ATTACHMENT 1: Overview of Various Public Participation Processes Employed by OPP

Six-Phase Public Participation Process for Tolerance Reassessment and Reregistration

Pre-Phase 1 - Stakeholder and Government Agency Engagement; Develop Updated Use/Usage Information. A significant focus is to engage stakeholders as early as possible so risk assessments reflect actual use and usage, available data, current labeling, and other information stakeholders can provide. About a year before Phase 1, OPP begins sharing use/usage information about a pesticide (noting what updated information would be valuable) with USDA, other Federal, State, and Tribal government agencies, and key stakeholders. To initiate Pre-Phase 1, EPA, USDA, and other Federal agencies may organize a meeting or meetings with key stakeholders to discuss use and usage. Within 60 days, OPP provides a summary of current use/usage for sites to be included in the risk assessments. Updated summary information contributed by stakeholders is compiled and also made publically available (via the Internet) to encourage further discussion.

Phase 1 (30 days) - Registrant "Error Only" Review. OPP sends human health and ecological risk assessments to the technical registrant(s) of the pesticide for a 30-day error correction review, asking them to identify and correct any computational or other errors. Soon after, OPP sends risk assessments to USDA/other Federal agencies as appropriate for their review and comment.

Phase 2 (up to 30 days) - OPP Considers Registrants' Comments. OPP considers errors identified by the registrant(s) and corrects the errors as appropriate. OPP considers USDA's and other Federal agencies' comments, and transmits an overview summarizing the risk assessments to the agencies. OPP completes the risk assessments for public release.

Phase 3 (60 to 90 days) - Public Comment on Risk Assessments and Risk Characterization. OPP publishes a Federal Register (FR) notice announcing availability of the risk assessments and related documents from the public docket and EPA's website, and opening a 60- to 90-day comment period. Federal, State and Tribal agencies engage stakeholders in dialogue on risk assessment/characterization.

Phase 4 (up to 90 days) - OPP Revises Risk Assessments, Develops Preliminary Risk Reduction Options. OPP considers public comments received during Phase 3, revises the risk assessments, and develops preliminary risk reduction options. OPP may prepare and release an initial benefits characterization, and may consult with CDC on public health benefits, as needed. EPA briefs other Federal agencies, and States and Tribes (often through a regulatory partners conference call); and participates in USDA-led stakeholder conference calls. OPP and USDA may host a Technical Briefing and/or stakeholder meetings to discuss the revised risk assessments and initial risk reduction options. The Federal agencies may begin a dialogue with stakeholders on benefits and transition.

Phase 5 (60 days) - Public Comment on Risk Reduction. OPP publishes an FR notice announcing availability of the revised risk assessments and response to comments. OPP also

releases and invites public comment during the next 60 days on preliminary risk reduction options, a qualitative impact discussion (when OPP has identified risks of concern), and a discussion of any potential transition issues. The public is encouraged to suggest risk management proposals. Federal agencies begin a dialogue with stakeholders on risk reduction and risk management.

Phase 6 (up to 60 days) - OPP Develops Final Risk Management. OPP considers comments and risk management ideas submitted during Phase 5. With input from other agencies and stakeholders, OPP develops a risk management decision. OPP releases the decision, including a benefits discussion/assessments as needed. USDA may prepare a transition strategy, if needed.

Modified, Four-Phase Public Participation Process for Tolerance Reassessment and Reregistration

Pre-Phase 1 - Stakeholder and Government Agency Engagement; Develop Updated Use/Usage Information. A significant focus is to engage stakeholders as early as possible so risk assessments reflect actual use and usage, available data, current labeling, and other information stakeholders can provide. About a year before Phase 1, OPP begins sharing use/usage information about a pesticide (noting what updated information would be valuable) with USDA, other Federal, State, and Tribal government agencies, and key stakeholders. To initiate Pre-Phase 1, OPP, USDA, and other Federal agencies may organize a meeting or meetings with key stakeholders to discuss use and usage. Within 60 days, OPP provides a summary of current use/usage for sites to be included in the risk assessments. Updated summary information contributed by stakeholders is compiled and also made publically available (via the Internet) to encourage further discussion.

Phase 1 (30 days) - Registrant "Error Only" Review. OPP sends human health and ecological risk assessments to the technical registrant(s) of the pesticide for a 30-day error correction review, asking them to identify and correct any computational or other errors. Soon after, OPP sends risk assessments to USDA/other Federal agencies as appropriate for their review and comment.

