

Implementing the Pesticide Registration Improvement Act - Fiscal Year 2013

Tenth Annual Report



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Process Improvements in the Pesticide Program

Science Review Improvements

EPA's Office of Pesticide Programs (OPP) is engaged in a number of projects to advance our strategic direction using "Integrated Approaches to Testing and Assessment" (IATA), which promotes a hypothesis based, systematic, integrative use of exposure and hazard information. Consistent with the 2007 report of the National Research Council (NRC) of the National Academy of Sciences on "Toxicology Testing in the 21st Century", the goal of IATA is to refine, reduce or even replace data requirements for complex laboratory animal studies while maintaining the scientific defensibility of pesticide assessments.

In 2013 OPP provided staff the "Guiding Principles for Data Requirements" to enhance consistency in the identification of data needs and to promote and optimize full use of existing knowledge and focus on the critical data needed for risk assessment. We also developed policies designed to reduce animal testing such as the "Part 158 Toxicology Data Requirements: Guidance for Neurotoxicity Battery, Subchronic Inhalation, Subchronic Dermal and Immunotoxicity Studies" for guidance on using a weight-of-evidence evaluation to determine data needs and the policies "Advances in Genetic Toxicology and Integration of in vivo Testing into Standard Repeat Dose Studies" and "Alternate Testing Framework for Classifying Eye Irritation Potential" for labeling antimicrobial pesticide products with cleaning claims under the U.S. EPA classification and labeling system. To increase the availability of alternative testing strategies, OPP played a major role in leading significant changes in leadership and strategic direction of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (<http://iccvam.niehs.nih.gov/announcements/ICCVAM-all/2013-02-06-EHP.htm>). In July 2013 OPP collaborated with stakeholders through the Pesticide Program Dialogue Committee's (PPDC) 21st Century Toxicology/New Integrated Testing Strategies Workgroup to hold a workshop entitled "Where Vision Meets Action: Practical Application of 21st Century Methods" intended to provide an opportunity to dialogue with stakeholders on how OPP envisions applying new science to change the way we evaluate the risks of pesticides, and to examine the challenges and benefits of making this transition.

Ecological Risk Assessments

The agency 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 include the following:

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 address four main goals: (1) develop a mechanism for efficiently communicating accurate and necessary information on pollinator incidents among regulatory authorities of member countries; (2) 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; (3) develop a mechanism for sharing risk management tools, including precautionary labeling, use restrictions, technologies, training

materials, best management practices, and integrated pest management practices used by various countries to mitigate pollinator risks and to recommend when and how tools should best be applied and characterize their effectiveness; and (4) establish a communication “clearinghouse” on research efforts to facilitate coordination and collaboration of research activities.

In 2013, the PEIP began developing portals for communicating pollinator incidents and sharing risk mitigation tools. In addition, the subgroup updated the pollinator testing guideline inventory and proposed priorities for future work related to testing and assessment needs.

In 2013, EPA staff participated in the OECD expert group meeting on larval honey bee toxicity test designs. As a result of this effort, OECD issued a formal guideline (OECD 237) on single dose toxicity testing with honey bee larvae in 2013. The OECD is currently considering a testing guideline on repeat dose testing of larvae that extends the study through adult bee emergence.

EPA staff are also working with the International Committee for Plant Pollinator Relationships (ICPPR) on possible standardized study designs for semi-field and full field pollinator toxicity tests as well as methods for laboratory-based toxicity tests with bumble bees (*Bombus terrestris*).

More Pollinator Activities. The EPA Pesticide Program continued to reach out and to meet with its state, federal, and global regulatory partners and advisory committees (the Pesticide Program Dialogue Committee) as well as other stakeholders, including the 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, presented posters and symposium papers at conferences and scientific meetings concerned with 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.

In September 2012, the Pesticide Program, in collaboration with the Canadian Pest Management Regulatory Agency (PMRA) and the California Department of Pesticide Regulation (CalDPR), presented a proposed framework for quantifying the potential risks of pesticides to honeybees to the FIFRA Scientific Advisory Panel (SAP). In response to comments received from the SAP, we have worked with PMRA and CalDPR to finalize the guidance document for assessing risk to bees. Consistent with our current pesticide risk assessment processes, the guidance describes a multi-tiered approach that initially relies on laboratory-based studies on individual bees, and then transitions to more realistic field-based studies involving whole colonies for chemicals that do not pass the screening-level assessment. The process has served as a basis for data call-ins in support of Registration Review and has been proposed for adoption by Mexico under the North American Free Trade Agreement (NAFTA).

