Implementing the Pesticide Registration Improvement Act - Fiscal Year 2018

Fifteenth Annual Report

Process Improvements in the Pesticide Program

Human Health Risk Assessments

Science Review Committees. Ensuring scientific integrity is at the core of the Pesticide Program. Several established review committees routinely consider all manner of issues related to the development of risk assessments. This includes review of risk assessments and their component pieces. It also includes development of science policies and administrative processes which enhance the ability of the organization to be more efficient and to complete quality, science-based risk assessments in a more consistent manner. Some examples of science policies have included requiring less residue data under certain conditions and development of more up to date exposure metrics for evaluating some pesticide uses. The number of meetings for each committee in 2018 is provided to illustrate the breadth of these activities. 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'18, the ROCKS reviewed 4 chemicals by conducting meetings and e-reviews. The Dose Adequacy Review Team (DART) met once. The Cancer Assessment Review Committee (CARC) reviewed 5 chemicals. The Toxicology Science Advisory Council (ToxSAC) reviewed 50 packages in 46 meetings. The Risk Assessment Review Committee (RARC) reviewed 17 chemicals. The Chemistry Science Advisory Council (ChemSAC) completed 22 meetings while the Dietary Exposure Science Advisory Council (DESAC) reviewed 59 assessments in 12 meetings. The Exposure Science Advisory Council (ExpoSAC) conducted 25 meetings and reviewed 81 non-dietary exposure assessments.

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 again in 2018. 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'18, HASPOC reviewed data waiver requests for a variety of toxicity studies, primarily for comparative thyroid assay (CTA), acute and subchronic neurotoxicity, developmental, reproductive, and subchronic inhalation toxicity studies. Waivers were granted for 62 of 71 requests resulting in savings of about 16,500 animals and approximately $8.9 million in the cost of conducting the studies.

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 2018, EPA made significant progress toward implementing alternative methods into regulatory use within the U.S. and around the world. The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)/Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) held the 5th annual Public Forum. ICCVAM started a new technical workgroup on ecotoxicology to help support the needs of EPA, Department of Interior, USDA, and other federal

agencies. Office of Pesticide Programs (OPP) scientists published papers in scientific journals on regulatory needs regarding alternative approaches related to ICCVAM activities. OPP helped co-organized and attended a ICCVAM workshop hosted by the National Toxicology Program on Predictive Models for Acute Oral Systemic Toxicity (https://ntp.niehs.nih.gov/pubhealth/evalatm/3rs-meetings/past-meetings/tox-models-2018/index.html) that may, in time, support a computational approach to the oral LD_{50}. Collaborative work by EPA, NICEATM, Consumer Product Safety Commission (CPSC), the European Union (EU) and Canada to develop a performance-based test OECD guideline for skin sensitization continues to advance through the technical workgroup on defined approaches. OPP in collaboration with OPPT released a new draft, interim science policy on Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing (https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0093-0090). This document describes an approach using *in vitro* studies to eliminate the use of laboratory animals for skin sensitization testing. OPP continued its pilot project requesting registrants voluntarily submit Globally Harmonized System of Classification and Labelling of Chemicals (GHS) additivity equation calculations for oral and inhalation formulation acute testing in combination with submitting the actual study. This pilot is designed to test the performance of the GHS additivity equation as a possible replacement for the animal study. NICEATM is also supporting OPP's collaborative project with CropLife America (CLA) & Health Canada's Pest Management Regulatory Agency (PMRA) related to the eye irritation and dermal irritation that will eventually lead to scientific improvements in the "six pack".

OPP began developing metrics for the use of *in vitro* studies for the "six pack" in FY'18. Specifically, OPP received 25 *in vitro* eye irritation assays, 13 skin irritation assays, and one skin sensitization assay. In addition, OPP received 18 waiver requests under the 2016 "Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis." With these new tracking metrics, OPP will in the future be able to gauge the extent to which new approaches and science policies are leading reductions in animal testing.

Preliminary eye irritation data from formulation testing across different agricultural formulation types in multiple *in vitro* studies became available in 2018 and was used to inform the next stage of prospective eye irritation testing.

In 2018, OPP and the Office of Pollution Prevention and Toxics (OPPT) developed the document "Evaluation of a Proposed Approach to Refine the Inhalation Risk Assessment for Point of Contact Toxicity: A Case Study Using a New Approach Methodology (NAM)" (https://www.epa.gov/pesticides/fifra-sap-meeting-evaluation-proposed-approach-refine-inhalation-risk-assessment-point). This document describes the use of a 3-dimensional *in vitro* system using human lung tissue coupled with computational fluid dynamic modeling as a possible replacement to inhalation testing in laboratory animals. This document was released in FY' 2018 in preparation for a meeting of the FIFRA SAP held in December 2018.

