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ACTION: Consultants in Toxicology, Risk Assessment and Product Safety (CTRAPS), a biomedical consulting firm, often comments on Federal risk assessments for private sector clients. As such, CTRAPS has standing to comment about Federal risk assessment policy. CTRAPS submits these comments in response to OMB's call for public comments about proposed risk assessment in the Federal Register 71(10): 2600 (January 17, 2006). Please note that CTRAPS previously commented on December 15, 2003, to Dr. Margo Schwab about OMB's proposed peer review bulletin (Bulletin 2003-34 of August 29, 2003).

SUMMARY: OMB's proposed risk assessment bulletin appears fundamentally sound and is consistent with the principles described in Introduction to Risk Analysis, which CTRAPS uses as a source document. [See: D.M. Byrd and C.R. Cothern, Introduction to Risk Analysis: A Systematic Approach to Science-Based Decision Making. (ISBN 0-86587-696-7) Government Institutes, Dallas, TX, pp. 433 (2000).] In summary, CTRAPS has the following advice:

(A) Define risk. OMB might incorporate a definition into the bulletin that includes "likelihood and severity," two factors that OMB's proposal already emphasizes. OMB will find ample historical and scholarly precedent for a definition. Such a definition will facilitate bringing financial and engineering risk coverage into OMB's bulletin.

Calling an assessment "a document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment ..." is consistent with Federal agency practices, although in private sector (1) companies often do not write down their assessments to avoid losing future litigation, and (2) risk assessments do lead to (and inform) decisions. Defining risk cannot hurt he guidance. Otherwise, OMB will seek to improve a process that analyses something vague, undefined (and unwritten).

CTRAPS does not foresee any problems with OMB laying out its expectations for client agencies, when they bring forward a risk assessment that they think justifies a regulation.

OMB will experience some advantages in defining risk and defining risk

in this way. OMB will obtain internal consistency within the bulletin.

A formal, axiomatic and logical analysis supports this definition. [See: P.C. Fishburn, Foundations of risk measurement I: Risk as probable loss. Management Science 30: 296-306 (1984); P.C. Fishburn, Foundations of risk measurement II: Effects of gain on risk. J. Mathematical Psychology 25: 226-242 (1984)].

One alternative to a duplex statement of risk, one that also has separate values for probability and severity, is a triplet value. [See: S. Kaplan and J. Garrick, On the Quantitative Definition of Risk. Risk Analysis 1: 11-27 (1981).] This view of risk incorporates the idea of a scenario, which the duplex value does not. Otherwise, the two definitions are consistent.

OMB might look for a definition of risk that incorporates the views of the financial and engineering risk communities.

(B) State the expected uncertainty in risk.

Variation has more of a physical, than a mathematical, meaning. As a physical concept, variation means that the analyst expects that repetition of the events that led to the measured risk will fall within a stated range. Variation is not a mathematical formula or the application of a mathematical formula. Thus, OMB needs to be concerned about agencies that think that the application of some mathematical formula somehow becomes more important than the estimation of variation.

Variation is large part of uncertainty, as explained by federal agencies in their risk assessments, so far. However, uncertainty may result in larger defections from expected results. OMB might want to use a hierarchical approach to uncertainty. [See: D.M. Byrd and E.T. Barfield, Empirical Degree-of-Belief Methods for Risk Assessments Based on Epidemiology Data: Application of a Procedure for Combinatorial Analysis of Risk-related Components to a Series of Occupational Studies of Leukemia Incidence Associated with Benzene Exposure at Several Rubber Hydrochloride Plants in Ohio. (In) R. Cothern and M. Mehlman (Eds.) Risk Assessment and Risk Management of Industrial Chemicals. Princeton Scientific Publishing (1988) pp. 209-223.]

(C) Use safety factors; Safety factors are not risks.

Many parts of society, including the federal government, use safety factors. However, CTRAPS believes that safety factors defines regions of relationships without risk. Thus, in the environment, health and safety sphere, safety factors define regions of dose-response (or exposure-response) relationships without risk. In addition, benchmark doses have some value, but a no-effect level is an experimental value. Thus, scientists should be able to replicate an experimental no-effect level, whereas they might not reproduce a benchmark dose, given new experimental data.

The risk assessment community has confused safety factors with risks. The U.S. Environmental Protection Agency (EPA) added to this confusion, when it tried to turn safety assessment into part of risk assessment. [See Federal Register 69(58): 15326-15328 (March 25, 2004)] Agency staff paper by the Risk Assessment Task Force, Examination of EPA Risk Assessment Principles and Practices. [EPA/100/B-04/001], Washington, DC 20460, pp. 192 (2004). Docket ID: ORD-2004-0004 (June 23, 2004).

Sincerely yours,

/s/

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