

OFFICE OF MANAGEMENT AND BUDGET

Proposed Risk Assessment Bulletin

SUMMARY: As part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public, the Office of Management and Budget (OMB), in consultation with the Office of Science and Technology Policy (OSTP), proposes to issue new technical guidance on risk assessments produced by the federal government.

DATES: Interested parties should submit comments to OMB's Office of Information and Regulatory Affairs on or before June 15, 2006.

ADDRESSES: Because of potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: OMB_RAbulletin@omb.eop.gov. Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number and e-mail address in the text of the message. Please be aware that all comments are available for public inspection. Accordingly, please do not submit comments containing trade secrets, confidential or proprietary commercial or financial information, or other information that you do not want to be made available to the public. Comments also may be submitted via facsimile to (202) 395-7245.

FOR FURTHER INFORMATION CONTACT: Dr. Nancy Beck, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., New Executive Office Building, Room 10201, Washington, DC, 20503. Telephone (202) 395-3093.

SUPPLEMENTARY INFORMATION:

Introduction

Risk assessment is a useful tool for estimating the likelihood and severity of risks to human health, safety and the environment and for informing decisions about how to manage those risks. For the purposes of this Bulletin, the term "risk assessment" refers to 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.

The acceptance of risk assessment in health, safety, and environmental policy was enhanced by the seminal report issued by the National Academy of Sciences (NAS) in 1983: *Risk*

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

Assessment in the Federal Government: Managing the Process. The report presented a logical approach to assessing environmental, health and safety risk that was widely accepted and used by government agencies.

Over twenty years after publication of the NAS report, there is general agreement that the risk assessment process can be improved. The process should be better understood, more transparent and more objective. Risk assessment can be most useful when those who rely on it to inform the risk management process understand its value, nature and limitations, and use it accordingly.

Many studies have supported the use of risk assessment and recommended improvements. For example, in 1993 the Carnegie Commission on Science, Technology, and Government issued “Risk and the Environment: Improving Regulatory Decision-making.”¹ In 1994, the NAS issued “Science and Judgment in Risk Assessment” to review and evaluate the risk assessment methods of EPA.² In 1995, the Harvard Center for Risk Analysis issued “Reform of Risk Regulation: Achieving More Protection at Less Cost.”³ In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management issued “Risk Assessment and Risk Management in Regulatory Decision-Making.”⁴ A series of NAS reports over the past 10 years have made useful recommendations on specific aspects and applications of risk assessment.⁵ The findings in these reports informed the development of this Bulletin.

OMB, in collaboration with OSTP, has a strong interest in the technical quality of agency risk assessments because these assessments play an important role in the development of public policies at the national, international, state and local levels. The increasing importance of risk assessment in the development of public policy, regulation, and decision making requires that the

¹ Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making*, New York, NY, June 1993.

² National Research Council *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994.

³ Harvard Group on Risk Management Reform, *Reform of Risk Regulation: Achieving More Protection at Less Cost*, Human and Ecological Risk Assessment, vol. 183, 1995, pp. 183-206.

⁴ Presidential/Congressional Commission on Risk Assessment and Risk Management, Vol. 2, *Risk Assessment and Risk Management in Regulatory Decision-Making*, hereinafter “*Risk Commission Report*,” 1997.

⁵ See, e.g., National Research Council, *Health Implications of Perchlorate Ingestion*, Washington DC: National Academy Press, 2005; National Research Council, *Arsenic in Drinking Water 2001 Update*, Washington DC: National Academy Press, 2001; National Research Council, *Toxicological Effects of Methylmercury*, Washington DC: National Academy Press, 2000; National Research Council, *Health Effects of Exposure to Radon, BEIR VI*, Washington DC: National Academy Press, 1999; National Research Council, *Science and the Endangered Species Act*, Washington, DC: National Academy Press, 1995; National Research Council, *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994; National Research Council, *Issues in Risk Assessment I: Use of the Maximum Tolerated Dose in Animal Bioassays for Carcinogenicity*, Washington DC: National Academy Press, 1993; National Research Council, *Issues in Risk Assessment II: The Two Stage Model of Carcinogenesis*, Washington DC: National Academy Press, 1993; National Research Council, *Issues in Risk Assessment III: A Paradigm for Ecological Risk Assessment*, Washington DC: National Academy Press, 1993; National Research Council, *Pesticides in the Diet of Infants and Children*, Washington DC: National Academy Press, 1993; National Academy of Engineering, *Keeping Pace with Science and Engineering: Case Studies in Environmental Regulation*, Washington DC: National Academy Press, 1993; National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, Washington DC: National Academy Press, 1983.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

technical quality and transparency of agency risk assessments meet high quality standards. Moreover, a risk assessment prepared by one federal agency may inform the policy decisions of another federal agency, or a risk assessment prepared by one or more federal agencies may inform decisions made by legislators or the judiciary. This Bulletin builds upon the historic interest that both OMB and OSTP have expressed in advancing the state of the art of risk assessment.⁶

The purpose of this Bulletin is to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards. Federal agencies should implement the technical guidance provided in this Bulletin, recognizing that the purposes and types of risk assessments vary. The Bulletin builds on OMB's Information Quality Guidelines and Information Quality Bulletin on Peer Review and is intended as a companion to OMB Circular A-4 (2003), which was designed to enhance the technical quality of regulatory impact analyses, especially benefit-cost analysis and cost-effectiveness analysis. Like OMB Circular A-4, this Bulletin will need to be updated periodically as agency practices and the peer-reviewed literature on risk assessment progress.

The audience for the Bulletin includes analysts and managers in federal agencies with responsibilities for assessing and managing risk or conducting research on improved approaches to risk assessment. The Bulletin should also be of interest to the broad range of specialists in the private and public sectors involved in or affected by risk assessments and/or decisions about risk and safety.

Although this Bulletin addresses certain technical aspects of risk assessment, it does not address in any detail the important processes of risk management and risk communication.⁷ The technical guidance provided here addresses the development of the underlying documents that may help inform risk management and communication, but the scope of this document does not encompass how federal agencies should manage or communicate risk.

Uses of Risk Assessments

Risk assessment is used for many purposes by the Federal Government. At a broad level, risk assessments can be used for priority setting, managing risk, and informing the public and other audiences. The purpose of the assessment may influence the scope of the analytic work, the type of data collected, the choice of analytic methods, and the approach taken to reporting the findings. Accordingly, the purpose of an assessment should be made clear before the analytical work begins.

⁶ See U.S. Office of Science and Technology Policy, *Chemical Carcinogens: A Review of the Science and Its Associated Principles*, 50 FR10371 (1985); and, U.S. Office of Management and Budget, Memorandum for the Regulatory Working Group, *Principles for Risk Analysis*, Jan 12, 1995.

