



15 June 2006

Via email to OMB_RAbulletin@omb.eop.gov

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th St., NW
New Executive Office Building, Room 10201
Washington, DC 20503

Re: Comments on OMB's Proposed Risk Assessment Bulletin, 71 FR 2600.

Dear Dr. Beck:

Rio Tinto Minerals is an international company with significant U.S. mining and processing operations in California, Montana, Vermont, and Texas. Rio Tinto Minerals (RTM) prides itself on safe and environmentally responsible operations and products and on our expertise to assist our customers in their operations and products. RTM is a leading producer of borates and talcs, marketed as the 20-Mule Team Borax[®] and Luzenac[®] talc brands. RTM also must understand and comply with governmental regulations and therefore welcomes the opportunity to comment on the Office of Management and Budget (OMB) proposed Risk Assessment Bulletin.

1. Improving risk assessment is a valuable goal.

OMB is to be commended for seeking to improve the quality of risk assessments used in the Federal government. Risk assessments have become common among regulatory agencies, but RTM shares a concern that the overall quality, clarity and consistency can be improved. Improvements would benefit both agencies and the public.

2. The proposal will not require excessive work for the agencies.

Although improvement to risk assessment quality is desirable, RTM observes that several US agencies have policies and practices in place that demonstrate excellent quality and clarity and would likely be able to comply with the OMB proposal with minimal effort. This was echoed by several agency staff members who spoke at the Society for Risk Analysis workshop in May. In direct response to a comment that compliance with the proposal might cause excessive delays and require extensive new resources, people from several agencies stated that they felt their agency had already achieved most of the practices called for by OMB and could meet the requirements without significant additional costs.

3. The OMB proposal encourages flexibility.

The OMB proposal is quite brief, four pages to be exact, with another 22 pages of introductory material. We commend OMB for taking such an approach because it provides flexibility for agencies to elaborate their own frameworks within their legislative mandates and regulatory programs. We urge OMB to resist calls to be extensively prescriptive and to write guidance documents that run into the hundreds of pages – it seems logical that individual agencies prepare their own guidance documents. We note, for example the US Environmental Protection Agency’s “Handbook on Risk Characterization” prepared by their Science Policy Council,¹ as an illustration of a guidance document that echoes most of the themes presented by the OMB proposal. Such documents provide OMB, the agency and the public with a valuable tool.

4. There are precedents for generic management standards, similar to the concisely-stated OMB proposal, and they are successful.

OMB might find an analogous situation in the ISO 9000 and 14000 standards being used to evaluate quality and environmental management systems. These standards, prepared by the International Organization for Standardization (ISO), are “generic” standards which means that they can be applied by any organization, large or small, whatever its product or service. Generic management system standards have a number of essential features, but do not specify the detailed requirements for a particular product, service or activity. The organization seeking to meet the generic standard must provide the details. Certification to the ISO standard requires demonstrating to an external party (an auditor) that the essential components are present and that the organization is acting in accordance with the detailed requirements it has set for itself. RTM and thousands of other companies have been certified to ISO 9001 and ISO 14001 standards.

The critical point is that there is already a well-established precedent for the approach taken by OMB in proposing a brief framework for management of risk assessment in Federal agencies. The ISO 9000 and 14000 standards are implemented by some 760,900 organizations in 154 countries, clearly indicating that this is a successful approach. By proposing a generic standard, OMB can describe what the target, a high-quality risk assessment, is like, but the agencies can apply their own expertise and experience to translate that target into meaningful practice. This is a workable approach.

5. The proposal recognizes the differing levels of detail needed for different risk assessments.

The OMB proposal states a principle of proportionality or rule of reason in the appropriate application of the standards. RTM supports these concepts and suggests that the frameworks developed by agencies are an appropriate tool to expand on how an agency would distinguish between its simpler and its more complex risk assessments.

6. To encourage consistency, few agency actions, if any, should be excluded from the proposal, and the proposal would benefit from clarification regarding excluded actions.

¹ US EPA Science Policy Council. Handbook on Risk Characterization. EPA 100-B-00-002, December 2000.

