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From: Francesca Grifo
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Cc: Timothy Donaghy
Subject: Union of Concerned Scientists comments on regulatory review
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On February 26, 2009 the Director of the Office of Management and Budget (OMB) called for public comments on improving "the process and principles governing regulation" in preparation for a new executive order on federal regulatory review. In response, the Union of Concerned Scientists submits these recommendations.

Thank you for the opportunity to comment. For further information, please contact Tim Donaghy at tdonaghy@ucsusa.org.

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Union of Concerned Scientists
Recommendations to Improve Federal Regulatory Review
March 24, 2009

On February 26, 2009 the Director of the Office of Management and Budget (OMB) called for public comments on improving “the process and principles governing regulation” in preparation for a new executive order on federal regulatory review.¹ In response, the Union of Concerned Scientists submits these recommendations.

Under the previous administration, the Union of Concerned Scientists documented multiple instances where the regulatory review process was the venue for political interference in the scientific work of the federal agencies.² In keeping with President Obama’s pledge to “restore science to its rightful place,” we hope the administration will put forth an improved regulatory review process that respects the scientific work of federal government experts, and provides greater information to the American public about how science was used in rule making.

Federal agencies were created to implement and enforce U.S. laws, with the understanding that specialization in certain areas is necessary. Each agency has developed the needed expertise, experience, processes, and policies to pursue its mission and fulfill its particular duties. While the White House is responsible for overseeing these agencies, a balance should be struck between administration priorities and agency independence.

We participated in a steering committee (convened by OMB Watch) to draft recommendations for improving the quality and timeliness of federal regulations; there are many valuable recommendations contained in that report.³ In these comments we focus on the role of scientific information in the regulatory process, and on three key themes: (1) respect for the expertise of the rule making agencies, (2) increased transparency, and (3) reforming cost-benefit analysis.

Respect for Agency Expertise

A new executive order on regulatory review should implement a process that exhibits greater deference to the experience, expertise and statutory authority of federal agencies. Such a process would require a different role for the OMB and its Office of Information and Regulatory Affairs (OIRA) than under past administrations. While OIRA has important transparency and coordination roles in the regulatory process, it should not serve as the *de facto* gatekeeper for all government regulations.

A corollary to this principle is that the power to initiate a rulemaking should reside with the Senate-confirmed agency head, rather than with a “regulatory policy officer” (RPO) who reports to the White House. President Obama has already repealed executive order 13422 (which expanded the role of RPOs) and we hope a new regulatory process will continue to invest the ultimate rulemaking authority in the agencies as directed by statute.

Review of Scientific Information

Of particular concern is that the scientific information considered in the process of crafting a regulation and the conclusions drawn by scientific experts be fully presented to the public without manipulation,

omission or editing by non-experts. Under the previous administration, OIRA hired a handful of scientists to create in-house scientific expertise in an office traditionally dominated by economists.⁴ The agency then began, for the first time, to review and criticize the scientific and technical basis for agency regulatory decisions.

Recent examples of OMB interference in the science underlying regulations include:

- *Formaldehyde Pollution from Plywood Plants*: In 2004, the OMB downplayed scientific studies linking formaldehyde with leukemia in order to facilitate approval of a new rule, conceived by the timber and chemical industries, which exempted more plywood plants from formaldehyde pollution regulation.⁵
- *Particulate Matter Air Pollution*: The EPA incorporated “last minute opinions and edits” from OMB in its decision not to tighten the ambient air quality standard for fine particulate matter in 2006. These edits sidestepped the peer review process and were disputed by the EPA’s panel of independent scientific experts. The incident marked the first time the EPA had overruled the recommendations of its expert panel regarding ambient air pollution standards.⁶
- *Ozone Air Pollution*: In 2007, OMB manipulated scientific knowledge about ozone-related mortality in an EPA assessment of the benefits of strengthening the ozone ambient air quality standard.⁷ Exposure to ground-level ozone, a component of smog, can cause and exacerbate a variety of respiratory health problems and can even lead to premature death.⁸ The White House further interfered by preventing the EPA from adopting a strong secondary standard intended to protect long-term public welfare, despite a clear consensus among EPA’s staff and scientific advisors.⁹
- *Climate Change Endangerment Finding*: In 2007, the OMB refused to read or accept a report by the EPA that stated global warming would “endanger” the public; the report would have required regulation of greenhouse gas emissions under the Clean Air Act.¹⁰ The EPA later released a watered down preliminary report that came to no conclusions, further delaying a decision on greenhouse gas emissions.¹¹