⁷ National Research Council *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC: National Academy Press, 1996; Risk Commission Report, Volume 2, 1997; National Research Council, *Improving Risk Communication*, Washington DC: National Academy Press, 1989.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

Priority Setting

Risk assessment is sometimes used as a tool to compare risks for priority-setting purposes.⁸ For example, in 1975 the Department of Transportation prepared a comparative assessment of traffic safety hazards related to highway and vehicle design as well as driver behavior.⁹ A wide range of countermeasures were compared to determine which measures would be most effective in saving lives and reducing injuries. Similarly, risk assessment models relating to food safety and agricultural health concerns may be used to rank relative risks from different hazards, diseases, or pests. In 1987 and again in 1990, the Environmental Protection Agency (EPA) prepared a comparative assessment of environmental hazards – both risks to human health and the environment – to inform the Agency’s priority setting.¹⁰ This work demonstrated that the environmental risks of greatest concern to the public often were not ranked as the greatest risks by agency managers and scientists.

Screening-level risk assessments are sometimes used as a first step in priority setting. The purpose of the “screen” is to determine, using conservative (or worst-case) assumptions, whether a risk could exist, and whether the risk could be sufficiently serious to justify agency action. If the screening-level assessment indicates that a potential hazard is not of concern, the agency may decide not to undertake a more comprehensive assessment. If the screening-level assessment indicates that the potential hazard may be of concern, then the agency may proceed to undertake a more comprehensive assessment to estimate the risk more accurately.¹¹

Informing Risk Management Decisions

Often, a risk assessment is conducted to help determine whether to reduce risk and, if so, to establish the appropriate level of stringency. A wide set of standards derived from statutes, regulations, and/or case law guide regulatory agencies in making risk management decisions. In such situations, the risk management standard is known a priori based on “acceptable risk” considerations.¹²

Risk assessments may be used to look at risk reduction under various policy alternatives to determine if these alternatives are effective in reducing risks. In some agency programs, the

⁸ Davies, J. C. (ed), *Comparing Environmental Risks: Tools for Setting Government Priorities*, Resources for the Future, Washington, DC, 1996; Minard, R, *State Comparative Risk Projects: A Force for Change*, Northeast Center for Comparative Risk, South Royalton, Vermont, March 1993.

⁹ U.S. Department of Transportation, *National Highway Safety Needs Report*, Washington, DC, April 1976.

¹⁰ U.S. Environmental Protection Agency, *Unfinished Business: A Comparative Assessment of Environmental Protection*, Washington, DC, 1987; U.S. Environmental Protection Agency, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, Science Advisory Board, Washington, DC, 1990.

¹¹ National Research Council, *Science and Judgment in Risk Assessment*, Washington DC: National Academy Press, 1994.

¹² Douglas, M, *Risk Acceptability According to the Social Sciences*, Russell Sage Foundation, New York, NY, 1985; Fischhoff, B, S Lichtenstein, P Slovic, SL Derby, RL Keeney, *Acceptable Risk*, Cambridge University Press, UK, 1981.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

results of risk assessments are an important technical input to benefit-cost analyses, which are then used to inform risk management decisions in rulemakings.¹³

Informing the Public

In some circumstances, risk assessments are undertaken to inform the public through education and informational programs.¹⁴ Such programs can help citizens make informed decisions in their personal lives. For example, Federal agencies alert the public about the risks of living in a home with elevated levels of radon gas, of purchasing a sport utility vehicle with a certain height-to-width ratio, and taking long-term estrogen therapy. The dissemination of public risk information, even if it is not accompanied by a regulation, can induce changes in the behavior of consumers, patients, workers, and businesses.

Sometimes, Federal agencies undertake large-scale risk assessments that are designed to inform multiple audiences. For example, the Surgeon General's Report on Smoking and Health has, over the years, contained a wide variety of health risk estimates. These estimates have been adopted in programs and documents disseminated by local and state governments, Federal agencies, private companies, and the public at large. In some cases, Federal scientists participate in an international effort to develop risk models that can be used to educate the public and inform decisions throughout the world.¹⁵

Types of Risk Assessments

Risk assessment is a broad term that encompasses a variety of analytic techniques that are used in different situations, depending upon the nature of the hazard, the available data, and needs of decision makers.¹⁶ The different techniques were developed by specialists from many disciplines, including toxicology, epidemiology, medicine, chemistry, biology, engineering, physics, statistics, management science, economics and the social sciences. Most risk assessments are performed by teams of specialists representing multiple disciplines. They are often prepared by government scientists or contractors to the government.

¹³ Breyer, S., *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harvard University Press, Cambridge, MA 1993; Hahn, RW (ed), *Risks, Costs and Lives Saved: Getting Better Results from Regulation*, Oxford University Press, New York, NY, 1996; Viscusi, WK, *Rational Risk Policy*, Clarendon Press, Oxford, UK, 1998; National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decisionmaking*, Washington, DC: National Academy Press, 1990.

¹⁴ Fischhoff, B, S Lichtenstein, P Slovic, SL Derby, RL Keeney, *Acceptable Risk*, Cambridge University Press, UK, 1981; Douglas, M, *Risk Acceptability According to the Social Sciences*, Russell Sage Foundation, New York, NY, 1985; Wilson, R, EAC Crouch, *Risk-Benefit Analysis*, Harvard University Press, Cambridge, MA, 2001.

¹⁵ Renn, O, *White Paper on Risk Governance: Towards an Integrative Approach*, International Risk Governance Council, Geneva, Switzerland, September 2005.

¹⁶ Haimes, YY, *Risk Modeling, Assessment, and Management*, John Wiley and Sons, New York, New York, 1998; Wilson, R, EAC Crouch, *Risk-Benefit Analysis*, Harvard University Press, Cambridge, MA, 2001.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

Actuarial Analysis of Real-World Human Data

When large amounts of historic data from humans are available, an actuarial risk assessment may be performed using classical statistical tools. For example, the safety risks associated with use of motor vehicles, including the risks of a vehicle's design features, may be estimated by applying statistical tools to historic data on crashes, injuries and/or fatalities. When sufficient numbers of people have been exposed to large doses of chemicals and radiation, it may be feasible to estimate risks using health data and statistical methods. The field of epidemiology, a branch of public health and medicine, performs such assessments by combining actuarial analyses with biologic theory and medical expertise.¹⁷ The field of radiation risk assessment has been informed by epidemiology, including studies of the World War II bombings at Hiroshima and Nagasaki and more recently the experiences of workers who were exposed to radiation on the job. Estimates of the health risks of tobacco products have been generated primarily on the basis of epidemiology.

