March 14, 2007

TESTIMONY OF JENNIFER SASS, PH.D.

SENIOR SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE

U.S HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

Legislative Hearing on

The Environmental Protection Agency Fiscal Year 2008

Research and Development Budget Proposal

March 14, 2007

2 PM, Room 2318, Rayburn House Office Building

**SUMMARY**

EPA is finding itself spiraling into an increasingly weaker scientific state. It has been dealt a decreasing budget for providing scientific infrastructure and resources, despite an increasing need for robust data to support human health and environmental protective policies and regulations. Unable to provide for all the data needs of the Agency, it is increasingly reliant on data supplied by the very industries that it regulates and by paid contractors who often have clients or members from the regulated industries. In all cases, the data are suspect, and in some cases, the data are selectively biased. To make matters worse, EPA is increasingly unable to provide adequate oversight of industry data submissions or contractor-generated scientific products due to lack of staff and resources. Moreover, industry data are often shielded from public scrutiny by claims of confidential business protections on matters that would have to be more transparent if the work was done by civil servants. The result is that EPA is increasingly under pressure to make regulatory and policy decisions with no data, inadequate data, or poor-quality data. These increasing scientific uncertainties leave EPA programs vulnerable to a poor grade by the Office of Management and Budget.

The Administration's fiscal year (FY) 2008 budget proposal cuts programs in the Environmental Protection Agency by $400 million from the Continuing Resolution for FY 2007 to $7.2 billion. This proposal represents the lowest funding request in this century in real dollars, FY 2004 being the high at $8.4 billion. In fact, this request cuts almost $2.5 billion from the agency high when accounting for inflation. The FY08 EPA funding dedicated to Research and Development (R&D) would be cut by 3.5% from the FY07 level, to $547 million.

Many of the cuts to EPA scientific research will not be compensated by related research spending in other agencies. Although overall federal investment in R&D would increase by 1.4% (to $143 billion) from FY07, an analysis by the American Association for the Advancement of Science indicates that the increase is all in development rather than research, and that generally, this budget, like last year's, increases spending for weapons, defense, and homeland security, while decreasing health, environment, and discretionary spending across the federal agencies.[1]

The mission of EPA is to protect and safeguard human health and environment; yet, this budget continues down the path of deep cuts and outsourcing in the face of overwhelming evidence of need.

We recommend that Congress increase the research budget for EPA specifically favoring programs that provide publicly available policy-relevant data for priority issues such as children's health, environmental justice, and susceptible populations.

**QUESTION ONE: Is the overall level of Science and Technology (S&T) funding in the FY 2008 budget request for EPA appropriate and does the budget request allocate funds in a way to best achieve the Agency's mission?**

---

[1] American Association for the Advancement of Science. AAAS Analysts See Mixed Prospects for Federal R&D Investment in 2007 and 2008. Edward W. Lempinen. February 12, 2007. www.aaas.org/news/releases/2007/0212budget.shtml

EPA's Office of Research and Development has identified the following high priority research goals in its FY08 multi-year plan, with a total level of appropriations of $539.8M:

- Goal 1 ($81.1M): Clean Air (Toxics; Particulates)
- Goal 2 ($105M): Clean Water (Drinking Water; Water Quality)
- Goal 3 ($32.4M): Land Preservation and Restoration (Contaminated Sites; Hazardous Waste)
- Goal 4 ($298.9M): Healthy Communities and Ecosystems (Ecological Research; Human Health; Human Health Risk Assessment; Global Change; Mercury; Endocrine Disruptors; Safe Pesticides/Safe Products)
- Goal 5 ($22.4M): Compliance and Environmental Stewardship (Economics and Decision Science; Science and Technology for Sustainability)

While these are laudable goals, sadly, the budget cuts to critical data collection and data assessment programs that support these priorities will leave the federal government with inadequate information upon which to base policies and regulations. In particular, there are gaps in policy-relevant research needs that will not be filled by other agencies, industry, or academia. Bluntly put, no, this budget allocation will *not* achieve the Agency's mission. Moreover, decreasing data and the consequent increasing scientific uncertainties leave EPA programs at a disadvantage during review by the Office of Management and Budget (OMB) Program Assessment Rating Tool (PART), which favors measurable program impacts and demonstrable efficiency and efficacy.[2]

My detailed response follows.