Phase 2 (30 to 60 days) - OPP Considers Registrants' Comments on Risk Assessments; Develops Preliminary Risk Reduction Options. OPP considers errors identified by the registrant(s) and corrects the errors as appropriate. OPP considers USDA's and other Federal agencies' comments, and transmits an overview summarizing the risk assessments to the agencies. OPP completes the risk assessments for public release. Because only nominal risk mitigation is needed for the pesticide, OPP also develops preliminary risk reduction options, making an effort to consult with stakeholders and other agencies. This consultation will continue through Phase 4.

Phase 3 (60 to 90 days) - Public Comment on Risk Assessments and Preliminary Risk Reduction Options. OPP publishes a Federal Register notice announcing availability of the risk assessments and preliminary risk reduction options for public comment. OPP continues significant efforts to consult with other government agencies and stakeholders on the pesticide's uses and possible risk management options.

Phase 4 (up to 90 days) - OPP Develops Final Risk Assessments and Risk Management. OPP considers public comments and risk management ideas and proposals received during Phase 3, continues the ongoing dialogue with other agencies and stakeholders as needed, and develops a risk management decision, which the Agency issues for public comment.

One-Phase or Low Risk Public Participation Process for Tolerance Reassessment and Reregistration

If OPP's initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, and/or poses low risk and requires little or no risk mitigation, neither the full six-phase nor the modified four-phase process is needed. Therefore, the Agency prepares a decision document for the pesticide, concluding the review process. OPP issues this decision document, the risk assessments, and related documents for public comment.

ATTACHMENT 2: Examples of Pesticide Risk Management Decisions Based on Risks to Subpopulations, Usually Children

Chemical	Nature of Risk	Description of Mitigation
Acephate	Residential/turf, including infants and children	Deleted uses and established longer Pre-Harvest Interval for sod
Atrazine	Drinking water and residential	Set-up water monitoring program with cancellation clause, changed formulation and application rates
Carbaryl	Residential/turf	Reduced maximum active ingredient in product, changed formulation and application rates
Chlorpyrifos	Residential, including infants and children	Canceled all termiticide and residential uses
Chromated copper arsenate	Residential	Canceled all residential uses
Cyhexatin	Dietary, children (from imported food commodities)	Revoking almost all tolerances
Diazinon	Residential, including infants and children	Canceled all residential uses
Dimethoate	Dietary, including infants and children	Canceled certain food uses and revoking certain tolerances
Disulfoton	Residential, including infants and children	Limited % active ingredient, deleted uses, required child resistant packaging
Endosulfan	Food and drinking water concerns	Deleted certain uses and revoking certain tolerances
Fenarimol,	Residential, including infants and children	Deleted uses
Formetanate HCL	Dietary	Deleted uses, reduced application rates, and revoking and lowering certain tolerances
Thiophanate-methyl	Residential turf, children	Reduced application rates
Thiram	Residential turf and dietary risk, infants and children	Deleted certain uses and revoking certain tolerances

ATTACHMENT 3: Highlights of OPP and ORD's Recent Collaboration, Including Research on Subgroups (Efforts to date)

Table 1: Key Contributions of ORD's Methods, Models or Data to Human Health Risk Assessments (1999-2005) - Data Submitted to OMB for PART Assessment as of August 3, 2005

Source	Risk Assessment	LTG	Risk Assessment Issue
FIFRA SAP 2004 & 2005	N-Methyl Carbamate Cumulative Risk Assessment: Strategies and Methodologies for Exposure Assessment	Agg/Cum	ORD data used to develop empirical approaches to develop relative potency factors using blood and brain Ch-E inhibition data from rat toxicology studies-addresses default additivity assumption for mixtures; Applies to the risk assessment of 10 N-carbamate pesticides. ORD provided data on time course and dose response profiles for seven of the N-methyl carbamates; these data were used to estimate benchmark doses and relative potency factors in the risk assessment. ORD conducted two mixture studies on the N-methyl carbamates to determine if dose-additive model was appropriate for calculation of cumulative risk. ORD presented a novel PBPK-based method for assessing cumulative exposures. ORD scientists provided technical support and critical skills for the SAB review
FIFRA SAP	Dimethoate: Issues Related to the Hazard and Dose Response Assessment	Mechanistic Information	ORD methods, models or data used to analyze pup mortality data and dose-response for acetylcholine esterase inhibition
FIFRA SAP	Malathion: Issues Related to the Hazard and Dose Response Assessment	Mechanistic Information	ORD methods and models used to analyze acetylcholine esterase inhibition dose-response. See additional information below.
FIFRA SAP	Probablistic exposure and risk assessment for children who contact CAA-treated wood on playsets and decks and CCA-containing soil around these structure	Susceptible Subpop-ulations	ORD developed probablistic exposure model for children. OPPTS used the model to determine the potential short-term, intermediate, and lifetime cancer risks for children in the US. See additional information below on SHEDS-Wood.
FIFRA SAP 2002 2001	Organophosphate pesticides: OP Cumulative Risk Assessment	Agg/Cum	ORD provided PK data in support of additivity default assumption in cumulative risk determination ORD provided model to determine OP dose-response effects, addresses default assumption of additivity. See additional information below on SHEDs-Chlorpyrifos

