Office of Research and Development's (ORD)
Safe Pesticides/Safe Products (SP2) Research Program
Mid-Cycle Progress Report to the Board of Scientific Counselors (BOSC)

July 12, 2010

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On February 7-9, 2007, the Safe Pesticides/Safe Products Research Program Subcommittee of the Board of Scientific Counselors (BOSC) met in Research Triangle Park, NC, to evaluate the Office of Research and Development's (ORD) Safe Pesticides/Safe Products Research Program (SP2RP). The Subcommittee presented a report of its findings and recommendations to the Executive Committee of the BOSC on May 24, 2007. The SP2 Research Program prepared a response (January 8, 2008) to the final BOSC report of the review, dated July 23, 2007.

ORD is providing a report on the SP2RP progress to address recommendations midway through the BOSC review cycle. The narrative below presents: an overview of specific recommendations made by the Subcommittee in its 2007 report, the original response that indicates how the SP2RP proposed in 2008 to take the findings into consideration, an updated response, and the progress that has been made to address the recommendations since that time. A table at the end of this report summarizes each recommendation, the original action proposed to be taken, the original schedule for completion of the action, and updates to the response and schedule.

Report Text

BOSC Recommendation # 1

An approach to include mitigation potential on gene transfer, effects on non-target organisms, and targeted species resistance should be included with the APGs within LTG 3. Other questions should be addressed including improvement of methods for tracking and quantifying products of genes or new technologies, and expanding the operative definition of "biotechnology."

Original Response

EPA's biotechnology research program is already addressing a number of the concerns raised by the BOSC Subcommittee. For example, ORD, along with researchers at Oregon State University, have investigated and evaluated the effects of plant incorporated protectant (PIP) crop effects on non-target organisms through the development of field scale protocols. The protocols are linked through a questionnaire based on a dichotomous key leading the study designer to incorporate features that substantially define a study and its objectives. This new approach permits proper design and implementation of field scale studies to ensure collection of necessary information to validate each study's findings. A component of the non-target research included instructions designed to enable the proper review of a finished non-target study. EPA held a workshop (2007) on "Pollen Mediated Gene Flow in the Environment Research" that explored non-target research issues and the future directions associated with it. The workshop was organized by ORD with a participant group consisting of government and industry members. ORD's biotechnology research program has historically been focused on the assessment monitoring and mitigation aspects of genetically modified (GM) Bt corn crops as the result of discussions with EPA's Office of Pesticide Programs (OPP) to address some of their highest priority research needs. Given the current level of resources for this program, it is unlikely that the program could be expanded to address all of the suggestions in this recommendation and in Recommendation 12.

Original Action/Timeline
Most recently, ORD investigated the effects of gene transfer in turf grass. However, EPA resources are insufficient to further develop methods to track and quantify the potential of gene transfer and/or species resistance in agricultural crops. In FY 2009, an EPA report will be completed which documents the testing and evaluation of resistance management models which track the development of resistance to control traits in PIP crops.

Updated Response
Since the BOSC review, the Long Term Goal (LTG) 3 Biotechnology Research Program resources either have been eliminated or realigned to address higher priority Agency issues. The resources for the National Exposure Research Laboratory (NERL) were aligned with the SP2RP LTG 2 ecology research program. The resources for the National Health and Ecological Effects Research Laboratory (NHEERL) have been realigned to LTG 2 and are leveraged with other research on characterizing the effects of chemical and non-chemical environmental stressors on plant populations. This research also supports ORD's new Biofuels Research Program. The realigned resources to the LTG 2 program are being used to develop an integrated exposure-effects ecological research program and to address cross-organization issues (as recommended by the BOSC and described in the updates to Recommendations #4, 9, and 10).

Prior to realignment of resources to the Biofuels Research Program, some of the biotechnology research conducted under LTG 3 characterized the ecological effects of gene transfer in canola and genetically modified herbicide resistant creeping bentgrass (a type of turf grass used on golf courses). In addition, ORD researchers developed methods to evaluate the ecological effects of gene flow on above-ground and below-ground plan community functions in the presence and absence of selective biological (insect pest) and abiotic (drift levels of herbicide) pressures. The methods and data obtained in the ecological effects of gene flow program using creeping bentgrass and canola have successfully positioned ORD for carrying out ecological effects studies with biofuels crops such as switchgrass, a perennial grass that is much taller and robust than creeping bentgrass (also a wind-pollinated perennial) and with camelina (an annual oilseed crop, that like canola is a dicot that is primarily pollinated by insects). Furthermore, collaborators have been identified in universities and the US Department of Agriculture's (USDA) Agriculture Research Service's (ARS) laboratories around the country who will be sending ORD soil samples from switchgrass fields and from nearby natural areas, for molecular and biological analyses. The methods under development represent the utilization of transdisciplinary approaches to develop tools to help inform regulatory and policy decisions of broad significance to the Agency, as well as to USDA, the Department of Energy, and the Department of Interior. The information will also help address basic questions regarding the impact of changes in land use for biofuels' production on above and below ground ecosystem services.

Current Progress
Several publications are currently 'In Press,' accepted, or in review, respectively, that describe the development of sunlit mesocosms developed for pollen confinement, above-and below-ground effects of glyphosate herbicide drift on constructed plant communities containing canola, bird'rape mustard (a compatible relative) and other plants found in field edges and roadsides, i.e., habitats that can harbor rare, threatened and endangered plant and beneficial insect species such

as pollinators, insect predators and parasitoids. A paper is currently in review on development of molecular markers to track introgression of genes from a turfgrass (*Agrostis stolonifera*) to compatible crop and wild relatives. With funding from the new Biofuels Research Program, the sunlit mesocosms and field plots have recently been planted with communities that simulate wet prairie or dry prairie grassland communities that contain feral biofuels crops, e.g., switchgrass or sorghum or camelina. Over the next few years, data will be obtained to determine the potential positive, negative or neutral impacts on above ground and below ground diversity and ecosystem services.

BOSC Recommendation # 2

The SP2 Program structure needs to remain flexible to emerging science, some of which will be produced by the program itself. Developing a structure for such an interactive, complex research program over multiple years is very difficult and impossible to do with great precision. This makes it even more important that the APGs and APMs be as clear as possible. This enables researchers to better envision goals and managers to better track the progress towards those goals.

Original Response

ORD concurs that the Multi-Year Plan (MYP) should strive to communicate a clear link between Annual Performance Goals (APGs) and their supporting Annual Performance Measures (APMs) so that, during the implementation of the research program, progress made toward completing significant milestones can be clearly understood and communicated. ORD also works toward having each APM and APG be measureable so that it is clear what constitutes achievement. ORD has developed a process to evaluate how well goals have been met for each of its research programs. As a measure of performance, ORD provides to the Office of Management and Budget (OMB) the extent to which committed APGs and APMs have been met over time. Because the establishment of performance metrics for OMB came about after the finalization of the SP2 MYP, a description of these metrics is not in the current MYP. ORD is currently revising its guidance for all MYPs and a section describing performance metrics for each program will be added. In addition, ORD's Office of Resources Management and Administration has provided new guidance for establishing products, milestones and impacts of annual performance measures. This guidance will be reflected in revised MYPs.

Original Action/Timeline

Improving APGs and APMs is an ongoing effort. The next update of the MYP will reflect new metrics agreed upon with OMB and the new ORD guidance.

Updated Response

The revised MYP guidance was issued in 2008 and provides more details concerning ORD's approach to capturing our work through APGs and APMs. One change to highlight is that APMs/APGs are no longer included in the MYP, but are web-based to be more flexible and facilitate the evolving nature of both the research and the efforts to capture and communicate the results. Also, ORD's National Homeland Security Research Center (NHSRC) initiated a one year pilot in October, 2009, that includes an effort to develop revised APMs that cover all of the research conducted as well as to include explicit mention of partner(s) and delivery dates within

the text of the APM. The effort also includes a partner "feedback loop" for key APMs. The results of the pilot will be evaluated later this year to inform ORD's guidance on these issues.

ORD's Executive Council decided that a new paradigm for research was needed – one that capitalized on the strengths of the multidisciplinary expertise within ORD. Their deliberations identified a need for a research program that was better aimed at solving critical problems in assuring the safety of chemicals. This research program, Safer Products for a Sustainable World (SPSW), will provide innovative, systematic, effective, and efficient approaches and tools to inform more sustainable approaches to develop, use, and otherwise manage chemicals throughout their life cycles, with the goals of reducing environmental and societal impact along with increasing economic value. The SPSW Research Program (SPSWRP) is being created by realigning and reorienting some or all of the following current ORD programs: Safe Pesticides/Safe Products, Endocrine Disruptors, Nanotechnology, Computational Toxicology, Human Health Research, and Human Health Risk Assessment.

Discussions on transforming ORD's research programs and realigning resources into a new program have been ongoing for several years. The focus on SPSWRP has become clearer over the last 18 months. Therefore, there has not been any effort to update the SP2RP MYP. This recommendation and others received from the BOSC will be considered in the development of the new research program and any new research plan.

Current Progress
ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to performance measures across all of ORD's research programs.

Parts of the SP2RP are being aligned with the newly developing SPSWRP. It is envisioned that by FY2012 that SPSWRP will be fully operational. It is unclear when a research plan or Multi-Year Plan will become available.

BOSC Recommendation # 3
Clarifications are needed so that the research is more consistent with the text. The relationship between the APMs related to each APG is not always clear. Some of the APMs are not clearly phrased, and the associated APGs are not clearly delineated. Also, even though research should be dynamic and future year changes are expected, each APG should have at least a few APMs each year until the APG is completed.

Original Response
ORD agrees that it is important for the reader of the MYP and reviewer of the research program to understand the content and context of the APGs and APMs. The following is a brief summary of how ORD has defined the relationship between APGs and APMs: *APGs* for ORD are typically major research outputs that are described in the context of the outcome to which they contribute. They represent significant, timely milestones along a critical path toward the accomplishment of LTGs. *APMs* are research outputs that contribute to the accomplishment of an APG by addressing the most important scientific issues for that particular annual performance

goal. The collection of APMs that address an APG should represent the critical research outputs that are both necessary and sufficient for achievement of the APG.

