# Process Improvements in the Pesticide Program

## Science Review Improvements

### OPP Science Policy Council

The EPA continues to improve the scientific basis of its review of and decision-making on applications. In June 2009, the agency established the Office of Pesticide Programs (OPP) Science Policy Council. The purpose of the council is to enhance the consistent use of the best available science in regulatory decisions and policies by providing a central forum that assists in identifying critical issues in pesticide safety, formulating solutions, and in transitioning new science, methodologies, and policies into the Pesticide Program. The Council focuses on cross-cutting science issues relevant across the program. The key functions of the Council are anticipating and proactively addressing emerging issues, establishing research priorities, and transitioning new science policies and methods into its processes.

In FY 2011, SciPoc provided input to the EPA's Office of Research and Development's (ORD) new integrated transdisciplinary research program called "Chemical Safety for Sustainability (CSS)" to ensure that the Pesticide Program's priorities were addressed. The CSS focuses on developing scientific knowledge, tools, and models needed to improve chemical safety information that can be used in risk assessments, and includes a systems approach to implementing the 2007 National Research Council (NRC) report recommendations on Toxicity Testing in the 21st Century. CSS began to be implemented in October 2011.

The SciPoc assisted with the development and review of materials for the May 24-26, 2011, FIFRA Scientific Review Panel (SAP) meeting on "Integrated Approaches to Testing and Assessment strategies (IATA): Use of New Computational and Molecular Tools". OPP is committed to improving and transforming its approaches to pesticide risk assessment and management via enhanced integrated approaches to testing and assessment. OPP plans to build on an established foundation of using a variety of tools in a tiered testing and assessment framework by systematically adding new tools, methodologies. The SAP's input was requested on plans to maximize the use of existing data on chemicals and similar groups of compounds, including the use of information from new computational and *in vitro* predictive models of toxicity to target the *in vivo* toxicity testing that is necessary to assess and manage chemical risks appropriately. The Panel agreed that the agency clearly articulated a sound scientific basis for utilizing the National Research Council's (2007) recommendations regarding "21st Century Toxicity Testing" in a manner that makes the risk assessment process more efficient and informative. They commented favorably on the agency's proposed use of the AOP (adverse outcome pathway) methodology to support its vision for employing IATA (Integrated Approaches to Testing and Assessment) strategies. The SAP's detailed recommendations can be found at: http://www.epa.gov/scipoly/sap/meetings/2011/may/052411minutes.pdf.

Integrated approaches to testing and assessment not only incorporate understanding chemical properties and toxicity but also exposure. Exposure and biomonitoring were crucial components of the 2007 NRC 21st Century vision. To help promote a dialogue on the role, need and future of biomonitoring, a workgroup of the Pesticide Program Dialogue Committee held a one day public meeting on October 11, 2011, at Potomac Yards, Arlington, VA on "Diagnostic Tools &

Biomarkers in Pesticide Medical Management, Exposure Surveillance, and Epidemiologic Research: State-of-the-Science, Challenges, and Opportunities". There was general agreement that a better understanding of exposure and advancing biomarker research/tools was an important aspect of the National Research Council's (2007) recommendations regarding "21st Century Toxicity Testing". Additional information may be found on http://epa.gov/pesticides/ppdc/testing/2011/october/october2011.html .

## Ecological Risk Assessments

The agency continued to improve its review and communication of ecotoxicity studies through the following efforts: joint review/work sharing of study reviews with other countries; harmonization of ecotoxicity endpoints with other EPA programs; verification of drift reduction technologies; development of new models; training, outreach activities, and development of risk assessment approaches for pollinators; development of harmonized field studies with OECD; and publication of peer-reviewed ecotoxicity values. Examples of these improvements include the following:

**OECD Activities.** In March 2011, the EPA participated in the Organization for Economic Cooperation and Development (OECD) Workshop on the Development of Harmonized International Guidance for Pesticide Terrestrial Field Dissipation Studies and a Crosswalk of North American and European Eco-regions. The purpose of the workshop was to solicit OECD country experts' input on issues related to harmonizing guidance for pesticide terrestrial field dissipation (TFD) studies and for constructing an eco-region crosswalk. The crosswalk objective included: 1) identifying similar eco-regions between North America and Europe, 2) providing a GIS-based decision support system to assist in the selection of regions for field study sites, and 3) providing background information on pesticide use areas (crop-based) soils and climate. An international harmonized TFD guidance document and an eco-region crosswalk tool will help European Union and North American countries satisfy the data requirements for both regions.