PBPK Collaboration. In 2018, OPP made significant progress towards implementing more physiologically based pharmacokinetic (PBPK) models in our human health risk assessments. An external panel of 10 members conducted a peer review to evaluate whether the PBPK models for deltamethrin and permethrin and the PBPK/pharmacodynamic (PD) model for carbaryl submitted by the registrants are appropriate for replacing/refining uncertainty factors applied in inter-species or

age-dependent extrapolations. The panel had the required expertise (computational modeling, toxicology/biology, risk assessment) to critically evaluated the model structure, parameterization, coding and scientific credibility for use in human health risk assessment. Their final report, model code and associated documents were posted in dockets EPA-HQ-OPP-2010-0230 (carbaryl), EPA-HQ-OPP-2009-0637 (deltamethrin) and EPA-HQ-OPP-2011-0039 (permethrin). These models are currently being revised to address reviewers' comments. Other registrants are collecting *in vitro* and *in vivo* data to support the development of PBPK/PD models for malathion and dimethoate. These models will also be used to replace/refine inter-species and age-dependent extrapolation factors. OPP and the Office of Research and Development (ORD) are collaborating with a new HESI project on developing best practices and approaches to PBPK model documentation/reporting, as well as evaluating model for use in risk assessment. In 2018-2019, OPP is involved in two active HESI tasks: (1) developing a template for modeler developers to report and submit their PBPK analysis to regulatory agencies; and (2) developing a framework for evaluating PBPK models for various risk assessment applications. Although this framework is initially developed for data-rich chemicals, such as pesticides, it will be expanded in the next phases to include strategies for evaluating models for data-poor chemicals.

Cumulative Risk Assessment Screening Framework. During FY'18, the Cumulative Risk Assessment (CRA) Working Group has continued its efforts analyzing groups of pesticides for potential common mechanisms of toxicity and developing cumulative risk screening assessments utilizing the recently developed guidance document, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose*. Specifically, it has determined that the data for antibiotics, acyl aminoacids, chitin synthesis inhibitors, and dinitroanilines do not support establishing a common mechanism group (CMG) and no further CRA work is necessary.

Comparative Thyroid Assay. In 2005, the EPA developed guidance for conducting a comparative thyroid assay (CTA) that uses a mechanistic approach to generate thyroid-specific data to address the uncertainties associated with life stage susceptibility and allow for the establishment of points of departure that would be protective of the effects of thyroid function disruption during potentially sensitive life stages (pregnancy, prenatal, and postnatal periods). 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). In FY'18, the Hazard and Science Policy Committee (HASPOC) used this approach to evaluate the need for a comparative thyroid assay for 8 chemicals (2 required, 6 waived). Until these data are submitted, a 10X uncertainty factor will be applied to all short-term, intermediate- term, and chronic exposure scenarios. EPA continues to dialogue with stakeholders about the utility and conduct of this study.

Dietary Exposure-Review of Proposed Crop Groups. EPA's ChemSAC reviewed proposals for the following revised crop groups: root and tuber and leaves of roots and tubers and legumes and foliage of legumes. Proposed rules based on these analyses are forthcoming.

Residue Chemistry-Streamlined Residue Chemistry Review of Import Tolerance Actions.

Work has continued on a streamlined approach for establishing tolerances without accompanying U.S. registrations (i.e., "import tolerances"). Instead of submitting the currently required residue chemistry field trial data, the petitioner will submit the final review of the residue chemistry data from the Joint FAO/WHO Meeting of Pesticide Residues (JMPR) or a National Authority. EPA will rely on these reviews to determine the appropriate tolerance level with the intent of harmonizing with the established Codex or National Authority MRL, provided the required safety finding can be made. EPA will continue to accept these submissions on a trial basis to determine if this a feasible approach and what the appropriate parameters would be to accept such submissions. After previously evaluating several of these pilot petitions a determination was made that this is an acceptable process and a flow-chart was developed for conducting these registration actions.

Residue Chemistry-Seed Treatment Policy. EPA in collaboration with PMRA, previously 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 streamlining is possible. A case study was also conducted to understand potential savings. Potential savings were identified for both petitioners and EPA 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. The policy was published in 2018 (https://www.epa.gov/pesticides/reduced-residue-chemistry-data-requirements-seed-treatment-uses).

