Implementing the Pesticide Registration Improvement Act - Fiscal Year 2016

Thirteenth Annual Report

March 1, 2017

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'16, the ROCKS held four meetings; two with international partners and two internal along with several informal co-chair consultations. The Dose Adequacy Review Team (DART) met twice with registrants on issues concerning cancer rat studies. The Cancer Assessment Review Committee (CARC) reviewed 2 chemicals with MOA data, held 4 internal pre CARC consultations, evaluated 2 external manuscripts, held 3 external consultations with stakeholders and responded to 1 cancer reclassification request. The Toxicology Science Advisory Council (ToxSAC) reviewed 57 packages in support of HED while also reviewing 9 packages for AD and 1 package for BPPD. The Risk Assessment Review Committee (RARC) met 22 times to peer review risk assessments, including 2 new active ingredients, 19 Registration Review risk assessments and the internal Draft Aggregate Guidance Document.

Implementation of 21st Century Toxicology and Exposure Assessment: International Collaboration, Integrated Approaches to Testing and Assessment, and Adverse Outcome Pathways. Consistent with National Academy of Sciences (NAS) reviews, and in collaboration with national and international bodies, EPA has continued to develop and implement 21st Century toxicology and exposure methods, including computer-modeling and *in vitro* testing techniques, to advance more efficient and effective risk assessments that support sound, risk-based, regulatory decision-making. In 2016, OPP continued to make progress toward implementing alternative methods into regulatory use within the U.S. and around the world. The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)/Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) hosted a Communities of Practice webinar with over 300 attendees from around the world and held the 3rd annual Public Forum. ICCVAM started a new technical workgroup on acute toxicity to help support the needs of EPA and the Department of Defense. Several from OPP attended a workshop hosted by NIH on the state of science on alternative approaches for acute systemic toxicity. NICEATM/ICCVAM developed an integrated testing strategy for skin sensitization which was published in the scientific literature. NICEATM/OPP developed a retrospective analysis of nearly 600 formulations and released draft waiver guidance for acute dermal formulation studies that received public comment; the draft waiver guidance will be finalized in Q1 FY2017. NICEATM is also supporting OPP's collaborative project with CLA & PMRA related to the eye irritation, dermal irritation, and skin sensitization assay that will eventually lead to scientific improvements in the "six pack".

In FY'16, HED and AD collaborated on finalizing and publishing the guidance document "P*rocess for establishing & implementing alternative approaches to traditional in vivo acute toxicity studies*" which creates a transparent process for evaluating and implementing alternative methods for the current 6 pack studies. During the public comment period, the great majority of comments on the draft document were positive and supportive of the proposed guidance. Stakeholders interested in proposing the use of a particular alternative method for regulatory purposes have been invited to consult with the agency.

EPA scientists continue to participate in OECD Joint Integrated Approach to Testing and Assessment (IATA) Projects such as the November 2014 Workshop on a Framework for the Development and Use Of Integrated Approaches to Testing and Assessment (OECD No. 215, http://www.oecd.org/env/ehs/testing/listsofprojectsontheaopdevelopmentprogrammeworkplan.htm#Section2). Prompted by the insights provided by OPP at the 2014 workshop, OECD invited OPP 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: PPARγ activation leading to decreased fertility in adult female rodents and PPARα 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 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.

International collaboration in FY'16 also include HED's review and comments on the OECD revision of test guidelines 421/422 (Reproduction/Developmental Screening Tests). HED also provided expert peer review of two proposed Adverse outcome Pathways (AOPs) developed by member countries under the auspices of OECD's Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST) which is in charge of AOP development. In 2016 HED also provided comments on a proposal to remove TG414/415 (2-gen reproductive toxicity OECD guideline) to have only the extended one gen (EOGRT) on OECD TGs Program.

PBPK Collaboration. In 2016, OPP continued to partner with the ORD and coordinate with industry on the development of PBPK models for atrazine and some pyrethroids.

