



REGULATORY CHECKBOOK

31 March 2009

The Honorable Peter Orszag
Director
Office of Management and Budget
Washington, DC 20503

Dear Director Orszag:

On 16 March 2009 I submitted a lengthy reply to the Office of Management and Budget's request for comment on potential revisions to Executive Order 12,866. In preparing my first letter, I had the opportunity to review many of the comments that had been submitted in the initial public comment period. I believe my comments were better informed because I had access to these comments. For that reason, yesterday I submitted a second public comment commending OMB for this revolutionary (for OMB) change in public disclosure practice. I contrasted it with the Office of Information and Regulatory Affairs' (1) timely but customer-unfriendly disclosure practices with respect to Executive Order 12,866 communications with nongovernmental entities and (2) its failure to provide timely access to public comments it receives under the Paperwork Reduction Act. OIRA's practice in the case of Executive Order 12,866 communications can be justified by the fact that OMB tolerates but does not encourage limited public participation. In the case of the Paperwork Reduction Act, however, OIRA's unwillingness to disclose public comments on agency Information Collection Requests until it has completed its review cannot be justified at all. I urged you to direct OIRA to remove this design defect from its database.¹

Since submitting my first comment, I've been reading more of the comments others have submitted and found this exercise extraordinarily fascinating. As of 30 March 2009, OIRA has uploaded 125 comments to the OIRA's web portal managed by GSA's Regulatory Information Service Center. I am writing a third time to take

¹ The database goes by the internal acronym ROCIS, which stands for the RISC and OIRA Consolidated Information System. That this system was predestined to have problems is hinted at by the fact that the acronym of the database consists of multiple acronyms.



advantage of the opportunity for virtual interactivity resulting from OMB's welcome decision to post public comments on its website as soon as practicable after receipt. Virtual interaction is especially useful in this case because OIRA has a small fraction of the staff resources that regulatory agencies have to review, fact-check, and analyze public comments.² This task is much easier if commenters can comment on others' comments, supporting them with additional evidence that they might not have had or challenging them with evidence that contradicts or refutes their position. Otherwise, OIRA staff will bear the entire burden of analysis and synthesis, and they will have to do so in a quasi-judicial adjudicatory style that does not permit them to directly "question the witnesses."³

RISK ASSESSMENT AND "IRIS"

With this as backdrop, I have noticed that risk assessment in general, and the U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) in particular, is a major source of controversy in presidential regulatory review. By my count, at least 27 of the 125 public comments posted to date discuss *risk assessment*, and seven specifically mention IRIS. Of these seven comments, five were submitted by persons or organizations who have historically and publicly opposed presidential regulatory review, and they all seek to insulate IRIS from presidential oversight.

Given that Executive Order 12,866 is silent about risk assessment, why does risk assessment (and especially IRIS) attract so much attention from public commenters? The answer is obvious for those who regularly participate in risk analysis. Since at least the 1983 National Research Council *Red Book*, there has been a clear distinction between *risk assessment* (the estimation of human health risk) and *risk management* (the exercise of policy judgment to decide what to do about it).

As performed by EPA, risk assessment is an active commingling of science and risk management policy judgment. This is not merely my opinion; it is the stated policy of EPA career scientists and senior managers, made public in a 2004 white paper in response to OMB and public pressure on the Agency to make its risk assessments scientifically objective. In response, EPA career scientists' rejected the

² The 125 public comments posted thus far consist of about 100 megabytes of written material.

³ They *will*, of course, have this ability with respect to interagency comments. The public will be excluded from this debate because, if past practice is any guide, OIRA will not post for public inspection, review, and fact-checking the written comments received from other federal agencies.

premise, stating that "a key objective for EPA's risk assessments is that they avoid both *underestimation* of risk and *gross overestimation* of risk" (emphasis added):⁴

[C]onsistent with its mission, EPA risk assessments tend towards protecting public and environmental health by preferring an approach that does not underestimate risk in the face of uncertainty and variability. In other words, *EPA seeks to adequately protect public and environmental health by ensuring that risk is not likely to be underestimated*. However, because there are many views on what "adequate" protection is, some may consider the risk assessment that supports a particular protection level to be "too conservative" (i.e., it overestimates risk), while others may feel it is "not conservative enough" (i.e., it underestimates risk) (emphasis added).