Dose-Response Analysis Using Experimental Data

Special techniques of risk assessment have been developed for settings where humans and/or animals are exposed – intermittently or continuously – to various doses of substances.¹⁸ The adverse effects of concern may range from different types of cancer to developmental, reproductive or neurological effects. Real-world data on adverse effects in humans or wildlife may not be available because (a) adequate data have not been collected, (b) the adverse effects (e.g., certain types of leukemia) are too rare to analyze directly, (c) the exposures of concern are associated with a new technology or product, or (d) adverse effects may occur only after a long period (e.g., several decades) of exposure.

When direct real-world data on toxicity are unavailable or are inadequate, risk assessments may be performed based on data from toxicity experiments with rodents, since rats and mice have relatively short lifetimes and are relatively inexpensive to house and feed. Toxicity experiments involving rodents, although controversial to some, have three important advantages: (1) the doses, whether administered by injection, in feed or by inhalation, can be measured precisely, (2) different doses can be applied to different groups of rodents by experimental design, and (3) pathology can be performed on rodents to make precise counts of tumors and other adverse events.

When dose-response data are available from a rodent experiment, the assessor usually faces two critical extrapolation issues: how effects observed in rodents are relevant to people or wildlife and how effects observed at the high doses used in experiments are relevant to the low doses typically found in the environment. Techniques have been developed to perform such extrapolations and to portray the resulting uncertainty in risk estimates associated with extrapolation.

¹⁷ Monson, R, *Occupational Epidemiology, Second Edition*, CRC Press, Boca Raton, Florida, 1990.

¹⁸ Rodricks, JV, *Calculated Risks: The Toxicity and Human Health Risks of Chemicals in Our Environment*, Cambridge, University Press, New York, NY, 1992.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

Infectious Disease and Epidemic Modeling

Risk assessments of infectious agents pose special challenges since the rate of diffusion of an infectious agent may play a critical role in determining the occurrence and severity of an epidemic. Risk assessments of the spread of the HIV virus, and the resulting cases of AIDs, were complicated by the different modes of transmission (e.g., sexual behavior, needle exchange and blood transfusion) and the analyst's need to understand the relative size and degree of mixing of these populations.¹⁹ Scientific understanding of both biology and human behavior are critical to performing accurate risk assessments for infectious agents.

Failure Analysis of Physical Structures

One of the best known types of risk assessments addresses low-probability, high-consequence events associated with the failure of physical structures.²⁰ Since these events are exceedingly rare (e.g., bridge failure or a major core meltdown at a nuclear reactor), it may not be feasible to compute risks based on historic data alone. Engineers have developed alternative techniques (e.g., fault-tree analysis) that estimate both the probability of catastrophic events and the magnitude of the resulting damages to people, property and the environment. Such "probabilistic" risk assessments are now widely used in the development of safety systems for dams, nuclear and chemical plants, liquefied natural gas terminals, space shuttles and other physical structures.

Legal Authority

This Bulletin is issued under statutory authority and OMB's general authorities to oversee the quality of agency analyses, information and regulatory actions.

In the "Information Quality Act," Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Pub. L. No. 106-554, § 515(a). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information." Moreover, Section 624 of the Treasury and General Government Appropriations Act of 2001, often called the "Regulatory Right-to-Know Act," (Public Law 106-554, 31 U.S.C. § 1105 note) directs OMB to "issue guidelines to agencies to standardize . . . measures of costs and benefits" of Federal rules.

¹⁹ Turner, CF., et al., *AIDS: Sexual Behavior and Intravenous Drug Use*, National Research Council, Washington, D.C., 1989, pp. 471-499.

²⁰ Pate-Cornell, ME, *Uncertainties in Risk Analysis: Six Levels of Treatment*, Reliability Engineering and System Safety, vol. 54(2-3), 1996, pp. 95-111; Haimes, YY, *Risk Modeling, Assessment, and Management*, John Wiley and Sons, New York, New York, 1998.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), establishes that OIRA is “the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency,” and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order requires that “[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information.” E.O. 12866, § 1(b)(7). The Order also directs that “[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of risks posed by various substances or activities within its jurisdiction.” E.O. 12866, § 1(b)(4). Finally, OMB has additional authorities to oversee the agencies in the administration of their programs.

All of these authorities support this Bulletin.

The Requirements of This Bulletin

This bulletin addresses quality standards for risk assessments disseminated by federal agencies.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB’s government-wide information quality guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.

The term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

The term “agency” has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1).

The term “Information Quality Act” means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000)).

The term “risk assessment” means a scientific and/or technical 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. For the purposes of this Bulletin, this definition applies to documents that could be used for risk assessment purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment as defined by the National Research Council.²¹ This definition includes documents that evaluate baseline risk as well as risk mitigation activities.

²¹ National Research Council *Risk Assessment in the Federal Government: Managing the Process*, Washington DC: National Academy Press, 1983.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

The term “influential risk assessment” means a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The term “influential” should be interpreted consistently with OMB’s government-wide Information Quality Guidelines and the Information Quality Guidelines of the relevant agency. A risk assessment can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government’s characterization of the risks associated with the use of the technology. Alternatively, the federal government’s assessment of risk can directly or indirectly influence the regulatory actions of state and local agencies or international bodies.

Examples of “influential risk assessments” include, but are not limited to, assessments that determine the level of risk regarding health (such as reference doses, reference concentrations, and minimal risk levels), safety and environment. Documents that address some but not all aspects of risk assessment are covered by this Bulletin. Specific examples of such risk assessments include: margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as part of economically significant rulemakings. Documents falling within these categories are presumed to be influential for the purposes of this Bulletin.

The term “available to the public” covers documents that are made available to the public by the agency or that are required to be disclosed under the Freedom of Information Act, 5 U.S.C. § 552.

Section II: Applicability

Section II states that, *to the extent appropriate*, all publicly available agency risk assessments shall comply with the standards of this Bulletin. This statement recognizes that there may be situations in which it is not appropriate for a particular risk assessment to comport with one or more specific standards contained in this Bulletin, including the general standards in Section IV, which apply to both influential and non-influential risk assessments. A rule of reason should prevail in the appropriate application of the standards in this Bulletin. For example, in a screening-level risk assessment, the analyst may be seeking to define an upper limit on the unknown risk that is not likely to be exceeded. Screening-level assessments, in this situation, would not have to meet the standard of “neither minimizing nor exaggerating the nature and magnitude of risk.” On the other hand, it is expected that every risk assessment (even screening-level assessments) will comply with other standards in Section IV. For example, it is expected that every risk assessment shall describe the data, methods, and assumptions with a high degree of transparency; shall identify key scientific limitations and uncertainties; and shall place the risk in perspective/context with other risks familiar to the target audience. Similarly, every quantitative risk assessment should provide a range of plausible risk estimates, when there is scientific uncertainty or variability.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

This Bulletin does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings, unless the agency determines that: (1) compliance with the Bulletin is practical and appropriate and (2) the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities. This Bulletin also shall not apply to risk assessments performed with respect to inspections relating to health, safety, or environment.