This project started in 2009 and has been carried out by an ad hoc Project Expert Group, co-led by Canada and the U.S., and also comprising representatives of Australia, the Netherlands, the EC, and EFSA. This project is part of the OECD Pesticide Programme and more specifically falls under the activities of the Registration Steering Group, which aims at encouraging work sharing among pesticide regulatory agencies and promoting harmonization in OECD countries and beyond. Both the guidance and the crosswalk, which will maximize the use of pesticide TFD studies, will eventually be available to regulatory agencies of all OECD and other countries, as well as to industry and other stakeholders.

The EPA Pesticide Program is also a member and co-chair of the newly formed OECD Pesticide Effects on Insect Pollinators (PEIP) sub-group of the Pollinator Expert Group. This sub-group is examining the extent to which pesticides and other factors may be contributing to the phenomenon referred to as Colony Collapse Disorder (CCD) and pollinator declines in general. It provides early alerts about beekill incidents and on key research findings to regulatory authorities. PEIP is intended 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 2011, scoping documents were prepared for each of the four themes, surveys were conducted, and an interim report on the results of the survey was submitted to OECD. Additionally, work on identifying a potential mechanism (i.e., pollinator portal) for sharing information among the regulatory authorities has begun.

**Pollinator Issues.** The EPA Pesticide Program continued to reach out and to meet with stakeholders who are involved in pollinator issues. These stakeholders included representatives of the National Honey Bee Advisory board (NHBAB), pesticide registrants, academic researchers, industry, environmental groups, beekeepers, and officials from other federal and state government agencies and offices in the EPA. EPA staff also participated in several seminars, conferences, and scientific meetings concerned with pollinator issues this year.

In January 2011, the program participated in a Society of Environmental Toxicology and Chemistry (SETAC) Global Pellston workshop, which was designed to identify test methods for measuring exposure and toxic effects of systemic and non-systemic pesticides to pollinators and to identify a risk assessment process for pollinators. After the workshop was held, the EPA developed interim guidance for determining what studies should be considered for measuring potential exposure and effects to pollinator species. The EPA's Pesticide Program will propose a quantitative risk assessment process and exposure and effects data needed to inform that process to a FIFRA Scientific Advisory Panel (SAP) in the summer of 2012.

**Dermal Exposure to Birds, Mammals, Reptiles, and Amphibians.** Currently, the EPA is developing a model (Dermal Uptake Screening Tool (DUST)) to estimate exposure to birds, mammals, reptiles, and amphibians through the dermal route. DUST compares a ratio of exposure to toxicity and then compares this ratio to a limit of concern to determine if dermal exposure warrants further exploration. After the model is finalized, it will be used as a qualitative tool to screen out pesticides that are not of concern when considering exposure through the dermal route.

**Aquatic Life Benchmarks.** In response to requests from FIFRA state lead agencies and state water quality agencies, the EPA published "benchmark" values for pesticides that can be used to interpret monitoring data and to identify and prioritize sites for further monitoring. The benchmarks, which are based on the most sensitive aquatic toxicity data used by the EPA in evaluating risks of pesticides to aquatic organisms, are estimates of the concentrations below which pesticides are not expected to harm aquatic life. The agency has posted benchmark values for pesticides on its Aquatic Life Benchmark website and has developed a public docket for easier access to the full ecological risk assessments for these pesticides. An additional 94 chemicals were added in 2011, bringing the total number of aquatic life benchmarks to 336.

