

# CPR Quarterly News

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## OMB Risk Assessment Bulletin: A Power Grab

Shortly after the start of the New Year, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) released a *Proposed Bulletin* on risk assessment and asked the National Academy of Sciences for peer review. This bulletin is the most powerful administrative fiat for changing the levels of legislatively mandated protections of public health and the environment. OMB has asked the National Academy of Sciences for peer review, and is accepting comments from the public during the public comment period through June 15, 2006. Public comment will be critical, especially from the scientific community.

The bulletin is available for download on CPR's website at [www.progressivereform.org/rab06.pdf](http://www.progressivereform.org/rab06.pdf).

CPR member scholars Rena Steinzor and John Applegate have identified the key areas in which the bulletin proposes chip away at vital protections. OMB's *Proposed Bulletin* is devastating because it weakens statutory protections by circumventing congressional authority, demands reproducibility of results in risk assessments, and prioritizes risk management options before settling on the risk to be assessed. Additionally, the proposal establishes an onerous set of rules for all government-generated risk assessments while establishing absolutely no standards for agency activities typically characterized by industry-generated risk assessments.

Furthermore, as it has done with all of its activities under the Information Quality Act, OMB has completely ignored the possibility of subjecting its own new requirements to a cost-benefit analysis. Had it done such an analysis, the inevitable conclusion would be that the hurdles erected by the *Proposed Bulletin* will impose large costs on agencies and will delay efforts to use risk assessment to impose affirmative protections, with no countervailing benefit in terms of better protection of human health and the environment.

### I. Weakening Protections without Congress: 'Unreasonable Risk' vs. 'Margin of Safety'

Using unilateral and extra-legal administrative guidance, the *Proposed Bulletin* would rewrite federal laws to make them far less protective of health and the environment. One method used to accomplish these radical changes is the substitution of an "unacceptable risk" standard for significantly stronger standards in such statutes as the Clean Air Act.

On page 4, OMB opines:

Often, a risk assessment is conducted to help determine whether to reduce risk and, if so, to establish the appropriate level of stringency. A wide set of standards derived from statutes, regulations, and/or case law guide regulatory agencies in making risk management decisions. In such situations, the risk management standard is known as *priori* (sic) based on "acceptable risk." (emphasis added)

See RISK ASSESSMENT, Page 5

*CPR Issue in Depth:  
OMB's 'Risk Assessment'  
Power Grab*

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## A Progressive's View

# The John Graham Legacy: Weaker Safeguards and a Cozier Relationship with Industry

by Rena Steinzor

The term of “Regulatory Czar” John Graham, who left the OMB Office of Information and Regulatory Affairs (OIRA) in February, will be remembered for a series of setbacks for health, safety and the environment. In filling the job, President Bush should choose a candidate committed to protecting the public, and to true transparency in the regulatory process.

Graham’s nomination as OIRA director was controversial because of his close industry ties and extremely conservative views on regulatory issues as head of the Harvard Center for Risk Analysis. Five years later, it’s clear that those suspicions were amply justified. Taken as a whole, his tenure has produced weaker safeguards for public health, safety, and the environment. His relationship with industry was overly cozy, and he presided over the implementation of a number of “reforms” that have the effect of significantly delaying sensible safeguards, while downplaying the role of science. Though his reign has impacted regulatory policy in many ways, the following four areas exemplify how broad and long lasting Graham’s ill effects are:



*Rena Steinzor*

**Regulatory Hit List.** Soon after his arrival, Dr. Graham used the public comment periods on its annual cost-benefit reports to Congress as a vehicle to solicit “nominations” of existing regulations that deserve review for potential regulatory reform; this process and its results have been dubbed the “hit list.” Forty-one commenters, including the Center for Progressive Reform, submitted 189 reform nominations. These were reduced by OMB to 76, all but two of which were submitted by industry groups or right-wing think tanks. Thirty-eight (one-half) of the total involved EPA, and all of these were nominated by industry groups. The result was that an Agency that does not have the resources to get the vast majority of statutorily mandated regulations out on time must now expend resources on exhaustive re-analysis of existing rules.

