62156

180pp

ORIGINAL

Bs-134

TSCA 403 FINAL RULE

RESPONSE TO COMMENTS

December 22, 2000

TSCA Section 403: Response to Comments

PART ONE -- General Comments

1.1 The section 403 standards should require hazards to be controlled. Moreover, the fact that the real estate industry has prematurely seized upon the proposed regulations as an excuse to do nothing . . . should be sufficient reason for the EPA to scrap these proposed regulations in their entirety. Evidence in support of this point is provided in the following excerpt from a local property owner newsletter.

> The final coup *de grace:* its all voluntary! The EPA states: "The regulations would not require private property owners to undertake hazard control actions when hazards are identified. Instead, the EPA expects that concern about children's health, liability exposure and other market forces will provide incentive for property owners to take action voluntarily."
>
> Abatement bureaucrats: pack your bags, the baby's dead!

Response: A review of this newsletter shows that the comment has taken this statement out of context. The sentence immediately preceding the quoted excerpt states that "the incentive would seem to be owners, take care of the hazard while its easy, before it becomes more serious trouble." This preceding sentence recognizes that property owners should take action, primarily through proper maintenance of property. Contrary to the comment's claim, this trade association has not seized upon the proposed regulations to do nothing. Furthermore, EPA believes that the exuberance of the quoted excerpt needs to be interpreted in context of the local requirements which included abatement of intact lead-based paint. This section 403 regulation recognizes, consistent with the statute that the emphasis needs to be placed on controlling lead-based paint hazards, not any lead-based paint. Furthermore, EPA has no authority to require action to be taken when a lead-based paint hazard is found. Rather, the structure of the statute shows that Congress was depending on local activism to get things done.

1.2 The decline in both the average blood lead levels among young children and the decline in the incidence of elevated blood lead levels shows that enforcement of current regulations are sufficient and that the section 403 standards are not needed.

Response: These standards are needed for several reasons. First, regulatory standards are required to fully implement important provisions of Title X including disclosure of lead-based paint hazards and evaluation and control of hazards in Federally-assisted and Federally-owned housing prior to disposition. Second, standards based on the best available data and analysis are needed to educate the public about conditions that require attention and action. Third given that there are still nearly 900,000 young children with elevated blood lead levels and substantial numbers of children with elevated levels in inner city neighborhoods, continued efforts to reduce exposure to lead are needed. Fourth, other than the interim standards issued as part of HUD's regulations promulgated under authority of Title X sections 1012 and 1013, there are no current regulatory standards that can be enforced. Moreover, HUD issued the interim standards with the expectation that EPA would issue standards under the authority of TSCA section 403.

1.3 EPA should wait before issuing standards until the availability of additional data and in light of the substantial uncertainty about the existing data and the need for Agency decisions to be based on adequate environmental and epidemiological data.

Response: EPA disagrees. The statutory deadline in Title X for this regulation shows that Congress did not envision substantial new research and data collection efforts. Rather, the intent was for EPA to use the information currently available. In some cases, EPA was able to incorporate newly available data sets without significantly delaying the regulatory development process (e.g. NHANES III, Phase 2). In other cases, EPA could not wait until final peer-reviewed data sets are available with significant delays in issuing the standards. Preliminary analysis of some of the most recent data (e.g., interim release of new HUD survey data, interim release of HUD abatement grant evaluation data), however, provides additional support for EPA's decisions. If significant new evidence becomes available that would that the standards need to be updated, EPA, as stated in the preamble to the final rule, will consider modifying the standards to reflect these data.

Further, EPA believes that, despite the uncertainty, the data used by the Agency are adequate for decision making. These data include the Rochester Lead-in-Dust study, which was designed specifically to support this regulation, the best available national blood-lead data (NHANES III), and best available national residential environmental lead data (the HUD National Survey). The Agency's Science Advisory Board (SAB) has endorsed the choices made by the Agency with regard to the data sets used to support the regulation.

1.4 EPA should undertake a rulemaking to change the definition of lead-based paint to lower the concentration level in the statute.

Response: There are several reasons for EPA's deciding not to alter the definition of lead-based paint. First, only HUD has the statutory authority to change the definition of lead-based paint for target housing. Second, the data for relating levels of lead in paint to blood lead is far less developed than data relating dust and soil lead to blood lead. Thus, there is significantly more uncertainty with respect to lead in paint than there is with respect to dust and soil. Third, there was a statutory deadline for issuing standards for lead-based paint hazards and no statutory mandate or deadline to change the definition of lead-based paint. Given the significant technical challenges involved with developing standards, EPA focused its efforts on developing the standards required by statute.

1.5 EPA should impose requirements to test for and/or control hazards or impose other requirements such as imposing an obligation on all owners of dwellings where young children reside to conduct a risk assessment using certified personnel or to forbid property owners from any action short of abatement.

Response Title IV of TSCA does not give EPA the authority to require property owners to take any action to evaluate and control hazards. Thus, the final regulation and accompanying guidance includes recommendations to act but not requirements.

1.6 It is inappropriate to create a single set of standards that should be applied to all areas of the nation because conditions of lead exposure vary greatly and the impacts of exposure are complex and difficult to understand. EPA's rule and its risk assessment should account for differing "conditions" such as bioavailability, particle size, and speciation. There is particular concern about the applicability of the standards to mining and ore-processing related sites, where factors such as lower bioavailability reduce risk and suggest that higher standards may be more appropriate.

Response: While EPA recognizes the role of bioavailability in determining risk, bioavailability is relatively consistent for most residential properties. As one commenter pointed out, gasoline and paint lead residues are found in nearly every community throughout the U.S. with similar particle size distribution. Significant differences in bioavailability, while expected in areas adjacent to certain industrial facilities, are expected to be the exception rather than the rule when considering the nation's housing stock as a whole.

While differences in bioavailability are usually found in lead mining and milling communities, EPA nontheless has decided not to set separate standards because of the technical and practical difficulties involved in characterizing the bioavailability of environmental lead, which would have to be determined on a site-specific basis. Consequently, EPA does not believe that differences in bioavailability should be considered as among the "conditions" considered in setting the lead-based paint hazard standards. Indeed, other than this one comment, no other "conditions" other than various environmental levels have been suggested by commenters as a basis to establish the standards. (See also Comment 2.2.3).