FIFRA SAP 2000	Atrazine Risk Assessment	Mechanistic Information	ORD data demonstrated that mechanism that produced turmors in rats is not relevant to humans and that the evidence did not support classifying atrazine as a likely human carcinogen. ORD publications were also used to set the acute LOAEL, the acute PAD
FIFRA SAP 2000	Common Mode of Action for Triazine Pesticides	Agg/Cum Risk	ORD research demonstrated the common MOA of action for chloroatrazine class of pesticides, which supports additivity default assumption for cumulative risk
OPP Registration 2000-2004	Risk Assessment of Chlorpyrifos	Susceptible Subpopulations	ORD research provided data to support application of 3X Safety Factor for Children. See additional information below on SHEDs-Chlorpyrifos.
OPP Registration 2000-2004	Risk Assessment of Methamidophos	Mechanistic Information	NOAEL with LOAEL obtained from ORD data, which eliminates default MF factor
OPP Registration 2000-2004	Data Call-in for Comparative Sensitivity	Susceptible Subpopulations	ORD research provided impetus for requesting comparative sensitivity data for all registered OPs. ORD scientists also provided detailed review of the registrant data on susceptibility of the young.

Table 2: Additional Research Influencing OPP Skills, Knowledge and Decision Making Activities

Research Area	Research	How Used By OPP
Frequency of mouthing behavior in young children	ORD research conducted to understand the key factors associated with estimating children's pesticide exposures from non-dietary ingestion. ORD and published collaborator data were assembled and analyzed. Data from these analyses have been published in the peer reviewed literature by Tulve, N.S., Suggs, J.C., McCurdy T., Cohen Hubal, E.A., Moya, J. "Frequency of mouthing behavior in young children" Journal of Exposure Analysis and Environmental Epidemiology 2002 12(4): 259-264.	Results of ORD analyses of data collected on children's mouthing behavior have been used by OPP to refine the default assumptions used in their exposure assessments. Data in Children's Exposure Factors Handbook.
Children's Exposure Measurement and Exposure Factors Data	ORD researchers have conducted a number of studies that have generated data on exposures to pesticides in homes and child care centers. In these studies, data has been collected to determine the most important routes of exposure and the factors that have the most significant impact on children's exposures. Data from studies such as the Children's Total Exposure to Pesticides and Other Persistent Pollutants (CTEPP) are provided directly to OPP in EPA final reports (EPA/600/R-04/193) and in peer-reviewed manuscripts (e.g., Morgan, M.K., Sheldon, L.S, Croghan, C.W., Jones, P.A., Robertson, G.L., Chuang, J.C., Wilson, N.K., and Lyu, C.W. "Exposures of preschool children to chlorpyrifos and its degradation product 3,5,6>trichloro>2>pyridinol in their everyday environments" Journal of Exposure Analysis and Environmental Epidemiology 2005 15(4):297-309).	Data from these studies fill critical data voids for children exposures and key factors influencing exposures. Data are also used to update the Children's Exposure Factors Handbooks used in the risk assessment process
NHEXAS and Minnesota Children's Study Data	ORD and it's collaborators examined human exposures (including children) to pesticides and other persistent pollutants through a variety of large-scale studies. The results of these studies were used to identify key factors associated with exposures, estimate the range of exposures for selected pollutants, and establish a framework for future studies in support of FQPA.	Data from these studies fill critical data voids for children exposures and key factors influencing exposures. Data are also used to update the Exposure Factors Handbook and the Children's Exposure Factors Handbook used in the risk assessment process
ORD STAR Studies Assessing Aggregate Exposure of Children to Pesticides	A series of NCER sponsored research projects on children's exposure to pesticides have been and continue to be conducted in Washington State, California and Minnesota. These data has been used in the development and evaluation of pesticides exposure models such as SHEDS which are used in assessing pesticide exposures by both EPA and Industry.	These data provide OPP an improved understanding of the sources and pathways of pesticide exposure among children and the factors that influence these pathways.