## I. The FY08 budget cuts funding to programs that gather reliable real-world data that would reduce scientific uncertainty, often leaving EPA increasingly reliant on either no data or data provided by the regulated industries.

EPA recognizes the need to reduce uncertainty in the science that supports risk assessment, risk management, and regulatory decisions in all of its programs. Sadly,

[2] http://www.whitehouse.gov/omb/part/

budget cuts to key monitoring and data collection programs will result in less data, and therefore greater scientific uncertainty. In many cases, "free" or "cheap" data are volunteered by the regulated industries. The increased reliance on data from the regulated industries calls into question the quality and credibility of the data. This problem is exacerbated by the decreasing ability of EPA to provide adequate oversight due to budget cuts for staffing, resulting in reduced technical expertise within EPA, and by frequent Confidential Business Information (CBI) protections that prevent public scrutiny to the data.

For example, the Clean Air Mercury Rule (CAMR, May, 2005) requires EPA to reduce and permanently cap mercury emissions from coal-fired power plants. Coal-fired power plants are the largest source of human-derived mercury emissions in the US, with much of it ending up in fish that people eat.[3] Although implementing this rule requires data to evaluate the effectiveness of reduction and control measures (S&T-8), EPA abandoned its promise to fund a mercury hot-spot monitoring study focused on mercury power plant emissions. The Scientific Advisory Board (SAB) noted that "the support for research on global sources, transport, and fates" of mercury is "seriously deficient", and that the 2007 budget levels "can not even begin to address the issue".[4] The reality of these budget slashes has left EPA reliant on the regulated industry to provide monitoring capacity (S&T-8), calling into question the ability of EPA to deliver credible, reliable data to inform and implement the CAMR adequately.

The Air Toxics Program presents another example of the impact of these budget cuts on acquiring reliable scientific data. The program identified the need to, "reduce uncertainty in both national- and community-scale assessments as well as residual risk" (S&T-65). It also noted that OMB rated its program more favorably when improvements were made to

[3] Once in the human body, mercury acts as a neurotoxin, interfering with the brain and nervous system. Exposure to mercury is particularly hazardous for developing fetuses and small children. More than 13 million lake-acres and 750 thousand river-miles in the United States are subject to fish consumption advisories due to mercury contamination. In addition to mercury, coal plants also emit soot and soot-forming pollutants, which can cause attacks, heart disease and other health problems, shortening the lives of nearly 24,000 Americans each year. Children and the elderly are especially vulnerable

[4] Report of the US EPA Scientific Advisory Board (SAB), 2007 Budget Review. March 2-3, 2006.

"reducing uncertainty in the science that supports standard-setting and air quality management decisions." (S&T-68). The budget report notes that the Air Toxics Program is reviewing other federal research programs with the goal of measuring progress "toward reduction in scientific uncertainty" (S&T-68). In fact, the FY08 budget provides additional funding to develop "quantitative risk assessment methods to allow improved analysis and characterization of uncertainty in human health risk assessment".[5] Despite the expressed need to reduce scientific uncertainty, air monitoring activities that would have provided EPA with real-world data to reduce uncertainty are significantly reduced. Although the SAB praised the Air Toxics Program for its efforts to evaluate the current air monitoring systems, SAB was highly critical of EPA's failure to support air monitoring resources overall, noting that this "diminishes the ability of EPA to make informed decisions on the effective and efficient management of air quality.[6] A robust, reliable empirical database is essential for reliable human health risk assessment.

## II. FY08 budget continues the trend of reducing funding for agency growth of scientific expertise, despite spending significant funds to outsource these tasks

One of the most significant changes at EPA in recent years has been the degree to which the Agency has outsourced responsibility for some of its important functions in a manner that undermines scientific credibility and public accountability.

EPA is accountable to the people of the United States, the Congress, and the Executive Branch to fulfill its mission in a manner that meets both the letter and intent of the law and that appropriately identifies protecting human health and the environment as the primary objective of the agency's activities. Both public trust and EPA's ability to meet its obligations to the public are seriously undermined when the Agency farms out critical task without any transparency, oversight or accountability, in many cases to the very industries that it is charged with regulating.

[5] Teichman, K. Acting Deputy Assistant Administrator for Science, ORD. Powerpoint presentation to the EPA Science Advisory Board Executive Committee. February 22,2007

[6] Report of the US EPA Scientific Advisory Board (SAB), 2007 Budget Review. March 2-3, 2006.

