

# Implementing the Pesticide Registration Improvement Act - Fiscal Year 2014

## Eleventh Annual Report



*March 1, 2015*

## Process Improvements in the Pesticide Program

### Ecological Risk Assessments

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

**New Harmonized Risk Assessment Guidance for Pollinators.** In June 2014, the EPA, working in collaboration with Health Canada's Pest Management Regulatory Agency (PMRA) and the California Department of Pesticide Regulation (CDPR), released harmonized guidance on assessing the risk of pesticides to bees and other pollinators ([http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf)). This guidance is based on a conceptual framework outlined in a white paper presented to the FIFRA Scientific Advisory Panel in 2012. The framework discussed in the white paper and reflected in the harmonized guidance document is consistent with the European and Mediterranean Plant Protection Organization (EPPO) scheme and the 2014 European Food Safety Authority (EFSA) guidance as well as the Society of Environmental Toxicology and Chemistry (SETAC) global Pellston Workshop held in 2011.

The guidance describes a tiered process beginning with a conservative screen (Tier 1) using laboratory-based acute and chronic toxicity studies of individual adult and larval honey bees coupled with model or default exposure values to derive risk estimates referred to as risk quotients (RQ), *i.e.*, exposure ÷ toxicity=risk). Depending on the results of the screening-level assessment, more refined estimates of exposure (*i.e.*, measured rather than estimated values) can be used to determine whether risk estimates can be refined below regulatory trigger levels (Levels of Concern). If risk estimates exceed levels of concern, higher tier studies may be required; these studies consist of semi-field tunnel or feeding studies with whole colonies at Tier 2 where exposure conditions are relatively controlled as well as full-field studies with whole colonies at Tier 3 where bees are free foraging and application conditions are as close to actual use conditions as possible.

Throughout the tiered process, risk assessors and risk managers consider whether mitigation measures (*e.g.*, reduced application rates, timing of application, number of applications) are sufficient to reduce exposure to a level where risk estimates are below thresholds for concern. In Tier 2 and Tier 3, whole colony responses are evaluated to determine whether effects from exposure are transient and whether the colony appears to recover from such impacts.

Based on the final harmonized guidance, EPA will be recommending additional laboratory-based Tier 1 studies to support the tiered risk assessment process for bees. These additional tests include acute testing for larvae and chronic testing for adults and larvae, and depending on the outcome of the Tier 1 studies, may also include semi- and full-field studies of whole colonies. Guidance for

risk assessors on additional exposure and effects data needed to support the tiered risk assessment process is expected to be developed and implemented in FY'15.

**OECD Pollinator Activities.** The EPA Pesticide Program is 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. In addition, the sub-group was formed to review study designs for pollinator toxicity tests to determine if they can be enhanced or if new tests are needed to better assess acute, chronic, and sub-lethal effects on pollinators and to develop such guidelines.

In 2014, the PEIP launched the “Pollinator Incidents Information System” and the “Managing Pesticide Risk to Insect Pollinators website”. The objective of the incident system is to efficiently communicate accurate and necessary information on pollinator incidents among regulatory authorities of OECD member countries. An official list of contact points from OECD member country regulatory authorities was established, and these official contact points have access to upload pollinator incident information on the Pollinator Incidents Information System. Regarding the risk management portal, this website is available to the general public and allows users to find websites of OECD member countries by linking to existing websites that contain information on actions aimed at mitigating potential risk of pesticides to insect pollinators. The relevant information includes regulatory agency information on label mitigation (and labeling guidelines), non-label mitigation, education and training materials, and laws, policies and guidance.

Regarding the development of toxicity testing guidelines, EPA has been working with OECD on efforts to develop standardized testing methods. As part of this effort, a draft OECD guidance has been developed for a 21-day chronic toxicity test with honey bee larvae that extends through emergence of the adult bee; this method is currently undergoing ring testing in Europe. The U.S. EPA acknowledges the uncertainty regarding the extent to which honey bees may be a reasonable surrogate for native insect pollinators, and we are working 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*) have been developed and will be considered by OECD member countries as formal guidelines in 2015. Work is also underway through the International Commission on Plant-Pollinator Relationships (ICP-PR) to develop additional tests with solitary bees and other insect pollinators.