While each APG has multiple supporting APMs that are planned over several years, it is not always practicable to have multiple APMs due each year as recommended. The program needs the flexibility to plan the critical, multi-year research outputs along a path that considers both the requirements of peer-review and completion of supporting work often completed by contract and grant recipients. This process can result in an uneven distribution of APM completion over the timeframe necessary to complete an APG. While the program attempts to have important deliverables annually, this is not always possible over the course of each APG. Furthermore, there has been guidance from the Agency and ORD toward having fewer and more aggregated APMs. Therefore, each APM often reflects an aggregated body of research for which related multiple internal milestones, some of which may have been more evenly distributed over multiple years, have been combined.

Original Action/Timeline
ORD will clarify the generic relationship between APGs and APMs in the next update of the MYP and will ensure greater consistency and clarity with the wording of the APGs and APMs.

Updated Response
See update to Recommendation #2 regarding APG/APM issues.

Current Progress
As noted under Recommendation #2, ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to all research program performance measures. In addition, the SP2RP MYP has not been updated because of ongoing discussions to merge parts of it with several other research programs into SPSWRP. It is not clear when the new research program will have a research plan or MYP, although SPSWRP is expected to be fully operation in FY2012.

BOSC Recommendation # 4
Address structural elements to afford a greater emphasis on exposure.

Original Response
ORD agrees that the program presented to the BOSC lacked sufficient emphasis on exposure research. As noted at the BOSC review, in response to this issue, there are several explanations for this: 1) exposure research has not been as high a priority need for OPPTS as effects-related research and 2) there is a lot of exposure-related research ongoing in other research programs that are linked to OPPTS' needs and to the SP2 Research Program. Nonetheless, since the BOSC review, ORD has initiated action to increase the number of full time equivalent employees (FTEs) conducting exposure research under the SP2 Research Program. In addition, the National Exposure Research Laboratory has initiated an Implementation Planning process for identifying the highest priority areas of exposure research for these additional FTEs to plan and conduct research in support of the SP2 MYP.

Original Action/Timeline
ORD is shifting FTEs for exposure research into the SP2 program and has initiated an Implementation Planning process which is expected to be completed in 2008. The next update of the MYP will provide stronger evidence of linkages to the exposure research of other ORD programs that is relevant to supporting OPPTS.

Updated Response
Significant progress has been made addressing the BOSC recommendations for increasing the emphasis on exposure research and also to link and improve the communications among the exposure, effects and risk management researchers. Activities related to two specific areas, ecological risk assessment and perfluorinated chemicals (PFCs), are provided as examples.

NERL has realigned full time equivalents (FTEs, personnel) to LTG 2 from other research programs to provide greater exposure emphasis and to support the development of an integrated exposure-effects research program addressing high priority spatially explicit ecological risk issues. NERL and NHEERL scientists conducted a series of problem formulation and research planning workshops with the Office of Chemical Safety and Pollution Prevention (OCSPP, formerly the Office of Prevention, Pesticides, and Toxic Substances) and Regional scientists. The highest priority Agency ecological risk assessment problems have been identified and a conceptual model for integrated ORD research developed. A LTG 2 collaborators workshop will be held on July 13-15, 2010 to develop an integrated, transdisciplinary research program that will address the highest priority needs.

Scientists from NERL, NHEERL, and the National Risk Management Research Laboratory (NRMRL) continue to collaborate and conduct high priority research to address key science issues related to PFCs under LTG 1. Collaborating with the Office of Pollution Prevention and Toxics (OPPT) and Regional scientists, the ORD scientists have designed and implemented an integrated PFCs exposure, effects, and risk management research program supporting OPPT's Enforceable Consent Agreement and PFOA Stewardship Programs. NHEERL and NERL scientists are conducting research supporting OPPT's Perfluorooctanoic Acid (PFOA) risk assessment. NERL and NRMRL research is investigating the potential for selected PFCs in commercial and consumer products to degrade through environmental and industrial processes. NERL scientists collaborated with Region 4 and OPPT scientists to develop and apply exposure methods for characterizing environmental and human exposures resulting from the land application of PFC-laden biosolids and the disposal of PFC-laden industrial wastewaters at two Region 4 geographical locations. These projects required collaborations among EPA, USDA, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Agency for Toxic Substances and Disease Registry (ATSDR) scientists. ORD's research results were used by Region 4, OPPT, and the Office of Water (OW) risk managers to develop Provisional Health Advisories for PFOA and perfluorooctyl sulfonate (PFOS) in drinking water and the design of risk management strategies. NERL scientists are collaborating with numerous regional, state, and non-governmental scientists to develop and apply exposure methods designed to characterize PFC concentrations in environmental and biological samples in selected national rivers and watersheds. NERL conducted a stakeholder's exposure research strategy workshop in March 2010 to identify Agency exposure needs and design future PFCs exposure research. ORD scientists have planned and supported two international PFC symposia

since the 2007 BOSC Review (June 2008 and 2010) that have been attended by over 260 scientists and managers from all sectors (EPA, other federal/state agencies, industry, academia) around the world. The PFCs state-of-the-science has been documented and opportunities for collaborative research address key science issues identified. Key papers from the workshops were/will be highlighted in symposia-dedicated peer-reviewed scientific journals.

Current Progress
The NERL FTEs were realigned into LTG 2. A July 2010 LTG 2 workshop is planned with key ORD, Program Office and Regional scientists to develop an integrated spatially-explicit ecological risk assessment research program. A draft research plan is anticipated to be completed in September 2010 and a final one in January of 2011. A PFCs' exposure research strategy workshop was conducted in March 2010 and priority exposure research needs identified. A workshop report will be available in July 2010, a draft research plan in August 2010, and a final research plan in December 2010. The third international PFCs symposium was conducted in June 2010. The key symposium results will be published in two symposia-dedicated peer-reviewed journals in late 2010/early 2011.

BOSC Recommendation # 5
Health scientists from LTG 1 and LTG 2 would be well served by having stronger interaction. A mechanism(s) to improve communications between groups doing research on these two LTGs is (are) recommended. For example, [posters] LTG 1A-12 and LTG 2-6 focus on physiological and behavioral studies with exactly the same fish. One project is emphasizing short timescales (days) and the other conducts apparently similar work, but at longer timescales (weeks).

Original Response
In general, ORD agrees that increased efforts on reinforcing cross-Laboratory and ORD research interaction and coordination will enhance and improve the efficiency of our research program. In the particular case presented on posters LTG 1A-12 and LTG 2-6 there are little commonalities other than the species being used. The goal of the research presented in poster LTG 1A-12 is to develop a high-throughput whole animal (fish embryo) screen for developmental neurotoxicants (DNTs) in conjunction with the research presented in poster LTG 1A-11 on high throughput *in vitro* assays for DNTs. The work represented on poster LTG 2-6 is part of the reproductive toxicity screening related to endocrine disruption and is being conducted in collaboration with research under LTG 3 under the Endocrine Disruptors Research Program.

Original Action/Timeline
Cross-laboratory coordination is continuously sought and achieved. In this particular instance, no further action is needed.

Updated Response
As noted in the update to Recommendation #4, there are significant cross-laboratory interactions, as can be evident in the two examples we provided. Several other examples include: utilization of the National Research Council's (NRC) Visiting Scientist Program to bring a former NERL post-doc to NRMRL to continue work with methods' development; NHEERL, NRMRL, and NERL committed to work with Region 5 on developing a Regional Applied Research (RARE)

project focused on the PFCs in wastewater biosolids and their potential as sources to the environment.

Current Progress
Cross-laboratory interactions are ongoing.

BOSC Recommendation # 6
The SP2 Subcommittee believes that an integrated evaluation of the entire program on health risk, whether it be in SP2, Human Health, EDCs, or other areas, be performed to provide advice on program balance, especially with respect to exposure.

Original Response
ORD appreciates the "noteworthy" recognition of the LTG 1C research program and recognizes that the LTG 1 A/B research programs could be enhanced with increased contribution from exposure researchers. As noted in response to Recommendation 4, ORD is increasing the exposure FTE resources in the SP2 plan and is using an Implementation Planning Process to identify the highest priority areas for an increased exposure component. The BOSC Subcommittee review and insights will be carefully considered in these discussions.

It should be pointed out that in 2004, ORD's Laboratory/Center/Office Directors recommended that research on aggregate exposure and cumulative risk, which had been ongoing through a separate research program on *Safe Foods* and was directly supportive of research needs identified through FQPA, be consolidated into related research in the Human Health Research Program. This consolidated research has been reviewed by the BOSC Subcommittee on Human Health Research (2005) and found to be "promising," "important work," that "provide[s] rapid response to the needs of the Agency's regulatory program," with "new and interesting results." In particular, they acknowledged that the research "will generate models for use in determining the cumulative risks of carbamates and pyrethroids and allow EPA to conduct state-of-the art cumulative assessment[s]."

As noted at the BOSC review and in response to Recommendation 4, other ORD research programs also carry out human health exposure research that is relevant to meeting the needs of OPPTS. Therefore, the ORD National Program Directors for the SP2, Human Health, EDCs, Air, and other research programs confer periodically to ensure that programs are not conducting duplicative efforts, that priority needs do not "fall through the cracks," and that the products of the research are disseminated to those who may find them of benefit. An approach for improved cross-program communication of the entire ORD human health exposure program will be developed for the update of the MYP

Original Action/Timeline
Additional FTEs for exposure research are being aligned under the SP2 program. The NERL SP2 Implementation Planning process should be completed in 2008. An approach to better communicate human health exposure research conducted across MYPs will be developed for the MYP update.

Updated Response
As noted under Recommendation #2, parts or all of the SP2, Endocrine Disruptors, Human Health, Human Health Risk Assessment, Nanotechnology, and Computational Toxicology Research Programs are undergoing realignment and reorientation to support the new SPSWRP. ORD is using a more rigorous and reiterative process than previously to work with Program and Regional Office partners, across all of its laboratories and centers, and with external stakeholders to develop the problem formulation and science questions that should be addressed under SPSWRP. The cross-organizational input will be ongoing from problem formulation through research product delivery. This process should not only improve the leveraging of resources and research efforts but also the communication of our research products.

