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05/05/2003 03:14:14 PM

Record Type:Record

To: Lorraine D. Hunt OIRA ECON GUIDE/OMB/EOP@EOP

cc:
Subject: Comments of Environmental Defense on OMB's Draft Guidelines for the Conduct of Regulatory Analysis

(See attached file: OMB reg analysis draft guidance - EnDef comments final.doc)

- OMB reg analysis draft guidance - EnDef comments final.doc

Karen_Florini@environmentaldefense.org
05/05/2003 04:27:18 PM

Record Type:Record

To: Lorraine D. Hunt OIRA ECON GUIDE/OMB/EOP@EOP

cc:
Subject: Comments of Environmental Defense on OMB's Draft Guidelines for the Conduct of Regulatory Analysis - minor revision

after submitting these earlier today, we realized that we inadvertantly omitted two individuals from the acknowledgements in footnote 5. That omission has been corrected on the attached. Please withdraw the prior version submitted at 3:14 pm today, and use this one instead.

We apologize for the inconvenience.

(See attached file: OMB reg analysis draft guidance - EnDef comments final rev.doc)

----- Forwarded by Karen Florini on 05/05/2003 04:21 PM -----

Karen Florini
05/05/2003 03:14 PM

To: OIRA.ECON.GUIDE@omb.eop.gov
cc:
Subject: Comments of Environmental Defense on OMB's Draft Guidelines for the Conduct of Regulatory Analysis

[previously attached file = OMB reg analysis draft guidance - EnDef comments final.doc]

- OMB reg analysis draft guidance - EnDef comments final rev.doc

May 5, 2003

Office of Management and Budget
Washington, DC
(Submitted via email to *OIRA.ECON.GUIDE@omb.eop.gov)*

1. Introduction and Summary.

This document sets forth the comments of Environmental Defense on the *Draft Guidelines for the Conduct of Regulatory Analysis* issued by the Office of Management and Budget (54 Fed. Reg. 5513-5527, Feb. 3, 2003).[1] Environmental Defense, a not-for-profit environmental advocacy organization with more than 300,000 members, focuses on four major areas: climate change, human health, biodiversity, and oceans. With a staff comprised of economists, scientists, attorneys, and analysts, Environmental Defense seeks pragmatic, lasting solutions to environmental problems.

Environmental Defense believes that evaluation of both benefits and costs of regulations is an important part of the regulatory decisionmaking process. In our view, assembling information on the key effects of various regulatory alternatives and approaches is critical in allowing decisionmakers to evaluate the impacts of their actions, and in enabling members of the public and of Congress to review and assess decisionmakers' actions.

However, we are deeply disturbed by recent trends toward extremely technical and formalistic analyses that rely heavily on discounting non-monetary benefits (particularly those involving avoided deaths, illnesses, and injuries) and on monetizing such benefits. Unfortunately, the draft Guidelines only exacerbate these problems.

At the outset, it is vital to note that discounting and monetizing are by no means necessary components of an analysis of the costs and benefits of a regulatory proposal. Although OMB states that "[t]he distinctive features of BCA [benefit-cost analysis] is that both benefits and costs are expressed in monetary units" (p. 5516), it is entirely possible to provide a narrative description (quantified where possible) of anticipated costs and benefits and the time frames over which they accrue. As discussed more fully below, for non-monetary benefits (and costs), in our view it is far more transparent to use such an approach than to use discounting techniques that derive from the time-value of money. Similarly, monetizing non-monetary benefits – particularly those involving avoided death, illness, and injury – makes analyses less transparent.

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[1] The Draft Guidelines appear as Appendix C to OMB's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations (54 Fed. Reg. 5492-5527, Feb. 3, 2003; notice of extension of public comment period to May 5, 2003, 54 Fed. Reg. 15772-73, Ap. 1, 2003). Environmental Defense has not prepared detailed comments on the Draft Report, in part because the extensive use of discounting and monetization makes the draft of questionable validity and utility for the reasons articulated below. Other flaws in the Draft Report have been identified elsewhere. See, e.g., Testimony of Lisa Heinzerling, Professor of Law, Georgetown University Law Center and Vice-President, Center for Progressive Regulation, Before the Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, Committee on Government Reform, U.S. House of Representatives, March 11, 2003.