These benchmarks have been used by federal agencies, states, and others in interpreting monitoring data and in planning future monitoring efforts. The agency plans to update the webpage and accompanying docket annually and to add to the number of chemicals represented. Information concerning these benchmarks can be found at the following website: http://www.epa.gov/oppfead1/cb/csb_page/updates/2007/aquatic-life.htm.

**OPP/OW Harmonization of Aquatic Life Assessments.** In response to concerns raised by states and other stakeholders, the EPA's Office of Pesticide Programs (OPP) together with the Office of Water (OW) and the Office of Research and Development (ORD) developed documents that describe their initial thinking on a harmonized approach between OPP and OW for assessing the effects of pesticides on aquatic organisms. In FY 2010, the three offices held six regional stakeholder meetings and one national stakeholders meeting to solicit input from the public regarding methods, tools, and approaches for developing a consistent and common set of effects characterization methods for both programs.

In 2011, ORD conducted analyses on the various tools under consideration by OW and OPP to supplement existing data used in characterizing effects on aquatic organisms/communities, and the three offices collaborated to develop a white paper on the status of these tools in addressing data needs. To facilitate this effort, OPP and OW developed complementary guidance on the use of open literature studies in ecological risk assessments. OPP also conducted a quality assurance review of acute and chronic toxicity data used in the ORD analyses.

In 2012, the three offices will ask the FIFRA Scientific Advisory Panel to provide advice on several proposed tools and methods to characterize the toxicity and effects of chemical stressors on aquatic animals and plants:

1. Use of Predictive Toxicity Tools in Characterizing Effects of Chemical Stressors to Aquatic Animals
2. Use of Assessment Factors (AF) in Characterizing Acute and Chronic Effects of Chemical Stressors on Aquatic Animals
3. Use of Species Sensitivity Distributions (SSD) in Characterizing Acute and Chronic Effects of Chemical Stressors on Aquatic Animals
4. Evaluation of Chronic Toxicity Data and the Estimation of Acute to Chronic Ratios (ACR) in Characterizing Chronic Effects of Stressors on Aquatic Animals
5. Methods for Characterizing Effects of Chemical Stressors to Aquatic Plants
6. Approaches for Characterizing Effects of Chemicals with Limited Data

Additional information about this topic is available on the following website: www.epa.gov/oppefed1/cwa_fifra_effects_methodology/index.html

**Drift Reduction Technologies.** In FY 2010, the Pesticide Program continued to work with the EPA's National Risk Management Research Laboratory (NRMRL) to identify and verify effective pesticide spray drift reduction technologies (DRT). Under the Environmental and Sustainable Technology Evaluation (ESTE) program, the EPA developed a draft verification protocol. The DRT testing protocol was adapted from standard test methods and regulatory methods used in other countries and describes the testing approach that will be used to generate

high-quality, peer-reviewed data for DRTs, including test design and quality assurance aspects. Both low-speed and high-speed wind tunnel tests were completed this year using a reference nozzle and two test nozzles to evaluate the performance of the generic DRT testing protocol. In FY 2011, the DRT testing protocol was reviewed by the Pesticide Program's Quality Assurance Director and comments from this review were incorporated into the protocol. By 2012, the EPA plans to finalize this testing protocol based on the test results attained by the EPA and stakeholders. As a next step, the EPA intends to encourage equipment manufacturers to voluntarily use the protocol for testing their equipment. Additional information is available on the following web site: http://www.epa.gov/pesticides/factsheets/spraydrift.htm.