The proposal is unclear about when agencies are not obligated to act in compliance with OMB guidance. In section II.2.b of the Bulletin, individual agency adjudications or permit proceedings (including a registration, approval, or licensing) are excluded from the Bulletin requirements. Would this include, for example, a pesticide registration by an applicant to EPA under the routine proceedings of FIFRA? Or to a human drug review by FDA? These are specific approvals that would seem to be the meat-and-potatoes instances where agencies use risk assessment to evaluate products used by the public.

The distinction of “influential” risk assessments seems also unclear. Page 9 provides some examples of “influential” risk assessments. Review of pesticide registrations typically includes development of reference dose or reference concentration estimates, implying that all pesticide registrations would be “influential” risk assessments. But if these are considered individual permit proceedings, it appears they might be excluded from all obligations.

A number of Agency assessment documents are procedural and the proposal is unclear about how these would be considered. For example, would procedures to designate new substances as hazardous air pollutants or hazardous wastes be considered “influential”? Such documents, often issued as “guidance” are extremely influential as they direct the nature of subsequent risk assessments. These documents often include case studies that illustrate application of the preferred risk assessment procedures. OMB should explicitly include such documents within the scope of the Bulletin – these provide extensive insight into how an agency will implement both the OMB risk assessment guidance and the data quality guidance.

The stated goal of the OMB proposal (improve the quality, utility and integrity of information disseminated by the federal government to the public) will not be served if exclusions apply to such actions. OMB has significantly broadened what it considers “risk assessment” for purposes of the Bulletin. To be consistent with this intent, it should not encourage blanket exclusions of procedural guidance documents nor of the more routine actions that evaluate product registrations and approvals.

7. Problem Formulation should go beyond iterative dialogue within an agency.

The Bulletin itself (section III.1) limits the goals related to Problem Formulation to the need for an iterative dialogue regarding the objective of the assessment. The preamble text (p. 10) makes iterative dialogue the single goal. This is problematic.

OMB could improve this section by better emphasis on the appropriate goals of problem formulation: to make clear choices regarding the objectives, scope and content of the assessment, to clarify the intended purpose(s) of the risk assessment, and to identify the scenarios or alternatives that will be evaluated within the resources available.

Problem formulation was introduced as a separate part of the risk assessment during development of ecological risk assessment procedures and was not part of the original NAS structure in 1983. The ecological risk assessment needs initial decisions about what ecological endpoints to consider (hazard identification), which conceptual models of

ecosystems to use (exposure patterns) and how to analyze the data.² The need for planning and scoping in human health risk assessments was recognized as planners worked with the 1983 NAS structure. However there is less need to decide about endpoints for human health, or which conceptual models to use.

Problem formulation is also recognized as an opportunity to encourage early involvement of stakeholders. While engaging stakeholders may not be necessary for every agency risk assessment, it should be noted as an aspirational goal. Knowing the needs of the larger audience has been found to be a very useful component of the acceptance and utility of risk assessments. The Bulletin encourages public engagement early in the process when discussing Goals related to Peer Review and Public Participation. This is probably done most efficiently during the Problem Formulation phase. If the public is invited to participate only after the document is fully written, then it may be perceived that the agency only wants public endorsement, not public engagement.

Iterative dialogue between the risk assessor and the agency decision-makers is only one possible mechanism to achieve the goals of problem formulation. It may not be adequate to improve the quality of many risk assessments. RTM suggests that this goal be reworded to encourage focus on the goals of problem formulation and similar attention be paid to the wording of the goal regarding public participation.

8. Obligations to “neither minimize nor exaggerate” the results should apply to all risk assessments.

The basic OMB position, stated in section IV.4.a of the Bulletin, that scientific objectivity requires neither maximizing nor minimizing the nature and magnitude of risks, is entirely appropriate. Consequently, the discussion of screening-level assessments (p.9) is problematic because it excuses such activities from this obligation. That section appears to provide unnecessary license for analysts to apply extreme scenarios to screening level assessments. Some time ago, “worst-case” scenarios were the routine approach to screening assessments. These became increasingly exaggerated, as creative analysts found ways to incorporate the most severe and extreme situations imaginable. This has been supplanted by what may be termed the “reasonable-worst-case.” The mechanisms built into most screening assessment procedures do not require distorting the nature and magnitude of risk. OMB does not need to depart from the sound instruction regarding minimizing or exaggerating risk. The example on p. 9 should be reworded to suggest that screening assessments provide ranges of risk estimates consistent with the use of conservative assumptions.