1.7 There should be a lower soil standard (50 ppm) for sandy soils or soils having a low content of organic matter.

Response: EPA is not setting separate soil standards for sandy soils and soils with low organic content. These characteristics affect the ability of lead deposited on the surface to migrate down to subsurface soil. In general, they do not affect bioavailability significantly. Moreover, even if it could be determined that these characteristics did have a substantial affect on bioavailability, EPA would not want to establish a separate standard due to difficulties associated with developing and using definitions of "sandy" and "low organic content."

1.8 EPA's media-specific approach would not result in optimal hazard control decisions. For example, a home with a soil-lead level slightly over the soil-lead standard and a dust-lead level well below the dust-lead standard would have a lower level of risk than a home with a soil-lead level and a dust-lead level just below the respective standard. Yet, hazard control would be recommended for the first house and not for the second. A better approach would be joint standards with ranges. In the low range hazard control would never be recommended. In the high range, hazard control would always be recommended. In the middle range, the recommendation as to whether to control would be based on site-specific conditions.

Response: The Agency has decided to retain the media-specific standards approach in the final regulations for reasons stated in the preamble to the final rule. It is unclear, furthermore, that the recommended approach would be any superior to the one EPA has chosen. EPA's media-specific approach in fact accounts for the contribution of each medium. Under the Agency's risk assessment, each medium was analyzed assuming that exposures from the other media were controlled. The interventions included in the analysis also are designed to control all sources. For example, soil abatement includes dust cleaning. The assumed effectiveness of dust cleaning depends on the type of paint and soil interventions performed. Thus the standards account for both the contribution of lead in all media to overall exposure as well as the contribution of lead from one medium to another.

In the circumstance cited in the comment, where two media are just below the respective hazard levels, it would be expected that some kind of action be considered. The regulations do not impose any requirements to control the media even if the levels exceed the hazard standards. Under the proposed approach, there is still a grey area where judgement is needed. That would not be any different from what would be recommended under EPA's regulation.

1.9 The following statement in the preamble to the proposed rule is the appropriate way in which this rule should operate:

> Ensuring that . . . resources are used in a manner that maximizes health protection means that EPA should establish lead hazard standards that direct resources to where the threats to public health are the greatest.

[63 *Fed. Reg.* at 30314.] This view is consistent with the public health arguments raised by the Massachusetts Department of Public Health, which urges that "it makes little sense to recommend spending this money (or in the case of federally funded housing, requiring it to be spent) on addressing such a limited source of lead exposure [i.e., lead in soil].... In fact, the soil abatement called for under these proposed regulations could cost more than real lead paint hazard abatement, and would purchase far, far less of a benefit in terms of children's health," (Massachusetts Public Health Comments, p. 4).

It is all the more critical that standards not trigger testing and abatement actions that divert scarce resources from more important hazards in low-income areas -- such as providing education and nutrition -- and end up jeopardizing the availability of affordable housing. This argument is supported by a recent study, reported in the *Washington Post,* that concluded that two families with incomes below the poverty line compete for every unit that comes on the market, the highest gap on record. *(Washington Post* 6/16/98, citing a study conducted by the Center on Budget and Policy Priorities). EPA correctly seeks to meet these objectives through a net benefits analysis. Resources spent on testing and abatement actions should only be triggered when they are expected to provide commensurate health benefits.

Response: EPA agrees with this statement to the extent that it indicates the analysis chosen by the Agency to determine lead hazards is designed to direct resources to where the public health threats are greatest and to the extent that activities should occur when they are expected to lead to expenditures that are commensurate with real health benefits.

However, the Agency parts company with the commenter, and the State of Massachusetts, to the extent they claim that soil abatement under these regulations would purchase little benefit in terms of children's health or divert resources from more important threats. In fact, EPA's use of the cost-benefit analysis should prevent just that kind of resource diversion.

1.10 The Agency's standards are designed only to make it easier for those with responsibility to accomplish cleanup at the expense of public health.

Response: EPA strongly disagrees with this statement. This rule will certainly provide a basis for improving the status quo. All persons commenting on this issue concede that adequate cleanup is not occurring. These comments could not disagree that these standards will provide a basis to force cleanup against the most egregious cases. EPA is trying by this rule to develop a set of standards that would cover the actual risks and avoid excessive reaction to the lower environmental levels at which there could very well be little to no risk.

PART TWO -- GENERAL LEGAL AND POLICY ISSUES

2.1. LEGAL ISSUES

2.1.1 Determining what constitutes a lead-based paint hazard does not require the high level of evidence that EPA claims it does.

Response: EPA needs to correct a misconception that it believes a "high" level of evidence is needed for establishing hazard standards. The Agency specifically rejected such a formulation, as discussed in the preamble to the proposed rule, and stands by that interpretation. See 63 FR 30312-13. EPA was, however, faced with deciding how to interpret the statutory language requiring hazards to be those conditions that "would result" in adverse health effects and the legislative history that explained that this meant there had to be "actual" hazards. No measure is perfect, but the Agency is charged with deriving a method to resolve uncertainty in the evidence and believes it has arrived at a reasonable one, as discussed elsewhere in the rulemaking record. Indeed, no comments have given EPA a better method than it has chosen to resolve the analytical uncertainties in relating environmental lead levels to blood lead levels.

On the other hand, EPA has acknowledged that it is not developing risk free standards, since the Agency has not been able to determine a threshold level of exposure below which there are no effects from lead. Risks exist at any level of lead exposure, but for regulatory purposes the Agency has determined that exposure above the hazard levels "would result" in adverse effects. The statute does not direct, or permit, the Agency to set a hazard level at any exposure above zero.

2.1.2 EPA is incorrect in claiming that it is required under the statute to consider risks and benefits in setting section 403 standards.

Response: EPA believes it needs to emphasize, in light of comments like this, that it is in no way claiming that use of cost-benefit analysis is required under the statute, only that the approach is permitted.

