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AN SAB REPORT: TECHNICAL REVIEW OF THE PROPOSED TSCA SECTION 403 REGULATION (IDENTIFICATION OF DANGEROUS LEVELS OF LEAD)

PREPARED BY THE ENVIRONMENTAL HEALTH COMMITTEE (EHC) OF THE SCIENCE ADVISORY BOARD (SAB)

November 20, 1998

EPA-SAB-EHC-99-004

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Subject: Technical review of the proposed TSCA Section 403 regulations (Identification of Dangerous Levels of Lead)

Dear Ms. Browner:

At the request of the EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS), Office of Pollution Prevention and Toxics (OPPT), the Environmental Health Committee (EHC) conducted a technical review of the Lead 403 Rule. The EHC met on September 8-9, 1998 in Arlington, Virginia. The EHC was charged to review the technical aspects of the risk analysis which was presented in *Risk Analysis to Support Standards for Lead in Paint, Dust, and Soils*, Volumes I and II, and on the net benefits (benefits minus cost) analysis which was presented in *Economic Analysis of Toxic Substances Control Act Section 403: Hazard Standards*. Subsequent to receipt of the charge, the EHC received the notice of the proposed lead rule under authority of section 403 of the Toxic Substances and Control Act (TSCA), in the Federal Register of June 3, 1998. The EHC found that some of the informative discussion in the Federal Register notice was additional to that in the Agency reports. Therefore, some of the recommendations relate to the information in the proposed rule.

The Agency is commended for the significant effort to provide a technical basis for the proposed standards for lead levels in dust and soil and for the wealth of knowledge displayed during the meeting. Overall, the EHC found many of the approaches used in the risk analysis to be technically sound, appropriate, and scientifically defensible. Detailed comments are contained in the full report.

The EHC has the following recommendations to improve and clarify the technical approach for conducting the risk analysis:

a) The Agency should provide a clearer presentation on how Intelligence Quotient (IQ) for risk and cost benefit analysis is used, the significance of lack of a threshold, the impact of IQ shifts, the use of additional literature references for the below 70 IQ scores, emphasis on IQ as a neurological surrogate, and the explanation that the IQ fractional point loss is valid for economic analysis but not for interpretations for individual children;

b) The Agency should add more animal data since they support human data by establishing causality, due to the absence of confounding variables, and potential mechanisms for adverse health effects;

c) The Agency should clarify the discussion regarding the basis for setting the lead standards given the marginal costs and marginal nets, including a plan for follow-up to specific interventions;

d) The Agency should evaluate the potential role of education as an intervention strategy;

e) The Agency should state, explicitly, the difference between a *soil-lead standard* of 2000 parts per million (ppm) and the *soil-lead level of concern* of 400 ppm and its impact on current practices by the Department of Housing and Development, as well as some States; this difference should be explained along with the initial presentation of the standards;

f) The sensitivity analysis should be expanded with a case study of a real community that is highly susceptible to lead exposure and a presentation of the costs and benefits associated with the case study; and

g) A plan should be developed for follow-up to evaluate the effectiveness of the specific interventions and lead standards on public health.

The EHC concurs that available data have not identified a clear threshold for the health effects from lead and with the rationale that the weight of scientific evidence shows that 10 µg/dl is a reasonable level of concern for childhood blood lead under the applicable statutory standard of "poses a threat." It is recommended that the numerous health effects be brought forward to emphasize that 10 µg/dl is not a threshold value and to show the diversity of potential health effects from lead.

There are critical differences in environmental lead-blood lead relationships found in local communities that should be considered in interpreting the Agency's results at the national level. These differences may be due to regional differences (especially lead in soil from non-paint sources), differences in genetic susceptibility to lead health effects due to genetic polymorphisms, and bioavailability differences for lead from different sources. These factors should be acknowledged in the document, although it is recognized that their use in risk analysis would require research. However, there is sufficient scientific evidence to indicate that delaying rulemaking for additional research would leave a significant number of children unnecessarily at risk. The Committee also provided several editorial comments on the Agency documents, *Risk*

Analysis to Support Standards for Lead in Paint, Dust, and Soils, which are included in Appendix D.

The Agency report documented that the most susceptible age range for children was 1-2 years and that the economic analysis was based on children aged zero to six years. The EHC felt that it would be useful for the literature about the standards to consistently reference the broader age range of 0-6 years. The EHC recommends this to eliminate the possible misconception that the risk is only for the 1-2 year old child.

The Agency is highly commended for its stated intent to prepare and distribute educational material tailored to specific circumstances for helping the public comply with the lead standards of the Lead 403 Rule. The EHC feels that guidance is particularly important since the requirement for homeowners to disclose a known lead risk may be a disincentive for testing.

The Committee appreciates the opportunity to review the Lead 403 Rule and looks forward to receiving a written response from the Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances.

Sincerely,

/signed/
Dr. Joan A. Daisey, Chair
Science Advisory Board

/signed/
Dr. Emil A. Pfitzer, Chair
Environmental Health Committee
Science Advisory Board

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This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

ABSTRACT

The Environmental Health Committee (EHC) commends the Agency for its effort to conduct a risk analysis for proposing standards for lead levels in dust and soil as required by the Lead 403 Rule and for the wealth of knowledge on the Lead 403 risk analysis that the Agency displayed during the meeting which was held on September 8-9, 1998. Overall, the EHC found many of the approaches used in the risk analysis to be technically sound, appropriate, and scientifically defensible.

The EHC offers several recommendations, including: a) providing a clearer presentation on how IQ is used for risk and cost benefit analysis, the significance of lack of a threshold, the impact of IQ shifts, the use of additional literature references for the below 70 IQ scores, emphasis on IQ as a neurological surrogate, and improving the explanation that the IQ fractional point loss is valid for risk and economic analysis but not for interpretations for individual children; b) adding more animal data since they support human data by establishing causality, due to the absence of confounding variables, and potential mechanisms for adverse health effects; c) clarifying the discussion regarding the basis for setting the lead standards given the marginal costs and marginal net benefits, d) including a plan for follow-up to specific interventions; e) evaluating the potential role of education as an intervention strategy; f) stating, explicitly, the difference between a soil-lead standard of 2000 parts per million (ppm) and the soil-lead level of concern of 400 parts per million (ppm) and its impact on current practices by the Department of Housing and Development, as well as some States; f) expanding the sensitivity analysis with a case study of a real community that is highly susceptible to lead exposure and a presentation of the costs and benefits associated with the case study; and h) developing a plan for follow-up to evaluate the effectiveness of the specific interventions and lead standards on public health.

Some of these recommendations will require further research. However, there is sufficient scientific evidence to indicate that delaying rulemaking for additional research would leave a significant number of children unnecessarily at risk.

The Agency is highly commended for its stated intent to prepare and distribute educational material tailored to specific circumstances for helping the public comply with the lead standards of the Lead 403 Rule.

Key Words: Lead 403 Rule, cost benefit analysis, Intelligence Quotient (IQ), soil-lead standard, soil-lead level of concern

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1. EXECUTIVE SUMMARY

At the request of the EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS), Office of Pollution Prevention and Toxics (OPPT), the Environmental Health Committee (EHC) conducted a technical review of the Lead 403 Rule. The EHC met on September 8-9, 1998 in Arlington, Virginia. The EHC was charged to review the technical aspects of the risk analysis which was presented in *Risk Analysis to Support Standards for Lead in Paint, Dust, and Soils*, Volumes I and II, and to review the net benefits (benefits minus cost) analysis which was presented in *Economic Analysis of Toxic Substances Control Act Section 403: Hazard Standards*. Subsequent to receipt of the proposed rule for the identification of dangerous levels of lead in the Federal Register of June 3, 1998, the EHC found that some of the informative discussion in the Federal Register notice was additional to that in the Agency reports. Therefore, some of the recommendations relate to the amount of information in the proposed rule.

The EHC commends the Agency for its effort to conduct a risk analysis for proposing standards for lead levels in dust and soil as required by the Lead 403 Rule and for the wealth of knowledge on the Lead 403 risk analysis that the Agency displayed during the meeting. Overall, the EHC found many of the approaches used in the risk analysis to be technically sound, appropriate, and scientifically defensible.

The EHC addressed the following 6 specific charge questions and 5 general charge questions:

a) Specific Charge Question 1: *The HUD National Survey, conducted in 1989-90, measured lead levels in paint, dust, and soil in 284 privately owned houses. Does our use of these data constitute a reasonable approach to estimating the national distribution of lead in paint, dust, and soil?*

The use of the data from the HUD National Survey is a reasonable approach since the data are the best currently available. The upcoming HUD survey should have greater power and should therefore increase the accuracy of the database.

b) Specific Charge Question 2: *The approach employs conversion factors to combine data from studies that used different sample collection techniques. Is this appropriate? Is the method for developing these conversion factors technically sound?*

Since both 'wipe' samples and 'vacuum' samples were used in different surveys, it was necessary to be able to equate sampling methods before combining data. The methods are considered to be appropriate, technically sound and well described in clear language.

c) <u>Specific Charge Question 3:</u> IQ point deficits.

