



FROM GUIDANCE TO DARKNESS *How Bootstrapping Exec. Order 13,422 & “Good Guidance” Bulletin Threatens Risk Assessment*

OMB’s new memorandum on risk assessment spends several pages saying very little — until the last page, when it declares that OMB’s policy for “good guidance practices” (Exec. Order No. 13,422 and accompanying Final Bulletin on Agency Good Guidance Practices) governs risk assessments. By bootstrapping the guidance policies onto the risk assessment memo, OMB has now declared open season on any controversial scientific assessment that industry has an interest in opposing.

Blink and You’ll Miss It

One strategically buried sentence: “Agencies should refer to OMB’s Final Bulletin for Agency Good Guidance Practices . . . for updated guidance regarding best practices for increasing public access and public comment concerning guidance documents and influential scientific information” (Memo at 13).

How It Works

Any risk assessment that is “significant” because it “may reasonably be anticipated to” —

1. Lead to an annual effect of \$100 million or more
2. Adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or [state/local/tribal government]
3. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency
4. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof
5. Raise novel legal or policy issues....

Will now be subject to the following new delays and political hoops:

Increased political review

- Review and approval by senior agency official (GGP Bull. § II(1)(a))
- And review and approval by OMB’s regulatory office, OIRA (EO § 7)

Time-wasting challenges by industry

- Open to challenge under *two* processes
 - Data Quality Act *and*
 - System for comment and challenge created by GGP Bull. § III
- If *economically* significant (factors #1-2 to the left): notice in *Federal Register* and opened to comment, followed by response-to-comments document (GGP Bull. § IV(1))

What It Means

Delay The National Research Council observed, “Many risk assessments take considerable time, some several years.” Noting that “[t]ime, like funds in the federal government, is a limited commodity,” the NRC rejected OMB’s earlier draft risk assessment bulletin, concluding *inter alia* that it would result in “fewer risk assessments (with the attendant consequences) or the same number of risk assessments but of lower quality.” By importing the laborious “good guidance practices” into standards for risk assessment, OMB has simply found another path to the same problems.

Politics over science Double the challenge by industry, double the review by political higher-ups: OMB’s new memo grants industry’s long-held wish to get a stranglehold over risk assessments that establish the case for regulatory protections.