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BEFORE THE
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Chairman Miller, Ranking Member Sensenbrenner, and distinguished Members of the Committee, thank you for inviting me to testify at today's hearing about the Environmental Protection Agency's Integrated Risk Information System (IRIS) database policy.

As the Administrator of the Office of Information and Regulatory Affairs (OIRA), I am pleased to be here today to talk with you about OIRA's role in ensuring that the highest quality of information, including scientific information, is used and disseminated by Federal agencies.

OIRA was created as part of the Office of Management and Budget (OMB) by the Paperwork Reduction Act of 1980. Staffed almost exclusively by career civil servants, OIRA has served Administrations, both Democratic and Republican, for decades by providing centralized oversight and interagency coordination of federal information, as well as regulatory and statistical policy.

Over the last 27 years, OIRA's interagency coordination role has been an integral part of government accountability – a non-partisan tool for understanding the likely effects of government policy. In recognition of the increasing importance of science-based regulation at

federal agencies, OIRA's staffing has evolved over the last 8 years to include scientific and engineering expertise to accompany a well established team of economists, statisticians, and information technology specialists. This more diversified pool of expertise enables us to engage with experts throughout the federal government on issues relevant to policy development.

EPA's Updated IRIS Process

The Environmental Protection Agency (EPA)'s Integrated Risk Information System (IRIS) is an online database prepared and maintained by the EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD). IRIS contains science and science policy information on chronic human health effects.[1] The hazard identification and dose-response assessment information in IRIS can be used in combination with exposure information to characterize the public health risks of a given substance in a given situation. These risk characterizations can form the basis for risk-based decision-making, regulatory activities, and other risk management decisions designed to characterize and protect public health. The IRIS database supports risk-based decision making not only by EPA, but by other federal agencies, state and local environmental programs, international regulatory bodies, academia, industry, and others. According to EPA, national and international users access the IRIS database approximately 9 million times a year.[2]

OMB recognizes the importance of IRIS assessments for making sound, science-based decisions across the government, throughout the country, and internationally as well. OMB has continually supported changes that will improve the quality and efficiency of the IRIS program.

[1] See EPA, "Revised IRIS Process Q&A's," (EPA Q&A) question 1, *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=472643.
[2] See U.S. Government Accountability Office, Report to Chairman, Committee on Environment and Public Works, U.S. Senate, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (March 2008), p. 6.

Since 2000, OMB has supported funding increases for the IRIS program of over 450 percent; as evidenced in the President's annual budgets, the funding requested has increased from $1.7 million in FY 2000 to $9.6 million in FY 2007.[3]

Despite these funding increases, concerns remain with the pace of development of IRIS assessments. EPA observes that prior assessments took an average of 5 years to complete, with some taking as long as 10 years.[4] In response to concerns both with delays in completion of IRIS assessments, and lack of transparency in the IRIS process, EPA has recently revised the process to provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. The revised process clarifies the role of the public and interagency reviewers, and promotes greater communication and sharing of information between all interested parties and EPA. EPA expects these changes to result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor.[5]

The nomination process for chemicals to be included in IRIS is transparent and open. ORD initiates the process through a Federal Register notice which invites nominations from the public and at the same time reaches out to the EPA Program and Regional Offices and other agencies for their nominations. After receiving the nominations and discussing them with other agencies and EPA Program and Regional Offices, EPA determines its IRIS agenda for the coming year, and publishes that in the Federal Register. EPA's determination is based on its published selection criteria, as well as its available work force and areas of expertise.

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[3] Id. at 14.
[4] See EPA Q&A, supra note 1, at question 13.
[5] Memorandum from EPA Deputy Administrator Marcus Peacock to EPA Assistant Administrator George Gray (Peacock Memo), "Implementation of Revised IRIS Process," (April 10, 2008), *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=472651.

EPA then begins the process of developing chemical health assessments that ultimately are posted to the IRIS database.[6] This assessment process consists of 13 steps:

1. A scientific literature search for each chemical;
2. A Federal Register notice seeking scientific information on selected chemical substances;
3. EPA development of draft qualitative IRIS health assessment;
4. Review of the draft qualitative assessment within EPA, by other agencies, and by the public, announced in the Federal Register;
5. EPA review of public and agency comments;
6. EPA evaluation of interagency interest in closing data gaps for mission critical chemicals;[7]
7. Design and implementation of new studies for mission critical chemicals, if needed;
8. EPA completion of its draft IRIS review, including quantitative values;
9. EPA initiation of interagency review (and revision of draft assessment documents as appropriate);
10. EPA initiation of independent external peer review and release of the draft IRIS assessment to the public;
11. EPA revision to the IRIS assessment and development of an IRIS summary based on expert review and public comment;
12. EPA initiation of final intra-agency and interagency review; and
13. EPA completion of the IRIS assessment and IRIS summary and posting of completed IRIS assessments on to the database.

