Implementing the Pesticide Registration Improvement Act - Fiscal Year 2017

Fourteenth Annual Report

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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 2017 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'17, the ROCKS reviewed 8 chemicals by conducting 4 meetings and 4 e-reviews. The Dose Adequacy Review Team (DART) met once. The Cancer Assessment Review Committee (CARC) reviewed 9 chemicals. The Toxicology Science Advisory Council (ToxSAC) reviewed 44 packages in 41 meetings. The Risk Assessment Review Committee (RARC) reviewed 35 chemicals. The Chemistry Science Advisory Council (ChemSAC) completed 26 meetings while the Dietary Exposure Science Advisory Council (DESAC) reviewed 63 assessments in 9 meetings. The Exposure Science Advisory Council (ExpoSAC) conducted 26 meetings and reviewed 80 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 2017. 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'17, 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 70 of 78 requests resulting in savings of about 41,000 animals and approximately $10.4 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 2017, EPA continued to make steady 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 4th annual Public Forum. ICCVAM started new technical workgroups on alternatives to developmental and reproductive toxicity, read across, and in vitro to in vivo extrapolation to help support the needs of EPA, Food and Drug Administration (FDA), 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. Several from OPP attended a ICCVAM workshop hosted by the National Institutes of Health (NIH) on the uses of oral acute systemic toxicity and associated needs for alternative assays data. EPA, NICEATM, and Consumer Product Safety Commission (CPSC) have co-sponsored an Organization for Economic Cooperation and Development (OECD) project proposal with the European Union (EU) and Canada to develop a performance-based test guideline for skin sensitization. NICEATM/OPP finalized a retrospective analysis of nearly 600 formulations and released waiver guidance for acute dermal formulation studies that received public comment; the draft waiver guidance in Q1 FY2017. OPP started a 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 continued to participate activities at the Health and Environmental Sciences Institute (HESI) to develop a framework for using alternative approaches in risk assessment.

International collaboration in FY'17 included EPA review and comments on over 30 documents (new or revised test guidelines and guidance documents) in the areas of human heath, ecotoxicity, antimicrobials and manufactured nanomaterials. USEPA also nominated experts to participate in several newly formed OECD Test Guidelines Programme Expert Groups (EGs) during 2017 (e.g.; EG on Developmental Neurotoxicity, Experts for Advisory Group on Intellectual Property, EG for Developing a GD on Reporting of Transcriptomics Data, EG on Revision GD 150; EG on GD on Good in vitro Method Practice). Additionally, USEPA/OPP led the development of Guidance Document on the OECD Joint Integrated Approach to Testing and Assessment (IATA) project for Eye Irritation Hazard Potential, which was approved during the 2017 OECD Working Group of the National Coordinators for the Test Guidelines Programme (WNT) and submitted a new project proposal on Performance Based Test Guideline for Defined Approaches for Skin Sensitization last year.

PBPK Collaboration. In 2017, OPP made significant progress towards implementing more

physiologically based pharmacokinetic (PBPK) models in our human health risk assessments. A draft white paper was developed reviewing PBPK models for six pesticides (carbaryl, deltamethrin, permethrin, acibenzolar, malathion, dimethoate). OPP and the Office of Research and Development (ORD) are collaborating with a new HESI project on PBPK modeling. EPA's white paper and the six PBPK models will be reviewed by the FIFRA SAP in 2018.

Cumulative Risk Assessment Screening Framework. During FY'17, 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 triazolones (propoxycarbazone, thiencarbazone) do not support establishing a common mechanism group (CMG) and no further CRA work is necessary. Cumulative screening analysis documents for the triazolones has been completed. Also, the CRA Working Group screened the anilinopyrimidines. It was concluded that a candidate common mechanism group (CMG) could be formed consisting of cyprodinil and pyrimethanil (but not mepanipyrim). The cumulative screening risk assessment for this CMG did not identify any risks of concern.

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'17, the Hazard and Science Policy Committee (HASPOC) used this approach to evaluate the need for a comparative thyroid assay for 21 chemicals (3 required, 19 waived). For two of these chemicals, the HASPOC determined that a CTA was not required based on the observation that the dog was the most sensitive species for thyroid toxicity. However, since there was still uncertainty regarding potential life stage susceptibility, additional *in vitro* comparative metabolism data were required to help elucidate the basis for the species differences in thyroid toxicity. Until these data are submitted, a 10X uncertainty factor will be applied to all short-term, intermediate-term, and chronic exposure scenarios.

Dietary Exposure-Finalization of the Proposed New Herb and Spice Crop Groups 25 and 26: EPA's ChemSAC reviewed proposals entitled "Recommendation for the New Crop Group 25

Herb and New Crop Group 26 Spice to Approve Its Members, Representative Commodities, Crop Subgroups, and Associated Commodity Definitions. A proposed rule based on this analysis will be finalized in 2018.

