United States
Environmental Protection Agency

2007 Mid-Cycle Peer Review
ORD's Human Health Research Program
January 24, 2007

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Table of Contents

I. Introduction

Every 4-5 years, research programs in the Office of Research and Development (ORD) undergo an independent review of their science. On February 28-March 2, 2005, the ORD's Board of Scientific Counselors conducted an initial review of the Human Health Research Program (HHRP). The BOSC was asked to comment specifically on the Relevance, Quality and Performance of the program, i.e., the Research and Development Investment Criteria. A summary of those comments is as follows:

Relevance- The BOSC found that: 1) the overall purpose of the HHRP was clear, i.e., it addresses limitations in human health risk assessment with a focus on biological modes of toxicity, aggregate and cumulative risk, susceptible subpopulations and evaluations of public health outcomes resulting from risk management decisions; 2) the program provides broad fundamental scientific information that will improve understanding of problem-driven human health issues arising from the Agency's program and regional offices, other federal agencies, international health organizations, the regulated community, and the academic community; 3) the HHRP was designed to address specific needs identified by external advisory bodies and clients and stakeholders of the program; 4) the outputs of the program were designed to address customer needs; and 5) the HHRP was multidisciplinary and displayed good stakeholder participation in the planning of the program.

Quality- the BOSC found that the HHRP: 1) was free of major flaws that would limit the program's effectiveness or efficiency; 2) was designed so that resources address the program's purpose directly and will reach intended beneficiaries; 3) awarded grants awarded on a clear competitive process that includes a qualified assessment of merit; 4) used a prioritization process to guide budget requests and funding decisions; 5) had good multidisciplinary approaches; 5) demonstrated considerable skill in applying quantitative techniques; and 6) provided rapid response to the needs of the Agency's regulatory program while still maintaining a strong, long-term research effort.

Performance- the BOSC noted that the HHRP program: 1) had a limited number of specific measures that can demonstrate progress toward achieving the program's Long-Term Goals (LTGs) and Annual Performance Measures (APMs); 2) had in place a process of independent evaluations of sufficient scope and quality to evaluate on a regular basis the effectiveness and relevance of the program; 3) regularly collected timely and credible performance information to manage the program and improve performance; 4) was a leader in developing research to support Agency risk assessments, which has allowed the Agency to conduct credible, nationally/internationally accepted risk assessments of chemicals of environmental concerns; 5) displayed a good balance between the extramural and intramural research programs; 6) had successfully utilized its extramural grants program to advance its research agenda; and 7) demonstrated a decisive propensity within the program to encourage the mining of available data and science to inform the risk assessment decisions of stakeholders.

The BOSC also made a number of observations and recommendations concerning the

HHRP. A written response to these comments was provided and a time-line for actions to be taken or planned was discussed in a briefing to the BOSC September13, 2005.

On January 24, 2007, the BOSC will meet with ORD staff and conduct a Mid-Cycle Review of the HHRP. In this review, the BOSC will evaluate the progress of the HHRP in addressing the recommendations from the 2005 program review. This assessment will provide ORD with an opportunity to gauge the program's progress relative to the commitments it made following the 2005 review.

II. Response to the 2005 Peer Review

In the BOSC report of August, 2005, there were several comments or recommendations. These were provided in the Section entitled "Overview Comments on Human Health Program" and in sections specific to each LTG In some cases similar comments were made in more than one section and these are cross-referenced in the following response:.

Overview Comments:
Issue: Scientists within the Human Health Research Program should contribute to EU research planning (also raised for LTG 2)
ORD Response: ORD scientists attended a EU workshop in Italy in June, 2005, and met with other investigators to identify ways to integrate ORD's human health research on toxic chemicals with on-going and planned EU activities. ORD scientists participate in a number of international activities and Table 7 in the 2005 documentation package attempted to summarize these interactions. Specific research collaborations were not, however, clearly articulated. For the next review, the documentation package will include a new section documenting specific research interactions of human health scientists with international programs.

Issue: The creation of the new National Center for Computational Toxicology (NCCT) may produce challenges with regard to teamwork (also raised for LTG 1)
ORD Response: The establishment of the NCCT transferred a number of productive HHRP scientists to the computational toxicology program. In response to the concerns of the BOSC, the acting NPD for HH and the Director of NCCT meet on a quarterly basis to discuss coordination of the respective research programs. Several HH researchers have received funds from the computational toxicology center for research relevant to the themes of the HHRP and their products are captured in the revised HH MYP. In addition, projects underway by some scientists transferred from HHRP to the NCCT continue, and products from their research program are also captured in the 2006 HH MYP. Finally, as the NCCT has developed its mission and expertise, new projects (e.g., developing biologically based models of arsenic toxicity) related to current HHRP themes have evolved.

Issue: The BOSC noted that a greater level of interaction between investigators in the externally funded University Centers and in-house researchers could results in more significant research progress (also raised for LTG 1)

ORD Response: ORD recognizes the need to better coordinate intramural research with the STAR grants program. The acting National Program Director (NPD) for HH has had discussions with the Director of the National Center for Environmental Research (NCER) concerning this issue. Interaction between NCER and other ORD laboratories has increased through enhanced participation by NCER representatives on the HH Research Coordination Team (RCT), more inclusive review of new RFAs for future extramural research, review of products coming from the grants program by ORD staff, and the hosting of scientist-to-scientist meetings involving intramural and extramural scientists. NCER routinely relies on scientists from ORD laboratories to sit on internal programmatic review teams to offer advice on final funding decisions on STAR grants. NCER has also started holding "initial investigator meetings" where a newly funded set of grantees are brought together with EPA scientists to discuss their research plans; these types of meetings encourage communication between extramural and intramural researchers. Products arising from extramural research are also more integrated into the 2006 HH MYP and the relationship of those products to the intramural program has been more clearly articulated.

Issue: It was difficult to determine the full extent of intergovernmental agency collaborations between the Human Health Research Program and its allied Agencies (also raised for LTG 1)
ORD Response: ORD scientists collaborate extensively with scientists from other Federal Agencies. Although the documentation package provided for the 2005 program review attempted to capture these collaborations in the biosketches and posters, this approach greatly underestimated the extent of these interactions. For the next review, the documentation package will include a section documenting specific interactions of human health researchers with scientists from other Federal agencies.

Issue: The public benefits from doing good science needs to be better articulated (also raised for LTGs 2 and 3)
ORD Response: The public health benefits of the HHRP are now linked to performance measures developed in collaboration with OMB (see Section III for a more detailed description). In addition, the HHRP intends to place more emphasis on developing methods, models and data to assist the Agency in evaluating the effectiveness of risk management decisions. In that respect, the development of biomarkers of effect or exposure to assess changes in human health will have public health benefits. ORD notes that the public health benefits for LTG 1 Use of Mechanistic Information in Risk Assessment were clearly articulated.