**Atrazine Monitoring Issues.** In April 2010, EPA scientists presented their approaches to the FIFRA Scientific Advisory Panel for evaluating water sampling strategies and frequency of monitoring and statistical evaluation of sampling performance for estimating maximum concentrations of atrazine of different durations. They also presented the agency's artificial neural network modeling of atrazine occurrence patterns. In July 2011, EPA scientists built on the scientific analyses and SAP feedback from the previous SAP meetings and participated in a FIFRA SAP meeting to consider and review statistical and modeling approaches for evaluating monitoring frequency in community water systems (CWS). The agency presented scientific analyses on an empirical approach for estimating internal dosimetry and calculation of benchmark dose estimates for purposes of deriving points of departure. In addition, the EPA presented a general strategy for designing a monitoring study to characterize drinking water exposures and discussed different methods for analyzing and interpreting monitoring data collected at different sampling frequencies. The agency will use feedback received from the SAP at the July 2011 meeting as it completes the scientific analysis for determining whether or not adjustments may be necessary in the sampling frequency of CWS monitoring.

**Endangered Species.** In March 2011, the EPA, USDA, and the Departments of Commerce and Interior formally requested the National Research Council (NRC) of the National Academy of Sciences to convene a committee of independent experts to review scientific and technical issues that have risen as the EPA has tried to meet its respective responsibilities under the Endangered Species Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The scientific and technical topics on which the EPA and other federal agencies are seeking advice pertain to the approaches used by the EPA, the Fish and Wildlife Service (FWS), and the National Marine Fisheries Service (NMFS) in assessing the effects of proposed FIFRA actions on endangered species and their habitats. These topics include the identification of best available scientific data and information; consideration of sub-lethal, indirect, and cumulative effects; the effects of chemical mixtures and inert ingredients; the use of models to assist in analyzing the effects of pesticide use; incorporating uncertainties into the evaluation of effects; and the use of geospatial information and datasets that can be employed by the EPA and the Services in the course of their assessments.

On November 3, 2011, the NRC committee held their first public meeting to begin their study on scientific and technical issues related to the methods and assumptions used by the EPA, FWS, and NMFS in their pesticide scientific assessments of endangered species. Experts from the EPA, NMFS, FWS, and USDA each presented their perspectives on the topics and issues that are to be deliberated by the committee. The agency's presentation described the recent NMFS Biological Opinions as examples of how each issue was considered by the Services.

Representatives from the Services discussed each of the topics generally, but focused on recent NMFS funded research on Pacific salmonids, including a study on the inhibition of chemical alarm signals by copper and data on mixtures of organophosphate and carbamate pesticides and their inhibition of olfactory response of salmonids. The USDA presentation focused on the availability of geospatial data and models that could be used to refine estimates of actual specific crop acreage and pesticide use rates, as well as the availability of data and information on temporal and spatial trends in disease/pest patterns and occurrence. The USDA also expressed concern that these models were not being used to refine estimates of pesticide application in the consultation process. The NRC committee will hold approximately four more meetings (at least one of those being a public meeting) during the 18-month study, which will culminate in recommendations concerning scientific principles and techniques the agencies might apply or use to improve methods and support decision-making.

**Use of Geospatial Tools and Information.** In FY 2011, the EPA continued its efforts to develop and incorporate spatial tools in its aquatic risk and exposure assessments that will enable the agency to better identify specific geographic areas where risks may occur. In particular, the agency continued to develop datasets and tools from the national-level SSURGO (Soil Survey Geographic) soils data, the 2006 NLCD (National Land Cover Database), and the NHD (National Hydrography Dataset) for use in exposure assessments. In addition, the agency has begun exploring the use of more spatially-detailed Cropland Data Layers (from USDA National Agricultural Statistics Service) to better characterize the extent of pesticide use areas. The EPA has made progress in acquiring and developing tools that that can be used to better identify drinking water sources and species habitats that are potentially the most vulnerable to pesticide impacts. The EPA plans to expand the use of these tools and data for human health (drinking water) and endangered species assessments in 2012.

