UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

OCT 2 1 2008

Mr. Scott Slaughter
Center for Regulatory Effectiveness
Suite 500
1601 Connecticut Avenue, NW
Washington DC 20009

RE: **Information Quality Guidelines Request for Correction (RFC) Regarding the Amphibian Metamorphosis Assay (RFC #08004)**

Dear Mr. Slaughter:

Thank you for your Request for Correction (RFC), filed under the Environmental Protection Agency Information Quality Guidelines (EPA IQG), and received by EPA via email on July 10, 2008. In your submission, on behalf of the Center for Regulatory Effectiveness (CRE), you requested that EPA ("Agency") make several corrections to the statements made in relation to the peer review results for the Amphibian Metamorphosis Assay. This letter responds to your request.

The Amphibian Metamorphosis Assay is one of several assays that EPA is considering for the Tier 1 screening battery that will be used in the Endocrine Disruptor Screening Program (EDSP) to identify substances with the potential to interact with the estrogen, androgen, or thyroid hormone systems. The Agency's approach for establishing the battery, including validation and peer review, and the status of each assay are available on EPA's Web site at http://www.epa.gov/endo. The Agency is in the process of finalizing its selection of the assays to be used for the EDSP Tier 1 screening battery based on all comments received to date.

In responding to IQG correction requests, the Office of Management and Budget (OMB) guidelines state: "Recognizing that many agencies already have a process in place to respond to public concerns, it is not necessarily OMB's intent to require these agencies to establish a new or different process."[1] This concept has been incorporated into the EPA IQG. Your RFC was received after the open comment period, but before the Agency completed its final response to comments process on the Tier 1 screening battery selection. In this case your request that EPA make several corrections to the information at issue will be treated as late public comments relating to the validation of the assays. The Agency will substantively address the comments in your RFC as part of the final response to comments for the Tier 1 battery selection. EPA believes that the thorough consideration provided by the response to comments process provides an opportunity for the correction of any information that does not comply with the EPA IQG, and does not duplicate or interfere with the orderly conduct of the action.

[1] 67 Fed. Reg. 8452 (February 22, 2002). http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

As such, we have referred your letter to the EPA team that is working on the final Tier 1 screening battery, and your substantive comments will be considered in that context. Upon completing the battery selection decision process, the Agency will publish a Federal Register Notice announcing its decision and the availability of a public docket that will provide the documentation for its decision, including responses to your concerns.

However, if at the conclusion of the selection of the EDSP Tier 1 screening battery, your concerns have not been addressed, you may submit a Request for Correction (RFC). If you choose to submit an RFC, please send your written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); electronic mail (quality@epa.gov); or fax [202-565-2441]. Additional information about how to submit an RFC is listed on the EPA Information Quality Guidelines Web site at http://www.epa.gov/quality/informationguideline.

Thank you for your interest in EPA's information quality. If you have additional questions, or require further assistance concerning the EDSP, please contact Gary Timm in EPA's Office of Science Coordination and Policy (OSCP) at 202-564-8474.

Sincerely,

James B. Gulliford
Assistant Administrator

cc: Kimberlie Orr (OEI)
Angela Hofmann (OPPTS)
Frank Sanders (OSCP)