Issue: Reviewers would have benefited from a bibliometric analysis of publications.
ORD Response: A bibliometric analysis of peer-reviewed papers supported by the HHRP was completed on April 18, 2005, and provided to the BOSC. For the purposes of the Mid-Cycle Review, the bibliography was updated and subjected to another analysis. A discussion of the results of these bibliometric analyses may be found in Section III "Results of the 2005 Program Assessment Rating Tool (PART)". Table 1 provides an updated frequency distribution of peer-reviewed publications by Long-Term Goal for the years 1999- October 2006. Section VII contains citations of publications from 2005 to

October, 2006.

Issue: The conceptual framework of the HHRP needs to be better articulated (also raised for LTG 3).
ORD Response: The revised HHRP MYP outlines the main objective of the program, which is to provide methods, models and data that will reduce reliance on default assumptions and uncertainties in the risk assessment process. This will be accomplished by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental agents. The main research themes of the HHRP remain the same as those from the 2005 program review (i.e., use of mechanistic data in risk assessment, cumulative risk, susceptible subpopulations, and approaches to evaluate risk management decisions). In 2005, OMB reviewed the HHRP, supported its strategic direction, and agreed that the performance measures need to focus on reducing reliance on default assumptions in the risk assessment process.

Issue: The direction of the research is too heavily influenced by external advisory bodies.
ORD Response: The process by which broad research themes (i.e., use of mechanistic information in risk assessment, cumulative risk, susceptible subpopulations, evaluating risk management decisions) are transformed into a research program was not clearly articulated during the 2005 program review. Once broad research themes have been identified by external bodies such as the NRC or SAB **and** recognized as high priority needs by the Agency, ORD relies on discussions with its clients (i.e., Program and Regional Offices) and with the scientific community to determine what research needs to be addressed from both a programmatic and a scientific point of view. Meetings are held with the Program and Regional Offices to understand their regulatory science priorities and confirm that the HHRP research is addressing these needs. Results of discussions with Program and Regional Office clients are summarized in Attachment B of the 2006 HH MYP. Emerging HHRP science needs are identified through ORD scientists attending scientific symposia, conferences, workshops, and scientist-to-scientist meetings. The programmatic and science needs are compiled and prioritized based on science and resources. Scientist-to-scientist meetings are used to develop approaches to address these questions from scientific point of view. Examples of scientist-to-scientist meetings related to the HHRP since June 2005 may be found in Table 2.

Issue: The program needs to plan for leadership succession.
ORD Response: ORD recognizes the reality of changing demographics in the near future. Individual Laboratories and Centers have developed their own approaches for dealing with this challenge. ORD has also institutionalized a postdoctoral training program with the goal of recruiting new scientists for future employment at ORD. Additionally, NCER manages the STAR Fellowship program which funds graduate level students who are studying environmental science. The disciplines of the students funded through this program are typically in line with Agency research. While not directly linked to planning for leadership succession within EPA, the STAR Fellowship program is providing funding for the training of the future generation of environmental scientists.

Interactions between STAR Fellows and EPA scientists are encouraged through annual Fellowship Conferences. Finally, NCER also manages the ASPH Fellowship program where recent graduates are placed in various fellowship assignments within EPA; the goal of the program is to provide professional training and employment for early-career public health professionals by enabling them to work in EPA on current and emerging environmental public health needs.

Long-Term Goal 1 Use of Mechanistic Information in Risk Assessment:
Issue: An area that needs to be better addressed by ORD is Office of Water's (OW) need for information on the carcinogencitiy of compounds containing hexavalent chromium when administered by the oral route.
ORD Response: This recommendation was discussed with OW members of the Human Health RCT and was not given a high priority relative to other water-related themes such as arsenic and non-carcinogenic disinfection by-products.

Issue: The extramural grants program needs to be better advertised.
ORD Response: NCER, which is responsible for the extramural Science to Achieve Results (STAR) grants program, has redesigned its Web site to provide greater access to information concerning the grants program. EPA has also provided better links to the grants program on its Web site. The newly developed Web site for the HHRP includes a major link called "Funding Opportunities". NCER has also increased the frequency of workshops to bring together extramurally funded researchers and advertise its upcoming RFAs. NCER has started conducting "initial investigator meetings" where a newly funded set of grantees are brought together with EPA scientists to discuss their research plans. NCER personnel also travel to major scientific conferences (such as the Society of Toxicology meeting and the American Public Health Association meeting) where they staff a booth in the meeting exhibition halls to provide conference attendees with information about NCER, including upcoming RFAs and Fellowship opportunities.

Issue: The HHRP Multi-Year Plan (MYP) needs to be revised.
ORD Response: A revised HH MYP was accepted by the ORD Science Council in June, 2006 (see Section IV for additional details). The 2006 MYP now serves as the road map for the HHRP for the period 2006 to 2013. Products (Annual Performance Measures) in the MYP will be updated annually and the plan will be revised in 2009. Recent scientist-to-scientist meetings (Table 2) provide the opportunity for refinement of research approaches relevant to HHRP research themes and dealing with emerging issues.

Long-Term Goal 2 Aggregate/Cumulative Risk:
Issue: The overall criteria and framework for decisions regarding why specific elements are vital and have been included in the research program were not clear.
ORD Response: ORD receives broad strategic direction from the Agency, which is influenced by external advisory bodies and pubic health concerns, and generates strategic approaches to address those broad goals. ORD scientists generate the research needed to address those concerns in collaboration with input from Program and Regional Office stakeholders. Articulation of annual products is derived from discussions by the Research Coordination Team, which includes ORD scientists and Agency stakeholders.

Issue: The BOSC suggested a broadening of the list of stakeholders (also raised in LTG 3).
ORD Response: ORD agrees that many of the research projects described at the 2005 program review were highly relevant to needs raised by the Food Quality Protection Act of 1996. Until recently, issues raised by the FQPA have been a significant driver for research in the HHRP. As a result, much of the research described at the 2005 review involved pesticides; research related to other stakeholders did not appear to have as high a priority. This impression may have been misleading because the HHRP is intended to address cross-cutting research needs of multiple stakeholders. Significant progress has been made since the 2005 program review to ensure the HHRP is a more balanced program. In preparation for this Mid-Cycle Review, ORD prepared a table (Table 3) which cross-walks on-going ORD research by stakeholder for each of our research themes. This table gives a much more inclusive picture of the current research portfolio as it relates to stakeholders other than OPPTS.

Issue: Exposure research should include a wider range of chemicals.
ORD Response: As noted earlier, issues related to the FQPA have served as a driver for much of the work in the HHRP, including our exposure research program. Exposure research does to some extent use pesticides as a class of chemicals to facilitate development and validation of models. Exposure research in the 2006 HH MYP focuses on developing more generic models that can be applied to any class of chemicals. Emerging issues related to community/ cumulative risk and evaluation of risk management decisions, as well as obtaining observational data on susceptible subpopulations, will be pertinent to all classes of chemicals.