2.1.3 Congress did not authorize EPA to use cost-benefit analysis because TSCA explicitly requires EPA to identify standards above which adverse human health effects would result and does not permit EPA to consider the costs of compliance. This position is supported by the fact that other provisions of TSCA do provide for the consideration of costs when Congress deemed cost-benefit analysis to be appropriate. For example, Section 6 of TSCA explicitly states that when promulgating rules on the handling of hazardous chemical substances and mixtures, EPA shall consider "the reasonably ascertainable economic consequences of the rule" and the beneficial use of the substances to the public, as well as the effects on human health and environment. (15 U.S.C. §2605(c).) That section also uses phrases such as "unreasonable risk of injury to health or the environment" and "to the extent necessary to protect adequately against such risk using the least burdensome requirement" suggesting that the benefits of the regulation must be measured against the costs. (15 U.S.C. § 2605(a).) In contrast, section 403 mandates EPA to "promulgate regulations which shall identify, for the purposes of this subchapter, and the Residential Lead-Based Paint Hazard Reduction Act of 1992 [42 U.S.C. § 4851 *et seq.*], lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil." (15 U.S.C. § 2683.) Unlike TSCA § 6, this section 403 does not require the consideration of cost in setting the appropriate standards.

Response: EPA disagrees with this comment. The fact that TSCA does not explicitly provide EPA must consider costs under section 403, or does provide in another section that costs must be considered, does not prevent the Agency from exercising its discretion to consider costs as appropriate under section 403. There is no indication in the language of TSCA or the legislative history of Title X (including TSCA Title IV) that prevents EPA from considering costs. Furthermore, as noted in responses to comments earlier in this document, the comments have not provided the Agency with any kind of rational basis for choosing alternative approaches.

The preambles to the proposed and final rules discuss EPA's argument that it has validly exercised its discretion to consider costs in determining the conditions under which adverse health effects would result within the meaning of TSCA section 403. The Agency refers to those discussions as part of the response to this comment. In addition, EPA notes that its determination in the preambles rejects the position that adverse effects "would result" only at the highest lead-containing levels at which risk is a certainty and that it is a legitimate exercise to consider costs to develop a regulatory cutoff as the analysis proceeds through various levels of increasing uncertainty under consideration for the hazard standards.

2.1.4 The case of Lead Industries Association v. EPA, 647 F.2d 1130, decided by the United States Court of Appeals for the District of Columbia Circuit in 1980, in which the court upheld the primary air quality standard for lead even though EPA had given no consideration to cost, supports the position that cost is not a relevant factor in making the scientific determination of the setting of a hazard level for soil.

Response: The comment misinterprets LIA. Furthermore, EPA strongly disagrees with any argument that because the Agency may decide in certain circumstances that it will not consider costs in making a decision the Agency is precluded from considering costs in any other decision. Nothing in TSCA section 403 precludes consideration of costs and the manner in which the Agency has considered costs is within its discretion.

The comment incorrectly interprets the LIA case and its applicability to this rule. In the first place, LIA involves interpretation of the Clean Air Act, a statute with a different set of regulatory criteria from TSCA Title IV. It is simply not a valid argument that, in the absence of any comparison of the statutes and applicable legislative history, the criteria for setting air quality standards is the same as that for setting hazard levels for existing amounts of lead in soil.

An examination of the LIA case reveals that it is inapposite to this rule. Three factors stand out in LIA with respect to the court's interpretation. See LIA at 1148-1150. First, the standards in LIA were required to be based on enumerated air quality criteria in another provision of the statute, which comprised several elements, all related to health. Second, the statute provided that the means of enforcement of the air standards, state implementation plans, could not take into account economic and technological feasibility if such consideration interfered with the timely attainment of ambient air standards, and that the Administrator could not consider such feasibility factors in deciding whether to approve the state plans. Third, the legislative history stated flatly that "existing sources of pollutants either should meet the standard of the law or be closed down." None of these statutory or legislative history factors are present in this case.

It is also useful to point out that the same court that decided LIA, in another decision under that Clean Air Act in 1987 made the following statement:

> We simply do not, announce the broad rule that an agency may never consider cost and technological feasibility, under any delegation of authority, and for any purpose, unless Congress specifically provides that the agency is authorized to consider these factors.

NRDC v. EPA, 824 F.2d 1146, 1158 (D.C.Cir, 1987).

EPA, accordingly, rejects the comment's reliance on LIA for purposes of this rule.

2.1.5 EPA improperly cited in support of its use of cost-benefit balancing one of the purposes of the Act -- the establishment of "priorities" to reduce lead based paint hazards. The proposed standards are clearly informational in nature since they do not require the regulated entities to take any remedial action in response to identified lead-based paint hazards. See Proposed 40 CFR § 745.61 (c). Rather, it is up to the individual residential property owner to determine the appropriate response to lead-based paint hazards in specific situations. The standards only mandate the disclosure of the presence of lead hazards and the use of certified lead-workers if lead-based paint hazards are removed. See Proposed 40 CFR § 745.61 and Title X, generally. Thus, the standards should communicate to the public the actual levels of lead in the environment that would put a child's health at risk and not some theoretical optimal point where the increase in the risk to a child's health is justified by the lessening of some theoretical economic burdens incurred by the standards.

Response: EPA disagrees with this comment. In the first place, reference to the legislative history on priority setting is supportive and not dispositive in the Agency's statutory interpretation. Neither the statute, itself, nor the legislative history precludes consideration of costs in determining a regulatory cutoff in the face of scientific and analytical uncertainty.

Nevertheless, EPA believes the reference to setting priorities applies to the whole statute and sees no reason why it should not apply to determination of hazard levels, particularly in setting standards where the evidence shows varying degrees of uncertainty of risk.

Finally, EPA believes it needs to respond to the comment that the Agency has developed a "theoretical" optimal point where risks are justified by theoretical lessening of burdens. In the first place, given the nature of the science, none of the comments can point to anything but "theoretical" levels of risk. Under the argument presented by the comment, because any molecule of lead presents risk, the Agency would be forced into standards that do not make any sense. In some sense, any analysis is "theoretical." [EPA notes, moreover, it is charged with determining "actual" risks (not "actual" levels, as described by the comment).] Even under the general exceedence probability argument espoused by various comments, the risks are certainly "theoretical." No comment has developed an alternative to the cost-benefit determined cutoff for circumstances that "would result" in adverse effects. EPA has developed a rational basis for determining whether adverse effects "would result" by finding those levels at which abatement of lead in dust and soil are commensurate with the risks being reduced.