Epidemiological Data. OPP is also continuing to increase our use of epidemiology data and integrating data from various lines of evidence. In FY'16 HED issued "Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides," a systematic literature review in collaboration with ORD of *in vivo* laboratory animal studies and epidemiology studies for OPs other than chlorpyrifos to support the single chemical Human Health Risk Assessments (HHRAs). It also provides an integrated weight of evidence analysis for all the OPs to support retention of the 10X FQPA Safety Factor. The expanded 2015 review includes consideration of the epidemiological data on any organophosphate (OP) pesticide, study designs beyond prospective cohort studies, and non-U.S. based studies. The results from this review showed relatively consistent elevated risks of autism spectrum disorders, intelligence decrements, attentional problems and ADHD, neurological effects near birth, and mental/psychomotor delays (6 months-11 years) associated with OP exposure. These results were not always consistent with magnitude of association and ages where associations were observed across studies. The totality of the evidence and uncertainty in the human dose-response relationship for neurodevelopmental effects prevents the agency from reducing or removing the statutory 10X FQPA Safety Factor for all OPs.

Cumulative Risk Assessment Screening Framework. In FY'16, HED published the final Cumulative Risk Assessment (CRA) Screening Framework. HED also implemented the document in the revised mectins screening CRA and the diacylhydrazine screening CRA. In addition, HED finalized a strategy for prioritizing groups for cumulative screening based on the registration review schedule.

Comparative Thyroid Assay. In 2005, the EPA developed guidance for conducting a comparative thyroid assay that uses a mechanistic approach to generate thyroid-specific data for various life stages, including gestation (pregnant females and fetus) and early postnatal. The life stage thyroid data inform endpoints for risk assessment and provide data specific for assessment under FQPA. In FY'16, HED worked with ORD to develop a set of criteria that can be used in a weight-of-evidence approach to determine whether a comparative thyroid assay should be required for risk assessment. This weight of evidence approach considers all relevant hazard and exposure information (e.g., pesticide use pattern, toxicity profile, and margins of exposure). The Hazard and Science Policy Committee (HASPOC) used this new approach in 2016 to evaluate the need for a comparative thyroid assay for 8 chemicals (5 required, 3 waived).

Hazard and Science Policy Committee. As a forum to address science, policy, hazard data waivers, and risk deliberation and coordination issues, the HASPOC was very active again in 2016. HASPOC plays an important role in the implementation of the vision of the 2007 NAS report on toxicity testing in the 21st century -- moving toward smarter testing strategies by waiving toxicity studies that do not provide useful information. In FY'16, HASPOC reviewed data waiver requests for a variety of toxicity studies, primarily for immunotoxicity, acute and subchronic neurotoxicity, developmental, reproductive, and subchronic inhalation toxicity

studies. Waivers were granted for 153 of 180 requests resulting in savings of about 44,000 animals and over $16 million in the cost of conducting the studies.

Crop Group Implementation. HED's Crop Group Implementation Focus Group completed two actions in FY'16. First, they evaluated moving from the Herb and Spice Crop Group to the proposed separate Herb Crop Group and Spice Crop Group. Recommendations addressed the potential lack of representative-commodity data for herbs and the lack of data for spices other than dill seed due to the majority of spices not being grown in the US. The second action was providing an opinion on the minimum amount and type of information needed to evaluate crop group implementations, for the purpose of streamlining crop group documentation. The Implementation Group is working on evaluating the root and tuber vegetables by early FY2017.

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.

Seed treatment policy: The HED ChemSAC, in collaboration with PMRA, performed a retrospective analysis of all seed treatment (ST) residue data that have been submitted to EPA/PMRA and developed a tiered approach for determining if current data requirements are appropriate or if some streamlining is possible. We also conducted a case study to understand potential savings. Potential savings were identified for both petitioners and the agency in terms of conducting, submitting, and reviewing the studies while still obtaining the data necessary to establish tolerances, as needed, using the proposed tiered approach. This project is included in the Regulatory Cooperation Council (RCC) work plan, and will be published jointly.