In fact, EPA is spending millions of dollars to fund entities that are specifically beholden to the industries that EPA regulates. Moreover, in many cases, this funding is directed toward activities that are central to the Agency's regulatory decision-making process. EPA does this without ensuring transparency, without adequate oversight, and without demanding public accountability. In particular, these arrangements are not subject to important "sunshine" laws intended to provide the public with access to the regulatory process and to prevent undue industry influence over Agency decisions. These laws, including the Federal Advisory Committee Act and the Freedom of Information Act, play a critical role in ensuring government accountability.

Originally the practice of encouraging these cooperative partnerships was intended to bring all stakeholders together for constructive dialogue regarding regulatory policy; however, in recent years it has transformed into something quite different, and many stakeholders (such as NRDC and other environmental and public health groups) have been shut out of the process. In many cases these partnerships have developed into little more than opportunities for the regulated industry to take over direct responsibility for key activities that provide the foundation for EPA's regulatory functions – in particular scientific analysis and risk assessment. This trend has had significant implications for the quality of the science upon which EPA relies for its regulatory activities.[7]

One example of a relationship that has demonstrably compromised the quality of EPA's scientific inquiry is the Agency's relationship with the International Life Sciences Institute (ILSI). ILSI represents several hundred corporations in the chemical, processed food, agro-chemical and pharmaceutical industries and received at least $2.1 million in EPA grants in 2005.[8] Members of ILSI include companies such as DuPont, 3M,

[7] A very similar issue was recently raised with regard to the National Institute of Health (NIH). In January of this year, Members of Congress, 44 prominent physicians, and 16 health organizations agreed that, in order to preserve scientific integrity, when appointing committees for drafting guidelines the NIH "must strive to ensure that all members are free from conflicts of interest." This letter was prompted in part by specific concerns regarding the fact that many recent committees have been dominated by members with conflicts of interest. These same problems exist, perhaps to an even greater degree, at EPA.

[8] The ILSI IRS Form 990 for 2005 lists $2.5 million in government contributions. The EPA Grants Awards Database reports over $2 million in awards to the ILSI Risk Science Institute. In a January, 2007 response

Syngenta, Eli Lilly, ExxonMobil Biomedical Sciences, and Dow Chemical.[9] ILSI routinely hosts workshops (often co-funded by EPA) where industry specialists, academics and agency officials come together to discuss science and policy. There often is little or no effort made to inform the public or the public interest community about these meetings, and as a result the public health and environmental voice is frequently entirely absent, marginalized, or ignored when final decisions are made. As a result, EPA policy decisions that emerge from this kind of process are flawed, and those decisions are being overturned.

For example, in 2003, EPA issued a proposed a guidance (based on a proposed policy that was drafted by a sub-group of ILSI) on how to assess a class of chemicals that includes perfluorochemicals used by DuPont to make Teflon. The ILSI-EPA proposed policy claimed that while these chemicals caused cancer in laboratory animals, they were not carcinogenic to humans. An independent scientific panel rejected the ILSI-EPA draft policy because it was not supported by data.[10] In fact, laboratory studies reported that these chemicals are associated with liver and testicular cancer, developmental impairment, and immune system suppression. Later, in December of 2005, DuPont paid more than $16 million to settle charges that it hid information for more than two decades showing that its Teflon chemicals are a significant threat to human health.[11]

In response to a request under FOIA, we have received a list of projects that EPA has undertaken with ILSI. Below we list selected current and recent-past projects between EPA and ILSI:[12]

---

to a FOIA request from NRDC, the EPA provided a list of the ILSI projects that EPA participates in. FOIA Request HQ-RIN-0029-07 to Jennifer Sass, NRDC.

[9] See the ILSI website for a full list of its membership: http://www.ilsi.org/AboutILSI/.

[10] See EPA Advisors Split Over Use of Animal Studies In Human Risk Reviews, Inside EPA (Dec. 10, 2003).

[11] See DuPont fined more than $10M over Teflon, Randall Chase, Associated Press (December 14th, 2005); Consent Agreement, December 14, 2005. (available at: www.epa.gov/compliance/resources/cases/civil/tsca/eabmemodupontpfoasettlement121405.pdf).

[12] Freedom of Information Request HQ-RIN-0606-07 to Jennifer Sass, NRDC.

