allowed Form A to be used to report emissions, releases, or disposal of persistent, bioaccumulative, and toxic (PBT) chemicals not exceeding 500 pounds. PBT chemicals include mercury, lead, and polychlorinated biphenyls (PCB), among other substances.

On March 11, 2009, Congress enacted, and President Obama signed into law, the Omnibus Appropriations Act of 2009 (Act), which required that no funds made available by the Act could be used to implement the 2006 Burden Reduction Rule, and that the 2006 Burden Reduction Rule would no longer have "force or effect." Congress specified that the TRI regulations would revert to the terms of the final rule that was in place prior to the enactment of the 2006 Burden Reduction Rule. Toxic Release Inventory Form A Eligibility Revisions Implementing the 2009 Omnibus Appropriations Act, 79 Fed. Reg. 19,001 (Apr. 27, 2009) (to be codified at 40 CFR Part 372). Accordingly, EPA issued the Toxics Release Inventory Form A Eligibility Revisions Implementing the 2009 Omnibus Appropriations Act Final Rule (2009 Rule) on April 27, 2009. *Id*. Because the 2009 Rule was an action required to comply with an act of Congress, EPA determined that it was not necessary to provide an opportunity for notice and comment.

Had Congress not passed the Act, EPA Administrator Lisa Jackson indicated that she would have reinstated the stricter TRI standards on her own initiative. In a February 27, 2009, interview regarding EPA's activities and program, Jackson reported that while the 2006 Burden Reduction Rule may have been designed to reduce a burden on those facilities that need to submit TRI reports, many such facilities were not taking advantage of it. Additionally, she noted that "there's been some indication that many facilities inappropriately used the shorter form." *Jackson Willing to Restore Tough Standards for TRI Reporting in Lieu of New Legislation*, 33 CHEM. REG. REP. 222, Mar. 9, 2009. Upon execution of the 2009 Rule, Jackson stated that "[r]estoring the TRI reporting requirements assures transparency and provides a crucial tool for safeguarding human health and the environment in our communities." *EPA Administrator Reinstates Full TRI Reporting Requirements*, EPA Press Release, Apr. 21, 2009.

The 2009 Rule reinstates the eligibility criteria for using Form A by requiring that the total of releases for non-PBT chemicals subject to TRI reporting may not exceed 500 pounds annually, nor may the chemical be manufactured, processed, or otherwise used at the facility in excess of one million pounds during the reporting year (RY). Additionally, under the 2009 Rule, PBT chemicals may not be reported using the Form A. Instead, all PBT chemicals are to be reported on the more detailed Form R.

The 2009 Rule became effective on April 27, 2009, immediately upon its publication in the *Federal Register*, and will affect TRI reports that are to be filed for RY 2008, which are due July 1, 2009. EPA has announced that since the Act set the Form A eligibility criteria to previous levels as of March 11, a facility that filed a TRI Form A for RY 2008 on or after March 11, 2009, using the 2006 Burden Reduction Rule eligibility guidelines, must reconsider its prior report to determine if the facility is still eligible to file Form A under the 2009 Rule. If the facility is not able to file Form A relying on the 2009 Rule standards, it must resubmit its RY 2008 report on the longer Form R.

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EPA UPDATES IRIS PROCESS, AGAIN

Lynn L. Bergeson

The U.S. Environmental Protection Agency (EPA) announced on May 21, 2009, that it has reformed the Integrated Risk Information System (IRIS), again. 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, Administrator Jackson 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 Web site. 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:

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

    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.

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 Web site posting;

C. ORD insures 508 Compliance and EPA Web site compliance;

D. ORD posts the assessment to the IRIS database; and

E. ORD completes and maintains the public record.

TOTAL: 23 Months

The House Committee on Science and Technology's Subcommittee on Investigations and Oversight (Subcommittee) scheduled a hearing for June 11, 2009, to review the changes. The Subcommittee wishes "to know how many new listings the EPA expects to post each year, how many staff will be assigned to the process, and whether OMB will still be involved if the only issue is a scientific determination," according to Subcommittee Chair Miller (D-NC).

The Subcommittee convened two hearings on IRIS last year, and introduced legislation to address what it

regarded as a loss of control by EPA over the scientific process, and a lack of speed with regard to the number of IRIS assessments produced each year. Under the draft legislation, EPA would be required to issue a minimum of fifteen assessments and five updated assessments each year.

Some in industry have expressed concern with a noticeable lack of checks and balances in the new process, in that EPA exclusively stewards that process almost entirely. The concern is that without more independent review by others, the process may suffer from a lack of objectivity.

Regardless of which side of the debate on which you sit, most would agree the IRIS process is broken. Whether the repairs most recently offered by EPA will fix the program remains to be seen.

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The Pesticides, Chemical Regulation, and Right-to-Know Committee welcomes the participation of members who are interested in preparing this newsletter. If you would like to lend a hand by writing, editing, identifying authors or identifying issues, please contact the editor, Lynn L. Bergeson, at (202) 557-3801 or

FROM THE CHAIR

Mark N. Duvall

The key issue before Congress that affects the Pesticides, Chemical Regulation, and Right-to-Know Committee is certainly potential overhaul of the Toxic Substances Control Act (TSCA). Already a subcommittee of the House Energy and Commerce Committee has held one hearing, with promises of more to come. On the Senate side, there is much anticipation about when Sen. Lautenberg will reintroduce the Kid-Safe Chemicals Act (KSCA), which last year stimulated debate about the future of TSCA in light of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and other developments.

Meanwhile, U.S. Environmental Protection Agency (EPA) Administrator Lisa Jackson has indicated that it will be an administration bill on TSCA amendments that EPA will likely support, rather than KSCA. The new leadership at EPA is getting up to speed on the Chemical Assessment and Management Program (ChAMP), which may prove to be influential in any administration bill.

It seems likely at this point that active Congressional consideration of TSCA amendments will be pushed at least into 2010. But that does not mean that the TSCA battle in Congress is inactive. A good case can be made that it has been going on since at least 2008, through both hearings on KSCA and surrogate battles on other legislation. One battle involved the Consumer Product Safety Improvement Act (CPSIA), which mandated bans on phthalates and lead in some consumer products, and for which amendments are under discussion now. Another is chemical plant security legislation, needed by October of this year to continue the statutory authority for the Department of Homeland Security Chemical Facility Anti-Terrorism Standards (CFATS). A third surrogate battle involves bisphenol A (BPA), the subject of federal, state, and local legislation to ban its use in some child care articles. A fourth is electronic waste (e-waste) take-back requirements under consideration at various levels.