

Steven C. Lewis, Ph.D., DABT
President & Principal Scientist
Integrative Policy & Science, Inc.
14 Merlin Drive
Washington, NJ 07882

Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Attn: Mabel Echols
Room 10102
New Executive Office Building
725 17th Street, NW.
Washington, DC 20503

Dear Ms. Echols:

Thank you and your colleagues for the opportunity to provide comments in response to Federal Register / Vol. 74, No. 37 / Thursday, February 26, 2009 / Notices 8819.

Regarding Executive Order 12866... For nearly two decades, provisions of the Executive Order have helped to establish a more positive environment for applying sound principles of analysis to policy development and administration. For sake of brevity, these comments will be confined to a small set of interconnected topics regarding improvements to risk assessments as they apply to protection of human health and the environment.

Overall, my comments reflect the fundamental belief that benefit-cost analyses – for comparing regulatory options – are essential to efficient and effective health protection regulations.

By way of background... Among toxicologists (my profession), the term “risk assessment” refers to the analytic/synthetic processes that provide probabilistic estimates of harm; such methods are confined almost exclusively to estimating the consequences from exposure to suspected carcinogens. In contrast, “safety assessment” refers to the analytic/synthetic processes that provide single numerical values as estimates of safe levels of exposure; such deterministic methods are widely employed for all other adverse effects, i.e., excluding cancer. The latter include the Reference Dose (RfD, as from U.S. EPA), Acceptable Daily Intake (ADI, as from U.S. FDA), and others.

Though distinctly different in nearly every other way, these two methods share one common characteristic; both need to be updated. Current assessment practices – of both sorts – must be advanced to provide outputs that are compatible with benefit-cost analysis. The most promising path to achieving that end rests with harmonization of the two, currently disparate, approaches.

Current safety assessment processes (i.e., assessments for hazards other than cancer) must be revised. Presently-employed methods provide only single numerical values (i.e., point estimates). Those single values inappropriately imply a high degree of precision. As a result, such point estimates foster the irrational notion that any exposure below the “safe” value is completely “risk-free,” and that any exposure above the “safe” value is categorically UNSafe or UNacceptable. The notion that a single value (aka, a “bright line”) separates “safe” from “unsafe” exposures is simply wrong. Moreover, such point estimates provide no information about the possible consequences from exposures above the “safe” value, and thus provide no useful input to benefit-cost analyses.

NOTE: the Information Quality Act, IQA, (<http://www.fws.gov/informationquality/section515.html>) requires that whenever Agencies disseminate information, that information must be useful for the intended purpose. Since current safety assessment methods are incompatible with benefit-cost analysis (i.e., do not provide information that can be incorporated into benefit-cost analysis), outputs from those methods cannot meet the IQA’s requirement for “utility.” The solution is straightforward; harmonize approaches to the assessment of any and all hazards, whether cancer or other. OIRA should encourage harmonization of methods for human health risk assessment.

The risk assessment processes (i.e., those for estimating probabilistic risks, as currently done only for cancer hazards) must be advanced. EPA’s 2005 Guidelines for Carcinogen Risk Assessment (<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=116283>) proposed that scientifically-superior alternatives to traditional default assumptions¹ be considered when assessing cancer risks. Although the Guidelines were finalized four years ago, actual practices remain largely unimproved. OIRA should encourage agencies to rely on the most-relevant and highest quality scientific evidence to support regulations.

Apart from the analytical conduct of a risk assessment, the presentation (aka, characterization) of probabilistic risks must be improved. NOTE: the Information Quality Act (<http://www.fws.gov/informationquality/section515.html>) compels the unbiased presentation of risk. However, the currently-common (and persistent) practice is to present only “upper-bound” estimates (i.e., the statistically highest estimate of risk). On some occasions, those “upper-bound estimates” are

¹ An example is the persistent notion that the risk from exposure to any carcinogen, regardless of its type or mode of action, can be best estimated by relying on a single statistical model based on the underlying assumption on a “linear, no threshold” extrapolation.

tersely-but-opaquely acknowledged to be unrealistic...by offering such qualifiers as, "...the risks are likely to be less...and possibly zero." The correction is simple. The full range of plausible values must be reported, including but not limited to, mean value, maximum-likelihood value, expected value, upper and lower statistical bounds, etc. Without these changes (if the practice of reporting only upper bound estimates continues), meaningful benefit-cost analysis is impossible.

In summary, my comments have focused on three inter-connected needs:

1. to establish benefit-cost analysis as a primary input to informed public policy-making, unless explicitly forbidden by statute;
2. to harmonize approaches to evaluating "risk" and "safety" such that, regardless of the nature of the adverse effect, all assessments yield outputs that are compatible with benefit-cost analysis;
3. to correct the current risk-characterization practice to report the full range of plausible risk estimates of risk.

If you have any questions or desire more detail regarding these comments, please feel free to contact me by phone, mail or email.

Thank you, again, for the opportunity to comment on this important matter.

Sincerely,
Steven C. Lewis