Because transparency is an essential component of governmental decision-making in a democracy, a narrative description is far preferable (with the possible exception of intergenerational effects, as discussed below, which in any event should be discounted at a rate no higher than the 1% level proposed in the draft Guidelines).

In addition, although not addressed at length in these comments, we also have serious concerns about the practical impacts of some of the additional analyses required or suggested by the Guidelines. The federal rulemaking process is already notoriously lengthy, and the time and resources needed for carrying out these additional analyses would further undercut the ability of federal agencies to issue effective safeguards on a timely basis. Every additional analytic requirement – such as the requirement for a formal probabilistic analysis for high-cost regulations – slows that process down still more. Such analyses will be highly burdensome and will leave decisionmakers with no additional information than would a far simpler narrative discussion of uncertainty of the costs and benefits.

Regulatory analyses should be required *only* when they demonstrably improve the regulatory process by providing decisionmakers and those who evaluate them with useful information that is not otherwise available. Thus, for example, it is a gross misallocation of taxpayers' money for OMB to suggest that federal agencies may (much less must) conduct cost-benefit analyses where the relevant statute disallows consideration of economic costs.

Unfortunately, although OMB acknowledges that "these proposed guidelines include some additional requirements on the agencies," it simply asserts its "belie[f]" that those added analyses "will yield improvements in the information provided in these analyses" and that those improved analyses will in turn result in "better designed regulations." However, OMB offers nothing more than its unsupported opinion in this regard. As further discussed below, there is substantial reason to question whether decisionmakers – at least the great majority of decisionmakers, those lacking advanced degrees in economic analysis or similar fields – will in fact select better-designed regulations if they are presented with analyses that rely on monetized/discounted descriptions of nonmonetary benefits (and hence decontextualized and non-transparent ones) than if they are provided with narrative descriptions of the actual benefits and the timeframes through which they accrue. Certainly, the vast majority of the public and most Members of Congress will be less able to accurately evaluate a monetized/discounted description of nonmonetary benefits than a narrative description.

Likewise, OMB offers no evidence that better decisions will result from its new requirements for cost-effectiveness analysis, and for probabilitistic analyses of key uncertainties for rules anticipated to have economic effects over $1 billion annually. Nor does OMB provide any information on the resources that will be required to prepare such analyses – much less of what other tasks those resources will be diverted from in an era of shrinking budgetary allocations for most regulatory agencies.

2. Issues Involving Discounting of Non-monetary Benefits.

Discounting can properly be applied to monetary benefits because of the clear time-value of money, as indicated by interest rates. With regard to non-monetary benefits, however, using a discount rate is at best an analogy – and a highly imperfect one at that. In the context of decisionmaking by public officials in a democracy, the imperfections are so severe that they outweigh any theoretical benefit of discounting.[2] Most policymakers – including those in federal agencies, as well as members of Congress, to say nothing of the media and the public – lack an advanced background in economics, and will not absorb or retain explanations or caveats from analytic documents. Thus, while some economists may regard the two following statements as interchangeable (using a 7% discount rate), non-economists would be extremely unlikely to do so:

1. The proposed regulation will avoid 100 deaths in 30 years.
2. The proposed regulation will avoid 13 deaths.

In short, the loss of transparency created by discounting nonmonetary benefits is simply unacceptable – particular where the benefit in question is the avoided impact on human life, health, or safety.

To the extent that benefits include avoided medical costs, it is appropriate to discount those costs, as they are monetary in nature. Likewise, in some instances, certain non-monetary benefits may be so analogous to monetary benefits that it may be appropriate to discount them (e.g., water-purification services provided by ecosystems, which otherwise would have to be provided by water treatment systems at a monetary cost).