- The Office of Pesticides (OPP) reports that they have numerous ILSI agreements that incurred the following costs: $58,000 in FY06, $60,500 in FY05, $245,000 in FY04, $150,000 in FY03, and $287,500 in FY02, for a cost to the program over five-years of $801,000.
- Project title: cross-study analyses of children's biomonitoring cohort studies. Description: ILSI Health and Environmental Sciences Institute (ILSI-HESI[13]) will identify relevant cohorts and data sets, recruit participation from researchers, work with researchers to develop a data analysis and quality assurance plan, compile the data, coordinate the cross-study analyses, and compile results for reporting to EPA. Timeline: EPA received a proposal from ILSI-HESI in December, 2006. Funding: Anticipated level of funding is $100,000 from EPA ORD under Goal 4 (Healthy Communities and Ecosystems).
- Project title: International biomonitoring workshop. Description: EPA co-sponsored a workshop on September, 2004 with ILSI-HESI and the American Chemistry Council, a trade organization for the chemical industry. Key questions relate to the use of biomonitoring data for environmental public health protection. Funding: $50,000 from EPA ORD under Goal 4 (Healthy Communities and Ecosystems).
- Project title: Cooperative agreement for working groups, workshops, and other events on topics in risk assessment. Time: 1999-2002. Funding: $333,330 over several years from ORD.
- Project title: Mode of action in assessing human relevance of animal tumors. Description: A systematic evaluation of comparability, or lack of comparability, between the postulated animal mode of toxicity and related information from human data sources. Time: 2000-2003. Funding: amount not disclosed. Cooperative agreement with the EPA Office of Pollution Prevention and Toxics

[13] The ILSI Health and Environmental Sciences Institute (HESI) reports to the ILSI Assembly of Members. Although HESI is structured and claims to operate as a, "public, non-profit scientific foundation" (www.hesiglobal.org/AboutUs/), they state in their recent job advertisement for an executive director of ILSI-HESI that this person should "ensure that the scientific issues important to [ILSI] member companies are raised and appropriately addressed by the organization." (Email to To: <hesi@hesiglobal.org. Subject: Executive Director of HESI Job Description. Tue, 10 Oct 2006).

(OPPTS) and Office of Pesticide Programs (OPP). Additional support was provided by Health Canada. http://rsi.ilsi.org/Projects/Human_Relevance.htm

- Project title: Using mode of action (MOA) and life stage information to evaluate the human relevance of animal toxicity data. Description: The purpose of this project was to draw on the ILSI-Risk Sciences Institute (ILSI-RSI) project for MOA analysis of animal tumors and to expand this into a harmonize framework for all endpoints including reproductive, neurological and developmental effects. Time: 2004-2005. Funding: amount not disclosed. ILSI-RSI project was funded by EPA's Office of Pollution Prevention and Toxics (OPPT) via their cooperative agreement and Health Canada. http://rsi.ilsi.org/Projects/Human_Relevance.htm
- Project title: Training course on use of mode of action in assessing human relevance. Description: The purpose of this project is to train the scientific community on how to conduct mode of action analyses for evaluating the human relevance of animal responses. Participants consisted of experts from various government agencies, including the EPA and Health Canada. Time: 2006, ongoing. Funding: amount not disclosed. http://rsi.ilsi.org/HumanRelevance.htm
- Project title: ILSI Risk Science Institute Developmental Neurotoxicity (DNT) Project. Description: The goal of this project was to assess the lessons learned from the implementation of standardized tests for developmental neurotoxicity in experimental animals, such as the U.S. EPA OPPTS Health Effects Test Guideline 870.6300 (Developmental Neurotoxicity Study) and similar protocols, and the subsequent application of test results to human health risk assessment. Time: 2004-2007. Funding: OPP funded this ILSI-RSI project via a Cooperative Agreement.

EPA's continued use of agency funds to support closed-door, industry-driven science that feeds directly or indirectly into the regulatory process raises tremendous concerns from a public health and sound science perspective.