**Circular A-4.** Graham’s OIRA has instructed all federal agencies to conduct cost-benefit analyses of every major rule they propose, under unusually detailed and complicated requirements set forth in Circular A-4, issued on September 17, 2003. The Circular applies even where the statute – most notably the Clean Air Act – instructs EPA to set health-based standards *without regard to costs*, considering costs only during the rulemaking phase that develops solutions to such problems. (This statutory “no costs” mandate was upheld 9-0 by the Supreme Court, in an opinion authored by Justice Antonin Scalia in 2001.) In addition to imposing this legally unsupportable requirement on the EPA, OIRA further instructs agencies to discount the value of future human lives, directing that all future lives saved should be discounted at a seven percent rate. Under this practice, 100 lives saved in 50 years would be worth 3.39 lives today. The result is a cost-benefit process where

human life is badly devalued because the “benefits” of reducing persistent toxics so that our children and their children are safe are low-balled to the point that no action is ever approved.

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**Bunk Science.** One of Graham’s fiercest initiatives has been to claim jurisdiction over scientific matters for OIRA. OMB’s staff is overwhelmingly dominated by economists, with a smattering of lawyers and other public policy experts. Graham has added a

handful of scientists to his staff. One of them, an adjunct professor at Johns Hopkins with little regulatory experience, drafted guidelines requiring that the vast majority of the scientific work done by the government be “peer reviewed,” preferably by private sector scientists. This “guidance” was opposed by most major scientific groups and several nationally prominent scientists, including the American Association for the Advancement of Science and Donald Kennedy, editor of Science magazine, former president of Stanford, and former Commissioner of the Food & Drug Administration.

See PROGRESSIVE, page 3

## No Judicial Review for IQA

The Information Quality Act (IQA) aims to ensure the “quality objectivity, utility and integrity” of information disseminated by federal agencies. The Act required first the Office of Management and Budget (OMB) and then federal agencies to establish information quality guidelines. The Act further requires that agencies establish an administrative process to allow members of the public to request that agencies correct information falling short of these guidelines. In its guidelines on implementing the Act, OMB broadened the requirement to include an administrative appeal process, also to be conducted by the agencies that “disseminate” covered information. The IQA, however, does not provide for judicial review. Instead, the IQA, alternately known as the Data Quality Act (DQA), rests oversight of agency implementation with OMB. Despite the congressional decision to leave the courts out of the IQA process, some intrepid industry petitioners have challenged agency decisions to reject IQA requests for correction in court.

So far, two United States District Courts have rejected attempts to seek judicial review of agency IQA decisions. The United States Court of Appeals for the Fourth Circuit recently considered the appeal of one of those decisions, *Salt Institute v. Leavitt*. On March 6, 2006, the court rendered its decision in that case finding that the IQA “does not create any legal right to information or its correctness.” *Salt Institute v. Leavitt*, No. 05-1097, 2006 WL 527949, at \*2 (4<sup>th</sup> Cir. Mar. 6, 2006). Accordingly, the court reasoned, Appellants, the Salt Institute and US Chamber of Commerce, lacked Article III standing to pursue their case in federal court because they failed to allege an invasion of a legal right, and thus failed to establish an injury in fact.

The Fourth Circuit’s word, however, will not be the last. Jim Tozzi, former OMB official, original proponent of the IQA and co-founder of the Center for Regulatory Effectiveness, has indicated that his group is “exploring other litigation in other circuits” to further test the IQA’s judicial reviewability. Moreover, following the Fourth Circuit’s decision in the *Salt* case, in a hearing before the Subcommittee on Regulatory Affairs of the House Committee on Government Reform, the US Chamber of Commerce renewed its call for Congress to make the IQA judicially reviewable. All the attention being paid to the question is warranted, for as the nonpartisan Congressional Research Service has observed, “[t]he determination of whether agencies’ actions are subject to judicial review under the IQA will clearly have a major effect on its implementation.”

In the wake of the Fourth Circuit’s ruling in the *Salt* case, before accepting at face value the simplistic position that the

IQA is a mere “good government” statute that agencies will only take seriously if enforced by the courts, Congress need carefully consider the arguments against authorizing judicial review of the IQA. Initially, the Act’s vague terms do not provide adequate standards for a reviewing court to apply in evaluating the propriety of agency action on an IQA petition. If Congress authorizes judicial review of the IQA under the theory that the OMB Guidelines offer sufficient supplementary guidance, it will delegate to the courts questions of policy properly left to the legislative and executive branches. Additionally, authorizing judicial review of the IQA will exacerbate many of the previously identified problems with the Act itself, including contributing to the ossification of rulemaking. Finally, creating a private right of action under the IQA would further burden the already overloaded federal courts with challenges so technical as to be administratively impracticable. In order to ensure that such concerns are carefully weighed, it is imperative that any legislative proposal to make the Act judicially reviewable be – unlike the IQA as originally passed – the subject of hearing and debate.