One illustration of the folly of discounting nonmonetary benefits is conveyed by the fact that suggested regulatory discount rates have varied dramatically over time. The value of the future surely does not fluctuate with the vagaries of interest rates but it does fluctuate with information, which is why we express a preference for disclosure of effects.

A. The Intergenerational Exception

Although narrative descriptions of time frames are thus generally far preferable to discounting, a narrative approach may be impractical in the context of intergenerational benefits that stretch to an indeterminate point in the future. As an initial point, we wish to applaud OMB for calling on agencies to expressly consider intergenerational impacts. But intergenerational benefits may differ from intragenerational benefits in a key way that may warrant use of a discount factor, namely the fact that intergenerational benefits may lack an outer time horizon, which can lead to anomalous results.

The potential problem is illustrated by the following example involving benefits of two ***alternative*** regulatory proposals (unlike the prior pair of examples, which were alternative descriptions of the benefits of a single proposal):

[2] Use of discounting may be of interest in the academic context, where analyses are primarily evaluated by economists who may be expected to appreciate the limitations of the techniques involved and the contexts in which those techniques are used.

1. The proposed regulation will avoid 100 million deaths in year 31.
2. The proposed regulation will avoid 1 death every year beginning in year 31.

With a zero discount rate, regulation 2's benefits would include infinite lives saved and would always trump proposal 1 simply because there is no outer limit for the analysis. In this intergenerational context, the only alternative to a discount rate is the specification of a limited time horizon for analysis. Because it does not appear feasible to propose a uniform outer limit for the time horizon and it seems undesirable to select one on a case-by-case basis, a 1% discount rate for intergenerational benefits may be appropriate.

Specifically, the value of each benefit is discounted by multiplying by the factor

$$\frac{1}{(1+discount\ rate)^t}$$

where *t* represents the number of years in the future when the costs or benefits are expected to occur. So the present value of total benefits from the project is calculated by the formula

$$\mathrm{B} = \sum_{t=0}^{t=\infty} VLt(1+\alpha)^{-t}$$

where α is the discount rate and VL is the value of life (or other benefits). If $VLt = VL \quad \forall t$ and $\alpha = 0$ then

$$\mathrm{B} = \sum_{t=0}^{t=\infty} VLt(1+\alpha)^{-t} = \sum_{t=0}^{t=\infty} VL = \infty .$$

Thus, a zero discount rate with an infinite horizon of calculation leads to an infinite economic value of benefits. Under this formulation, whatever investment is proposed would be justified. The analysis does not help decisionmakers discriminate among options, nor allow them to evaluate which will provide benefits earlier.

Further, the assumption of an infinite horizon is not necessarily appropriate. Each project or policy has a life cycle. Each analysis presumes a matrix of technologies producing impacts. At some point in time, the matrix will likely change – optimistically, to be replaced by something more efficient and more environmentally friendly. Thus, the benefit horizon (like the cost horizon) should be something less than infinity. A 1% discount rate does a pretty good job of balancing the intergenerational need with the need to introduce dynamics.

Any discount for intergenerational benefits should not exceed 1%, since otherwise the time frames involved will automatically trivialize the future benefits out of all recognition. Thus, OMB should *not* require agencies to also evaluate intergenerational impacts using a 3% and 7% discount rate.

3. Issues Involving Monetizing of Non-monetary Benefits.

Just as discounting reduces the transparency of cost-benefit analyses, so does monetizing non-monetary benefits, particularly those for avoided death, illness, and injury. Moreover, several commentators have pointed out that the actual values assigned often rest on highly questionable assumptions.[3]

Fundamentally, putting non-monetary benefits into monetary terms hides useful information from decisionmakers and the public, and removes important contextual information about the nature of the benefits involved. This kind of "decontextualizing" should be anathema to those who aim to make regulatory decisions as transparent as possible.

There are also immense methodological difficulties with monetizing nonmonetary benefits. Willingness-to-pay measurements largely reflect the financial status of the interviewee, since his or her willingness will be limited by the size of his or her discretionary income. These measurements thus discriminate most sharply against lower-income individuals. Calculations of pay-for-risk are also unreliable as indicators of monetary value of health and safety benefits, because – by definition – the individuals who accept those positions are those who require the *lowest* risk premium for higher-hazard work compared to everyone else in our society.