2.1.6 EPA improperly cited in support of its position that cost-benefit balancing is appropriate the statement in the legislative history that actions taken should be "commensurate with the degree of risk." When Congress was addressing the cost-benefit of certain control actions in the legislative history, it was considering the types of control action that would be appropriate for specific situations and not whether the health standards should be set based on cost-benefit balancing. Thus, the Senate Report indicates that interim measures "should be commensurate with the degree of risk ... where moderately elevated dust levels exist but there is little deterioration in the paint, an appropriate interim response might be limited to supercleaning leaded surfaces. Where children are present and paint is peeling, interim controls might require a more substantial effort and expense to prevent exposure from paint chips and dust." (63 Fed.

Reg. at 30313, quoting (*National Affordable Housing Act Amendments of 1992*, Report of the Committee on Banking, Housing, and Urban Affairs, S. Rep. 102-332, 102d Cong., 2nd Sess., at 115.))

Response: EPA disagrees with this comment. As with the reference to priority setting, the reference to actions commensurate with the risk does not show that EPA is precluded from considering costs in setting hazard standards. The reference in the legislative history gives examples of particular actions that the Senate thought would be commensurate with the risk, but certainly evinces a congressional concern that the statute as a whole would accomplish such actions. EPA does not interpret this discussion in the legislative history as referring only to the examples given.

2.1.7 EPA's consideration of costs and benefits in this case are in violation of Executive Order 12898, which requires consideration of Environmental Justice concerns, and Executive Order 13045, which requires consideration of children's health.

Response: EPA does not consider the fact that it needs to consider (and in fact did consider) issues of environmental justice and children's health to preclude consideration of costs and benefits as it did in this case. EPA finds no specific arguments in the comments that show how any of its analyses are incompatible with the Executive Orders 12898 and 13045. In fact, as noted in responses later in this document on these two executive orders, EPA shows that it properly considered the relevant issues. EPA believes that this rule promotes both environmental justice and children's health, regardless of whether it uses a cost-benefit analysis.

2.1.8 If Congress had wanted to allow consideration of costs and include priority setting as a goal in the section 403 standards, they very easily could have stated that a lead-based paint hazard exists where there is an unacceptable likelihood that adverse human health effects would occur.

Response: EPA does not find that this argument persuasive. EPA likely would have interpreted this language as permitting it to consider costs. However, the Agency could also determine that this language would not require it to do so. Neither this language, nor the language of 403 (along with the statutory structure and legislative history) appears to treat in any different way the Agency's discretion to consider costs in circumstances such as those found in this rule.

2.1.9 In the proposed regulation, EPA took the position that the standards apply to all lead in household dust and bare residential soil regardless of the source of lead. In other words, the source of lead need not be lead-based paint. The National Multi-Housing Council (NMHC) submitted an extensive comment arguing that EPA is over-reaching its statutory authority by seeking to define a "lead-based paint hazard" to include dust or soil containing lead in excess of certain levels regardless of whether the lead in question is derived from lead-based paint. In addition, NMHC raised this same issue in a lawsuit against EPA, National Multi-Housing Council v. EPA, Docket No. 97-1372 (D.C. Cir.). The lawsuit was dismissed as premature. However, EPA believes it is appropriate to respond to all relevant arguments raised in that litigation on the merits of the Agency's interpretation. EPA incorporates the record for the litigation in the record for this rule.

A general summary of NMHC's argument follows.

NMHC argues that the title of the statute, "The Residential Lead-Based Paint Hazard reduction Act of 1992," makes clear that it addresses the hazards of lead-based paint. In addition, several provisions of the statute indicate it is limited to lead from paint. In particular, the statute is limited in a number of respects to "target housing," which is housing constructed prior to 1978, when lead paint was banned. Housing built after 1978, which could have lead in the soil or dust from sources other than paint, is not subject to the statute. Also, the purposes of Title X only refer to dust containing lead in the context of deteriorating, abraded, chipping or peeling paint. See Title X §§ 1002(4)-(6). Section 1018 of Title X, the provision requiring disclosure of known lead hazards in the transfer of real property, contains a warning statement that refers at one point to "lead from lead-based paint."

NMHC refers to a number of legal maxims to argue that "lead-contaminated dust" and "lead-contaminated soil" can only be understood in the same general sense as the associated term "lead-based paint." These maxims are referred to as *noscitur sociis* and *ejusdem generis*. The general point is that where general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.

NMHC extensively refers to the legislative history of Title X, in particular S. Rep. No. 332, 102nd Cong., 2d Sess. (1992), with numerous citations stating that Congress was concerned with paint in enacting this statute and then asserts, without citation, that lead contaminated soil and dust are within the scope of Title X only to the extent that the soil or dust were contaminated by lead-based paint. Other quotations are cited from the Senate Report to argue that the statute is limited in scope -- that is, it is only the first step in solving the entire lead problem.

Response: EPA strongly disagrees with this comment. EPA's depiction of the terms "lead-contaminated dust" and "lead-contaminated soil" as including lead from non-paint sources reflects the plain language of the statute, is consistent with Title X and TSCA's structure, history and purpose, and is consistent with existing regulations.

NMHC is plainly wrong that the plain language of the statute demonstrates that the only purpose of Title X and TSCA was to regulate lead from paint. Although EPA agrees that concern about the dangers of lead-based paint was a prime motivating force in the statutory scheme crafted here, NMHC ignored the statutes' other legitimate provisions which do not place a restriction on regulatory authority over other sources of lead in dust and soil.

In the first place, this comment misstates the applicable definitions of both Title X and TSCA. These definitions are those for "lead-based paint," "lead-contaminated dust," and "lead-contaminated soil." Title X provides that:

> (14) The term "lead-based paint" means paint or other surface coatings that contain lead in excess of limits established under [section 302(c) of the Lead-Based Paint Poisoning Prevention Act].
>
> . . . .
>
> (16) The term "lead-contaminated dust" means surface dust in residential dwellings that contains an area or mass concentration of lead in excess of levels determined by the appropriate Federal Agency to pose a threat of adverse health effects in pregnant women or young children.
>
> (17) The term "lead-contaminated soil" means bare soil on residential real property that contains lead at or in excess of the levels determined to be hazardous to human health by the

appropriate Federal Agency.