Download CPR’s new white paper, *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review*, at [www.progressivereform.org](http://www.progressivereform.org).



*PROGRESSIVE*, from page 2

**Paralysis by Analysis.** On the eve of his departure, Graham has issued yet another proposed “guidance,” this time demanding that every “influential” risk assessment performed by *any agency in the government* meet a series of burdensome, expensive, and absolutely unnecessary requirements that will make it very difficult to produce the analyses that have become the *quid pro quo* for regulation. The only exceptions to these overly broad and demanding requirements are risk assessments prepared by private industry in the context of pesticide registrations and drug approvals, as well as inspections of such “hazardous” facilities as nuclear plants. Notably, OMB did not subject its proposal to a cost-benefit analysis, nor does it have any plans to do so.

When you pull the camera back a clear pattern emerges. Dr. Graham has developed so-called reforms that make it easier for industry to gum up the works, make it harder for the public to know what’s going on, and used a mortally flawed method of cost-benefit analysis as cover for a pro-polluter, and anti-consumer agenda. In choosing his successor, President Bush needs to find a candidate committed to protecting the public, and to true transparency in the regulatory process.



## Bridging the Data Gaps

In a new white paper, *Strategies for Closing the Chemical Data Gap*, CPR offers a series of new proposals for defeating what has come to be known as the “data gaps” problem – that neither industry nor the government have gathered the data necessary to be confident that the majority of high-production toxic chemicals used in commerce in the United States are in fact safe.

Congress attempted to address the problem in 1976 with the passage of the Toxic Substances Control Act (TSCA), which called for a series of regulatory approaches for gathering needed data. But several studies since have made clear that TSCA has not had the desired effect. The report cites a 1998 U.S. Environmental Protection Agency (EPA) report, which found that there is no toxicity information available for 43 percent of high production volume chemicals and that a full set of basic toxicity information is available for only 7 percent.

Under the current approach, gathering the data necessary to be certain of such chemicals’ safety is unlikely because Congress is unwilling to require industry to demonstrate chemicals’ safety. Some chemicals were on the market for years before TSCA, and were “grandfathered.” Manufacturers have no incentive to conduct toxicity studies, and Congress has not allocated funding so that the government could sponsor the needed research.

“There’s far too much we don’t know about the safety of a host of toxic chemicals. It’s time for new approaches to filling or bridging the data gaps,” Applegate said in releasing the white paper. His white paper, *Strategies for Closing the Chemical Data Gap*, written with CPR policy analyst Katherine Baer, offers a series of recommendations:

- *Create a New Institutional Design for Toxicity Testing.* Research on toxic substances currently occurs in many parts of the federal government. The National Toxicology Program (NTP), EPA, and others perform toxics testing, but there is little government-wide coordination. There are several ways to remedy this situation, including, for example, the creation of a centralized National Agency for Toxicity Testing.
- *Establish Incentives for Information Production.* The most powerful such incentive would be to shift the burden of proof from the government (to prove that a chemical is unsafe) to the manufacturer (to prove that it is safe).
- *Reinvent TSCA.* Congress should amend TSCA to facilitate EPA’s ability to require testing of existing chemicals.

- *Increase Research Funding.* The political challenge aside, the inescapable reality is that the government must fund more research and data-generation about the toxicity of chemicals in commerce.

- *Reinvigorate IRIS.* EPA’s Integrated Risk Information System is missing values for many chemicals, and the addition of new values is slowed by an ossified peer review process, lack of resources, increasing political meddling, and a priority list that omits many statutory needs. Although the IRIS process generates synthesis assessments and not raw toxicological data, the program should be coordinated with other federal testing programs and used to generate research priorities to simultaneously close the gaps in basic data and IRIS chemical assessments.

- *Encourage Development of Emerging Technologies.* Although new technologies must not be relied upon to be a magic bullet, such emerging technologies as toxicogenomics (changes in expression of genes in cells or tissues in response to toxic exposure) should continue to be developed as a potential method to understand a chemical’s health effects.

- *Prohibit non-disclosure contracts* between industry and university scientists as a criterion for federal aid eligibility.