It is sometimes argued that the fact that the tort system provides monetary compensation for injury or loss of life warrants monetizing of nonmonetary benefits in the regulatory context. This argument ignores the fact that *there is no alternative* in the tort system. By definition, the plaintiff in a tort suit has already suffered injury; the only available option is to provide compensation. But in the regulatory context, the regulations are intended to *prevent* harm. And the purpose of the regulatory analysis is to help inform decisionmakers and the public. That can be accomplished far more transparently by eschewing monetization and discounting of nonmonetary benefits.

4. Issues Involving Cost-Effectiveness Analysis

While cost-effectiveness analysis avoids the problem of monetizing of nonmonetary benefits, OMB nonetheless goes astray by insisting that nonmonetary benefits be discounted before being evaluated. For reasons set forth above, we strongly oppose this approach (except for using a 1% discount rate for intergenerational benefits).

Another disturbing feature of OMB's approach is the use of life-years saved as opposed to lives saved. Again, a narrative description of the benefits and the cohorts to whom they are expected to apply is far preferable. Evaluating life-years saved rather than lives saved raises profoundly troubling questions about devaluing the lives of the elderly. We are aware of no instance in which Congress has adopted such an approach. This kind of fundamental policy decision is surely in the purview of Congress rather than OMB in the first instance.

[3] See, e.g., Heinzerling, cited in footnote 1.

While not directly controlling, several of the observations offered by the U.S. Supreme Court in *Washington v. Glucksberg*, 521 U.S. 702 (1997), are germane to this discussion. There, the Court unanimously upheld a State of Washington statute banning assisted suicide against a constitutional challenge. Chief Justice Rehnquist, writing for himself and Justices Scalia, Thomas, O'Connor and Kennedy, stressed the American legal system's long history of prohibiting both the commission of suicide and the facilitation of it, noting:

> [T]he prohibitions against assisting suicide never contained exceptions for those who were near death. Rather, 'the life of those to whom life had become a burden--of those who were hopelessly diseased or fatally wounded--nay, even the lives of criminals condemned to death, were under the protection of the law, equally as the lives of those who were in the full tide of life's enjoyment, and anxious to continue to live.' *Blackburn v. State*, 23 Ohio St. 146, 163 (1872); see [*Commonwealth v. Bowen*, 13 Mass. 356, 360 (1816)] (prisoner who persuaded another to commit suicide could be tried for murder, even though victim was scheduled shortly to be executed).

521 U.S. at 714-15.

The Supreme Court expressly rejected the lower court's adoption of a "sliding-scale" approach, under which the State's interest in preserving life "depends on the medical condition and the wishes of the person whose life is at stake." Id. 729 (citation and internal quotations omitted):

> [The] *Washington* [decision] ... rejected this sliding-scale approach and, through its assisted suicide-ban, insists that all persons' lives, from beginning to end, regardless of physical or mental condition, are under the full protection of the law. See *United States v. Rutherford*, 442 U.S. 544, 558, 99 S. Ct. 2470, 2478-79, 61 L. Ed. 2d 68 (1979) ('. . . Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise'). As we have previously affirmed, the States 'may properly decline to make judgments about the "quality" of life that a particular individual may enjoy,' *Cruzan* [v. *Director, Mo. Dept. of Health*], 497 U. S. [261], 282 [1990]. This remains true, as *Cruzan* makes clear, even for those who are near death.

Id. 729-30.

Likewise, the Chief Justice ruled that "[t]he State's interest here goes beyond protecting the vulnerable from coercion; it extends to protecting disabled and terminally ill people from prejudice, negative and inaccurate stereotypes, and 'societal indifference.'" Id. 732 (citation omitted). Thus, "[t]he State's assisted-suicide ban reflects and reinforces its policy that the lives of terminally ill, disabled, and elderly people must be no less valued than the lives of the young and healthy." Id.