Current Progress
An improved research planning, implementation, and communication process is being developed through the development of the SPSWRP. The program is anticipated being fully operational in FY2012.

BOSC Recommendation # 7
The SP2 Program should emphasize the need for explicit and transparent validation/verification of both analytical methods and models used within the program or developed by the program.

Original Response
ORD agrees that future versions of the MYP need to clarify the distinction that while ORD research may lead to the development of a method or model, that the validation of that method/model is done by an independent group of experts. ORD thanks the BOSC Subcommittee for identifying the inaccuracy that exists in the wording of one of our APGs under LTG 1: "Develop and validate virtual chemical and alternative methods for risk-based prioritization and screening of chemicals." This will be reworded in the next version of the MYP to reflect that ORD will "develop" the methods and, subsequently "submit them for validation."

Original Action/Timeline
The APG will be reworded in the update of the MYP.

Updated Response
As noted previously, the SP2RP MYP has not been updated because of the merger of the research program with others to form SPSWRP. This recommendation will be considered in the development of the new SPSWRP and its accompanying research plan and MYP.

Current Progress
It is not clear when the new research program will have a research plan or MYP, although SPSWRP is expected to be fully operation in FY2012

BOSC Recommendation # 8
Clarify the criteria used to select new compounds for study, and expand the list of compounds under LTG 1C using the methods currently in use. There are many additional compounds in LTG 1C that merit study, and the criteria for selection of compounds that will be studied for effects and exposure are not clear.

Original Response
As noted in the Subcommittee report, OPPTS actually identifies and prioritizes those elements of our research program that need to be accomplished in the shorter-term, that is those that are consistent with LTG 1C. OPPTS' priorities are often based upon regulatory decisions that they see forthcoming in the near future (e.g., the lead (Pb) R&R rule, announcement on the value of use of sealants on CCA-treated wood), or a critical piece of data that needs to be developed to interpret or complement data that have been submitted by industry (e.g., as with a pesticide's registration package). When there are insufficient resources to conduct both new and previous research that we have committed to completing for them, we ask them to identify which element(s) of our research portfolio could be deferred in order to conduct the newer high priority effort. The next version of the MYP will clarify how these determinations are accomplished.

Original Action/Timeline
The next version of the MYP will clarify how determinations of short-term research priorities are accomplished.

Updated Response
Through the development of the new SPSWRP, as noted under the update to Recommendation #6, ORD is engaging Program and Regional Office representatives to a greater degree to develop the problem formulation and identify and prioritize the problem areas that the research should address. The process being used to develop SPSWRP will be captured in whatever research plan or MYP is developed for it, thereby addressing this recommendation.

Current Progress
It is not clear when the new research program will have a research plan or MYP, although SPSWRP is expected to be fully operation in FY2012

BOSC Recommendation # 9
There is a need to begin movement towards an ecosystems approach that fully and accurately assesses population and community risks associated with various aspects of SP2.

Original Response
As part of the ongoing planning process, ORD is considering how additional FTEs can be fully integrated into the existing LTG 2 program and is planning new research that moves towards an integrated, spatially explicit risk assessment program for targeted population and communities of concern that adds a new exposure component to the existing ecological effects modeling efforts. To define the integrated new research program, as noted in response to Recommendation 6, the National Exposure Research Laboratory in collaboration with the other ORD Laboratories/Centers, OPPTS, and the Regional Offices has initiated an Implementation

Planning process for identifying the highest priority areas of exposure research which will allow improved integration of the exposure research with the effects research already represented in the National Health and Environmental Effects Research Laboratory SP2 Implementation Plan.

Original Action/Timeline
The NERL SP2 Implementation Planning process should be completed in 2008. The NHEERL SP2 Implementation Plan was completed in 2005.

Updated Response
See the update to Recommendation #4 for the latest information on progress related to increasing the support to develop an integrated exposure-effects research program addressing high priority spatially explicit ecological risk assessment issues.

Current Progress
NERL FTEs were realigned into LTG 2. A July 2010 LTG 2 workshop is planned with key ORD, Program Office and Regional scientists to develop an integrated spatially-explicit ecological risk assessment research program. A draft research plan will be available September 2010 and a final one in January 2011.

BOSC Recommendation # 10
There is a need to develop further the mathematical foundations that underpin the current modeling efforts, with greater rigor associated with statistical applications in risk assessment. Research in LTG 2 largely focused on empirical and analytical methods to reduce the uncertainties associated with strict reliance on population measures.

Original Response
ORD agrees that the quality of the models developed within LTG 2 is only as good as the mathematical and ecological foundations on which they are based. ORD will take the comments of the BOSC and implement them to encourage greater integration of our ecological modeling efforts to include exposure and the effect of changes in habitat to expand the utility of the currently available models.

Original Action/Timeline
The process for development of the NERL SP2 Implementation Plan, which will be completed in 2008, will lead to addressing this recommendation.

Updated Response
See the updates to Recommendations #4 and 9. Emphasis will be placed on enhancing the current models Agency risk assessors and managers use for regulatory processes and applying advanced statistical/bioinformatics techniques for reducing uncertainty. An inventory of models has been conducted and key gaps identified. Research addressing these key modeling gaps are a high priority. The ORD researchers will seek opportunities to integrate the readily available, innovative computing, statistical and bioinformatics tools when designing and implementing research to reduce the modeling gaps identified through the model assessment activity.

Current Progress
A July, 2010, workshop with key ORD, Program Office and Regional scientists will be held to develop the future integrated research program. A draft research plan will be available September, 2010, and a final one in January, 2011.

BOSC Recommendation # 11
Pursue collaborative relationships to advance methods and techniques in the area of high-performance computing (grid and cluster computing and scientific data visualization) to facilitate development and applications of state-of-the-art coupled biophysical spatial models that integrate biology, predator-prey systems, habitats, physics, and humans for probabilistic risk assessment.

Original Response
ORD agrees that information technology is advancing rapidly and that cluster computing along with other high performance computing capability would increase the speed and breadth of applications we could develop. One important aspect that is a critical component of ORD's research program is technology transfer to the end-user community in EPA, the States, and Tribes. In consideration of the end-user community, it is necessary that predictive modeling programs be available on standard platforms that do not require high-level computing skill or hardware. With that consideration in mind, a significant portion of the work under LTG 2 is development of web-based applications that are and will be available publicly. In addition, ORD's National Center for Computational Toxicology (NCCT) is pursuing several research programs that use EPA's supercomputer or grid system, including a project to evaluate ligand-receptor interactions for a large number of chemicals and proteins and for visualization of virtual tissue models. As with the above, the products of such research would be made web-accessible to the general public.

Original Action/Timeline
Activities are ongoing in the development of web-based applications of ORD's research products for use by our clients, and the identification and pursuit of research partners to help provide tools that our clients can use.

Updated Response
See updates to Recommendations #4, 9 and 10. In addition, EPA's Office of Environmental Information (OEI) has convened several workshops across ORD to demonstrate EPA's state-of-the-science high performance computing and visualization techniques. The OEI scientists are invited to participate in the development of the integrated modeling research plans and are being asked to help incorporate these innovative capabilities in the design of the future research implementation plans.

Furthermore, ORD's National Center for Computational Toxicology (NCCT) is continuing its research to build a Virtual Tissues knowledgebase and a cell-based tissue simulator. This research is focused on the Virtual Liver (v-Liver™) and the Virtual Embryo (v-Embryo™). The Virtual Tissues knowledgebase will be a free publically available tool that efficiently synthesizes published experimental observations on the biological effects of chemicals and any new data that analyzes the potential toxicologic processes. The knowledgebase will include an ontology that

describes inter-relationships between normal physiologic events and their perturbations by chemicals across dose, time, species (*in vitro* and *in vivo*), and genders. It will link chemical effects networks to produce computable models of key molecular, cellular and circulatory systems in the human model. The cell-based tissue simulator will simulate chemical-induced effects in the liver and the embryo using three interconnected systems micro-circulation, cell and molecular response, and tissue response.

Current Progress
A July 2010 workshop with key ORD, Program Office and Regional scientists will be held to develop an integrated ecological risk assessment research program. Participants will include OEI scientists who will bring with them expertise regarding innovative modeling and visualization techniques.

All of the currently available published experimental observations on the biological effects of chemicals and any new data for the embryo and liver are now collated into the Virtual Tissues knowledgebase. NCCT's Virtual Tissues research team is currently working to finalize a user-friendly version that can be posted online for public use. The Virtual Tissues research team is now using the knowledgebase as an internal resource. The Virtual Tissues Knowledgebase will be available online to the public at the end of this year (2010).

BOSC Recommendation # 12
It is recommended that knowledge on early products of agricultural biotechnology be broadened to meet future releases of PIP crops (e.g., to PIP crops with multiple engineered traits and other agricultural systems and environments). The research area is currently very narrow to address the most urgent needs and evaluate the products currently on the market. In addition, the following research topics, which are not included in the current program, should be addressed: (1) the need for monitoring the proteins fate/transfer/effect in the environment; (2) development of improved analytical methods for environmental matrices; and (3) looking ahead at biopharming (e.g., production of pharmaceutical products by transgenic crops) and future commercialization of PIP crops.

Original Response
As the BOSC Subcommittee has noted, the current research area is addressing the highest priority needs identified by OPPTS. When the biotechnology initiative began in FY 2003, it was funded at a level of $4.9 M. Since then, there have been sequential reductions to the program so that in the FY 2008 President's Budget, proposed funding is at $3.6 M (a 26% decrease from that of the initiative). The level of funding is sufficient to support the intramural researchers and approximately $1 M/year for the STAR program on potential allergenicity. It is for these reasons that, although the additional areas that have been recommended by the BOSC sound interesting and would thrust us into the forefront of this field more so than our current efforts, it will not be possible to expand the program. As with other elements of our research program, we will continue to seek partners with whom we can leverage our expertise and resources. For example, since the BOSC review we have issued a joint solicitation for research proposals with the National Institute on Allergy and Infectious Diseases (NIAID) on Exploratory Investigations on Food Allergy, where we have specified that EPA's interest is in the development and

application of methods, identification of biomarkers, and evaluation of protein characteristics (including those of novel proteins) associated with food allergy.