Updated Occupational Exposure Metrics – Revisions to *Unit Exposure (UE)* 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. OPP will continue to update this surrogate reference table as additional pertinent exposure data become available from, for example, 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 OPP 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. In FY'17, AHETF data for wettable powder and water-soluble packet formulations were reviewed, and handler UEs were updated. Where revised UE data impacted post-harvest handler scenarios, they were updated as well. In FY' 18, new exposure data from the AHETF was reviewed/approved and supplanted older monitoring data as the data source for assessment of handlers manually loading granule pesticide formulations.

Policy Improvements for Non-Dietary Exposure Assessments. During FY'17, several exposure policies were reviewed and updated to utilize the best available data and assumptions. AHETF phase II seed treatment survey data for amount of seed treated were incorporated into handler exposure assumptions. New methodologies were also implemented to assess a range of potential dust to liquid ratio exposures for residential handlers of pet collars. Policy or guidance documents that were drafted, updated, or finalized in FY'17

include the draft Residential SOP update to add residential exposures from aquatic-use pesticides, the draft mosquito adulticide SOP for ground and aerial/ultra-low volume application, and the revised commercial and on-farm seed treatment policy for the amount of seed treated and planted per day. In FY' 18 OPP formally incorporated the respiratory protection factor assumed by OSHA and NIOSH for filtering facepiece respirators (PF10: 90% inhalation exposure reduction) and finalized guidance on mapping pesticide application records in the REJV consumer use pesticide survey to the "Residential SOP" exposure assessment scenarios, a tool that can help assessors characterize characteristics of consumer pesticide use such as application frequency.

OECD Activities. OPP continued to coordinate US Government participation in the Organization for Economic Cooperation and Development (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 Corp of Engineers.

EPA provided international collaboration for review and comment on several documents in the areas of human heath, ecotoxicity, antimicrobials and manufactured nanomaterials during FY'18. EPA input included the review of 21 new or revised test guidelines and guidance documents, review of 15 new project proposals, review of 3 new Adverse Outcome Pathways and input to 3 surveys (e.g., Use of Systematic Literature Review for ED; Country-Specific Guidance or Other Relevant Documents on OECD's Joint Integrated Approach to Testing and Assessment (IATA)). Additionally, EPA nominated experts to participate in 6 newly formed OECD Test Guidelines Programme Expert Groups (EGs) during 2018 (e.g.; EG on Pig-a Gene Mutation Assay; Transgenic Rodent Assay Expert Group; EG for Guidance on Best Practices for Licensing of Protected Elements in OECD TGs; Consolidate the EG on Biotransformation; EG on Defined Approaches for Skin Sensitization; and EG for Developing a GD on Reporting of Metabolomics Data) and OPP continued to lead the project on the development of the Performance Based Test Guideline for Defined Approaches for Skin Sensitization.

Chemistry and Acute Toxicology Science Advisory Council (CATSAC). The Chemistry and Acute Toxicology Science Advisory Council (CATSAC), which was formalized in 2016, 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 acute toxicity and product chemistry studies that do not provide useful information for product registration. In 2018 the

CATSAC continued to follow the newly finalized Standard Operating Procedure (2017) and worked toward developing a Standard Evaluation Procedure (SEP) which will provide guidance on criteria for substantially similar products and the potential for bridging data. The SEP will support consistency in evaluations across OPP. In FY 2018, the CATSAC bridged the acute toxicity 6-pack requirement 3 times, saving almost 400 animals and over $100,000 in study costs.

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 2015, the White House issued the National Strategy to Promote the Health of Honey Bees and other Pollinators that identified factors associated with declines in honey bee (*Apis mellifera*) health and outlined efforts to address those factors. OPP is continuing to collaborate with the Office of Research and Development (ORD) to address uncertainties regarding exposure and effects of pesticides on honey bees and non-*Apis* bees. In 2018, the ORD Strategic Research Action Plan identified pollinators as a priority research area aimed at addressing needs identified in the Pollinator Research Action Plan (PRAP), which is part of the National Strategy. Researchers the ORD National Health and Environmental Effects Research Laboratory (NHERL) are collaborating with OPP's Environmental Fate and Effects Division (EFED) technical staff and EPA Regional offices to develop methods for testing the effects of pesticides on bumble bee *(Bombus impatiens*) microcolonies. Also, consistent with recommendations from the 2012 FIFRA Scientific Advisory Panel on assessing risks of pesticides to bees, OPP and ORD have also continued to collaborate with researchers in the USDA Agricultural Research Service to further parameterize and validate the USDA honey bee colony simulation model (VarroaPop). Once sufficiently vetted, the model can be used to evaluate the potential effects of pesticides on honey bee colony performance and potentially reduce the need for whole colony testing.