Writing separately to uphold the ban, other justices also identified a range of concerns that doing otherwise would allow inappropriate economic considerations to come into play: "Physicians, and their hospitals, have their own financial incentives, too, in this new age of managed care." Id. 784.

Similarly, Justice Stevens, in arguing that individuals might in some circumstances have the right to choose to end life, did not dispute the State's "unqualified interest in the preservation of human life, which is equated with the sanctity of life." Id. 746 (citations and internal quotations omitted). Indeed, "[t]hat interest not only justifies – it commands – maximum protection of every individual's interest in remaining alive." Id.

Far from being based on a lower valuation of the old or sick, Justice Stevens' approach rested on notions of individual autonomy fully consistent with assigning equal worth to *all* human life:

> "Allowing the individual, rather than the State, to make judgments about the quality of life that a particular individual may enjoy does not mean that the lives of terminally ill, disabled people have less value than the lives of those who are healthy." Id. 746 (citations and internal quotations omitted). Rather, it simply "gives proper recognition to the individual's interest in choosing a final chapter that accords with her life story, rather than one that demeans her values and poisons memories of her."

Id. 746-47 (citation omitted).

Finally, OMB implicitly ignores the fact that cost-effectiveness analysis requires a great deal of information – not only qualitative knowledge of the nature of the harm, but also quantitative knowledge of the dose-response curve or other response pattern. By calling for cost-effectiveness analysis, OMB seemingly ignores the significant gaps that now exist in the public record on health effects of even widely used chemicals. This issue is more fully discussed in the following section of these comments.

5. "Precautionary" approaches

Noting that "[r]egulators often must decide on an appropriate course of action to protect public health, safety or the environment before science has resolved all the key factual questions about a potential hazard" (p. 5498), OMB requests comment on use of "precautionary" approaches by U.S. regulatory agencies and on how the U.S. "balances precautionary approaches to health, safety, and environmental risks with other interests such as economic growth and technological innovation." We believe that this formulation of the question misses a fundamental point: namely, the need to structure regulatory systems to create incentives to *reduce* those uncertainties, by generating missing information.

Risk-based regulatory approaches are effective only to the extent that quantitative risk data are available. Approaches that are termed precautionary create strong incentives for those who benefit from commercial activities to produce the data needed to fully evaluate the potential hazards from those activities, since "precautionary" approaches by definition address how decisions are to be made in the face of lack of complete information.

By the same token, limiting precautionary approaches undercuts incentives for generating data on risk. While it is possible in theory to directly mandate that commercial entities generate such

data and make it available to the public and government, in practice this occurs only rarely. As a result, gaps in publicly available hazard information are the norm.

For example, gaps in the public availability of even screening-level hazard information exist for *more than 90%* of the highest-volume industrial chemicals (i.e., chemicals other than pesticides, food additives, drugs, and cosmetics that are produced in quantities exceeding one million pounds annually). This startling finding was documented by independent studies in 1998 by the Chemical Manufacturers Association (subsequently renamed the American Chemistry Council, ACC) and the Environmental Protection Agency, following Environmental Defense's 1997 report titled *Toxic Ignorance.*

These data gaps exist even though EPA has long had authority to mandate testing. Indeed, more than 25 years ago, in the Toxic Substances Control Act (TSCA) of 1976, Congress declared that it is the policy of the United States that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [defined to include import] and those who process such chemical substances and mixtures." (TSCA authorizes EPA to issue test rules, though the statutory provisions for doing so have proven clunky at best.)

In late 1998, EPA, Environmental Defense, and ACC jointly developed a framework for the High Production Volume (HPV) Chemical Challenge, under which chemical manufacturers voluntarily agree to sponsor chemicals they produce. More than 450 companies have sponsored more than 2,200 chemicals, and are to ensure that basic data sets are publicly available by 2005.

