

Risk Policy Report

An exclusive weekly report for scientists interested in environmental policymaking and policymakers interested in science

from Vol. 13, No. 21, May 23, 2006

Guest Perspective

THE LEGACY OF JOHN GRAHAM: STRAIT-JACKETING RISK ASSESSMENT

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Economists at Every Table

Risk assessment is the coin of the environmental realm, figuratively and literally. It is also the primary source of the most draining, counterproductive disputes preoccupying the Environmental Protection Agency (EPA). Risk assessment is not the only regulatory methodology used by EPA and other agencies assigned to protect public health, safety, and the environment. Different tools — most notably the technology-based controls that underlie the great successes of statutes such as the Clean Water Act — have accomplished more protection, in many cases for less money. But beginning in the mid-1980's, decision-makers have felt disgraced if they do not take a run at conducting a risk assessment on a problem, translating the results into numbers that are deceptively precise. Curtailing this trend is not in the cards for the foreseeable future.

Given its importance, it was no surprise when John Graham's parting salvo as the director of the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) was a *Proposed Risk Assessment Bulletin* (bulletin) that was intended to be the most prominent aspect of his legacy.¹⁷ The 26-page document would establish uniform, government-wide standards for risk assessments regarding human health, safety, or the environment.¹⁸ OMB will accept comments until June 15, 2006 and a National Academy of Sciences (NAS) panel is conducting a review of the proposal.¹⁹

Graham's assertion that OMB is qualified to define what constitutes an acceptable risk assessment displays misplaced confidence of the first order. Despite his aspiration to enlarge OIRA's role in science policy, Graham cannot possibly have added more than a handful of scientists to a staff overwhelmingly dominated by economists and budget analysts. If OIRA succeeds in this remarkable power grab, unqualified economists will take their seats beside toxicologists, epidemiologists, pediatricians, neurologists, engineers, statisticians, and other qualified experts as the complex implications of scientific uncertainty are debated.

By raising the "expertise" question, I do not mean to pick a shop-worn, counterproductive fight about whether OMB is entitled to conduct regulatory oversight on behalf of the president. Risk assessment is a cornerstone of many important decisions that OIRA reviews. Yet this effort to control every form of risk assessment *pre*-rulemaking goes far beyond that basic function, even assuming that the polarized spectrum of OIRA's constituencies could agree on its appropriate oversight role.

Under the bulletin, any assessment, no matter what its nature or scope, must estimate the "central" risk likely to result from exposure, using a formula for "weighting" model results that is as vague as it is pseudo-scientific. Agencies will be compelled to fast forward to the end of their decision-making process, determining all available options for managing risk before they complete assessments. Risk assessments will be rejected unless they are based on research determining "No Observed Adverse Effects Levels" (NOAELs), as opposed to the long-standing practice of determining "No Observed Effect Levels" (NOEL). And any perceived misstep along the way could trigger challenges to agencies' compliance with the Information Quality Act (IQA) (or Data Quality Act), one of the worst appropriations riders enacted by Congress. OMB claims legal authority to interfere with the scientific process in this aggressive and inappropriate manner under the IQA, although the one-page law says nothing specific about its authority in this arena.

Tobacco for Everything

The IQA says that information "disseminated" by the government must be "correct" and of high "quality, objectivity, utility and integrity."²⁰ The concept for such a mandate originated with EPA's report on second-hand smoke.²¹ Philip Morris Inc. was fighting a rear-guard battle against further controls of tobacco and was heavily

invested in picking apart every detail of the report. The company hired Jim Tozzi, a Reagan-era OIRA veteran, to persuade his former colleagues to accomplish this charmingly over-simplistic mandate administratively. After all, who could oppose the idea that government should establish a process for outside parties to challenge its dissemination of incorrect information?

As it turned out, seasoned bureaucrats could easily harbor misgivings about this new approach to obstruction and Clinton-era OMB officials were no exception. Frustrated by their indifference, Tozzi went to Capitol Hill where he achieved relief via a rider on 2001 “must pass” appropriations legislation. From these modest origins, the IQA has spawned guidance from every federal agency and department for how they will consider requests for correction of a wide variety of information.

