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# B.O.S.C

BOARD OF SCIENTIFIC COUNSELORS

August 25, 2010

Dr. Paul Anastas  
Assistant Administrator  
Office of Research and Development  
U.S. Environmental Protection Agency

Ms. Becki Clark  
Acting Director  
National Center for Environmental Assessment  
U.S. Environmental Protection Agency

Dear Dr. Anastas and Ms. Clark:

This is a letter report from the Board of Scientific Counselors' (BOSC) Executive Committee concerning its July 12, 2010 review of the Office of Research and Development (ORD) Human Health Risk Assessment (HHRA) Program mid-cycle progress report. The Executive Committee conducted its review during the course of its July 12-13, 2010 meeting at the ORD National Health and Environmental Effects Research Laboratory, Western Ecology Division, Corvallis, Oregon. Dr. George Daston, a former BOSC Executive Committee member and Chair of the 2007 BOSC HHRA Program Review Subcommittee, also was invited to comment and provide his perspective on the HHRA mid-cycle progress report.

Under current BOSC program review policy, mid-cycle program reviews are conducted only in response to an ORD request or as recommended by the BOSC and ORD as a perceived need following Executive Committee review of a mid-cycle progress report. As part of this process, Ms. Becki Clark presented the mid-cycle progress report at the BOSC's July 2010 face-to-face meeting. The Executive Committee is pleased to find excellent progress on the part of the HHRA Program and does not recommend a mid-cycle program review.

The HHRA Program has clear goals and measures that are being met, and a small but active research program that is innovative and whose priorities are well aligned with the goals of the Program and the needs of the Agency. The previous review noted that the HHRA staff has strong core competency in risk assessment that often is relied upon in crisis situations. This expertise is a by-product of the fine work that is done by the Program as part of its Multi-Year Plan (MYP).

Chair  
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The 2007 BOSC review recommended that the HHRA Program develop a more transparent and participatory process for nominating and prioritizing chemicals for assessment. The mid-cycle report describes steps that have been taken in that direction, but it does not appear that the new process has been implemented yet. This should be in place before the next full HHRA program review. The 2007 BOSC review also recommended that the Program make more connections with the National Center for Computational Toxicology (NCCT). The mid-cycle progress report indicates that a good level of interaction has occurred that has been positive for both NCCT and the HHRA Program, ensuring that the former is as relevant as possible to EPA's mission, and that the latter is aware of and using state-of-the-art data streams and methods. It should be expected that the level of interaction continue and that the use of outputs from NCCT programs increases prior to the next full HHRA program review.

The HHRA Program previously was encouraged to bring in a few more senior scientists. The mid-cycle progress report describes some efforts to do so, but for the most part this has not happened to the extent envisioned during the prior BOSC program review. In defense of the HHRA Program, the lack of progress seems to be largely out of its control. One senior scientist recruited from within the Agency left to take a different job within the government and events outside EPA have made it difficult, at least in the short run, to recruit Title 42 candidates. The mid-cycle progress report does describe interactions with senior scientists via fellowship programs with non-EPA institutions, which is laudable but insufficient to fulfill the BOSC recommendation. It is hoped that the program will be able to make more progress towards this goal before the next program review.

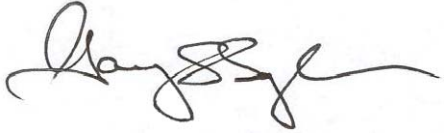
In summary, the HHRA Program is making concerted efforts to enact the recommendations made during the 2007 program review. The Executive Committee finds that the HHRA Program is a strong program whose output is crucial to much of the work of EPA's offices and regions. The preparation of high quality Integrated Risk Information System (IRIS) and Provisional Peer Reviewed Toxicity Value (PPRTV) assessments, however, is a labor-intensive process, such that the number that can be produced in a given year is finite and does not fully meet the demand of the regions and program offices. This problem is compounded by the fact that these assessments need to be updated on a regular basis, which also adds to the workload. The mid-cycle progress report describes a number of steps that the Program has taken to increase throughput including the IRIS update plan. Some steps include increasing resources, which also has its limits, but also the leveraging of other organizations. The Program leadership is to be commended for its outreach to other organizations with similar missions.

It also is noted that IRIS assessments and Integrated Science Assessments (ISA) are among the most heavily peer-reviewed documents produced by scientists anywhere. Although it is clear that good peer-review makes for better documents, it is not clear that all of the steps in the current process add value. EPA is encouraged to reach out to the Office of Management and Budget (OMB), and others if necessary (e.g., National Academies), to determine how much peer review is really needed and to identify the tipping point between a review that makes the report 1 percent better at the cost of postponing the release of a document that has real public health value, or which limits the number of reports that can be prepared.

The BOSC is pleased to submit this letter report on the progress of the HHRA Program and it is the Board's hope that this report is useful in developing any mid course-adjustment envisioned.

The report also should be useful in planning for the next full program review and the BOSC looks forward to assisting in that process in due course.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Saylor", written in a cursive style.

Gary S. Saylor  
Chair, BOSC