EPA career scientists imply that they are walking a tightrope between over- and underestimation of risk, and they attempt to justify erring in favor of overestimation because of the Agency's mission. In doing so, they have subtly changed the subject. Whereas the issue properly understood has to do with the role of risk assessment—the *objective* assessment of risk—they characterize the debate as one of what magnitude of *purposeful and subjective bias* is acceptable. What they are actually doing is systematically treading on the discretion accorded by law to the Agency's political appointees.

These practices were well known by OIRA career staff and others long before Executive Order 12,866 was enacted in 1993.⁵ OIRA Administrator Sally Katzen attempted to reassert the prerogatives of presidential appointees when she issued *Principles for Risk Analysis* in 1995.⁶ OIRA Administrator John Graham also tried, but

⁴ **U.S. Environmental Protection Agency Office of the Science Advisor.** "An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001," 2004. This asymmetry implies that the social costs of underestimating risk are always less than the social costs of overestimating risks.

⁵ OIRA publicly discussed problems with federal agency risk assessment almost 20 years ago. See **Office of Management and Budget.** "Current Regulatory Issues in Risk Assessment and Risk Management," *Regulatory Program of the United States, April 1, 1990 -- March 31, 1991*. Washington, DC: Office of Management and Budget, 1990, 13-26. Others have done so as well. See, e.g., **Nichols, Albert L. and Zeckhauser, Richard J.** "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," V. K. Smith, *Advances in Applied Micro-Economics: Risk, Uncertainty, and the Valuation of Benefits and Costs*. Greenwich, Conn.: JAI Press, 1986, 55-82.

⁶ **Katzen, Sally.** "Principles for Risk Analysis," Office of Management and Budget, Washington, D.C., 1995.

also failed.⁷ There is no public evidence that agencies have paid any attention to Katzen's "Risk Principles," which the public did not even learn existed until OIRA Administrator Susan Dudley republished them in 2007.⁸

When EPA publishes final toxicological assessments and incorporates selected hazard values into IRIS, the regulatory consequences can be rapid. Sometimes this occurs by the operation of State law (e.g., California's Proposition 65). However, the crucial elements of EPA risk assessments often become presumptive (and sometimes automatic) risk management standards. States even rely on *draft* IRIS values as the basis for setting State risk management standards, and EPA regional offices frequently use them as the basis for permit requirements and cleanup standards.⁹ IRIS files have permanent regulatory effects, even if EPA never intended for that to be so, and they rarely change even when science changes.

⁷ See **Office of Management and Budget**. "Proposed Risk Assessment Bulletin; Notice of proposed Bulletin and request for comments." *Federal Register*, 2006, 71(10), **National Research Council**. *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*. Washington, DC: National Academies Press, 2007.

⁸ **Dudley, Susan E. and Hays, Sharon L.** "Updated Principles for Risk Analysis," Office of Management and Budget and Office of Science Technology Policy, Washington, D.C., 2007, 13. In fact, the 2007 text is not "updated" at all. It is identical to the 1995 version, even including a typographical error.

The reason why agencies have ignored the "Risk Principles" is that they employ hortatory language. The word "shall" appears only once (in a section quoting a provision of Executive Order 12,866) and "must" appears twice (in ways that do not actually constrain agency behavior). Twenty-seven times in the text, the "Risk Principles" identify things agencies "should" do. Agencies respond to hortatory language by ignoring it.

⁹ By definition, *draft* IRIS values are not the official position of EPA. If they are distributed for any purpose other than external peer review, they are fully subject to OMB's and EPA's 2002 government-wide information quality guidelines. An exception to this rule was carved out by OMB in its 2005 government-wide bulletin on peer review. A draft risk assessment (containing draft IRIS values) is not "disseminated" (as that term of art was defined) if and only if it is distributed solely for external peer review and is accompanied by a very specific disclaimer:

"This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by [the agency]. It does not represent and should not be construed to represent any agency determination or policy."

To the best of my knowledge, the extent to which this disclaimer has deterred States from inferring draft risk assessments to be official, or relying on them as if they were official for risk management purposes, has not been systematically studied.

THE CONVOLUTED IRIS PROCESS

In short, EPA risk assessment is not a strictly scientific enterprise. It has scientific components, and its outputs have the look and feel of “science.” But these outputs are governed by the risk management preferences of the Agency’s career scientists and managers. That means EPA risk assessment in general, and the IRIS process in particular, are economically significant regulatory actions (as those terms are defined in Executive Order 12,866) promulgated outside the boundaries of the Administrative Procedure Act.¹⁰ Moreover, IRIS files are regulatory actions largely immune to the influence of the President, his senior advisors in the Executive Office of the President, and even the EPA Administrator.

