

Comments on the OMB Proposed Risk Assessment Bulletin  
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The effort to clarify the standards for risk assessments represented by the OMB Proposed Guidelines is laudable. There are, however, some conceptual muddles in the document, muddles which point to some pitfalls in the project as it is currently framed, pitfalls which will likely hamper the effectiveness of the document once implemented. In these comments, I begin with the issue closest to my area of expertise, the nature of scientific objectivity.

Through the Data Quality Act, OMB is mandated to ensure and improve upon the objectivity of information presented through risk assessments. Yet scientific objectivity is a notoriously difficult concept with which to work. In the section on objectivity (pp. 14-15) in the guidelines, it is unclear what is meant by objectivity. We are told that “objectivity ensures accurate, reliable, and unbiased information.” These are all desirable qualities, but it is highly doubtful that the bulletin’s advice on achieving objectivity would *ensure* anything like these results. Giving weight to positive and negative studies is important, but ensures nothing about the ultimate reliability of the risk assessment. It may well turn out that one side of the spectrum proves incorrect or deeply flawed. Nor does such an approach to objectivity ensure accuracy. One can have an ostensibly objective risk assessment (in that one looked and weighed carefully positive and negative studies) that proves inaccurate in the end.

In addition, there are several meanings of unbiased that could be at play here. We can all agree that deliberately distorting the weight of evidence to produce a particular desired outcome would be unacceptable bias. However, risk assessors often have “professional judgment” reasons for trusting one study more than another. Risk assessors can also *legitimately* be concerned about some sources of uncertainty more than others, either for methodological *or ethical* reasons. (Douglas 2000) The call to make uncertainty estimates clearer and more precise is useful here, but judgments about the sufficiency of evidence for a risk assessment, or about the sufficiency of an uncertainty estimate for that risk assessment, can not be eliminated by increased quantification. The need for judgment, and perspective that informs that judgment, can be considered a bias, but it is not the kind of bias that threatens scientific objectivity. The OMB should be careful not to confuse bias that arises from informed perspective and bias that arises from the desire to produce a pre-determined outcome.

I suspect that these problems arise from the bulletin because there is no clear understanding of the nature of objectivity in the bulletin. As historians and philosophers have examined the concept of scientific objectivity in recent decades, they have uncovered a deeply complex concept. The OMB is drawing upon at least two general senses of the term at once, and conflating them. They are suggesting the objective claims relate, or map onto, the world directly (a claim for which we can have no definitive test), and they are simultaneously suggesting that objective claims are free of bias or of inappropriate values. Unfortunately, even capturing successfully one of these two senses of objectivity fails to ensure that the other is present. We could easily have a bias free claim that proves simply false, and we can have very biased claims that prove true (bias in either of the two senses discussed above). For further clarification of the concept of objectivity, OMB might consult my article listed below. (Douglas 2004)

My concerns about the OMB handling of standards related to objectivity are framed by a broader concern about the document as whole. The efforts to oversee and regularize the risk assessments is laudable, but caution should be employed whenever attempts are made to create greater quantitative formality for these complex technical judgments. As emphasized by the NRC report *Understanding Risk* (which is not a risk communication document as suggest on p. 3 of the proposed bulletin, but rather a risk assessment document that deserves full attention on p. 2), risk assessments, as a whole, are best understood as an analytic-deliberative process. Being clear about both the analytic components (e.g., the data and uncertainty analysis) and the deliberative components (e.g., the scope of the risk assessment and the weighing of evidence) is essential. However, no procedure can eliminate the need for the deliberative components. Indeed, these deliberative components point to a third source for scientific objectivity completely neglected by the OMB in this document—robust discussion among groups of scientific experts. This source for objectivity has become increasingly important among philosophers of science in the past decade, yet the OMB proposal reads as though a formal quantification of diverse opinion is useful and sufficient. (see especially p.15, sec. 5; for the philosophy literature, begin with Longino 1990, chap. 4) These pushes toward layers of quantitative analysis run directly counter to the need for greater transparency and accessibility of the risk assessments for the public. One cannot have increased layers of quantitative analysis and at the same time seek to meet the standards of public accessibility from the Safe Water Drinking Act discussed on p. 13.

In sum, what the OMB should strive for is greater clarity about the nature of judgments made to complete a risk assessment, and perhaps even improved writing of public documents. But seeking an overwhelmingly analysis-based approach is doomed to frustration and failure.

#### Works Cited

Douglas, Heather (2004), “The Irreducible Complexity of Objectivity,” *Synthese*, vol. 138 no. 3, pp.453-473.

Douglas, Heather (2000), "Inductive Risk and Values in Science," *Philosophy of Science*, vol. 67 n. 4, pp. 559-579.

Longino, Helen (1990). *Science as Social Knowledge: Values and Objectivity in Scientific Inquiry*. Princeton: Princeton University Press.