U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HEARING CHARTER

Strengthening the Scientific Backbone of the EPA: An Examination of Agency Practices and Foundations for Regulations Affecting the American Economy

Thursday, June 28, 2012
10:00 a.m. to 1:00 p.m.
2318 Rayburn House Office Building

PURPOSE

On Thursday, June 28, 2012 at 10:00 a.m. the House Committee on Science, Space, and Technology will hold a hearing to examine science and technology activities at the Environmental Protection Agency (EPA). Specifically, the hearing will review Agency-wide policies and practices related to the development and use of science in regulatory decisions; the role of independent scientific advisory bodies such as the EPA Science Advisory Board (SAB) and Clean Air Scientific Advisory Committee (CASAC); and the importance of transparency, integrity, peer review, prioritization, accountability, and sustainability in the Agency's science activities.

WITNESS LIST

The Honorable Lisa Jackson, Administrator, Environmental Protection Agency

BACKGROUND

Science has been central to EPA's mission and functions since its establishment in 1970. In his message to Congress regarding the creation of EPA, President Nixon stated that a principal role of the agency should be "[t]he conduct of research on the adverse effects of pollution and on methods and equipment for controlling it, the gathering of information on pollution, and the use of this information in strengthening environmental protection programs and recommending policy changes."[1]

Today, with significantly expanded regulatory authorities and a fiscal year 2012 budget of over $8 billion, science remains an important component of the Agency's mission and core activities. EPA's February 2012 policy on scientific integrity states:

> "Science is the backbone of the EPA's decision-making. The Agency's ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. The environmental policies, decisions, guidance, and

[1] http://www.epa.gov/aboutepa/history/org/origins/reorg.html

> regulations that impact the lives of all Americans every day must be grounded, at a most fundamental level, in sound, high quality science."[2]

EPA Administrator Jackson echoed this priority in her confirmation hearing, stating that "science must be the backbone of what EPA does. The environmental and public-health laws Congress has enacted direct the EPA administrator to base decision on the best available science."[3] A recent speech by the Administrator elaborated on this further:

> "On my first day on the job as Administrator – and many times since – I have reinforced the notion that science is the backbone of everything we do at the EPA. It is the compass that guides every decision we make, every standard we set, every enforcement action and every emergency response. It is at the core of our mission to protect human health and the environment – which is why the EPA has the largest scientific staff of any federal Agency besides NASA."[4]

Overview of EPA Science Activities and Organization

The President's FY 2013 budget request for the Environmental Protection Agency (EPA) is $8.34 billion, a reduction of 1.0 percent below FY 2012 levels. (A summary of this budget by Agency goal is provided in Appendix 1, and EPA's organizational chart is provided in Appendix 2.) EPA funding provided in the FY 2013 House Appropriations Committee's introduced bill is $7.06 billion. In addition to its general responsibility for EPA science issues across the Agecny, the Committee on Science, Space, and Technology has direct jurisdiction over the Science and Technology budget listed in Table 1 below.

Table 2: EPA FY 2013 Budget Request (dollars in millions)

Account	FY11 Enacted	FY12 Enacted	FY13 Request	FY13 House Appropriations
Science and Technology	813.5	793.7	807.3	738.4
Office of Research and Development	581.7	568.0	575.6	N/A
Superfund R&D	26.8	23.0	23.2	N/A

EPA's science-related authorities and activities are derived from a number of statutes. The Environmental Research, Development, and Demonstration Authorization Act (ERDDA), P.L. 95-155, authorizes Agency research and science activities broadly, and created the Office of Research and Development (ORD) and Science Advisory Board (SAB).

[2] http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf
[3] January 14, 2009. Opening statement. Confirmation Hearing. Senate Environment and Public Works Committee.
[4] Administrator Lisa P. Jackson, Madison Medal Lecture at Princeton University: "A Laboratory of One's Own," February 25, 2012.

In addition to ERDDA, EPA also derives authority for research and development activities through other major environmental statutes. For example, under the Clean Air Act, the EPA Administrator must issue air quality criteria that, "shall accurately reflect the latest scientific knowledge useful in indicating the kind of extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air."[5] Through the Safe Drinking Water Act (SDWA), EPA sets standards based on, "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[6] Similarly, the Clean Water Act (CWA) requires EPA to publish water quality information "accurately reflecting the latest scientific knowledge."[7]

The science enterprise at EPA is spread across program offices and regions. ORD is organized into three national labs (comprised of 18 separate labs) and four national centers (which have 19 divisions). In addition to 18 labs within ORD, there are 9 labs split among several program offices and each of the 10 regions has its own lab. In FY2012, the appropriations level for EPA Science and Technology activities (S&T includes ORD and the other 19 labs) is $794 million. The fragmented nature of EPA R&D presents a challenge to program management and coordination, and has complicated efforts to evaluate the effectiveness of these activities. Numerous studies conducted by the EPA Office of Inspector General (OIG), the Government Accountability Office (GAO), the National Academies of Science (NAS) and other outside groups over the years cited significant concerns with the science activities of the Agency and the difficulties in evaluating the usefulness of the science to program needs.