Original Action/Timeline
ORD will continue to seek research partners in this area. A joint request for proposals was issued with NIAID on August 23, 2007. No other action is proposed based upon limitations in available funds for biotechnology research.

Updated Response
See update to Recommendation #1 regarding the elimination or realignment of the Biotechnology Research Program.

ORD, through its extramural Science to Achieve Results (STAR) grants program, sought partnerships to advance the science regarding the potential allergenicity of genetically engineered crops. ORD, the National Institute of Allergy and Infectious Diseases (NIAID), the Food Allergy Project, and the Food Allergy and Anaphylaxis Network, jointly issued a Request for Applications (RFA) in 2007 for proposals on mechanisms and risk factors contributing to food allergenicity and the development of animal models through which to study food allergenicity. Collectively, 16 proposals were funded (four by ORD). A joint workshop was held to bring the awardees and others in the scientific field together to evaluate the state of the science and determine the remaining research needs. The findings of the workshop were published. Some of the grantees were brought together for a symposium at the 2009 Society of Toxicology Annual Meeting. In October, 2009, ORD by itself issued another RFA for proposals that characterized the key factors that influence human immune responses to dietary proteins in order to develop improved methods for assessing the potential dietary allergenicity of pesticide proteins in genetically engineered crops. The submitted proposals are still undergoing review; but it is anticipated that four new awards will be made. After this, no additional research is planned in the area of biotechnology.

Current Progress
ORD continues to track the 16 awards made jointly with NIAID and the other organizations. Most of those grants end in late 2010/early 2011. Within the next few months ORD will announce four additional awards, a result of the 2009 RFA. The new awards will be for a period of three years.

BOSC Recommendation # 13
It is important to maintain the existing cross-disciplinary and cross-organizational collaborations that exist and build upon them, where appropriate. Significant scientific interrelationships exist across the SP2 Program, with some flowing into others. Such scientific and resource leverage benefits the program. For example, a method developed under one program may be applied to another program.

Original Response
ORD appreciates the positive feedback regarding our cross-disciplinary and cross-organizational collaborations. The program will continue to work toward seeking other partners, inside and

outside the Agency, whose interests/efforts are complementary and with whom we can leverage resources.

Original Action/Timeline
ORD will continue leveraging the research program with others, both within and outside the organization. Efforts are ongoing.

Updated Response
Since the BOSC review, the SP2RP has strived to work collaboratively across organizations, within ORD, within EPA, and with organizations outside of EPA. The updates to Recommendations #1, 4, 5, 6, and 12, for example, provide examples of these interrelationships.

Further, ORD, under the leadership of its new Assistant Administrator Paul Anastas, is transforming its research portfolio to developing and implementing better integrated transdisciplinary (ITR) research programs that provide relevant and responsive science and tools addressing current and emerging Program Office and Regional issues. As described previously, under the update to Recommendation #2, the developing SPSWRP, which includes resources from the SP2 research program, is under development using the principles of ITR. The newly developing program emphasizes the establishment of strong collaborations/partnerships within and outside ORD.

Current Progress
The SP2RP has further strengthened its implementation of cross-organizational and cross-disciplinary expertise in addressing its goals. The SPSWRP, which is being developed in part with some of the SP2RP resources, is incorporating principles of ITR. The program is expected to be operational in FY2012.

BOSC Recommendation # 14
Revise the language to better express the program. For example, an APG should be accomplishable over the life of that APG with the resources available. This is primarily an issue of clarification because the projects themselves flow well. The sequencing of projects for LTG 1 A/B, as described in the text above, is not possible to follow accurately because the phrasing of the APMs and the APGs is not consistent with resources or projects being performed.

Original Response
As noted previously in the response to Recommendation 3, ORD agrees that the wording for the APG on development of methods needs to be revised to reflect that we would submit the methods for validation to another party. As ORD revises the MYP it will also consider modifications to other APGs, as well to better reflect the intent of the Goal. The BOSC Subcommittee has pointed out that greater resources are needed to attain the APG on "evaluate…current test methods…." It should be noted that in developing the MYP, ORD took into consideration the resources it had as of FY 2007 and assumed an even budget in future years in developing the APGs and APMs. It may very well be that, as the period of time for the APG continues, ORD may determine that additional research and time are needed to adequately

address the APG. Modifications would be made to the MYP at that time to accommodate these needs.

Original Action/Timeline
As noted in response to Recommendation 3, ORD will clarify the generic relationship between APGs and APMs in the next update of the MYP and ensure greater consistency and clarity with the wording of the APGs and APMs. The APGs and APMs will continue to be identified keeping in mind the budget.

Updated Response
See update for Recommendation #2 for the latest information on APGs and APMs. Also, as noted under the update for Recommendation #2, the SP2RP MYP has not been updated because of its merging with other research programs to form SPSWRP. This recommendation will be considered in the development of the new SPSWRP and its accompanying research plan and MYP.

Current Progress
ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to performance measures across ORD programs. It is not clear when the new research program will have a research plan or MYP, although SPSWRP is expected to be fully operation in FY2012

BOSC Recommendation # 15
ORD should more rapidly develop its own research program in nanotechnology, and encourage other funding organizations internationally to also work in the area. There will always be "high priorities" that exceed resources available. Thus, prioritization within the "high" category is essential. SP2 has done this reasonably well, with one major exception: the health and environmental risk implications of nanotechnology. Virtually all stakeholders and interested parties nationally and internationally are calling for a vastly expanded research program on implications, but it is not happening to a significant degree.

Original Response
ORD appreciates the Subcommittee's comments regarding the need for EPA to demonstrate leadership and develop a nanotechnology research program quickly. Several years ago, ORD realized that, although some studies had been done to determine potential toxicity of certain nanoparticles to humans and other organisms (both *in vivo* and *in vitro*), very little research had been performed on environmental fate and transport, transformation, and exposure potential. Research also is lacking on technologies and methods to detect and quantify nanomaterials in various environmental media. In addition, studies indicate that the toxicity of the nanomaterial will vary with size, surface charge, coating, state of agglomeration, etc. Consequently, the Agency has developed a Nanomaterial Research Strategy (NRS) that is currently undergoing Program and Regional Office review. An external peer review is planned to take place in March, 2008. The scope of this research document is strategic in that it discusses broad themes and general approaches. The purpose of this strategy is to guide the ORD program in nanomaterial research. The strategy builds on, and is consistent with, the foundation of scientific needs identified in the report by the Nanotechnology Environmental and Health Implications (NEHI)

Workgroup (NSTC, 2006), and on the EPA White Paper on Nanotechnology (EPA, 2007). Special attention is given to EPA's role among Federal Agencies in addressing data needs for hazard assessment, risk assessment, and risk management relevant to the EPA mission and regulatory responsibilities. ORD will use the NRS and incorporate these research activities into the multi-year planning process.

Original Action/Timeline
Beginning in fiscal year 2007, ORD focused on the following high priority areas: environmental fate, transport, transformation and exposure; and monitoring and detection methods. Resulting data will be used to inform and develop effects and exposure assessment methods and identify important points of releases for potential management. Having laid a foundation for understanding possible material alterations under various conditions, ORD will direct a greater share of fiscal year 2009 and 2010 resources to exploring the effects, specifically toxicity of the altered materials as identified in the first two years. To complement its own research program, EPA is working with other federal agencies to develop research portfolios that address environmental and human health needs. In addition, the Agency is collaborating with academia and industry to fill knowledge gaps in these areas. Finally, the Agency is working internationally and is part of the Organization of Economic Cooperation and Development's efforts on the topic of the implications of manufactured nanomaterials.

Updated Response
ORD has implemented the NRS, and in fiscal year 2007 added an intramural component to its nanomaterials research program. The STAR grants portion of the program has issued joint and coordinated RFAs with other federal agencies as well as internationally with the United Kingdom (UK) and the European Commission (EC), focusing on environmental fate and transport and ecological toxicity. The new in-house program is conducting research that complements that of other federal agencies, and is collaborating with other governments' research through the Organization for Economic Cooperation and Development (OECD).

Current Progress
The EPA Nanomaterial Research Strategy was published in June, 2009. The ORD nanotechnology budget has steadily increased every year since 2007: the fiscal year 2011 President's Budget Request for ORD nanotechnology research is $20.1 million.

BOSC Recommendation # 16
Describe criteria for prioritization of future work and discuss how the additional projects meet the criteria. The priorities for ongoing work are appropriately described. However, the priorities for future work, if new funds became available, are poorly described.

Original Response
In FY 2006, OMB introduced a pilot program within the Agency, resulting in an additional $4.5M for research provided for the Pesticides and Toxics Offices. In response to this budget increase, teams of managers and scientists from across ORD's Laboratories and Centers, the Office of Pesticide Programs, the Office of Pollution Prevention and Toxics, the Office of Science Coordination and Policy, and the lead Region for pesticides and toxics held a series of

meetings to determine how these additional resources would be used. Within a short period of time, the multiple parties reached a consensus on identifying the research needed and allocating the resources accordingly. The planners used the previous SP2 MYP as the overall framework to guide their decisions. In a number of instances, the additional resources went to accelerate projects already planned. In other cases, new research that was complementary to ongoing efforts was identified. Many of these efforts are described within the SP2 MYP. This approach and partnership resulted in a portfolio of research that is already having an impact on Agency decisions about a year and a half after implementation. Therefore, a similar approach would likely be used should additional resources become available in the future.

Original Action/Timeline
The Appendix in the update of the MYP will provide greater detail on the process identified above which was used successfully to accelerate research in areas that had previously been identified as high priority. In addition, the updated Appendix and will provide stronger descriptions of options for potential new research directions based upon discussions with OPPTS senior managers.