(1) *the approach characterizes IQ decrements in the baseline blood-lead distribution, essentially implying that any blood-lead level above zero results in IQ effects. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate?*

Since the available data do not demonstrate a clear threshold for relating IQ decrements to blood-lead levels, there is sufficient technical justification to use an empirical fit that assumes that any blood-lead level above zero results in IQ effect, as long as it is used only for predictive models and economic analysis. The EHC recommends that the justification should be improved by a clearer presentation of: a) how IQ measures are used for risk and cost benefit analyses; b) the significance of a lack of a threshold; c) the relevance to other methodologies such as NOAEL and Benchmark Dose; and d) additional references to the literature, particularly relevant animal data that support causality, due to the absence of confounding variables, and mechanism. IQ should be described as a surrogate for potential neurological deficits for which we lack adequate metrics [and may not be the most sensitive marker]. The approach is defensible and appropriate for descriptions of population effects suitable for predictive models and economic analysis, but should not be used for predictions about an individual.

The EHC concurs that the available data have not identified a clear threshold for the health effects from lead and with the rationale that the weight of scientific evidence shows that 10 µg/dl is a reasonable level of concern for childhood blood lead under the applicable statutory standard of "poses a threat." It is recommended that the list of numerous health effects presented on page 30316 of the Federal Register be brought forward to emphasize that 10 µg/dl is not a threshold value and to show the diversity of potential health effects from lead.

(2) *the characterization of IQ point loss in the population includes the summation of fractional IQ points over the entire population of children. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate?*

With recognition of the principle that small effects distributed across a large population exert large total health effects, the technical justification in the Agency report needs a more direct explanation. Some readers may be confused because they interpret the exercise as awarding fractional IQ points to individual children. The relatively large test-retest variation for an individual measurement of IQ should be acknowledged. Again, the approach is defensible and appropriate as utilized for population predictions.

(3) *one of the IQ-related endpoints is incidence of IQ less than 70. Should consideration be given to what the IQ score was, or would have been, prior to the decrement (i.e., should different consideration be given to cases where a small, or even fractional, point decrement causes the 70 occurrence vs. being 70 due to larger decrements)? If so, how might this be done?*

The Agency report relies on the probabilistic analysis devised by Wallsten and Whitfield in 1986 for estimating IQ scores below 70 due to lead exposure. This report by Wallsten and Whitefield which was not published in the peer-reviewed literature was based on expert estimates as a substitute for data. Expert judgment is no longer needed for such calculations because later publications with data are available.

The issues of IQ shifts, complexities of IQ measurements, significance of fractional IQ units, and potential influence of socioeconomic status require a more complete and clear presentation. Several examples for alternative presentations are provided.

d) Specific Charge Question 4: *Are the assumptions regarding duration, effectiveness, and costs of intervention activities reasonable?*

Six interventions were defined for lead based paint (LBP) and for lead in soil and dust. The interventions are dust cleaning, interior or exterior LBP maintenance, interior or exterior LBP encapsulation/abatement, and soil removal. The expected duration of effectiveness of these interventions as described in Table 6-1 of the Agency report was considered reasonable. The EHC recommends that further consideration be given to the selection of housing units that trigger intervention, and the biases that affect the number of housing units triggered by pre-intervention dust-lead loadings. Although education as an intervention strategy has been reported to not work well in disadvantaged communities, it is recommended that the potential role of education as an intervention strategy be evaluated.

The major problems with the cost benefit analysis for interventions to lead hazards are an overestimation of cost and an underestimation of benefits. These divergent estimations tend to be additive to each other rather than negating each other, however, the standards for lead were not based solely on the benefits and costs. It is important to recognize that values derived from the cost benefit analysis are only relative values that are not rigorous, scientifically defensible numbers in and of themselves. It is also important to keep in mind that the risk analysis is a tool to systematically compare various standards options in a uniform manner looking for the combination that maximizes net benefits. Whether the calculated costs and benefits are highly accurate of what actual costs and benefits will be is less important than the comparative relationships and the methodology's ability to discriminate between standard options. Recommendations for improving the cost benefit analysis include (a) clarifying the discussion regarding the basis for setting the lead standards given the marginal costs and marginal nets, and (b) including a plan for follow-up to specific interventions. A more detailed review of the economic analysis is included as Appendix E which was written by an EHC Consultant.

e) Specific Charge Question 5: *Are the combinations of standards used in Chapter 6 of the risk analysis reasonably employed given the potential interrelationships between levels of lead in different media? Are additional data available on the interrelationship between lead levels in paint, dust, and soil prior to and after abatement?*

One might say, in an almost self-evident way, that the various combinations of standards were reasonably employed in that they provided a basis for the Agency to select specific standards for the proposed rule. The EHC would like to have seen a table of the estimated distribution of health effect and blood-lead concentration endpoints using the actual proposed standards and a more complete discussion of implications of the predictions of the models. The EHC was not aware of additional data on the interrelationships among lead levels in paint, dust and soil prior to and after abatement. Subsequently, the EHC received the publication by Ashley, et. al (1997) describing the use of stable lead isotopes techniques to identify probable sources of lead and to design appropriate source specific interventions.

f) Specific Charge Question 6: *The approach for estimating health effect and blood-lead concentration endpoints after interventions is based upon scaling projected declines in the distribution of children's blood-lead concentrations to the distribution reported in Phase 2 of the National Health and Human Nutrition Examination Survey (NHANES) III. Under this approach, data collected in the HUD National Survey are utilized to generate model-predicted distributions of blood-lead concentrations prior to and after the rule making. The difference between the pre section 403 and post section 403 model predicted distributions is used to estimate the decline in the distribution of children's blood-lead concentration. This decline is then mathematically applied to the distribution reported in NHANES III. Is this adjustment scientifically defensible in general, and in the specific case where the environmental data -- from the HUD Survey -- and the blood lead data -- from NHANES III -- were collected at different times (1989-90 vs. 1991-1994)?*

The EHC found the adjustment to be scientifically defensible given that the various conversion factors are clearly delineated and well justified. The Agency report provides a useful discussion of the assumptions and limitations of each of the models. However, the EHC found the description of the approach in the report to be very complex and difficult to understand and recommends the use of the illustration in Appendix B, as was provided by the Agency at the meeting, and annotated by the Agency after the meeting to further improve its clarity.

g) General Charge Question 1: *In each of the specific areas identified above, have we used the best available data? Have we used these data appropriately? Have we fairly characterized the variability, uncertainties and limitations of the data and our analyses?*

The data sets are considered the best available in this area and the Agency has used them in an appropriate manner for the task. The support documents go to considerable length to characterize the variability, uncertainties and limitations of the data, models used and analyses. The human epidemiological data seem to have been chosen judiciously. A number of additional references are provided that should support the data used.

With regard to fair characterization, the proposed standards for lead in dust and soil, as presented on page 30303 of the Federal Register, do not make it clear that the probability of exceeding a blood-lead level of 10 μg/dl is higher for the soil-lead standard than it is for the dust-lead standards. The EHC recommends that this difference be explained along with the initial presentation of the standards. It is also recommended that the *soil-lead standard* of 2,000 ppm and the *soil-lead level of concern* of 400 ppm be explained with regard to the impact on current practices of the Department of Housing and Urban Development (HUD) and certain States.

h) General Charge Question 2: *Are there alternative approaches that would improve our ability to assess the relative risk impacts of candidate options for paint, dust, and soil hazard standards?*

The approaches taken were considered to be reasonable. While a variety of alternatives are possible, most of them would require additional research. The EHC felt that it would be useful for the literature about the standards to consistently reference the broader age range of 0-6 years. The EHC makes this recommendation to eliminate the possible misconception that the risk is only for the 1-2 year old child.

i) <u>General Charge Question 3</u>: *The approach employs risk analysis models that were primarily developed for use in site-specific or localized assessments. Has the use and application of the Integrated Exposure Uptake Biokinetic Model (IEUBK) and empirical model in this context been sufficiently explained and justified? Is our use of these tools to estimate nationwide impacts technically sound?*

The general characteristics, uses and application of the IEUBK and empirical models are well described, explained and justified. However, the complexity presented in the Agency report was difficult to follow. The discussion (page 30315 of the Federal Register notice) on the strengths and weaknesses of a mechanistic model vs. a model based on empirical data was helpful and the EHC recommends that it be included in the report. There is no perfect model. Thus the use of two models (IEUBK and empirical) is appropriate and helpful, even though both are flawed. Although each of the models has its limitations and uncertainties, the estimates from these two complementary models overlap. To that end, it would be helpful to provide greater emphasis upon the commonalties found and when possible utilize the empirical data from the supportive studies to validate the observations.