ISSUES FOR CONSIDERATION

There have been concerns about the role of science at EPA since its inception in 1970. As early as 1974, a National Research Council (NRC) panel outlined concerns about the EPA's scientific mission.[8] Through the years, a series of reports documented problems with science at EPA, including a lack of uniformity of the peer-review process, failure to evaluate impacts of regulations, and a lack of transparency. In 1992, an independent panel of academics stated, "Currently, EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation."[9] Beyond the actual science conducted at the Agency, and used to generate regulations, the public perception is that EPA does not use science in an effective manner. "A perception exists that regulation based on unsound science have led to unneeded economic and social burdens, and that unsound science has sometimes led to decisions that expose people and ecosystems to avoidable risks."[10]

Regulatory Science

Science plays a foundational but not necessarily determinative role in support of EPA's mission to protect human health and the environment. EPA states that, "the role and use of science at

[5] 42 U.S.C. §7408 (a)(2) (2000).
[6] 42 U.S.C. §300g-1(b)(3)(A)(i).
[7] 33 U.S.C. §1314 (a)(1).
[8] NRC. *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices.* National Academy Press, 2000.
[9] EPA. *Safeguarding the Future: Credible Science, Credible Decisions.* 1992.
[10] Ibid.

EPA are determined by the nature of the scientific information and how it fits with the context of Agency decision-making."[11] This role is further elaborated upon as follows:

> Science does not drive EPA's policy and regulatory decisions, but rather, along with other relevant factors, informs and supports those decisions. Implementation costs and technological feasibility, local autonomy versus federal control, and justice and equity--all of which impact our quality of life and standard of living--are among the considerations that need to be factored into EPA's decisions without compromising scientific integrity, the Agency's mission, or statutory mandates. The impacts or limitations of these non-science factors, as well as the current state-of-the-science, will influence how scientific considerations are brought to bear on a particular environmental problem facing the Agency.[12]

Numerous entities have raised concerns regarding possible shortcomings in the quality and use of science at the Agency. The FY2012 Annual Plan of the EPA's OIG raises concerns about science and technology activities at the Agency, stating that "[q]uestions exist as to whether EPA is collecting the right data, of sufficient quality, and is making that data available."[13] In terms of EPA's regulatory process, the OIG further stated that "[m]any policies are out of date or are based on outdated science and technology."[14] More broadly, the chair of a 2009 National Academy of Sciences panel on ways to improve the Agency's risk assessment told the EPA's SAB and Board of Scientific Counselors (BOSC) earlier this year that the "The sleeping giant is that EPA science is on the rocks," and that risk assessment process was the Agency's "Achilles heel."[15]

Transparency and Data Access

Part of transparency is the ability of the public to review the scientific basis for Agency decisions and follow the logic used by EPA to make its decisions. Such evaluation requires that the information used by the Agency is also available for public review. In an attempt to enhance transparency within scientific processes, EPA's recently released Scientific Integrity Policy (from EPA's perspective):[16]

- "Ensures scientific findings are generated and disseminated in a timely and transparent manner, including scientific research performed by contractors, grantees, or other Agency partners who assist with developing or applying the results of scientific activities.
- Establishes the expectation that when communicating scientific findings, Agency employees include a clear explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections, if applicable.

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[11] http://www.epa.gov/epahome/science.htm
[12] Ibid.
[13] EPA Inspector General (IG), "FY 2012 Annual Plan," November 2011, http://www.epa.gov/oig/reports/2012/EPA_OIG_FY2012_AnnualPlan.pdf.
[14] Ibid.
[15] *Inside EPA*, "Key Adviser Warns EPA to Improve Agency Science Or Face A 'Crisis'," July 6, 2011.
[16] http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf

- Facilitates the free flow of scientific information. The Agency will continue to expand and promote access to scientific information by making it available online in open formats in a timely manner, including access to data and non-proprietary models underlying Agency policy decisions. Further, the use of non-proprietary data and models are encouraged, when feasible, to increase transparency."