Updated Response
As noted in the update to Recommendation #6, ORD is using a more rigorous and iterative process than previously to work with Program and Regional Office partners, across all of its laboratories and centers, and with external stakeholders, to develop the problem formulation and science questions that should be addressed under SPSWRP. The process will include prioritization of the science questions. The cross-organizational input will be ongoing from problem formulation through research product delivery. This process should not only improve the leveraging and prioritization of resources and research efforts, but also the communication of our research products to ensure that product delivery is responsive and timely.

Current Progress
An improved research planning, implementation, and communication process is being developed through the development of the SPSWRP. This new process will be captured in whatever research plan or MYP is developed. While it is not clear when the new research program will have a research plan or MYP, SPSWRP is expected to be fully operation in FY2012

BOSC Recommendation # 17
In the areas of statistical analyses, bioinformatics, theoretical and mathematical model building and probabilistic risk assessments, a strong need for and growth of collaborations is recommended. Some of the strongest program elements reviewed have been those that demonstrated strong intra-Agency, inter-Agency and vibrant academic collaborations.

Original Response
The National Center for Environmental Research (NCER), as part of the Science to Achieve Results (STAR) program, has completed its second year of funding for two environmental bioinformatics centers. The STAR-funded centers are The *Carolina Environmental Bioinformatics Research Center at the University of North Carolina at Chapel Hill* and the *New*

Jersey Research Center for Environmental Bioinformatics and Computational Toxicology. Both Centers will be funded through 2010.

The Centers bring together multiple investigators and disciplines, combining expertise in biostatistics, bioinformatics, cheminformatics, computational biology, and computer science. They are developing novel analytic and computational methods, creating efficient user-friendly tools to disseminate the methods to the wider community, and are applying the computational methods to data from molecular toxicology and other studies.

Both Centers are being funded as cooperative agreements, enabling collaboration with scientists from the ORD's National Center for Computational Toxicology and National Center for Environmental Assessment. Interactions between the STAR Environmental Bioinformatic Centers and ORD will further be facilitated by a seminar program that brings scientists to Research Triangle Park, NC., on a bimonthly basis starting in 2008. This supplants the teleconference seminars that were conducted throughout 2007 targeted at introducing the goals and objectives of the STAR Centers to the intramural workforce.

Both NHEERL and NCCT have committed to increasing the breadth of the intramural workforce in bioinformatics and systems biology and collectively they have added four senior level staff in these areas and who are collaborating with the researchers from the extramural Bioinformatics Centers.

Original Action/Timeline
Significant efforts of collaboration across ORD and with extramural scientists in the areas of bioinformatics have been ongoing for the last two years and will continue for at least another three. As noted previously, ORD continuously seeks opportunities to leverage our resources and expertise with others and we will continue to do so in this area.

Updated Response
The activities described in the original response have continued. The two original Bioinformatics Centers are in their last year of funding. Other STAR awards have also been made in the form of cooperative agreements to nurture and facilitate collaborations with NCCT and other ORD scientists. In 2008, the Carolina Center for Computational Toxicology was established as a result of a $3.4 million award to the University of North Carolina – Chapel Hill. Scientists at the Center are working collaboratively with NCCT scientists to develop complex predictive modeling solutions that span mechanistic- to discovery-based efforts. In addition, in 2009, ORD awarded nearly $3.2 million to the University of Houston for a new STAR Center to investigate how toxic chemicals might impact developing organisms. This innovative research uses genetic and cellular methods to help build models that predict possible toxicity at the organism level. The University of Houston researchers are working with Texas A & M , Indiana University at Bloomington, and EPA's Virtual Embryo project to further the development of computer models that could predict how chemicals interact with a fetus and lead to birth defects.

ORD's Computational Toxicology Research Program has established two Communities of Practice (CoP) in the areas of Chemical Prioritization and Exposure Science. The purpose of the CoP is to bring together EPA and the outside scientific community to help promote common

practices and ontologies adoption, guide development of common databases and software, aid in training material development, provide recommendations on efficiencies of relevant operations, and act as a public outreach mechanisms for EPA's Comp Tox research efforts. Each CoP has a charter and open membership policy, and meets through teleconferences, face-to-face meetings, team rooms and workshops, and includes hundreds of participants from around the world and different sectors.

In an effort to further increase its breadth of expertise in systems biology, NHEERL underwent a reorganization of its human health divisions and created an Integrated Systems Toxicology Division. A solicitation for a senior level staff Director has been advertised.

Current Progress
ORD has continued seeking opportunities to partner with scientists outside the Agency to leverage our expertise and resources in the areas of bioinformatics and systems biology. Several different mechanisms offer examples of our commitment to do so – continued issuance of RFAs and funding of new STAR Comp. Tox. Centers in the form of cooperative agreements, developing CoP, and reorganizing to establish a stronger systems biology/toxicology intramural program. The two new Comp Tox Centers will be funded until 2012. As an example of our frequent interactions with scientists in the Centers, in May, 2010, ORD's NCCT, NCER and NHEERL research team and the project lead from each academic institution of the University of Houston Center met to discuss how the collaboration will develop alternative model platforms (zebrafish embryos and embryonic stem cells) and develop high-throughput screening resources pertaining to *in vitro* and *in silico* models of developmental toxicity pathways.

BOSC Recommendation # 18
The SP2 Program is large and far-flung. On occasion, the panel found it difficult to identify the relationship between high quality work and a specific goal. The Subcommittee believes it might be useful to have service awards (as well as peer-reviewed papers) mapped to individual program elements to better designate high quality products.

Original Response
ORD has and will continue to include service awards in biosketches for all programs. In addition, for the SP2 Research Program Review, additional materials were provided as background that pulled information such as awards, editorial positions, positions in professional societies, etc., into integrated tabular form. There has been some discussion among ORD managers recently on the merit of deliberately tracking and reporting awards within each program, but there is not consensus at this time that summary-level award information, aligned as recommended, is appropriate for all programs. ORD is intending to bring this subject up as part of the discussion on program metrics before the BOSC Executive Committee (EC) in January, 2008. This interaction with the BOSC EC on this topic will inform the policy on systematically collecting this type of information for future BOSC reviews.

Original Action/Timeline
Information will continue to be supplied in biosketches and other formats when possible. Discussions at the January, 2008, meeting with the BOSC EC will lead to a determination of a

policy regarding the value-added of collection and presentation of detailed information for future BOSC reviews.

Updated Response
The BOSC EC meeting referenced above did not appear to result in any agreement or stated policy regarding the tracking and reporting of awards for ORD's program reviews. However, the subject of demonstrating the high-quality of our research remains a priority for ORD. The current plan is to demonstrate the perceived quality of the research team and their technical and scientific products by providing partner/client testimonials and interviews, and bibliometric analysis. Recognizing the limited success of using the current bibliometric techniques of high impact and highly cited publications to evaluate quality, ORD is exploring new bibliometric approaches to measure not only quality of the work but also performance of the various research programs. ORD will continue to engage the BOSC EC in developing appropriate bibliometric measures to be used in the program reviews to assist the BOSC in evaluating the quality and performance of our research.

Current Progress
ORD anticipates having new bibliometric measures by June 2011.

BOSC Recommendation # 19
The peer-review process used by the SP2 Program should be continued. The SP2 Program effectively uses appropriate external and internal peer-review mechanisms in the Science to Achieve Results (STAR) Program selection process and in the development of research priorities and products.

Original Response
ORD appreciates the positive feedback regarding the use of peer review mechanisms. While we feel that our existing peer review policy and procedures provide the necessary framework for our peer review program, we continually look to identify ways to build on our successes to further strengthen peer review within ORD and across EPA. Consistent Agency-wide application of peer review has been an EPA priority for many years. Since issuing our peer review policy in 1993, we have taken several major steps to support and strengthen the policy. But proof of a policy's value lies in its implementation, and here also EPA has been very active to ensure that our peer review policy is not only understood across the Agency, but is *applied* rigorously across EPA's program and regional offices. Use of the 2006 *Peer Review Handbook, 3rd Edition*, which we believe is one of the most advanced treatments of peer review for intramural research and scientific/technical analysis of any Federal Agency, keeps the Agency aware of the importance of peer review and provides guidance for the application of peer review. Regular training helps reinforce adherence to the policy and procedures.

Original Action/Timeline
ORD will continue to follow existing guidance and policies to ensure its research programs and products are appropriately peer reviewed. Efforts are ongoing.

Updated Response
The 2006 *Peer Review Handbook, 3rd Edition* still governs our approach to peer review ORD-wide.

Current Progress
ORD continues to follow the peer review guidance and policies.

BOSC Recommendation # 20
Continue to reward scientific excellence and minimize administrative burdens. Maintaining this leadership position requires constant attention to supporting an organizational culture that favors research that makes a difference to EPA's mission. Recruitment and retention of the "best and brightest" is fundamental to success and is enhanced by such a culture. This can be difficult because it requires a wide array of resources (personnel and funds) and focuses on long-term as well as short-term research issues.

Original Response
ORD appreciates the positive feedback regarding our rewarding scientific excellence and seeking ways to continue to minimize administrative burdens. ORD agrees that recruiting and retaining excellent scientists is key to the continued success of this research program. ORD will continue to use the variety of mechanisms it has to do so. In addition to recruiting and retaining our own personnel (Full Time Equivalents- FTEs), ORD can rely on other innovative mechanisms to supplement and complement the scientists in the SP2 Research Program. One approach has been to use existing vehicles to bring on board postdoctoral fellows, recently graduated students, student interns, and other fellows (i.e., through the Association of Schools of Public Health, American Association for the Advancement of Science) who do not count against our personnel ceiling. Another mechanism is to use a newly acquired authority to hire a few senior-level internationally renowned scientists to work with us for a defined period of time. Both the junior-level and senior-level scientists tend to bring vibrancy to research programs.

Original Action/Timeline
ORD will continue to use all mechanisms available to reward and retain its scientists and to recruit new ones. Efforts are ongoing.

Updated Response
As noted in our original response, ORD continues to use all the mechanisms it has to recruit and retain our own personnel (FTEs) and complement them with other talented individuals who do not count against our personnel ceiling. Since the 2007 BOSC Review, the SP2RP has brought on board postdoctoral fellows, graduate students, student interns, and ASPH Fellows. In addition, some of the individuals hired by the National Laboratories through the new senior-level (Title 42) authority spend some of their time on issues related to the SP2RP. Researchers and managers continue to receive rewards for their efforts devoted to the SP2RP through the Agency's Awards', ORD's Awards', or the Science and Technology Achievement Awards processes.

