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MEMORANDUM

Via E-Mail

DATE: May 27, 2009
TO: Firm Clients and Friends
FROM: Bergeson & Campbell, P.C.
RE: EPA Updates IRIS Process

The U.S. Environmental Protection Agency (EPA) announced on May 21, 2009, that it has reformed the Integrated Risk Information System (IRIS). According to EPA, the revisions are intended to “revitalize the program and ensure its scientific quality, integrity, transparency and timeliness.” In a May 21, 2009, memorandum, Lisa P. Jackson, EPA Administrator, states that recent changes, including procedures formalized in an April 21, 2008, memorandum, “have reduced the transparency, timeliness, and scientific integrity of the IRIS process.” According to Jackson, President Obama’s emphasis on the importance of transparency and scientific integrity in government decision-making “compelled a rethinking of the IRIS process.” The new process will be entirely managed by EPA, which will have final responsibility for the content of all IRIS assessments. To ensure the scientific quality of IRIS assessments, the process will include the opportunity for public comment and rely on “a rigorous, open, and independent external peer review.” The IRIS process will be shortened to 23 months, “speeding the availability of IRIS assessments to the risk assessor community and the public and providing for more timely action to protect public health.” Jackson’s May 21, 2009, memorandum and other materials are available on the Internet at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045>.

Prior to the development of a draft IRIS assessment, EPA will conduct a scientific literature search and initiate a data call-in. EPA will post the completed literature search on its website. Once EPA has completed literature searches for a set of chemicals, EPA will publish a *Federal Register* notice announcing their availability and requesting the submission of additional scientific information. Once the literature search and data call-in are complete, EPA will develop the IRIS human health assessment, using the seven steps described below. EPA states that although IRIS assessments are expected to be completed approximately two years from the Step 1 start date, some may take longer “because of their complexity, large scientific literature base, or high profile.” The seven steps are:



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1. EPA Develops and Completes a Draft IRIS Toxicological Review (Duration 345 days):
 - A. The Office of Research and Development (ORD) assembles an IRIS assessment team;
 - B. ORD assesses the data in the scientific literature and any information submitted as a result of the data call-in and develops a draft assessment for the chemical being assessed; and
 - C. ORD completes the draft IRIS Toxicological Review.
2. Internal EPA Review (Duration 60 days):
 - A. ORD submits the draft IRIS Toxicological Review for internal agency review;
 - B. Internal agency review includes scientists from EPA programs and regions; and
 - C. Internal agency review identifies any scientific issues to determine the level of peer review, needed panel member disciplines, and the scope of the review.
3. EPA Initiates Interagency Science Consultation on Draft IRIS Toxicological Review (Duration 45 days):
 - A. EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other federal agencies and White House offices for a science consultation;
 - B. EPA manages and coordinates the science consultation step;
 - C. All written comments received during the Interagency Science Consultation become part of the public record;
 - D. ORD revises the draft assessment documents, as appropriate; and



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- E. If EPA considers appropriate, science questions that arise during science consultation may be included as part of a charge question to the peer review panel.
- 4. EPA Initiates Independent External Peer Review of Draft IRIS Toxicological Review, Public Review and Comment on Draft IRIS Toxicological Review, and Holds a Public Listening Session (Duration 105 days):
 - A. External Peer Review;
 - B. Public Review and Comment; and
 - C. Public Listening Session.
- 5. EPA Revises IRIS Toxicological Review and Develops IRIS Summary (Duration 60 days):
 - A. ORD evaluates the external peer review panel report and all public comments;
 - B. ORD revises the draft IRIS Toxicological Review, as appropriate, and develops the IRIS Summary;
 - C. Length of revision process may depend on the complexity of the IRIS Toxicological Review and complexity and number of peer reviewer and public comments; and
 - D. ORD develops a disposition of peer reviewer and public comments and provides these as an appendix to the IRIS Toxicological Review.
- 6A. Internal EPA Review of Final IRIS Toxicological Review and IRIS Summary (Duration 45 days):
 - A. ORD sends the IRIS Toxicological Review and IRIS Summary for final internal agency review; and
 - B. This review is intended as a final check-in with agency program and regions.



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- 6B. EPA-led Interagency Science Discussion (Duration 45 days -- concurrent with Step 6A):
 - A. EPA provides other agencies and White House offices with the final draft of the IRIS Summary and Toxicological Review and appendix describing disposition of peer review and public comments;
 - B. Other agency and White House Office scientists have opportunity to provide written scientific feedback;
 - C. EPA hosts meeting with White House offices and other agencies to discuss any scientific issues related to the final draft of the IRIS Summary and Toxicological Review and appendix; and
 - D. All written comments by other agencies and White House offices documented in the record.

- 7. EPA Completion of IRIS Toxicological Review and IRIS Summary (Duration 30 days):
 - A. ORD completes the IRIS Toxicological Review and IRIS Summary;
 - B. ORD prepares the final assessment for the agency's website posting;
 - C. ORD insures 508 Compliance and EPA website compliance;
 - D. ORD posts the assessment to the IRIS database; and
 - E. ORD completes and maintains the public record.

TOTAL: 23 Months

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We hope this information is helpful. As always, please call if you have any questions.