The EHC concluded that the Agency's use of these tools was technically sound with the caveats noted in the responses to the specific questions above (e.g., 10 µg/dl is not a threshold). The EHC also concluded that the use of the tools to estimate nationwide impacts is technically sound but that there are uncertainties because the Agency is not using an absolute predictor.

j) <u>General Charge Question 4:</u> *Are there any critical differences in environmental lead-blood lead relationships found in local communities that should be considered in interpreting our results at the national level?*

There are differences in environmental lead-blood lead relationships found in local communities. These differences may be attributable to factors such as regional differences in the bioavailability of lead dependent on the source of the lead (especially lead in soil from non-point sources), nutrition, age, and genetic susceptibility. However, data on the effect of these factors on environmental lead-blood lead relationships are limited and additional research would be required to consider these factors in interpreting the Agency's results for lead-blood lead relationships at the national level. The EHC acknowledges the Agency's plans for flexibility at the regional level for complying with the lead standards.

k) <u>General Charge Question 5:</u> *In view of the issues discussed and analyzed in sensitivity analyses contained in the two documents, in what specific areas should* *we focus (e.g., refine our approach, gather additional data, etc.) between now and the final rule?*

The EHC recommends three specific projects for inclusion in the final rule: (1) an expansion of the sensitivity analysis to include a case study of a real community that is highly susceptible to lead exposure and a presentation of the costs and benefits associated with that case study, (2) development of a plan for follow-up to evaluate the effectiveness of the specific interventions, and (3) sensitivity analyses that carry through all the way to cost for conversion factors used to compare media loadings and for assumptions regarding the housing industry.

In this report the EHC has made a number of recommendations for improving the scientific basis for the standards in the Lead 403 Rule. Some of these recommendations will require further research. However, there is sufficient scientific evidence to indicate that delaying rulemaking for additional research would leave a significant number of children unnecessarily at risk.

The Agency is highly commended for its stated intent to prepare and distribute educational material to provide guidance for complying with the standards. This material should be tailored to specific circumstances. The EHC feels that guidance is particularly important since the requirement for homeowners to disclose a known lead risk may be a disincentive for testing.

2. INTRODUCTION

2.1 Background

The Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851) includes an amendment to the Toxic Substances Control Act (TSCA). This amendment requires the EPA Administrator to enact a variety of activities to identify and reduce environmental exposure to lead hazards. This amendment is referred to as Section 403 of TSCA and includes the following language, "... the Administrator shall promulgate regulations which shall identify, for purposes of this title and the Residential Lead-Based Paint Hazard Reduction Act of 1992, lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil."

The reports reviewed by the EHC were *Risk Analysis to Support Standards for Lead in Paint, Dust, and Soils*, Volumes I and II, which presented the methods and findings of risk analysis that provides the scientific foundation for the proposed standards and *Economic Analysis of Toxic Substances Control Act Section 403: Hazard Standards* presenting a net benefits (benefits minus cost) analysis. Subsequent to receipt of the charge, the EHC received the notice of the proposed regulation for the Lead 403 Rule in the Federal Register of June 3, 1998. The EHC found that some of the informative discussion in the Federal Register notice was additional to that in the Agency reports. Therefore, some of the recommendations relate to the amount of information in the proposed rule.

The population of interest for the risk analysis was U.S. children aged 1-2 years. To characterize the health risk associated with lead exposures to children aged 1-2 years, the risk analysis considered elevated blood-lead concentration and IQ point deficit as the health endpoints. The national distribution of blood-lead concentration in children aged 1-2 years was determined from data collected in Phase 2 of the third National Health and Nutrition Examination Survey (NHANES III), conducted from 1991-1994. Environmental-lead levels in the nation's housing stock were obtained from the National Survey of Lead-Based Paint in Housing, conducted from 1989-1990 by the U.S. Department of Housing and Urban Development (HUD). In analyzing data from the HUD National Survey, the Agency used conversion factors to combine data from studies that used different sample collection techniques. The Agency obtained data on the number of housing units and on children within specified housing groups from the U.S. Bureau of the Census.

Two statistical models were used to characterize the risks posed by lead exposure to the nation's population of children aged 1-2 years: the Agency's Integrated Exposure, Uptake, Biokinetic (IEUBK) Model for Lead in Children (version 0.99D) and an empirical regression model developed for the risk analysis. The IEUBK model was reviewed by the Science Advisory Board Indoor Air Quality and Total Human Exposure Committee in March 1992 (SAB, 1992). The empirical model, which was developed specifically for this study, is based on data collected in a single lead exposure study (Lanphear et al., 1995). The empirical model was developed to address some aspects of lead exposure that were important to the risk management analyses but could not be directly addressed by the IEUBK model. However, both models have their limitations. For example, the empirical model can predict blood-lead concentration based on dust-lead loadings rather than concentration, using data on lead loadings in window sill dust as well as floor dust, and representing the effect of pica tendency in the presence of deteriorated lead-based paint. The IEUBK model does not have this capability. On the other hand, the empirical model uses data from one site as representative of a national level. Since neither of the models is optimal for application within the risk analysis, the Agency used both models to obtain two distributions of blood-lead concentration. Both models were used for obtaining blood-lead distributions using floor-lead and soil-lead data, while only the empirical model was used for window sills-lead data.

The Agency ultimately estimated the national distribution of blood-lead concentrations that represented conditions after implementing the proposed Lead 403 rule and that was directly comparable to the baseline distribution. The IEUBK model and a third statistical model, the Rochester multimedia model, were used to determine "individual risks" which was defined by the Agency as risks associated with children exposed to specified environmental-lead levels. The Agency also estimated "population-based risks", the risk to an entire population of children aged 1-2 years, given exposure to baseline levels of lead in the nation's housing stock.

As part of the development of standards for lead dust and paint exposure under Section 403 of the Toxic Substances Control Act, the Economic and Policy Branch of OPPT performed a benefit-cost analysis (BCA). The BCA is conducted from a national perspective, covering a 50-year period. As soon as a child between 0 and 6 years of age enters a house where lead is present, abatement activities are assumed to be conducted until the child reaches 6 years of age. This process is repeated for as many times as a house has a child less than 6 years of age in it over the 50 years. The optimal standards are those that maximize present net benefits of those abatement activities. In conducting the net benefits analysis, the Agency used several default assumptions including estimates for paint pica tendencies, the duration of repairing paint, and the duration of encapsulation/abatement methodology.

The Agency has recognized that available data have not identified a clear threshold for several lead effects and that biological changes can occur at lower levels. However, the Agency has rejected a zero risk basis for dust- and soil-lead levels of concern for a variety of reasons. For purposes of the proposed rule, 10 µg/dl has been selected as a reasonable level of concern for childhood blood-lead under the applicable statutory standard of “poses a threat.” Thus the proposed standards for lead in dust and soil were designed (based on the technical approaches of the risk analysis) on the basis of predicting that children, living in a residence that had been cleaned to these standards, would have a very low probability of having a blood-lead concentration equal to or exceeding 10 µg/dl.

2.2 The Review and Charge

On September 8-9, 1998, the EHC met in Arlington, Virginia to conduct a technical review of the Lead 403 Rule. The EHC was charged to respond to six specific and five general questions. These charge questions and their responses by EHC are presented in the next section.

3. RESPONSE TO CHARGE QUESTIONS

3.1 Specific Charge Question 1

The HUD National Survey, conducted in 1989-90, measured lead levels in paint, dust, and soil in 284 privately owned houses. Does our use of these data constitute a reasonable approach to estimating the national distribution of lead in paint, dust, and soil?

Findings and Recommendations

The HUD National Survey of Lead-Based Paint in Housing is the only available study designed specifically to provide nationally representative estimates of environmental lead in dust and soil in private housing stock. The EHC considered that it was a well-designed survey using appropriate methodologies. Although the study is more than five years old, it is considered unlikely that the housing stock lead-based paint status has either improved or deteriorated significantly to affect the estimates on a nationwide basis. As with any survey, in retrospect, a larger sample size with more environmental samples per dwelling would have provided more robust descriptive statistics, greater confidence that the analysis of sample results were representative, and increased its utility for the current modeling needs. Empirical data from the community studies discussed in the support documents, and especially the HUD Lead Based Paint Hazard Control Grants, add confidence that the National Survey data remain representative and the relationships between environmental-lead data elements are still appropriate. The adjustments for loss of housing stock (made to arrive at the 1997 estimates of pre-1980 housing stock) are considered appropriate. The necessary conversion factors to account for technical advances in methodology (see Specific Charge Question 2) may be more problematic than the sampling design of a survey completed five years ago.

The upcoming HUD survey of 1,000 homes should have greater power and should, therefore, increase the accuracy of the database used to estimate the national distribution of lead in paint, dust, and soil.

3.2 Specific Charge Question 2

The approach employs conversion factors to combine data from studies that used different sample collection techniques. Is this appropriate? Is the method for developing these conversion factors technically sound?

Findings and Recommendations

Dust-lead measurements from floors and window sills in the HUD National Survey were collected by the Blue Nozzle (BN) vacuum method. In addition the Baltimore Repair and Maintenance (BRM) study used a BRM vacuum technique. Since standards for dust in the 403 Rule will be expressed as a measured lead loading collected by a dust wipe sample, it was necessary to convert the BN and BRM vacuum data to wipe-equivalent dust-lead loadings before combining data for risk analysis. Several studies were presented that reported side-by-side wipe and vacuum dust-lead measurements.

The EHC found that the specific conversion factors were appropriate, technically sound, and well described in clear language in the review document.