Issue: Broad strategies need to be developed to manage exposure and risks from thousands of new chemicals.
ORD Response: ORD's NCCT is dedicated to developing computational approaches to identify and manage risks for larger numbers of new chemicals, i.e., approaches to improve prioritization for screening and testing. One of the research themes in the HHRP is linked to that effort by developing emerging methods and models that can be used for computational models. Other MYPs (Safe Pesticides/Safe Products, Drinking Water, Endocrine Disruptors) also supprt research to develop approaches for prioritization of chemicals for screening and testing relative to their specific problem-driven areas. A new research area in Long-Term Goal 2 is designed to develop and evaluate tools for identifying communities at risk from real-world cumulative exposures to chemical (mixtures) and non-chemical stressors.

Issue: There needs to be better integration between exposure and effects research.
ORD Response: ORD recognizes that some of the fundamental research in the HHRP is Laboratory or Center-specific. Research on toxicity pathways or modes of action clearly falls into that category. Multidisciplinary research projects are emphasized to a greater degree in the 2006 MYP. For example, areas such as PD/PK model development, development of biomarkers, community risk, susceptible populations, and evaluation of risk management decisions depend on multi-disciplinary integration.

Long-Term Goal 3 Susceptible Subpopulations:
Issue: Peer-review will be enhanced by providing critiques from previous reviews.
ORD Response: The ORD *Human Health Research Strategy* document was externally reviewed in 2003 by a panel of the Science Advisory Board. The HHRP program, however, had not been reviewed prior to 2005. At the next review of the HHRP, projected for fall of 2008, comments from the 2005 review, ORD's response to the review, and the results from the 2007 Mid-Cycle Review will be included. ORD Laboratories/Centers supporting human health research also have periodic scientific reviews at the Divisional and/or programmatic level. Results of those reviews are available, if requested.

Issue: The asthma research program should have regular group meetings.
ORD Response: A coordinator for asthma research (Dr. Hillel Koren) has been appointed and an asthma research team has been formed. This group now sponsors a seminar series which invites senior asthma researchers to ORD to share the latest in their research activities.

Issue: Researchers working on aging should meet with those working on children's issues.
ORD Response: As described in the 2006 MYP, ORD views research on children and aging from a life-stage perspective. Most of the scientists working on children's issue are either actively involved with research being planned and implemented to address issues for the maturing populations or they interact directly with those more specifically involved with the aging end of the life stage spectrum.

Issue: Source-to-effect research should progress to include pharmacodynamic issues.
ORD Response: As indicated in Table 3, biomarker research in LTG 2 is developing state-of-the science mathematical and statistical modeling techniques to estimate target tissue dose, individual exposure, and apportion these results to sources. Once such models have been evaluated, they will be linked to studies that focus on pharmacodynamic issues. Research on developing linkages between PK and PD models is also covered in LTG 1 where PK/PD models for pyrethroid pesticides and arsenic are being developed. The NCCT is providing leadership for the development of systems biological approaches to investigate differences in tissue response.

Issue: There is a need to expand program expertise to include community-based participatory research.
ORD Response: Much of the research supported by the STAR program includes community-based participatory research. Specifically, the Children's Environmental Health Research Center RFAs required community-based participatory research (CBPR) from the program's inception. The Children's Center investigators are considered experts in the use of CBPR in environmental health research; they have published on the subject of CBPR and have organized scientific sessions at meetings on the subject of CBPR in environmental health research. Additionally, the newly developing intramural research program related to community risk will require community-based participatory research.

The intramural program initial steps include: 1) inventorying the available tools; 2) establishing collaborations with groups conducting community-based research to gain expertise and to test these tools; and 3) revising the tools for addressing future needs.

Long-Term Goal 4 Evaluation of Public Health Outcomes:
Issue: This Long-Term Goal needs to be better focused.
ORD Response: A steering committee consisting of members from ORD's Laboratories and Centers has been formed to develop a research framework that will serve to focus work on approaches to evaluate risk management decisions (see Section V for additional details).

Issue: Goals and a process for decision-making need to be established for this LTG.
ORD Response: Once a strategic framework for research in LTG 4 has been developed, ORD intends to sponsor a scientist-to-scientist meeting to help develop an implementation plan with goals and mechanisms for determining priorities of research related to this LTG.

Issue: The criteria for demonstration projects need to be explicit.
ORD Response: Proposals for the demonstration projects were evaluated by a panel of Regional Office and ORD scientists. The following criteria were used to evaluate those proposals:

1. Clarity of the objectives of the proposed research. As noted in the RFA, each of these projects derived from a pre-proposal to study an Agency action. Do the objectives appear to be consistent and responsive to the solicitation? (total 20 points).
2. Scientific merit of the proposed approach in addressing the objectives (total 20 points).

3. Qualifications and competency of the staff identified for the project in light of their demonstrated prior performance in the proposed or related research areas. An effort has been made to form multidisciplinary teams from across ORD to address the problems in Accountability (total 10 points).

4. Strengths and weaknesses of the project as related to the probability of the project accomplishing the stated objectives.

5. Recommendations for suggested modifications or further clarification that would improve the proposed project.

Issue: This LTG should be reviewed externally on a periodic basis.
ORD Response: A scientist-to-scientist meeting involving multiple stakeholders will provide the basis for an implementation plan related to this LTG. Once that plan is in place, research will be evaluated by the RCT during the prioritization phase of the budget cycle. Like other themes in the HH MYP, research to develop approaches to evaluate risk management decisions will undergo external peer review by the BOSC on a periodic

basis.

Issue: The program will require additional resources.
ORD Response: ORD realizes that additional resources (expertise and extramural support) may be needed to support research in this LTG. ORD is currently developing a strategic framework to identify the knowledge gaps and limitations that would serve as a starting point for developing an implementation plan. Once concrete research approaches have been identified, issues related to obtaining the necessary resources would be addressed.

III. Results of the 2005 Program Assessment Rating Tool (PART)

The Office of Management and Budget used the Program Assessment Rating Tool (PART) to evaluate the HHRP in the spring and summer of 2005. As a result of that review, OMB rated the HHRP as "Adequate" and had the following comments:

- The program has an unambiguous, focused design, and there is no evidence of major flaws that would limit the program's effectiveness or efficiency
- The program has meaningful annual and long-term performance measures
- The program's research results are being used to reduce uncertainty in risk assessment

OMB also noted that the HHRP needed to develop verifiable ambitious long-term measures and define what outcomes would represent a successful program and that the HHRP needs more data and clearer long-term targets to show that it is making continued progress. The HHRP is taking steps to improve the ability to link budget resources to annual and long-term performance targets, develop ambitious long-term performance targets that clearly define what outcomes would represent a successful program, and continue to use independent expert external reviews to assess program planning, performance and implementation of OMB's recommendations.

The PART process led to the development of four types of performance metrics, including Long-Term Outcomes for each LTG, Annual Outcomes for each LTG, an overall program measure tied to the four-year review cycle, and an annual efficiency measure (see Table 4 for summary). ORD is also considering the use of a client survey to evaluate the responsiveness of the program to the needs of Agency risk assessors and risk managers and how much the research is being used to inform decisions to achieve results.

Long-Term Outcome- External Expert Review. The BOSC will provide an evaluation of progress of the program toward meeting its LTGs every four years. The evaluation will consist of two components intended to provide advice for ORD to direct program improvements rather than a measure of performance that would connote a grade. Such an evaluation would, however, inform the OMB PART analysis, which seeks a definitive measure of program performance.