**More Pollinator Activities.** In response to the June 2014 Presidential Memorandum (<http://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b>) to promote the health of honey bees and other

pollinators, EPA has been working as co-chair of the Pollinator Health Task Force (along with USDA and multiple other federal agencies) to develop a National Pollinator Health Strategy. The Strategy will include a research action plan and a public education plan that highlights existing and recommended new public-private partnerships. EPA actions will be addressed in the Strategy, scheduled for release in the winter of 2015, including the following: EPA's plans to assess the effects of pesticides, including neonicotinoids, on bee and other pollinator health; to engage state and tribal environmental, agricultural, and wildlife agencies in the development of state and tribal pollinator protection plans; to encourage the incorporation of pollinator protection and habitat planting activities into green infrastructure and Superfund projects; and to expedite the review of registration applications for new products targeting pests harmful to pollinators. During FY'14, EPA co-chaired the Task Force activities, participated in the research action plan and education plan subgroups, collaborated with public-private partners, and began working with our state and tribal partners to develop locally-based pollinator protection plans.

OPP has been engaged with multiple stakeholder groups toward advancing our understanding of factors associated with pollinator declines and potential tools for mitigating those factors. OPP is a member of the USDA-led Colony Collapse Disorder (CCD) and Honey Bee Health Coalition Steering Committee and has assisted in the organization of multiple stakeholder workshops including the Varroa Mite Summit and the Honey Bee Forage and Nutrition Summit, both of which were conducted in 2014. OPP is an *ex officio* member of the Honey Bee Health Coalition Steering Committee and an *ex officio* member of the Pollinator Partnerships' Corn Dust Research Consortium Advisory Committee. OPP is a steering committee member of the International Commission on Plant-Pollinator Relationships Bee Protection Group and served as a keynote speaker at their 11<sup>th</sup> International Symposium on the hazards of pesticides to bees in 2014.

Through a Regionally Administered Research Effort grant from EPA Region 5, OPP has been collaborating with EPA's Office of Research and Development, the Land Grant University Ohio State University, and other cooperators (e.g., USDA and PMRA) to examine the effects on bees of dusts generated during the planting of treated seed. Data from these studies are being used to expand the USDA BeePop colony simulation model and advance our understanding of tools that can be used to estimate effects of multiple factors (e.g., pesticides and Varroa mites) on bee colony performance.

In 2014, a North American Free Trade Act (NAFTA) project was initiated to develop guidance for assessing risks to pollinators from use of pesticides in agricultural and urban environments. The goal of the project is to develop harmonized guidance for risk assessors and risk managers for evaluating the potential risk of pesticides to pollinators, particularly honey bees.

The EPA Pesticide Program continued to reach out and to meet with its state, federal, and global regulatory partners and its federal advisory committee (the Pesticide Program Dialogue Committee), as well as other stakeholders, including beekeeping organizations (American Beekeeping Association and the American Honey Producers Association), pesticide registrants,

academic researchers, industry, and environmental groups, on pollinator protection efforts that focus on (1) advancing tools for risk assessment, (2) advancing tools for risk management, and (3) communication and outreach. EPA staff also co-chaired platform sessions and presented posters and symposium papers at conferences and scientific meetings on pollinator issues this year. OPP staff have also presented a series of webinars to EPA regional offices and to stakeholder groups on agency pollinator protection efforts.

**OPP/OW Harmonization of Aquatic Life Assessments.** OPP and EPA's Office of Water (OW), with support from the Office of Research and Development (ORD), presented a Common Effects Methodology, showing possible methods to harmonize the analysis and characterization of aquatic ecotoxicity data, to the SAP on January 31 through February 2, 2012. 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 issued a written response to these analyses on April 30, 2012. In general, the SAP report provided positive feedback on the analysis and made recommendations for future efforts. OPP, OW and ORD have identified short term and long term research efforts to advance and achieve the EPA's goal of improved harmonization between OPP and OW to characterize the aquatic toxicity effects of pesticides. OPP and OW are currently piloting an interim approach to develop community-level benchmarks that relies on the existing Tier II method and utilizes extrapolation factors developed under the Great Lakes Initiative (GLI). In FY'14, preliminary results from three pilot chemicals, which compare GLI-derived values with OPP benchmark values, were completed and the results are being evaluated by OPP and OW. Ultimately, these community-level benchmarks will conservatively approximate an Aquatic Life Criteria (ALC) value.

