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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP

cc:

Subject: Proposed Bulletin on Peer Review and Information Quality: 68 Fed. Reg. 54023

Dear Sir/Madam:

Attached as a Word file and included in the text of this e-mail below are the Comments of the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States, Inc. on OMB's Proposed Bulletin on Peer Review and Information Quality.

If you have any questions about these Comments, please let me know.

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Before the
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President

**Comments of the
Nickel Development Institute
Nickel Producers Environmental Research Association
and
Inco United States, Inc.**

on the

**PROPOSED BULLETIN ON
PEER REVIEW AND INFORMATION QUALITY**

68 FED. REG. 54023 (SEPTEMBER 15, 2003)

Communications regarding these Comments
should be addressed to:

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Introduction

The Nickel Development Institute (“NiDI”), the Nickel Producers Environmental Research Association (“NiPERA”), and Inco United States, Inc. (“Inco”) are pleased to submit these Comments on the Proposed Bulletin on Peer Review and Information Quality (“Peer Review Bulletin”) issued by the Office of Management and Budget (“OMB”) and published in the Federal Register on September 15, 2003. 68 Fed. Reg. 54023. NiDI and NiPERA are organizations of the world’s primary nickel producers, and Inco’s parent company, Inco Limited (a Canadian corporation), is a member of NiDI and NiPERA. As such, Inco, NiDI and NiPERA have an interest in scientific evaluations and regulatory actions affecting nickel—and believe strongly that nickel-related information and other determinations reflecting regulatory science should be subjected to meaningful peer review before being used or disseminated by Federal agencies.

In the comments below, we express support for the peer review requirements of the proposed Bulletin and suggest certain revisions or clarifications that we believe would make the Bulletin even more effective in achieving the benefits of meaningful peer review. We also endorse the proposals relating to the handling of correction requests submitted to agencies pursuant to the Information Quality Act, P.L. 106-554, § 515(b)(2)(B), and implementing OMB Guidance.

I. OMB Should Establish a Standardized Process for Subjecting All Significant Regulatory Science Documents to Peer Review by Qualified Specialists in Appropriate Technical Disciplines.

In the proposed Bulletin, OMB’s Office of Information and Regulatory Affairs (“OIRA”) seeks to institutionalize at Federal agencies a “more uniform peer review policy . . . [designed] to

make regulatory science more competent and credible”^{1/} and to ensure that “the benefits of meaningful peer review of the most important science disseminated by the Federal Government regarding regulatory topics” are realized.^{2/} These peer review requirements would be established in the exercise of authority conferred on OMB under the Information Quality Act, P.L. 106-554, the Paperwork Reduction Act, 44 U.S.C. §§ 3504(d)(1), 3506(a)(1)(B), and Executive Order 12866. NiDI, NiPERA, and Inco agree that OMB has the authority to establish these peer review requirements and believe that doing so would advance the Administration’s “smart-regulation agenda,” provide greater public confidence in the scientific basis for Federal regulatory actions, and create an environment in which Federal regulations would draw fewer lawsuits and be less vulnerable to challenge in those instances where lawsuits are brought.

As OMB points out, the use of peer review mechanisms to ensure the quality and integrity of science is a broadly accepted practice in the scientific community.^{3/} Reflecting that fact, the Presidential/Congressional Commission on Risk Assessment and Risk Management recommended that “[p]eer reviews should be conducted both to enhance the credibility of agency decisions and positions and to improve their technical quality.”^{4/} “Peer review policies,” the Commission advised,

^{1/} See Press Release 2003-34 (Aug. 29, 2003), quoting OIRA Administrator Dr. John D. Graham.

^{2/} 68 Fed. Reg. at 54024.

^{3/} See *id.*, quoting GAO Report, Peer Review Practices at Federal Science Agencies Vary (March 1999) at 1.