## III. FY08 budget is cutting funding to core priorities such as susceptible populations, ecological research, and human health

Research on human health and ecosystems has seen a steadily declining budget over the last three years, from $242.9 M (2006), to $228.2 M (2007), to $217.5 M (2008) (S&T-3). However, from the FY08 budget it is impossible to identify exactly what programs will be impacted, because the document fails to clearly link funding amounts with projects, and fails to clearly identify projects that will be reduced or eliminated. A short list of specific programs that are slated to be reduced or eliminated was identified in a powerpoint presentation by ORD Acting Deputy Assistant Administrator for Science[14]. This list included:

- The loss of data collection in the lower Mississippi River and Gulf of Mexico wetlands, despite the increased awareness that these precious areas are critical to mitigating severe flooding in the Katrina and Rita hurricane hit areas.
- The loss of funding for ECOTOX, a critical searchable, publicly-available web-based database of ecological effects of toxic chemicals.
- Reduce assistance to states for development of their watershed management plans and establishment of Total Maximum Daily Load values, which are the maximum allowable level of a pollutant that a waterbody can receive without exceeding water quality standards. These standards are set to protect the drinking water supply, swimming areas, and aquatic life.
- Reduced efforts to collect data on the exposure and effects of toxic chemicals in children, adolescents, older adults, and other identifiable susceptible populations
- Reduce support for the National Children's Study

These cuts will eliminate significant research and public access to important data. They will also diminish the ability of EPA to make informed and effective regulatory decisions, to allocate its resources wisely, and to evaluate the efficacy of its programs. In particular, much of the results of the ecological research identified above is particularly valuable to regional, state, and local communities and regulators who are tasked with assessing real-world problems in regional ecological systems such as watersheds. The

[14] Teichman, K. Acting Deputy Assistant Administrator for Science, ORD. Powerpoint presentation to the EPA Science Advisory Board Executive Committee. February 22,2007

SAB identified that the need for these data are of great importance to EPA, and that the data are not likely to be supplied by other sources such as industry and academia. [15]

The reduced support for the National Children's Study highlights the extent to which vulnerable subpopulations will suffer under the proposed budget. As noted in a 2006 letter from pediatricians, public health specialists, and patient advocacy groups to the Senate Committee on Appropriations, the National Children's Study would provide substantial information for regulators to allocate resources directed towards improvements in the health of children and adults. [16] The research results of this important study are estimated to provide potential health care savings in the range of $3.3 – 5.5 billion annually based on an economic analysis by the National Institute of Child Health and Human Development (NICHHD). Information from the National Children's Study will enhance global understanding of childhood afflictions such as obesity, autism, early-onset diabetes, developmental delay, mental illness, learning disorders, lead poisoning, asthma, autoimmune disease, and chemical intolerance/sensitivity. The data from these and similar initiatives will be of particular help to economically-disadvantaged communities whose members often must play, work, and learn in polluted outdoor and indoor environments. Compared with adults, prenatal and later periods of development are uniquely vulnerable to many pollutants in both the outdoor and indoor environments, due in part to rapid growth and development, behaviors and activities, eating patterns, and physiology. Understanding and reducing the severity and/or incidence of diseases and disabilities will require sustained public investment in research on childhood exposures to environmental toxicants.

## IV. FY08 budget eliminates or diminishes support for publicly available information on toxics: the IRIS chemical evaluation program, EPA libraries

[15] Report of the US EPA Scientific Advisory Board (SAB), 2007 Budget Review. March 2-3, 2006.

[16] Letter to Honorable Thad Cochran, Chairman, and Honorable Robert C. Byrd, Ranking Member. Senate Committee on Appropriations. From E Miller, R Zdenek, D Croser, J Greenwood, C Gavigan, F Perera, P Shah, J Balbus, PJ Wood, N Gendel C Barnett, D Wallinga, S Gilbert, T Hill, K Lawson, J Behm, H Loukmas, L Redwood, T Schettler, V Garry. February 14, 2006

***Inadequate resources and OMB interference have prevented EPA from keeping the IRIS chemical database as up-to-date as would be expected for a source of information so important to U.S. policy decisions.***

Many of the EPA assessments of regulated chemicals are publicly available on its database, the Integrated Risk Information System (IRIS), which contains EPA scientific consensus positions on potential human health effects from environmental contaminants. While not a legal regulatory standard *per se*, such information is used by regulators at the state and federal level and by the international community in combination with exposure data to set cleanup standards and various exposure standards for air, water, soil, and food). The database receives over a half-million visits monthly, from over fifty countries, underscoring its widespread use. At this time, there are over 540 chemicals listed on IRIS. While a substantial number of these chemicals are economically significant (i.e., they are produced or imported at a rate greater than 10,000 pounds per site annually), these chemicals make up a small percentage of the over 8,000 economically significant chemicals found in the U.S and 15,000 chemicals in commerce altogether.[17] Even when compared to a smaller subset of chemicals that should have assessments available, IRIS is obviously insufficient. For instance, the EPA is responsible for regulating the emissions of 188 hazardous air pollutants (HAPs) under the Clean Air Act. Of these 188 HAPs, only 129 do appear in the IRIS database – meaning that in almost 20 years since IRIS, the EPA has been unable to complete assessments of the toxicity and carcinogenicity of nearly one-third of these dangerous pollutants. Even when important chemicals are on the IRIS database, the risk assessments available for these chemicals are often quite old. The average assessment on IRIS is over 13 years old.