3.3 Specific Charge Question 3

The three parts (a,b,c) of this question dealing with IQ point deficits are addressed separately.

a) *the approach characterizes IQ decrements in the baseline blood-lead distribution, essentially implying that any blood-lead level above zero results in IQ effects. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate?*

Findings and Recommendations

Because available data have not identified a clear threshold, the assumption of no threshold for lead effects on IQ score is both defensible and appropriate statistically. However, the EHC recommends that the technical justifications should be documented more thoroughly. Because much of the public, and even some scientists, are confused about what IQ scores measure, the document should clarify how IQ measures are used in the risk and cost benefit analyses. It should state explicitly that, at least for the Agency's purposes, IQ tests are not used to gauge some abstract quality called "intelligence," but, instead, comprise a sample of performance with a defined degree of predictive power that facilitates the economic analysis. Presenting IQ scores in this way might help avoid misunderstandings on the part of some observers who convert the analyses into a claim that "intelligence" determines earnings rather than as a description of an empirical relationship. The document should clearly indicate the limitations of reliance on single criterion that may not be the most sensitive response index, rather than the multiple endpoints of neurotoxicity. (See Mendelson et al., 1998; Wasserman et al., 1998; Needleman et al., 1996; and Sreissguth et al., 1996)

IQ should be recognized as a surrogate for potential neurological deficits for which we lack adequate metrics. The complex relationships surrounding IQ scores further argue for presenting IQ tests as samples of behavior rather than as measures of some pure and unitary dimension. It also relates to the argument that the path between IQ score and economic benefits is not necessarily one of direct causation. Despite their universally acknowledged flaws, IQ scores are more readily translated into predictive models to provide the basis for risk and threshold calculations.

The EHC considered that the arguments about thresholds were somewhat amorphous in the Agency report. The report should elaborate on the attempts to calculate a threshold by testing the suitability of a linear fit to the dose response function (see Tong et al., 1996; Hawk et al., 1986; Wyzga, 1990; and Schwartz, 1993). In addition the EHC found the last paragraph on page 4-22 of the report to be unclear with regard to the assumption that linear models reduce the likelihood of overestimating the number of children at risk with low blood-lead concentrations. If this is an important point it may be clarified with graphical illustrations. The EHC concurs that the available data have not identified a clear threshold for the health effects from lead' and with the rationale that the weight of scientific evidence shows that 10 µg/dl is a reasonable level of concern for childhood blood lead under the applicable statutory standard of "poses a threat." It is recommended that the list of numerous health effects presented on page 30316 of the Federal Register be brought forward to emphasize that 10 µg/dl is not a threshold value and to show the diversity of potential health effects from lead.

Human data, with all the intrinsic flaws of epidemiology, are generally given precedence over animal data for risk analysis. Nevertheless, animal data are able to establish causality (due to the absence of confounding variables) and mechanisms for adverse health effects. This is certainly true for effects of lead and the animal data supply confidence for the human data when the human data have large uncertainties. The EHC recommends that additional animal data be included in the Agency report as support for the use of the human data. Important references include: a) Cory-Slechta, 1997 (which establishes relationships among lead exposure, biological indices, neurochemical systems and behavior with significant effects at blood-lead levels of 10 – 20 µg/dl), and b) Rice, 1996 (which indicates that functional deficits occur in monkeys with steady-state blood-lead levels since infancy as low as 11 µg/dl/.)

The EHC also considered that a discussion of the standard procedures involving NOAEL, benchmark dose and uncertainty factors for risk analyses from animal data should be presented. If the experimental animal data were to be treated by these conventional standards, an acceptable level of lead exposure would likely be an order to two orders of magnitude less. Clarifying the alternatives in this fashion may help the public understand the course adopted by the Agency.

b) *the characterization of IQ point loss in the population includes the summation of fractional IQ points over the entire population of children. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate?*

Findings and Recommendations

The EHC considered that the Agency report should emphasize a core principle of public health; namely, that small effects distributed across a large population exert large total health effects. Thus the characterization of IQ point loss by the summation of fractional IQ points over the entire population of children is considered defensible and appropriate. It was also considered that the technical justification needed to be explained more clearly. In developing the final rule should be very careful when referencing effects in individual children. Some readers, understandably, may be confused because they interpret the exercise as awarding fractional IQ points to individual children. The relatively large test-retest variation associated with any individual measure of IQ should be clearly presented.

c) *one of the IQ-related endpoints is incidence of IQ less than 70. Should consideration be given to what the IQ score was, or would have been, prior to the decrement (i.e., should different consideration be given to cases where a small, or even fractional, point decrement causes the <70 occurrence vs. being <70 due to larger decrements)? If so, how might this be done?*

Findings and Recommendations

The EHC found this question to be the most problematic of all questions about the Agency report, and recommends some reconsiderations.

The report relies on the probabilistic analysis devised by Wallsten and Whitfield in 1986 for estimating IQ scores below 70 due to lead exposure. This report which was not published in the peer-reviewed literature was based on expert estimates as a substitute for data and appeared before the key papers of Bellinger et al. (1987), Dietrich et al. (1987a, 1987b), and others used for Schwartz's (1994) analysis. Expert judgment is no longer needed for such calculations.

The implications of shifts in IQ distribution should be expanded. If, based on the Schwartz meta-analysis, the mean IQ decrement due to lead is 1.06, what does such a shift do to the entire IQ distribution? The document is focused on IQ's below 70, but corresponding changes occur at the other extreme of the distribution as well. An example here would be useful; for instance, describe what would happen with a prototypical IQ distribution (mean=100, SD=15) if the mean were to be displaced by 1% or 1 IQ point; or, 3% or 3 IQ points. How many individuals would be classified as retarded, for example? How many would be demoted from the superior category? In addition, what are the implications for especially vulnerable, highly exposed subpopulations. Largely low incomes and their associated health risks are common in these subpopulations. If lead shifts IQ distributions toward lower scores, its effects are amplified in these subpopulations because their distributions are already displaced toward lower scores. Does including them in the population at large when calculating total IQ displacements underestimate the effects of lead exposure?

The Stanford-Binet and the Weschler Intelligence Scale for Children generally assume a standard deviation of 15 (based on the validation population) and a mean of 100. The Bayley Scales of Infant Development generally conform to these figures. A shift in the population mean of 1% means a shift in the original population mean of 1/15 standard deviation, and an increase in the proportion of scores below 70 from 0.0228 to 0.0266. In a population of 8,000,000 (about the size of the population of children 1-2 years of age), it means a rise from 182,400 to 212,800 children scoring below 70. A shift of 3% would correspond to a rise from 182,400 to 287,200. A graphical depiction appears in Figure 1 of Appendix C and may be useful in communicating this kind of information to readers. Presenting the data in this way should make it unnecessary to deal with the question of fractional point decrements as stated in the Charge Questions. If the risk analysis calculates the mean IQ shift, which can involve fractional percentages, it would provide the corresponding proportion of cases below an IQ of 70.

A second problem with the calculations is the assumption of a United States (U.S.) population mean of 100. Although useful for illustrative purposes, and still in use by schools for classification purposes, it is not considered a realistic assumption for risk characterization. IQ scores around the world have been rising, at roughly 0.3 IQ points annually. This is known as the Flynn Effect, named after James Flynn, a New Zealand political scientist, and is extensively documented and a critical consideration in lead risk analysis. Table 1 in Appendix C shows how the proportion of individuals scoring below 70 varies with mean IQ. If the rise observed during the past several decades continues, standardized test scores will continue to lag this trend and the proportion below 70 will continue to fall. As a result, the risks attributable to lead exposure will be underestimated.

Because of the Flynn Effect, a more useful characterization of low IQ risk might be to discuss it in terms of z-scores. That is, transform risk of IQ less than 70 to risk of falling lower than -2 SD of the standard population which would make it independent of mean population score. The present analysis, based on a mean equal to 100, would then be used for illustrative purposed only. By adopting this approach, the basis for linking lead exposure to IQ would then be expressed in terms of population and subpopulation divergence. An example might compare a subpopulation with a mean blood-lead of 10.8 μg/dl to one with a mean blood-lead of 3.0 μg/dl. On the basis of the Schwartz meta-analysis (one μg/dl equates to 0.257 IQ units, See Schwartz (1994)), this would represent a shift of 2 IQ points [(10.8 - 3.0)(0.257)]. The assessor would then calculate how many children in the subpopulation have been displaced by 2 standard deviations or more below the overall population mean.

A major thrust of the risk analysis is to elucidate the effects of diminished lead exposure on populations with disadvantaged socioeconomic status (SES). As the report notes, minority children in low SES households tend to exhibit higher lead levels. They also tend to score lower on IQ tests. The result is that, for an equivalent displacement of mean IQ, such communities (in the aggregate, not as individuals) would experience a relatively greater impact than those in higher SES groupings for indices such as proportions of IQ scores below 70 or lower than -2 standard deviations. Even SES represents only one of the many risk factors. The cumulative effects of many risk factors, in combination with lead, would need to be determined to fully describe its adverse effects (see Sameroff et al., 1987). Community characteristics pertaining primarily to lead levels are available from several sources (see Lanphear et al., 1996). Among these are race, population density, poverty, and education levels. It is particularly critical, for lead, that these interactive variables are considered. Schwartz's (1994) analysis yielded a lower mean loss in IQ scores attributable to lead in disadvantaged than in advantaged populations. This finding, as noted by the paper, may be a product, if not an artifact, of the greater cumulative risks to development suffered by such populations. The eventual impact on earnings, however, might lie in the opposite direction due to the relationship between IQ and opportunities for education (see Ceci and Williams, 1997) and because of the actual impact of IQ losses on advantaged and disadvantaged populations.