^{4/} Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making (Final Report, Vol. 2, 1997) at 103.

should . . . provide guidance to agency staff for effectively framing the responsibilities of peer review panels, which should at a minimum include determining whether all the relevant data were evaluated, whether the conclusions based on those data are justified by the evidence, and whether the conclusions are communicated in a manner that reflects the weight of the scientific evidence.^{5/}

In other words, as OMB points out, “it is . . . essential to grant the peer reviewers access to sufficient information and to provide them with an appropriately broad mandate.”^{6/}

It also is important, to the extent practicable, to utilize peer reviewers who not only have the necessary technical expertise but also are independent of the agency whose work is being reviewed. To quote the National Research Council of the National Academy of Sciences:

External experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns. Evaluation by external reviewers thus can enhance the credibility of the peer review process by avoiding both the reality and the appearance of conflict of interest.^{7/}

The mere fact that an individual is not on the agency’s direct payroll, however, does not mean he or she will be completely “independent” of the agency. As OMB notes: “A peer reviewer who is financially dependent on the agency, or at least hopes to profit financially from other dealings with the agency, may not always be completely independent, or appear truly independent.”^{8/} Thus, while concerns over potential conflicts of interest traditionally focus on cases where a peer reviewer has financial ties to a regulated business that would be impacted by

^{5/} *Id.* at 104.

^{6/} 68 Fed. Reg. at 54025.

^{7/} National Research Council, *Peer Review in Environmental Technology Development Programs: The Department of Energy’s Office of Science and Technology* (1998) at 3.

^{8/} 68 Fed. Reg. at 54025.

the regulatory action at issue, it also is true that “scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency’s regulatory position.”^{9/}

Finally, peer reviews should be transparent, so that interested members of the public can understand the nature of the particular peer review, the conclusions reached by the peer reviewers, and the agency’s response to the peer review. In the absence of such transparency, peer review will not “enhance the credibility of agency decisions”^{10/} as much as it should and will fall short of providing full public confidence in the scientific basis for Federal regulatory actions.

The proposed Bulletin would go a long way toward ensuring meaningful peer review of important scientific and technical information relevant to significant decisions and policies of Federal agencies. For that reason, we support issuance of the Bulletin. However, we believe it can be improved in several respects as discussed in Part II below.

II. The Proposed Bulletin Should Be Clarified and Modified in Certain Respects.

The proposed Bulletin is generally a well designed guide for obtaining meaningful peer review of significant scientific and technical information disseminated by Federal agencies or used by them in making regulatory decisions. However, we believe certain clarifications and modifications would make the Bulletin an even more effective tool for ensuring that agency sponsored peer reviews are reliable, independent, and transparent. In this Part of our Comments, we suggest several clarifications and modifications of the proposed Bulletin, addressing the various Sections of the Bulletin seriatim.

^{9/} *Id.* at 54024.

^{10/} Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making (Final Report, Vol. 2, 1997) at 103.

Section 1. Definitions.

The term “Major regulatory action” is defined in Section 1 of the Bulletin by reference to Section 1(f)(1) of Executive Order 12866. We believe the correct reference is Section 3(f)(1) of Executive Order 12866.

The definition of “Regulatory information” states: “Information is relevant to regulatory policy if it might be used by local, state, regional, federal and/or international regulatory bodies.” This definition might be usefully clarified by adding the following clause at the end of the sentence: “even if it is not used by the agency generating or disseminating the information as a basis for its own rulemaking actions.” In addition, OMB should make clear that information is relevant to regulatory policy if it is prepared in response to a specific request from Congress.

Section 2. Peer Review of Significant Regulatory Information

Section 2 of the Bulletin establishes peer review requirements for “significant regulatory information.” These Section 2 requirements are less stringent and much more general in nature than the series of clear and specific requirements that apply to peer review of “especially significant regulatory information” under Section 3 of the Bulletin. In contrast to the seven specific topical directives contained in Section 3 (ranging from Selection of Peer Reviewers to Certification in Administrative Record), Section 2 calls upon agencies only to “have an appropriate and scientifically-rigorous peer review conducted on all significant regulatory information that the agency intends to disseminate.”^{11/}

While a distinction between peer review of Section 2 and Section 3 information is warranted, we believe a modified version of some of the Section 3 requirements would be appropriate for peer review of Section 2 information as well. In suggesting this, we are mindful

^{11/} 68 Fed. Reg. at 54027.

of the fact that Section 2 gives agencies broad discretion to “select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science.”^{12/} This would allow agencies to tailor Section 3 requirements so that they are suitable for application to Section 2 information.