Of course, “truth” and “correctness” are elusive concepts when the science, technology, and economics underlying such decisions become ever more complex. As the tobacco industry well understood, challenging any debatable assertion, no matter how minor, contained in every piece of unfavorable research is the best way to muddy the waters to confound regulators, stalling decisions until the tide of research turns completely and washes away these last outposts of resistance.

Enforcing the Bulletin

This “corpuscularization” of science, to use the term coined by Professor Thomas McGarity,²² is the foundation of the “sound science” movement that is in full swing both in the U.S. and internationally. Its central tactic is the flyspecking of scientific studies to find individual “errors” of three distinct kinds: (1) clear misstatements of fact; (2) decisions that could have been made differently; and (3) science policy judgments that are unpopular with special interests.

The problem with the discovery of factual mistakes is that corpuscularists demand the exclusion of an entire study whether the error is major or minor, preventing scientists from using their expertise in a “weight of evidence” evaluation that takes mistakes into account in evaluating — but nevertheless using — such research. As for the second and third categories, the sound science movement’s has achieved great, if undeserved, rhetorical success by labeling as “incorrect” scientific judgments regulated industries do not like, regardless of whether such judgments are legitimate, common, and transparent. Scientists adopt assumptions all the time in order to proceed with their work. They may decide to use groups of 25, not 40, rats in a bioassay. By challenging such judgments as mistakes that should discredit a study, corpuscularists put everyone on a treadmill of controversy with no easy escape. Similarly, such science policy judgments as the use of “safety factors” to compensate for uncertainties in animal testing may be a legitimate concern in deciding how to evaluate a study but are not a sensible reason to ignore it entirely.

The campaign to deconstruct science in order to gain the upper hand in regulatory decisionmaking has continued at a rapidly quickening pace in all arenas — from rulemaking to judicial proceedings to the scientific literature. Thus far, the IQA has played only a supporting role. Government-wide, IQA “Requests for Correction” number in the hundreds, not thousands, and agencies have rejected most of them in short order. All that could change, however, if the IQA provides a route to judicial review, especially for studies, reports, toxicological profiles, and risk assessments issued before or apart from rulemaking. Whether or not regulated industries win such appeals, opportunities to undermine the validity of adverse information and delay decision-making could well be worth the litigation costs.

A few weeks ago, the U.S. Court of Appeals for the Fourth Circuit made short shrift of a bid to obtain judicial review of agency IQA decisions under existing language. Judge J. Michael Luttig wrote that the IQA does not create a cause of action for any particular person or group to challenge the correctness of information in court because Congress did not specify who would have standing in such circumstances.²³ Of course, Congress could fix this problem and the Chamber of Commerce has pledged to go this route. If the matter is debated fully, and industry lobbying does not win out over the long-standing concerns of the House and Senate judiciary committees about acute docket overload in the federal courts, the IQA could be transformed from nuisance to major wrench in the works of health and safety regulation. In effect, it would then amount to a codification of corpuscularization, especially with respect to documents such as risk assessments covered by the bulletin, which was supposedly written to implement the IQA.

One Small Size Does Not Fit All

The threshold problem with the bulletin is that it reflects the naïve belief that uniform, government-wide standards would improve a process that has almost as many iterations as it does results. The bulletin requires agencies to include a “central or expected” risk estimate whenever a “quantitative characterization of risk” is made available, and mandates that quantitative estimates should be done “whenever possible.”²⁴ Just how would one calculate this central estimate?

This bulletin uses the terms ‘central’ and ‘expected’ estimates synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using *standard statistical tools*. When model uncertainty is substantial, the central or expected estimate may be a *weighted average of results* from alternative models. *Formal probability assessments* supplied by qualified experts can help assessors obtain central or

expected estimates of risk in the face of model uncertainty.²⁵

Suppose we must conduct a risk assessment of a single toxic substance (think arsenic, dioxin, perchlorate, mercury, or vinyl chloride) and have available chemical structure analyses, animal and epidemiological studies, and fate and transport models. Each piece of research has its strengths and weaknesses, including the inevitable policy-laden, default assumptions about the shape of the dose response curve, the level of exposure of both animal and human populations, and the pharmacokinetics of what happens to the chemical once it enters the body.

