the analysis and made recommendations for future efforts. OPP, OW and ORD have identified short term and long term research efforts to advance and achieve the EPA's goal of improved harmonization between OPP and OW to characterize the aquatic toxicity effects of pesticides. OPP and OW are currently piloting an interim approach to develop community-level benchmarks that relies on the existing Tier II method and utilizes extrapolation factors developed under the Great Lakes Initiative (GLI). In FY'14, OPP and OW began an effort to test the approach with three pilot chemicals and the GLI-derived values were compared with OPP benchmark values. In FY'15, this effort was expanded to a set of 18 pesticides with robust data sets. Preliminary results from this expanded effort were also compared to OPP benchmark values. These comparisons continue to be evaluated by OPP and OW. Ultimately, these community-level benchmarks will conservatively approximate an Aquatic Life Criteria (ALC) value.

**Aquatic Life Benchmarks for Pesticides.** OPP's Aquatic Life Benchmarks for Pesticides Registration webpage (<http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-pesticide-registration>) currently includes entries for 466 pesticide active ingredients and degradates. In November 2014, we added new benchmarks or updates to existing benchmarks for 71 active ingredients and 40 degradates/transformation products for which updated risk assessment or problem formulation documents became available during FY 2013. In December 2015, EFED plans to add new benchmarks or updates to existing benchmarks for 71 active ingredients and 52 degradates/transformation products consistent with risk assessment or problem formulation documents that were published in FY 2014. OPP's Aquatic Life Benchmarks for Pesticides Registration webpage is also accessible via the OECD eChemPortal ([http://www.echemportal.org/echemportal/index?pageID=0&request\\_locale=en](http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)).

**Drift Reduction Technologies.** In FY'15, the Pesticide Program continued work on the Drift Reduction Technology (DRT) Program. The purpose of this voluntary program is to encourage the identification and use of spray application technologies capable of significantly reducing pesticide spray drift. OPP developed study review guidance including the Data Evaluation Review (DER) format for both the wind tunnel and field studies for use by OPP staff. This guidance provides the basic requirements and critical elements that need to be included in studies submitted to EPA. As a result of public comment, EPA updated the DRT protocol for rating adjuvant and nozzle combinations. This information is posted on the DRT web page (<http://www.epa.gov/reducing-pesticide-drift>). In addition, OPP staff provided several

presentations at national scientific/technical meetings as well as various stakeholder meetings as part of the ongoing outreach effort for the DRT program.

**Endangered Species.** In FY15, the EPA, USDA and the Departments of Commerce and Interior continued to work together to carry out the advice of the National Research Council (NRC) of the National Academy of Sciences (NAS) for assessing the risks of pesticides to species listed as endangered or threatened under the Endangered Species Act (ESA). In its 2013 report, “*Assessing Risks to Endangered and Threatened Species from Pesticides*” the NAS considered a range of scientific and technical questions related to determining the risks to listed species posed by pesticides considered for registration under FIFRA.

EPA, USDA, Commerce and Interior had sought the NAS’s advice regarding the approaches used by the EPA, the Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) to assess the effects of proposed FIFRA actions on endangered species and their habitats. Topics included best available scientific data, consideration of sub-lethal, indirect, and cumulative effects, assessing the effects of pesticide mixtures and inert ingredients, the role and use of models, the use of geospatial information and datasets, and finally, uncertainty. The report is available at: [http://www.nap.edu/catalog.php?record\\_id=18344](http://www.nap.edu/catalog.php?record_id=18344).

During FY15, EPA and the Services continued to work together to further refine shared interim scientific approaches that reflect the advice provided by NAS (<http://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf>) for assessing the risks of pesticides to listed species. The agencies intend to vet these interim approaches in the context of nationwide consultations for five chemicals (carbaryl, chlorpyrifos, diazinon, malathion, and methomyl), based on recent settlement agreements as part of ongoing litigation against EPA and the Services. During FY15, the agencies continued to work on draft Biological Evaluations for the first three pilot chemicals (chlorpyrifos, diazinon, and malathion) which are expected to be released for public comment in FY16. In addition, joint efforts in FY15 included multiple interagency workshops, meetings with stakeholders, and presentations at scientific/technical conferences; efforts to obtain refined geospatial data for listed species; and development of new models and tools intended to analyze and visualize the estimated exposures and available effects data in an automated fashion.

The agencies’ report to Congress describes the approaches and actions taken to implement the NAS report recommendations, ensure public participation and transparency during implementation of the recommendations, and minimize delays in integrating applicable pesticide registration and registration review requirements with species and habitat protections. This report was submitted to Congress in November 2015 and is intended to satisfy the requirement for an interim report under section 10013(a) of the Agriculture Act of 2014 (P.L. 113-79).

**Bulletins Live! Two Implementation.** In FY15, EPA released Bulletins Live! Two, an upgraded version of Bulletins Live!, a web-based map application used to access geographically-specific threatened and endangered species protection Bulletins. This system is an important tool for pesticide users since it makes it easier to find pesticide use limitations for specific areas. The application is available at: <http://www.epa.gov/endangered-species/endangered-species-protection-bulletins>.

