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THE INFORMATIONAL REQUIREMENTS FOR EFFECTIVE REGULATORY REVIEW: AN ANALYSIS OF THE EPA LEAD STANDARD

W. Kip Viscusi

THE REGULATORY REVIEW PROCESS

Since November, 1974, all significant proposed regulations have been subjected to systematic White House review. The chief elements of the review process include the preparation of an economic analysis of the regulation's likely effects (e.g., costs and comparison with regulatory alternatives) and public comment on these proposals by the White House staff. During the Ford and Carter administrations, this review function was the responsibility of the Council on Wage and Price Stability, which often worked in collaboration with the staff of the Office of Management and Budget and the Council on Economic Advisers. The regulatory review staff was transferred to the Office of Management and Budget after Reagan abolished the Council on Wage and Price Stability in 1981.

Notwithstanding changes in administrations, the staff and functions of the regulatory review process have remained fairly constant. From 1975-1980 there was an average of about 50 regulatory analyses submitted annually by the Council on Wage and Price Stability. Of these, approximately one-third were risk-related. Perhaps the most notable trend is the growing importance of EPA regulations, as EPA efforts accounted for one-sixth of all reviews from 1975-1980 and one-third of all analyses during 1979 and 1980.

The focus of this paper will be on the information one would like to have in order to frame effective risk regulation policies within the context of such a review process. More specifically, I will consider the supporting analysis prepared for the EPA lead standard. The nature of the information prepared for the regulatory oversight process highlights many of the deficiencies of both the review process itself as well as the standard-setting process within EPA. The purpose of this paper is not to analyze these institutional inadequacies directly; rather, I will assess the information available for policy design, the relation of this information to the criteria used in selecting the regulatory policy, and the divergence between the actual regulatory process and what would be required under a system that selected regulatory policies optimally.

In the following discussion I will assume that the objective of regulatory policies should be to maximize the net benefits (i.e., benefits less costs) to society. Although the implementation of this objective for risk regulation is by no means straightforward, particularly with regard to the valuation of health effects, using a benefit-cost framework is an instructive technique for tallying the pertinent effects of policies and for general guidance to regulation.[1]

LEAD AND THE BENEFITS OF REGULATION[2]

Lead emissions are a typical example of an economic externality since the market decisions regarding the level of lead emissions will not reflect the

adverse effects of lead on society in the absence of some emissions penalty or emissions standard. The chief source of lead emissions is antiknock additives in gasoline, which accounted for 12 times as many lead emissions as did all stationary sources in 1975. Although the role of auto emissions is expected to diminish due to the limits imposed on alkyl lead additives in gasoline, the stationary sources which were the focus of the EPA lead standard will continue to contribute to only a small portion of an individual's lead exposure.

To address this problem, EPA established a lead standard of 1.5 micrograms per cubic meter of air (for simplicity, I will omit this metric in the discussion below, referring simply to an air lead level of 1.5).[3] States were required to develop plans regulating stationary source emissions to meet this standard.

Two features of this policy should be noted at the outset. First, the emissions standard was set uniformly for all states. If there is heterogeneity in either the incremental costs of compliance or the incremental benefits from lead exposure reduction, such a policy will not be optimal. The uniformity that should prevail is that the pollution standard for each state should equalize the incremental net benefits from further tightening of the standard. For example, other things being equal, a state with a large affected population should have a tighter standard, and states with an industry mix for which compliance is very costly should have a looser standard. The failure to reflect this heterogeneity stems from EPA's more general problem of focusing on an incorrect objective for regulation, as will be discussed further below.

A second inadequacy of setting standards for stationary sources is that they constitute only a small portion of lead exposures. Although EPA correctly concluded that there was no major conflict among different lead regulation policies, such as the OSHA lead exposure standard and CPSC lead paint regulations, there was no attempt to analyze the most cost-effective policy mix. In the absence of such analysis, it is doubtful whether the independent selection of these policies will be the least expensive means for reducing air concentrations of lead. Since non-air sources of lead received even less consideration, the policymakers neglected a potentially effective means for affecting the fundamental matter of concern, which is the levels of lead concentration in human blood, not in the air.

