

June 15, 2006

Office of Information and Regulatory Affairs
Office of Management and Budget

RE: Public Comments on the Proposed Risk Assessment Bulletin

Dear Sir or Madam:

I am writing this letter in response to the request for public comments on the risk assessment bulletin that has been recently proposed by the OMB. While I believe that there is a continuing need to improve the risk assessment procedures in the Federal Government, I have a number of concerns about the current proposal. Primarily, I am concerned that the proposed guidelines will create data requirements and set standards that are sufficiently high as to impede and unnecessarily delay the assessment of risks of important environmental and occupational chemicals. Since these higher standards are not attached to additional funding or legislation that will generate the necessary high quality data, for many chemicals, the assessment and re-assessment of these agents is likely to grind to a halt or else proceed very slowly. This may be a cost-saving measure for some stakeholders but may also result in substantially increased costs in terms of human health and environmental degradation. As a result, I believe that increased data requirements should be complemented by increased funding and/or legislation that will permit the generation of the necessary data. Additional comments on the proposed bulletin are outlined below:

- 1) Risk assessment has primarily been considered a scientific process whereas risk management is largely a political process. In proposing this bulletin, the OMB – a management and budgetary office – is proposing to shape and establish standards for a scientific process. Because of the encompassing nature of the bulletin, I believe that the proposed bulletin should undergo a detailed scientific review by an expert panel convened by an independent authoritative organization such as the National Academies of Science.
- 2) I believe that the stated requirement for peer-reviewed science and supporting studies while superficially sounding acceptable is unnecessarily limiting. The goal should be to use the best available scientific studies and information. While peer review is one method for helping to ensure that the data is of high quality, it should not be a strict requirement. For example, consensus documents such as the chemical and technical monographs produced by the International Agency for Research on Cancer (IARC) or other authoritative bodies are not technically peer-reviewed and would not be allowable under a strict interpretation of the current guidelines. I believe that information from such documents (such as the IARC Monographs on the Evaluation of Chemical Risks to Humans) is very valuable and should be included in the risk assessment process.
- 3) The requirement for an agency to present the results from multiple assessments using different results, while useful for showing the range of possible outcomes, will likely make the assessment of risks more difficult to perform and unnecessarily complicate the process. I believe that only the results of the most highly recommended or a select number of recommended models should be included in the primary presentation of the risk

assessment results. The presentation of other models, if justified, should not be included in the key results and summary recommendation sections.

4) I believe that the statement that “Adversity typically implies some functional impairment or pathological lesion that affects the performance of the whole organism or reduces and organism’s ability to withstand or respond to additional environmental challenges.” is unduly narrow. I believe that most toxicologists as well as the general public would consider certain biochemical or genetic effects to be adverse even though they are not directly connected to functional impairment or pathological lesion. For example, I would consider certain genetic alterations such as increases in chromosomal aberrations in peripheral blood lymphocytes as undesirable and adverse even though there is no obvious or immediate functional impairment associated with their presence. In the case of structural chromosomal aberrations, individuals exhibiting elevated levels of these aberrations have been shown in prospective studies to have an elevated risk of developing cancer in the future. Similarly the measurement of plasma cholinesterase can be quite valuable for establishing reference doses of a chemical even though decreases in plasma cholinesterase are not directly associated with functional impairment.

5) I am also concerned that the proposed limitation on the types of measured effects that can be considered adverse will limit the use of biomarker or precursor lesion data in the risk assessment process. It would also appear to be contrary to the spirit of the new 2005 EPA Cancer Risk Assessment Guidelines, which allow and encourage the use of precursor lesion data to inform mode of action decisions and contribute to other steps in the overall risk assessment process.

I hope that these comments will assist you as you work to improve the proposed risk assessment bulletin. Thank you for your efforts to improve the risk assessment process.

Sincerely,

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