Current Progress
Efforts are ongoing to use all mechanisms available to reward and retain the SP2RP scientists and managers and recruit new ones when warranted.

BOSC Recommendation # 21
More emphasis should be placed on scientist-to-scientist communication through workshops and other suggested interactions. Further, better communication with other laboratories within the federal government (e.g., Department of Energy laboratories) is recommended. ORD managers and scientists view OPPTS as their primary client. Less emphasis is placed on communications to other organizations.

Original Response
The SP2 Research Program uses a variety of mechanisms to communicate the results of its research with our clients and other organizations and scientists. Under section "IX. Communication," the MYP describes the efforts ORD undertakes to communicate with others during the planning, conduct, and after completion of the research. ORD will consider expanding this section in the next version of the MYP to provide greater detail on how this is done. For example, ORD may consider adding an Appendix that lists examples of the planning meetings, progress reviews, workshops, seminars, etc. that have taken place to promote communication. Furthermore, under Section "III. Relationship of EPA's Research to that of Other Organizations," ORD describes the various outside collaborations. These relationships were further explained in a table prepared for the Office of Management and Budget for our Program Assessment Rating Tool submission in 2007. ORD will consider including this or a table similar to it, in the update of the MYP.

Original Action/Timeline
The MYP update will provide greater detail on communications with other federal agencies and other research organizations.

Updated Response
ORD is significantly improving the visibility of its SP2RP through the establishment of research collaborations and the communication of research programs/results with its partners/collaborators/stakeholders. Just a few examples are highlighted here:

- The two ORD-led international symposia on PFC research and science issues are described in detail under the update for Recommendation #4. As noted previously, ORD scientists, working with their counterparts at USDA, FDA, and CDC, developed and applied methods to characterize environmental and human exposures and risk resulting from the disposal of PFC-laden biosolids and waste waters.
- Two EPA-sponsored governmental stakeholder workshops (EPA, CPSC, CDC, and various state agencies) have been conducted since 2009 to communicate research results and understand potential exposures to artificial turf field constituents. NERL scientists reported the results of their pilot study on the evaluation of exposure methods.
- NERL and NRMRL scientists are collaborating with scientists from EPA's Office of Children's Health Protection, the Department of Education, and the Department of Housing and Urban Development to design exposure and risk management research to

understand and reduce potential PCB exposures for school-aged children resulting from past use of PCB-laden caulk.

- ORD, OPPT, CPSC, and HUD scientists communicated their research and technical support activities supporting EPA's lead remediation rule. NERL communicated the results of their methods' development activities and provided laboratory standards to interested governmental and commercial entities. NRMRL established an ETV program for verifying the performance of commercially available Pb test kits.
- NRMRL led the development of a research proposal submitted to the Department of Defense (DOD) Strategic Environmental Research and Development Program with DOD, state, and academic partners to investigate the fate of PFC containing fire fighting foams.
- As noted in the Recommendation #1 update, ORD is collaborating with USDA's ARS laboratories on biofuels research.
- As noted in the update to Recommendation #12, ORD issued a joint RFA with NIAID, the Food Allergenicity Project, and the Food Allergenicity and Anaphylaxis Network, which resulted in collectively funding 12 research proposals.
- Recently the ORD-OCSPP Seminar Series has been reinstated as a means to improve the communication of our research results and encourage discussions on "hot" topics of interest. Anyone inside or outside the Agency can attend these seminars through a webinar.

As noted under the update to Recommendation #2, the SP2RP MYP has not been updated, as the research program will become part of a larger more integrated and more transdisciplinary research program, SPSWRP. This recommendation will be considered in the development of the new research program.

Current Progress

ORD has continued to collaborate with other federal agencies and research organizations. Some of these collaborations are ongoing and others are completed. The results of these research activities have been communicated through publications, and national/international workshops, conferences and symposia.

As noted under Recommendation #2, the SP2RP MYP has not been updated because of ongoing discussions to merge parts of it into the SPSWRP. It is not clear when the new research program will have a research plan or MYP, although SPSWRP is expected to be fully operation in FY2012.

BOSC Recommendation # 22

It is recommended that a more focused communications program be developed to disseminate information from SP2 research out to the Regions and other Program Offices. Some of the research in the SP2 Program has fundamental value to other programs (e.g., endocrine disruptors, human health, ecological assessment, etc.) so managers there should be part of the communication strategy. Because these other programs also have value to the SP2 Program, information from these programs should be communicated more regularly to OPPTS.

Original Response
ORD concurs that there is a need to continue striving to improve our coordination and communications across our research programs to better serve our clients. The MYP, under section "VII Relationship to Other Multi-Year Plans," describes how the SP2 Research Program provides either direct or indirect benefit to other ORD research programs, how other programs benefit SP2, and how communication takes place across the programs. The MYP states the following: "The mechanisms for collaboration with outside-ORD organizations are highlighted in Section III. In order to improve coordination across the MYPs within ORD, the NPD for the Pesticides and Toxics Research Program meets periodically with the NPDs for each of the relevant MYPs as well as the leaders for other programmatic areas (e.g., computational toxicology, nanotechnology, homeland security) who oversee research that is ongoing in support of OPPTS. These discussions are important not only to ensure that are programs are not conducting duplicative efforts but also so that we ensure that the products of the research are disseminated to those who may find them of indirect benefit." ORD recognizes that there is a continued need for improvements. Since the inception of the National Program Directors and similar leadership positions across all of ORD's research programs, there have been a number of discussions on how to improve the cross-program coordination and communication. Through continued discussions, greater understanding of opportunities for partnership and better service to and products for our clients will be accomplished. For example, a meeting between the ORD and OPPTS senior managers will be held in early 2008 to discuss the status of research and identify priorities. While the SP2 Research Program has the lead in organizing the meeting, the research programs that will be discussed also include those on Endocrine Disruptors, Nanotechnology, Computational Toxicology, Human Health, and Ecosystems.

Original Action/Timeline
Striving to improve coordination and communications is an ongoing process. As an example, a coordinated meeting of those research programs that provide the highest priority needs to OPPTS will be held in 2008 among ORD and OPPTS senior managers.

Updated Response
Since the 2007 BOSC Review, ORD has continued efforts to improve communications. Communications between ORD and the primary SP2 Program Office, OCSPP, have been robust and continue to improve. In addition, communication with other Program Offices and Regions are growing. Coordination is occurring from the point of identifying needed research and research prioritization through completion of the research. Program and Regional Offices and ORD are seeking this interaction. In addition, research progress and findings are communicated using several techniques including face to face visits, seminars, teleconferences, and exchange of research products. Funding opportunities such as RARE are being used to supplement SP2RP funds to enhance communications with Regional staff. Examples of efforts to improve communications are further described in the updates to Recommendations #4, 6, 16, and 21.

As part of the discussions with SP2 researchers it has become clear that communications among researchers, Program Offices, and Regions are strong in some areas. It is possible that this strength was not documented or communicated in the background materials for the original BOSC review. Efforts are underway to more effectively document communication efforts.

Documentation will assist in identifying strong communication actions and opportunities, building on existing strengths and applying useful techniques to other areas of the SP2RP.

The meeting among ORD and OCSPP senior managers took place in November, 2009, and provided a valuable forum to discuss critical research needs and help set priorities. Further, as noted previously, ORD is using a more rigorous and reiterative process than previously to work with Program and Regional Office partners, across all of its laboratories and centers, and with external stakeholders in the development, implementation, and communication of the SPSWRP. The cross-organizational input will be ongoing from problem formulation through research product delivery. This process should not only improve the leveraging of resources and research efforts, but also the communication of our research products.

Current Progress
Guided by BOSC recommendations, ORD has pursued improved communications with Program Offices and Regions. As noted in updates to earlier Recommendations, ORD is using different mechanisms to communicate with its partners. Examples, include monthly conference calls among ORD, OCSPP, OW, Region 4, and the Office of Solid Waste and Emergency Response (OSWER) on PFCs; the ORD-OCSPP monthly seminar series; periodic meetings and workshops on ecological risk assessment models development; a PFCs exposure research workshop among ORD, OCSPP, OW, OSWER, and Regions 4, 5 and 6; an OW visit to ORD-Cincinnati labs to discuss research progress on emerging contaminants; periodic technical assistance to OCSPP to prepare them for meetings with industry on PFCs; OCSPP and OW review and clearance of ORD work products, such as peer reviewed scientific papers and EPA reports; and, collaboration on a RARE project with Region 5 on monitoring of PFCs in surface waters and wastewater treatment.

The meeting among ORD and OCSPP senior managers took place in November, 2009, with agreement to continue to hold similar meetings at least once a year.

An improved research planning, implementation, and communication process is being developed through the development of the SPSWRP. The program is anticipated being fully operational in FY2012.