This Bulletin also does not apply to any risk assessment performed with respect to an individual product label, or any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use. An example of this type of risk assessment includes risk assessments performed for labeling of individual pharmaceutical products. This Bulletin does apply to risk assessments performed with respect to classes of products. An example of this type of risk assessment is the risk assessment performed by FDA in their evaluation of the labeling for products containing trans-fatty acids.

Section III: Goals

For each covered risk assessment, this Bulletin lays out five aspirational goals.

1. Goals Related to Problem Formulation

As a risk assessment is prepared, risk assessors should engage in an iterative dialogue with the agency decision maker(s) who will use the assessment. There will be many choices regarding the objectives, scope, and content of the assessment, and an iterative dialogue will help ensure that the risk assessment serves its intended purpose and is developed in a cost-effective manner. For example, a risk manager may be interested in estimates of population and/or individual risk and an iterative dialogue would ideally bring this to the attention of a risk assessor early in the process.

2. Goals Related to Completeness

There is often a tension between the desire for completeness in the scientific sense and the desire for a well-defined scope that limits the inquiry to a set of practical, tractable, and relevant questions. The scope of an assessment should reflect a balance between the desire for scientific completeness and the need to provide relevant information to decision makers. The concept of considering the benefits and cost of acquiring further information (e.g., a broader scope or better data on a more narrow scope) is presented in the OMB Information Quality Guidelines, the OMB Information Quality Bulletin for Peer Review, and OMB Circular A-4.²²

²² US Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8452-8460 Feb. 22, 2002; US Office of Management and Budget, *Final Information Quality Bulletin for Peer Review*, 70 FR 2664-2677, Jan 14, 2005; and

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

3. Goals Related to Effort Expended

The level of effort should be commensurate with the importance of the risk assessment, taking into consideration the nature of the potential hazard, the available data, and the decision needs. For instance, if an agency is only interested in a screening-level assessment, then an assessment which explores alternative dose-response models may not be warranted.

4. Goals Related to Resources Expended

Agencies should take into account the importance of the risk assessment in gauging the resources, including time and money, required to meet the requirements of this Bulletin.²³

5. Goals Related to Peer Review and Public Participation

Agencies should consider appropriate procedures for peer review and public participation in the process of preparing the risk assessment. When a draft assessment is made publicly available for comment or peer review, the agency is required to clarify that the report does not represent the official views of the federal government. Precise disclaimer language is recommended in OMB's Information Quality Bulletin on Peer Review. Public comments can play an important role in helping to inform agency deliberations.²⁴ When people are engaged early in the process, the public typically has an easier time concurring with government documents and decisions which may affect them.²⁵

Section IV: General Risk Assessment and Reporting Standards

Each risk assessment disseminated by a Federal agency is subject to OMB's Information Quality Guidelines and the agency's Information Quality Guidelines. These guidelines require risk assessments to meet the three key attributes of utility, objectivity, and integrity.

US Office of Management and Budget, *Circular A-4*, Sept 2003 available at: <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

²³ See Risk Commission Report, Vol. 2, at 63 (“Deciding to go forward with a risk assessment is a risk management decision, and scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial.”); *id.*, at 21 (“The level of detail considered in a risk assessment and included in the risk characterization should be commensurate with the problem’s importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.”), 1997.

²⁴ Risk Commission Report, Vol. 2, at 21 (“Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns that they would like to see addressed.” *id.*, at 185, 1997.

²⁵ National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC: National Academy Press, 1996.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

This Bulletin identifies six standards that apply to both influential and non-influential risk assessments. An additional seventh standard is also presented for risk assessments that are likely to be used in regulatory analysis.

1. Standards Relating to Informational Needs and Objectives

A risk assessment should clearly state the informational needs driving the assessment as well as the objectives of the assessment. This simple requirement will ensure that readers and users are able to understand the questions the assessment sought to answer and will help to ensure that risk assessments are used for their intended purposes. This is particularly important in cases where likely users of the risk assessment are not the original intended audience for the document. For example, an explicit statement of the ranges of chemical doses for which the assessment is relevant will inform other users as to whether or not the assessment is relevant their purposes.

2. Standards Relating to Scope

Every risk assessment should clearly summarize the scope of the assessment. The statement of scope may necessitate policy judgments made by accountable policy officials and managers as well as analysts. The scope of some assessments may be highly discretionary while others may be rigidly determined or influenced by statutory requirements, court deadlines or scarcity of available agency resources. In cases where the scope of an assessment has been restricted primarily due to external considerations beyond the agency's control, policy makers and other participants in the process should be made aware of those complicating circumstances and the technical limitations they have introduced in the agency's work product.

To begin framing the scope of a risk assessment, the first step should be to specify and describe the agent, technology and/or activity that is the subject of the assessment. The next step entails describing the hazard of concern. In order for an assessment to be complete, the assessment must address all of the factors within the intended scope of the assessment. For example, a risk assessment informing a general regulatory decision as to whether exposure to a chemical should be reduced would not be constrained to a one-disease process (e.g., cancer) when valid and relevant information about other disease processes (e.g., neurological effects or reproductive effects) are of importance to decision making.

The third step in framing the scope of the assessment entails identifying the affected entities. Affected entities can include populations, subpopulations, individuals, natural resources, animals, plants or other entities. If a risk assessment is to address only specific subpopulations, the scope should be very clear about this limitation. An analytic product may be incomplete when it addresses only risks to adults when there is information suggesting that children are more exposed and/or more susceptible to adverse effects than are adults.

Once the affected entities are defined, the assessment should define the exposure or event scenarios relevant to the purpose of the assessment as well as the type of event-consequence or dose-response relationship for the exposure or event ranges that are relevant to the objectives of the risk assessment. Although scientific completeness may entail analysis of different health

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

effects and multiple target populations, the search for completeness will vary depending upon the nature of the assessment. In a fault-tree analysis of nuclear power accidents, an aspect of completeness may be whether pathways to accidents based on errors in human behavior have been addressed as well as pathways to accidents based on defects in engineering design or physical processes.

When agencies ask whether a particular chemical or technology causes or contributes to a particular disease, completeness in a scientific sense may entail consideration of evidence regarding the causative role of other factors in producing the disease of interest. For example, an assessment of radon exposure and lung cancer may need to consider the role of cigarette smoking as a potential confounding factor that influences the estimated risk of radon. Alternatively, the evidence on smoking may suggest that the risks of radon are larger for smokers than non-smokers, a so-called risk-modifying or synergistic factor. The scientific process of considering confounding and/or synergistic factors may assist policy makers in developing a broader sense of how risk can be reduced significantly and the range of decision options that need to be considered if maximum risk reduction is to be achieved.