## 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 2011, the ROCKS held 15 meetings on 15 chemicals, in addition to two training sessions for new committee members. The Dose Adequacy Review Team (DART) reviewed study protocols submitted by various registrants for 22 chemicals. The Cancer Assessment Review Committee (CARC) met ten times on numerous chemicals, and the Toxicology Science Advisory Council (ToxSAC) met 15 times to discuss and determine end-points of concern. The Risk Assessment Review Committee (RARC) met eight 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 which includes collaboration between the EPA, Canada's Pest Management Regulatory Agency (PMRA), and the Food and Drug Administration (FDA). Efforts continued within the 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 composer is being used by the Pesticide Program 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 May 2011, the Pesticide Program consulted the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on Integrated Approaches to Testing and Assessment strategies (IATA): Use of New Computational and Molecular Tools.

**Global Review Process Efficiency.** Agency scientists collaborated to increase the efficiency and consistency in the global review process, through development of 1) the checklist for global review teams that addresses pre-submission discussions with global partners, as well as up-front planning on handling of science reviews, 2) suggested file nomenclature systems for incoming data submissions to facilitate easier processing and access to data, 3) a way to provide study classifications consistent with those of our global partners, and 4) an overview of consistency issues addressed by staff in the Health Effect Division in evaluating a major new class of fungicides (carboxamides). The Division also improved outreach to global review partners by inviting them to participate in more peer review meetings to review residues of concern, interim disciplinary chapters, and draft risk assessments. It also began a conversation with its global partners on guidance and agreement on inputs for the OECD calculator, which will lead to a smoother, more consistent process for MRL (maximum residue level) setting.

**OECD MRL Calculator.** The pesticides program is a key member of the Organization for Economic Cooperation and Development (OECD) Maximum Residue Limit (MRL) Workgroup, which developed a statistically based approach for calculating MRLs based on residue concentrations from supervised field trials. This process has been fairly automated and implemented in spreadsheet form. The spreadsheet incorporates some policy decisions, such as how to set MRLs when there are significant number of censored values and how MRL calculations should be rounded. The OECD Workgroup performed various tests and simulations to quantify the calculator's performance under various policy options to help elucidate the implications of these policy decisions. The result of this Workgroup's effort is an internationally harmonized approach to calculating MRLs by means of a spreadsheet that is relatively simple to use. The OECD MRL calculator will improve the global review process for establishing MRLs for new uses.

**New Occupational Pesticide Exposure Data.** In an effort to increase transparency, the EPA has recently developed two new web pages that contain technical information and the most current guidance for assessing pesticide exposure for workers who work with pesticides or where they have recently been applied. This information is intended for anyone conducting occupational pesticide exposure assessments. Updated information includes the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table," September 2011, and the "Science Advisory Council for Exposure (ExpoSAC) Policy 3," June 2011, that describes the agency's use of Agricultural Re-entry Task Force transfer coefficient data to assess occupational post-application pesticide exposure. The information on occupational pesticide handlers can be found at http://www.epa.gov/pesticides/science/handler-exposure-data.html, while the information on occupational pesticide post-application exposure data can be found at http://www.epa.gov/pesticides/science/post-app-exposure-data.html .

**Updated Food Commodity Intake Database (FCID) and Recipes for Dietary Exposure.** The EPA updated the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID) to include more recent food commodity consumption data and recipes derived from the National Health and Nutrition Examination Survey /"What We Eat in America Survey" for 2003-2006 in place of the USDA Continuing Survey of Food Intake by Individuals, 1994-96/1998 data that is currently used in dietary assessments. DEEM-FCID is a dietary exposure analysis system for performing chronic and acute exposure assessments. The food commodity and recipe database is available on the US FDA/University of Maryland's Joint Institute for Food Safety and Applied Nutrition's (JIFSAN) foodrisk.org website, and can be freely and publicly available to any interested party or stakeholder. The updated database has been written to provide a user -friendly "point and click" graphical user interface, which can be used and understood by virtually anyone. All the background information (e.g., statistical survey weights, strata, etc.) is also available "underneath" in the form of MS Access files such that those with a statistical background and appropriate statistical software can take full advantage of the data and perform deeper, more technically complex and appropriate analyses.