Overall Report Summary Table

Recommendation	ORD Action	Timeline for Action
Recommendation # 1: Include approach to address issues of mitigation potential on gene transfer, effects on non-target organisms, and targeted species resistance within the APGs in LTG 3. Also, improve methods for tracking and quantifying products of genes or new technologies, and expand the operative definition of	**Original Response**: Some efforts are already underway that address Subcommittee concerns, including developing/applying field scale protocols for non target species effects, holding a workshop in 2007 on "Pollen Mediated Gene Flow in the Environment Research," and investigating effects of gene transfer in turf grass. Resources for further development of methods are not available.	**Original Action/Timeline**: A workshop was held in FY 2007. In FY 2009, an EPA report will be completed which documents the testing and evaluation of resistance management models which track the development of resistance to control traits in PIP crops. **Current Progress**: No additional research is planned for the

"biotechnology."	**Updated Response**: Biotechnology resources have been eliminated or redirected to support higher priority Agency issues. Some realignments went to: support an integrated exposure-effects research program on spatially explicit ecological risk, to address impact of stressors on plant populations, and support Biofuels Research Program. Continued research on ecological effects of gene transfer from genetically engineered plants will be valuable in assessing ecological impacts with crops used as feedstock in biofuels. Collaborations have been developed with scientists in academia and in USDA ARS laboratories	biotechnology program. Results from past activities have been submitted for publication and are either in press, accepted, or in review. Research is being redirected with funding from the new Biofuels Research Program. In the next few years, results will become available on the potential impact of increased planting of biofuels feedstock on above and below ground diversity and ecosystem services.
Recommendation # 2: Retain flexibility of structure to emerging science, some of which will be produced by the program itself. APGs and APMs need to be as clear as possible.	**Original Response**: ORD concurs. ORD has provided OMB with performance metrics for APGs and APMs. ORMA has provided new guidance for establishing products, milestones, and impacts of APMs. **Updated Response**: NHSRC pilot on revising APMs to include partners and feedback loop. 2008 MYP guidance since BOSC review in 2007. ORD Executive Council decided transformation was needed. SP2RP is part of the transformation of merging research programs into new SPSWRP. As a result SP2RP MYP has not been updated. Recommendation will be considered in development of new research program.	**Original Action/Timeline**: Improving APGs and APMs is ongoing. The next update of the MYP will reflect new metrics agreed upon with OMB and new ORD guidance. **Current Progress**: ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to all research programs' performance measures. SPSWRP will be fully operational by FY2012.
Recommendation # 3: Clarify relationship between APMs and each APG to make the research more consistent with the text. Each APG should have at least a few APMs each year until the APG is completed.	**Original Response**: ORD will clarify the generic relationship between APGs and APMs and will ensure greater consistency and clarity with the wording of the APGs and APMs. **Updated Response**: See Recommendation #2 for the latest information on APGs and APMs. The SP2RP MYP has not been updated because of ongoing discussions to merge the program with other ones. Recommendation will be considered in development of new research program.	**Original Action/Timeline**: The next update of the MYP will reflect improvements in clarity and consistency in the APGs and APMs. **Current Progress**: ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to all research programs' performance measures. SPSWRP will be fully operational by FY2012.
Recommendation # 4: Greater emphasis is need on exposure-	**Original Response**: ORD has initiated a shift to increase the number of full time	**Original Action/Timeline**: ORD is shifting FTEs for exposure

related research.	equivalent employees (FTEs) conducting exposure research under the SP2 Research Program. NERL has initiated an Implementation Planning process to identify high priority areas of exposure research for the additional FTEs in support of the SP2 MYP. Other ORD research programs are providing relevant exposure-related products in support of OPPTS. **Updated Response**: Exposure FTEs have been shifted into SP2RP. Workshops and conferences to identify Agency needs and plan for an integrated ORD spatially explicit ecological research program have been conducted. A July 2010 stakeholders' workshop will be held to develop specific research plans and initiate responsive research programs. Integrated multidisciplinary research is being conducted to address the Agency's highest priorities related to PFCs. A PFC exposure research strategy workshop was conducted in March 2010. The third international PFCs symposium was convened in June 2010.	research into the SP2 program. In 2008, the NERL SP2 Implementation Plan will be completed. The next update of the MYP will provide stronger evidence of linkages to the exposure research of other ORD programs relevant to OPPTS' needs. **Current Progress**: For ecological risk assessment research program: workshop 7/10, draft research plan 9/10, final research plan 1/11. For PFCs exposure research strategy: workshop 3/10, workshop report 7/10, draft research plan 8/10, final research plan 12/10. Key symposia highlights from the 2010 PFCs' international symposium will be published in two symposium-dedicated peer review journals in late 2010/early 2011.
Recommendation # 5: A mechanism(s) to improve communications between groups doing research in the LTGs 1 and 2 is (are) recommended (specific examples were given).	**Original Response**: Cross-laboratory coordination is continuously sought and achieved. In this particular instance, no further action is needed, because the research between the two identified areas is unrelated. **Updated Response**: Cross-laboratory interactions are encouraged and ongoing. See Recommendation #4 for some examples. Others include using NRC Visiting Scientist Program to exchange scientists across labs, multi-disciplinary collaborations with Region 5 on a RARE project.	**Original Action/Timeline**: Cross-laboratory coordination is ongoing. **Current Progress**: Cross-laboratory interactions continue.
Recommendation # 6: Perform an integrated evaluation of the entire program on health risk, whether it be in SP2, Human Health, EDCs, or other areas, to provide advice on program balance, especially with respect to exposure.	**Original Response**: ORD is increasing the exposure FTE resources in the SP2 research program, is using an Implementation Planning Process to identify the highest priority areas, and taking into consideration the BOSC's insights for an increased exposure component. The BOSC Human Health Subcommittee reviewed the aggregate exposure/cumulative risk research (2005) and found it to be relevant and timely.	**Original Action/Timeline**: Additional FTEs for exposure research are being aligned under the SP2 program. In 2008, the NERL SP2 Implementation Plan will be completed. The MYP update will include an approach to better communicate human health exposure research across MYPs. **Current Progress**: SPSWRP will be fully operational in FY2012.

	Updated Response: Exposure FTEs were realigned and two areas of emphasis were identified – PFCs and spatially explicit ecological risk assessment. Further, as noted under Recommendation #2, parts of the SP2RP are merging with other research programs into new SPSWRP. Improved research planning, implementation, and communication process is being developed with SPSWRP. As a result SP2 MYP has not been updated. Recommendation will be considered in the development of new research program.	
Recommendation # 7: The SP2 Program should emphasize the need for explicit and transparent validation/verification of both analytical methods and models used within the program or developed by the program.	**Original Response**: ORD agrees to clarify the distinction that it develops a method or model, while the validation of that method/model is done by an independent group of experts. **Updated Response**: The MYP has not been updated because parts of the SP2RP will be merged with other research programs. Recommendation will be considered in development of new research program.	**Original Action/Timeline**: The next update of the MYP will reword the APG. **Current Progress**: SPSWRP will be operational in FY2012.
Recommendation # 8: Clarify the criteria used to select new compounds for study, and expand the list of compounds under LTG 1C using the methods currently in use.	**Original Response**: OPPTS identifies and prioritizes those elements of our research program that need to be accomplished in the shorter-term, based on impending regulatory decisions or gaps in industry-submitted data. **Updated Response**: Program and Regional Office representatives are engaged to develop the problem formulation and identify and prioritize the problem areas that SPSWRP should address. The SPSWRP research plan or MYP will capture this process and thereby address this recommendation.	**Original Action/Timeline**: The next update of the MYP will clarify how determinations of short-term research priorities are accomplished. **Current Progress**: It is not clear when the research plan or MYP will be developed but the SPSWRP is expected to be fully operational in FY2012.
Recommendation # 9: Begin movement towards an ecosystems approach that fully and accurately assesses population and community risks associated with various aspects of SP2.	**Original Response**: ORD is considering how additional FTEs can be fully integrated into the existing LTG 2 program and is planning new research that moves toward an integrated, spatially explicit risk assessment program for targeted population and communities of concern that adds a new exposure component to the existing ecological effects modeling efforts. **Updated Response**: See Update to	**Original Action/Timeline**: The NERL SP2 Implementation Planning Process will address this issue. It will be completed in 2008 and will complement the NHEERL SP2 Implementation Plan that was completed in 2005. **Current Progress**: Problem formulation workshops with key stakeholders have been conducted. A July 2010 workshop will be held

	Recommendation #4. Two priority research areas – Screening Level Models and Full Implementation of the Wildlife Research Strategy – being developed.	to develop an integrated research program. A draft research plan is anticipated to be completed by 9/10 and a final one by 1/11.
Recommendation # 10: Mathematical foundations that underpin the current modeling efforts should be further developed, with greater rigor associated with statistical applications in risk assessment.	**Original Response**: ORD agrees to encourage greater development and integration of our ecological modeling efforts to expand their utility. **Updated Response**: See updates to Recommendations #4 and 9. Emphasis will be placed on improving the exposure and effects models and applying statistical/bioinformatics tools for reducing uncertainties in risk assessment.	**Original Action/Timeline**: The NERL SP2 Implementation Planning Process, which will be completed in 2008, will address this issue. **Current Progress**: A July 2010 workshop will be held to develop the integrated research program. A draft research plan is anticipated to be completed by 9/10 and a final one by 1/11.
Recommendation # 11: Pursue collaborative relationships and extended development to advance high performance computing methods and techniques to facilitate the use of biophysical spatial models that integrate biology, predator-prey systems, habitats, physics, and humans for probabilistic risk assessment.	**Original Response**: It is critical that ORD's end users be able to access the predictive models we develop. Therefore, we will continue to develop web-based applications and make them available publicly. NCCT is pursuing several research programs that use EPA's supercomputer or grid system which will also be made web-accessible to the general public. **Updated Response**: Exposure FTEs have been shifted into SP2. See Recommendations 4, #9, and 10 updates. Further, OEI scientists have demonstrated the innovative high performance computing and visualization techniques to the ORD scientists for consideration in modeling research design and implementation. NCCT is continuing its research to build a Virtual Tissues knowledgebase and a cell-based tissue simulator focused on the Virtual Liver (v-Liver™) and the Virtual Embryo (v-Embryo™). The Virtual Tissues knowledgebase will be a free publically available tool that synthesizes published experimental observations on the effects of chemicals on the potential toxicologic processes. The cell-based tissue simulator will simulate chemical-induced effects in the liver and the embryo using three interconnected systems micro-circulation, cell and molecular response, and tissue response.	**Original Action/Timeline**: Efforts are ongoing to develop web-based applications of ORD research products and to identify and pursue research partners to help provide tools that our clients can readily access. **Current Progress**: For ecological risk assessment research program: workshop 7/10, draft research plan 9/10, final research plan 1/11. For Virtual Tissues, all published experimental observations on the biological effects of chemicals and any new data for the embryo and liver are now collated into the knowledgebase which is being finalized into a user-friendly version for public use. The Virtual Tissues Knowledgebase will be available online to the public at the end of this year (2010).
Recommendation # 12: It is recommended that knowledge on early products of agricultural	**Original Response**: Limitations in resources in the biotechnology research program prevent its expansion to address	**Original Action/Timeline**: Efforts are ongoing to seek research partners in biotechnology. In FY