Residue Chemistry-Streamlined Residue Chemistry Review of Import Tolerance Actions: A streamlined approach for establishing tolerances without accompanying US registrations (i.e., "import tolerances") was reviewed. Instead of submitting the currently required residue chemistry field trial data, the petitioner would submit the final review of the residue chemistry data from the Joint FAO/WHO Meeting of Pesticide Residues (JMPR) or a National Authority. EPA would 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 now 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 evaluating several of these pilot petitions a determination was made in FY'17 that this is an acceptable process and a flow-chart was developed for conducting these registration actions.

Improvements to Model for Dietary Exposure Assessment. Work continued in FY'17 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.

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 draft policy will be published in 2018.

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 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 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. UE data were updated for post-harvest handler scenarios.

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. Additionally, several policies or guidance documents were drafted, updated, or finalized in FY'17 including: 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.

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.

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

As part of research efforts associated with 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's (ORD) National Health and Environmental Effects Research Laboratory (NHERL) are collaborating with OPP's Environmental Fate and Effects Division (EFED) technical staff to develop methods for testing the effects of pesticides on bumble bee *(Bombus impatiens*) microcolonies. In January 2017, EPA hosted a workshop bringing together a broad range of experts on non-*Apis* bee biology, ecology, ecotoxicology, pollinator risk. There were a total 40 participants (35% from academia; 40% government; 22% industry; 3% non-government organization) from seven countries. The purpose of the workshop was to determine the extent to which honey bees are suitable surrogates for assessing exposure for non-*Apis* bees. The proceedings of the workshop will be published in a peer-reviewed venue later in 2018.

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 January 2018, EPA released 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) draft risk assessments for these compounds were completed and released in December 2017, and 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 finalized a policy document restricting application of pesticides that represent an acute risk to bees on crops that require pollination services from managed pollinators and responded to public comments. This policy document reflects input received during the public comment period which drew 113,000 comments. EPA continues to received feedback from stakeholders on the acute risk mitigation policy and is considering additional changes to that policy to address stakeholder comments and

concerns.

Harmonized Risk Assessment Guidance for Pollinators. 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.* 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. These commodity groups continued to be updated in 2017 and were considered in 2017 evaluations. The 2017 guidance is found at the following link: https://www.ars.usda.gov/ARSUserFiles/OPMP/Attractiveness%20of%20Agriculture%20Crops%20to%20Pollinating%20Bees%20Report-FINAL_Web%20Version_Jan%203_2018.pdf.

OECD and International 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 assisted in developing the structure and content of a Pollinator Seminar for the OECD WGP in 2017, and facilitated that Pollinator Seminar in June 2017. The Seminar had sessions discussing pollinator safety, global drivers and actions; pollinator risk assessment – evolving/harmonizing the science; and pollinator risk management.

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 contact and oral toxicity tests with bumble bees (*Bombus terrestris; B. impatiens*) were finalized in 2017.

In October 2017, OPP participated in the International Commission for Plant-Pollinator Relationships (ICP-PR) Bee Protection Group 13th International Symposium on the Hazard of Pesticides to Bees. 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. Symposium sessions were focused on risk assessment, effects assessment in honey bee (*Apis mellifera*) brood (eggs, larvae, pupae), methods for testing non-*Apis* bees, semi- and full-

field testing, and monitoring study designs. The symposium provided an opportunity to announce the finalized OECD Test Guidelines on 10-day adult bee toxicity (OECD TG 245), bumble bee (*Bombus* spp) acute contact toxicity (OECD TG 246), and the bumble bee acute oral toxicity test (OECD 247). 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.

More Pollinator Activities. 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.

Internally, in 2017, EPA formed a team ensure consistent review of pollinator studies/protocols/waiver requests, and to conduct a retrospective analysis of pollinator data to make determinations on future data needs.

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.

EPA has also provided technical assistance on the pollinator risk assessment process to regulatory counterparts in other countries. In September 2017, EPA participated in workshop with the Brazilian Institute of Environment and Renewable Natural Resources (Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis; IBAMA) to participate in a discussion of innovations related to pesticides, specifically regarding ecological risk assessment, which includes 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.

In collaboration with ORD and university researchers, EPA developed 6 Adverse Outcome

Pathways (AOPs) for describing perturbation of the honey bee nicotinic acetylcholine receptor leading to colony death. This sentinel work furthers EPA's understanding of the role neonicotinoids play in pollinator decline and was published in Science of the Total Environment.

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 toxicity data to guide testing requirements to reduce animal testing.

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. 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 publically available.

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 will be releasing that approach for public comment in 2018.

Endangered Species. In FY17, 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.

Additionally, joint efforts in FY17 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. EPA released final BEs and responses to public comments on the draft BEs for the three pilot chemicals in early 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 the full extent of 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 FY17, EPA scientists continued to incorporate feedback from the 2015 Scientific Advisory Panel into SAM, and plans to develop and release new SAM modeling scenarios in 2018.