**Echols, Mabel E.**

**From:** Vic Kimm
**Sent:** Monday, March 16, 2009 9:01 AM
**To:** FN-OMB-OIRA-Submission
**Subject:** ederal Regulatory Review

March 16, 2009

The Honorable Peter Orszag
Director
Office of Management and Budget
725 17th Street
Washington, DC20503

**Re: Plans to Rewrite an Executive Order on Federal Regulatory Review**

Dear Mr. Orzag:

I am pleased to participate in the new Administration's reassessment of the role of OIRA in development of environmental, health and safety regulations and in the redrafting of EO 12866. I hope that this will be the beginning of an iterative process with further opportunities for public comment once the Administration determines how it plans to proceed.

These comments represent a practitioner's perspective on the process. I served as a senior line manager at EPA for more than 25 years, including a decade as the Director of the Drinking Water Program and another decade as the career Deputy Assistant Administrator in the Office of Pesticides, Prevention and Toxic Substances. During these assignments I was the agency's lead in dealing with OIRA over dozens of major regulations.

Everyone concerned with environmental, health and safety protection is pleased by the initial actions of the new President to promote openness, public participation and collaboration within the government. We are also encouraged by his recent directive to agency heads to protect the scientific integrity within the regulatory agencies. Both of these messages will be particularly well received by the career people within the regulatory agencies. They will also ensure the public that regulatory agencies will make use of the best scientific and technical knowledge in decision making and will avoid undue political influence to alter these inputs in formulating regulations.

**Recommended Changes**

These comments provide a practitioners perspective about how best to address the complex challenges facing the regulatory agencies which mix applications of science and technology with value judgments in order to decide how rigorously to regulate under specific legislative mandates.The changes proposed below are designed to promote the development of better regulations by strengthening the decision making process within the agencies and facilitating public participation in the process.

In recent years OIRA has pressed the regulatory agencies toward fully quantified cost benefit analyses (CBA). This practice is quite inappropriate for many types of environmental, health and safety regulations where the cost and benefit streams of proposed actions include factors that are difficult or impossible to quantify let alone monetize in any meaningful way. The practical consequences of such approaches, as discussed later in these comments, are to mask these uncertainties and valuation problems within numerical calculations and imply an inappropriate accuracy and precision in the findings. In addition, reducing regulatory choices to numbers often obscures the underlying issues the agency is trying to balance and inhibits meaningful public comment on the process.

**Recommended Changes**

The following changes in the way regulations are reviewed by OMB are recommended for your consideration.

1. The role of OIRA should be modified to assisting the agencies develop better regulations by clarifying the underlying factors impacting the content of the proposed requirements rather than to control their activities to prevent excessive regulations. To implement this major cultural change will require significant leadership by the new political appointees within OMB.
2. The scope of OIRA's mandatory reviews should be very limited to a small number of proposed actions which include very large economic impacts and/or significant interagency issues. This change would shift more responsibility to the regulatory agencies for generating innovative regulations and developing regulatory impact statements (RIA's) that clearly identify the factors driving the decisions.
3. The OIRA process needs to be streamlined to avoid delaying the promulgation of important regulatory actions. By reducing the number of review transactions as proposed above, OIRA's limited staff could focus on major issues rather than try to review all regulations and guidance as seems to be current practice. If some oversight of all regulations is deemed necessary, a tiered approach should be considered that assigns the bulk of the staff resources to "major issues" and minimum "checklist" reviews to other agency initiatives.
4. Clearly related to streamlining the process is the need to establish and enforce time constraints on OIRA for responses and comments so that the agencies can plan for the orderly development of new regulations.
5. The transparency of the interagency review process should be improved so that the public can track comments to the agencies that resulted in significant modifications to proposed regulations. Without such transparency, opportunities for public participation are diminished and some may fear that the OIRA reviews are providing the regulated community additional opportunities to influence outcomes late in the process.
6. Procedures should be established to strengthen the regulatory agencies decision process by giving greater weight to the technical and scientific expertise of the regulatory agencies. This work should be conducted with the active participation of the agency's responsible political leadership throughout the process. Critical steps in the process include: assessing the risks posed in the absence of regulation; formulating potential regulatory options; evaluating the analyses needed to support policy choices; selecting regulatory actions and ensuring that the related regulatory impact analyses (RIA's) identify the key factors leading to the selection of the stringency of new regulations.

The changes proposed above relate exclusively to OIRA's role in reviewing agency regulations, guidelines and policies as opposed to their responsibilities under other legislation such as maintaining a government-wide regulatory agenda or overseeing the implementation of the Paperwork Reduction Act etc.