**Drift Reduction Technologies.** In FY'14, 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. Under ORD's Environmental and Sustainable Technology Evaluation program, OPP and ORD, with input from external experts, developed a draft verification protocol and guidance document. The DRT testing protocol was adapted from standard test methods and regulatory methods used in the U.S. and other countries, and it describes the testing approach that will be used to generate high-quality, peer-reviewed data for DRTs. The protocol also describes the test design and quality assurance aspects. On November 21, 2012, EPA published a Notice in the *Federal Register* announcing this proposed information collection activity and provided a 60-day public comment period. That Notice as well as the support documents (draft DRT testing protocol and descriptions of the program) and the comments submitted are available at [regulations.gov](http://www.regulations.gov) under the docket identifier EPA-HQ-OPP-2012-0631. The agency revised the draft protocol and guidance document based on the comments. EPA

announced the DRT program via the Federal Register in October 2014 (<http://www.gpo.gov/fdsys/pkg/FR-2014-10-15/html/2014-24525.htm>). Additional information is available at: <http://www2.epa.gov/reducing-pesticide-drift>.

**Endangered Species.** In April 2013, the National Research Council (NRC) of the National Academy of Sciences (NAS) released a report entitled, “*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 under the Endangered Species Act (ESA) posed by pesticides considered for registration under FIFRA. The EPA, USDA and the Departments of Commerce and Interior sought the NAS’s advice regarding the approaches used by the EPA, the Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) to assess the effects of proposed FIFRA actions on endangered species and their habitats. Topics included best available scientific data, consideration of sub-lethal, indirect, and cumulative effects, assessing the effects of pesticide mixtures and inert ingredients, the role and use of models, the use of geospatial information and datasets, and finally, uncertainty. The report is available at: [http://www.nap.edu/catalog.php?record\\_id=18344](http://www.nap.edu/catalog.php?record_id=18344).

Since receiving the NAS report, the four agencies have been working together to develop shared scientific approaches that reflect the advice provided by NAS and have developed interim scientific approaches (<http://www.epa.gov/espp/2013/interagency.pdf>) for assessing the risks of pesticides to listed species. Joint efforts to date include: collaborative relationship building between EPA, the Services, and USDA; clearer roles and responsibilities for the EPA, the Services, and the USDA; new agency processes to improve stakeholder engagement and transparency during review and consultation; two joint agency workshops resulting in interim scientific approaches; a plan and schedule for applying the interim approaches to a set of pesticide compounds; and multiple workshops and meetings with stakeholders.

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

**ESA Knowledge Base.** EPA’s current ecological risk assessments for pesticides consider potential impacts of pesticides on broad taxa (e.g., freshwater fish, terrestrial plants, birds). For terrestrial animals, including mammals, birds, reptiles and terrestrial-phase amphibians, generic body weights and diets are used to estimate pesticide exposures and resultant risks. For terrestrial plants, taxonomy may affect sensitivity to herbicides, and habitat may affect the potential for exposures based on certain pesticide use patterns. The most conservative exposure and toxicity estimates from these generic animals are used to assess risks to federally listed endangered and threatened species ("listed species"), and without data suggesting otherwise, we assume that an

individual of a listed species may be located on or adjacent to a pesticide use site. In order to consider species-specific body weights and diets for more representative, less conservative estimates of pesticide exposure and risk, EPA has compiled data on all currently listed species of mammals, birds, reptiles and amphibians. Data are from FWS and NMFS documentation describing species (e.g., recovery plans, critical habitat descriptions) as well as published scientific literature. We have added species-specific parameters to the current terrestrial vertebrate exposure models (T-REX and KABAM) to allow risk assessors to calculate risk quotients for individual listed species of mammals, birds, reptiles and amphibians. For terrestrial plants and aquatic organisms, habitat and taxonomic information will allow OPP scientists to make specific effects determinations by applying more representative toxicity values and exposure estimates to a listed species based on the available data. We have also collected other data, such as obligate relationships, habitat descriptions, and elevation restrictions, all of which may be used in species-specific effects determinations for pesticides that may be used on a national scale. All data are captured in a series of reports that include the source information as well as justification for model parameterization. We are also capturing species specific information in a database designed to house biological and geographic data on all listed species (terrestrial animals as well as aquatic animals and plants). This database will allow users to search for species based on their characteristics.