Research Area	Research	How Used By OPP
Children's exposures to pesticides associated normal play with household pets	ORD intramural research documented the potential for children's exposures to pesticides contained in pet flea collars through normal activities and play activities with household pets. Morgan, M. K., Stout, D. M., II; Wilson, N. K. "Feasibility study of the potential for human exposure to pet-borne diazinon residues following lawn applications." Bull. Environ. Contamin. Toxicol. **2001,** 66, 295-300. Under an EPA STAR grant, researchers have developed a protocol for measuring pesticides on pet fur using a "glove" method.	The data and protocol have been incorporated into the revised pesticide exposure guidelines for use in pesticide registration.
Methods for Estimating Pesticide Exposures to Children Occurring via Flea Control Products	Recent studies sponsored by the STAR program have provided method to determine pesticide residue concentrations on pet fur for use in estimating children's exposure occurring via the use of flea control products employed in the child's home.	These methods have been incorporated into EPA Exposure Assessment Guidelines.
Farmworker Pesticide Exposure Studies	Several ORD sponsored studies (Berkeley, UW, AHS, NAFTA, etc.) have conducted research to understand how farmworker family exposures to agricultural pesticides, including small children, compare with pesticide exposures for the general populations. Research has also been designed to identify the key factors influencing these exposures.	The results of these studies suggest have been used to determine if the labeling practices are sufficiently protective for these populations.
Children's Longitudinal Exposure to Pyrethoids.	The Research Triangle Institute, under a STAR Grant, has conducted a Longitudinal Study of Children's Exposure to the pyrethroid pesticide permethrin. As part of this study the investigators have developed and published a method for collecting urine samples in very young children using commercially available disposable diapers. Pyrethroids are increasingly used as replacements for organophosphates (OPs) in home pesticide applications. Collecting urine samples from very young (pre-potty trained) children has been a problem in the past. This provides a method for use in large scale studies and for use by pesticide registrants for collecting urine samples from very young children.	This methods has been incorporated in to EPA Exposure Assessment Guidelines.
The Impact of Recent EPA Mandated Restrictions on Organophosphate Pesticides Use	NCER's Center for Children's Environmental Health Research at Mount Sinai School of Medicine has provided epidemiologic evidence that the recent OPP restrictions on the use of certain OP pesticides in the home has reduced the exposure of both mothers and infants to these pesticides. *Environ Health Perspect* 112:1125-1132 (2004).	This is an important demonstration of the use of epidemiological data to evaluate the effectiveness of an environmental regulatory decision.

Research Area	Research	How Used By OPP
SHEDS Pesticide Model Application to an OP - Chlorpyrifos Case Study	ORD initiated the SHEDS-Pesticides modeling research program to address specific FQPA needs for evaluating aggregate and cumulative human exposures to OP and other pesticides. SHEDS-Pesticides improves the quantification of infants and children's exposure and dose to pesticides and provides a framework for identifying and prioritizing measurement needs under the FQPA. SHEDS-Pesticides is the only EPA probabilistic aggregate exposure model that explicitly characterizes both the variability and the uncertainty in the predicted exposure and dose estimates. The model was initially developed and tested first for a selected OP, chlorpyrifos, to identify the critical residential pathways of children's exposure to chlorpyrifos and the major uncertainties in exposures from these pathways. During subsequent refinements, OPP scientists assisted ORD in improving the methodology and the data bases of the dietary module of the SHEDS-Pesticides model.	The findings from this workshop provided future directions of both modeling and measurements research in the area of aggregate human exposure assessment.
Scientist-to-Scientist Aggregate Modeling Workshop	A scientist-to-scientist exposure model comparison workshop was co-organized by ORD and OPP and held in RTP, NC, in October 2001. The main objective of this workshop was to compare and contrast the four available (EPA and commercial) aggregate residential pesticide exposure models, including the SHEDS model, that are considered by OPP for conducting the OP aggregate and cumulative risk assessments under the FQPA.	This workshop provided OPP insights regarding the strengths and vulnerabilities of each of the various aggregate exposure models used in their risk assessment applications.