According to its website on "what's new" (www.epa.gov/iris/whatsnewarch.htm), in addition to performing a literature screen and confirming about a dozen existing IRIS assessments annually, EPA finalized the following number of new chemical assessments:

- In 2006, IRIS finalized 2 new assessments

[17] American Chemistry Council: Federal Regulations That Help Ensure Chemical Safety, *available at* http://www.accnewsmedia.com/docs/1200/1156.pdf (last updated April 1, 2003).

- In 2005, IRIS finalized 5 new assessments (n-hexane, toluene, zinc and compounds, barium and compounds, perchlorate and perchlorate salts)
- In 2004, IRIS finalized 3 new assessments (boron and compounds, dibromomethane, lead and inorganic compounds)

With so few assessments finalized each year, it is evident that EPA needs more resources, both money and personnel, to develop robust timely IRIS assessments. The FY08 budget promises that IRIS will complete 16 health hazard assessments of high priority chemicals and post 8 finalized assessments on the internet (S&T-89). Its hard to see how IRIS is going to finalize eight assessments, given its recent trend of finalizing 2-5 each year. In fact, the IRIS program should be finalizing as many as 16 assessments each year. Unfortunately, the reality is that IRIS is likely to slow its pace further because of FY08 initiatives to "expand opportunities for interagency review and public comment" and expand "consulting with the National Academies of Sciences" on risk assessment methods and approaches (S&T-89), as required by the OMB PART review (S&T-90). These costly and time-consuming delays will significantly slow an already delayed process. Moreover, OMB interference has also weakened the utility of IRIS assessments:

- OMB has blocked IRIS from posting acute (less than 24 hr) risk values.[18] Acute risk values are relevant to communities that are exposed by burst releases of toxics (smokestacks, etc.) that may not exceed short-term (days-weeks) or long-term (months-years) regulatory standards, but may still pose a hazard to acutely exposed individuals.
- OMB is blocking IRIS from posting summaries of its assessments, arguing that the summaries give a naïve public and regulators inaccurate impressions, contribute to misunderstandings, and are mis-used. EP staff should be able to post summaries of IRIS data on chemicals to the public.

[18] *EPA Eyes Expanded Risk Database Used In Toxic Regulation, Cleanups*. The managers of an EPA chemical risk database are considering adding short-term and acute exposure categories on several chemicals to gauge the resources needed to add the broader risk data to the system. January 27, 2003. Inside Washington Publishers

- OMB has blocked the implimentation of the supplemental cancer guidelines on children's exposure.[19] Ethylene oxide is the first example where IRIS staff recommended applying a 10-fold safety factor to site-specific assessments where children may be exposed. OMB blocked this. The next relevant chemical for this process will be acrylamide, for which children's exposures are high.

IRIS has come under intense scrutiny from OMB and the regulated industries, and that the EPA goal of producing robust scientific assessments of toxic chemicals in a timely manner is *not* shared by OMB.

***Closing EPA Libraries limits public access to information***

For decades, EPA's network of 26 scientific libraries has served as a gold mine of resources for scientists, community members, and EPA's own staff. Expert librarians made themselves available to locate information, and the library collections themselves contained unique materials, not available elsewhere. Over the past four months EPA has closed five libraries and reduced access at four others, including my local EPA library.[20]

According to press reports, the EPA libraries fielded about 134,000 information requests in fiscal year 2005.[21] Of these, the now-closed EPA regional libraries in Chicago, Kansas City, and Dallas handled more than 32,000 requests for information.[22] Representatives of 10,000 EPA scientists, engineers, environmental protection specialists and support staff protested the closure of the technical libraries in a letter to the chair and ranking member of the Senate Appropriations Committee, Interior and Related Agencies Subcommittee in

