

Comments on the Office of Management and Budget's Proposed Risk Assessment Bulletin – Minnesota Department of Health

The Minnesota Department of Health (MDH) commends the Office of Management and Budget's (OMB) efforts to standardize and increase the quality of risk assessments produced by federal agencies. MDH understands and supports the concept of using the highest quality data in the regulatory arena. However, given the likelihood that OMB's Risk Assessment Bulletin (Bulletin) will not only affect the efforts of federal agencies, but will have impacts on state and local agencies as well, the general nature of the guidance and the proposed incorporation of changes to traditional risk assessment approaches raises a number of concerns for MDH. Although these concerns are addressed below, MDH emphasizes that each of the following comments are offered with apprehension regarding the Bulletin's potential impacts on the ability of agencies at all levels to carry out activities to protect the public's health.

General Comments:

The Minnesota Department of Health (MDH), like many other state agencies, has relied heavily on the information made available by federal agencies such as the U.S. EPA and the ATSDR for the development and promulgation of health based values used in the control of water and air contaminants in Minnesota. This dependence exists because, like most state agencies, MDH simply does not have the resources available to carry out the development of this information on its own. An added benefit of using this information is that the peer-reviewed products of these agencies have been widely accepted by the risk assessment community. Despite the good intentions of OMB's proposed Bulletin, MDH is concerned that an unintended consequence of the bulletin (particularly the OMB's redefinition of what constitutes a risk assessment) will be a dramatic slow-down of information made available to the states by federal agencies. The MDH is also concerned about the potential for these guidelines to inhibit the ability of federal agencies to share components of risk assessments (such as dose response evaluation or exposure analysis) as they are being developed.

An additional general concern is that, although the stated intent of the bulletin is to direct federal agencies with regulatory roles, there may be attempts by the regulated community to use many components of these guidelines to slow the regulatory process at the state level. Such an impact could have serious public health consequences because many states have limited resources for their risk assessment and rule making efforts, and slowing or impeding these processes would deny state agencies the necessary tools to carry out their public health protection duties.

Specific Comments:

In addition to the general concerns presented above, MDH has concerns with specific parts of the draft Bulletin.

The Bulletin defines a risk assessment as “a scientific and or technical document that assembles and synthesizes scientific information (page 23, I., Definitions).” It goes on to state in the supplementary information that this definition is intended to include “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.” MDH contends that this is inappropriate since these documents would be subject to the Bulletin’s guidance if or when they were used “for risk assessments purposes.” Perhaps this redefinition would be easier to understand if the OMB would clearly explain the intent of this proposed deviation from National Research Council guidance.

In addition, the Bulletin (again in the supplementary information) provides examples of influential risk assessments as “margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments that support EPA National Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTO substance profiles, NIOSH current intelligence bulletins and criteria documents” Such a redefinition of what have traditionally been considered to be components of a risk assessment as individual risk assessments (eg., hazard IDs, exposure assessment, etc.) will have significant impacts on what have served as primary sources of information for states. Health-based values produced by these agencies in the form of RfD/RfCs, MRLs, etc., while of high quality, are generated slowly. Of the tens of thousands of chemicals that are used in commerce or that occur as pollutants, only hundreds have had health protective values developed for them. The MDH is concerned that imposing additional burdens in the name of “information quality” can only slow the rate of production of these numbers – without a significant gain for the state level end-users of the values.

Many of the comments that follow are based on the assumption that the OMB will continue to both define individual components of a risk assessment (hazard identification, dose response analysis, RfDs, RfCs. MRLs, etc.) and to define products of the U.S. EPA’s IRIS database, ATSDR toxicological profiles, NTP substance profiles, etc. as influential risk assessments.

- 1) Under goals (page 23, III. 1) the risk assessment is appropriately described as an activity that is conducted at the discretion of the assessor and the agency decision-maker, yet much of what follows is heavily prescriptive.
- 2) In Part IV., 2, d. – again it is hard to see how IRIS values fit within the “exposure/event scenarios....”
- 3) By directing risk assessors to include a range of plausible risk estimates (and the limitations associated with these estimates) in their assessments and discouraging the “practice of highlighting” high end estimates of risk, the Bulletin (IV., 3) is proposing a move away from the traditional approach of providing upper bound point estimates of risks for risk assessments. The Bulletin also states that influential risk assessments

shall “highlight the central estimates as well as high end and low end estimates of risk when such estimates are uncertain” (V., 3). This is a marked departure from the way public health and environmental agencies have traditionally expressed risks. Because agencies such as MDH are committed to protecting the most sensitive portion of a population and to assuring that risks are not underestimated, most agencies will attempt to protect at the 95th or the 99th percentile. While a central or expected estimate of risk may typically provide a more accurate risk estimate and an adequate level of protection for the general population, prudent public health policy dictates, that in the face of uncertainty, caution needs to be used to protect vulnerable portions of the population.