Before outlining our suggested modifications, we wish to propose one clarification in Section 2. As currently drafted, Section 2 states:

Agencies need not . . . have peer review conducted on studies that have already been subjected to adequate independent peer review. For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate.^{13/}

We do not quibble with this position. However, OMB should make clear that when an agency uses such a study as part of its own analysis of a scientific or technical issue, *the agency’s own analysis* should be subjected to peer review even though the study itself need not be peer reviewed a second time. For example, an agency may perform a risk assessment in which it utilizes, interprets, or extrapolates from the results of a number of epidemiological or toxicological studies that have been published in scientific journals. In such a case, the agency’s risk assessment (assuming it qualifies as “significant regulatory information”) should be subjected to peer review under Section 2 of the Bulletin, even though the epidemiological or toxicological studies themselves need not be subjected to a new round of peer review.

Turning to desirable modifications of Section 2, we suggest that the following be considered.

^{12/} *Id.*

^{13/} *Id.*

- Selection of Peer Reviewers: While Section 3’s full set of requirements for selecting peer reviewers external to the agency need not apply to Section 2 information, the requirement that peer reviewers “be selected primarily on the basis of necessary scientific and technical expertise”^{14/} should apply under Section 2 as well as Section 3. As pointed out by the Presidential/Congressional Commission on Risk Assessment and Risk Management: “The primary criterion for membership on peer review panels should be expertise in the area of concern.”^{15/} Moreover, as OMB appears to recognize, if peer reviewers are employed by the agency, they should, at a minimum, reside in a separate agency program from the one sponsoring the peer review. Finally, while conflict of interest concerns may not be as compelling under Section 2 as under Section 3, agencies still should be encouraged to identify experts who are independent of the agency as well as of regulated entities, particularly where the scientific issues to be reviewed are highly novel or complex or where the subject of the review has large cost or benefit implications.

- Charge to the Peer Reviewers: While an elaborate charge need not be developed for peer review of Section 2 information, it “should at a minimum include determining whether all the relevant data were evaluated, whether the conclusions based on those data are justified by the evidence, and whether the conclusions are communicated in a manner that reflects the weight of the scientific evidence.”^{16/}

^{14/} *Id.*

^{15/} Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making (Final Report, Vol. 2, 1997) at 103.

^{16/} *Id.* at 104.

- Opportunity for Public Comment: By definition, “significant regulatory information” covered by Section 2 of the Bulletin is information whose dissemination, “the agency can reasonably determine . . . will have or does have a clear and substantial impact on important public policies or important private sector decisions.”^{17/} That being the case, there should be an opportunity for interested members of the public to bring scientific or technical points to the attention of the peer reviewers. Where the significant regulatory information is developed in the context of a rulemaking, the rulemaking comments could simply be made available to the peer reviewers. Where the significant regulatory information is developed independent of a rulemaking, the agency should provide some other means for persons who would be most directly impacted by dissemination of the information to present their views on the relevant scientific or technical issues to the peer reviewers.

- Peer Review Reports: If a peer review is conducted, there should be a report, even if quite brief, setting forth the peer reviewers’ conclusions and recommendations. This is true whether the peer review addresses “significant regulatory information” (Section 2) or “especially significant regulatory information” (Section 3)—though the report presumably would be more elaborate in the latter case than in the former.^{18/} Moreover, in the interest of transparency, the report should be made available to the public—for example, by being placed in the administrative record of any rulemaking to which the peer reviewed information relates, and/or by being attached to the information whenever it is disseminated by the agency.

^{17/} See Definition of “Significant regulatory information” in Section 1 of the Bulletin, 68 Fed. Reg. at 54027, referencing the definition of “influential” in OMB’s Information Quality Guidelines.

^{18/} Similarly, the obligation of an agency to prepare a written response to the peer review report may be limited to cases where “especially significant regulatory information” is involved.

Section 3. Peer Review of Especially Significant Regulatory Information

Most of our thoughts on Section 3 of the Bulletin relate to the Selection of Peer Reviewers, as to which we would like to make the following points.

First, we believe an appropriate balance between avoiding potential conflicts of interest, on the one hand, and unduly burdening prospective peer reviewers, on the other, counsels in favor of limiting peer reviewers' disclosure requirements to activities occurring within the previous five years.

Second, we would not require that an external body select peer reviewers for “especially significant regulatory information” developed by the agency. However, while agencies should not be precluded from making the selection in such cases, the peer reviewers being considered should all be from outside the agency, and they should be required to disclose fully any ties they may have to the agency.