EPA scientists have criticized this profound change in how science is used in the regulatory process. Responding to a 2007 UCS survey, nearly 100 EPA scientists identified the OMB as the agency most responsible for degrading the scientific integrity of EPA’s decisions. As one EPA scientist put it:

“[OMB] is a true source of frustration. They truly interfere and want to stamp the White House Agenda over every document that is sent to them for review. Truly few realize the impact that they have. They have hired their own scientists and play the ‘my scientist is better than yours’ game.”¹²

A new executive order should expressly prevent OIRA (and OMB in general) from reviewing, selecting or critiquing the scientific information prepared by agencies in support of a rulemaking. If review and editing of technical information is needed, it should be done by qualified scientists—either agency experts or federal advisory committee members—through a transparent formal peer-review process. OIRA does not have the expertise to credibly review the scientific findings underlying regulatory decisions across multiple federal agencies.

Under the previous administration, OIRA also expanded its authority to review agency guidance documents, many of which are primarily scientific in nature (e.g. risk assessments). A new executive order should greatly scale back OIRA's review of agency guidance documents and should similarly prohibit review or editing of scientific information in those documents.

Interagency Review

In April 2008, the Environmental Protection Agency (EPA) announced a new review process granting greater control over its public chemical database—known as the Integrated Risk Information System (IRIS)—to other federal agencies. The changes allow agencies, many with clear conflicts of interest such as the Department of Defense (DOD), Department of Energy, the National Aeronautics and Space Administration, and the OMB, to delay scientific assessments of the toxicological and cancerous effects of chemicals.

This new process represents interagency review run amok and serves to institutionalize political interference in crucial scientific and public health information. Numerous IRIS risk assessments are already years behind schedule, and this new process will only slow it down further. The GAO strongly criticized the new process saying it “limits the credibility of IRIS assessments and hinders EPA’s ability to manage them.”¹³

The president should terminate inappropriate or excessive interagency review. The administration should clarify which agencies have primary authority in various areas of scientific expertise, and limit other agencies’ review of scientific information to advice and comment. The delay and political manipulation of EPA’s risk assessments reveal the perils of allowing other entities to influence an agency’s scientific investigations, or to limit that agency’s dissemination of scientific information to the public.

Broader Guidelines on Scientific Practices

Under its previous leadership, OMB attempted to issue strict guidelines for how federal regulatory agencies may conduct scientific peer review and risk assessments. Both proposed bulletins generated sharp criticism from the scientific community and the National Academies. In both cases the guidelines were modified to be more flexible, but concerns remained that such “one-size-fits-all” policies would lead to excessive delays in finalizing needed regulations.

OIRA should not attempt to police federal scientific work through over-prescriptive “one-size-fits-all” policies on scientific practices. If guidelines are needed they should be drafted in a transparent and participatory process in consultation with agency scientists and the National Academies, and should be flexible enough for individual agencies to craft policies that meet their particular needs.

Increased Transparency

The OMB should work with federal agencies to increase the transparency of the regulatory process, expand rule-making dockets, and make them more user-friendly. It is currently very difficult for the public to find comprehensive information on how regulations are crafted, thus reducing the ability of the public to provide input into regulatory proposals.

As a first defense against inappropriate review or editing of agency scientific information by the White House or other agencies, we call for the release of drafts of agency scientific documents before any OMB or interagency review. We understand the usefulness of not having every initial discussion take

place in the public spotlight, so this early release of draft scientific documents would simply refer to the final, peer-reviewed document put together by agency staff and external advisors and include the scientific pieces of the docket described below. Having an early draft available will allow the public to understand what changes are being requested by the OMB or other agencies.

Agencies should disclose more information about how a regulation was developed. The rule-making docket should contain:

- All scientific studies in an agency's possession related to a proposed regulation, regardless of whether the study was directly cited or whether it directly informed the final decision, including documentation of dissenting opinions by agency scientists.
- All official interagency communications regarding rules under review, including those from the White House.
- Completed and peer-reviewed drafts of agency documents prepared by scientific or technical staff before they are subjected to White House or interagency review.