In many surveys, the differences in mean IQ scores of these populations approximate about 15 points. One may assume, then, for modeling purposes, that initial IQ distributions will have respective means of 100 and 85, both with standard deviations of 15. As an impact index, the number of scores below 70 can be calculated. With population sizes of 100,000 each, as shown in Figure 2 of Appendix C, a loss of 1 IQ point in the advantaged population will increase the number of individuals below 70 from 2,280 to 2,660. In the disadvantaged population, the loss assigns 17,530 rather than 15,870 individuals to the below 70 category. Although the proportional shift is greater in the advantaged population (16.7%) than in the disadvantaged population (10.5%), the number of individuals added to the developmentally disabled category is much larger in the disadvantaged population (1,660) than in the advantaged population (380).

3.4 Specific Charge Question 4

Are the assumptions regarding duration, effectiveness, and costs of intervention activities reasonable?

Findings and Recommendations

Six interventions were defined for lead based paint (LBP) and for lead in soil and dust. The interventions are dust cleaning, interior or exterior LBP maintenance, interior or exterior LBP encapsulation/abatement, and soil removal. The expected duration of effectiveness of these interventions as described in Table 6-1 of the report was considered reasonable. The EHC recommends that further consideration be given to the selection of housing units that trigger intervention, and the biases that affect the number of housing units triggered by pre-intervention dust-lead loadings. Although education as an intervention strategy has been reported to not work well in disadvantaged communities, it is recommended that the potential role of education as an intervention strategy be evaluated.

As part of the development of standards for lead dust and paint exposure under Section 403 of the Toxic Substances Control Act, the Agency had a benefit-cost analysis (BCA) performed. The BCA appears to have played a major, if not decisive, role in the choice of standards; indeed, the Federal Register proposed rule notes that the legislation implicitly supports the use of BCA in designating the proposed standards (pp. 30312-30314).

The EHC found the overall process used in the economic analysis to be reasonable. The major problems with the cost benefit analysis for interventions to lead hazards are an overestimation of cost and an underestimation of benefits. These divergent estimations tend to be additive to each other rather than negating each other. The following two factors result in an underestimation of benefits: 1) the use of IQ point deficit as an indicator of adverse health effects, and 2) the exclusion of reduced inspection and abatement/remediation cost associated with fewer children with blood levels exceeding 15 µg/dl. The latter benefit should be applied for universal screening and should be included in the cost benefit analysis. By not taking into account the fact that people will undertake some of the abatement measure (such as repainting) even in the absence of lead will probably result in an overestimation of cost since all painting expenses (both lead abatement and non-lead abatement) are counted as lead abatement expenses. The EHC supports the use of a discount rate of 3% rather than the OMB use of 7% for the economic analysis. A more detailed review of the economic analysis is included as Appendix E which was written by an EHC Consultant.

Most of the default assumptions used in the economic analysis were found to be reasonable as discussed in the detailed review in Appendix E. The EHC recommends that the discussion on the basis for setting the lead standards given the marginal costs and marginal nets be rewritten because it was difficult to follow. It is important to recognize that values derived from the cost benefit analysis are only relative values that are not rigorous, scientifically defensible numbers in and of themselves. It is also important to keep in mind that the risk analysis is a tool to systematically compare various standards options in a uniform manner looking for the combination that maximizes net benefit. Whether the calculated costs and benefits are highly accurate of what actual costs and benefits will be is less important than the comparative relationships and the methodology's ability to discriminate between standard options.

The EHC commends the Agency plans to develop educational material tailored to specific circumstances for helping the public comply with the lead standards of the Lead 403 Rule. For example, a decision tree which answers questions regarding the regulation and guidance should address differences in the age of the children residing in a house, the length of stay in the house and the sensitivity of the children to other toxins. The EHC considers that such guidance is particularly important since the requirement for homeowners to disclose a known lead risk may be a disincentive for testing.

3.5 Specific Charge Question 5

Are the combinations of standards used in Chapter 6 of the risk analysis reasonably employed given the potential interrelationships between levels of lead in different media? Are additional data available on the interrelationship between lead levels in paint, dust, and soil prior to and after abatement?

Findings and Recommendations

The response to the second question above was straightforward in that the EHC was not aware of additional data on the interrelationships among lead levels in paint, dust and soil prior to and after abatement. Subsequently, the EHC received the publication by Ashley et al. (1997) describing the use of stable lead isotope techniques to identify probable sources of lead and to design appropriate source specific interventions.

The first question above was more troublesome for the EHC. One might say, in an almost self-evident way, that the various combinations of standards were reasonably employed in that they provided a basis for the Agency to select specific standards for the proposed rule. What would have been of interest, then, would be a chart in the Federal Register like Table 6-8, but using the actual proposed standards. The EHC thought the more relevant issues were the implications of the predictions from the models based on the standards. For example, (1) what is the contribution of natural lead (lead present not due to human interventions), or lead from water and food as a function of different communities?, (2) should exposure sources in individual units be identified and abated simultaneously?, (3) how often should blood-lead levels be monitored as an indication of effectiveness?, and (4) when should a community's lead exposure be addressed in a global fashion instead of one dwelling unit at a time.

3.6 Specific Charge Question 6

The approach for estimating health effect and blood-lead concentration endpoints after interventions is based upon scaling projected declines in the distribution of children's blood-lead concentrations to the distribution reported in Phase 2 of the National Health and Human Nutrition Examination Survey (NHANES) III. Under this approach, data collected in the HUD National Survey are utilized to generate model-predicted distributions of blood-lead concentrations prior to and after the rule making. The difference between the pre section 403 and post section 403 model predicted distributions is used to estimate the decline in the distribution of children's blood-lead concentration. This decline is then mathematically applied to the distribution reported in NHANES III. Is this adjustment scientifically defensible in general, and in the specific case where the environmental data -- from the HUD Survey -- and the blood lead data -- from NHANES III -- were collected at different times (1989-90 vs. 1991-1994)?

Findings and Recommendations

While one would prefer to have all data sets contemporary to one another and the analytic time frame, this rarely occurs. In this instance, the data sets are nearly contemporary to each other, as all large, complex national surveys are never truly cross-sectional point-in-time, but rather, practicality necessitates implementation over a number of years. The survey design protocols often include statistical sampling methods to minimize the impact of the duration of the survey. The adjustments made to estimate 1997 housing status and the 1-2 year old population blood lead distribution are likely to contribute more uncertainty than the fact that the data sets were not gathered during the exact same periods. Using the geometric mean and geometric standard deviation as the primary descriptive statistics should minimize any impact of outlier shifts.

The EHC considered that the adjustment was scientifically defensible on the basis that the various conversion factors were clearly delineated and justified. Mathematical transformation factors are routinely used in many calculations where it is of scientific value to integrate or compare data sets from two different sources which were collected at two different times. As long as both data sets are scientifically valid, there is no reason why such adjustments cannot be made in principle. The Lead 403 Rule document (Sections 4.1 - 4.3) provides a useful discussion of assumptions and limitations of each of the models used for conversions. The application of the HUD data set to the distribution of blood lead values observed in the NHANES III was appropriate since the NHANES III data set was the largest body of blood-lead data available which is reflective of the general U.S. population. It should hence give the best distributional fit.

The available data and the risk analysis primary objectives (compare 1997 pre-403 standards baseline to post-403 implementation and select the environmental-lead measurements that maximize the net benefit) made it necessary to design a multi-step, multi-model protocol to achieve the necessary comparisons. However, it is difficult to devise a more simplistic approach that would not interject other uncertainties for those removed. The EHC found the description of the approach in the Agency report to be very complex and difficult to understand and recommends the use of the illustration in Appendix B, as was provided by the Agency at the meeting and annotated by the Agency after the meeting.

3.7 General Charge Question 1

In each of the specific areas identified above, have we used the best available data? Have we used these data appropriately? Have we fairly characterized the variability, uncertainties and limitations of the data and our analyses?

Findings and Recommendations

To the best knowledge of members of the EHC, the Agency report has used the best available data sets for making its calculations. The NHANES III and HUD data sets are considered the best available in this area and the Agency has used them in an appropriate manner for the task. The support documents characterize, in considerable length, the variability, uncertainties and limitations of the data, models used, and analyses. The human epidemiological data seem to have been chosen judiciously and their limitations described at length except for the reliance on expert estimates for calculations of IQ scores less than 70. Papers published since then make such reliance unnecessary. In the responses to the questions above, a number of additional references are provided in the response to Specific Charge Question 3 that should support the data used.

With regard to fair characterization, the proposed standards for lead in dust and soil, as presented on page 30303 of the Federal Register, do not make it clear that the probability of exceeding a blood-lead level of 10 µg/dl is higher for the soil-lead standard than it is for the dust-lead standards. The EHC recommends that this difference be explained along with the initial presentation of the standards. It is also recommended that the *soil-lead standard* of 2,000 parts per million (ppm) and the *soil-lead level of concern* of 400 parts per million (ppm) be explained with regard to the impact on current practices of the Department of Housing and Urban Development (HUD) and certain States.

3.8 General Charge Question 2

Are there alternative approaches that would improve our ability to assess the relative risk impacts of candidate options for paint, dust, and soil hazard standards?