If we abstract from these broader issues and focus on the benefits from regulating stationary sources of lead emissions, the critical inputs needed to assess the benefits are the following: 1) the sources of lead emissions and their impact on airborne concentrations of lead, 2) the relation between air exposure levels and lead levels in the blood, 3) the health implications of these blood concentrations, and 4) the dollar value of these health effects.

The final category of considerations was ignored altogether. Although precise dollar equivalents for many health effects may be difficult to obtain, the relative severity of the health effects should have been analyzed. Moreover, even if the dollar value for different health impacts is unclear, it is usually instructive to make cost-effectiveness comparisons, indicating whether the cost per case of anemia prevented is $10,000 or $10 million.

EPA did address the first three considerations needed to assess benefits, although the information provided did not serve as a fully adequate basis for

decision. The first issue—the source of airborne lead exposures—was addressed reasonably well on an aggregate basis. It was noted, for example, that the lead standard would have its greatest effect on the operation of the metal and metal products industries, such as primary smelting, secondary smelting, battery manufacturing, pigment manufacturing, and nonferrous foundries. However, information about the level of lead emissions in other areas is required in order to assess the benefits from reductions in these lead emissions adequately. Any regional variation in the implications of lead emissions will make it desirable to have different lead standards rather than a uniform national standard.

The second consideration—the effect of air exposure levels on blood lead levels—was treated by assuming that each microgram (per cubic meter) of air lead exposure increases the blood level by two micrograms (per deciliter of blood) for the group most affected by lead, young children. Although the accuracy of this rule of thumb is questionable, its role is limited to estimating the incremental effects of lead exposures. The actual blood lead level also depends on the level due to non-air sources as well, which EPA analyzed in some detail.

The greatest deficiency in the analysis is in the third and most fundamental category of concerns, the health implications of blood levels. A meaningful analysis of these health effects would assess the number of people with different lead-related ailments in the absence of regulation and the incremental effect on these health outcomes of different lead standards. In conjunction with information regarding the severity of the impacts and the costs of the different policies, the policy tradeoffs involved could be addressed directly.

Unfortunately, EPA was not guided by overall effects but instead attempted to provide an "adequate margin of safety," as directed by section 109 of the Clean Air Act. This mandate was interpreted to require that 99.5 percent of the most sensitive population be substantially below the threshold for adverse health effects. This criterion is based on an arbitrarily selected probability of safety, is independent of the number or severity of adverse health effects, and is totally independent of cost considerations. Quite simply, it has no economic justification whatsoever.

The shortcoming that I will focus on here is the use of health effect thresholds, since the threshold approach is quite common in risk analyses. Based on the limited medical available evidence, EPA concluded that the maximum safe blood level was 30 micrograms per deciliter. At that level there is some evidence of impaired heme synthesis in cells, although the link to hemoglobin production or any other significant health impact is unclear. The lowest level at which there is a reasonably well-established link to a serious health effect is a blood level of 40, at which anemia is possible. More severe effects such as brain damage, have been identified at blood levels from 80-100. EPA selected 30 as the critical threshold to provide a margin of safety.

Even if 30 micrograms per deciliter is accepted as the level at which some adverse health effects may occur, the existence of such a threshold only implies that there is some possible risk at that level. There is substantial debate within the medical profession as to whether threshold dose-response models are meaningful. Other frameworks, such as log-probit models or logistic

models, often have superior statistical properties. Even when a threshold model is appropriate, the existence of a threshold only identifies the exposure level at which the risk is not zero. In the usual case, it is assumed that the risk is zero just below the threshold, in just above zero at the threshold, and increases linearly with exposure levels above the threshold. The probability of the adverse outcome typically does not jump from zero to one simply because the threshold has been reached. In the case of the EPA lead standard, the regulatory cost that can be justified will be quite different if the health risk at the threshold is .1 or .0001.

The net affect of the EPA approach is to assure that only 0.5 percent of the most sensitive segment of the population would have lead levels in their blood associated with some possibly adverse effect. Moreover, even this blood level is relatively safe, since more serious effects such as anemia do not occur until lead levels ten micrograms higher. This policy was formulated independent of the number of adverse health effects prevented, the severity of these effects, and the costs imposed on society. Such an approach can only be justified if society places an infinite value on even minor health effects, which is a rather tenuous basis for policy.

