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March 16, 2009

Mark A. Greenwood



Kevin F. Neyland, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Attn: Mabel Echols, Room 10102, NEOB
725 17th Street, N.W.
Washington DC 20503

Dear Mr. Neyland:

On behalf of the Coalition for Effective Environmental Information ("CEEI"), we are providing comments concerning a new Executive Order on Federal Regulatory Review, as requested in a Federal Register notice issued on February 26, 2009 (74 Fed. Reg. 8819) by the Office of Management and Budget ("OMB").

CEEI is a group of major companies and business organizations that share a common interest in improving how government collects, manages, uses and disseminates environmental information.¹ CEEI supports public policies that encourage development and use of high-quality data, governmental accountability, efficient data collection, alignment of data with strategic goals and consistent management of environmental information resources. These topics are particularly important considerations in the formulation of policies guiding review of federal regulations. For that reason, we appreciate the opportunity to offer comments on the potential design of a new Executive Order on Federal Regulatory Review.

An Executive Order ("EO") on regulatory review must necessarily define what management responsibilities OMB will have in the conduct of rulemaking across the federal agencies, recognizing of course that agencies will carry on the bulk of regulatory development activity. As a general matter, our members support the existing framework for regulatory review in EO 12866, which has been in place for over 15 years. As the Administration evaluates requests that federal rulemakings be expedited, it is important to retain an oversight mechanism that can assess the value of regulatory solutions to public concerns and assure that regulations are necessary, well-designed

¹ CEEI includes representatives from the aerospace, chemical, petroleum, energy, electronics and consumer products industries.

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and consistent with other Presidential priorities. We support the President's statement that regulatory review should "offer a dispassionate and analytical 'second opinion' on agency actions."²

In executing its oversight role on federal regulations, CEEI urges OMB to perform two important roles. First, OMB should be an advocate for greater transparency in the rulemaking process. The relevant documents that are before an agency during a rulemaking process should be disclosed, and the agency should provide timely public access to those documents. Second, OMB should be an advocate for the use of high-quality information to guide agency decisions. Reliance on accurate factual information is certainly a starting point. It is also necessary, however, for agencies to conduct their analytical work with a high degree of transparency, using information that is specifically relevant to the policy questions at hand and that reflects a high degree of scientific and technical reliability. All information, from whatever source, should be held to the same standards of acceptability and credibility.

CEEI believes that existing EO 12866 can be enhanced to help OMB better perform these roles. Accordingly, we offer the following recommendations:

1. Section 1(b)(7): Best Reasonably Obtainable Information

EO 12866 established the principle that "Each agency shall base its decision on the best reasonably obtainable scientific, technical, economic and other information concerning the need for, and consequences of, the intended regulation." This principle is compelling. It has remained unchanged since 1993 and has been reinforced in the last several years by the Information Quality Act ("IQA"), OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies ("OMB Guidelines"), and the agencies' own Information Quality Guidelines.

It is valuable to retain and reinforce this principle because it represents the foundation of all rational regulations. The public expects no less of its government. Even where quick action is needed, agencies should base their actions on the "best reasonably obtainable" information.

This principle is one of several policies reflected in the IQA and the OMB Guidelines that this Administration should embrace. The IQA has, over the last several years, been mischaracterized by some as a law that somehow impedes effective regulations. Those charges reflect rhetorical excess. The record shows that the OMB Guidelines have been helpful policy guides to agencies in defining and refining the concept of "data quality", and the procedural aspects of the IQA have not played any significant role in the timing of federal regulations. OMB should continue its support for the principles embodied in the IQA and acknowledge their relevance to the regulatory process.

² Memorandum for the Heads of Executive Departments and Agencies, Regulatory Review (hereafter "Regulatory Review Memo"), 74 Fed. Reg. 5977 (February 3, 2009).

CEEI urges OMB to refine this regulatory principle by providing further definition of its content. Specifically, OMB should indicate in a new EO or revised EO 12866 that the "best reasonably obtainable" information obligation includes the following elements:

- Accuracy of factual information;
- Transparency in analytical work, revealing any assumptions, default values and algorithms that guide technical analyses;³
- Documentation of the sources of data used for an analysis;
- Systematic explanations, based on clear and consistent criteria, about what information does not warrant consideration in an analysis, what information warrants consideration and what weight to give such information;
- Relevance of information to the situation addressed by a regulation;⁴ and
- Indicators of information reliability, such as independent peer review and replication.

2. Section 1(b)(12): Understandable Regulations

EO 12866 states that "Each agency shall draft its regulations and guidance documents to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty." CEEI supports this principle, but believes that it should be expanded to reflect a broader principle of transparency for the whole regulatory process, under which clearly articulating legal obligations is just one of several elements of the agency's responsibility.