9. The use of comparative risks is a helpful way to provide context and identify trade-offs. Several sections in the Bulletin (IV.6.d and IV.7.b) state the need to provide a context for risk characterizations and the use of comparative risk as a way to provide such context. This represents a significant way to improve the utility of risk assessment.

Most risk assessments have some comparative dimension to them, i.e., comparison of the probability of adverse effects if the agency takes a specific action with the probable result

² US EPA, 1992, “Framework for Ecological Risk Assessment” EPA/630/R-92/001.

of no action. Some agencies already instruct their staff that putting the risks into context with similar risks is necessary and that comparisons are an important part of assisting the risk manager.³

In a similar way, the OMB preamble is helpful in pointing out that management decisions make use of “acceptable risk” concepts (p. 4). Unfortunately, not all users of risk assessments are attuned to the impossibility of zero risk in many endeavors. Increasing the use of comparative risk techniques will serve to improve public understanding of management options and decisions.

Regarding the characterization of results, comparative risk approaches allow presentation of the consequences of alternative theories, data and assessments (p. 19). With influential risk assessments in particular, the decisions are likely to involve balancing several risks. RTM encourages OMB to require comparing risks associated with or as a consequence of agency decisions in influential risk assessments.

For example, some minerals are known to be essential for human health or for organisms of interest in an ecological risk assessment. A risk assessment that only describes potential hazards from over-exposure (toxicity) but ignores adverse effects from under-exposure (nutritional deficiency) should be regarded as incomplete and inappropriate. A review of risk assessment procedures for essential nutrients by an expert working panel organized by the World Health Organization⁴ noted that data on toxicity and deficiency should receive equal critical evaluation. They noted that the use of typical uncertainty factors can suggest the need for very low exposures to prevent toxicity, but ignore the substantial risk of disease from nutritional deficiency. A desirable standard for risk assessment would require full consideration of both types of risks.

Another example of the need to compare risks is seen in characterizing risks from consumption of fish containing methylmercury. As stated by FDA⁵, the risks to consumers from methylmercury need to be evaluated against to the risks of poor diets resulting from not eating fish.

The need to balance risks was one of the major lessons reported by former EPA Administrator Bill Reilly, who noted “that tradeoffs are unavoidable and that evolving technology and growing transparency will illuminate them more starkly, heightening further the importance of keeping the public’s confidence in EPA and other regulatory bodies.”⁶ This significant learning should be incorporated into OMB guidance through encouraging use of comparative risk approaches.

³ See, for example, section 3.2.3 of EPA’s Handbook on Risk Characterization (EPA 100B-00-002, December 2002).

⁴ World Health Organization, 2002. “Principles and Methods for the assessment of risk from essential trace elements.” Environ. Health Criteria 228. (Available at www.inchem.org/documents/ehc/ehc/ehc228.htm.)

⁵ Letter from Dr. LM Crawford, Commissioner of Food and Drugs, August 12, 2005 to Mr. B. Lockyer, Attorney General of the State of California.

⁶ Reilly, WK, 2002, in DJ Paustenbach. “Human and Ecological Risk Assessment, Theory and Practice” Wiley Interscience, p. xiii.

10. *Default assumptions and factors should be described and justified but procedures to generate and use data-derived values should also be presented by agencies.*

The OMB proposal describes the role of critical assumptions and the need to consider how the risk assessment is affected by such assumptions (e.g., Sections III.5 and V.4 of the Bulletin). OMB also states the need to update risk assessments when relevant new data is available to replace or update the older assumptions (Section VI).

