



**Jim Tate@ios.doi.gov**  
05/28/2002 06:00:17 PM

Record Type: Record

To: John F. Morrall III/OMB/EOP@EOP  
cc: Indur\_Goklany@ios.doi.gov, Rosalyn\_Worthan@ios.doi.gov  
Subject: draft letter [Virus checked]

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Attached please find Department of the Interior comments on regulatory impact analyses. -TATE

James Tate, Jr., Ph.D.  
Science Advisor to the Secretary  
U.S. Department of the Interior  
1849 C Street NW, Room 6127  
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(See attached file: 02052801 DRAFT LETTER.wpd)



- 02052801 DRAFT LETTER.wpd

May 28,2002

Mr. John Morrall  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
NEOB, Room 10235  
725 Seventeenth Street, NW  
Washington, DC 20503

Re: Draft Report to Congress on the Costs and Benefits of Federal Regulations

Dear Mr. Morrall:

This is in response to the Federal Register notice published on March 28,2002, requesting comments on analytical issues that should be addressed in the refinement of OMB's analytic guidelines for regulatory impact analyses. In addition to the issues raised on p. 15021 (2<sup>nd</sup> and 3<sup>rd</sup> columns), the Department of the Interior believes that the refinement should also address the following:

- o Despite the fact that a regulation's benefits might be estimated to exceed costs, other unused opportunities might be available to society that would, for example, provide similar benefits at lesser costs (or at a higher benefit-cost, B-C, ratio).<sup>1</sup> Unless some comparison of B-C ratios is attempted, it is conceivable that some regulations (if enacted) might lock society into employing third- or fourth-best opportunities to reduce risks while the best or second-best opportunities are un- or under-utilized. The guidelines should attempt to address methods of reducing, if not avoiding, such less-than-optimal outcomes, especially if the B-C ratios of what are proposed (or adopted) are substantially smaller than other unused opportunities. We recognize that there may be legal or other reasons why sub-optimal solutions might have to be employed, but the regulatory impact analyses and the accompanying Federal Register notices should air all these factors and considerations, and provide a convincing rationale why a sub-optimal solution must be used, when other better solutions are available.
- o Considering that (as noted above), B-C analysis is one of several factors that decides the shape and stringency of regulations, the guidelines should also evaluate whether it makes more sense

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<sup>1</sup> The draft report itself indicates that there is a wide variation in benefit-cost ratios for the various regulations. See also: T. Tengs and J. Graham, "The opportunity costs of haphazard societal investments in life-saving," in R Hahn (Ed.) *Risks, Costs, and Lives Saved: Getting Better Results from Regulation* (Oxford University Press, 1996); T. Tengs, M. Adams, J. Pliskin, D. Safran, J. Siegel, M. Weinstein, and J. Graham, "Five-hundred life-saving interventions and their cost-effectiveness," *Risk Analysis* (1995, no. 3), 369-390.

to: (a) use conservative assumptions and analytic routines (including the use of safety factors) before, during or within the process of estimating risks, benefits or costs, or (b) make an effort to come up with best estimates (untainted by conservative or liberal assumptions) and then, if necessary, employ a “safety-factor” on the final B-C (or risk-cost) ratios. An argument can be made that the first approach—using conservative/liberal assumptions—skew the final results and make comparisons regarding the merits of different regulatory approaches (including the option of “not acting”) difficult, if not impossible (unless identical assumptions are made each step of the way).

- Whether and what extent the use of an approach using life-years (quality-adjusted or not) would be sufficient to account for the value of improvements to children’s health.
- Whether and to what extent the use of life-year approaches would be at odds with other risk assessment methods that might account for specific subpopulations.
- One of the issues that ought to be addressed is how to better incorporate into the regulatory information analyses ecological **risks**, benefits and costs that might follow from actions or options under consideration.

Thank you for giving us an opportunity to comment on the draft report. If you have any questions on the above comments, please call Indur Goklany, Manager, Science and Engineering, Office of Policy Analysis at 202-208-4951 or by e-mail at [igoklany@ios.doi.gov](mailto:igoklany@ios.doi.gov).

Sincerely,

[SIGNED ORIGINAL TO FOLLOW BY POST]

James Tate, Jr., Ph.D.  
Science Advisor to the Secretary



**Rosalyn** Worthan@ios.doi.gov  
05'28'2002 05:40:13 PM

Record Type: Record

To: John F. Morrall III/OMB/EOP@EOP  
cc:  
Subject: Letter on regulatory impacts [Virus checked]

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Attached is an electronically signed letter from Jim Tate re: Draft Report to Congress on the Costs and Benefits of Federal Regulations.

If you have any questions, please call me at the number listed below.

Rosalyn Worthan

(See attached file: Morrall052802)

Rosalyn Worthan  
Secretarial Assistant/Office of the Secretary  
U.S. Department of the Interior  
1849 C Street NW, Room 6124  
Washington, DC 20240  
(202) 208-4123  
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- Morrall052802

May 28,2002

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Office of Management and Budget  
NEOB, Room 10235  
725 Seventeenth Street, NW  
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- Despite the fact that a regulation's benefits might be estimated to exceed costs, other unused opportunities might be available to society that would, for example, provide similar benefits at lesser costs (or at a higher benefit-cost, B-C, ratio).<sup>1</sup> Unless some comparison of B-C ratios is attempted, it is conceivable that some regulations (if enacted) might lock society into employing third- or fourth-best opportunities to reduce risks while the best or second-best opportunities are un- or under-utilized. The guidelines should attempt to address methods of reducing, if not avoiding, such less-than-optimal outcomes, especially if the B-C ratios of what are proposed (or adopted) are substantially smaller than other unused opportunities. We recognize that there may be legal or other reasons why sub-optimal solutions might have to be employed, but the regulatory impact analyses and the accompanying Federal Register notices should air all these factors and considerations, and provide a convincing rationale why a sub-optimal solution must be used, when other better solutions are available.

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- Considering that (as noted above), B-C analysis is one of several factors that decides the shape and stringency of regulations, the guidelines should also evaluate whether it makes more sense to: (a) use conservative assumptions and analytic routines (including the use of safety factors) before, during or within the process of estimating risks, benefits or costs, or (b) make an effort to come up with best estimates (untainted by conservative or liberal assumptions) and then, if necessary, employ a "safety-factor" on the final B-C (or risk-cost) ratios. **An** argument can be made that the first approach—using conservative/liberal assumptions—skew the final results and make comparisons regarding the merits of different regulatory approaches (including the option of "not acting") difficult, if not impossible (unless identical assumptions are made each step of the way).
- <sup>a</sup> Whether and what extent the use of an approach using life-years (quality-adjusted or not) would be sufficient to account for the value of improvements to children's health.
- Whether and to what extent the use of life-year approaches would be at odds with other risk assessment methods that might account for specific subpopulations.
- <sup>a</sup> One of the issues that ought to be addressed is how to better incorporate into the regulatory information analyses ecological risks, benefits and costs that might follow from actions or options under consideration.

*Thank* you for giving us an opportunity to comment on the draft report. If you have any questions on the above comments, please call Indur Goklany, Manager, Science and Engineering, Office of Policy Analysis at 202-208-4951 or by e-mail at [igoklany@ios.doi.gov](mailto:igoklany@ios.doi.gov).

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