The rule-making docket should also incorporate the following reforms:

- The OMB should overhaul www.regulations.gov to make it a truly consumer-oriented and user-friendly portal for information about proposed, pending and final regulations. This website is a first step toward bringing rule making into the information age; improving its search and browsing functionality will help it live up to its full potential.
- The OMB should encourage the use of interactive technology to engage the public in the regulatory process. Individual agencies should be allowed to innovate better methods for communicating information to the public and receiving feedback on proposed regulations.
- The OMB should also develop a regulatory tracking system that provides information on regulatory proposals earlier in the rule-making process. The OMB currently only produces twice-yearly reports on the president's regulatory agenda and the status of any rules in preparation. A regularly updated tracking system would provide the public with more accurate and timely information about pending regulations and any associated paperwork requirements.

Reform Cost-Benefit Analysis

In 2003 OIRA required federal agencies to adhere to a narrow form of cost-benefit analysis (CBA) when assessing the impact of proposed regulations. Other observers have submitted extensive comments on how and when CBA should be used in the regulatory process; our concern with CBA is that such analyses have proven highly susceptible to manipulation of scientific and technical information.

In 2007 OIRA intervened in the EPA's regulatory impact assessment for its proposed ozone air pollution standard. OIRA's edits distorted both the costs and the benefits of the regulation in order to undermine the rationale for a strong ozone standard.¹⁴ In two additional cases, researchers at the Fish and Wildlife Service (FWS) were directed to delete any reference to the economic benefits of protecting critical habitat for two endangered species: the bull trout and the red-legged frog. In one case FWS researchers were told to insert language from the OMB into their analysis that stated that it was "not feasible to 'monetize' the benefits of land protection."¹⁵ Such incidents have degraded the credibility of cost-benefit analysis as a regulatory decision making tool.

The next OIRA administrator should:

- Revise OMB Circular A-4 and set forth narrow restrictions on how CBA will be used in the regulatory process. These guidelines should emphasize that cost-benefit analysis:
 - Should be used only at the discretion of the regulatory agency
 - Should be used only when consistent with the intent of the relevant statute
 - Should not determine the regulatory outcome (unless specifically required by statute)
- The cost-benefit analysis process should also be fully transparent and the White House should never manipulate or alter the results of such an analysis.

President Obama has spoken on many occasions about the importance of transparency, citizen participation and scientific integrity. A new executive order on regulatory reform represents a crucial opportunity to put those ideas into practice. We urge the president and OMB Director Orszag to implement these changes in order to create a more transparent, more robust and more credible rule making system.

Sincerely,

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¹ Memorandum for the Heads of Executive Departments and Agencies, Subject: Regulatory Review. January 30, 2009; Federal Regulatory Review, request for comments. Federal Register, Vol. 74, No. 37, p. 8819. February 26, 2009.

² Union of Concerned Scientists (UCS). 2008. *Interference at the EPA*. Cambridge, MA. Online at <http://www.ucsusa.org/EPAscience>.

³ Bass, G.D. et al. 2008. *Advancing the Public Interest Through Regulatory Reform*. November. Online at <http://ombwatch.org/files/regulatoryreformrecs.pdf>.

⁴ OMB Watch. 2003. OMB expands influence over scientific decisions. Online at <http://www.ombwatch.org/node/1427>.

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⁷ OMB Watch. 2007 *Polluted Logic*. December 5. Online at <http://www.ombwatch.org/node/3558>.

⁸ Shprentz, D. 2007. Top ten ozone studies: Public testimony on EPA's proposed revisions to the National Ambient Air Quality Standards for ozone. Philadelphia, August 30. Deborah Shprentz is a consultant to the American Lung Association. Online at <http://www.cleanairstandards.org/article/2007/08/743>.

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¹² UCS 2008.

¹³ U.S. Government Accountability Office (GAO). 2008. Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System. GAO-08-440. Online at <http://www.gao.gov/new.items/d08440.pdf>.

¹⁴ OMB Watch. 2007.

¹⁵ Wilson, J. 2005. Habitats may shrink by leaps, bounds. *Los Angeles Times*, November 4.

¹⁶ For further information contact tdonaghy@ucsusa.org.