- *Extend disclosure requirements for publicly funded research to private research used in regulatory processes.* The government should be able to see and review industry data if it is to be used in any regulatory process or government database, including the data that underlies forms and other industry submissions. For example, because EPA cannot demand industry data, the IRIS program has relied on industry models and tolerance values without being able to evaluate or reanalyze the data.

- *Decrease and penalize overuse of confidential business information (CBI) claims.* The widespread industry practice of submitting scientific data to the government, but gratuitously stamping it “Confidential Business Information” prevents agencies from releasing information to the public and fellow scientists.

- *Create a registry of studies and study results.* Existing studies should be added to a registry of studies to increase the availability of existing information. Registration could be required as a condition of using the information in rulemakings or other government functions. Furthermore, notification of the start of the study should be required for inclusion in the registry and use in decision-making, to ensure that the public receives all studies, not just ones favorable to the proponent of the chemical.

- *Require corporate data disclosure.* Congress should enact a Sarbanes-Oxley-type requirement that CEOs, under pain of personal liability, certify the accuracy of submissions related

to environmental issues to the Securities and Exchange Commission.

- *Require industry to furnish EPA with data it submits to foreign governments.* Under TSCA, EPA should require chemical producers to provide to EPA environmental and health effects data that have been submitted to foreign governments – a requirement that will have significant impact with the implementation of the European REACH program.

*Strategies for Closing the Chemical Data Gap* draws on a forthcoming book written and edited by CPR scholars, *Rescuing Science from Politics*, to be published by Cambridge Press in summer 2006. On March 24, 2006, CPR will host a symposium at Indiana University School of Law – Bloomington to compare the data gap in the chemical and conservation areas of environmental law.

*Strategies for Closing the Chemical Data Gap* is available for download on CPR's website, [www.progressivereform.org](http://www.progressivereform.org).



## **RISK ASSESSMENT, from page 1**

This “acceptable risk” language suggests that some level of risk must be tolerated, and it is analogous to the standard embodied in the Toxic Substances Control Act. TSCA is the least protective of the federal environmental statutes because it directs the Environmental Protection Agency (EPA) to act only if it finds an “unreasonable” risk, to be determined by a comparison of costs versus benefits. This language is a sharp departure from the standards embodied in other environmental statutes, such as the Clean Air Act (“adequate margin of safety”) or the Resource Conservation and Recovery Act (“protect human health and the environment”). Under past orders, OMB already illegally requires agencies like EPA to conduct cost-benefit analysis even where such a test is explicitly prohibited by the statute. OMB's sleight-of-hand redefinition of risk-based standards is a similarly inappropriate appropriation of congressional legislative authority.

### **‘Central Estimate’ vs. ‘Worst Case Scenario’**

OMB's lowest common denominator approach further usurps legislative authority by insisting that agencies apply risk assessment standards contained in a single statute – the Safe Drinking Water Act (SDWA) – to risk assessments under laws that do not contain this language and may well contain different, even contradictory, standards. (See page 13 of the

*Proposed Bulletin*.) SDWA requires that agencies develop a “central risk estimate” that will drive decisions to control risk toward the determination of what exposures are best documented, as opposed to adopting the conservative – or **precautionary** – approach typically used by EPA. Once again, this outcome would directly violate standards, such as those contained in the Clean Air Act, that EPA protect health with an “adequate margin of safety.”

The *Proposed Bulletin* requires that risk assessments present quantifications of risk in the form of “ranges,” as opposed to a single “best” estimate. (See page 13 of the *Proposed Bulletin*.) Regulatory programs simply cannot function with vague ranges of risks. The nature of rules is definiteness; they are not useful otherwise. As an analogy, states impose speed limits (50, 65, etc.) rather than giving drivers a range of possible speeds (40-70).

Compounding these problems, OMB actually suggests that where models are used to predict risk, agencies simply derive a “weighted average” of their numerical results. (See page 18 of the *Proposed Bulletin*.) This overly simplistic, mathematical combination of complex and uncertain approaches to predicting risk not only mixes apples and oranges, but blends them into a misleading mush.

Finally, OMB requires agencies to adopt elaborate procedural requirements without at the same time requiring them to use the additional information to protect the public. For example, the 1996 amendments to the Safe Drinking Water Act imposed some of the requirements contained in the *Proposed Bulletin* on risk assessments used for setting safe drinking water standards (and not for any other area of environmental regulation). But those amendments also required EPA to use the additional detail to protect specially affected subpopulations (for example, children, the elderly, and people with immunological deficiencies). By lifting the central estimate language without these additional protections, the *Proposed Bulletin* in effect “cherry picks” the statute: adding complex and costly analyses, but none of SDWA's mandated goal of preserving public health.