Processing factors policy: The HED ChemSAC developed an approach (outlined in a decision tree concerning the need/procedure) for setting tolerances for processed commodities that do not currently appear in OCSPP 860.1000 Table 1. The outlined procedure differs from current HED guidance in that it provides direction concerning the setting of tolerances for commodities that are not in Table 1. The ChemSAC is also recommending that dietary exposure analyses assume theoretical processing factors for all commodities in the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID, ver. 3.16) but not in OCSPP 860.1000 Table 1. A translation guide is in development.

WHO/GEMS Request for Food Consumption Data: HED provided a variety of food consumption statistics to the U.N. World Health Organization, Global Environment Monitoring Systems (GEMS) program. At the request of WHO, HED generated a variety of per capita and consumers only food consumption statistics using the WWEIA-FCID 2005-2015 data. WHO added the data to a Food Consumption Database. WHO is proposing to combine the data from all countries within each cluster, which can then be used to perform a cluster-level (acute or chronic) dietary risk assessment.

Advances in Occupational and Residential Assessment

Draft volatilization screening analysis. HED received a number of public comments on the draft volatilization screening analysis with majority of comments focusing on ways to further refine the screen. We made revisions to the screening analysis based on public comments and published a response to comments document. These documents are targeted to be released in early FY'17 along with data call-ins for route-specific inhalation toxicity studies as well as flux studies.

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. In FY'16 work continued on related data, including planned reviews of completed studies by the Human Studies Review Board and completion of seed treatment handler data analysis.

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 Endocrine Disruptor Screening Program (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. For each global review decision, 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.

Ecological Risk Assessments

The EPA continued to develop and implement new scientific methods, tools, models, and databases for use in pesticide ecological risk (including endangered species) 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[1] to promote the health of honey bees and other pollinators, EPA and USDA have continued to serve as co-chairs of the Pollinator Health Task Force, which includes multiple other federal agencies. In May 2015, the Task Force released the *National Strategy to Promote the Health of Honey Bees and Other Pollinators*[2] which outlines a comprehensive approach to reducing the impact of multiple stressors (*e.g.*, pests, pathogens, pesticides, poor nutrition) on pollinator health. In June 2016, the Task Force released the Pollinator Partnership Action Plan (PRAP) [3] to amplify the Federal actions advanced under the Presidential Memorandum through complementary state and private-sector actions. In addition, EPA and USDA developed a charter for the Honey Bees and Other Pollinators (HBOP) Steering Committee to implement the National Strategy and PRAP and to communicate effectively on such efforts to the Federal Task Force. The HBOP Steering Committee will continue to build upon the structure and accomplishments of the Colony Collapse Disorder and Honey Bee Health (CCD-HBH) Steering Committee[4] and to guide and coordinate pollinator health activities identified in the National Strategy.

EPA is continuing to engage environmental, agricultural and wildlife agencies in the development of state and tribal managed pollinator protection plans (MP3s) and has formed a workgroup within its Federal Advisory Committee, (the Pesticide Program Dialogue Committee) to develop recommendations for how to evaluate and measure the effectiveness of state-and tribal-recognized pollinator protection plans at the national level and to develop a strategy to communicate that effectiveness to the public.

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[1] 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

[2] 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

[3] White House. 2016. Pollinator Partnership Action Plan. Pollinator Health Task Force. June 2016. https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Blog/PPAP_2016.pdf

[4] USDA. 2015. Colony Collapse Disorder and Honey Bee Health Action Plan. CCD and Honey Bee Health Steering Committee. May 21st, 2015. https://www.ree.usda.gov/ree/news/CCD-HBH_Action_Plan_05-19-2015-Dated-FINAL.pdf

As part of research efforts associated with another element of the National Strategy, the Pollinator Research Action Plan (PRAP), EPA is continuing to develop proper assessment tools for evaluating the lethal and sublethal effects of pesticides on managed and native pollinators using both laboratory and field-based measures of exposure and effects. Researchers in the Office of Research and Development National Health and Environmental Effects Research Laboratory are collaborating with EFED technical staff to develop methods for testing the effects of pesticides on bumble bee *(Bombus impatiens*) microcolonies.