We completed database development, data entry, and QA/QC for birds, mammals, reptiles, and amphibians in 2013, although we continue to enhance the database. In 2014, we collected information and completed QA/QC for all listed plant species in the lower 48 states. We have collected information for all listed aquatic organisms, but have not yet completed QA/QC. The individual species reports summarize biological and habitat data necessary to characterize the potential for pesticide exposure, and sensitivity, and to make pesticide effects determinations for listed terrestrial plants and aquatic organisms. The information collection was subject to a strict and formal review process and was entered into the Knowledgebase. We added or enhanced a number of database functions in 2014 including naming and storing all reference documents for automatic import into the database. We are investigating further enhancements to the Knowledgebase for terrestrial plants and aquatic organisms, including automation of data collection.

**Modeling – Use of Geospatial Tools.** The EPA is developing a Spatial Aquatic Model (SAM) for use in aquatic exposure assessments for pesticides. Currently we model aquatic exposures with PRZM-EXAMS, which uses scenarios to represent a combination of factors that are expected to contribute to high-end pesticide concentrations in water. Although representative of vulnerable areas where a pesticide may be used, these modeling scenarios do not identify specific geographic areas where off-site transport of a pesticide may pose a risk. With the increased demand for a spatial context to both human health (drinking water) and ecological (endangered species) aquatic exposure assessments, we need a way to add a spatial context to

aquatic exposure in an efficient, consistent way without increasing the workload for the risk assessor.

In 2014, we were able to move a test version of SAM to a “cloud hosted” environment, a key step for managing large datasets and outputs derived from a national scale model and for eventually making this tool available to stakeholders. Work continues on validating the model against pesticide monitoring data. In FY’15, we will hold several seminars with external and internal stakeholders to solicit evaluation of the model. In addition, SAM will be presented to the FIFRA Scientific Advisory Panel.

**Modeling – PRZM-GW.** EPA scientists have been using SCI-GROW (Screening Concentration in Groundwater) as a screening-level tool to estimate drinking water exposure concentrations from groundwater resulting from pesticide use (Barrett, 1997). SCI-GROW is strictly a screening-level exposure tool and does not have the capability to consider mitigating circumstances such as variability in leaching potential of different soils, weather (including rainfall), cumulative yearly applications or depth to aquifer. If SCI-GROW-based assessment results indicate that pesticide concentrations in drinking water may exceed the level of risk concern, our ability to refine the assessment is limited. In 2004, we began evaluating advanced methods for estimating pesticide concentrations in groundwater as part of the cumulative risk assessment of carbamate pesticides. Similarly in 2004, Health Canada’s PMRA published information outlining an initial direction on use of modeling to estimate pesticides in groundwater. Because groundwater resources in Canada and the United States are similar and many modeling aspects and needs are the same, the two organizations combined efforts under NAFTA to develop a harmonized groundwater modeling protocol. The NAFTA team developed and harmonized the groundwater conceptual model with input from the FIFRA Scientific Advisory Panel. The NAFTA project was finalized in 2013. In 2014, PRZM-GW was fully implemented. Implementation of PRZM-GW in OPP’s assessment methodology increases our ability to refine assessments and tailor risk mitigation decisions to various geographic conditions across the country, supporting the agency’s mission by ensuring the safe use of pesticides and protecting human health.

## 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’14, the ROCKS held seven meetings on seven chemicals. The Dose Adequacy Review Team (DART) reviewed study protocols submitted by various registrants for 4 chemicals. The Cancer Assessment Review Committee (CARC) met ten times on numerous chemicals, and the Toxicology Science Advisory Council (ToxSAC) met 28 times to discuss and determine end-points of concern. The Risk Assessment Review Committee (RARC) met fifteen times to peer review risk assessments that will undergo public comment.