The first component of the evaluation will be to capture performance of the entire

research program and activities in support of the program's LTGs. The BOSC will provide a narrative assessment of charge questions related to program relevance, program structure, program performance, program quality, scientific leadership, coordination and communication, and outcomes.

The second component is intended to arrive at a summary assessment of performance for each LTG. The BOSC will be asked to provide a qualitative score for each LTG that reflects the quality and significance of the research as well as the extent to which the program is meeting or making measurable progress toward the goal. Scores will be given in the form of clearly defined adjectives (i.e., exceptional, satisfactory, and not-satisfactory) to provide consistency among reviews.

Although such an evaluation may not be suitable for establishing baselines for setting targets for LTGs at Mid-Cycle Reviews, ORD is asking the BOSC to use an adjectival rating to describe how much progress ORD's research program is making (i.e., exceptional, satisfactory, or unstatisfactory) in moving the program forward in response to the BOSC review of 2005.

Long-Term Outcome- Documentation of Use of Products. LTGs are defined to be outcome-oriented, i.e., risk assessors or risk managers use ORD methods, models or data to reduce reliance on default assumptions, characterize cumulative risk, or protect susceptible subpopulations. As part of each PART evaluation, ORD will document how frequently ORD's methods, models and data are used by Agency risk assessors and risk managers in the risk assessment process. This entails identifying the number of risk assessments conducted within a five-year period (e.g., from the IRIS database, Office of Pesticide Programs (OPP) Registration/Re-registration packages) and determining specific cases in which peer-reviewed ORD scientific products (i.e., paper published in a journal) were used to support a critical component of the risk assessment, e.g., cited as supporting a decision to apply or change a default assumption in the risk assessment process such as uncertainty or safety factors. Such an analysis in 2005 identified 62 risk assessments performed from 2000-2005. Evidence of ORD products used to support the risk assessment was documented in 17 cases- 12 for the use of mechanistic data, 3 for cumulative risk, and 2 for susceptible subpopulations. These cases are summarized in Table 5. OMB accepted an incremental increase in the number of documented cases as a measure of progress for the next PART review.

Annual Outputs. For many of the ORD research programs, OMB has accepted an evaluation of annual performance measures (APMs) delivered relative to APMs projected for each Long-Term Goal. APMs are products listed in the MYP in support of achieving the Long-Term Goals, i.e., achieving the APMs is taken as support that progress is being made toward achieving Long-Term Goals. Table 6 illustrates the results of this analysis conducted for OMB in 2005. The Table also indicates the projected targets for the APMs in FY07 and beyond. The data indicate a gradual improvement in achieving program APMs since the inception of the program in 2000. It is understood that programs should meet 100% of their projected APMs each year. The main reasons for not achieving APMs include shifts in resources, difficulties in getting approval to proceed with certain studies,

and critical personnel leaving the Agency.

Overall Program Measure- Bibliometric Analysis. ORD is a science organization and its products are peer-reviewed scientific papers. One client for these products is the scientific community and one way to measure client use is to perform a bibliometric analysis. A bibliometric analysis of 839 papers published from 1999 through January 2005 was performed for the 2005 BOSC review. The analysis used Thomson's Essential Science Indicators (ESI) and Journal Citation Reports (JCR) as benchmarks. The analysis found that 24% of the HH publications are highly cited papers (top 10% based on ESI criteria). OMB has accepted an incremental increase in highly cited papers over time as a performance measure.

An updated bibliography of human health program publications was analyzed in November, 2006. As in the previous analysis, more than 25% of the publications were found to be highly cited based on ESI critieria. These data indicate that the HHRP continues to have a consistent impact on the scientific literature and the scientific community. Another bibliometric analysis is planned for the 2009 BOSC review.

Annual Efficency Measure-Time to Process Grants- As a measure of efficiency, ORD will determine the average time (in days) to process research grant proposals from RFA closure to submittal to EPA's Grants Administration Division, while maintaining a credible and efficient competitive merit review system. OMB has agreed to specific targets of reduce time as an efficiency measure.

IV. Revision of the Human Health Multi-Year Plan

ORD's MYPs describe what research ORD proposes to accomplish over a 5-10 year period. The plans permit ORD to consider the strategic direction of the Agency and how research can evolve to best contribute to the Agency's mission to protect human health and the environment. The MYPs describe overall objectives of the research, present significant outputs from the various Laboratories and Centers, and serve as a communication tool within ORD and with stakeholders and clients.

Following the review of the HHRP in 2005, ORD solicited input from various stakeholders concerning the revision of the MYP, including recommendations of the BOSC, Program and Regional Offices (see Attachment B in the 2006 HH MYP), ORD senior managements (Laboratory and Center Directors, Executive Council), OMB (i.e., definition of long-term goals to be outcome-oriented), and the National Center for Environmental Assessment (NCEA). ORD-NCEA, which contributed research products to the previous version of the HH MYP, has reassessed its mission and no longer undertakes primary research. The primary mission of NCEA is to receive data and primary methods from external and internal sources, including the HHRP, in order to undertake risk assessment activities for the Agency. NCEA is now considered to be significant client of research outputs from the HHRP.

An ORD Steering Group was assembled to assimilate these recommendations and revise the HH MYP. Teams of scientists (see Attachment E in the 2006 HH MYP) were assembled to develop the scientific approaches to address the recommendations provided by the stakeholders. A draft MYP was circulated to the various stakeholders in the spring of 2006 and a final version of the MYP was accepted by the Science Council in June, 2006.

There are several significant changes in the 2006 version of the HH MYP relative to 2003. A listing of significant changes in the current version of the HH MYP is as follows:

- LTGs are defined to focus on outcomes
- The theme of the program was centered on the need to reduce reliance on default assumptions in risk assessment, e.g., extrapolation issues, as negotiated with OMB
- Research on aggregate exposures was deemphasized due to budgetary concerns
- Research on cumulative risk was expanded to include research on community-based cumulative risk assessment
- Research on susceptible subpopulations was focused on life-stage as the primary theme, i.e., how to protect populations as a function of life-stage
- Older adults were emphasized to a greater degree in the revised MYP
- Work on asthma focused more on life-stage issues (i.e., asthma in children)
- The National Children's Study was eliminated as an organizing theme in the plan due to uncertainties in funding
- The description of research on public health outcomes was changed to "evaluation of risk management decisions" to be more descriptive of the work being proposed
- Research from the HHRP contributed to outputs generated by NCEA
- The revised MYP contains a number of new APGs and APMs that were not included in the 2003 plan
- Some APGs were eliminated and replaced with goals that more clearly articulate a critical path for the research and available resources
- Themes in the revised MYP were cross-linked to complementary research themes articulated in respective problem-driven areas (i.e., Drinking Water, Safe Products/Safe Pesticides, Endocrine Disruptors)
- Products (APMs) were more clearly linked to stakeholders and a lead ORD scientist was identified for each product

As mentioned previously, the 2006 HH MYP will serve as the guiding document for planning research during the 2006-2013 period. However, it is understood that products articulated in the MYP will be updated on an annual basis and that the MYP will be revised in approximately 3 years.