While the program is making significant progress, it is far from clear that it will be completed on schedule, as Environmental Defense recently concluded in our detailed status report on the program, *Facing the Challenge: A Status Report on the U.S. HPV Challenge Program* (March 2003) (www.environmentaldefense.org/go/hpvchallenge). And several hundred high-volume chemicals have not been sponsored at all.

Moreover, there are fundamental limitations in the HPV program. First, as noted above, the program does not include pesticides, food additives, drugs, and cosmetics, and covers other chemicals only if they are produced in quantities exceeding one million pounds annually. It thus fails to reach more than 10,000 chemicals that are produced in quantities between 10,000 and one million pounds annually, as well as chemicals produced for use as pesticides, food additives, drugs, and cosmetics.

Second, even for covered chemicals, the program only generates *screening-level* data – which in most instances is not sufficient for a full characterization of hazard or the kind of a detailed dose-response curve needed for conducting cost-effectiveness or cost-benefit analyses. No program now exists to provide that more detailed information for the vast majority of chemicals now in commerce.

In addition to severe limitations on the availability of hazard information, health-outcome information is likewise scant. It simply is not the case that "we would know it" if products and

practices in widespread use were causing significant increases in chronic disease, as the data needed to conduct such analyses – much less identify their environmental contributors – simply are not collected for most types of chronic disease. As recently noted by researchers at the Johns Hopkins School of Public Health:[4]

- "Only four states report tracking autoimmune diseases, such as Lupus, even though there is increasing evidence to believe rates of these diseases are rising and the environmental links remain unknown.
- "Despite evidence that learning disabilities have risen 50 percent in the past 10 years, only six states track these disorders. Most states do not track severe developmental disabilities like autism, cerebral palsy and mental retardation. A recent report of the National Academy of Sciences estimates that 25 percent of developmental disorders in children are caused by environmental factors.
- "Endocrine and metabolic disorders such as diabetes, and neurological conditions such as migraines and multiple sclerosis, have increased approximately 20 percent between 1986 and 1995, based on surveys by the Centers for Disease Control and Prevention (CDC). Most states do not systematically track these diseases and conditions.
- "For most of the United States, there is no systematic tracking of asthma despite the disease having reached epidemic proportions and being the No. 1 cause of school absenteeism. Between 1980 and 1994, the number of people with asthma in the United States jumped by 75 percent.
- "Birth defects are the leading cause of infant mortality in the United States, with about 6,500 deaths annually. Since the mid-1980s, rates of low birth weight and pre-term births have been rising steadily despite increased prevention efforts. The causes of 80 percent of all birth defects and related conditions remain elusive even as evidence mounts that environmental factors play an important role. …. [L]ess than half the nation's population is covered by state birth defect registries…."

In short, until and unless adequate information on health hazards exists, precautionary approaches serve a vital role – not only in protecting public health directly, but also in creating incentives to produce additional information on risk. Conversely, limiting precautionary approaches undercuts incentives to generate additional information.

Conclusion

In sum, OMB should revamp the Guidance to require a narrative presentation of costs and benefits without use of discounting of nonmonetary costs or benefits, and without monetizing of nonmonetary costs and benefits – particularly where the benefits consist of avoided illnesses, injuries, or deaths.

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[4] *America's Environmental Health Gap: Why the Country Needs a Nationwide Health Tracking Network*, report to The Pew Environmental Health Commission by the Environmental Health Tracking Project Team, Johns Hopkins School of Hygiene and Public Health, September 2000. Available at http://healthyamericans.org/resources/files/healthgap.pdf.

The inclusion of intergenerational benefits is a very significant improvement in the procedure for reasons described above. In the case where the period of benefits is intergenerational, we laud the use of a 1% (but no higher) discount rate.

Thank you for this opportunity to comment.[5]

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[5] The assistance of three members of the Environmental Defense staff – Senior Economist Daniel Dudek, Ph.D., Economist Alexander Golub, Ph.D., and Research Associate Ben Zipperer – in preparing section 2 of these comments is gratefully acknowledged, as is the assistance of Howard Fox, Managing Attorney, Earthjustice, in preparing section 4.