



ADVOCACY GROUP

Federal Regulatory & Housing Policy

June 15, 2006

The Honorable Steven D. Aitken
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building, Room 262
17th Street and Pennsylvania Avenue, NW
Washington, DC 20503
Electronic Address: OMB_RAbulletin@omb.eop.gov

Re: Comments on OMB's Proposed Risk Assessment Bulletin

Dear Mr. Aitken:

On behalf of the National Association of Home Builders (NAHB), I am pleased to present these comments on the "Proposed Risk Assessment Bulletin" ("proposal") published by the Office of Management and Budget (OMB). The proposal is a very positive step toward incorporating logical and careful analysis of uncertain outcomes into government decisionmaking. This guidance is especially welcome in the regulatory arena, where many people's lives may be affected by an agency decision that must be based on incomplete and imperfect information.

NAHB represents more than 225,000 member firms involved in home building, remodeling, multifamily construction, property management, housing finance, building product manufacturing and other aspects of residential and light commercial construction. NAHB's builder members will build more than 80 percent of the 2 million homes expected to be built in this country in 2006. As the largest and almost the only industry to expand during the recent recession, housing has shown itself to be one of the strongest drivers of economic growth, thus anything that affects housing will reverberate throughout the rest of the economy.

Risk Assessment Is Not Policy Formulation

Perhaps the most welcome aspect of the proposal is the careful distinction between risk assessment and risk management. Risk assessment must remain a matter of information; risk management is an issue of policy. Formation of sound policy depends on good information, so it is imperative that risk assessments be performed so as to illuminate the policy-maker's task and facilitate the decisionmaking process; it must never be the purpose of risk assessment to support the policy maker's decision. Scientists must keep to their assigned role of evaluating scientific truth, not making policy recommendations.

Characterization of Risks

Another welcome step is the attention paid to distributions of risks or outcomes, as discussed in Standards 3 and 6 for Influential risk Assessments. NAHB hopes these concepts will be extended to all risk assessments. As OMB observes, use of merely the highest or lowest extreme value gives very little information about the risk; it only states one possible outcome. It is important to include measures of dispersion—such as standard deviations or quartiles—as well as measures of central tendency like mean and expectation. That said, NAHB has a reservation about using the expected value or mean as the measure of central tendency. The mean is an appropriate measure where the data are distributed symmetrically, as with a normal or logistic distribution. However, NAHB deals extensively with data that are famously asymmetrical in distribution, including income and house price. In these cases, the median is a preferred measure of central tendency, even though it will be somewhat lower than the expected value (in the case of the two variables mentioned). Median is the measure used in many programs at the Department of Housing and Urban Development (HUD), especially for low income housing programs, and it appears to be more informative than the mean for the problems HUD seeks to address.

The use of models also presents some dangers. Some models are well known and understood, and there is extensive knowledge of what happens when one or more of the model's assumptions are not satisfied; the economic model of perfect competition is such a model. As OMB points out, however, other models are less well understood, such as dose-response models. The IEUBK model of lead uptake is a basis for some lead related regulations, and it is quite controversial. The less is known about a model, the less reliance can be placed on it.

As OMB has suggested, several models may be necessary, though it is not clear how one would implement OMB's suggestion to take a weighted average of results of alternative models (page 18). It is not apparent how to determine the weights without deciding *a priori* which models are more valid. Agencies should present the alternative models it has considered, along with descriptions of the strengths and weakness of each. If an Agency prefers one model, it should explain why; if it chooses to synthesize the models, it should explain how it did so and why that method of synthesis is appropriate. For example, if the synthesis method was to take a weighted average of the alternative model results, the Agency should justify the weights and explain how they were derived

Purpose and Consequences of Risk Assessments

NAHB would like to commend OMB for its discussion of Standard 7 for Influential Risk Assessments, which emphasizes that adversity of the outcome is what is relevant for risk assessment, not mere exposure to a risk source. A crucial part of risk assessment is to investigate the linkage between source of the risk and actual damage or impairment. For example, it is not informative to show that someone may be exposed to sounds of a certain loudness; that only would become informative if it were shown that such exposure induced hearing loss. This demonstration of linkage is not only part of risk assessment; it is essential to a rational basis for any rule. A rule must have a reasonable probability that it will work.