## **II. Reproducibility of Results**

One of the most dangerous – and most carefully camouflaged – elements of the *Proposed Bulletin* is the requirement that, with respect to “influential” risk assessments, any analysis must be “capable of being substantially reproduced.” This requirement is defined to mean that “independent reanalysis of the original or supporting data using the same methods would generate similar analytical results.” (See page 16 of

the *Proposed Bulletin*.) This burdensome mandate will inevitably require the public release of any information about how a *government-sponsored* study was performed, including laboratory notebooks and detailed information about test subjects. It will also serve as a rich source of delay as industries potentially affected by the government's risk assessment attempt to "reproduce" such findings.

Further, many important and well-conducted studies that detect long-latency, low-probability risks involve a great deal of scientific judgment (e.g., reading tumors, compensating for the inevitable weaknesses of epidemiological studies). Consequently, reproducing them as you would a physics experiment is impossible. Making reproducibility the *quid pro quo* of their acceptability in making regulatory decisions would amount to excluding much of this data and could cripple protective chemical regulation.

### 'No Observable Effect Level' vs. 'Lowest Observed Adverse Effect Level'

Of a piece with the "reproducibility" requirement, the *Proposed Bulletin* imposes the extremely controversial requirement that agencies exclude tests that document changes in a body or organism and consider only studies that define and document "**adverse**" health effects. (See page 20 of the *Proposed Bulletin*.) The definition of what constitutes an adverse health effect is subjective and invariably results in less protective standards. This requirement seems to demand that the effects studied must themselves be "adverse" in the sense of actual illness. The consensus of reputable scientific opinion does not favor such an approach, and instead focuses on changes caused by toxic exposure or other disruptive activities that are the precursors of other, irreversible illnesses like cancer. The principal objective of much environmental regulation is the **prevention** of injury **before** it occurs. Once an initial effect is observed, it is often too late to prevent disease. This radical shift from "No Observable Effect Level" (NOEL) to "Lowest Observed Adverse Effect Level" (LOAEL) rewrites environmental law, with potentially devastating results.

### III. Comparative Risk Analysis

Agencies commonly compare the efficacy of various risk **management** options once they have completed the risk **assessment** process (e.g., would vehicle safety requirements work better than speed limits on public highways to reduce traffic fatalities?). However, the *Proposed Bulletin* conflates this

two-step process – recommended by the National Academy of Sciences and mandated by statutes like the Clean Air Act – by requiring instead that agencies engage in a search for management options before they settle on an assessment of the risk to be prevented. This conflation of assessment and management means that risk assessors will

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be forced to consider costs before they have characterized risks, ultimately subverting dispassionate assessments.

The requirement to compare risks is cleverly hidden in the mandate that all agencies must provide not only "context" for the risks being described, but must also analyze alternative regulatory measures:

The scope of the risk assessment should include evaluation of **alternative options**, clearly establishing the baseline risk analysis and the **risk reduction alternatives** that will be evaluated. When relevant, knowledge of the hazard and anticipated countermeasures should be understood in order to accurately capture the baseline risk. (*Proposed Bulletin* at page 16; emphasis added.)

This elaborate requirement that EPA analyze alternative risk reduction methods has been imposed by a single Court of Appeals interpreting the "unreasonable risk" standard under the unique "least burdensome requirements" language of the least protective of environmental statutes, the Toxic Substances Control Act. See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). While analyzing alternatives as part of risk assessment may sound attractive in the abstract, it makes risk assessment extremely burdensome and will slow regulatory action to a crawl, as it has for TSCA. For that reason, Congress required risk comparison and alternatives analysis in very few environmental, safety, and health laws.

Moreover – and more importantly – it would be a violation of such statutes for agencies to consider “context” or alternatives in setting regulatory standards.

Agencies like EPA do not have legal authority to withhold protective action because they – much less OMB – decide that regulatory costs could be more effectively spent elsewhere. By enacting environmental laws, Congress has already made decisions when and where to spend money to protect the public. Finally, it is far from clear that money “saved” in one regulatory context will be spent on other measures to better protect the public, as opposed to simply being pocketed as a windfall by regulated industries.