Third, while the four factors or criteria OMB has identified for evaluating potential conflicts of interest seem appropriate, we believe factor (iii) needs to be expanded to encompass individuals who are currently receiving or seeking substantial funding from a private entity potentially affected by the information that is to be peer reviewed. As drafted, this provision seems to cover only individuals who are receiving or seeking substantial funding from the agency itself.

Fourth, the last sentence of the paragraph on Selection of Peer Reviewers—calling for the selection of reviewers with offsetting biases—needs further consideration. For one thing, the fact that an individual does not satisfy each of the four criteria set forth in Section 3 does not mean he or she is “biased,” only that a possible perception of conflict of interest may exist. Hence, we would hesitate to describe such an individual as “biased.” Moreover, the proposed

solution for cases where it is necessary to select an individual who does not satisfy each of the four criteria (*i.e.*, appoint a reviewer with a contrary bias) will not work in most cases. The “offsetting bias” solution may work when the problem is that one reviewer has advocated a position on the *specific* matter at issue in recent years. In such a case, the agency can offset the potential bias by appointing another reviewer who has advocated the contrary position. But when the problem is that the first reviewer has a financial interest in the matter at issue, it cannot be solved by appointing another reviewer who has no financial interest in the matter. Similarly, if the problem is that the first reviewer has conducted multiple peer reviews for the same agency in recent years (or has conducted a peer review for the same agency on the same specific matter in recent years), it cannot be solved by appointing another reviewer who has not conducted a peer review for the agency. The same is true where the first reviewer is currently receiving or seeking funding from the agency. In short, there may be cases where a particular peer reviewer with a potential conflict of interest is essential and where an “offsetting bias” solution simply is not feasible.

Section 6. Reports on Agency Peer Reviews

Section 6 of the Bulletin requires agencies to report to OIRA at least annually on their plans for conducting peer reviews of scientific or technical studies that might constitute or support significant regulatory information. Section 6 should state explicitly that for each such study, the agency must indicate whether or not it intends to treat the study as “especially significant regulatory information” subject to the peer review requirements of Section 3 of the Bulletin. That will permit the Administrator of OIRA, in appropriate cases, to determine that the regulatory information at issue should be subjected to formal, independent, external peer review

under Section 3 because it “is of significant interagency interest or is relevant to an Administration policy priority.”^{19/}

III. Monitoring of Correction Requests Under the Information Quality Act

Section 7 of the Bulletin establishes a mechanism to ensure that OIRA will be informed of all information correction requests submitted to an agency under the Information Quality Act (“IQA”), and it makes clear that OIRA has discretion to review an agency’s draft response to each such request. Our experience suggests that this effort to regularize OIRA’s role in monitoring agencies’ handling of correction requests is both appropriate and desirable. On April 9, 2003, NiDI, NiPERA, and Inco submitted a request to the National Institutes of Health (“NIH”), seeking the correction of certain information disseminated in the National Toxicology Program’s Tenth Report on Carcinogens. Although the applicable NIH and Department of Health and Human Services (“HHS”) Guidelines contemplate that NIH will respond to requests for corrections within sixty days,^{20/} the response period has now been extended three times without any explanation of the reason for the delay—except that the request “is still under review.” The latest prediction is that a response will be issued by October 31, 2003. If a response is, indeed, sent by that date (based on experience thus far, we have little confidence that it will be), the response period will have expanded to more than three times the period specified in the NIH and HHS Guidelines. This does not mean that the response, once received, will be unsatisfactory. But it does suggest that a more active monitoring role by OIRA would be desirable.

^{19/} See 68 Fed. Reg. at 54027.

^{20/} See NIH, Guidelines for Ensuring the Quality of Information Disseminated to the Public, Part VI.3; HHS Guidelines for Ensuring the Quality of Information Disseminated to the Public, Part I.E.

Conclusion

NiDI, NiPERA, and Inco support OMB's proposal to establish a more uniform peer review policy for significant regulatory information disseminated by Federal agencies. At the same time, we believe that certain clarifications and modifications (suggested above) would make the Bulletin an even more effective instrument for ensuring that regulatory science becomes more competent and credible through implementation of a reliable, independent, and transparent peer review process.