3. Standards Related to Characterization of Risk

Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively.²⁶ When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.²⁷ Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates.

In the 1996 amendments to the Safe Drinking Water Act (SDWA), Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g- 1(b)(3)(B), the agency is directed “to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable.” The agency is further directed “in a document made available to the public in support of a regulation [to] specify, to the extent practicable— (i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and

²⁶ National Research Council, *Science and Judgment in Risk Assessment*, at 185, (“EPA should make uncertainties explicit and present them as accurately and fully as feasible and needed for risk management decision-making. To the greatest extent feasible, EPA should present quantitative, as opposed to qualitative, representations of uncertainty.”), Washington DC: National Academy Press, 1994.

²⁷ See Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making*, New York, NY, June 1993, at 87 (“Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates.”).

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

the methodology used to reconcile inconsistencies in the scientific data.’’ These SDWA quality standards should be met, where feasible, in all risk assessments which address adverse health effects.

4. Standards Related to Objectivity

Risk assessments must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risks. On a substantive level, objectivity ensures accurate, reliable and unbiased information. When determining whether a potential hazard exists, weight should be given to both positive and negative studies, in light of each study’s technical quality. The original and supporting data for the risk assessment must be generated, and the analytical results developed, using sound statistical and research methods.

Beyond the basic objectivity standards, risk assessments subject to this Bulletin should use the best available data and should be based on the weight of the available scientific evidence.²⁸ The requirement for using the best available scientific evidence was applied by Congress to risk information used and disseminated pursuant to the SDWA Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A)&(B)). Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed ‘‘to the degree that an agency action is based on science,’’ to use ‘‘(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).’’ Agencies have adopted or adapted this SDWA standard in their Information Quality Guidelines for risk assessments which analyze risks to human health, safety, and the environment. We are similarly requiring this as a general standard for all risk assessments subject to this Bulletin.

In addition to meeting substantive objectivity standards, risk assessments must be accurate, clear, complete and unbiased in the presentation of information about risk. The information must be presented in proper context. The agency also must identify the sources of the underlying information (consistent with confidentiality protections) and the supporting data and models, so that the public can judge for itself whether there may be some reason to question objectivity. Data should be accurately documented, and error sources affecting data quality should be identified and disclosed to users.

A risk assessment report should also have a high degree of transparency with respect to data, assumptions, and methods that have been considered. Transparency will increase the credibility

²⁸ Risk Commission Report, Vol. 1, at 38 (‘‘Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.’’) The Risk Commission Report provides examples of the kinds of considerations entailed in making judgments on the basis of the weight of the scientific evidence in a toxicity study: quality of the toxicity study; appropriateness of the toxicity study methods; consistency of results across studies; biological plausibility of statistical associations; and similarity of results to responses and effects in humans. Vol. 2 at 20,1997.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

of the risk assessment, and will allow interested individuals, internal and external to the agency, to understand better the technical basis of the assessment.

5. Standards Related to Critical Assumptions

Risk assessments should explain the basis of each critical assumption and those assumptions which affect the key findings of the risk assessment. If the assumption is supported by, or conflicts with, empirical data, that information should be discussed. This should include discussion of the range of scientific opinions regarding the likelihood of plausible alternate assumptions and the direction and magnitude of any resulting changes that might arise in the assessment due to changes in key assumptions. Whenever possible, a quantitative evaluation of reasonable alternative assumptions should be provided. If an assessment combines multiple assumptions, the basis and rationale for combining the assumptions should be clearly explained.

6. Standards Related to the Executive Summary

Every risk assessment should contain an executive summary which discloses the objectives and scope, the key findings of the assessment, and the key scientific limitations and uncertainties in the risk assessment. Presentation of this information in a helpful and concise introductory section of the report will not only foster improved communication of the findings, but will also help ensure that the risk assessment is appropriately utilized by diverse end users. Major limitations are those that are most likely to affect significantly the determinations and/or estimates of risk presented in the assessment.

The executive summary should also place the estimates of risk in context/perspective with other risks familiar to the target audience. Due care must be taken in making risk comparisons. Agencies might want to consult the risk communication literature when considering appropriate comparisons. Although the risk assessor has considerable latitude in making risk comparisons, the fundamental point is that risk should be placed in a context that is useful and relevant for the intended audience.²⁹

7. Standards Related to Regulatory Analysis

When a risk assessment is being produced to support or aid decision making related to regulatory analysis, there are additional standards that should be met. Risk assessors should consult OMB Circular A-4, which addresses requirements designed to improve the quality of regulatory impact analyses. For major rules involving annual economic effects of \$1 billion or more, a formal quantitative analysis of the relevant uncertainties about benefits and costs is required.³⁰ In this Bulletin, we highlight important aspects of risk assessments useful for regulatory analysis:

²⁹ National Research Council, *Improving Risk Communication*, Washington DC: National Academy Press, 1989, at 165-79; see also Risk Commission Report, Volume 1, at 4, One of the key recommendations of the Risk Commission Report was that the problems a regulation is intended to address should be placed in their “public health and ecological context.”, 1997.

³⁰ US Office of Management and Budget, *Circular A-4*, Sept, 2003, available at: <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

1) The scope of the risk assessment should include evaluation of alternative options, clearly establishing the baseline risk analysis and the risk reduction alternatives that will be evaluated. When relevant, knowledge of the hazard and anticipated countermeasures should be understood in order to accurately capture the baseline risk.

2) The risk assessment should include a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and describe, to the extent feasible, any significant countervailing risks caused by alternative mitigation measures.³¹

3) The risk assessment should include information on the timing of exposure and the onset of the adverse effect(s) as well as the timing of control measures and the reduction or cessation of adverse effects.

4) When estimates of individual risk are developed, estimates of population risk should also be developed. Estimates of population risk are necessary to compare the overall costs and benefits of regulatory alternatives.

5) When a quantitative characterization of risk is made available, this should include a range of plausible risk estimates, including central estimates. A “central estimate” of risk is the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution.³² The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk.³³

Section V: Special Standards for Influential Risk Assessments

In addition to the standards presented in section IV, all influential risk assessments should meet certain additional standards. When it is not appropriate for an influential risk assessment to adhere to one or more of the standards in this section of the Bulletin, the risk assessment should contain a rationale explaining why the standard(s) was (were) not met.

1. Standard for Reproducibility

Influential risk assessments should be capable of being substantially reproduced. As described in the OMB Information Quality Guidelines, this means that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of precision. Public access to original data is necessary to satisfy

³¹ Graham, J.D., Jonathan B. Wiener (eds), *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment*, Harvard University Press, Cambridge, MA, 1995.

³² See, e.g., Holloway, CA, *Decision Making Under Uncertainty: Models and Choices* (1979), at 76, 214, 91-127 Theodore Colton, *Statistics in Medicine* (1974), at 28-31.