IV. Progress on Research to Develop Approaches to Evaluate Risk Management Decisions

In response to BOSC recommendations, a Steering Committee consisting of representatives from all ORD Laboratories and Centers, as well as the Office of Environmental Information, was formed. The purpose of the Steering Committee is to develop a framework document that provides a definition, overall objective, and research needs for a research program to evaluate the effectivenss of risk management decisions.

The Steering Committee met on October 16, 2006, to discuss the development of a framework document. A working group was charged with developing an outline for the document by February 1, 2007. It is projected that a completed document would be ready for review by Program and Regional offices and external peer-review by spring, 2007. The framework document would then serve as the basis for working with external and internal scientists to develop an implementation plan.

At the meeting on October 16, 2006, Peter Preuss, Director of the National Center for Environmental Assessment, indicated that the Report on the Environment (ROE) is being used with greater frequency to develop strategic planning for the Agency and for budgeting and prioritization of research within ORD. Many of the research needs articulated in the ROE, i.e., need to develop linkages between exposure and human health outcome, consideration of cumulative exposures, and stratification of susceptible populations, are themes contained in the HHRP. It is likely that the framework document and the ROE will have a significant influence on planning HH research in the future.

Resources (FTEs and Total Costs) for the HHRP since 1999 are summarized in Table 7.

VI. Tables

Table 1 Peer-Reviewed Publications from 1999-2006 by Long-Term Goal

Year	LTG 1	LTG 2	LTG 3	LTG 4	Total
1999	58	31	79	0	168
2000	80	26	126	0	232
2001	84	33	107	2	226
2002	75	37	101	2	215
2003	71	27	162	2	262
2004	80	47	140	4	271
2005	88	44	256	2	390
2006*	72	17	126	4	219

***As of October 1, 2006**

Table 2 Scientist-to-Scientist Meetings (2005-2007)

Scheduled Meetings:

NIEHS/EPA Scientist-to-Scientist Meeting on Children's Health Research- RTP, July 11-12, 2005.

Scientist-to-scientist workshop on Research and Risk Assessment for Arsenic- Sheperdstown, WV, May 30-June 2, 2006.

Workshop on Research Projects on Perfluoroalkyl Acids (PFAA)- RTP, July 10-11, 2006

Conference on Human Subject Protection- RTP, September 25-26, 2006

Workshop on Mechanistic Models of Mode of Action and Cancer Risk Assessment- RTP, September 29, 2006

Workshop on Understanding Human Biomonitoring-University of Ottawa, October 5, 2006

Workshop on Uncertainty and Variability in Physiologically Based Pharmacokinetic Models- RTP, October 31-November 2, 2006

Scientist-to-Scientist Meeting on Using Oxidative Stress Research in Human Health Risk Assessment- RPT, October 23-24, 2006.

State-of-the-Science Approaches for Observational Exposure Measurement Studies-Durham, NC, November 28-29, 2006.

Workshop on Early Indicators of Environmentally Induced Disease- RTP, January 9, 2007

Future of Risk Assessment- meeting of Program and Regional Office and intramural and extramural scientists to discuss novel approaches to risk assessment- scheduled for Dallas, late January 15-18, 2007

Children's Environmental Health Research- Past, Present and Future- NIEHS/EPA Children's Centers, RTP, Janurary 22-23, 2007

Meetings being planned:

Scientist-to-Scientist Workshop on Susceptibility-planned for late February, 2007

Colloquium on the Use of Mode of Action Information in Risk Assessment- collaboration with NCEA to promote and better coordinate MOA research in ORD and its application to risk assessment- site and date to be determined

Community-Based Risk Assessment Workshop- meeting of Program and Regional Office and intramural scientists to develop research program on community risk- site and date to be determined

Workshop on Accountability Research- meeting to discussimplementation of research related to evaluation of human health risk management decisions- site and date to be determined

Scientist-to-scientist meeting on biomarkers research – planned for Fall 2007

Table 3 Cross-Walk of Research Needs from Program/Regional Offices and ORD Research Projects

LTG	Need	P/R Office	ORD Research Projects
LTG 1 Use of Mechanistic Data in Risk Assessment	"Omics" Methods for Prioritization and Markers	OPPTS OW	ORD is conducting research to provide a framework for using genomic and toxicological data to identify key events in toxicity. Research focuses on applying an understanding of MOA to extrapolations from high to low dose, from animals to humans, from *in vitro* data to *in vivo* exposures in risk assessment, and in the identification of common mechanism groups for cumulative risk assessment. This research also contributes to developing tools for prioritization and screening of environmental toxicants through rapid identification of key toxicity pathways. Projects addressing these goals include research on conazole fungicides, arsenic, and halogenated contaminants in drinking water.
LTG 1 Use of Mechanistic Data in Risk Assessment	MOA research for hazard identification	OPPTS, OW, OAR	ORD is conducting research to provide mechanistic information for evaluation of risk from compounds with a neuroendocrine MOA, including the chlorotriazines, phthalates, and PFOA. The key events leading to toxicity from these compounds are generally related to critical windows during development. These toxicants may act through dissimilar (lower order) molecular mechanisms that ultimately affect the same higher order key toxicity pathway. Examples of this include adverse effects of chemical compounds on the lutenizing hormone or androgenic pathways and reproductive development and thyroid disrupting effects on neural development. This research will generate dose response information *in vivo* and in tissues derived from both animal and human cell lines to promote animal-to-human extrapolation and for evaluation of cumulative risk. ORD is conducting research to provide mechanistic information for extrapolating from high to low doses. Mechanistic information is a key factor in deciding on the choice of linear vs non-linear extrapolation models and for the harmonization of cancer and non-cancer risk assessments. The HH program includes research to develop pharmacodynamic representations of key events in specific target organs (e.g., bladder, skin, lung) and develop PK-PD linkages to existing models of arsenical metabolism in both specific cell types and the whole organism on arsenicals. This work also addresses the need for data to inform the use of default assumptions in animal-to-human extrapolation in risk assessment. ORD research is exploring the possibility that oxidative stress is a ubiquitous biological measure that may change following exposure to a number of environmental stressors. Current research is focused on the role of oxidative stress in particulate matter-mediated pulmonary health effects. Information from this research has implications for supporting aggregate and cumulative risk