#### IV. Paralysis through Analysis

In preparing this *Proposed Bulletin*, OMB has completely ignored the possibility of subjecting its own new requirements to a cost-benefit analysis. Had it done such an analysis, the inevitable conclusion would be that the hurdles erected by the Proposed Bulletin will impose large costs on agencies and will delay efforts to use risk assessment to impose affirmative protections, with no countervailing benefit in terms of better protection of human health and the environment.

These hurdles are more extensive for “influential” than for (presumably) routine risk assessments. Yet there is no clear distinction between these two categories. “Influential” risk assessment is defined to mean a “risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policy *or private sector decisions*.” (See page 9 of the Proposed Bulletin; emphasis added.) This expansive definition is designed to sweep into the purview of the new requirements not just regulatory proceedings, but the publication of any scientific or technical materials that may affect the bottom line of regulated industries. The following bullets summarize the most troubling new requirements.

- **All Diseases or Conditions and All Causes of Adverse Effects.** Risk assessments must account for all diseases or conditions related to the chemical or activity, not just the most serious or prevalent problems. They must also identify other causes of these adverse effects in order to determine whether the toxic chemical – or substance or practice – under assessment is a significant problem. (See page 13 of the *Proposed Bulletin*.) These requirements are impossible to satisfy for the large majority of toxic chemicals for which we have no or inadequate toxicity data. In effect, they mean that agencies must consider – and then rule out – all other diseases and causes before they are allowed to make a determination

that exposure to the focus of the assessment is, in fact, a problem.

- **Any Peer Reviewed Study.** Risk assessments must consider *any* peer reviewed study “known to the agency” that is “relevant” to its risk estimates, in effect requiring agencies to take account of such studies whether or not they are considered reliable. (See page 13-14 of the *Proposed Bulletin*.) Peer review, for many reasons, is not a foolproof method for ensuring the accuracy and reliability of science, as recent reports on the falsification of cloning experiments in Korea demonstrate.

- **Onerous and Inappropriate Cost-Benefit Analytical Requirements.** The Proposed Bulletin instructs agencies to “consult OMB Circular A-4, which addresses requirements designed to improve the quality of regulatory impact analyses. For major rules involving annual economic effects of \$1 billion or more, a formal quantitative analysis of the relevant uncertainties about benefits and costs is required.” (See page 15 of the *Proposed Bulletin*.) In addition to the objections to Circular A-4 raised earlier (i.e., that it is illegal to require agencies to perform such analyses for statutes that do not allow the consideration of costs at various stages of regulation), this requirement appears to mean that agencies must complete risk assessments and cost-benefit analyses *at least simultaneously* because their assessment work will not be done until their cost-benefit work is also complete. Not only does this anomalous requirement open agencies to challenges for sequencing their work in a reasonable order, it means that an agency must (once again) take costs into account while it is assessing risk, confusing a scientific process and an economic one.

- **Baseline Risk and Exposure Analysis.** The *Proposed Bulletin* mandates that agencies establish a “baseline risk” for comparison with “risk associated with the alternative mitigation measures being considered.” (See page 16 of the *Proposed Bulletin*.) In the toxics context, establishment of a baseline risk implies the creation of a “control group” of unexposed populations, a notoriously difficult task that undermines many epidemiological studies. If there is evidence that exposure at given levels cause disease, the further search for populations not exposed can only serve to bog down the risk assessment interminably.

- **Previous Risk Assessments.** The *Proposed Bulletin* further requires that agencies “find and examine” any “previously conducted risk assessments “on the same topic” and compare such assessments to the assessment they are currently conducting, again whether or not the Agency believes such prior work is reliable. (See page 17 of the *Proposed Bulletin*.)

## V. Double Standard for Industry

Lest there be any doubt that the goal of the *Proposed Bulletin* is paralysis of protective regulation and not a general commitment to “sound science,” the bulletin establishes one extremely onerous set of rules for all government-generated risk assessments – regardless of purpose or type – and establishes **absolutely no standards** whatsoever for agency activities that typically rely on industry-generated risk assessments. Language at the top of page 10 **exempts** pesticide registration, all other forms of **licensing, inspections** of hazardous facilities (e.g., nuclear plants), and FDA **drug approvals**. These exemptions, which are never explained, make clear OMB’s intent to make risk assessments sponsored by EPA the target of this new procedural and substantive gauntlet while at the same giving the analyses prepared by regulated industries, in effect, a “free pass.”