42 U.S.C. § 4851b(14), (16), (17). TSCA section 401 defines "lead-based paint," "lead-contaminated dust" and "lead-contaminated soil" in terms almost identical to Title X. 15 U.S.C. § 2681(9), (11), (12). None of these definitions limits the source of lead-contaminated dust or soil to lead-based paint. The definition for lead-based paint does not include the terms "lead-contaminated dust" or "lead-contaminated soil." See Title X § 1004 (14), 42 U.S.C. § 4851b (14); TSCA § 401 (9), 15 U.S.C. § 2681(9). Conversely, the definitions for lead-contaminated dust and lead-contaminated soil do not include lead-paint or any reference to paint as the source of lead in dust or soil. See Title X § 1004 (15), (16), 42 U.S.C. § 4851b (15), (16); TSCA § 401 (11), (12), 15 U.S.C. § 2681 (11), (12).

This becomes significant in light of the definition provided for "lead-based paint hazard." Both Title X section 1004 and TSCA section 401 define "lead-based paint hazard" to include exposure to lead from lead-contaminated dust and soil as sources of lead contamination separate from -- and not explicitly linked to -- lead-contaminated paint:

> "[L]ead-based paint hazard" means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces, or impact surfaces that would result in adverse human health effects as established by the appropriate Federal agency.

Title X § 1004(15), 42 U.S.C. § 4851b(15). If the lead in dust or soil were meant to be derived from paint, then the separate references to lead-contaminated dust and soil would be unnecessary. NMHC's reading strips the inclusion of the three distinct terms of any meaning they might have in the definition of lead-based paint hazard.

Not only are the terms "lead-based paint," "lead-contaminated dust," and "lead-contaminated soil" defined separately and distinctly in both statutes, but the structure of TSCA section 403 presumes that the standards EPA must promulgate include these distinct categories. Section 403 directs EPA to "promulgate regulations which shall identify for the purposes of [TSCA subchapter IV and Title X], lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil." TSCA § 403, 15 U.S.C. § 2683. If the definitions for lead-contaminated dust and soil were meant to include only lead from paint, it would not have been necessary to list them separately in TSCA section 403.

EPA also rejects NMHC's argument that the lead in lead-contaminated dust must only refer to lead from paint because the governing statute is entitled "the Residential Lead-Based Paint Hazard Reduction Act;" the statute only regulates "target housing," which is housing built before 1978, the date after which lead based paint was no longer used in housing; and the lead warning statement crafted by Congress speaks only of lead-based paint and lead-based paint hazards. While the title of the statute is certainly one indication of its purpose, it simply does not mean, as NMHC suggests, that it is limited to one goal. Likewise, that target housing is defined by the date upon which lead paint was no longer used in housing does not mean that the statute could not have as an additional goal, the regulation of lead in dust in or around housing from other sources. The fact that Congress did not include lead-contaminated dust or soil in the lead warning statement for section 1018 does not eliminate the broader purpose of those terms as Congress defined them. In other words, that the primary focus in the statutory language is on lead in paint, does not mean that lead in dust or soil that is generated from other sources could not also be addressed in the same statute. At best, these examples taken together support the conclusion that the primary focus of the statute is on regulating lead from paint. However, in light of the broad definitions of lead-contaminated dust and soil, the converse conclusion, that the statute only regulates lead from paint, is not supported.

Additionally, EPA rejects another argument made by NMHC that Title X's directive that HUD research other lead source reduction strategies demonstrates that the statute only regulates lead from paint. However, the provision NMHC cites, Title X section 1051, does not support this conclusion. There is no clear explanation in the statute or legislative history of what "other sources" refers to. See Title X § 1051, 42 U.S.C. § 4854. The list of examples is not particularly instructive either, because it is not all-inclusive. Furthermore, because the list of examples includes "exterior soil and interior lead dust in carpets, furniture, and forced air ducts," it could be that by "sources," Congress was referring to the location of the source rather than the products containing lead that break down and contribute to lead in dust or soil. Finally, the items listed, such as furniture, could also include lead-based paint. In any event, this section cannot fairly be construed to cancel out the broadly defined terms of lead-contaminated dust and soil for which EPA was instructed to develop standards.

Likewise, EPA rejects NMHC's argument that the Agency's interpretation is completely inconsistent with the Disclosure Rule of section 1018 of Title X. The Disclosure Rule sets forth the parameters of disclosure of lead-based paint, lead-based paint hazards, lead-contaminated dust and lead-contaminated soil. The Rule explains that a "lead-based paint hazard means any condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, or lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces, or impact surfaces that would result in adverse human health effects as established by the appropriate Federal Agency." 40 C.F.R. § 745.103, 61 Fed. Reg. at 9086, This description is consistent with the terms as they are defined in Title X and in TSCA in that it assumes that the lead source in dust or soil is broader than paint.

EPA's interpretation is also consistent with EPA's regulations under TSCA section 402 and guidance the Agency has issued as an interim measure before promulgation of the section 403 . EPA regulations under TSCA section 402 describe the scope of EPA's authority in the context of TSCA's definitions for lead-based paint, lead-contaminated dust and lead-contaminated soil. 40 C.F.R. pt. 745. Under the section 402 regulations, the work practice standards for lead-based paint activities provide separate paint, dust and soil standards for lead hazard screening, risk assessments and abatement. 40 C.F.R. § 745.227. Soil and dust activities are not at any place within the section 402 regulations conditioned upon finding that lead-based paint is present.

Likewise, EPA's TSCA section 403 guidance demonstrates that lead-based paint is just one of many possible sources of lead in lead-contaminated soils or dusts that contribute to lead-based paint hazards. 60 Fed. Reg. 47,248-57 (Sept. 11, 1995). Specifically, EPA indicates that sources other than paint should be evaluated to determine whether dust could become a lead-based paint hazard:

> [I]f interior paint has been ruled out as a source, and dust concentrations approach those of exterior soil, it may well be the result of soil being tracked into the house from outside. Also, if paint is in sound condition and soil concentrations are low but the interior dust concentrations are high, it is possible that other sources, such as dust carried home from lead-related work, are present. Through a systematic process of elimination, many of the

> sources of lead in house dust can often be determined.