			of air pollutants, identification of risk factors for susceptible subpopulations, identifying common MOAs for cancer and non-cancer toxicity pathways.
LTG 1 Use of Mechanistic Data in Risk Assessment	PD/PK Linkages	OAR, OPPTS, OW	ORD is conducting research to develop linkages between pharmacokinetic and pharmacodynamic models. Pharmacokinetic models will be integrated with the MOA models to predict dose-response effects that could be used for risk assessment, as well as develop the basis for conducting cumulative risk assessment. This work also addresses the need for data to inform the use of default assumptions in animal-to-human extrapolation in risk assessment. Projects addressing these goals include the development of a physiological and mathematical models to describe the mode of action (MOA) for different types of pyrethroids and establish the relationship of the MOA to adverse effects in the nervous system, the development of models for compounds that work through nuclear receptors, PK/PD modeling of multi-route exposure to arsenic, and the relationship between the pharmacokinetics and adverse reproductive and developmental effects of halogenated chemical contaminants in drinking water
LTG 2 Cumulative Risk	Biomarkers	OPPTS, OW, OAR, Regions	ORD and the STAR grant researchers are conducting biomarker research in five areas to produce methods, models and data for improving cumulative risk assessments: Biomarker Methods Development. ORD, collaborating with CDC and the STAR grantees, is developing and validating methods for characterizing biomarkers for selected environmental pollutants or their metabolites in various matrices (saliva, hair, meconium, urine, sputum, cord blood, and blood). Specific examples of research include: the development of pulmonary biomarkers of exposure based on alterations in protein expression following exposure to arsenic; biomarkers resulting from PAH, perfluorinated chemicals, halogenated organic chemicals, pesticides, and air toxics exposures, and biomarkers for predicting childhood asthma. Special emphasis is being placed on developing low cost, low burden exposure biomarker methods for use in future field studies to assess, relate, and reduce exposures to children, the elderly, and other susceptible populations. Interpreting Biomarker Results. ORD and the STAR scientists are developing tools for reconstructing individual exposures from the biomarker data being reported by ORD, CDC, and other researchers and apportioning these individual exposures to their primary sources. State-of-the-science mathematical modeling techniques (physiologically based pharmacokinetic) are being developed and applied in reverse to first estimate the target tissue dose and then the individual's aggregate exposure(s). Innovative statistical models are being developed to assess, prioritize, and apportion known sources of the environmental chemical(s) of interest, their source contributions to various environmental media, and

			the key factors influencing the modeled aggregate exposures. Through this research, ORD will develop the tools to link the biomarker results to their sources and key factors. The research results will be used to inform the development of appropriate risk reduction, risk management strategies. Longitudinal Exposures. ORD and the STAR scientists are conducting research to assess the intra- and inter-personal variability of biomarker measurements over time. Urinary biomarker data (e.g., bisphenol-A, dialkyl phosphates, pyrethroid metabolites) from the Children's Total Exposure to Pesticides and other Persistent Pollutants (CTEPP) are being analyzed to understand inter-personal variability. Probabilistic methods are being developed to predict aggregate pesticide exposures from the CTEPP biomarker data. Ancillary CTEPP meta-data are being used to examine how an individual's weight influences the biomarker measures. The results will be used to design future research addressing the uncertainties in characterizing lifetime exposures for risk assessment. Protocols for Future Studies. ORD scientists are developing tools for guiding the collection of biomarker samples for future studies. The guidance documents, based on the knowledge gained above, will describe when to collect the biomarker samples (timing of collection, frequency of collection, etc.), the methods for collecting and analyzing the samples that will provide the user with data of known quality (sensitivity, precision, accuracy), and the collection of ancillary environmental and personal activity data required for interpreting the biomarker results and linking the biomarker results to the sources and the individual's activities. Cumulative Risk of Pyrethroid Pesticides. ORD is also conducting research to develop biomarkers for cumulative risk of pyrethroid pesticides. This work will address multi-component exposures and the cumulative biomarker impacts and observational studies of pyrethroids in human body fluids or tissues to address the linkage between biomarkers and activity patterns, as well as age group differences impacts on biological availability.
LTG 2 Cumulative Risk	Exposure and Dose Models for Cumulative Risk	OPPTS, OAR, Regions OW	ORD is conducting research to develop, evaluate, and link its source, exposure and dose models, and related databases, for supporting Agency cumulative risk assessments. Front-end source modules, for both primary and secondary pollutant sources, are being developed for upgrading ORD's indoor chemistry models and predicting the formation of secondary pollutants due to interactions of multiple pollutants and their interactions with interior surfaces. A parameter estimation program PARAMS, a "toolbox" consisting of 30 parameter estimation methods, is being developed for developing quantitative structure-activity relationship (QSAR) models. ORD's Stochastic Human Exposure Dose Simulation (SHEDS) model,

			previously an aggregate exposure model, is being upgraded to assess cumulative exposures. Selected modules for the Exposure-Related Dose Estimation Model (ERDEM) are being refined for estimating internal doses from exposures. The Human Exposure Database System (HEDS) and the Consolidated Human Activity Database (CHAD) are being updated with the validated results from recently completed ORD and collaborator exposure studies. ORD scientists are implementing research to link these models and databases, make them readily available, and apply them to address Program Office and Regional Office issues (e.g., N-methyl carbamates and pyrethroid pesticides, air toxics in Region 1)
LTG 2 Cumulative Risk	Research on Chemical Mixtures	OPPTS	ORD is conducting research to develop principles of dose-additivity for pesticides in mixtures and develop and implement dose-response models for use in cumulative risk assessments. These principles include optimization of experimental design to test chemical mixtures and to assess the effects of acute, chronic and episodic exposure. Previous work has focused on organophosphorous pesticides. Future research will complete work on carbamate pesticides and mixtures of organophosphates and carbamates, as well as the pyrethroid pesticides
LTG 2 Cumulative Risk	Community Risk	Regions OPPTS, OAR	ORD is initiating research to address the impact of multiple stressors on risk to populations and communities. This new research program is initially being focused on determining what exposure assessment tools (models, methods, protocols, approaches, data) are readily available, assessing the strengths of each tool, and determining where new tools need to be developed for conducting community-based, cumulative risk assessments. The available exposure assessment tools will be evaluated, and ORD expertise gained, through the conduct of small scale collaborative studies (e.g., automotive shop emissions in Lawrence MA) with Regional, State, and STAR grantee community risk assessors. Exposure tools will be developed to identify and prioritize populations and communities at greatest risk, along with identifying the key factors contributing to the risks. The refined tools will be employed at selected locations to characterize community risks (with State, Regional, and Program Office input) and to generate high quality exposure data to support the development of risk reduction and/or risk management strategies. The tools developed through these research activities will provide the foundation for assessing exposures in support of ongoing Agency accountability programs.
LTG 3 Susceptible Subpopulations	Long-Term Effects of Early Exposure	OCHPEE, OPPTS, OW, Regions	ORD is conducting research on the long-term effects of developmental exposure. This research addresses the role of the developmental environment in setting physiological parameters ("programming") that affect later risk of disease and that may be propagated across generations by epigenetic effects. This work addresses issues related to the development of appropriate testing methods that would be sensitive to long-term effects of chemicals. Work will