Research Area	Research	How Used By OPP
SHEDS-Wood	The FIFRA Scientific Advisory Panel (SAP) recommended OPP use probabilistic modeling for estimating children's exposure to wood preservatives from playsets and home decks (US EPA, 2001b). OPP's Antimicrobial Division contacted ORD seeking assistance in developing a probabilistic exposure and dose model for use in regulatory risk assessments for CCA. The SHEDS model for the wood preservative scenario (SHEDS-Wood) model was developed by ORD to determine the potential health risks to children from frequent contact with CCA-treated wood in playsets and home decks and CCA-contaminated soil around these structures. The methodology of SHEDS-Wood was presented to the August 30, 2002 FIFRA SAP, and comments from both the Panel and public were incorporated into the refined model and analyses that was presented to the subsequent FIFRA SAP on December 2003. In close consultation with ORD, OPP has conducted a draft risk assessment on children's risks to CCA using the results from ORD's SHEDS-Wood model.	These preliminary risk results were also presented at the December 2003 SAP meeting. OPP plans soon to complete their CCA risk assessment using the final results of ORD's exposure and dose modeling analyses (completed early in 2005).
Pyrethroid Cumulative Risk Assessment	The ORD "Safe Food Research Project", started in 2002, supports the efforts of Agency scientists to develop and evaluate innovative exposure-dose-response models for assessing cumulative risks of pyrethroid pesticides with potentially multiple modes of action commonly found in food and the residential environment. This project involves a multi-disciplinary effort which includes participation by the ORD Labs/ Centers and OPP scientists. Regular team interaction occur via monthly project calls and through collaborative research assignments. On a monthly basis, representatives from OPP participate and share technical information with the ORD study team. OPP and ORD also regularly participate in various scientific and regulatory outreach activities which involve presentations at the Pyrethroid Working Group meetings. The objective of this project is to develop an exposure-dose-response model that will allow for more well-informed decisions by the OPP, on managing the potential cumulative risks associated with exposures to pyrethroids. Technical guidance from OPP has been vital to ORD, and has been a major factor in the selection of key pyrethroids for designing the experimental animal studies and in the development of new methodologies for exposure (SHEDS-pesticides), PBPK (ERDEM) and effects modeling.	The research results will enable OPP and the Agency to have new information to be able to more accurately assess the nature and magnitude of potential risks posed to children and adults from aggregate and cumulative exposures to pyrethroid pesticides, and to formulate scientifically sound decisions in order to mitigate exposures that are of health concern.

Research Area	Research	How Used By OPP
Application of PBPK Modeling to the Risk Assessment of Malathion Used as Treatment for Head Lice in Children	ORD's PBPK model for the organophosphorus insecticide parathion-ethyl was modified to include parameters specific to malathion. Data from metabolism studies in laboratory rats were used to adjust model parameters. One of the benefits of PBPK models is the ability to extrapolate across species to humans. Separate PBPK modules were built for each age and gender within the Exposure Relating Dose Estimating Model (ERDEM). The simulations were used to predict concentrations of malathion and the toxic metabolite, malaoxon, in target tissues of interest, such as blood and brain. In the simulations, malathion must first be absorbed through the skin of the scalp after 12 hours of shampoo treatment. The rate of absorption was expected to influence formation of malaoxon, the agent of toxicity. Time course predictions were used to obtain peak values in blood and other tissues for up to 72 hours following treatment. These concentration values were reported to OPP for their analysis. PBPK modeling using ERDEM proved instructive in extrapolating information from laboratory rats to humans. Predictions of tissue concentrations of malathion and malaoxon in specified organs were readily obtained for each age group and gender. This approach holds great promise for risk assessment where there is an absence of specific human exposure data.	The results of this modeling effort will directly impact the risk assessment for the commercially available head-lice treatment (Ovide) in children. To our knowledge, this is the first time that a PBPK model has been applied to the risk assessment of a pharmacological agent. ORD modified ERDEM to assess children's exposures to malathion to support this assessment.