To build greater understanding and credibility for its regulations, an agency should provide more effective public access to the data, studies and regulatory documents before the agency in the development of those regulations. This information should include the full range of documents that the agency receives, including those documents containing information with which the agency disagrees. The "record" of a rulemaking is not just the data and analysis that an agency endorses. The history of a rulemaking also includes the information that the agency decided to reject, along

³ The OMB Guidelines expressed this transparency principle as a "reproducibility" obligation. Essentially agencies were expected to explain their analyses in sufficient detail that a third party would be able to reproduce the results using the same analytical framework that the agency had selected. This "reproducibility" concept is a useful way to implement the broader concept of transparency.

⁴ Emphasizing the need to show the relevance of data to a regulation will help address what some have called the "secondary use of data" problem. Agencies typically collect data for specific purposes at specific times. Once they have this data, they may try to use it in making decisions in other related areas. Sometimes this translation of information into a new context will not be appropriate, due to factors such as the timing of the information collection, the statistical precision of the information, differences in sampling techniques, and other factors.

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with an explanation of the agency's reasons for doing so. In addition, agencies should consider sharing the memoranda, draft regulations, options papers and other "internal" documents that help the public understand the factors that were considered in the development of a rule.

Access to the documents considered in a rulemaking needs to be provided on a timely basis to facilitate effective interaction with the agency by the public. Transparency is more than a disclosure obligation that occurs when a rulemaking comes to a close. Effective transparency is an ongoing process that allows the public to understand the course of an agency's deliberations in real time. The key to making this process work is an ongoing responsibility for agency personnel to provide public access to relevant documents soon after they are produced.

The need for greater transparency is particularly valuable for the scientific and technical information underlying many rules. Such information is often essential to the logic and credibility of the rule. Typically this kind of information is complex, reflecting a mix of factual information, assumptions, informed judgments, policies and past practices. On March 9, 2009, the President issued a Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity.⁵ This Memorandum state that "each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions." CEEI fully supports this policy and emphasizes that effective implementation of its intent requires that the many layers of scientific and technical analyses, including raw data, assumptions, algorithms, default values and models are transparent in the regulatory process.

Once a rule is issued, the regulation itself should certainly be written so that it is understood by the intended audience. At the same time, it is valuable for agencies to communicate effectively to the public the "why" behind the rule. What problem is the rule addressing? What alternative solutions to the problem did the agency consider? Why does the agency believe the rule is likely to be effective in addressing the problem? How does the action by the federal agency align with the actions of other parties, including state and local governments, international organizations, business organizations, non-governmental organizations? What, if any, expectations does the agency have for how private citizens will help address the problem that is the target of the regulation?

Better public communication of this contextual information about a rule draws from lessons of behavioral science, a consideration noted in the Regulatory Review Memo. Rules are more likely to be implemented effectively if the public and the regulated parties are provided with understandable explanations of why the rule will provide clear public (and individual) benefits and how the behavior expected under the rule will deliver those benefits. As part of this type of communication, CEEI particularly emphasizes the need for government agencies to improve how they explain health and environmental risks to the public, certainly in the context of regulations but also more broadly. Besides being a tool for assisting implementation of a rule, requiring agencies to

⁵ 74 Fed. Reg. 10671 (March 11, 2009).

develop understandable explanations of the risks or other problems they are trying to address, and how their solutions will address those concerns in a reasonable way, provides a useful check on whether the rule itself actually makes sense.

In the context of Section 1(b)(12) of EO 12866, CEEI recommends that the language be modified so that each agency is directed to develop regulations in a transparent manner that at least includes the following responsibilities:

- Timely disclosure of the information considered by or presented to the agency in a rulemaking, including facts and data, scientific and technical analyses, and public comments and other communications from interested parties, regardless of whether such information supports or challenges the agency's policy position on the rule;
- Timely disclosure, where feasible, of agency draft regulations, background papers and decision documents that were used in the agency's policy deliberations on the regulations;
- Drafting regulations that are simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty; and
- Understandable public explanations during the rulemaking of the problem the agency is trying to address, the alternative solutions considered by the agency, the intent and value of the rule, and the role of the rule in relation to actions by others, including the general public.

3. Section 6(a)(1): Transparency in the Rulemaking Process

EO 12866 provides that each agency shall "provide the public with meaningful participation in the regulatory process." As part of this obligation, "before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation."

In many cases, the practice of agencies has been to withhold from the public large volumes of complex information used in the development of a proposed rule, and then share that information at the time that the rule is proposed. For those who try to participate effectively in a rulemaking, this pattern makes it extremely difficult to review the relevant information and provide effective comments on a proposed rule in a short period of time. This agency practice almost inevitably results in understandable requests for extension of the comment period, many of which are granted. Thus, the absence of effective transparency in the early stages of a rulemaking tends to lengthen the rulemaking process.