Bulletins generated by the application contain enforceable, geographically-specific pesticide use limitations that are necessary to ensure using a pesticide will not harm a threatened or endangered species or their critical habitat designated under the Endangered Species Act. A reference to Bulletins on a pesticide label ensures that the Bulletin's pesticide use limitations are enforceable under the Federal Insecticide, Fungicide, and Rodenticide Act.

Bulletins Live! Two has several new features, including

- an interactive map;
- different base-maps (satellite, street, geographic, etc.) to help users determine if specific pesticide use limitations apply in areas where the pesticide is intended for use;
- advanced searches for
  - active ingredient,
  - product (by name or registration number),
  - location (state, county, specific address); and
- an enhanced system to receive public comments on draft Bulletins.

**ESA Knowledge Base.** EPA's current ecological risk assessments for pesticides consider potential impacts of pesticides on broad taxa (e.g., freshwater fish, terrestrial plants, birds). For terrestrial animals, including mammals, birds, reptiles and terrestrial-phase amphibians, generic body weights and diets are used to estimate pesticide exposures and resultant risks. For terrestrial plants, taxonomy may affect sensitivity to herbicides, and habitat may affect the potential for exposures based on certain pesticide use patterns. The most conservative exposure and toxicity estimates from these generic animals are used to assess risks to federally listed endangered and threatened species ("listed species"), and without data suggesting otherwise, we assume that an individual of a listed species may be located on or adjacent to a pesticide use site. In order to consider species-specific body weights and diets for more representative, less conservative estimates of pesticide exposure and risk, EPA has compiled data on all currently listed species. Data are from FWS and NMFS documentation describing species (e.g., recovery plans, critical habitat descriptions), as well as published scientific literature. We have added species-specific parameters to the current terrestrial vertebrate exposure models (T-REX and KABAM) to allow risk assessors to calculate risk quotients for individual listed species of mammals, birds, reptiles and amphibians. For terrestrial plants and aquatic organisms, habitat and taxonomic information will allow OPP scientists to make specific effects determinations by applying more representative toxicity values and exposure estimates to a listed species based on the available data. We have also collected other data, such as obligate relationships, habitat descriptions, and elevation restrictions, all of which may be used in species-specific effects determinations for pesticides that may be used on a national scale. All data are captured in a series of reports that include the source information as well as justification for model parameterization. We are also capturing species specific information in a database designed to house biological and geographic

data on all listed species (terrestrial animals as well as aquatic animals and plants). This database will allow users to search for species based on their characteristics.

We completed database development, data entry, and QA/QC for birds, mammals, reptiles, and amphibians in 2013, although we continue to enhance the database. In 2014, we collected information and completed QA/QC for all listed plant species in the lower 48 states. We also collected information for all listed aquatic organisms. In 2015, we completed the remaining data collection and QA/QC for listed plant species and completed the QA/QC for all listed aquatic species. The individual species reports summarize biological and habitat data necessary to characterize the potential for pesticide exposure, and sensitivity and make pesticide effects determinations for listed terrestrial plants and aquatic organisms. The information collection was subject to a strict and formal review process and was entered into the Knowledgebase. We added or enhanced a number of database functions in 2015 including the ability for users to add newly listed species to the database and tracking when and by whom changes to the database were made. We are investigating methods to automate data import into the database for terrestrial plants and aquatic organisms.

**Modeling – Use of Geospatial Tools.** The EPA is developing a Spatial Aquatic Model (SAM) for use in aquatic exposure assessments for pesticides. Currently we model aquatic exposures with PRZM-EXAMS, which uses scenarios to represent a combination of factors that are expected to contribute to high-end pesticide concentrations in water. Although representative of vulnerable areas where a pesticide may be used, these modeling scenarios do not identify specific geographic areas where off-site transport of a pesticide may pose a risk. With the increased demand for a spatial context to both human health (drinking water) and ecological (endangered species) aquatic exposure assessments, we need a way to add a spatial context to aquatic exposure in an efficient, consistent way without increasing the workload for the risk assessor.

In 2015, EPA scientists presented the SAM model to the FIFRA Scientific Advisory Panel for external peer review. Based on discussions with the panel, we anticipate concurrence with the modeling approach for SAM and recommendations for improving the model to be included in the final report due in December 2015. Next steps in 2016 include evaluating modeling approaches for irrigated agriculture in the western United States and refinements for modeling compounds strongly adsorbed to organic matter.

**Invasive Species Control Efforts.** As part of the Great Lakes and Mississippi River Inter-basin Study (GLMRIS; <http://glmrис.anl.gov/>), the Army Corps of Engineers has identified a range of control options (including piscicides) to prevent the movement of Asian carp (silver, black, and bighead) into the Great Lakes where the fish could negatively impact the ecology. In FY 2015, OPP continued to work the U.S. Geological Survey (USGS) and the U.S. Fish and Wildlife Service (FWS) to refine protocols for testing chemicals proposed for use in controlling the

movement of invasive species. OPP has met with both USGS and FWS to identify ways to improve efficiencies in registering new uses and refining standard operating procedures for the use of these compounds under both FIFRA and ESA.