Also consistent with the Pollinator Partnership Action Plan of the National Strategy, EPA has continued to engage with external stakeholder groups (*e.g.*, Pollinator Partnership; Honey Bee Health Coalition) and has contributed to the development of outreach materials to better inform beekeepers and the agricultural community of challenges and means of addressing factors affecting pollinator declines including best management practices for beekeepers and growers.

Assessing Exposure and Effects of Pesticides. In December 2018, the proceedings of an EPA-hosted workshop on assessing pesticide exposure to non-*Apis* bees and determining whether honey bees are suitable surrogates for assessing exposure were published in the peer-reviewed journal Environmental Toxicology. The international workshop and subsequent publication underscored the utility of using honey bees as a surrogate when examining the primary routes of exposure for honey bees, *i.e.*, contact and ingestion of residues in pollen and nectar. The publication identified areas where additional research is needed to determine whether current methods for evaluating exposure are protective for non-*Apis* bees contacting/ingesting leaf materials and/or mud used in constructing nests.

In 2018, OPP initiated a retrospective analysis of honey bee toxicity data from laboratory-based studies. These analyses are responsive to National Academy of Sciences recommendations for toxicity testing in the 21st Century toward reduced reliance on whole animal testing and will help inform decisions on whether missing toxicity endpoints can be reliably/consistently extrapolated for particular chemical classes based on existing data. The analyses are intended to also identify possible situations where testing burden may be reduced and still support risk assessment/characterization while reducing the level of resources needed to conduct and review such studies.

In response to questions from the regulated community and the public, in 2018 OPP published to the web responses to frequently asked questions (FAQs) surrounding the conduct and analysis of both laboratory-based studies of individual bees and field-based exposure and effect studies on honey bee colonies. The FAQs are intended to complement existing EPA and OECD test guidelines and guidance documents and provide researchers with additional information on study design elements toward increasing consistency and reliability of studies conduct to support regulatory decisions.

Stakeholder Outreach. The EPA Pesticide Program also 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.

In 2018, EPA worked with the PPDC to identify a means of evaluating voluntary state and tribal Pollinator Protection Plans focusing on managed pollinators (*i.e.,* MP3s) and/or native pollinators (*i.e.*, P3s). These plans are intended to foster/increase communication between relevant stakeholders within states and Indian Lands to reduce potential exposure of bees to pesticides. The PPDC recommended that EPA consider the offer by state lead agencies (*i.e.*, the State FIFRA Issues Research and Evaluation Group [SFIREG] and the American Association of Pest Control Officers [AAPCO]) to develop a survey instrument to collectively evaluate the individualized, state-specific approaches to pollinator protection. Tribal Nations are working with the Tribal Pesticide Program Council (TPPC) to develop similar metrics for evaluating the native pollinator

protection efforts; however, the tribes have the option of utilizing the MP3 survey instrument developed by the state lead agencies. The MP3 survey will be administered annually beginning in 2019 and the results will serve as a line evidence with which EPA can determine the efficacy of MP3 and P3 relative to reducing bee exposure of pesticides.

EPA is continuing to work collaboratively with the USDA on the guidance entitled *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen.* Consistent with the process used since the USDA guidance was first released in 2015, both agencies have continued to review petitions from various commodity groups to update the Guidance document on the extent to which particular crops are attractive sources of pollen and/or nectar to honey bees and non-*Apis* bees and to accurately reflect the extent to which and circumstances when a crop may require managed pollination services.

EPA has continued to work in collaboration with USDA and researchers in academia and industry in identifying new tools for controlling varroa mites, a serious pest of honey bees. In 2018, the first year of a 3-yr grant from the Foundation for Food and Agriculture Research (a foundation of the USDA), approximately 8 out of 24 chemicals tested for varroacidal activity under laboratory conditions will be advanced to semi-field testing with honey bees.