Peer Review and Advisory Panels

EPA's Peer Review Handbook provides guidance to the Agency regarding use of peer review to enhance the quality and objectivity of scientific or technical work products. Specifically, EPA's peer review policy, "encourages and expects peer review of all scientific and technical information that is intended to inform or support Agency decisions and notes that influential scientific information, including highly influential scientific assessments,[17] should be peer reviewed in accordance with this Handbook."[18]

The EPA OIG report *"EPA Can Improve Its Process for Establishing Peer Review Panels"*[19] cited a number of areas in which the processes EPA utilized for selecting peer-review panels are vague and inconsistent. For example, the report notes EPA's National Center for Environmental Assessment lacks procedures for addressing conflicts of interest or potential biases, and finds that the Center "… can improve its system for populating and managing expert panels by better documenting conflict of interest decisions, establishing guidance for handling conflict of interest issues that arise after the panel has completed its deliberations, and providing more consistency between contractor and other third party procedures for selecting panels."[20]

With respect to advisory panels, concerns have been raised regarding the make-up, transparency, and rigor provided by EPA advisory panels such as SAB and CASAC. Despite the requirement under the Federal Advisory Committee Act that panels be "fairly balanced in terms of points of view presented and the functions to be performed by the advisory committee,"[21] GAO has found that, "[m]any advisory committee members are not appropriately screened for potential conflicts of interest or points of view."[22]

[17] Highly Influential Scientific Assessments require more extensive peer review and are generally defined as studies with the potential impact of $500 million per year.
[18] http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf
[19] EPA OIG. "EPA Can Improve Its Process for Establishing Peer Review Panels", April 29, 2009. http://www.epa.gov/oig/reports/2009/20090429-09-P-0147.pdf
[20] *Ibid.*
[21] 5 U.S.C. App
[22] GAO, "Ensuring Sound Science." See also: John Stephenson, GAO, Testimony before the Committee on Environment and Public Works, U.S. Senate, "SCIENTIFIC INTEGRITY: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes," June 9, 2009, http://www.gao.gov/products/GAO-09-773T.

Cost-Benefit Analysis

EPA regulations are playing a greater role in the overall federal regulatory enterprise as measured in rulemaking and overall costs and benefits.[23] In its *Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*,[24] the Office of Information and Regulatory Affairs (OIRA) notes the prominence of EPA Clean Air Act rules in the overall regulatory apparatus, disclosing that such rules represent 60 to 81 percent of the Agency-estimated monetized benefits and 44 to 54 percent of the monetized costs of all federal regulations.

The report further notes that 97 to 98 percent of EPA's claimed benefits come from air quality rules, and that "the large estimated benefits of EPA rules are mostly attributable to the reduction in public exposure to a single air pollutant: fine particulate matter."[25] While footnoting six major areas of uncertainty about EPA's assumptions regarding particulate matter (PM) and premature mortality and stating that "further scientific work is important in this domain" and "[m]ore research remains to be done on several key questions," OIRA continues to accept EPA's particulate matter-related benefits claims to justify the costs of air quality regulations on PM as well as other pollutants. The reliance on PM can also be seen in EPA's March 2011 report, *Benefits and Costs of the Clean Air Act from 1990 to 2020*, which focused almost exclusively on ambient PM reductions in claiming that the overall benefits of the Clean Air Act ($2 trillion) outweighed overall costs ($65 billion) by a factor of 30 to 1.[26] In the regulatory analysis accompanying the Agency's December 2011 Mercury and Air Toxics Standards for power plants,[27] PM co-benefits represented over 99 percent of the overall benefits, rather than the air toxics being regulated.[28]

Risk Assessment and Communication

A major EPA function within the Committee's jurisdiction is risk assessment. EPA efforts in risk assessment aim to "characterize the nature and magnitude of health risks to humans (e.g., residents, workers, recreational visitors) and ecological receptors (e.g., birds, fish, wildlife) from chemical contaminants and other stressors that may be present in the environment."[29] EPA's primary program for assessing human health risks is known as the Integrated Risk Information System (IRIS).

The National Research Council (NRC) recently noted that as the science of risk assessment has become more complex, "improved analytical techniques have produced more data that lead to question(s) about how to address issues of, for example, multiple chemical exposures, multiple