It therefore should be no surprise that many EPA risk assessments are so controversial. By the time a regulatory issue involving risk assessment has risen to the level of the President’s appointees, most risk management decisions have already been made—by EPA career scientists. The President’s appointees have two alternatives: (1) ratify the career scientists’ risk management preferences, thereby conceding that staff have the de facto power to exercise the statutory authorities conferred by law on the President’s appointees, or (2) challenge the career scientists’ arrogation of power, and be accused of interfering with the Agency’s scientists.

Having been unable to directly manage the problem of purposeful bias in EPA risk assessment, appointees of both Republican and Democratic presidents have tried to do so indirectly by creating and managing various new interagency risk assessment procedures. These processes include internal and external *scientific* peer review, and multiple opportunities for interagency *scientific and policy* review. To the chagrin of the opponents of presidential regulatory review, this process is overseen by OIRA and the Office of Science and Technology Policy.¹¹ The current process is certainly a convoluted one, as shown by a diagram produced by Public Citizen and provided to OMB in a public comment (#019). What makes the process

¹⁰ Except in rare cases, EPA is not statutorily authorized to perform risk assessment. Risk assessment is a necessary intermediate task that must be performed en route to regulation. When EPA issues a risk assessment but does not promulgate a statutorily authorized regulation, no final agency action occurs so no one has standing to challenge it, even if it has extraordinary indirect impacts.

¹¹ Joint management by OIRA and OSTP is usually justified on the ground that OIRA lacks scientific expertise, which OSTP has. This is misleading. OIRA has more scientific expertise within its career staff than its opponents want to admit, and OSTP is largely staffed by federal agency detailees. When they try to serve as honest brokers, these detailees have an inherent conflict of interest between serving the President and serving the agency that pays their salaries and controls their professional advancement.

convoluted, however, is not the science of risk assessment but the embedded risk management policy content.

At first blush, one might think that no one would seriously argue against objectivity in risk assessment, or that career agency scientists ought not make risk management decisions reserved by law to the President and his appointees. This is not the case. Many of the public comments submitted to OMB that raise risk assessment as an issue characterize the involvement of the President and his appointees as "interfering with science." These commenters typically elide the issue of whether risk assessments prepared by career scientists contain crucial risk management content, and if so, whether it is ethical for them to make risk management decisions under the cover of science. These commenters express strong preferences for allowing agency scientists to use whatever risk assessment methods they want—but without rigorous and independent scientific peer review, without information quality standards, without oversight by presidential appointees in their agencies, without interagency review, and especially without presidential oversight.

CONCLUSION

The purpose of presidential regulatory review is to provide the same kind of presidential oversight of regulatory matters that OMB has for generations exercised with respect to the federal budget. Most regulation proceeds in accordance with the Administrative Procedure Act, and regulatory actions that exceed Executive Order 12,866's threshold for "significance" are subject to presidential regulatory review. Much federal risk assessment, and EPA risk assessment in particular, is de facto regulation promulgated outside of these systems. The stakes are even greater for these quasi-regulations because they are exempt from judicial review irrespective of the magnitude of their indirect regulatory effects.

Because there are no statutory or judicial checks and balances on regulation by risk assessment, an informal alternate system has evolved. OIRA has set quality standards for risk assessment, including objectivity, transparency and reproducibility. Interagency review procedures have been established to permit affected sister agencies to review, comment, and occasionally object to either the scientific content or the embedded risk management policy choices in draft risk assessments. Finally, OIRA also has issued guidance on the use of scientific peer review to assure that agency risk assessments satisfy the highest scientific standards. Each of these elements is imperfect, and each imperfection leads to new tweaks in the system.

Many believe that IRIS is now broken, that it cannot produce the quantity and quality of risk assessments that are needed under the weight of this convoluted informal system. For several public commenters, the solution is to do away with



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peer review, interagency review, and presidential oversight by OIRA. Stripping away these checks and balances might enable the IRIS program to improve its throughput. That would not, however, make these risk assessments any less controversial, nor would it improve their scientific objectivity or attenuate their indirect regulatory effects. Perhaps a way forward can be found in which risk assessments could be fast-tracked—exempted from most interagency review and presidential oversight—provided that they were independently certified to be scientifically objective and free of embedded risk management decisions.

Sincerely,



President
Regulatory Checkbook