³³ National Research Council, *Science and Judgment in Risk Assessment*, at 170-75, Washington DC: National Academy Press, 1994.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

this standard, though such access should respect confidentiality and other compelling considerations.³⁴ It is not necessary that the results of the risk assessment be reproduced. Rather, someone with the appropriate expertise should be able to substantially reproduce the results of the risk assessment, given the underlying data and a transparent description of the assumptions and methodology.

2. Standard for Comparison to Other Results

By definition, influential risk assessments have a significant impact. In such situations, it is appropriate for an agency to find and examine previously conducted risk assessments on the same topic, and compare these risk assessments to the agency risk assessment. A discussion of this comparison should be incorporated into the risk assessment.

3. Standard for Presentation of Numerical Estimates

When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks. Influential risk assessments should characterize uncertainty by highlighting central estimates as well high-end and low-end estimates of risk. The practice of highlighting only high-end or only low-end estimates of risk is discouraged.

This Bulletin uses the terms “central” and “expected” estimate synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using standard statistical tools. When model uncertainty is substantial, the central or expected estimate may be a weighted average of results from alternative models. Formal probability assessments supplied by qualified experts can help assessors obtain central or expected estimates of risk in the face of model uncertainty.³⁵

4. Standard for Characterizing Uncertainty

Influential risk assessments should characterize uncertainty with a sensitivity analysis and, where feasible, through use of a numeric distribution (e.g., likelihood distribution of risk for a given individual, exposure/event scenario, population, or subpopulation). Where appropriate,

³⁴ See US Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 FR 8456, (“However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.”) Feb. 22, 2002.

³⁵ National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, Washington, DC: National Academies Press, 2002; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; Evans, JS, JD Graham, GM Gray, RL Sielken, *A Distributional Approach to Characterizing Low-Dose Cancer Risk*, *Risk Analysis*, vol. 14(1), 1994, pp. 25-34; Hoffman, O, S Kaplan, *Beyond the Domain of Direct Observation: How to Specify a Probability Distribution that Represents the State-of-the-Knowledge About Uncertain Inputs*, *Risk Analysis*, vol. 19(1), 1999, pp. 131-134; Morgan, MG, M Henrion, M Small, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

this should include sufficient description so that the lower and upper percentiles and the median, mean, mode, and shape of the uncertainty distribution are apparent.

When one or more assumptions are used in a risk assessment, the assessor may evaluate how plausible changes in the assumptions influence the results of the assessment. An assumption may be used for a variety of reasons (e.g., to address a data gap or to justify the selection of a specific model or statistical procedure). Professional judgment is required to determine what range of assumptions is plausible enough to justify inclusion in the sensitivity analysis. Sensitivity analysis is particularly useful in pinpointing which assumptions are appropriate candidates for additional data collection to narrow the degree of uncertainty in the results. Sensitivity analysis is generally considered a minimum, necessary component of a quality risk assessment report.

A model is a mathematical representation -- usually a simplified one -- of reality. Where a risk can be plausibly characterized by alternative models, the difference between the results of the alternative models is model uncertainty. For example, when cancer risks observed at high doses of chemical exposure are extrapolated to low doses (i.e., doses below the range of empirical detection of cancer risk), a dose-response model must be employed to compute low-dose risks. Biological knowledge may be inadequate to predict the shape of the dose-response curve for cancer in the low-dose region. While it is common for risk assessors to use a model where cancer risk is proportional to dose (even at low doses), there are cases where it has been demonstrated, through huge epidemiological studies or detailed biologic data from the laboratory, that a non-linear dose-response shape is appropriate. When risk assessors face model uncertainty, they need to document and disclose the nature and degree of model uncertainty. This can be done by performing multiple assessments with different models and reporting the extent of the differences in results.³⁶ A weighted average of results from alternative models based on expert weightings may also be informative.³⁷

When the model used by assessors is well established, the central or expected estimate may be computed using classical statistics. When model uncertainty is substantial, the central or expected estimate may be a weighted average of the results from alternative models.³⁸ Judgmental probabilities supplied by scientific experts can help assessors obtain central or

³⁶ Holland, CH, RL Sielken, *Quantitative Cancer Modeling and Risk Assessment*, Prentice-Hall, Englewood Cliffs, New Jersey, 1993; Olin, S, W Farland, C Park, L Rhomberg, R Scheuplein, T Starr, J Wilson (eds), *Low-Dose Extrapolation of Cancer Risks: Issues and Perspectives*, International Life Sciences Institute, Washington, DC, 1995.

³⁷ Morgan, MG, M Henrion, M Small, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; National Research Council, *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, Washington, DC: National Academies Press, 2002.

³⁸ Clemen, RT, *Making Hard Decisions: An Introduction to Decision Analysis*, Second Edition, Duxbury Press, Pacific Grove, CA, 1996; Morgan, MG, M Henrion, M Small, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Hoffman, O, S Kaplan, *Beyond the Domain of Direct Observation: How to Specify a Probability Distribution that Represents the State-of-the-Knowledge About Uncertain Inputs*, *Risk Analysis*, vol. 19(1), 1999, pp. 131-134.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

expected estimates of risk in the face of model uncertainty.³⁹ Central or expected estimates of risk play an especially critical role in decision analysis and cost-benefit analysis.⁴⁰

Statistical uncertainty sometimes referred to as data uncertainty or parameter uncertainty occurs when some data exist on the value of an input, but the value of the input is not known with certainty. If a sample of data exists on an input, the degree of statistical uncertainty in the input value is influenced by the size of the sample and other factors. Risk assessors should document and disclose the nature and degree of statistical uncertainty.

5. *Standard for Characterizing Results*

Results based on different effects observed and/or different studies should be presented to convey how the choice of effect and/or study influences the assessment. Authors of the assessment have a special obligation to evaluate and discuss alternative theories, data, studies and assessments that suggest different or contrary results than are contained in the risk assessment. When relying on data from one study over others, the agency should discuss the scientific justification for its choice.

6. *Standard for Characterizing Variability*

A risk is variable when there are known differences in risk for different individuals, subpopulations, or ecosystems. In some cases variability in risk is described with a distribution. Where feasible, characterization of variability should include sufficient description of the variability distribution so that the lower and upper percentiles and the median, mean, and mode are apparent.⁴¹ This section should also disclose and evaluate the most influential contributors to variation in risk. This characterization should reflect the different affected populations (e.g., children or the elderly), time scales, geography, and other parameters relevant to the needs and objectives of the risk assessment. If highly exposed or sensitive subpopulations are highlighted, the assessment should also highlight the general population to portray the range of variability.⁴²

³⁹ Morgan, MG, M Henrion, M Small, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, Cambridge, UK, 1990; Cooke, RM, *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press, New York, NY, 1991; Evans, JS, JD Graham, GM Gray, RL Sielken, *A Distributional Approach to Characterizing Low-Dose Cancer Risk*, *Risk Analysis*, vol. 14(1), 1994, pp. 25-34.