**Integrated Approaches to Testing and Assessment.** EPA scientists continue to participate in the OECD Joint Integrated Approach to Testing and Assessment (IATA) Projects on computational tools such as Quantitative Structure-Activity Relationship models ((Q)SAR) and MetaPath. Efforts continued within the OECD MetaPath Users Group (MUG) to further explore opportunities to use MetaPath in global pesticide risk assessments and to continue its database development, along with the customization of the MetaPath Data Evaluation Record (DER) Composer. The Pesticide Program is using the composer for rat and livestock metabolism studies. Current international collaborators include: Health Canada's PMRA, EFSA, the Australian Pesticides and Veterinary Medicines Authority, France, Austria and Germany. In addition, the 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>). The first AOP KB module is the [AOP Wiki](#): an interactive and virtual encyclopedia for AOP development. OPP participated in a workshop on Implementing AOPs in a regulatory setting.

**International Collaboration for 21<sup>st</sup> Century Toxicology and Exposure Assessment.**

Consistent with NAS reviews, and in collaboration with national and international bodies, the agency worked to develop and implement 21<sup>st</sup> Century toxicology and exposure methods, including computer-modeling and *in vitro* techniques, to advance more efficient and effective risk assessments that support sound, risk-based regulatory decision-making. In 2014, OPP continued its implementation of guiding principles for data requirements and waiver guidance for inhalation, dermal, neurotoxicity, and immunotoxicity studies (See <http://www.epa.gov/pesticides/science/guidelines.htm>). The OECD published an IATA for skin corrosion and irritation ([http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2014\)19&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)19&doclanguage=en)). In addition, the international community continues to make great strides toward developing an integrated testing strategy for skin sensitization based on the adverse outcome pathway that does not involve whole animal testing (<http://www.oecd.org/env/ehs/testing/listsofprojectsontheaopdevelopmentprogrammeworkplan.htm>). In FY'14, we initiated a multi-stakeholder project to accelerate the implementation of alternative approaches for registration of pesticide formulations in the areas of eye irritation, skin irritation, and skin sensitization. Members of the multi-stakeholder group include Canada's PMRA, NIEHS-NICEATM, CropLife America, PETA, the Humane Society, and Physicians Committee for Responsible Medicine. In FY'15, we will continue to work with OECD, WHO, and ICCVAM to continue progress on reducing animal use for the acute 'six pack' studies. In 2013, we initiated a collaborative project with NIEHS-NICEATM to evaluate oral and dermal acute lethality studies to consider the potential for waiving such dermal studies to reduce the use of animals and to improve efficiency in labeling. FY'14 saw good progress on this analysis, and a draft will be published in FY'15. In addition, we have improved the integration of *in vitro* and *in vivo* experimental toxicology and human information by applying the adverse outcome pathway concept as the unifying concept for evaluating the strengths and limitations of data across different levels of biological organization. An example of 21<sup>st</sup> century approaches is a large scale research effort by a group of pyrethroid registrants to evaluate potential for juvenile

sensitivity to pyrethroids. This research involves a combination of multiple *in vitro* assays, computational approaches, and sophisticated pharmacokinetic and population- based modeling. We expect these data and models to become available for review in FY'15 and will be used for the pyrethroid risk assessment. Furthermore, the overall approach and lessons learned can be used as a foundation for similar 21<sup>st</sup> century approaches for more classes of chemicals.

**Hazard and Science Policy Committee (HASPOC).** As a forum to address science, policy, hazard data waivers, and risk deliberation and coordination issues, the HASPOC was very active this year. HASPOC plays an important role in the implementation of the vision of the 2007 NAS report on toxicity testing in the 21<sup>st</sup> century -- moving toward smarter testing strategies by waiving toxicity studies that do not provide useful information. In FY'14, HASPOC reviewed data waivers for a variety of toxicity studies, primarily for immunotoxicity, acute and subchronic neurotoxicity, and subchronic inhalation toxicity studies. Waivers were granted for 173 requests resulting in the saving of over 30,000 animals and over \$30 million in the cost of conducting the studies.

**Crop Grouping.** Work continued in FY'14 with the American Herbal Association, the American Spice Trade Association and other groups to update the Herb and Spice crop group. We expect this update to significantly expand the number of included herbs and spices and to facilitate international harmonization and trade for these important products.

**Pesticide Use Site Index.** We completed an updated Pesticide Use Site Index, which helps registration applicants identify the specific requirements needed to register a pesticide product. Now available at <http://www2.epa.gov/pesticide-registration/pesticide-use-site-index>, this index introduces information needed to complete the registration process including pesticide use sites and major pesticide use patterns. For example, after identifying desired pesticide use sites, registrant's are directed to one or more major use patterns which, in turn, point to the technical data requirements in 40 CFR part 158. The Pesticide Use Site Index replaces Appendix A "Data Requirements for Registration" last published in the July 1, 2006 version of 40 CFR part 158.