[19] *OMB Opposes First-Time Child Cancer Factor Use In EPA Risk Assessment.* The White House Office of Management & Budget (OMB) is reportedly objecting to EPA's first-time use of a new children's cancer guideline in a draft risk assessment for ethylene oxide (EO) that seeks to significantly strengthen the safe exposure level, according to EPA sources… The draft risk assessment, released Sept. 22 of last year by the agency's National Center for Environmental Assessment, proposes tightening the agency's 1985 bench point of 3.6 parts per billion to 0.06 parts per trillion -- a significant change that could have a host of ramifications for industry… Ethylene oxide is a common chemical that is widely manufactured, and is used as a medical sterilant as well as to make anti-freeze, detergents and polyester. January 26, 2007. Inside Washington Publishers

[20] Congressional Research Service. Restructuring EPA's Libraries: Background and Issues for Congress. RS22533. January 3, 2007.

[21] Joal A. Mintz and Rebecca Bratspies. Closing Agency Libraries Deals Serious Blow. South Florida Sun-Sentinel. December 11, 2006.

[22] Robert McClure. EPA gets an earful on library closures. Seattle Post-Intelligencer. January 22, 2007.

June of 2006.[23] This letter noted that EPA's own cost-benefit analysis[24] estimated that the library networks saved Agency staff time, resulting in annual cost savings of approximately $7.5 million, far more than the library budget of $2.5 million. Thus, the Public Employees for Environmental Responsibility suggest that, "while cloaked as a budgetary measure, the actual motives appear to be rooted more in controlling access by both EPA staff and the public to information".[25]

Linda Travers, acting Assistant Administrator for the EPA Office of Environmental Information said in December 2006 that "all EPA-generated documents from the closed libraries would be online by January and the rest of the agency's 51,000 reports would be digitized within two years."[26] Not surprisingly, this has not been done. Digitizing between 50,000 and 80,000 reports is a monumental task and there does not appear to be any budget for carrying this out. Rather than saving the agency money, these closures will cost the agency in staff productivity, and in money and time for digitization. The cost to local communities is hard to calculate, since information – when you really need it – is priceless.

## IV. The FY08 budget increased funding to support research on new technology areas such as nanotechnologies, but has failed to develop a clear research agenda that would support policy and regulatory needs

Nanotechnology (the convergence of biology, chemistry, and engineering at the nano-scale) has emerged as one of the most rapidly developing, dynamic, and exciting fields of scientific research and commercial development. Nano-scale materials approximately 100 nanometers (nm) or less in any dimension offer potentially tremendous advances in fields ranging from medical technologies to power generation and storage to

[23] Letter from Dwight A. Welch et al. Presidents of 16 Local Unions to Conrad Burns and Byron Dorgan, United States Senate. June 29, 2006. www.peer.org/docs/epa/06_29_6_union_library_ltr.pdf

[24] EPA Office of Environmental Information. Business Case for Information Services: EPA's Regional Libraries and Centers. EPA 260-R-04-001. January 2004.

[25] http://www.peer.org/campaigns/publichealth/epa_library/index.php

[26] Tim Reiterman. Closure of 6 federal libraries angers scientists: Cost-cutting moves at the EPA and elsewhere deny researchers and the public access to vital data, critics say. Los Angeles Times, December 8, 2006.

environmental remediation strategies. However, the rapid emergence of new nanomaterials and their increasing use in products and processes raises serious concerns regarding the potential for adverse impacts on human health and the environment. Already, EPA has reviewed 15 new chemical uses that were small enough to be considered nanoscale; all are protected by Confidential Business Information (CBI) provisions under the Toxic Substances Control Act; the public is unable to learn the names of these chemicals, their uses, or even their manufacturers.