⁴⁰ Pate-Cornell, ME, *Uncertainties in Risk Analysis: Six Levels of Treatment*, *Reliability Engineering and System Safety*, vol. 54(2-3), 1996, pp. 95-111; Clemen, RT, *Making Hard Decisions: An Introduction to Decision Analysis*, Second Edition, Duxbury Press, Pacific Grove, CA, 1996; Viscusi, WK, *Rational Risk Policy*, Clarendon Press, Oxford, UK, 1998.

⁴¹ Burmaster, DE, PD Anderson, *Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Analysis*, *Risk Analysis*, vol. 14(4), 1994, pp.477-481.

⁴² Cullen, AC, HC Frey, *Probabilistic Techniques in Exposure Assessment: A Handbook for Dealing with Variability and Uncertainty in Models and Inputs*, Plenum Press, New York, NY, 1999; Hattis, D, DE Burmaster, *Assessment of Variability and Uncertainty Distributions for Practical Risk Analyses*, *Risk Analysis*, vol. 14(5), 1994, pp.713-730; National Research Council, *Human Exposure for Airborne Pollutants: Advances and Opportunities*, Washington, DC: National Academies Press 1991.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

7. Standard for Characterizing Human Health Effects

Since the dictionary definition of "risk" refers to the possibility of an adverse consequence or adverse effect, it may be necessary for risk assessment reports to distinguish effects which are adverse from those which are non-adverse. Given that the capacity of science to detect effects is rapidly growing, sometimes faster than our ability to understand whether detected or predicted effects are adverse, the adversity determination is not always an obvious one.

Where human health effects are a concern, determination of which effects are adverse shall be specifically identified and justified based on the best available scientific information generally accepted in the relevant clinical and toxicological communities.

In chemical risk assessment, for example, measuring the concentration of a chemical metabolite in a target tissue of the body is not a demonstration of an adverse effect, though it may be a valid indicator of chemical exposure. Even the measurement of a biological event in the human body resulting from exposure to a specific chemical may not be a demonstration of an adverse effect. Adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges. In cases where qualified specialists disagree as to whether a measured effect is adverse or likely to be adverse, the extent of the differences in scientific opinion about adversity should be disclosed in the risk assessment report. In order to convey how the choice of the adverse effect influences a safety assessment, it is useful for the analyst to provide a graphical portrayal of different "safe levels" based on different effects observed in various experiments. If an unusual or mild effect is used in making the adverse-effect determination, the assessment should describe the ramifications of the effect and its degree of adversity compared to adverse effects that are better understood and commonly used in safety assessment.

Although the language in this section explicitly addresses human health endpoints, for other endpoints, such as ecological health, it is expected that the agency would rely upon information from a relevant group of experts, such as ecologists or habitat biologists, when making determinations regarding adversity of effects.

8. Standard for Discussing Scientific Limitations

Influential risk assessments should, to the extent possible, provide a discussion regarding the nature, difficulty, feasibility, cost and time associated with undertaking research to resolve a report's key scientific limitations and uncertainties.

9. Standard for Addressing Significant Comments

An agency is expected to consider all of the significant comments received on a draft influential risk assessment report. Scientific comments shall be presumed to be significant. In order to ensure that agency staff is rigorous in considering each significant comment, it is typically useful to prepare a "response-to-comment" document, to be issued with, or as part of,

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

the final assessment report, to summarize the significant comments and the agency's responses to those comments. Agency responses may range from revisions to the draft report or an acknowledgement that the agency has taken a different position than the one suggested by the commenter. Where agencies take different positions than commenters, the agency response to comments should provide an explicit rationale for why the agency has not adopted the position suggested by the commenter (e.g., why the agency position is preferable or defensible).

Section VI: Updates

Influential risk assessments should provide information or analysis, within the intended scope of the assessment, which assists policy makers in determining whether more data needs to be gathered or whether the assessment can be based on the data and assumptions currently available. Since risk assessment is typically an iterative process, with risk estimates subject to refinement as additional data are gathered, it is useful for assessments to disclose how fast the relevant database and assumptions are evolving and how likely it is that the database and assumptions will be significantly different within several months or years. While risk assessments should offer insight into what additional scientific understanding might be achieved through additional data collection and/or analysis, the decisions about whether to invest in additional inquiry, whether to take interim protective steps while additional inquiry is underway, or whether to act promptly without additional inquiry are policy decisions that are beyond the scope of the risk assessment report.

Each agency should, taking into account the resources available, priorities, and the importance of the document, consider revising its influential risk assessments as relevant and scientifically plausible information becomes available. Each agency should (1) have procedures in place that would ensure it is aware of new, relevant information that might alter a previously conducted influential risk assessment, and (2) have procedures in place to ensure that this new, relevant information is considered in the context of a decision to revise its previously conducted assessment. In addition, as relevant and scientifically plausible information becomes available, each agency shall consider updating or replacing its assumptions to reflect new data or scientific understandings.⁴³

Section VII: Certification

For each risk assessment subject to this Bulletin, the agency shall include a certification, as part of the risk assessment document, explaining that the agency has complied with the

⁴³ See National Research Council, *Science and Judgment in Risk Assessment*, at 90, Washington DC: National Academy Press, 1994, (“Over time, the choice of defaults should have decreasing impact on regulatory decision-making. As scientific knowledge increases, uncertainty diminishes. Better data and increased understanding of biological mechanisms should enable risk assessments that are less dependent on default assumptions and more accurate as predictions of human risk.”); Risk Commission Report, Volume 2, at iv (“Agencies should continue to move away from the hypothetical . . . toward more realistic assumptions based on available scientific data.”), 1997.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

requirements of this Bulletin and the applicable Information Quality Guidelines, except as provided in Section VIII.

Section VIII: Deferral and Waiver

The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale. In each such instance, the agency shall include a statement in the risk assessment document that the agency is exercising a deferral or waiver as well as a brief explanation for the deferral or waiver. If the agency head defers the risk assessment requirements prior to dissemination, the risk assessment requirements shall be complied with as soon as practicable. A compelling rationale might cover health and safety risk assessments which are time-sensitive or need to be released due to an emergency situation. It is expected that a need for such a deferral would be an infrequent event. In the rare case of a time-sensitive necessary release, a complete risk assessment, which meets the standards set out in this Bulletin, should be provided to the public as soon as is practicable.

Section IX: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of this Bulletin. OIRA and OSTP shall foster learning about risk assessment practices across agencies.