			characterize the long-term effects of prenatal exposure to PFAAs, atrazine and dexamethasone in rodent models. This work could have a significant impact on testing guidelines for reproductive and developmental toxicants.
LTG 3 Susceptible Subpopulations	Differential Exposure and Life Sensitivity	OPPTS, OCHPEE, OW, OAR	ORD is conducting research to characterize the variability inherent in the exposure and response of Americans to environmental toxicants. This includes understanding whether the default factor of 10 for inntraspecies variability is sufficient to protect potentially susceptible individuals such as women of child-bearing years, the developing embryo, children and adolescents and older Americans ORD is conducting research on exposures and effects of pesticides in children. This work will continue on-going studies to characterize the differential response of the young to the neurobehavioral and neurochemical effects of pesticides (e.g., carbamates and organophosphates) and determine the biological mechanisms for these differences. A set of highly focused research studies is being developed by ORD to fill critical data gaps related to children's exposures to chemicals in their everyday environments. Exposure measurement studies are being performed to identify important exposure pathways and exposure factors for a wide range of persistent and non-persistent chemicals, including phthalates, acid herbicides, organochlorine pesticides, organophosphate pesticides, and current-use pyrethroid pesticides. ORD research is providing a fundamental understanding of the many exposure factors that can lead to increased risk to vulnerable or susceptible populations. This research is designed to improve understanding of differences in exposure to environmental pollutants as a result of life stage and the key factors influencing these exposures as well as subsequent effects of these exposures. Other research is determining which methods and models are most appropriate for assessing short-term and lifetime exposures to environmental pollutants. ORD is conducting research to reduce the health risks to school children by promoting healthy indoor environments in schools (also known as the Buy Clean Initiative). Mitigation and/or reduction of differential health risks to school-age children is the focus of this study. Research activities include: identification of potentially high-risk consumer products; identification of hazardous chemicals; and the characterization of chemical emissions under "real world" conditions. Additionally, decision-support models and databases are being developed to assist school managers in their risk management decisions, such as the selection of less hazardous cleaning products. To date, two potentially high-risk products have been evaluated: hard-surface cleaners and erasable markers. Hazardous air pollutants were identified in both product categories. Simple tools are been developed for selecting "green"

			products. Future research focuses on products that may have broad implications to exposure of school-age children and other susceptible subpopulations, such as evaluation of the health benefits and potential adverse effects of various types of air cleaning devices widely available on the market.
LTG 3 Susceptible Subpopulations	Longitudinal Children's Studies	OCHPEE, OAR, OPPTS, OW, Regions	ORD research is also developing and refining the tools to support children's exposure and effects assessments in longitudinal studies. In addition, the systematic approach developed for aggregate exposure to pesticides will be used to develop the approaches, tools, and methods for assessing the cumulative exposures and risks to other classes of chemicals routinely found in children's everyday environments. Classes of chemicals under consideration include pesticides, VOCs, metals, phthalates, brominated flame retardants, and perfluorinated chemicals.
LTG 3 Susceptible Subpopulations	Research with Older Individuals	OCHPEE	ORD research is addressing the environmental health of older Americans. The population of older Americans is growing rapidly; environmental health risks to this population may have considerable economic and societal costs. ORD research addresses 1) behavior/activity patterns and exposure to the pollutants in the microenvironments of older adults; 2) changes in absorption, distribution, metabolism, and excretion with aging; and 3) alterations in reserve capacity that alter the body's ability to compensate for the effects of environmental exposures. This research will provide data for a database of pharmacokinetic and physiological factors for evaluation of risk across the lifespan.
LTG 3 Susceptible Subpopulations	Asthma	OAR, OCHPEE, Regions	ORD research is also focusing on the potential long-term effects of exposure *in utero* to prevalent air pollutants such as diesel exhaust. Research will address adverse effects on immune system development and asthma. Because asthma is a significant health concern for children, and indoor mold has been implicated in the initiation and exacerbation of asthma, research is being implemented to evaluate innovative methods for characterizing mold species and their relative potency with respect to allergic response, and relate these data to indoor air quality.
LTG 4 Evaluation of Risk Management Decisions (Accountability)	Develop approaches for Accoun-tability	OCHPEE, OPPTS, OW, Regions OAR	ORD research is focusing on developing and validating environmental public health indicators intended to reflect the actual impact of environmental decision-making on public health and to help clarify the health benefits and financial costs associated with further incremental environmental improvements. One demonstration project focuses on the assessing the cumulative impact of a suite of air pollution reduction programs on environmental public health indicators for children and older populations. A second project focuses on evaluating the potential use of direct health measures for assessing the impact of drinking water regulations related to microbial pathogens. ORD researchers are also involved in revising the Report on the Environment which is a continuing Agency-wide effort to compile and assess information that helps answer broad questions important to the Agency concerning the state of the nation's whole environment – air, water, land, human

			health, and ecological condition. Finally, the STAR program is soliciting research on the development of outcome-based environmental health indicators. NCER is soliciting research through the STAR grants program on the use of existing databases of environmental (ambient), biological and/or health-related data to develop indicators that reliably signal the impact of changes in environmental conditions, management approaches or policies on human health. Key to the development of such indicators is a clearer understanding of the sequence of events that link changes in the environment to human exposure and adverse health outcomes. It is anticipated that these indicators will be sufficiently characterized to act as surrogates of environmental exposure and/or health outcomes and be used to track the impact of environmental management decisions or policy changes.

OAR= Office of Air and Radiation
OW= Office of Water
OPPTS= Office of Prevention, Pesticides and Toxic Substances
OCHPEE= Office of Children's Health Protection and Environmental Education

Table 4 Summary of Long-Term and Annual Measures for PART

Long-Term Goal 1 Use of Mechanistic Data in Risk Assessment	Long-Term Outcome	Risk assessors and risk managers use ORD's methods, models and data to use mechanistic (mode of action) information to reduce uncertainty in risk assessment (as evaluated by external expert review)
	Long-Term Outcome	Percentage of peer-reviewed EPA risk assessments in which ORD's mechanistic information is cited as supporting a decision to more away from or to apply default risk assessment assumption.
	Annual Output	Percentage of planned outputs delievered in support of mechanistic data long-term goal
Long-Term Goal 2 Cumulative Risk	Long-Term Outcome	Risk assesssors and risk managers use ORD's methods, models and data to characterize aggregate and cumulative risk to manage risk of humans exposed to multiple environmental stressors (as evaluated by external expert review)
	Long-Term Outcome	Percentage of peer-reviewed EPA risk assessments in which ORD's characterization of aggregate/cumulative risk is cited as supporting a decision to move away from or to apply default risk assessment assumptions
	Annual Output	Percentage of planned outputs delivered in support of the aggregate and cumulative risk long-term goal
Long-Term Goal 3 Protect Susceptible Subpopulations	Long-Term Outcome	Risk assessors and risk managers use ORD's methods and data to characterize and provide adequate protection for susceptible subpopulations (as evaluated by external expert review)
	Long-Term Outcome	Percentage of peer-reviewed EPA risk assessments in which ORD's methods, models or data for assessing risk to susceptible subpopulations is cited as supporting a decision to move away from or to apply default risk assessment assumptions
	Annual Output	Percentage of planned outputs delievered in support of the susceptible subpopulations long-term goal
Long-Term Goal 4 Evaluate Risk Management Decision (public health outcomes)	Long-Term Outcome	Risk assessors and risk managers use ORD's methods and models to evaluate the effectiveness of public health outcomes (as evaluated by external expert review)
	Annual Output	Percentage of planned outputs delivered in support of the public health outcomes long-term goal
Human Health Research Program	Four-Year Cycle	Percentage of Human Health program publications rated as highly cited papers (top 10% in field) in research journals
Human Health Research Program	Annual Efficiency	Average time (in days) to process research grant proposals from RFA closure to submittal

		to EPA's Grants Administration Division, while maintaining a credible and efficient competitive merit review system (as evaluated by external expert review)