[6] Id.

OMB Role in the IRIS Process

Since the fall of 2005, OMB has coordinated review of IRIS assessments (steps 9 and 12 in the new process). Interagency coordination allows EPA to take advantage of the broad scientific expertise that exists throughout the government. The science in IRIS assessments is growing more and more complex, and vigorous discussion that involves a diverse set of governmental experts helps EPA ensure that the IRIS assessments represent the consensus opinions of the government's leading scientists. In addition, risk assessment involves science policy judgments which help to shape the risk assessment process. As many accepted 'default' positions are based on scientific consensus opinions, a frank and broad discussion among interagency experts helps to inform EPA's choices.[8] The agencies involved in any interagency review process will vary depending on the chemical in question, agencies' expertise, and agencies' interest in it. The interagency group may consist of representatives from the following offices and departments:

- Office of Management and Budget (OMB),
- Office of Science and Technology Policy (OSTP),
- Council on Environmental Quality,
- Department of Health and Human Services (HHS) [including representation from the Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), National Institute for Environmental Health Sciences (NIEHS), National Institute

[7] EPA defines a "mission critical chemical" as one that is an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operation. Id. at n. 1.

for Occupational Safety and Health (NIOSH) and Food and Drug Administration (FDA)],

- Department of Defense (DoD),
- Department of the Interior (DOI),
- Department of Labor (DOL),
- National Air and Space Administration (NASA),
- Department of Energy (DOE),
- Department of Transportation (DOT),
- Department of Agriculture (USDA), and
- the Consumer Product Safety Commission (CPSC).

In step 9 noted above, EPA provides OMB the draft health assessment and the draft charge to the external peer reviewers. OMB distributes these draft documents to the others in the interagency group for review and comment. EPA then revises the draft health assessment and charge, as appropriate, to respond to the interagency comments. After completing interagency review, EPA publishes the draft assessment in the Federal Register for public comment and begins independent peer review. After revising the IRIS assessment based on peer review and public comment, EPA again shares the assessment with OMB and other federal agencies (step 12 listed above).

[8] See EPA, Office of the Science Advisor, Staff Paper, "Risk Assessment Principles and Practices," (March 2004),

Under EPA's revised system, OMB will continue to coordinate interagency review to help assure timely responses from agencies within designated review periods. For step 9, interagency review comments are due within 30 to 60 days, depending on the complexity of draft assessment documents.[9] EPA will respond, as appropriate, in 15-30 days.[10] At step 12, interagency and intra-agency review comments are provided to ORD within 30 days[11] and ORD addresses any remaining issues within 15 days.[12] In addition, the EPA webpage allows the public to track the progress of each chemical as it moves through the IRIS assessment process.[13]

OMB supports the new EPA IRIS process and EPA's efforts to provide greater transparency, and opportunities for the public to share information and comment on EPA's assessment. For example, the public has an opportunity to comment on EPA's initial literature review and to present additional information on a chemical. The public can also comment on the draft qualitative assessment and participate in an EPA-sponsored "listening session." This "listening session" will allow for broad public participation earlier in the assessment process. The new process also defines appropriate roles for the public and interagency interactions with ORD and also allows the interagency group, as well as the EPA Program and Regional Offices, in addition to the public, opportunities to share information and comment on EPA's draft assessments.[14] All of these steps will also help to ensure the high quality of IRIS assessments. OMB also believes that the new process will increase efficiencies in the IRIS program. EPA estimates that the new process will reduce the time to complete an IRIS assessment from the historical average of over

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available at http://www.epa.gov/OSA/pdfs/ratf-final.pdf. Sections 2.1.3 and 4.1.2 discuss the science policy used in risk assessment and in determining default assumptions.

[9] See Peacock Memo, supra note 5, at step 9(C)(a).

[10] Id. at step 9(E).

[11] Id. at step 12(D)(a).

[12] Id. at step 12(E).

[13] See www.epa.gov/iris.

[14] See EPA Q&A, supra note 4, at questions 6 and 12.

5 years to 3 to 4.5 years, with perhaps an additional 1-2.5 yrs for the smaller number of mission critical chemicals.[15] Thus this revised process not only allows for earlier public and agency involvement, but also streamlines the process such that EPA will be able to release IRIS assessments in a more timely manner.

Conclusion

Thank you for the opportunity to testify in today's hearing. EPA's IRIS database is highly regarded and widely used. EPA's recent clarifications to the process for developing IRIS assessments should improve both the quality and efficiency of the assessments by engaging the public as well as experts within and outside the government earlier in the process and providing streamlined opportunity for review. I would be happy to answer any questions you may have.

[15] Id. at question 13.