In 2013, EPA in collaboration with USDA hosted a pollinator summit to discuss the multiple ways in which stakeholders have been engaged in reducing potential exposure of pollinators to dust generated through the abrasion of pesticide-treated seed during planting (dust-off). We have been working closely with USDA and Health Canada's PMRA to encourage the development of alternative lubricants to talc and graphite to reduce the potential for dust-off during planting.

OPP is working with EPA Region 5 and the EPA's Office of Research and Development (ORD) through a Regionally-Administered Research Effort (RARE) grant to collaborate with USDA and Health Canada's PMRA in examining factors associated with pollinator bee kill incidents in the Midwest and to develop a simulation model for estimating the potential effects on honeybee colonies from pesticides. This effort is consistent with recommendations from the FIFRA SAP on the importance of developing tools such as simulation models for characterizing potential risks from pesticides.

CETIS Implementation. In FY 2013, OPP implemented use of a new statistical program known as CETIS (Comprehensive Environmental Toxicity Information System). The platform is a Microsoft Access-based system, and functions as both a tool for statistical analysis as well as a central repository for all data analyzed within. With this latter function as a database, future plans are to conduct a meta-analysis, e.g. identify the most sensitive endpoint for a given taxa for a given class of chemicals. The platform effectively replaces five different statistical programs previously used by OPP scientists, some being outdated in terms of user interface and data entry, others requiring a license available only to a few staff. As part of the CETIS implementation, OPP conducted a thorough QC process, in which studies were analyzed using CETIS and older statistical programs to ensure consistency in endpoint selection. In the past year that the program has been implemented, OPP and its contractor have successfully transitioned to the CETIS platform, which will allow greater flexibility to analyze additional guideline studies in the future, such as pollinator toxicity studies.

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 in the characterization of aquatic effects (toxicity) of pesticides. OPP and OW are currently piloting an interim approach to develop community-level benchmarks that relies on the existing Tier II method that utilizes extrapolation factors developed under the Great Lakes Initiative (GLI). These community-level benchmarks will conservatively approximate an Aquatic Life Criteria (ALC) value and will initially be piloted for a few pesticides.

Drift Reduction Technologies. In FY 2013, the Pesticide Program continued to work on developing 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 providing 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) using the docket identifier EPA-HQ-OPP-2012-0631. The agency revised the draft protocol and guidance document based on the comments. In early 2014, EPA plans to publish another *Federal Register* Notice that the revised documents will be submitted to OMB. The focus of this test protocol is for technologies used for ground boom and aerial applications to row and field crops. Additional information is available at: http://www.epa.gov/oppfead1/cb/csb_page/updates/2012/drift-reduction.html.

Endangered Species. In April of 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 in a report entitled, ". 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.

Since receiving the NAS report, the four agencies have been working together to collectively develop shared scientific approaches that reflect the advice provided by NAS and have developed interim scientific approaches for assessing the risks of pesticides to listed species. The interim approaches for the pesticide ESA consultation process, which are based on shared

assumptions, data, analytical processes and models, will be applied collaboratively as part of EPA's Registration Review program beginning in 2014.

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 subsequent risks. The most conservative exposure estimates from these generic animals are currently used to assess risks to federally listed endangered and threatened species (referred to as "listed species"). In order to consider species-specific body weights and diets that result in more representative, less conservative estimates of pesticide exposure and risk, the EPA has compiled data on all currently listed species of mammals, birds, reptiles and amphibians. We obtained these data from USFWS and NMFS documentation describing species (e.g., recovery plans, critical habitat descriptions) as well as published scientific literature. We have entered species specific parameters into our current exposure models (T-REX and KABAM) to allow our scientists to calculate risk quotients for individual listed species of mammals, birds, reptiles and amphibians. 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. In addition, species specific information are being captured in a database that is designed to house biological and geographic data on all listed species (including terrestrial animals as well as aquatic animals and plants). This database will allow users to search for species based on their characteristics.