Table 5 Risk Assessments Using ORD Products (1999-2005)

Source	Risk Assessment	LTG	Risk Assessment Issue
FIFRA SAP 2004	N-Methyl Carbamate Cumulative Risk Assessment: Strategies and Methodologies for Exposure Assessment	Cumulative Risk	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)*
FIFRA SAP	Dimethoate: Issues Related to the Hazard and Dose Response Assessment	Mechanistic Information	ORD methods, models or data not used [ORD data used to support BMD5 value in Bench Mark Dose calculation in lieu of default NOAEL/LOAEL]
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
FIFRA SAP 2002 2001	Organophosphate pesticides: OP Cumulative Risk Assessment	Cumulative Risk	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
FIFRA SAP 2000	Atrazine Risk Assessment	Mechanistic Information	ORD data indicated 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
FIFRA SAP 2000	Common Mode of Action for Triazine Pesticides	Cumulative Risk	ORD research indicates 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 Subpopulati ons	ORD research provided data to support application of 3X Safety Factor for Children
OPP Registration 2000-2004	Risk Assessment of Methamidophos	Mechanistic Information	NOAEL with LOAEL obtained from ORD data, which eliminates default MF factor
NAS	Dioxin Reassessment	Mechanistic Information Cumulative Risk	ORD data provided basis for comparability of dosimetry between animals and humans (addresses default that animals can be compared to humans) and provided basis for TEF approach for cumulative risk assessment, supporting the additivity default position
NAS	Arsenic	Mechanistic Information	ORD data used to support default linear model for risk assessment
IRIS	Risk Assessment for Bromate	Mechanistic Information	ORD data provided NOAEL and LOAEL, which eliminated default MF

IRIS	Risk Assessment for 1,3 Butadiene	Mechanistic Information	ORD methods, models or data not used [ORD data used to derive non-cancer RfC and ORD model used to generate risk estimates rather than use default approach]
IRIS	Risk Assessment for Chloroform	Mechanistic Information	ORD methods, models or data not used (ORD dermal exposure model used to validate PK model used in risk assessment- the hepatotoxicity is dependent on the rate of metabolism; humans and animals metabolize in comparable way, so animal models are appropriate, which supports the default position; ORD data also support biological meaningfulness of critical endpoint)
IRIS	Risk Assessment for Dichloroacetic acid	Mechanistic Information	ORD PK model developed to predict tissue concentrations; Data support that one or more metabolite is toxic in animals and humans; DCA found to be a direct acting genotoxic, suggesting a linear DR for R/A; data support reducing UF for interspecies
IRIS	Risk Assessment for Diesel Exhaust	Mechanistic Data	ORD data used to support exposure assessment and to support application of default animal to human UF
NAAQS	Particulate Matter	Mechanistic Information	Data support the default animal to human extrapolation UF
NAAQS	Ozone	Mechanistic Information	Data support the default animal to human extrapolation UF

Table 6 Actual Annual Performance Measures Delivered Relative to Projected

	LTG 1		LTG 2		LTG 3		LTG 4		Total	
Fiscal Year	**Actual**	**Total**	**Actual**	**Total**	**Actual**	**Total**	**Actual**	**Total**	**Actual**	**Total**
2000*	3	3	3	4	6	6	0	0	12 (92.3%)	13
2001	3	3	1	1	8	9	0	0	12 (92.3%)	13
2002	2	2	5	7	8	9	1	1	16 (84.2%)	19
2003	7	7	11	11	7	8	0	0	25 (96.2%)	26
2004	5	5	7	8	11	11	1	1	24 (96.0%)	25
2005	15	15	11	11	16	16	1	1	43 (100%)	43
2006	11	11	2	2	15	16	2	2	30 (96.8%)	31
2007**		5		10		9		1		25
2008		11		13		12		2		38
2009		8		13		9		1		31
2010		6		7		17		2		42
2011		2		9		1		0		12
2012		7		2		3		1		13

* Data used for the 2005 OMB PART review based on FY03 MYP

** Projections based on revised 2006 HH MYP

Table 7 Resources for the Human Health Research Program (1999-2006)

Fiscal Year	Total FTEs	Total Extramural Resources ($K)*
1999	218.9	$ 50.2 M
2000	186.6	$ 49.1 M
2001	170.8	$ 51.4 M
2002	170.0	$ 49.9 M
2003	164.8	$ 43.6 M**
2004	143.2	$ 50.7 M***
2005	173.1	$ 60.5 M
2006	194.2	$ 61.8 M

* Includes all administrative and budget personnel and total costs of program operations (e.g., research costs, travel, salaries)

** Human Health Risk Assessment Research removed from HHRP

*** Chemical mixtures research moved from Pesticides/Toxics

VI. Peer-Reviewed Publications (2005-October 2006)

Long-Term Goal 1: Use of Mechanistic Information in Risk Assessment

Abbott, BD, Best, DS and Narotsky, MG. Teratogenic effects of retinoic acid are modulated in mice lacking expression of epidermal growth factor and transforming growth factor-alpha. **Birth Defects Research A Clinical and Molecular Teratology** 73: 204-217, 2005.

Abbott, BD, Buckalew, AR and Leffler, KE. Effects of epidermal factor (EGF), transforming growth factor-alpha (TGF alpha), and 2,3,7,8-tetrachlorodibenzo-p-dioxin on fusion of embryonic palates in serum-free organ culture using wild-type, EGF knockout, and TGFalpha knockout mouse strains. **Birth Defects Research A Clinical and Molecular Teratology** 73: 447-454, 2005.

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Adair, BM, Hudgens, E, Calderon, RL and Thomas, DJ. Total arsenic concentrations in toenails quantified by two techniques provide a useful biomarker of chronic arsenic exposure in drinking water. **Environmental Research** 101: 213-220, 2006.

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Bao, W, Schmid, J, Goetz, A, Ren, H and Dix, D. A database for tracking toxicogenomic samples and procedures. **Reproductive Toxicology** 19: 411-419, 2005.

Barton, HA, Tang, J, Sey, YM, Stanko, JP, Murrell, RN, Rockett, JC, and Dix, DJ. Metabolism of myclobutanil and triadimefon by human and rat cytochrome P450 enzymes and liver microsomes. **Xenobiotica** 36:793-806, 2006.

Basha, MR, Braddy, NS, Zawia, NH and Kodavanti, PR. Ontogenetic alterations in prototypical transcription factors in the rat cerebellum and hippocampus following perinatal exposure to a commercial PCB mixture. **NeuroToxicology** 27: 118-124, 2006.

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Long-Term Goal 4: Public Health Outcomes

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