Also as part of its commitment to the National Strategy, EPA has accelerated the schedule for assessing the environmental fate and ecological risks of the neonicotinoid insecticides in the Registration Review process. A preliminary assessment of the potential risks of imidacloprid to bees was released for public comment early in 2016. In early 2017, EPA intends to release a status update on the imidacloprid pollinator assessment as well as preliminary pollinator risk assessments for thiamethoxam and clothianidin (combined) and dinotefuran for public comment. The environmental (non-pollinator) risk assessments for these compounds will be completed in 2017 and will consider potential risks across a broad range of taxa [including potential risks to humans] as well as the benefits of these compounds compared to current alternatives.

In 2014, based on concerns regarding the effects that neonicotinoids may have on bees, EPA required label modifications for nitroguanidine-substituted neonicotinoids intended to reduce the likelihood of adverse effects on bees from acute exposure. In FY'17, EPA expects to release a policy document restricting application of pesticides that represent an acute risk to bees on crops that require pollination services from managed pollinators. This policy document reflects input received during the public comment period which drew 113,000 comments. At the same time, EPA will release general responses to the public comments.

EPA has been working in collaboration with USDA and researchers at the University of Maryland (Bee Informed Partnership) to quantify pesticide residues in bee-related matrices (pollen, bee bread, bee carcasses) using broad spectrum (multi-residue) analyses on samples collected during almond pollination in 2015 and 2016. The Analytical Chemistry Laboratory of the Biological and Economic Analysis Division, the USDA National Science Laboratory and the California Department of Food and Agriculture have worked closely to ensure that the methods used in these analyses provide consistent and reliable test results across a broad range of analytes. The data generated through these analyses are helping to inform EPA's understanding of the extent to which pesticides are detected in bee-related matrices (pollen and bee carcasses). The California Department of Pesticide Regulation (CDPR) has cooperated in EPA efforts to identify commonly used tank mixtures applied during almond pollination by providing Pesticide Use Report (PUR) data well in advance of their typical release schedules. CDPR PUR data are being compared to available residue data as well as colony health information (pest/disease loads; colony condition) collected by the Bee Informed Partnership technical teams on the

colonies from which samples were collected. Preliminary review of the CDPR PUR data suggest that tank mixing of fungicides plus insect growth regulators (IGRs) has declined substantially from 2014 to 2016 and may be a reflection of grower/applicator adoption of best management practices (BMPs) identified by the Almond Board of California.

Harmonized Risk Assessment Guidance for Pollinators.

In July 2016, in support of the 2014 harmonized risk assessment guidance for pollinators[5], OPP released its *Guidance on Exposure and Effects Testing for Assessing Risks to Bees*[6]. This document provides guidance to OPP risk assessors on how to determine which exposure and effects (toxicity) studies should be considered when characterizing potential risks of pesticides to bees. EPA also released a document entitled *Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees during Registration and Registration Review.*[7] The intent of this document is to provide interim guidance to the public and staff within OPP to determine when honey bee exposure and effects data identified in the 2014 guidance are required.

In FY'16 EPA translated the harmonized pollinator 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.

EPA is continuing with its 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 in FY'17.

EPA is continuing to work in close collaboration with the U.S. Department of Agriculture Office of Pest Management Policy to update the 2015 guidance entitled *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*[8]. In 2016, several commodity groups provided additional data/references, which were reviewed by the USDA/EPA Crop Attractiveness Review Board (CARB), and used to update the guidance to reflect which agricultural crops are attractive sources of pollen and/or nectar to honey bees, bumble bees, and other non-*Apis* bees, and whether those crops require pollination by managed pollinators.

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[5] 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 (last accessed 08/08/2014).

[6] USEPA. 2016. Guidance of Exposure and Effects Testing for Assessing Risks to Bees. https://www.epa.gov/sites/production/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf

[7] USEPA. 2016. Process for Requiring Exposure and Effects Testing for Assessing Risks to Bees during Registration and Registration Review. https://www.epa.gov/sites/production/files/2016-08/documents/bee_guidance.pdf

[8] 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

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 also reviews 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. In 2016, the OECD Working Group on Pesticides (WGP) reviewed the status of the various activities of the PEIP, and in December 2016, technical staff from OPP will assist in developing the structure and content of a Pollinator Seminar for the OECD WGP in 2017.