THE COSTS OF THE EPA LEAD STANDARD

The most beneficial consequence of the White House regulatory review process is that agencies now calculate the projected costs of significant new regulations. The proposed lead standard, which was based on monthly exposure levels of 1.5, entailed capital investment costs of $620 million and annualized costs of $137 million.[4] The variation in the impact by industry is considerable, with two-thirds of the burden being on two industries—primary copper smelting and grey iron foundry casting—and almost all of the remainder borne by three industries—primary lead smelting, secondary lead smelting, and the lead-acid battery industry.

The relative impact of these costs also varied substantially, as the lead standard would require capital investments almost five times greater than the current level of capital expenditures in the primary copper smelting industry, almost a doubling of such expenditures for the secondary lead smelting and grey iron foundry casting industries, and considerably smaller effects on other industries.

The differential burdens imposed on these industries suggest that there is also likely to be wide variation in the incremental costs of lead emission reduction across different industries. Since within any particular area the benefits of lead exposure reduction depend on the level in the air, not on which source has been affected, the most cost-effective way to reduce lead exposures is to vary the emissions standard across industries to equalize the incremental costs of lead emissions reductions.

This type of calculation is not possible with the data available since the focus of the cost estimates was on the overall cost for the economy rather than on the variation of these costs with different standards. As with the benefit information discussed earlier, EPA did not generate the type of information needed to make an informed policy choice since their own policy objectives

were misguided, and the requirements imposed by the regulatory review process were not sufficient to redirect EPA's efforts as fully as is needed.

CONCLUSION

It is generally agreed that the impact of the regulatory review process on risk regulations in the 1970s was, at best, relatively modest. To some extent, the failure to reform risk regulation was attributable to the absence of more effective political power for the regulatory review agency. But even if the influence of the regulatory oversight group had been strengthened, optimal decisions would not have resulted since the information needed to make these choices was never provided.

Ideally, one would like to have perfect information about the implications of policies so that the policy choice can be based on the relative merits of the available alternatives. Unfortunately, some key ingredients of the analysis, such as the nature of the dose-response relationships, are not well known. In these cases, policymakers should explore the implications of different assumptions about the nature of these relationships; the present approach to decisions can only be justified if one assumes that the risk jumps from zero to one once a critical threshold is reached.

Many presently omitted components of the analysis are excluded because of EPA's misguided policy objective rather than because of the absence of the necessary information. Regional variations in the benefits of a regulation hinge primarily on the size and composition of the exposed population. Similarly, the heterogeneity in the costs imposed by a regulation also depends on usually well known parameters, such as the region's industry mix and the difference in the costs of compliance by industry. (See Viscusi, forthcoming, for examples of heterogeneous costs for occupational risk regulations.)

Establishment of a sound basis for regulation will promote the better utilization of currently available information and will enable policymakers to make more precise judgments on the sensitivity of the optimal policy choice to the values of parameters that are not known. Moreover, since the information provided by agency staff and by contractors to the agency is usually linked to the agency's policy objectives, the provision of pertinent information should be enhanced by the use of better criteria for selecting policies.

Meaningful reform of risk regulation requires not only the establishment of further benefit-cost requirements for purposes of White House review, but also a revision of the regulatory agencies' legislative mandates so that these tradeoffs will be recognized in the design and implementation of policies. At present, agencies promulgate risk regulations based on policy objectives that fail to explicitly incorporate the extent or severity of health effects involved, the level of costs associated with the regulation, or the heterogeneity of the costs imposed in different areas and on different industries. Until this kind of information becomes the basis for regulatory policies, risk regulations will continue to impose substantial costs on society, while conferring few significant benefits.

FOOTNOTES

1. For further discussion of the valuation of health effects and related policy issues, see Viscusi (1979).

2. The supporting technical information prepared by EPA is contained primarily in the EPA's *Air Quality Criteria for Lead* (1977).

3. For a description of this final rulemaking, see the *Federal Register,* Vol. 43, No. 194 (October 5, 1978):46246-46258.

4. These estimates are based on EPA's *Background Support Document for Economic Impact Assessment of the Lead Ambient Air Quality Standard* (January, 1978). These cost estimates were analyzed in some detail within the White House oversight unit in the internal memorandum by Thomas Hopkins and Dianne Levine.

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