Section X: Effective Date

The requirements of this Bulletin apply to: (1) final public risk assessments disseminated after 12 months following the publication of this Bulletin in final form, and (2) draft risk assessments disseminated after six months following the publication of this Bulletin in final form. These dates are necessary to ensure Federal agencies have sufficient time to both (1) become familiar with these standards and (2) incorporate these standards into ongoing risk assessments.

Section XI: Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.



RISK ASSESSMENT BULLETIN

I. Definitions.

For purposes of this Bulletin, the term—

1. “agency” has the same meaning as the Paperwork Reduction Act, 44 U.S.C. § 3502(1);
2. “influential risk assessment” means a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions;
3. “risk assessment” means a scientific and/or technical 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.

II. Applicability.

1. To the extent ~~appropriate~~, all agency risk assessments available to the public shall comply with the standards of this Bulletin.
2. This Bulletin does not apply to risk assessments performed with respect to:
 - a. inspections relating to health, safety, or environment;
 - b. individual agency adjudications or permit proceedings (including a registration, approval, or licensing) unless the agency determines that
 - i. compliance with this Bulletin is practical and appropriate and
 - ii. the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings; and
 - c. an individual product label, or a risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use.

III. Goals.

1. The objectives of the assessment shall be a product of an iterative dialogue between the assessor(s) and the agency decisionmaker(s).
2. The scope and content of the risk assessment shall be determined based on the objectives of the assessment and best professional judgment, considering the benefits and costs of acquiring additional information before undertaking the assessment.
3. The type of risk assessment prepared shall be responsive to the nature of the potential ~~hazard~~, the available data, and the decision needs.
4. The level of effort put into the risk assessment shall be commensurate with the importance of the risk assessment.
5. The agency shall follow appropriate procedures for peer review and public participation in the process of preparing the risk assessment.

IV. General Risk Assessment and Reporting Standards.

Each agency risk assessment shall:

1. Provide a clear statement of the informational needs of decision makers, including the objectives of the risk assessment.
2. Clearly summarize the scope of the assessment, including a description of:
 - a. the agent, technology and/or activity that is the subject of the assessment;

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

- b. the hazard of concern;
- c. the affected entities (population(s), subpopulation(s), individuals, natural resources, ecosystems, or other) that are the subject of the assessment;
- d. the exposure/event scenarios relevant to the objectives of the assessment; and
- e. the type of event-consequence or dose-response relationship for the hazard of concern.

3. Provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates shall be provided.

- 4. Be scientifically objective:
 - a. as a matter of substance, neither minimizing nor exaggerating the nature and magnitude of risks;
 - b. giving weight to both positive and negative studies in light of each study's technical quality; and
 - c. as a matter of presentation:
 - i. presenting the information about risk in an accurate, clear, complete and unbiased manner; and
 - ii. describing the data, methods, and assumptions used in the assessment with a high degree of transparency.

5. For critical assumptions in the assessment, whenever possible, include a quantitative evaluation of reasonable alternative assumptions and their implications for the key findings of the assessment.

- 6. Provide an executive summary including:
 - a. key elements of the assessment's objectives and scope;
 - b. key findings;
 - c. key scientific limitations and uncertainties and, whenever possible, their quantitative implications; and
 - d. information that places the risk in context/perspective with other risks familiar to the target audience.


7. For risk assessments that will be used for regulatory analysis, the risk assessment also shall include:

- a. an evaluation of alternative options, clearly establishing the baseline risk as well as the risk reduction alternatives that will be evaluated;
- b. a comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered, and assess, to the extent feasible, countervailing risks caused by alternative mitigation measures;
- c. information on the timing of exposure and the onset of the adverse effect(s), as well as the timing of control measures and the reduction or cessation of adverse effects;
- d. estimates of population risk when estimates of individual risk are developed; and
- e. whenever possible, a range of plausible risk estimates, including central or expected estimates, when a quantitative characterization of risk is made available.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

V. Special Standards for Influential Risk Assessments.

All influential agency risk assessments shall:

1. Be “capable of being substantially reproduced” as defined in the OMB Information Quality Guidelines.
2. Compare the results of the assessment to other results published on the same topic from qualified scientific organizations.
3. Highlight central estimates as well as high-end and low-end estimates of risk when such estimates are uncertain.
4. Characterize uncertainty with respect to the major findings of the assessment including:
 - a. document and disclose the nature and quantitative implications of model uncertainty, and the relative plausibility of different models based on scientific judgment; and where feasible:
 - b. include a sensitivity analysis; and
 - c. provide a quantitative distribution of the uncertainty.
5. Portray results based on different effects observed and/or different studies to convey how the choice of effect and/or study influences the assessment.
6. Characterize, to the extent feasible, variability through a quantitative distribution, reflecting different affected population(s), time scales, geography, or other parameters relevant to the needs and objectives of the assessment.
7. Where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified based on the best available scientific information ~~generally accepted in the relevant clinical and toxicological communities.~~ 
8. Provide discussion, to the extent possible, of the nature, difficulty, feasibility, cost and time associated with undertaking research to resolve a report's key scientific limitations and uncertainties.
9. Consider all significant comments received on a draft risk assessment report and:
 - a. issue a "response-to-comment" document that summarizes the significant comments received and the agency's responses to those comments; and
 - b. provide a rationale for why the agency has not adopted the position suggested by commenters and why the agency position is preferable.

VI. Updates.

As relevant and scientifically plausible information becomes available, each agency shall, considering the resources available, consider:

1. revising its risk assessment to incorporate such information; and
2. updating or replacing its assumptions to reflect new data or scientific understandings.

VII. Certification.

For each risk assessment subject to this Bulletin, the agency shall include a certification explaining that the agency has complied with the requirements of this Bulletin and the applicable Information Quality Guidelines, except as provided in Section VIII.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.

VIII. Deferral and Waiver.

The agency head may waive or defer some or all of the requirements of this Bulletin where warranted by compelling rationale. In each such instance, the agency shall include a statement in the risk assessment document that the agency is exercising a deferral or waiver as well as a brief explanation for the deferral or waiver. If the agency head defers the requirements prior to dissemination, the agency shall comply with them as soon as practicable.

IX. OIRA and OSTP Responsibilities.

OIRA, in consultation with OSTP, shall be responsible for overseeing agency implementation of this Bulletin. OIRA and OSTP shall foster better understanding about risk assessment practices and assess progress in implementing this Bulletin.

X. Effective Date.

The requirements of this Bulletin apply to: (1) final public risk assessments disseminated after twelve months following the publication of this Bulletin in final form, and (2) draft risk assessments disseminated after six months following the publication of this Bulletin in final form.

XI. Judicial Review.

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

This proposed bulletin is being released for peer review and public comment. It should not be construed to represent the official policy of the U.S. Office of Management and Budget.