EPA acknowledges the uncertainty regarding the extent to which honey bees are 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 drafted and reviewed by OECD member countries as formal guidelines in 2016.

In April 2016, EPA participated in a meeting of the International Commission on Plant-Pollinator Relationships (ICP-PR) non-*Apis* subgroup to discuss the status of additional tests with social (*e.g.*, *Bombus terrestris*; *B. impatiens*) and 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 ICP-PR Managed Pollinator Protection and Health Working Group (Bee Protection Group) which is helping to coordinate international research efforts to advance testing methods for consideration by OECD.

In March 2016, EPA participated in a workshop on future research needs on bee health and pollination organized by the European Food Safety Authority (EFSA) on behalf of the European Commission. The workshop synthesized the results of an EFSA survey of the invited participants on the status of previously identified pollinator-related research objectives. During the workshop, invited participants were asked to prioritize future research needs and to identify whether the priority represented applied or fundamental (basic) research. EPA emphasized the economy of effort that may be achieved through closer collaboration on research to address uncertainties related to identifying and mitigating factors associated with pollinator declines.

More Pollinator Activities. Consistent with the 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.

As an ex officio member of the Honey Bee Health Coalition (HBHC), EPA has provided technical input on revisions to guidance documents developed by the coalition such as the *Tools for Varroa Management A Guide to Effective Varroa Sampling and Control*[9] and the series of twelve videos depicting tools for varroa management[10]

As an *ex officio* member of the Corn Dust Research Consortium[11], EPA has continued to provide technical input on research proposals and study reports evaluating the potential exposure routes of honey bees to dusts generated during the planting of pesticide-treated seed as well as potential options to mitigate such exposure.

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.

EPA has also provided technical assistance on the pollinator risk assessment process to regulatory counterparts in other countries. In 2016, EPA participated in a week-long workshop with the Brazilian Institute of Environment and Renewable Natural Resources (Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis; IBAMA) on assessing ecological risks of pesticides including discussions of the pollinator risk assessment process.

EPA has also been working with USDA, Health Canada's Pest Management Regulatory Agency and the Honey Bee Health Coalition in efforts to develop additional measures to control varroa mites. Preliminary screening of a series of chemicals is underway examining their effectiveness as possible varroacides.

EPA is also collaborating with the U.S. Fish and Wildlife Service to identify voluntary conservation measures for reducing exposure of monarch butterflies to insecticides.

OPP/OW Harmonization of Aquatic Life Assessments. In FY'16 OPP and EPA's Office of Water (OW) continued follow-up analysis that expanded on efforts initiated in 2012 when OPP and OW, with support from the Office of Research and Development (ORD), presented a Common Effects Methodology, showing possible methods to harmonize the analysis and

[9] 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/
[10] HBHC. 2016. Varroa Videos Tools for Varroa Management. http://honeybeehealthcoalition.org/varroa/#videos
[11] Pollinator Partnership. 2016. Corn Dust Research Consortium (CRDC). http://www.pollinator.org/CDRC.htm

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 of pesticides. OPP and OW are currently piloting an interim approach to develop community-level benchmarks that rely 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 and into FY'16, 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. OPP and OW continue to evaluate these comparisons. 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 539 pesticide active ingredients and degradates. In November 2015, we added new benchmarks or updates to existing benchmarks for 73 active ingredients and degradates/transformation products for which updated risk assessment or problem formulation documents became available during FY 2014. In December 2016, EPA is adding new benchmarks or updates to existing benchmarks for 10 active ingredients and 15 degradates/transformation products consistent with risk assessment or problem formulation documents that were published in FY 2015.

Drift Reduction Technologies. In FY'16, 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 updated study review guidance to correct editorial errors and provide clearer guidance to technology developers and submitters. This guidance provides the basic requirements and critical elements that need to be included in studies submitted to EPA. As a response to public comment, EPA updated the DRT protocol for rating adjuvant and nozzle combinations. This information is posted on the DRT web page (http://www2.epa.gov/reducing-pesticide-drift). In addition, OPP staff gave several presentations at national scientific/technical meetings as well as at various stakeholder meetings as part of the ongoing outreach effort for the DRT program and held conference calls with individual stakeholders to help facilitate submissions.