**Role of quantitative CBA in framing Environmental, Health and Safety Regulations**

At the core of these proposals are concerns about the inappropriate over use of fully quantified CBA as currently pursued by OIRA. This approach is attractive in that it appears to minimize subjective judgments in the process and support comparisons about the cost effectiveness of regulations across programs. Unfortunately, this practice is quite inappropriate for many types of environmental, health and safety regulations in that excessive use of quantified estimates tends to obscure the uncertainties in the factors being considered and mask the underlying issues the agency is trying to balance.

An exhaustive assessment of CBA analysis is contained in a thoughtful and scholarly article by Shapiro and Schroeder entitled "Beyond Cost Benefit Analysis: A Pragmatic Reorientation". Their paper does a much more thorough job of discussing the limitations of CBA then presented here and should be carefully read by interested parties. They also propose a more pragmatic type of analysis which is worth considering.

To clarify these concerns let me offer the following observations:

1. There is no disagreement that regulations ought to be generated in response to legislative mandates and generally balance the intended benefits with the costs and consequences of alternative responses to reducing the perceived risks of the uncontrolled situation. It is also generally agreed that correctly applied, CBA analysis can be helpful in this process as can be other techniques like cost effectiveness analysis, etc.

2. However, where appropriate, ranges of numbers rather than point estimates should be used with quantitative and monetized factors to indicate the uncertainties included in the numbers. Qualitative descriptions of possible outcomes should be used with factors that are not really quantifiable.
3. Among the concerns with quantified CBA is that such analyses assume that all impacts are fully understood with equal certainty. In the real world, most regulations include some impacts that mainstream science would evaluate consistently. There is far less agreement about how other factors such as environmental impacts can be quantified and monetized. Full CBA also fails to account for distributional effects or to deal with the special problems of sensitive populations such as pregnant women and children or environmental justice issues which are of increasing public and Congressional concerns.
4. Particularly problematic are efforts to monetize benefits within CBA especially for impacts that do not have values established in the market place. In these circumstances the analyst is driven into a number of techniques to generate shadow prices or bridge values employing approaches like willingness to pay (WTP) or willingness to accept (WTA) leading to values of statistical lives (VST) for undesired outcomes. Such valuations are often based on the wage premiums paid to workers doing risky tasks and assume that these valuations are the outcome of informed negotiations between employees and management which is seldom the case. These types of calculations are quite subjective, fail to recognize that most people value voluntary and involuntary exposure to risks differently and raise significant economic, social and ethical issues with many members of the public. These approaches should generally not be routinely employed unless the related limitations are fully disclosed. In real world situations, the choice for the decision-maker and for society as a whole may be the appropriate tradeoff between monetized compliance costs for an industry, a qualified and qualified stream of health improvements to an exposed population and a qualified impact on habitat and natural resources. Rigid CBA can mask the complexities and nuances of the decisions to be made.
5. Overzealous applications of numerical CBA's can lead to significant misunderstandings and public confusion. For example, an article by Cass R. Sunstein entitled " The Arithmetic of Arsenic" concludes that reasonable people could conclude that the benefits of the arsenic in drinking water rule, based on the analysis being critiqued, could be valued as low as 10 million or as high as 1.2 billion dollars. Presenting any point estimates within such a range is not generally helpful to decision makers or as a basis for public comments.
6. As a practitioner, I can't remember any cases where we had the relevant data to quantify all of the impacts of major rules let alone methods to monetize such impacts in any meaningful or consistent way. On the other hand, it was often the case that careful analyses of the cost streams associated with alternative regulatory approaches were very helpful in constructing cost effective regulations.
7. What is suggested here is that agencies be given greater flexibility to employ pragmatic approaches to rulemaking as they undertake the complex task of balancing all of the relevant factors that go in deciding how stringently to regulate on a rule by rule basis in keeping with the related legislative mandates. Quantification should be used where appropriate and other impacts that are less well understood described in words resulting in decisions based on a "weight of the evidence" determination.

**Conclusion**

Simply stated, these comments recommend a more decentralized process in which the agencies are given greater flexibility to regulate and challenged to find better ways of describing the related tradeoffs. These approaches should promote more informed decision making within the agencies and better opportunities for interested stakeholders to understand and comment on the major factors driving the choice of specific regulatory actions. Hopefully, the judiciary will continue to give deference to the responsible officials if the logic of their decision process is clear and if it is consistent with the enabling legislation.

I appreciate this opportunity to comment and hope that these thoughts will contribute to your deliberative process.

Yours truly,
Victor J. Kimm