60 Fed. Reg. at 47,251. Thus, if an evaluation determines that the interior lead dust levels are high and yet the paint appears to be intact, there are many potential alternate sources of lead to investigate.

The TSCA section 403 guidance is equally clear in its consideration of sources other than lead paint for lead levels in lead-contaminated soils. Specifically, the section 403 guidance provides that:

> Common sources of lead in residential soil include deteriorating exterior lead-based paint and historical airborne deposition onto the soil surface as the result of point source emissions or leaded gasoline. These sources have added substantially to the naturally occurring lead in soils, which generally range from 5 - 50 parts per million. Also, industrial sources such as smelters, recycling facilities, and mining activities can result in lead contamination at residential areas.

60 Fed. Reg. at 47,251.

In light of the above, the breadth of the definition for lead-contaminated dust and soil taken together with the structures of both Title X and TSCA demonstrate that the lead source in lead-contaminated dust and soil covered by these statutes is not limited to lead from paint.

NMHC's references to the legislative history of Title X and section 403 only what is already clear from the face of the statute: that Congress' primary concern was harmful exposure to lead-based paint in housing. However, NMHC conveniently ignores and disregards the portion of the legislative history that demonstrates that Congress intended the terms "lead-contaminated dust" and "lead-contaminated soil" to include sources other than paint.

NMHC refers to several statements in the legislative history where various senators and representatives refer to the term "lead-based paint" and the problems of lead dust from paint. The provisions of a statute are not to be regarded as modified by examples set forth in the legislative history; an example illustrates a statute's operation in practice but is not a definitive interpretation of the statute's scope. Thus, that the legislative history is replete with examples of concerns about the harmful effects of lead in paint and lead from paint in dust does not mean that Congress intended to limit regulation solely to dust containing lead from paint. At best, it shows that lead-based paint was a concern to Congress. More importantly however, although NMHC has provided plenty of examples of congressional concerns about lead in paint, the evidence in the record it ignores seriously undercuts its claims.

First, there is evidence to show that Congress could have limited the lead in dust to paint if it had so desired. Title X was based, in part, on a bill introduced earlier in the House of Representatives, H.R. 5730, 102d Cong. (1992). See 138 Cong. Rec., H11459 (daily ed. Oct. 5, 1992). Section 402(a)(8) of H.R. 5730 specified that "lead-based paint abatement activities" includes activities involving "materials containing lead from lead-based paint." H.R. Rep. No. 102-852, pt. 1, at 3. The Section-By-Section discussion in the House Report states that these activities include "interior dust that contains lead *from lead-based paint*." Id., at H.R. No. 102-852, pt. 1, at 38-39 (emphasis added). However, this specific limitation was not included in the final version of the statute. "Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." Russello v. United States, 464 U.S. 16, 23-24 (1983). The above provision demonstrates that Congress knew how to limit the scope of the regulation in the manner NMHC contends but chose not to do so.

Second, contrary to NMHC's claims, the Senate debates on the conference report likewise reveal that the source of lead in soil covered by the statute is not limited to lead from paint. See 138 Cong. Rec. S17930 (daily ed. Oct. 8, 1992). Senator Brown was concerned that EPA would interpret the application of the definition of "lead-contaminated soils" to result in overly stringent regulation of soils in Colorado that were contaminated with lead from mine tailings rather than paint. Id. He thus cautioned EPA to use the site-by-site analysis implicit in the definition of "lead-contaminated soils." See id. It is significant that although Senator Brown assumed that the lead in lead-contaminated soil could include a non-paint source, not one member of Congress contradicted his view by claiming that the definition of "lead-contaminated soils" only referred to lead from paint. Senator's Brown's statement is the only colloquy in the legislative history that directly refers to the meaning of the term "lead-contaminated," albeit for soil. Because the term lead-contaminated soil, like the term lead-contaminated dust, is described without the restriction of lead from paint, Senator Brown's statements are equally instructive on the definition of lead-contaminated dust. Senator Brown's comments directly relate to the definition of "lead-contaminated soil" contained in TSCA; he refers to the cleanup of a Superfund contaminated site only as an example. See 138 Cong. Rec. S17930. His use of the contaminated site as an example does not lessen in any way the significance of his basic assumption that the sources of lead in "lead-contaminated soil" includes more than paint.

Furthermore, there are other references in the congressional dialogues that refer to the fact that the very bill passed would aid the problem of childhood lead poisoning and the need to reduce lead hazards, in general. See, e.g., 138 Cong. Rec. H11459 (daily ed. Oct. 5, 1992) (remarks of Congressman Waxman). These included discussions which recognized that there were problems with housing renovation and lead hazards but which do not in any way suggest a limitation to paint as the source of the hazards. See id.

If the legislative history is read as NMHC desires, the broad language defining the terms lead-contaminated dust and soil would be effectively written out of the statute. However, as demonstrated above, and in light of the broad definitions of lead-contaminated dust and lead-contaminated soil in the statutes, the legislative history supports the conclusion that Congress intended lead-contaminated dust to include lead from sources other than paint.

Given that the plain language of Title X and TSCA define lead-contaminated dust broadly, and in light of the fact that Congress was aware of how to limit coverage to lead from paint and chose not to do so, EPA's determination that the lead in lead contaminated dust includes lead from non-paint sources is reasonable.

Another NMHC argument that EPA rejects is NMHC's assertion that EPA's interpretation is unreasonable because the section 1018 Disclosure Rule exempts lead-based paint-free housing from its coverage. It is significant, however, that the Disclosure Rule only exempts rental housing that is free of lead-based paint. 40 C.F.R. § 745.101. Thus, owners who remove lead-based paint before renting the unit do not have to disclose the prior tests for lead to renters. 61 Fed. Reg. at 9067. EPA determined that this exemption was warranted because it would "provide a valuable incentive to building owners to conduct inspections and remove lead-based paint where present." Id. EPA recognized that the required disclosure for rental units was "limited to the disclosure of known lead-based paint and/or lead-based paint hazards, provision of available records and reports, provision of a lead hazard information pamphlet, and creation and retention of lead warning and acknowledgment language." Id. EPA concluded however, that these reporting "activities provide[d] substantially fewer benefits when the housing is lead-based paint free." Id. However, EPA did not extend this exception to sales transactions. Thus, the owners must still retain and report to buyers any information on testing conducted for lead-based paint, dust and soil. That the Agency acted within its discretion and made a decision to exempt a subset of the regulated housing from reporting requirements in order to encourage lead-based paint abatement does not in any way undermine its interpretation of the terms "lead-contaminated dust or soil."