Endangered Species. In FY16, EPA, U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS), collectively referred to as the Services, 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 posed by 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 covered under the Endangered Species Act (ESA) posed by pesticides considered for registration under FIFRA.

EPA, the Services, and USDA had sought the NAS's advice regarding the approaches used by EPA and the Services 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.

During FY16, EPA and the Services continued to work together to further refine shared interim scientific approaches that reflect NAS advice (http://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf) for assessing the risks of pesticides to listed species. EPA released the first nationwide draft Biological Evaluations (BEs) for three pilot chemicals including chlorpyrifos, diazinon, and malathion in April 2016. During a 60-day public comment period, EPA received over 78,600 comments with about 120 substantive comments meriting detailed review.
In June 2016, EPA and the Services held a two-day meeting that provided a forum for stakeholder suggestions for refining some of the interim scientific methods used in the April 2016 draft BEs. The meeting included opening and closing plenary sessions and breakout sessions intended to address inter-agency developed charge questions related to potential refinements for aquatic modeling, spatial and non-spatial refinements to Step 2 (i.e., EPA's determination of "likely to adversely affect" or "not likely to adversely affect"), and refinements to the weight-of-evidence (WoE) approach for plants and animals. Meeting materials including the agenda, charge questions, the opening plenary presentations, and the closing plenary reports are available at: https://www.epa.gov/endangered-species/5th-esa-workshop-joint-interim-approaches-nas-recommendations. EPA and the Services have reviewed the recommendations and identified those that can be addressed in the short-, mid-, and long-term.

Additionly, joint efforts in FY16 included multiple interagency workshops, and presentations at scientific/technical conferences; efforts to obtain refined geospatial data for listed species and pesticide use; and development of new models and tools intended to analyze and visualize the estimated exposures and available effects data in an automated fashion. The development these new tools and models, available at https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments is intended to advance the science used in the BEs, to improve efficiencies, to manage large amounts of data, and to ensure consistency and transparency in the pesticide consultation process.

In FY16, EPA and the Services also worked on the final *Report to Congress*, updating the November 2014 interim *Report to Congress*. As directed by the Agriculture Act of 2014 (P.L.

113-79), the final report will inform Congress of actions that have been, and will be taken, to establish that: (1) the Agencies utilize the best available science; (2) Reasonable and Prudent Alternatives (RPAs) will be technologically and economically feasible; (3) Reasonable and Prudent Measures (RPMs) will be necessary and appropriate; and (4) the Agencies will ensure public participation and transparency in developing RPAs and RPMs.

EPA expects to release final BEs and responses to public comments on the draft BEs for the three pilot chemicals in early 2017, followed by draft BEs for carbaryl and methomyl in the spring of 2017.

ESA Knowledgebase. 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, terrestrial Exposure and KABAM, KOW-based Aquatic BioAccumulation Model) 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 Knowledge Data Base. 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. In 2016, we added features to better manage species with multiple populations and to allow for more specialized profiles for different taxa. 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.

During FY16, EPA scientists incorporated feedback from the 2015 Scientific Advisory Panel into SAM. EPA has clarified the conceptual model and further developed the models fate and transport processes. Resource constraints delayed the evaluation of modeling scenarios for irrigated agriculture which EPA expects to conduct during FY 2017.

Invasive Species Control Efforts. Consistent with the President's Executive Order to safeguard the Nation from impacts of invasive species[12] and as part of the Great Lakes and Mississippi River Inter-basin Study (GLMRIS; http://glmris.anl.gov/), the Army Corps of Engineers has identified a range of control options (including piscicides) to prevent aquatic nuisance species transfer between the Great Lakes and Mississippi River basins through aquatic pathways where such species could negatively impact the ecology. In FY 2016, 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.

[12] White House. 2016. Executive Order: Safeguarding the Nation from the Impacts of Invasive Species. https://www.whitehouse.gov/the-press-office/2016/12/05/executive-order-safeguarding-nation-impacts-invasive-species