Findings and Recommendations

The EHC found the approaches taken to be reasonable. A variety of alternatives , most of which would require additional research for use in the models for risk analysis, were discussed. These included concern for variations in particle size of lead dust, the chemical form of the lead, the variations in absorption from the gastrointestinal tract (50% for children vs. 10% for adults), the potential influence of homes with porches, and the regional variation in climate that may influence the time that windows are open.

The Agency report documented that the most susceptible age range for children was 1-2 years and that the economic analysis was based on children aged zero to six years. The EHC felt that it would be useful for the literature about the standards to consistently reference the broader age range of 0-6 years. The EHC recommends this to eliminate the possible misconception that the risk is only for the 1-2 year old child.

3.9 General Charge Question 3

The approach employs risk analysis models that were primarily developed for use in site-specific or localized assessments. Has the use and application of the Integrated Exposure Uptake Biokinetic Model (IEUBK) and empirical model in this context been sufficiently explained and justified? Is our use of these tools to estimate nationwide impacts technically sound?

Findings and Recommendations

The general characteristics, uses and application of the IEUBK and empirical models are well described, explained and justified. However, the complexity presented in the Agency report was difficult to follow. The discussion (page 30315 of the Federal Register notice) on the strengths and weaknesses of a mechanistic model vs. a model based on empirical data was helpful and the EHC recommends that it be included in the report. There is no perfect model. Thus the use of two models (IEUBK and empirical) is appropriate and helpful, even though both are flawed. Although each of the models has its limitations and uncertainties, the estimates from these two complementary models overlap. To that end, it would be helpful to provide greater emphasis upon the commonalties found and when possible utilize the empirical data from the supportive studies to validate the observations. The EHC concluded that the Agency's use of these tools was technically sound with the caveats noted in the responses to the specific questions above (e.g., 10 µg/dl is not a threshold). The EHC also concluded that the use of the tools to estimate nationwide impacts is technically sound but that there are uncertainties because the Agency is not using an absolute predictor.

3.10 General Charge Question 4

Are there any critical differences in environmental lead-blood lead relationships found in local communities that should be considered in interpreting our results at the national level?

Findings and Recommendations

It is important that the Agency define the term "local community" as a community with a significant risk of lead-contaminated housing. There are differences in environmental lead-blood lead relationships found in local communities. These differences may be attributable to factors such as regional differences in the bioavailability of lead dependent on the source of the lead (e.g., smelter vs. urban environment) and individual susceptibility (e.g., genetic polymorphisms and nutritional status). There are also differences in the amount of lead paint applied during painting which varied based on the harshness of the environment and when the paint was manufactured (pre vs. post 1940). However, data on the effect of these factors on environmental lead-blood lead relationships are limited and additional research would be required to consider these factors in interpreting the Agency's results for lead-blood lead relationships at the national level. Given that there are some regional differences in blood-lead lead relationships, the EHC emphasizes the need for flexibility at the regional level for complying with the lead standards and acknowledges the Agency's plans for flexibility as outlined on page 30344 of the Federal Register notification of proposed rulemaking.

Since the particle size of lead paint dust is generally much finer than that of the larger particles usually found in former mining sites, it is reasonable to assume that the lead component from these particles is more biologically available and, hence, a conservative approach is warranted. The question of whether this approach is technically sound for all soil environments encountered across the U.S. should probably be discussed in relation to the nature of the soils. Soils vary in their acidity and presence of other chelating minerals which could influence the bioavailability of lead from a given soil type. It is possible that weighting factors may be developed for some of these factors. This would in turn influence the predicted lead absorption coefficient inserted into a given model. This type of factoring would be a refinement of the calculation not a substantive change in the model itself.

Other factors that may vary from community to community include age demographics of the population of concern, diet, clusters of housing units, other toxic agents and perhaps genetic susceptibility. These factors may exert a real influence on the actual measure of safety conferred by interventions according to the proposed standards.

3.11 General Charge Question 5

In view of the issues discussed and analyzed in sensitivity analyses contained in the two documents, in what specific areas should we focus (e.g., refine our approach, gather additional data, etc.) between now and the final rule?

Findings and Recommendations

The sensitivity analyses provided are helpful in identifying the impact of critical factors. Unfortunately, there is no one model or analytic methodology that is obviously superior. There are always alternative approaches and additional factors to consider (see the multiple suggestions in responses above). While gathering additional data would always be helpful, the EHC does not believe that the Lead 403 rule should be delayed for any significant time. It would be useful to have a discussion added on how the Lead 403 standards may relate to the state based activities to investigate and order remediation of homes where lead poisoned children are found. These investigations are, by definition, site specific, while the Lead 403 standards are more generic.

The EHC recommends three specific projects for inclusion in the final rule: a) an expansion of the sensitivity analysis to include a case study of a real community that is highly susceptible to lead exposure and a presentation of the costs and benefits associated with that case study, b) the development of a plan for follow-up to evaluate the effectiveness of the specific interventions (details should include the type of measurements to be made, the locations for the measurements, and the timetable for the validation process), and c) sensitivity analyses that carry through all the way to cost for conversion factors used to compare media loadings and for assumptions regarding the housing industry.

4. SUMMARY OF RECOMMENDATIONS AND CONCLUSIONS

In this report the EHC has made a number of recommendations for improving the scientific basis for the standards in the Lead 403 Rule, including the following:

a) The Agency should provide a clearer presentation on how Intelligence Quotient (IQ) is used for risk and cost benefit analysis, the significance of lack of a threshold, the impact of IQ shifts, the use of additional literature references for the below 70 IQ scores, emphasis on IQ as a neurological surrogate, and improving the explanation that the IQ fractional point loss is valid for economic analysis but not for interpretations for individual children;

b) The Agency should add more animal data since they support human data by establishing causality, due to the absence of confounding variables, and potential mechanisms for adverse health effects;

c) The Agency should clarify the discussion regarding the basis for setting the lead standards given the marginal costs and marginal nets, including a plan for follow-up to specific interventions;

d) The Agency should evaluate the potential role of education as an intervention strategy;

e) The Agency should state, explicitly, the difference between a *soil-lead standard* of 2000 parts per million (ppm) and the *soil-lead level of concern* of 400 parts per million (ppm) and its impact on current practices by the Department of Housing and Development, as well as some States; this difference should be explained along with the initial presentation of the standards

f) The sensitivity analysis should be expanded with a case study of a real community that is highly susceptible to lead exposure and a presentation of the costs and benefits associated with the case study;

g) A plan should be developed for follow-up to evaluate the effectiveness of the specific interventions and lead standards on public health.

Some of these recommendations will require further research. However, there is sufficient scientific evidence to indicate that delaying rulemaking for additional research would leave a significant number of children unnecessarily at risk.

The Agency is highly commended for its stated intent to prepare and distribute educational material to provide guidance for complying with the standards. This material should be tailored to specific circumstances. The EHC feels that guidance is particularly important since the requirement for homeowners to disclose a known lead risk may be a disincentive for testing.

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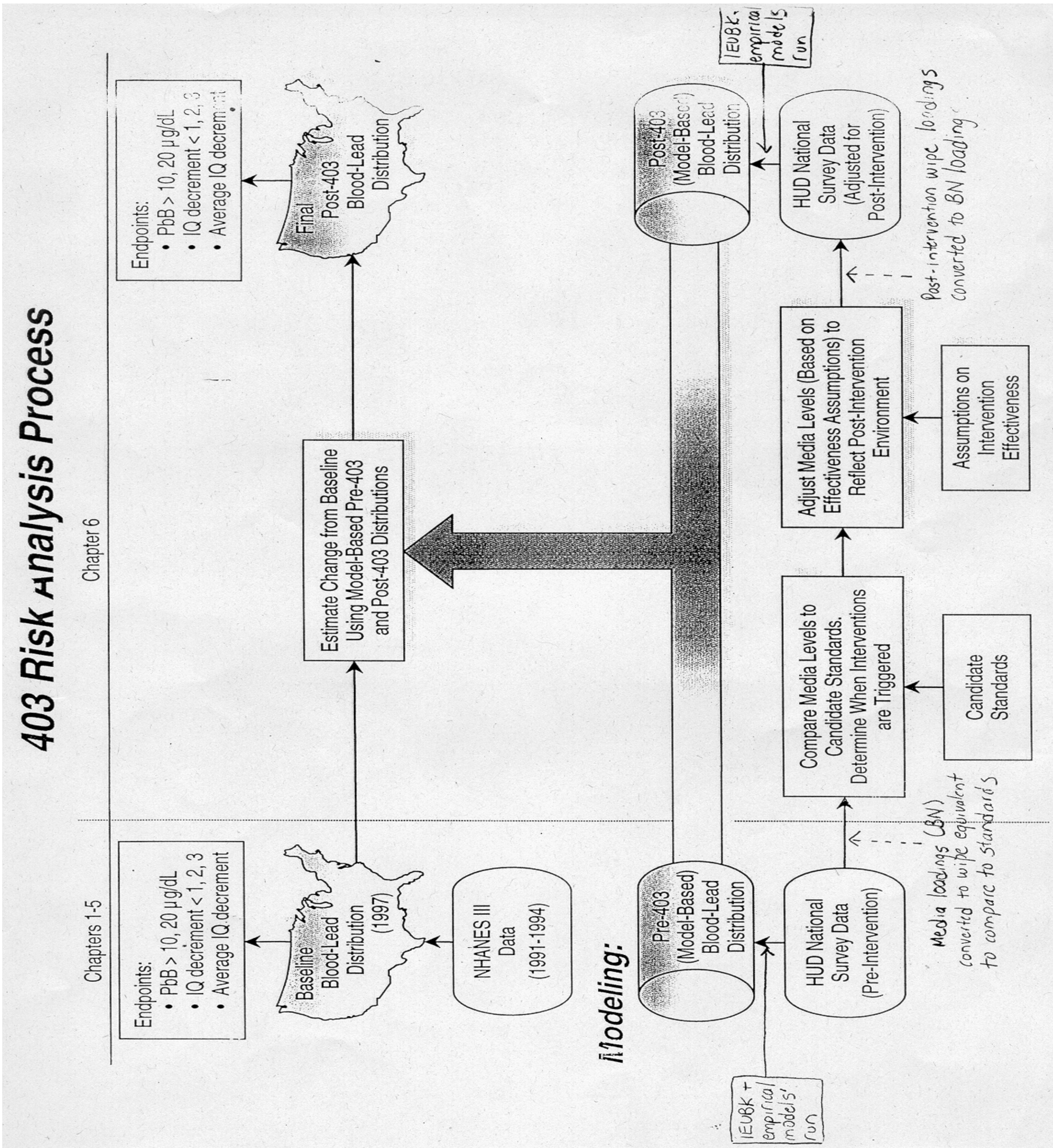
APPENDIX A - ACRONYMS AND ABBREVIATIONS