The proposal's definition of "Influential Risk Assessment" contains a recognition that risk assessments, like other government data disseminations, can "have a clear and substantial impact on important...private sector decisions" (page 9). The same paragraph subsequently admonishes the agencies, "A risk assessment can have a significant economic impact even if it is not part of a rulemaking." NAHB is pleased to see this forthright recognition, and urges OMB to follow through by ensuring an effective remedy for arbitrarily or unreasonably defective risk assessments, when the assessment is the final agency action.

Evaluation of Risk Assessments

Standard 9 for Influential Risk Assessments focuses attention on a question that should be answered somewhere in the guidelines: what is science within the meaning of a risk assessment? Presumably, it would include physics, chemistry, astronomy, epidemiology, and other physical studies were relevant; does it include all the disciplines mentioned in the last paragraph of page 5 (the first paragraph of the section "Types of Risk Assessments")?

Not only must OMB define what constitutes a science for risk assessment purposes, but the Office must also decide who is a scientist to be qualified to comment. Is it only academics and agency employees, or can members of the public qualify, also? Are other scientists to be excluded? Some people seem to think that scientists working in the regulated industry are not qualified to give an opinion; OMB should make clear that all knowledgeable persons are invited to comment. The agencies should respond to all lucid, informed comments, whether the agency thinks the commenter's point is significant or not.

Section VI, pertaining to updates, implies a very important concept for risk assessment, which is that sometimes there are simply not enough data to assess the risk or make a decision about the risk. It should be clear that the use of merely the available data may not provide enough information to be the basis for a risk assessment, let alone a policy decision. Though OMB correctly states that it is beyond the scope of risk assessment to ask or determine whether to invest in additional inquiry or to take interim steps pending additional inquiry, it remains properly in the scope of the risk assessment to state whether the data are adequate to assess the risk. It is the agency's response to the assessment that is beyond the scope of the assessment itself.

Suggestions about Terminology

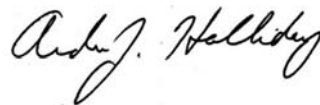
Finally, some housekeeping or editorial changes could make the proposal more useful. First, in section IV.7 about regulatory analysis, the term "baseline" is introduced without any definition. Since this term has been the subject of considerable debate, it would be helpful to define what OMB means by "baseline" in the context of this proposal. The meaning is not clear from the context, and the surrounding controversy disallows an assumption that readers know the meaning.

The second housekeeping point is a consequence of OMB's commendable efforts to keep the proposal flexible. As a speaker observed at the workshop on the proposal held at the National Academies of Science, the proposal is rife with the term "appropriate;" in fact, it is used nineteen times, or nearly once every page. As important a concept as "appropriate" is, it is really a goal rather than a description, so it gives no guidance. The proposal would be improved by a description what criteria would bear on the appropriateness of a procedure in the cases OMB discusses. Use of alternative terminology will probably not suffice; "feasible" and "possible" are already used eleven times each, and they, too, can be murky concepts. Guidance that relates conditions to actions would be most useful, though NAHB appreciates the difficulty of treading the narrow path between specificity and flexibility.

OMB has produced an important document that could be a valuable guide to the agencies and a strong shield for the public in the process of risk assessment. It will help ensure that risks are not evaluated according to the policy preferences of administrators, but rather will be based on demonstrable fact and transparent process. Solid risk assessments will not only protect the public from arbitrary action, but they will also assist agencies to execute the will of Congress when the risks are understood more fully.

Thank you for the opportunity to submit these comments. If you have any questions or would like any further information or clarifications, please contact the undersigned at 202-266-8305 or aholliday@nahb.com.

Sincerely,

A handwritten signature in cursive script that reads "Andrew J. Holliday".

Andrew Jackson Holliday, J.D., Ph.D.
Regulatory Counsel
National Association of Home Builders