The bulletin appears to require that the numeric results of specific subgroups of models be averaged together. One example is the hotly contested area of dose-response curve models that use either traditional, “no threshold” assumptions or assume that low doses of specific chemicals are “acceptable.” But the bulletin does not stop there. Instead, it appears to require that the numeric results of the full range of “apples and oranges” models somehow be subject to number crunching, also yielding a single estimate of risk.

Given the right, balanced, and suitably skillful risk assessor, a reference dose (RfD) for a single chemical can be calculated, although the calculation will require a series of scientific findings *and* science policy judgments that must remain fully transparent so that they can be debated fully. These difficulties are the reason why NAS panels routinely wring their hands over such numbers and either add a series of safety factors to hedge their bets²⁶ or pronounce the EPA RfD “justifiable,”²⁷ as they did with EPA’s mercury and arsenic reviews.

Now suppose that we are doing a risk assessment that has considerably more dimensions: an assessment of the risks posed by a substantial expansion of nuclear energy or the implications of a terrorist attack on the chemical industry. Anyone familiar with the practice of risk assessment in this broader context would recognize the foolishness of attempting to calculate a central number that reflects the wide variety of models and other methodologies used by multi-disciplinary approaches. Reducing such disparate pieces of data to one number can only produce the “junk” science that sound science advocates assure us they are determined to eradicate. Even constructing a meaningful *qualitative* statement summarizing central risk poses substantial challenges.

The Great Conflation

The fact is that risk assessments come in all shapes and sizes. They can take weeks, months, years, or decades. The perceived magnitude of the risk inevitably plays a crucial role in determining an assessment’s nature and scope, and OMB wisely advises risk assessors to be transparent about these decisions.²⁸ But it is one thing to acknowledge that science policymakers cannot help but think about the importance of a problem and what they might be able to do about it when they design an assessment and quite another to say that they must identify and assess those solutions *before* the nature of the risk is established. And yet the bulletin demands that they undertake exactly this task:

“[R]isk assessments that will be used for regulatory analysis ... shall include ... an evaluation of alternative options, clearly establishing the baseline risk, as well as the risk reduction alternatives that will be evaluated [and] a *comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered.*”²⁹ (italics added)

Distinctions between *risk assessment* and *risk management* have provoked many a lengthy and esoteric argument in the rarified circles that undertake this troublesome work. Across the political spectrum, many believe that there is no clear line between the two, especially in the sense that policymaking, as opposed to “pure” science, infects both aspects of any problem. “Hard” science informs the design of experiments and determines the results, while “trans-science” permeates everything that happens to those results before they affect human affairs.

Acknowledging this reality is not the same thing as accepting the very large stride that is necessary to get to the idea that risk assessors must worry about the difficulty of finding a remedy before they have assessed the risk. One especially pungent example is testimony by Colonel Dan Rogers, a lawyer by training and Department of Defense’s point person on perchlorate, before the NAS panel reviewing EPA’s RfD on perchlorate:

Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others. ... [T]here is no room for reliance on science *policy* precaution for its own sake ... Every layer of science *policy* precaution inhibits our ability to train ... *[putting] our combat forces and, ultimately, our nation at risk.* (italics added) Colonel Daniel Rogers, U.S. Air Force³⁰

Or, in other words, the bulletin supports Colonel Rogers’ demands that the panel consider his dire warnings about diminution of national security at the same time that it grapples with how perchlorate might pose a risk to public health.

Prove Rather Than Prevent Harm

One of the well-established practices used to both simplify and ensure the protectiveness of risk assessments is to apply the “No Observed Effect Level” (NOEL) as a starting point for dose-response analysis. The reasoning is that since we do not have a firm handle on why certain chemicals cause disease, or how diseases like cancer are initiated and spread, *any* change detected in an organism following exposure is the right place to begin charting whether additional exposure will cause harm. However, science has evolved in some cases to allow us to consider that some

organisms can endure such changes without suffering damage. In those instances, it may well be appropriate to begin charting a dose-response curve at the “No Observed *Adverse* Effect Level” (NOAEL).