In addition, there is technical basis for not separating out paint and non-paint sources from the hazard standards. See response to Comment 2.2.3, below.

2.2. General Policy Concerns

2.2.1 EPA should not be emphasizing cost at the expense of protection of public health by using a cost-benefit analysis to choose hazard standards. By using the word "balancing" in its analysis, EPA is leaving the impression that its analysis has the trappings of objectivity and fairness. Yet, clearly the focus by EPA on economics leaves the impression that the concern for public health has taken a back seat to the economic considerations.

Response: In light of comments such as these EPA believes it is appropriate to make clear that the Agency is in no way emphasizing cost at the expense of protection of public health. The overarching emphasis in this rule is protection of public health. The standards in this rule cover any levels at which there are unquestioned actual risks from levels of lead in paint, dust and soil. The cost-benefit analysis only serves to help the Agency to distinguish among the various levels at which the evidence of actual risks shows no clear picture.

At the highest amounts of deteriorated paint or levels in dust or soil the analysis shows there are hazards. Indeed, if the cost-benefit analysis were not to show regulatory hazards at the highest levels, the Agency would need to seriously question the analysis or reject it altogether. The fact of the matter is that under any kind of legitimate cost-benefit analysis, as risks approach certainty, the resources that society is willing to spend would be correspondingly higher -- and cost has little to no bearing at the highest levels of risk. The regulatory cutoff which the Agency is charged with determining is at that level where the science gives no clear answers, but at which there are actual risks.

One difficulty EPA has in responding to these comments is that they do not provide the Agency with any real alternative to picking the regulatory cutoff based on cost-benefit analysis. While a number of comments claim EPA should choose the levels based on what they characterize as a "health-based" determination, regardless of cost, they provide no rational basis for choosing between any of the levels which they advocate. Generally, the comments argue that the Agency should set the hazard levels at those environmental levels at which some studies show that a certain percentage of children will exceed some blood lead level. The probabilities are generally in the 5 percent range, but no reasoning is given for why 1 percent, or even a lower percentage, wouldn't be "health-based." Furthermore, when the 5 percent exceedence probability is applied to different target blood lead levels of concern, the whole exercise provides no rational basis for choosing hazard levels. The comments suggest blood lead levels that vary among a variety of ranges and a variety of probabilities with no particular rationale for choosing the cutoff.

Comments recommended levels as low as 2 ug/dl as the blood lead level of concern. If a so-called "safety factor" is chosen, the blood lead level could be up to 1,000 times less than 10 ug/dl (EPA's blood lead level of concern) or 0.01 ug/dl – clearly an unreachable level and one at which risks would appear to be almost non-existent.

In addressing this issue, it is instructive to consider comments that try to provide various alternative standards for dust based solely on a numerical cutoff involving the percentage of children above a blood lead level. These comments are based on a technical analysis that claims to show that a floor dust standard of 5 $\mu g/ft^2$ would be required to ensure that 95 percent of children do not have blood lead levels greater than 10 µg/dl. (EPA discusses why it disagrees with this analysis later in this Response to Comment document.) Nevertheless, these comments would not think it appropriate to set such a low standard and suggest a higher level of 40 $\mu g/ft^2$, based on cost and feasibility. However, if the technical analysis is correct, it turns out that 40 $\mu g/ft^2$ would be the level at which 5 percent of children would have blood lead levels above 15 µg/dl. This is the level at which the Centers for Disease Control (CDC) recommend environmental intervention. EPA would strongly disagree that a health-based standard should be established at a level where a large number of children would have such high blood lead levels. Indeed, these comments do not discuss why the level shouldn't be as high as 20 ug/dl or higher, where CDC recommends medical intervention.

After consideration of these alternatives, EPA believes that for determining lead-based paint hazards under section 403, a cost-benefit analysis is the better method to be used to resolve uncertainties in the relationship of environmental lead levels to blood lead levels. EPA in fact has determined that 40 $\mu g/ft^2$ should be the dust-lead hazard level, but does not agree with analyses that say 5% of children would have blood lead levels of 15 µg/dl.

Finally, a word about EPA's use of the term, "balancing." The Agency is not attempting to balance the "pocketbooks" of landlords against public health. Rather, the Agency's analysis is designed to balance among a number of different kinds of actions. EPA wants to avoid excessive cleanup in those situations in which the existence of actual risk is not clear, to ensure those actions occur which clearly need to be done, to encourage actions that will prevent real risks, and ultimately to help ensure that all actions taken will be commensurate with the risk that exists.

2.2.2 The 1975 National Academy of Sciences (NAS) report "Decision Making for Regulating Chemicals in the Environment" (pp. 7, 44) concluded that "highly formalized methods of cost-benefit analysis can seldom be used for making decisions about regulating chemicals in the environment." Further, a 1977 NAS report on "Drinking Water and Health" (Vol. 1, pp. 30-31) stated "numerical benefit-cost ratios can carry with them a spurious precision that no disclaimer can dispel. In addition, expressions of benefits and costs in monetary terms assume that it is meaningful to convert lives, health, and other consequences of decisions to dollars, an assumption that many are unwilling to accept."

Response: EPA disagrees that these comments show the Agency should not have used a cost-benefit analysis. In the first place, all EPA statutes call upon the Agency to exercise its judgment on difficult public health issues. EPA also does not view this analysis as being "highly formalized" and in fact the Agency, from the beginning, has justified the cost-benefit analysis here because it is a technique to allow the Agency to arrive at a range of options on which the Agency exercises its administrative judgment. Quantitative modeling is used as a tool to derive the boundaries of the Agency's inquiry, not as the sole basis for decisions. See preamble to proposed rule at 30314. Further, EPA does not view the numbers with precision. Rather, the Agency has explained that it used a normative analysis because it is difficult, if not impossible, to estimate expected costs and benefits with precision. See id. In addition, the objective of the analysis has been to provide estimates that allow Agency decision makers to compare costs and benefits of various options. This would assist in decision making because EPA believes that the relative balance of costs and benefits estimated by the analysis is unlikely to be very different from the relative balance of actual costs and benefits. The Agency is not claiming that the costs in the analysis are those that will in fact occur, or that the benefits will in fact occur.