BCA	-	benefit cost analysis
BN	-	blue nozzle
BRM	-	Baltimore Repair and Maintenance
CDC	-	Centers for Disease Control
EHC	-	Environmental Health Committee
HUD	-	United States Department of Housing and Urban Development
IEUBK	-	Integrated Exposure Uptake Biokinetic Model
IQ	-	Intelligence Quotient
LBP	-	Lead based paint
LOAEL	-	lowest-observed-adverse-effect level
LOEL	-	lowest-observed-effect level
NHANES	-	National Health and Human Nutrition Examination Survey
NOAEL	-	no-observed-adverse-effect level
OMB	-	Office of Management and Budget
OPPT	-	Office of Pollution Prevention and Toxics
OPPTS	-	Office of Prevention, Pesticides and Toxic Substances
ppm	-	parts per million
SAB	-	Science Advisory Board
SD	-	standard deviation
SES	-	socioeconomic status
TSCA	-	Toxic Substances and Control Act
U.S.C.	-	United States Code

APPENDIX B - ANNOTATED OVERVIEW OF THE LEAD 403 RULE



APPENDIX C - TABLE AND FIGURES ON IQ

Table 1. Calculations of IQs below 70 based on SD=15 and different means

Proportion < 70	**Mean**
0.0475	95
0.0415	96
0.0359	97
0.0309	98
0.0266	99
0.0228	100
0.0194	101
0.0165	102
0.0139	103
0.0117	104
0.0098	105

Assume that SD=15 and z-score mean = 70; area is derived from tables of the normal curve.

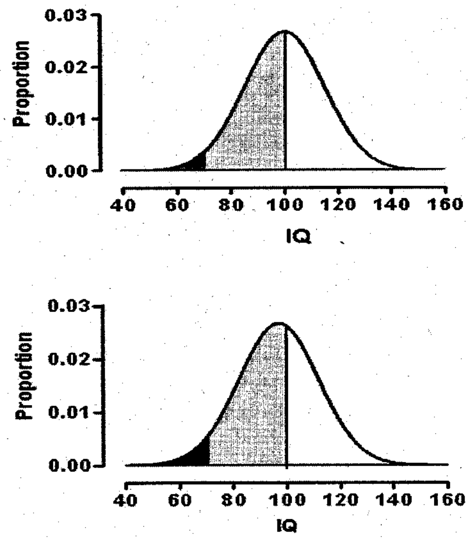


Figure 1. Effects of a 3% (3-point) shift in mean IQ score on the proportion of a population with scores falling below 70. Upper chart shows an IQ distribution with a mean of 100 and SD of 15. The dark area represents the 2.3%of the population below 70. The light area represents those with IQs below 100 and above 70. The lower chart depicts an IQ distribution with a mean of 97. Here, 3.6% of the population falls below 70. IQ of 100 is drawn on both charts for orientation.

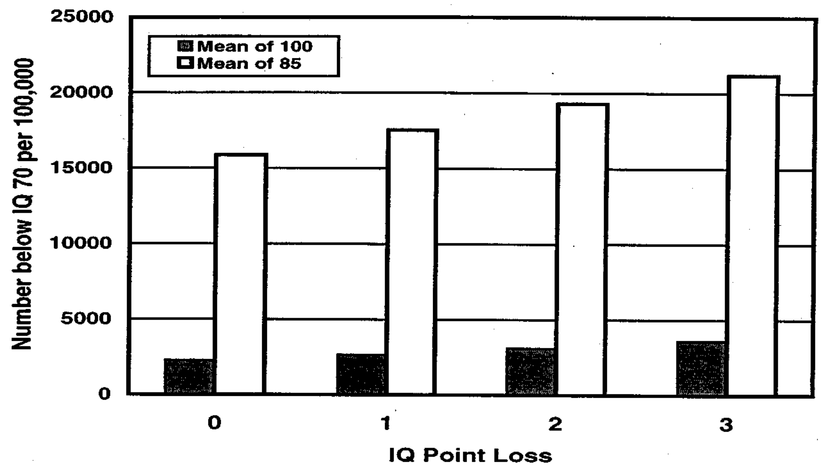


Figure 2. Comparative effects of IQ point losses on an "Advantaged" population with a mean IQ score of 100 (SD=15) and a "Disadvantaged" population with a mean IQ score of 85 (SD=15).

APPENDIX D - EDITORIAL COMMENTS ON EPA DOCUMENTS

Page	Comment
ES-2	Young children are acknowledged as a highly vulnerable subpopulation, but the document should also note the recent data implicating the elderly as another vulnerable subpopulation.
ES-4	Especially in the Executive Summary, the document should note that 10 µg/dL is not a threshold of toxicity, but an action level, so to speak. The same ambiguity appears in the body of the document.
2-6	A target audience for the document was not specified, but the discussion of neurotoxic effects (Section 2.2.2) is inappropriate for the non-specialist.
2-10-11	This section (2.3.1) makes only passing reference to low birth weight and prematurity, but the medical literature indicates that both are risk factors for reduced IQ. It needs more emphasis. In addition, the data indicating correlations between blood lead and IQ in older children should be discussed more specifically in risk terms.
2-12	Performance IQ yields parts of the WISC score.
2-13	A question lurking below the surface of the risk assessment is the contribution of lead in context. That, is, lead effects are small in magnitude compared to maternal IQ, SES, etc. This comparison leads some observers to question the significance of lead hazards. The analysis should recognize these objections and note the importance of the lead contribution as an independent factor.
2-13	It may be important to note that the Needleman (1979) data classified children with a blood lead mean of 24 µg/dL as “low lead,” especially because on pages 2-15 and 2-17 “low” and “high” describe different concentration ranges. Views of “low” and “high” have changed since the 1970's.
2-19	Table 2-1 uses the term “lead poisoning.” It is not appropriate in this context because it implies a clinical syndrome, not the purview of this risk assessment document.
2-20	The standard deviation associated with IQ tests is typically 15, not 5 points.
3-64	As noted in Table 3-36, children 3-5 seem to show a higher incidence of extreme values than children 1-2. The full distributions might be edifying.
3-66	Table 3-38 shows different risks as a function of family income. The document might clarify the problem by providing relevant IQ distributions for each income level. Also, as noted elsewhere, if IQ means are different in different income groups, the proportion of scores less than 70 will also be different. Shouldn’t disproportionate impact be a part of risk characterization and management?
5-4	Plots of different IQ distributions based on different blood lead distributions would amplify portions of this section.
5-9	Table 5-1 is unclear in some respects. It is difficult to determine how the IQ score less than 70 entry yields 9,130 children.
5-25	Define “tap weight” in Table 5-8.
5-26	In Table 509a, the calculation of the number of children with IQ<70 is unclear.

APPENDIX E – REVIEW OF THE ECONOMIC ANALYSIS

(Prepared by Dr. Gloria E. Helfand)

The Scope of the Benefit-Cost Analysis

In many ways, it is peculiar for the Agency to conduct a benefit-cost analysis (BCA) of proposed standards for which there is no required action. Typically, BCA is used to weigh the advantages and disadvantages of taking a particular action, such as building a dam or requiring new pollution abatement measures. In this case, the Agency's only action is to set the rule; the Agency requires no action and undertakes little activity (other than some information provision). Though there may well be legal ramification from that rule-setting; such as lenders becoming less willing to finance mortgages for properties exceeding the standards, these actions are not under the Agency's control. Instead, whether to act, as well as the levels of costs and benefits of any actions, will be decided entirely in the private sector. Individuals, real estate owners and managers, renters, lenders, and others involved in the housing markets are likely to want to undertake their own BCAs of lead abatement, possibly in response to this rule, or possibly independently. The Agency is not responsible in any obvious way for these actions.