In 2013, data entry was completed for all listed terrestrial birds, mammals, amphibians, and reptiles following a strict and formal review process. Additional information including identification of federal lands with listed species and primary constituent elements associated with designated critical habitat was also gathered. A number of database functions were added or enhanced in 2013 including searching and reporting functionalities in addition to document storage capabilities. Reports were completed that summarize biological data necessary for making pesticide effects determinations for listed mammals, birds, reptiles, and amphibians. Biological characteristics necessary for making pesticide effects determinations were identified for listed plants and aquatic organisms as well. Data collection has begun for listed plant species and will soon begin for listed aquatic species.

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 2013 we succeeded in running a pilot version of SAM for the Ohio River basin, simulating water flow and pesticide concentrations over a range of water body sizes for both reservoirs and streams/ivers. Model results are being compared with USGS streamgage stations (for hydrology) and intensive pesticide monitoring data in order to improve the model components. Based on the pilot results, a remote server, cloud, or similar options for data storage, analysis, and model processing will be necessary to run the model on a national scale. Model users would connect with SAM remotely from their desktops. We plan to engage end users, risk managers, and other interested parties as we develop and implement SAM for national scale modeling.

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 exceed the level of risk concern, the ability to refine the assessment is limited. In 2004, we initiated evaluation of advanced methods for estimating pesticide concentrations in groundwater as part of the cumulative risk assessment of carbamate pesticides. Similarly in 2004, Health Canada's Pest Management Regulatory Agency (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 as part of the North American Free Trade Agreement (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. Concurrently we are phasing in implementation of PRZM-GW. During 2013, PRZM-GW and SCI-GROW results were compiled. This information will be evaluated as part of the final implementation of PRZM-GW, and the results will be reported at an Exposure Modeling Public Meeting in 2014. 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 fiscal year 2013, the ROCKS held four meetings on four 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 nineteen times to peer review risk assessments that will undergo public comment.

Integrated Approaches to Testing and Assessment. Agency scientists continue to participate in the NAFTA Joint Integrated Approach to Testing and Assessment (IATA) Projects on computational tools such as Quantitative Structure-Activity Relationship models ((Q)SAR) and MetaPath. Included in this NAFTA project is the development of a guidance document for use of (Q)SAR in pesticide risk assessments. This is an on-going project that includes collaboration between the EPA, Canada's Pest Management Regulatory Agency (PMRA), and the Food and Drug Administration (FDA). Efforts continued within the Organization for Economic and Cooperative Development (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 DER Composer. The Pesticide Program is using the composer for rat and livestock metabolism studies. Current international collaborators include: Health Canada, PMRA, the European Food Safety Authority (EFSA), the Australian Pesticides and Veterinary Medicines Authority (APVMA), France, and Germany. In addition, the OECD initiated a project on Adverse Outcome Pathways (AOP), a conceptual framework designed to portray causal and predictive linkages between molecular-cellular disruption (initiation of a toxicity or disease pathway) and adverse outcomes of regulatory significance in individuals or populations.

International Collaboration for 21st Century Toxicology and Exposure Assessment. Consistent with National Academy of Sciences reviews, and in collaboration with national and international bodies, the agency worked to develop and implement 21st 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 2013, advancements were made in the completion of guiding principles for data requirements; waiver guidance for inhalation, dermal, neurotoxicity, and immunotoxicity studies; and in alternative testing for skin irritation (See <http://www.epa.gov/pesticides/science/guidelines.htm>). The international community has made great strides towards 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 2014, we will be working with OECD, WHO, and ICCVAM to continue progress on

such an integrated testing strategy for skin sensitization. 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. 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 the implementation of 21st 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. These data and models are expected to become available for review in FY2014 and will be used directly for the pyrethroid risk assessment. However, the overall approach and associated lessons learned can be used as a foundation for similar 21st century approaches for more classes of chemicals.