We agree that a procedure to use relevant and credible scientific information to replace assumptions is very important to the improvement of risk assessments. As OMB noted in footnotes, the National Research Council expected that the use of defaults should be expected to decrease over time (page 21). Experience suggests that most risk assessment schemes cling tightly to various default assumptions and that the NRC expectation was optimistic.

EPA recently completed a toxicological review of boron and compounds via the IRIS program.⁷ Through a partnership with RTM (then US Borax), EPA scientists guided the planning, conduct and interpretation of studies done at the University of California at Irvine to replace default uncertainty factors with data-derived values for toxicokinetic processes. The good news was that this led to a more accurate estimate of the noncancer risk of these substances. The unfortunate news was that this was seen as a precedent-setting example of developing and using data-derived values to replace default values.

Progress toward using data seems to be lagging behind policy statements that endorse the concept. RTM hopes that OMB's standards regarding critical assumptions and updates will encourage progress.

To clarify the issue, OMB could point out the need for agency processes to include a description of the default assumptions, but also to present the justification for their use, and, more critically, how the default values would be supplanted by data-derived values.

11. *Risk Assessments, both human and ecological, should identify and justify which effects are considered "adverse".*

OMB proposes that "adverse" effects be specifically identified and justified based on generally accepted information (Section V.7) for influential risk assessments. RTM agrees and notes that ecological risk assessments also must identify "adverse" effects.

OMB correctly notes the proliferation of tools that measure increasingly fine levels of tissue chemical concentrations or of molecular structures in cells or cell extracts. It is common for new "-omics" tools to survey tens of thousands of proteins or DNA base pairs and find differences associated with chemical exposures. Whether these are significant adverse effects is much less clear. OMB has correctly pointed out that these measurements are subject to differences of interpretation about adversity. Further, the instruction to evaluate how much the choice of endpoints affects the risk assessment is extremely useful.

⁷ US EPA, 2004. Toxicological Review of Boron and Compounds (CAS No., 7440-42-8) in support of summary information on the Integrated Risk Information System (IRIS). EPA 635/04/052

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It may be essential for OMB to state a separate standard for characterizing ecological effects. Because of the variety of ecological systems, no single endpoint or suite of endpoints has been found universally appropriate. Consequently, a vague concept such as "ecological health" is not useful. In practice, ecological risk assessment frameworks recommend that early discussions identify which ecological aspects are important and how those can be reliably measured.

Determining what constitutes an adverse ecological effect should be resolved during the problem formulation stage. Dr. A Sargeant⁸ described some criteria for selecting ecological assessment endpoints that might be useful for OMB to consider: ecological relevance (the organism or community should be a current or historical part of the ecosystem), susceptibility (they should both be exposed and susceptible to effects of the chemical or stressor), and relevance to societal and management goals (something important and something within the decision-maker's authority). In characterizing ecological effects, the assessment should discuss the lines of evidence that associate a chemical or stressor with ecological effects, and the extent of adversity (the nature and intensity of effects, the spatial and temporal scales where effects might occur, and the potential of the ecosystem to recover from effects).

Perhaps a separate standard regarding the characterization of ecological effects might be an appropriate change. There is a significant body of knowledge and practice in ecological risk assessment that agencies may draw upon. The quality of ecological risk assessments is important, so much so that OMB might wish to incorporate more recent information about current practice into the Bulletin.

In sum, RTM commends OMB for focusing on the improvement of quality in risk assessments produced for and used by Federal agencies. As proposed, the Bulletin outlines a management framework that appears workable and would encourage agencies to improve the credibility, transparency and utility of risk assessments.

We understand that OMB is waiting for a report from the National Academy of Sciences workshop and that OMB will consider all comments. If clarification of our comments is desired, please contact me at michael.harrass@riotinto.com or 847-755-0619,

Thank you for the opportunity to provide comments.

Sincerely,



Michael C. Harrass
Principal Health and Environment Scientist

⁸ A Sargeant, 2002. "Ecological Risk Assessment: History and Fundamentals" in Paustenbach, Human and Ecological Risk Assessment: Theory and Practice, Wiley Interscience, pp. 369-442.