**Dietary Exposure Assessment.** The EPA released an updated version of the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID)/Calendex software in September 2014, which replaced the previous version posted on the EPA website in June 2012. The DEEM-FCID software can be found and downloaded at: <http://www.epa.gov/pesticides/science/deem/>. This most recent release updated the dietary consumption data to the NHANES/ "What We Eat in America" 2005-2010 data, incorporating the most recent NHANES survey data from 2009-2010.

To increase the transparency and public availability of dietary exposure software, these most recent DEEM dietary consumption data are now available on the website of the University of Maryland's Joint Institute of Food Safety and Nutrition (JIFSAN) at <http://fcid.foodrisk.org>. In addition, JIFSAN developed and posted several updates to its online applications to facilitate public access to and interpretation of information from the raw data. An updated [FAQ list](#) describes the data and information available on the JIFSAN foodrisk.org website as well as the

history of, sources for, and background behind the EPA's development of FCID for dietary exposure assessments.

**Updated Transfer Coefficient (TC) Policy.** Since the 2011 policy for evaluating the risks associated with hand labor activities for all major commercial crops (<http://www.epa.gov/opp00001/science/post-app-exposure-data.html>), periodic updates have been added. In 2014 we began to review a proposal from the Agricultural Reentry Task Force (ARTF) that would change transfer coefficients for some activities in grapes and hops.

**Revised Residential Standard Operating Procedures (SOPs).** The Revised Residential SOPs were first released in January 2012 and billed as a “living document” subject to revision based on new or more contemporary information. In early FY'13, we released the second update to include revisions to the outdoor fogger and insect repellent SOPs. In addition, it included new versions of the SOP spreadsheet calculators as reflected on the Residential SOP webpage (<http://www.epa.gov/opp00001/science/residential-exposure-sop.html>). All of these changes were the result of close work with stakeholders to ensure the SOPs stay up-to-date and reflect the current state of the science. In FY'14 we began additional revisions to incorporate calculations that would allow for better incorporation of route-specific inhalation toxicity studies, a new scenario to address aquatic use pesticides, and other miscellaneous edits.

**Updated Unit Exposure (UE) Surrogate Table.** Continuing a multi-year effort, OPP continued to maintain 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 which will be included in an upcoming revision to the reference table.

**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. Although the Office of Pesticide Programs coordinates the OECD Test Guideline efforts, other EPA offices participate, as do representatives of the Food and Drug Administration, Consumer Product Safety Commission, National Institute for Environmental Health Sciences, and the US Army.

**Global Review Work.** OPP is a leader of global joint review activities for new conventional pesticides. In addition to tackling a larger portion of the primary reviews for several large submissions, OPP's Residues of Concern Knowledge-Based Subcommittee (ROCKS) of the RARC supported the international residues-of-concern discussion. For each of the global review decisions, we shared documentation and perspectives with our international partners. Without this leadership, each country's team would have had to make a chemical-by-chemical decision. In addition to the ROCKS committee, international partners were invited to participate on numerous peer review committees, including ChemSAC, ToxSAC, RARC, and CARC. The agency has taken a leadership role by providing draft documents for review, resulting in better support for proposed decisions, and more buy-in from global partners.

**Global Harmonization Work.** OPP continued to serve as Chair of the OECD Residue Chemistry Expert Group (RCEG), facilitating the update on the crop field trial guidance that encourages the use of proportionality, or adjusting field trial residues by application rate. OECD will likely approve the guidance in FY15. The RCEG will be drafting new guidance on rotational crop studies in FY15, with approval proposed for FY16. Furthermore, OPP is working with Crop Life America, USDA's IR-4, and Canada's PMRA to evaluate the extent to which geographic zones contribute materially to determining residue levels for a given crop/pesticide combination. We have assembled a large dataset to evaluate this question, and expect to present the results to Codex this spring and JMPR later in the fall. To the extent that global zones are not contributors to systematic differences in residues between regions, common global MRL's could be seen as appropriate.

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