Hazard and Science Policy Committee (HASPOC). As the central forum to address science, policy, hazard data waivers, and risk deliberation and coordination issues of central importance to OPP, 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 21st century -- moving towards smarter testing strategies by waiving toxicity studies that do not provide useful information. In 2013, HASPOC reviewed data waivers for a variety of toxicity studies, primarily for the immunotoxicity, acute and subchronic neurotoxicity, and subchronic inhalation toxicity studies. Waivers were granted for 232 of 322 requests resulting in the saving of over 15,000 animals and over \$20 million in the cost of conducting the studies.

Crop Grouping Work. The EPA and PMRA approved two tropical fruit groups with over 250 commodities. In addition, work continues with the American Herbal Association, the American Spice Trade Association and other groups on updating the Herb and Spice crop group in 2014. This update is expected to greatly expand the number of herbs and spices that are included in this crop group and facilitate international harmonization and trade for these important products.

Dietary Exposure Assessment. The EPA released an updated version of the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID)/Calendex software, which replaces 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/>.

As an additional move to increase the transparency and public availability of dietary exposure software, the data used by DEEM were made available on the website of the University of Maryland's Joint Institute of Food Safety and Nutrition (JIFSAN) at <http://fcid.foodrisk.org>. With the release of the updated version of DEEM-FCID/Calendex software, the JIFSAN website also makes available the 2003-2008 FCID raw data files that were incorporated into DEEM-FCID/Calendex. In addition, JIFSAN developed and posted several online applications to facilitate public access to and interpretation of information from the raw data, including a consumption calculator that considerably simplifies the use of the data for routine food and food commodity consumption queries. A 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. Efforts to make these files more publically available, transparent, and considerably easier to use were funded by the U.S. Department of Agriculture and the U.S. Food and Drug Administration.

Updated *Transfer Coefficient (TC)* Policy. We updated the policy that provides a systematic basis for evaluating the risks associated with hand labor activities for all major commercial crops. It also identifies activities that do not require assessments because their exposure potential is deemed to be negligible (e.g., operation of a mechanical combine for grain harvest). This guidance represents the culmination of a 25-year effort that a 1992 Data Call-In, guideline development, collaboration with the Agricultural Re-Entry Task Force (ARTF) and other regulatory agencies (e.g., Cal-DPR and PMRA), and a consultation with the FIFRA Scientific Advisory Panel.

Revised Residential 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. 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.

Updated *Unit Exposure (UE)* Surrogate Table. Continuing a multi-year effort, OPP updated elements of the unit exposure surrogate table, a quick reference guide that presents the current recommended unit exposures for standard agency occupational pesticide handler exposure scenarios. This surrogate reference table continues to be updated 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.

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. Although the Office of Pesticide Programs coordinates the OECD Test Guideline efforts, several EPA offices participate, as well as 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 continued to lead in collaboration on global joint review activities for new conventional pesticides. In addition to tackling a larger portion of the primary reviews for several large submissions, OPP prepared documents to support the international residues of concern discussion through the agency's Residues of Concern Knowledge-Based Subcommittee (ROCKS) of the RARC. For each of the global reviews, we shared documentation and proposed decisions with international partners and considered their perspectives in preparing the final decision. Without this leadership, decisions would have to be made by individual teams on a per-chemical basis. In addition to the ROCKS committee, international partners were invited to participate in numerous peer review committees, including ChemSAC, ToxSAC, RARC, and CARC. The agency has taken a leadership role by providing draft documents for review, ultimately resulting in better support for proposed decisions, including buy-in from global partners.

Global Harmonization Work. OPP worked closely with the OECD's Residue Expert Working Group (REWG) and others on issues associated with translation of field trial data across application rates to estimate internationally harmonized MRLs. Issues associated with adjusting field trial residues by application rate were resolved in the REWG and forwarded to, discussed in, and agreed to in principle by Codex. The work does "double-duty" in that it completes one component of the joint US-Canada Regulatory Cooperation Counsel (RCC) agreements. The advancement of this "proportionality principle" completes an effort that was originally conceived more than a decade ago and is expected to result in broader international acceptance of field trials. It is designed to complement an effort beginning in earnest in 2014 that will attempt to evaluate the importance of global zones in determining pesticide residues and the extent to which field trials can be exchanged among regions.

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. The HHBPs were developed jointly by OPP and OW under Administrator Jackson's new drinking water strategy 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.