The BCA is conducted from a national perspective, covering a 50-year period. As soon as a child between 0 and 6 years of age enters a house where lead is present, abatement activities are assumed to be conducted until the child reaches 6 years of age. This process is repeated for as many times as a house has a child less than 6 years of age in it over the 50 years. The optimal standards are those that maximize present net benefits of those abatement activities.

Since the actions and effects are virtually entirely private, it might be more appropriate for the Agency to provide guidance to individual real estate owners or occupants on what the activities that are desirable for their circumstances, rather than conduct a national-level, 50-year analysis. That information could prove more useful to individuals in deciding whether and when to act on lead hazards.

On the other hand, the Agency argues that one set of national standards is desirable for clarity and simplicity (Federal Register, page 30307); while that decision could be debated, it is not necessarily a bad idea. Then, in essence, the proposed standard is really an average guidance on when it is efficient to undertake abatement activities. In this case, a critical issue is who will undertake actions, and when. The assumption here is that all houses in violation of the standards will undertake remedial action. As is noted in the BCA, this assumption is quite a strong one. It seems more likely that some houses in violation of the standard will not comply than that houses in compliance with the standard will abate anyway. As a result, the costs and benefits (at the national level) are likely to be overstated, though it's hard to say whether costs or benefits are more overstated. On the other hand, because it is very hard as well to identify any reasonable alternative assumption on behaviors, it is hard to fault the analysis for using this assumption.

Because this process develops, in essence, an average standard for when interventions should be conducted, it does not provide guidance to specific individuals on whether or when to abate for lead. Indeed, it does not even provide guidance on when an individual should test for lead, possibly the most critical step in the process. There even appears to be a disincentive on the part of property owners to test for lead, since they are required to disclose lead risk if it is known (and are then likely to receive lower value for their property).

Despite all of the above comments, this approach to a national-scale benefit-cost analysis with a 50-year time horizon has its usefulness. The current approach in essence provides an average value for when abatement activities provide increased net benefits. This information will be most valuable when the future occupants of a unit are unknown and the owner of the unit is deciding whether to abate. For instance, HUD low-income housing may wish to use this standard, since it is unlikely to be able to predict who will move into a specific unit. In that case, a societal, long-term perspective makes sense.

At the same time, more specific guidance would be very valuable to individuals owning or purchasing a unit. For instance, a family with several children under the age of 6, or with children more sensitive to lead for some reason, should probably be encouraged to conduct abatement activities that another family with one 5-year-old should not be so encouraged. The Agency should provide a guidance document, perhaps in the form of a decision tree, to help people decide whether or when to abate for their specific circumstances.

Regarding the comment by Lee et al. (1998) on whether the appropriate trigger should be the “birth trigger” used by the Agency or real-estate transactions: the birth trigger is more appropriate for the social BCA that the Agency has conducted, since, from a societal perspective, that point is when interventions should be considered. The real estate trigger is what may actually happen in some cases, but at that point the specific guidance suggested above should be used, since specific circumstances are likely to be better known.

Estimation of Costs

Development of costs for different standards involved, first, relating treatment options with reductions in exposure, and secondly, calculating costs of the treatment options; the result is a cost associated with a specified standard. This procedure seems appropriate.

One serious concern is that the cost estimates do not take into account the fact that people will undertake some of the abatement measure (such as repainting) even in the absence of lead. If people do maintain their homes, then the appropriate measure of cost of lead abatement is the cost over and above that associated with routine maintenance. It is impossible from the information presented to determine how significant a cost overestimate results from the method used here. Some very useful information, both to regulators and to owners of residences, would be descriptions of what activities beyond routine maintenance are required for lead abatement, and the costs of those activities. The current approach of, e.g., counting all painting expenses as lead abatement expenses is likely a significant overestimate of the costs of abatement.

One odd thing about the costs is that the marginal costs (the cost of increasing abatement by one unit) do not increase as the standard is tightened for any of the potential standards; instead, they bounce around. Typically marginal costs would be expected to be constant or increase, an indication that it's easier to clean up lead when there's a lot of lead rather than when there's only a little of it. The fluctuating marginal costs may be an artifact of very discrete abatement measures, but it is a peculiarity.

Responses to a few points raised by Lee, et al.(1998) follow, including; first, 1) that real estate transactions will become in fact the critical point of action; and 2) second, that costs do not include changes in property values associated with identification of lead hazards in properties. The first issue relates back to the scope of the BCA, and whether the analysis conducted by the Agency really answers a question relevant to the policy process or to individual landowners. There are no federal requirements; private markets are responding to the issuance of the standards. Yet the analysis is conducted from a public policy perspective of net social benefits. It is unclear as to whether or not there is a "right" answer to this issue. The Agency should discuss this issue with the real estate industry and other affected parties, including mortgage lenders to clarify the issue. On the second issue, there is disagreement. If a property is found to have lead, the loss of property value is not a loss to society; rather, not incorporating the existence of the lead into the property value is an implicit real estate subsidy to those properties containing lead. Just as pollution is, in the economic framework, a cost of some business activities that the businesses may not recognize, the cost of lead in a property is real and should be reflected in the property's value

Estimation of Benefits

To estimate benefits, different standards were associated with changes in blood lead level concentrations, which were then associated with changes in IQ, which were then assigned monetary values. This procedure seems appropriate.

As with marginal costs, marginal benefits also show odd fluctuations. Typically marginal benefits would be expected to decrease as the standard gets tighter: the greatest gains come from controlling lead when there is a lot of it, and smaller gains are likely when there is little, reflecting that the most important impacts result from the initial abatement, not the last units. In Exhibits 6.1, 6.4, and 6.7 in the economic analysis document, marginal benefits not only appear to increase as the standard tightens, but they increase and then decrease. Again, this oddity may be due to these functions reflecting the nature of the housing stock. Tightening the standard leads to more houses being recommended for abatement; the relationship between any standard and the number of affected houses often has a relatively flat area (see Figures 6-4, 6-6, 6-8, 6-9 of Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil). That shape may lead to the marginal benefits and cost curves having the shapes they do.

The advantage of the typical shapes is that they indicate a unique level that maximizes net benefits (where marginal benefits crosses marginal costs from above – to the left of that point, the marginal net benefits are positive, while the marginal net benefits are negative to the right of the standard). In this case, there is no unique set of standards that maximizes net benefits. There is often a range where the net benefits are almost constant. The Federal Register discussion of how standards were actually chosen indicates that those setting the standards understood the implications of these strange functions and incorporated additional factors into their choice of the lead standards. That procedure seems very appropriate in this case.

The economic analysis notes, validly, that reductions in IQ should probably not all be valued the same: a 5-point IQ reduction from 150 is probably less significant than a 5-point IQ reduction from 80. The economic analysis, however, values both these changes the same. Given that there do not appear to be data to do any differently, one can't validly conclude that the analysis was conducted incorrectly. Some discussions of whether the value of IQ used is likely to correspond more to the high-IQ part of the scale or the low-IQ part of the scale, and therefore whether it likely overstates or understates benefits, could be useful.

The value of an IQ point as developed here seems to be calculated appropriately. Previous reviewers have asked why this value differs from the value used in an Agency study of air quality. While sensitivity analysis is done on this point, there is no discussion of why these two values differ and why the lower value is considered not appropriate. An explanation of these points should be included.

The economic analysis assumes that distribution of blood-lead levels in the population, in the absence of abatement activities, will stay constant over time (p. 5-3). Comments by Lee, et al., (1998) that blood lead levels have shown a decrease over time due to reduction in lead from other environmental sources seems to be an important one and should be considered. Ignoring these reductions, if they are expected to continue, leads to an overstatement of benefits.

Lee et al. (1998) also claim that the analysis does not take into account that older houses are being removed from the market. While it's not entirely clear from the economic analysis, it appears that in fact the Agency has included changes in the housing stock in their analysis, through the term ϵ_t on page 5-20.

In sum, the benefit-cost analysis appears to have been done honestly and uses (for the most part) the best available information and methods. It is considered that the costs are overstated through ignoring the abatement activities that would normally be expected to be conducted; that benefits may be understated through incorporating only IQ-related effects; and that benefits may be overstated if there is expected to be a continuing reduction in blood lead levels due to factors other than abatement under this rule. If these effects were incorporated, the likely effect would be that the proposed standards ask for less abatement than is optimal (though, “optimal” is hard to define here and needs to involve other factors).

Calculating Net Present Value

Net present value, or net benefits, is merely the difference between benefits and costs. Typically, if marginal costs increase with a tighter standard and marginal benefits decrease, there is a unique point where marginal benefits equal marginal costs; at this point, net benefits are maximized. Here, as noted, the marginal benefits and marginal costs are quite erratic in their behavior; therefore, there is no unique value where marginal benefits equal marginal costs. The Federal Register discussion of the choice of standards suggests that the maximum net benefits values were considered as starting points; then other factors were brought to bear on the decision. This approach seems reasonable.

The Discount Rate

The economic analysis uses a discount rate of 3%, with a sensitivity analysis using 7%. Lee et al. (1998) believe that the economic analysis should be done using OMB's recommended rate of 7%, representing the opportunity cost of capital in the long run. Chapter 3 of the economic analysis (pp. 3-19 to 3-22) has a very nice discussion of the choice of the 3% discount rate; I have no quarrel with the Agency's choice of that value.

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