biotechnology be broadened to meet future releases of PIP crops. Additional research topics were identified for addressing.	the additional recommended topics; however, we continue to seek partners with whom we can leverage our expertise and resources. **Updated Response**: EPA, NIAID, the Food Allergy Project, and the Food Allergy and Anaphylaxis Network collectively awarded 16 grants (4 by EPA) on factors contributing to food allergenicity. Joint workshop held and paper on state of the science and remaining research needs published. Session at SOT held. EPA issued a new RFA in 2009 and awards are pending.	2007, a joint request for proposals on Exploratory Investigations on Food Allergy was issued with the National Institute on Allergy and Infectious Diseases (NIAID). **Current Progress**: ORD continues to track 16 awards made jointly many of which will end 2010/2011. ORD will announce four additional awards within the next few months which will be funded for three years.
Recommendation # 13: It is important to maintain the existing cross-disciplinary and cross-organizational collaborations that exist and build upon them, where appropriate.	**Original Response**: ORD will continue leveraging the research program with others both within and outside the organization. **Updated Response**: SP2RP has continued to work across organizations and disciplines to address its goals. Further, ORD is advancing its use of ITR principles in its development of the new SPSWRP to which the SP2RP has provided some of the resources. The BOSC recommendations for the SP2 MYP will be considered in the design and implementation of the SPSWRP.	**Original Action/Timeline**: Efforts are ongoing. **Current Progress**: SP2RP has strengthened its cross-organizational and cross-disciplinary partnerships. These will be further advanced through the development and implementation of SPSWRP which is expected to be operational in 2012.
Recommendation # 14: Revise the language of certain APGs to ensure that there are sufficient resources with which to meet the goals and, thus, to better express the program.	**Original Response**: As noted in response to Recommendation 3, ORD will clarify the generic relationship between APGs and APMs in the next update of the MYP and will ensure greater consistency and clarity with the wording of the APGs and APMs. The APGs and APMs will continue to be identified keeping the budget in mind. **Updated Response**: See update for Recommendation #2 for information on APGs and APMs and the decision to merge several research programs, including parts of SP2RP, into new SPSWRP. As a result SP2RP MYP has not been updated. Recommendation will be considered in development of new research program.	**Original Action/Timeline**: The next update of the MYP will reflect improvements in clarity and consistency in the APGs and APMs. **Current Progress**: ORD will evaluate the NHSRC pilot in the winter of 2010 for potential changes to performance measures across ORD programs. SPSWRP is anticipated to be operational in FY2012.
Recommendation # 15: ORD should more rapidly develop its own research program in nanotechnology, and encourage	**Original Response**: The Agency has developed a Nanomaterial Research Strategy (NRS) to guide the ORD program in nanomaterial research. To	**Original Action/Timeline**: Beginning in FY 2007 there was an increase in resources focusing on high priority areas. An external

other funding organizations internationally to also work in the area.	complement its own research program, EPA is working with other federal agencies, collaborating with academia and industry, and working internationally on the implications of manufactured nanomaterials. **Updated Response**: ORD has implemented the NRS, and added an intramural component to its nanomaterials research program. The STAR program has issued joint and coordinated RFAs with other federal agencies and the UK and EC. The new in-house research complements that of other federal agencies, and is collaborating with other governments' research through the OECD.	peer review of the NRS will be held in March 2008. ORD will direct a greater share of FY 2009 and 2010 resources to exploring the toxicity of altered nanomaterials. **Current Progress**: The EPA Nanomaterial Research Strategy was published in June 2009. ORD nanotechnology budget has steadily increased every year since 2007.
Recommendation # 16: Describe criteria for prioritization of future work and discuss how the additional projects meet the criteria.	**Original Response**: The current MYP already describes how teams of managers and scientists from across ORD's Laboratories and Centers, OPPTS, and the lead Region for pesticides and toxics partner to identify research needs and resource allocations with the previous SP2 MYP as a guiding framework. Resources go to accelerate existing projects or to new complementary research. The updated MYP will strengthen these descriptions. **Updated Response**: See updates for Recommendations #2, 3, 6, 7, and 8. Improved research planning, implementation, and communication process is being developed with SPSWRP. As a result SP2 MYP has not been updated. Recommendation will be considered in the development of new research program.	**Original Action/Timeline**: The Appendix of the next update of the MYP will provide greater detail on the prioritization process used to accelerate research previously identified as high priority. In addition, the updated Appendix will provide stronger descriptions of potential new research directions based on discussions with OPPTS senior managers. **Current Progress**: Improved research planning, implementation, and communication process for development of the SPSWRP will be captured in research plan or MYP when it is developed. SPSWRP is expected to be fully operation in FY2012
Recommendation # 17: In the areas of statistical analyses, bioinformatics, theoretical and mathematical model building and probabilistic risk assessments, a strong need for and growth of collaborations is recommended.	**Original Response**: ORD scientists are collaborating with academic scientists from the STAR-*funded Environmental Bioinformatics Research Centers*. ORD has recently hired four senior level staff in the areas of bioinformatics and systems biology. ORD continuously seeks opportunities to leverage our resources and expertise with others and we will continue to do so in this area as well. **Updated Response**: ORD has continued and expanded the practices described in the original response. EPA has awarded	**Original Action/Timeline**: Significant efforts of collaboration across ORD and with extramural scientists in the areas of bioinformatics have been ongoing for the last two years and will continue for at least another three. Newly acquired hiring authority has been used to bring on board four senior bioinformaticians and systems biologists. **Current Progress**: ORD has continued seeking opportunities to

	two new STAR Centers in the form of cooperative agreements to allow for greater interactions between EPA and academic scientists. NCCT uses CoP approaches to communicate and receive input from scientists across sectors from around the world. NHEERL has established a new Integrated Systems Toxicology Division and has advertised for a senior level Director.	partner with scientists outside the Agency to leverage our expertise and resources in the areas of bioinformatics and systems– e.g., continued issuance of requests for applications and funding of new STAR Comp Tox Centers in the form of cooperative agreements (2008, 2009), developing CoP, and reorganizing to establish a stronger systems biology/toxicology intramural program. The two new Comp Tox Centers will be funded until 2012. Meetings between EPA and academic scientists from the Centers occur frequently – the most recent one was May 2010.
Recommendation # 18: Map service awards (as well as peer-reviewed papers) to individual program elements to better designate high quality products.	**Original Response**: ORD has and will continue to include service awards in biosketches for all programs. Additionally, the SP2 Research Program Review provides background materials that pull information on awards, editorial positions, positions in professional societies, etc., into integrated tables. **Updated Response**: ORD is exploring new bibliometric approaches to measure not only quality of the work but also performance of the various research programs.	**Original Action/Timeline**: In January 2008, a meeting with the BOSC EC will lead to a policy regarding the value-added of collection and presentation of detailed information for future BOSC reviews. **Current Progress**: ORD anticipates having new bibliometric measures by June 2011.
Recommendation # 19: The peer-review process used by the SP2 Program should be continued.	**Original Response**: ORD will continue to follow existing guidance and policies to ensure its research programs and products are appropriately peer reviewed. **Updated Response**: The 2006 *Peer Review Handbook, 3rd Edition* still governs our approach to peer review ORD-wide.	**Original Action/Timeline**: Efforts are ongoing. **Current Progress**: Efforts are still ongoing.
Recommendation # 20: Continue to reward scientific excellence and minimize administrative burdens.	**Original Response**: ORD will continue to use all mechanisms available to reward and retain its scientists and to recruit new ones. **Updated Response**: Efforts are ongoing.	**Original Action/Timeline**: Efforts are ongoing. **Current Progress**: Efforts are ongoing.
Recommendation # 21: Place more emphasis on scientist-to-scientist communication with other laboratories within the federal government (e.g., Department of Energy	**Original Response**: The MYP describes ORD efforts to communicate with others during the planning, conduct, and after completion of the research; and describes various outside collaborations. ORD will consider expanding these sections of the	**Original Action/Timeline**: The MYP update will provide greater detail on communications with other federal agencies and other research organizations.

laboratories) through workshops and other suggested interactions.	MYP. **Updated Response**: ORD is significantly improving the visibility of its SP2RP through the establishment of research collaborations and the communication of research programs/results with its partners/collaborators/stakeholders. A few examples are highlighted. SP2RP MYP has not been updated because part of the program will be merged into the SPSWRP. Recommendation will be considered in development of new research program.	**Current Progress**: Collaborations with other federal agencies and organizations are in different stages. Some are ongoing and others are completed. For example, completed: two PFCs workshops, environmental monitoring to support PFCs remediation studies, support for the Pb Test Kits, establishment of ETV program for kits, pilot study for artificial turf constituents. Ongoing: pilot study on PCBs in caulk, biofuels, monitoring progress on 16 food allergenicity grants, seminar series, awaiting decision on DOD proposal. SPSWRP will be operational in 2012.
Recommendation # 22: Develop a more focused communications program to disseminate information from SP2 research out to the regions and other program offices.	**Original Response**: ORD concurs that there is a continued need to improve coordination and communications to better serve our clients. The MYP describes current actions to do so. A meeting between ORD and OPPTS senior managers will be held to discuss the status of research across multiple relevant programs and identify priorities. **Updated Response**: ORD is significantly improving the visibility of its SP2RP through the establishment of research collaborations and the communication of research programs/results with its partners/ collaborators/stakeholders. Multiple types of mechanisms are being used to communicate our results. A few examples are highlighted. The ORD-OCSPP senior managers' meeting was held and priorities identified. Improved research planning, implementation, and communication process is being developed with SPSWRP.	**Original Action/Timeline**: Efforts to improve coordination and communications are ongoing. An ORD-OPPTS senior managers' meeting will be held in 2008. **Current Progress**: ORD is using different mechanisms t o communicate its research activities and results to its partners/collaborators/stakeholders. Examples are highlighted. The ORD and OCSPP senior managers' meeting was held in November 2009 with an agreement to meet at least once a year. The SPSWRP will be operational in FY2012.