OECD and International Pollinator Activities. EPA is continuing to work with its international regulatory counterparts to develop appropriate assessment tools for evaluating the potential lethal and sublethal effects of pesticides on managed and native pollinators using both laboratory and field-based measures of exposure and effects. EPA has continued its efforts as a member of the international OECD's 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. As part of that effort, in 2018 OPP science staff provided OECD comments on a proposed test guideline for evaluating the acute toxicity of pesticides to the solitary non-*Apis* mason bee (*Osmia spp*.). This test design, if ratified, would provide a further means of evaluating the extent to which non-*Apis* bees may be affected by exposure to pesticides when such higher-tier tests are deemed necessary. This methodology compliments the standardized OECD test guidelines published in 2017 for evaluating the effects of pesticides on social non-*Apis* bumble bees (*Bombus spp*.)

EPA has continued to serve as a member of the Steering Committed for International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group which is helping to coordinate international research efforts to advance testing methods for consideration by OECD. EPA staff members are co-chairing subgroups tasked with identifying standardized testing methods for conducting semi-field and full-field studies of conventional pesticides with honey bee colonies and for identifying suitable test methods for evaluating microbial pesticides. International researchers within the ICP-PR network have been largely responsible for developing the protocols for conducting such tests and have participated in the ring testing used to verify the reproducibility and reliability of these test methods. The collective efforts of these researchers will be presented at the 14th International Symposium of the ICP-PR Bee Protection Group in Bern, Switzerland in October 2019.

21st Century Methods and Reducing Animal Testing. Furthering the Agency's goal of incorporating 21st century methods into risk assessment, EPA initiated a collaborative project with the National Institute of Environmental Health Sciences to analyze warm water and cold-water fish species acute toxicity data to guide testing requirements to reduce animal testing. The goal of the effort is to determine if testing on fewer test species will allow the Agency to sufficiently assess hazard to fish.

EPA has also collaborated with People for the Ethical Treatment of Animals (PETA) on a project to determine if avian risks can be confidently and protectively assessed for most chemicals using acute single oral dose study endpoints, thereby obviating the need for sub-acute dietary studies in birds. PETA and EPA are collaborating on the publication of our findings in the scientific literature, with publication expected in 2019. EPA also anticipates developing a policy clarifying our avian toxicity data needs.

Aquatic Life Benchmarks for Pesticides. OPP's Aquatic Life Benchmarks for Pesticides Registration webpage (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-and-ecological-risk) currently includes entries for hundreds of pesticide active ingredients and degradates. This is a collaborative effort between EPA and the California Department of Pesticide Regulation and is responsive to requests from state lead agencies for hazard information on pesticide active ingredients. Since 2015, EFED continues to add new benchmarks or updates to existing benchmarks for active ingredients and degradates/transformation products for which updated risk assessment or problem formulation documents become publicly available. The FY'18 aquatic life benchmarks report includes 615 chemicals, an increase of 6% from the FY'17 report.

Greater Than Additive Effects. EPA developed an approach to considering information from patent data suggesting synergistic effects, or greater than additive effects, in ecological risk assessment, which ensures that the Agency is adhering to the National Academy of Science's recommendation to consider pesticide interactions to the extent supported by scientific evidence in regulatory decision making. EPA anticipates releasing that approach for public comment in 2019.

Endangered Species. In FY'18, 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 FY'18, EPA and the Services along with USDA 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. An interagency workshop was held to evaluate how usage data can be incorporated into the consultation process. From that workshop, an interagency workgroup met on a regular basis to develop methods to incorporate usage data into Step 1 (identify the action area) of the consultation process. EPA also presented updates on the consultation process and the potential utility of usage data at scientific/technical conferences.

A final biological opinion (BiOp) was released in early FY'18 from the National Marine Fisheries Services (NMFS) on the first three pilot chemicals, chlorpyrifos, diazinon, and malathion. EPA initiated consultation on these pesticides the prior fiscal year. EPA sought public comments on the final BiOp and received approximately 125 substantive comments. An additional approximately 19,000 comments were received as part of a signature campaign. Additional refinements based on lessons learned from the first pilot BEs, including public input, continue to be developed.

Also in FY'18, EPA along with Department of the Interior and Department of Commerce signed a memorandum of agreement creating a working group to provide recommendations for improving the ESA consultation process for pesticide registration and registration review. They are charged with reviewing statutory requirements, regulations and case, and making recommendation to improve scientific and policy approaches.

Modeling – Use of Geospatial Tools. The EPA is developing updated scenarios 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 the full extent of specific geographic areas where off-site transport of a pesticide may pose a risk.

During FY'18, EPA scientists initited an update to the modeling scenarios, and plans to get public input in 2019.