Rather than allow this approach to evolve at the same pace as the science, however, OMB waves a wand and transforms it to the default assumption in all risk assessments.³¹ With respect to human health effects, measuring the concentration of a chemical metabolite in a target tissue is “not a demonstration of an adverse effect” although it does indicate exposure.³² Nor does measurement of a “biological event in the human body” demonstrate an adverse effect.³³ Instead, “adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism’s ability to withstand or respond to additional environmental challenges.”³⁴

At least two things are notable about these stark instructions. First, this aspect makes it clear, if there was any doubt, that the bulletin is not a summary of consensus risk assessment principles, however carefully OMB hedges the language in most sections. If OMB actually uses this language to ride herd over assessments, much less if the courts become involved, the bulletin will skew risk assessments in the direction favored by regulated industries.

Second, OMB is obviously preoccupied with *EPA* risk assessments dealing with toxic chemicals where NOELs and NOAELs are relevant to decisions whether to control exposure. Rather than simply pursue this narrow, albeit controversial, goal, OMB does its best to camouflage its intentions with lofty expressions of overall concerns about improving the quality of assessments government-wide.

Politicized Double Standard

As added evidence that OMB is pursuing a political, as opposed to a scientific or even objective agenda, the bulletin *exempts* from coverage risk assessments prepared by regulated industries, including new drug approvals, pesticide registrations, and the licensing of individual (e.g., nuclear or chemical) plants. In these contexts, risk assessments are used to determine whether to allow activities to occur, from the marketing of Vioxx to the use of pesticides to the operation of Three Mile Island. If OMB sincerely perceives a problem with risk assessment used in a regulatory context, and believes it has the legal authority and scientific expertise to define and police the preparation of such analyses, this double standard is as unwarranted as it is unexplained.

Conclusion

OMB’s foray into peer review was a misadventure of sizeable proportions. The bulletin shows that OMB learned little from that experience, although it is also possible that OMB is cheerfully immune to such controversy and expects to be barraged by the same wide variety of stakeholders as those that attacked its peer review proposal. Given the relative importance of the bulletin, we can only hope that it is not disappointed.

Footnotes

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² OMB, Proposed Risk Assessment Bulletin, posted at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq>. A *Federal Register Notice* regarding the Bulletin appeared at 71 FR 2600 (Jan. 17, 2006) [hereinafter *Bulletin*].

³ *Id.* at 23 (definition of “risk assessment”).

⁴ Information on the NAS panel appears at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=34282>.

⁵ Section 515 of the FY 2001 Appropriations Act, P.L.106-554, 114 Stat. 2763A-153-154 (December 21, 2000).

⁶ For a complete account of this history, see Thomas O. McGarity et. al, *Truth and Science Betrayed: The Case Against the Information Quality Act* (March 2005), available at <http://www.progressivereform.org/articles/iqa.pdf>; Sidney A. Shapiro, et al., *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review* (February 2006), available at http://www.progressivereform.org/articles/CPR_IQA_601.pdf.

⁷ For an explanation, see Thomas O. McGarity, *Our Science Is Good Science and Their Science Is Junk Science: Science-based Strategies for Avoiding Accountability and Responsibility for Risk-producing Products and Activities*, 52 Kan. L. Rev. 897 (2004).

⁸ *Salt Institute v. Thompson*, 440 F. 3d 156 (4th Cir. 2006).

⁹ *Bulletin* at 23-24

¹⁰ *Id.* at 17 (emphasis added).

¹¹ See, e.g., National Research Council, *Health Implications of Perchlorate Ingestion* (Washington, D.C.: National Academy Press, 2005).

¹² See, e.g., National Research Council, *Toxicological Effects of Methyl Mercury* (Washington, D.C.: National Academy Press, 2000), available at <http://books.nap.edu/openbook/0309071402/html/index.html> (bet hedging)

¹³ *Bulletin* at 12.

¹⁴ *Id.* at 24. (emphasis added)

¹⁵ Col. Daniel Rogers, United States Air Force, Presentation to the National Academy of Sciences Committee to Assess the Health Implications of Perchlorate Ingestion (Oct. 27, 2003) (on file with author) (emphasis added), at 2-3.

¹⁶ *Bulletin* at 20.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*