In addition, many stakeholders are concerned that increasingly agencies are conducting their actual policy deliberations prior to the proposal of a rule for public comment. By the time a rule is proposed for public comment, the agency has set its course, and views the public comment period

as another procedural step to take, rather than an opportunity for real discourse with the public. This perception, felt by many stakeholders, has increased pressure for the creation of pre-proposal opportunities for public comment, such as Advanced Notices of Proposed Rulemaking, and other opportunities for formal stakeholder engagement.

CEEI recommends that OMB and the agencies provide greater transparency about deliberations on a rule during the pre-proposal stage. This transparency will allow interested stakeholders to monitor rules under development and provide relevant information in a more timely and targeted manner. It will reduce the potential for an agency to make a major factual or analytic error before a rule is proposed, and could also avoid major investments of agency time and resources on issues that might not be significant in the development or implementation of a rule.

The tools to develop a more transparent rulemaking system are readily at hand. Federal agencies are now utilizing the Regulations.gov Website to provide electronic access to the documents in rulemaking dockets. That Website now offers various software tools, such as Really Simple Syndication ("RSS") feeds, that could be improved to provide electronic notification when new documents are added to the docket on a particular regulation. As a broader point, CEEI would emphasize that improving the notification functionality of Regulations.gov through upgrades in RSS feeds is one of several changes that could be made to this site to greatly enhance the quality of public access to regulatory information.

Federal agencies have taken a range of approaches concerning early access to information supporting a rule. Some agencies continue to hold back relevant information until a rule is proposed. Others are making efforts to notify the public about rules under development. For example, the U.S. Environmental Protection Agency ("EPA") has been publishing a monthly Action Initiation List ("AIL") providing a general description of regulations under development that are at least one year away from publication as a proposed rule.⁶ The rules discussed in the AIL are not, however, linked to an open docket in Regulations.gov that could be the home for the public dissemination of pre-proposal documents concerning the planned rule. Creation of formal dockets in Regulations.gov at the time a rulemaking is begun, along with public notification similar to EPA's initiative, would be a useful as a general agency practice.

In addition, implementation of a robust system for pre-proposal transparency of information depends on a key behavioral change: agency staff must place relevant documents in these electronic dockets shortly after they are received or prepared so that the public has an opportunity to provide meaningful comment on them. While agencies may have a range of internal policies and procedures to provide early access to regulatory documents, it will be important to establish clear expectations about what is meant by timely disclosure of information relevant to a rulemaking.

⁶ <http://www.epa.gov/lawsregs/search/ail.html>

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For submissions from parties outside the agency, where the primary management issues relate to document control and electronic formatting, it should be possible to establish specific timeframes for posting of documents. In the case of documents developed internally within an agency, OMB and the agencies should define guidelines concerning when the document is deemed relevant and when it is sufficiently final to be used for internal decisionmaking. In this regard, the question of whether a document is "final" for this purpose should be resolved through a functional test concerning whether the document is being used for resolving issues concerning the rule, not whether the physical document carries a "final" label. Once a document, particularly one carrying a scientific or technical judgment, is ready to be relied on for decisionmaking, it should be posted promptly to the online public docket.

When agencies release major technical documents during the pre-proposal stage, it typically will make sense to request public comments. When this occurs, it will be important for agencies to provide comment periods that are commensurate with the size and complexity of the documents. For example, it is unreasonable to provide 60 days of comment on a 1000-page risk assessment that an agency has been working on for several years, especially where the agency has not previously solicited public involvement in the development of the assessment.

To summarize CEEI's perspective on these issues, we recommend that the revised EO 12866 require agencies to take the following steps:

- Establish a public docket, potentially through Regulations.gov, for a rule shortly after the agency decides to initiate a rulemaking;
- Provide public notification of the creation of such a docket and ongoing notification for the posting of documents in that docket, which could be accomplished through electronic mechanisms provided through Regulations.gov;
- Establish policies and procedures, including firm deadlines, for posting in the public docket all documents relevant to rulemaking, including documents submitted from outside the agency, documents that do not support the agency's position and documents generated within the agency that are used to resolve issues concerning the rule; and
- When an agency seeks comment on information to be used in a rulemaking prior to formal proposal of a rule, establish a comment period that is commensurate with the complexity of the information.

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CEEI appreciates this opportunity to provide comment on the design of the Presidential Executive Order on Regulatory Review. We look forward to further opportunities to offer comments on the developing policies of the Obama Administration concerning information-related policies. Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Greenwood". The signature is written in a cursive, slightly slanted style.

Mark A. Greenwood