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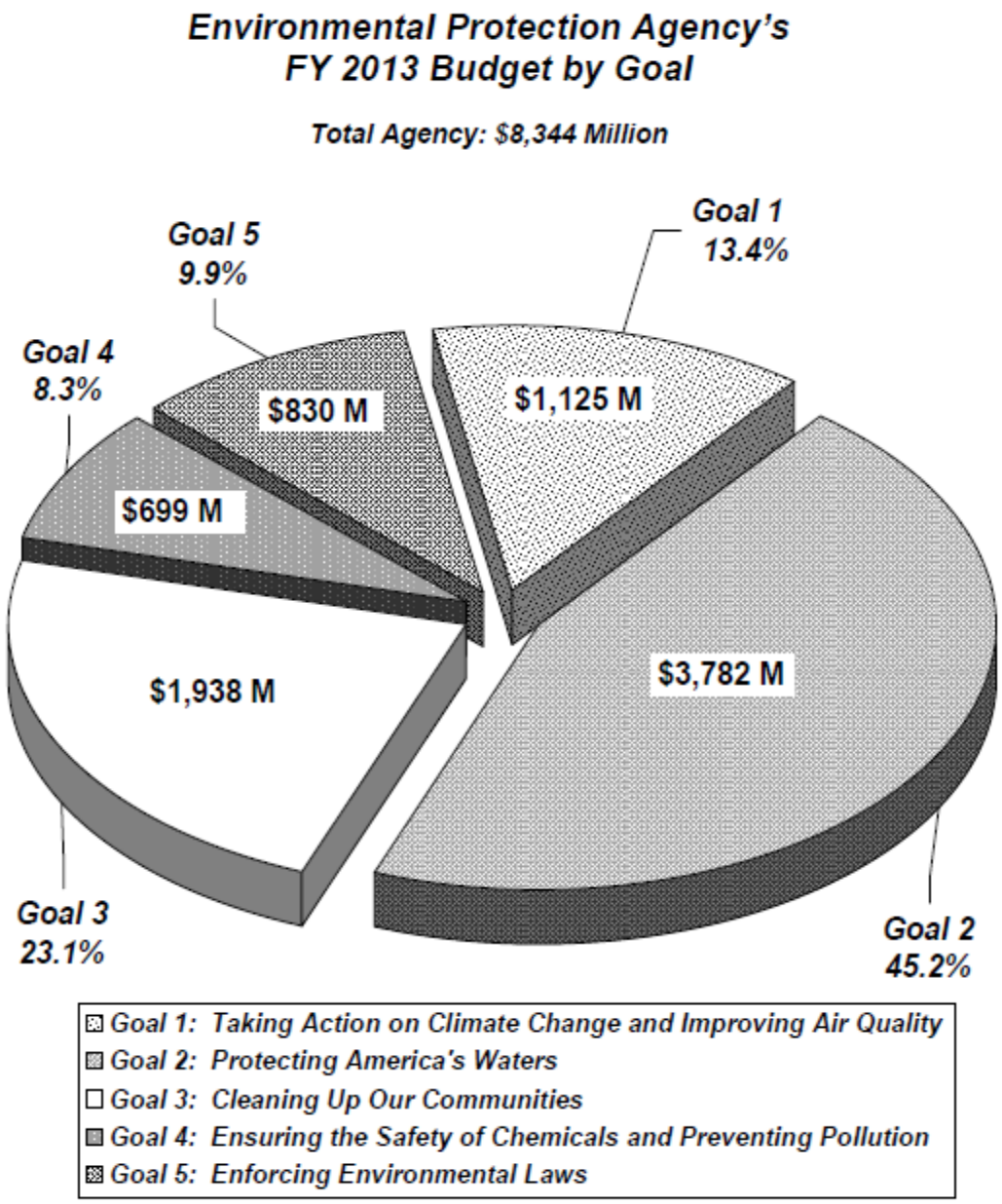
[23] In the Clean Air Act, National Ambient Air Quality Standards (NAAQS) are not required to be subject to cost-benefit analysis. However, EPA still issues a Regulatory Impact Analysis complete with cost-benefit analysis when issuing new NAAQS standards.
[24] http://www.whitehouse.gov/sites/default/files/omb/oira/draft_2012_cost_benefit_report.pdf.
[25] Ibid.
[26] http://www.epa.gov/air/sect812/prospective2.html.
[27] 77 Federal Register 9304.
[28] Testimony of Anne Smith, October 4, 2011, http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/100411_smith_0.pdf.
[29] http://epa.gov/riskassessment/basicinformation.htm#arisk

risks and susceptibility in populations."[30] Despite understanding the increasing complexity of and greater need for data and information, chemical risk assessment at EPA remains on GAO's High-Risk Program and was targeted for reform in P.L. 112-74, the Consolidated Appropriations Act of 2012. Additionally, a 2011 NRC report made specific recommendations to EPA regarding how best to improve the IRIS process, stating for example that:[31]

> "All critical studies need to be thoroughly evaluated with standardized approaches that are clearly formulated and based on the type of research, for example, observational epidemiologic or animal bioassays"; and
>
> "Strengthened, more integrative, and more transparent discussions of weight of evidence are needed. The discussions would benefit from more rigorous and systematic coverage of the various determinants of weight of evidence, such as consistency."

[30] NRC. "Science and Decisions: Advancing Risk Assessment". 2009
[31] http://www.nap.edu/catalog.php?record_id=13142

Appendix I[32]



[32] FY 2013 EPA Budget Request. Available at http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100DRB5.PDF

Appendix 2

EPA United States Environmental Protection Agency

U.S. EPA Organizational Chart