There is no conceivable reason that environmental, safety, and health *regulations* should be subject to one standard of procedure in risk assessment, while the **approval** of drugs and pesticides and the issuance of permits for hazardous chemical manufacturing facilities or nuclear power plants should be subject to no standards at all. Especially in light of America’s fear of terrorism, this double standard will surely slow down regulatory requirements that companies find inconvenient and inexpensive, while at the same time assuring that they receive the permits and approvals regardless of major risks and in pursuit of unjustified profits. The dichotomy between the treatment of government-sponsored risk assessments and similar documents prepared by regulated industries emphasizes the *Proposed Bulletin*’s inevitable result: the slowing, and even total paralysis, of all affirmative decisions to protect health and environmental quality.

## VI. Enforcement Mechanism: Correction under the IQA

The *Proposed Bulletin* contains the standard boilerplate for executive orders: “[This Bulletin] is intended to improve the internal management of the Executive Branch and is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.” (See *Proposed Bulletin* at page 22.) However, because it purports to define what a correct or valid risk assessment should contain, the *Proposed Bulletin* does expose agencies that ignore its mandates to requests for correction under the Information Quality Act – indeed, it would have little value to regulated industries if it did not.

The courts are still considering whether requests for correction are judicially reviewable. (SEE article, “No Judicial Review in the IQA” below.) If they are, then the *Proposed Bulletin* will become an overpowering tool for threatening agencies with litigation if they do not dot every “i” and cross every “t” of its extensive requirements. Even if the courts do not find decisions made under the Act to be judicially reviewable, the Chamber of Commerce has announced that it will seek a congressional amendment to that effect. And even if the Act is ultimately determined not to provide a vehicle for court review, the prospect of answering interminable requests for correction will provide ample incentive for agencies to comply with its burdensome and unnecessary conditions.

## VII. One Size Does Not Fit All

By creating exemptions for risk assessments prepared privately by regulated industries, the *Proposed Bulletin* is far too narrow to accomplish its ostensible goal of improving the risk assessments that agencies rely upon. At the same time, however, the scope of the *Proposed Bulletin* is far too broad, leading to paralysis of affirmative actions to protect public health and the environment. First, the *Proposed Bulletin* includes risk assessments that are not even part of the regulatory process, such as the preparation of toxicological profiles for the Integrated Risk Information System (IRIS). (See the top of page 9 of the *Proposed Bulletin*.) IRIS, which has fallen far behind in its efforts to update toxicological profiles and address new risks, will be further crippled by the new requirements. Second, the *Proposed Bulletin* requires application of the requirements to both **draft** (“prior to dissemination”) and **final** risk assessments, except in the “infrequent” case where an agency head defers or waives their application. (See top of page 22 of the *Proposed Bulletin*.)

Third, the *Proposed Bulletin* establishes a “one size fits all” approach, imposing the detailed analysis that dominates cancer risk assessment on risk analysis of all kinds, including the Department of Transportation, the Federal Emergency Management Association, and the Army Corps of Engineers. Not only does this impossibly broad approach assure a poor fit between the supposed problem and the cure, but it is undertaken with no analysis whatsoever of the utility of the requirements. In other bulletins and circulars, OMB has required agencies to analyze in detail the usefulness of the information that it requires – but it imposes no such restrictions on itself.

## VIII. Dismissing Public Comments

“Scientific” comments on risk assessments are presumptively significant and need to be considered. The general public’s

comments need not be. (See pages 20-21 of the *Proposed Bulletin*.) Industry, which employs tens of thousands of

scientists, will always be able to produce “scientific” comments on risk assessments. But the objections of the general public – affected individuals, grassroots groups, and public interest organizations that don’t have industrial dollars behind them – can be dismissed as non-scientific, and the agency can simply ignore them without comment. On a playing surface that was never level to begin with, the *Proposed Bulletin* now permits the game to be played with only one team on the field.

## IX. Conclusion

OMB’s *Proposed Bulletin* on risk assessment will not improve the quality of agency risk assessments. Instead, these new requirements propose to exclude activities typically characterized by industry-generated risk assessments, while increasing costs and delaying efforts for all government-generated risk assessments without any countervailing benefit in terms of better protection of human health and the environment.



### *About the Center for Progressive Reform*

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. Direct media inquiries to Matthew Freeman at [mfreeman@progressivereform.org](mailto:mfreeman@progressivereform.org). For general information, email [info@progressivereform.org](mailto:info@progressivereform.org). Visit CPR’s website at [www.progressivereform.org](http://www.progressivereform.org).



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