Research Area	Research	How Used By OPP
A PBPK Modeling Approach for Assessing Pyrethroid Exposures in Support of Cumulative Risk Assessments	Pyrethroids are among the most potent and effective insecticides available, and are applied singly or in combination in agricultural and indoor insect control. The Food Quality Protection Act (FQPA) of 1996 requires the US EPA to consider the cumulative (multi-chemical) effects of exposure to pesticides having a common mechanism of toxicity. For the risk assessment of pyrethroids, estimation of the extent of exposure and detailed knowledge of their kinetics is of prime importance. Towards this end, we have developed a physiologically-based pharmacokinetic (PBPK) model for evaluating dose resulting from residential and dietary exposures in humans. The application of PBPK models in risk assessment offers key benefits including: prediction of target dose, dose extrapolation in cases of non-linearity, and route of exposure extrapolation. In this project, studies examining the pharmacokinetics of permethrin and deltamethrin in rodents were used to derive the basic model structure. The model included skin, fat, liver, brain, and lumped tissue compartments. Physiological values were obtained from the literature. Tissue-blood partition coefficients were based on Log[Kow] and tissue composition. The model provides a systematic and quantitative framework for considering the impact of aggregate exposure routes (dermal, oral, inhalation). Human urinary excretion studies and computational methods were employed to derive parameters relevant to humans. The low coefficients of dermal permeability (Kp) of these highly lipophillic pesticides (Log[Kow]: 4.5-7) and their low volatility (Vapor Pressure: 10 -11 - 10 -7 mm Hg) suggest that the oral routes (dietary and oral non-dietary) and inhalation (aerosol) have greatest influence on target tissue dosemodel of pyrethroids.	These preliminary findings will aid in shaping the development of a innovative approach for assessing cumulative risk for a group of pesticides with potentially multiple modes of action.
Children's Exposure Factors Handbook	A key FQPA mandate was the challenge to safeguard children. Children are not small adults, and therefore research was needed to identify the critical scenarios where children are exposed to pesticides and uncertain the key factors associated with these exposures. ORD conducted numerous research activities to better understand children's exposures. ORD developed a Children's Exposure Factors Handbook reflecting the key differences in factors that influence children's exposures to pesticides and made this available for risk assessors.	The Children's Exposure Factors Handbook is used in conducting risk assessments that require consideration of children's exposures by lifestage.

	Research	How Used By OPP
Endocrine Disruptors Screening Program (EDSP)	Through enactment of the FQPA, Congress directed EPA to screen pesticides for estrogenic activity in humans using validated studies or other scientifically relevant information and gave the Agency discretionary authority to screen for other endocrine effects as well. EPA organized an independent expert advisory panel, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), composed of scientists and key stakeholders. EDSTAC recommended expanding the endocrine disruptor screening program to include wildlife, androgens and thyroid hormones and a broad universe of chemicals. EPA proposed to enact a two tier screening program based on EDSTAC's recommendations. The first tier would identify substances that have the potential to interact with the endocrine system. The second tier would provide data for risk identification and risk assessment for those substances that tested positive in the first tier. Since 1996, ORD's ED research program has been conducting research to develop protocols that could be used by OPPTS in implementation of the EDSP. ORD research is developing/ improving in vivo and in vitro assays in support of the implementation of EDSP. Particular attention is focused on refining mammalian assays for estrogen, androgen, and thyroid activity and in developing and standardizing amphibian and fish bioassays. As ORD completes the development of the scientific methods, OPPTS is putting them through a rigorous validation process which includes: a substantial review of the relevant literature and preparation of a background review document and development of an initial protocol; prevalidation, a demonstration of relevance, standardization of the protocol and preliminary estimates on transferability; validation in multiple laboratories in which relevance and reliability are demonstrated; scientific peer review; and regulatory acceptance and implementation. EPA is using another advisory committee to provide review and insights on method validation.	OPPTS is using the screening and testing assays developed by ORD - e.g., estrogen receptor binding, androgen receptor binding, steroidogenesis, aromatase, male rat pubertal, female rat pubertal, frog thyroid, fish reproduction - to create validated methods for EDSP List of assays currently undergoing validation: http://www.epa.gov/scipoly/oscpendo/assayvalidation/status.htmhttp://www.epa.gov/scipoly/oscpendo/assayvalidation/status.htm<current document>http://www.epa.gov/scipoly/oscpendo/assayvalidation/status.htm Impact on Tolerance Setting: Other endocrine disruptors research is providing valuable information for the Agency to interpret data submitted to EPA for the purposes of risk assessment and to make informed decisions about managing any unreasonable risks. This research has been used by OPP in its decision making process. For example, research that enabled OPP to characterize the mechanism of action and dose response of atrazine and vinclozolin was critical in setting tolerance levels for these two pesticides.