Current EPA research activities include assessing potential ecological and human health exposures and effects from nanomaterials likely to be released into the environment (S&T-108, 109). However, this research is poorly coordinated, inadequately funded, and poorly tailored to EPA's authority to regulate nanomaterials.[27] In fact, in September, 2006, the House Science Committee Chairman Sherwood Boehlert (R-NY), Ranking Minority Member Bart Gordon (D-TN) and non-government witnesses identified the need for EPA to develop a better-funded research strategy to address health and environmental risks, noting that the current research agenda lacked coordination.[28]

A voluntary pilot program now under consideration by the EPA will request that industry participants submit data on material characterization, toxicity, exposure potential, and risk management practices. While this program may act as a stopgap to fill the regulatory breech, it would only involve those companies that volunteer to participate and would gather data regarding only those products that participating companies choose to disclose. Companies with the riskiest products, as well as those with poor business ethics—that is, those most likely to need government oversight—are least likely to participate. A coalition of more than 20 public interest groups including NRDC, Friends of the Earth, Greenpeace, and Sierra Club insist that a voluntary program without a mandatory

[27] Summary Report of the Peer Review Workshop on the Nanotechnology White Paper: External Review Draft. Washington, DC April 19-20, 2006. Prepared by the US EPA Office of the Science Advisor, by Versar, Inc.. www.epa.gov/OSA/pdfs/nanotech/nanotechnology-peer-review-workshop-summary-report-final-070706.pdf

[28] US House of Representatives (www.house.gov/science) Science Committee. Boehlert calls for better coordination and greater funding to understand nanotechnology risks: Administration Releases Report on "Research Needs". September 21, 2006

regulatory component will not be able to address potential risks. The reliance on voluntary stewardship initiatives has left a regulatory void that could harm both human health and the economic stability of the nanotechnology industry. Nonetheless, the EPA appears unwilling to commit to comprehensive, enforceable regulations.

Congress should specifically direct EPA to allocate adequate resources not only to examine nanomaterial toxicity (an absolutely essential first step), but also simultaneously and aggressively develop a robust regulatory framework that will adequately ensure that nano-materials in the marketplace are safe, and that unsafe materials are appropriately managed from cradle to grave. Any such framework should be based on a precautionary approach to managing toxic chemicals and should:

- **Prohibit the untested or unsafe use of nanomaterials.** Because preliminary data demonstrates the potential for toxicity, unsafe or untested nanomaterials should not be used in a manner that may result in human exposures or environmental releases over the lifecycle of the material.
- **Conduct full lifecycle environment, health, and safety impact assessments as a prerequisite to commercialization.** Robust testing is urgently needed to identify potential risks early in development, across the lifecycle of the material. The results of testing should made available to the public.
- **Facilitate full and meaningful participation by the public and workers in nanotechnologies development and control; consider the social and ethical impacts of nanotechnologies.** The potential of nanotechnologies to transform the global social, economic, and political landscape means we must move the decision-making out of corporate boardrooms and into the public realm.
- **Implement precautionary regulatory requirements for nanomaterials.** We urgently need regulations to ensure that risks are adequately addressed and that communities and workers are protected.

Nanomaterials represent a large, but not a new, challenge for the regulatory agencies. The need to regulate a commercial material about which little is known of its safety is reminiscent of our introduction of asbestos into global markets. By the 1930s, asbestos

was being linked to deaths; as of 2004, the cumulative financial liabilities from the substance were projected at more than $200 billion. In the U.S., we still have more than one death per hour—approximately 10,000 per year—as a legacy from past and continuing exposure to asbestos; the global death rate is estimated at 10 times higher. Insurer Lloyds of London and Swiss Re have already noted that asbestos serves as a warning to the nanotech industry. To use another analogy, with nanotechnologies we are right now at the point of deciding whether to put lead into gasoline.

**QUESTION TWO: What roles should research partnerships, extramural grants, contracts, and in-house research play in helping the Agency to obtain the scientific information needed to serve their mission of environmental and public health protection?**

Congress adopted strong sunshine laws in part to prevent clandestine manipulation of the regulatory process, and that objective is in serious jeopardy if EPA is permitted to outsource critical responsibilities. Congress should ensure that the money going to EPA is used in a manner that preserves the scientific integrity of the regulatory process and that any important science activities funded by EPA are conducted with adequate transparency and direct lines of public accountability. In particular, EPA should not be funding or relying on regulated industries or their representatives to develop EPA guidance or policy documents, or to develop scientific assessments of their own chemicals for EPA. Rather, industry-funded or industry-supported assessments and recommendations should be submitted to EPA as a public comment, publicly available, and subjected to the same consideration and review as all public comments.

EPA should support and expand its use of in-house scientific and technical experts. These people represent the nation's brain-trust, and their work products should be publicly available. The Agency's own technical experts have to be enabled to investigate and disclose what dangers we truly face from environmental pollutants, despite myriad influences of business interests. Grievous and irreversible damage is being done to this Agency's capacity to protect human health and the environment.