4) The Bulletin suggests/requires the inclusion of estimates of baseline or background risks in risk assessments (IV., 7a). Attempts to establish baseline or background risks that result from environmental exposures are a good idea and would likely provide valuable information for risk managers as they make their decisions. However, including personal risks based on behavior is problematic. Public health practitioners are always cautious about comparing risks. Risk perception is value-laden and can vary markedly in any given group of people. Using information such as smoking rates to assess baseline or background risks such as radon in risk assessments is using a questionable technique of comparing risks from voluntary behavior to involuntary exposures – certain to increase outrage in at least a portion of the exposed population. A cynical observer might suggest that, if the proportion of smokers is high, there might be no need to worry about ambient air because the risk from smoking would greatly exceed the risk from breathing most contaminants in ambient air.

5) The inclusion of reasonable or plausible alternatives for major proposals and a discussion of why they weren’t selected (IV., 7, e.) is an important function of risk-based decisions, that is risk management. A risk assessor may be instructed by a risk manager to conduct risk assessments on multiple alternatives. Requiring this of all risk assessments rather than on a case-by-case basis ventures into the area of risk management rather than risk assessment and will provide still another opportunity for delay. The OMB should incorporate some flexibility in this requirement and provide criteria for determining whether or not it is indeed necessary to include this information. By requiring that a risk assessment contain a quantitative evaluation of reasonable alternative assumptions the Bulletin will likely increase the time it takes to complete a project and forestall the communication of potential risks to individuals that are faced with increased levels of exposure to chemicals.

6) The requirements for an uncertainty characterization, including a model sensitivity analysis and a quantitative distribution of uncertainty, will provide for a more transparent process – a good thing – but will also add to the length of time required to conduct an assessment. The need for these steps should be determined on a case-by-case basis. The concern is that it also provides additional opportunity for questions regarding the professional or scientific judgment of the risk assessor.

7) The proposal for the use of a weight of evidence approach that would include both positive and negative information if they are of sufficient quality will place an additional burden on the risk assessor and likely slow the process. In fact, a good dose response assessment and a good exposure evaluation do need to consider all available data and the exercise of judgment when both positive and negative data are available.

8) While the notion that there should be more interaction between the risk assessor and the risk manager, especially during the scoping portion of a risk assessment, has merit, it is not clear how this can happen with the new OMB definition of risk assessment. Traditional hazard assessments conducted by the NTP and safety assessments (RfDs, RfCs, MRLs) conducted by the U.S. EPA and ATSDR don't have risk managers. The bulletin has defined the information provided by these agencies as examples of influential risk assessments but individuals not traditionally identified as risk managers (i.e., clinicians and public health practitioners) use them for purposes other than formal risk assessments e.g., specific applications or immediate use in managing exposures.

9) New requirements that agencies "consider all of the significant (scientific) comments" and "provide explicit rationale for why the agency has not adopted the position suggested by the commenter" will add to the time it takes to develop a response-to-comments document. While scientific scrutiny is an important part of risk assessments, these requirements seem to provide an opportunity to slow the risk assessment process by allowing controversies regarding scientific judgment to be created.

10) While the term adversity is not defined in the bulletin, the definition provided in the supplementary information section is one that has been previously used but is limited, particularly with the tremendous advances currently being made in fields like molecular biology and molecular epidemiology. Narrowing the definition of adversity is counterintuitive to the OMB's objective of providing for risk assessments that are data driven and scientifically sound. It seems likely that without the push provided by a potential for practical application of information such as that generated by such promising areas toxicogenomics, a major incentive for new development of new research tools will be removed. It is also likely that requiring the discussion of "the extent of differences in scientific opinion about adversity" will formally open the risk assessment to extended and perhaps irresolvable discussions of the appropriateness of the assessor's professional or scientific judgment.

11) V., 2. Who are the "qualified scientific organizations" referred to. OMB will need to establish qualifying criteria.

12) The Bulletin seems to place a great deal of importance on the risk manager as the "decision maker" and considers risk assessment simply a tool for risk management rather than something that really drives the process. In fact, a number of the issues dealt with in the Bulletin seem to be addressing problems with risk management and

not necessarily risk assessment. This suggests that it is not that the risk assessment process that needs to be drastically modified, but that risk managers and the public need to have a better understanding of what current risk assessments are and what they are not. Given this, perhaps OMB should consider developing additional guidance for risk managers to consider when evaluating risk assessments.

13) Finally, given the likelihood that adherence to the guidance provided by the Bulletin will increase both the time and cost of conducting risk assessments, perhaps it would be advisable to conduct a benefit cost analysis of the proposed guidelines themselves. Will the added information provided to the risk manager (or the end user) benefit the decision making process sufficiently to outweigh the additional costs that seem inevitable? Again this is particularly important if the Bulletin continues to both define individual components of a risk assessment (hazard identification, dose response analysis, RfDs, RfCs, MRLs, etc.) and to define products of the U.S. EPA's IRIS database, ATSDR toxicological profiles, NTP substance profiles, etc. as influential risk assessments.

MDH congratulates the OMB on having described good risk assessment practice. The MDH understands the desire to increase the quality of risk assessments and thereby increase their value to risk managers. However, the MDH is concerned that the Bulletin, as written, will result in a reduction of the frequency of risk assessments and leave the public facing potentially greater levels of risk because the information needed to aid in the decisions of risk managers is lacking. In addition, it is worrisome that the Bulletin in its current version is too general. The development of the final Bulletin and guidance on how to use the Bulletin in a way that doesn't impede information flow will be critical to states that rely on federal agencies for information used in protecting the public's health.