2.2.3 The non-paint sources of lead would not present the same risks as the lead from paint due to differences in bioavailability among the different lead species. In fact, EPA acknowledged in the 1995 TSCA section 403 guidance that different lead sources may inflict different types and levels of harm. Therefore, there appears to be a technical basis for not including the non-paint sources of lead in the rule.

Response: EPA strongly disagrees with this comment. In the first place, the 403 guidance very plainly provides that all sources of lead should be evaluated in order to reduce the risks from lead poisoning. 60 Fed. Reg. at 47,251. Even lead with relatively low bioavailability can, in some circumstances, present significant risk. Moreover, neither NMHC nor any other person has provided any methodology to assess risks based on differences in the types of lead, even though EPA has acknowledged that it could be possible for States to develop such standards based on local conditions (see preamble to proposed rule at 63 FR 30344).

Furthermore, even if there were a practical method to distinguish the risks based on bioavailability, as a practical matter, with current scientific technology, it is not possible to determine with good precision how much of the lead in dust or soil in a specific room or area originated from lead paint in a specific dwelling unit on a specific building component. It is, however, sometimes possible in detailed laboratory and field analysis to arrive at some conclusions whether paint might be a source of lead in dust or soil -- see preamble to proposed rule at 30330-31 on paint as a source of lead exposure. However, there is a distinct absence of a scientific method to determine conclusively that the source of lead in dust or soil is not paint on a routine basis.

While lead studies involving stable isotope ratios, like those mentioned above, may successfully identify the source of environmental- or blood-lead, they have only been proven successful when there are at most only are a few, well-characterized (isotopically) lead sources. In such studies, the ratios of certain lead isotopes that are present in suspected sources (e.g., paint on a specific surface) are compared to the ratio of those isotopes in the environmental medium being examined (e.g., dust in a child's bedroom soil) or even the lead in a child's blood. If, for example, the ratios of the various isotopes in the medium being investigated is the same as the ratios in the suspected source, that source is likely to be the cause of the lead in that medium (see, e.g., Yaffe, et. al., "Identification of lead sources in California children using the stable isotope ratio technique." *Arch Environmental Health.* July - August 38(4).273-45 and 9Rabinowitz, M.B. 1987. "Stable isotope Mass Spectrometry in Childhood Lead Poisoning." *Biological Trace Element Research.* 12: 223-229). Unfortunately, this procedure is not likely to be successful when several lead sources are involved. Such other sources can be other paint, particulates from industrial processes (which is further complicated by the fact that isotopic ratios in waste streams can vary temporally), and soil contaminated with lead from various sources. In such cases, the isotope ratio in the medium being examined could be the result of any number of combinations of relative contributions from the many sources. Since environmental lead in residential environments is usually the result of numerous sources, this technique usually does not produce definitive results.

Accordingly, while EPA's decision to cover lead in dust or soil regardless of the source of the lead is based on the directives of the statute, there is nevertheless no good technical basis to exclude from coverage, based on the lead source, dust or soil -- particularly dust and soil with high levels of lead.

2.2.4 The result of EPA's "regardless of the source" determination is that the Agency would be imposing responsibilities on residential real property owners and managers for a widespread environmental pollutant which may be found on properties which lack any history of lead-based paint. Residential property owners are thus being singled out to bear the financial burden for remediating a problem which is far more wide spread than lead-based paint contamination and for which they bear no direct responsibility.

Response: It would be far more constructive if NMHC were to make arguments based on a risk determination regarding the levels EPA has chosen, instead of this technical basis. The fact is that EPA's analysis found certain levels of lead (without considering the source) in a random survey of pre-1978 housing. The higher levels are hazards. NMHC has not presented any way to change the Agency's risk analysis based on eliminating non-paint sources.

Another reason to reject NMHC's view on the source of lead is that it would place the burden of showing a hazard under this regulation on the very people whom the law is designed to protect. NMHC would exclude from the definition of lead hazards dust and soil with extremely high levels of lead unless there were proof that the lead came from paint. This is not a situation EPA would find tolerable.

2.2.5 EPA should have recognized and compensated for multi-media exposure to lead.

Response: The standards do account for multiple sources of exposure. The standards are supported by analyses that account for multiples sources of exposure. The IEUBK model has inputs for exposure to other sources including air, water, and diet. The Agency used the default values recommended in the model guidance document for these inputs. The Empirical model estimates a relationship between environmental lead and blood lead based on analysis of empirical data. The model includes specific terms for lead in paint, dust and soil. All other environmental sources and factors affecting the relationship between environmental lead and blood lead are accounted for in the intercept or error term of the model.

2.2.6 The proposed standards are insufficiently protective because they are based on analysis that considered risks for one to two year olds instead of all children under six. Researchers have documented impacts for children up to seven and that Dr. Herbert Needle man has linked lead exposure with behavioral problems among teenagers. Consequently, the restriction of the analysis to one to two year olds underestimates the potential effects of exposure. The SAB specifically addressed this issue and noted that there was confusion with respect to this issue and that EPA should consistently refer to children under the age of six to eliminate the possible misconception that the risk is only for one to two year olds.

Response: EPA recognizes that there was some confusion about the age range of children used in the analysis and offers this explanation to address this confusion. EPA used one to two year olds was to establish the relationship between lead exposure and health effects. For purposes of estimating benefits, however, EPA used this relationship to estimate lifetime benefits for all children born during the 50-year time frame of the analysis. Because all children born after the regulation becomes effective, barring mortality, will pass through the one to two year old age range, the age range selected to estimate the relationship between environmental lead and blood lead, does not limit the children who are included in the benefits analysis.

2.2.7 Standards should be set at natural background levels because there should be "no space for human loadings."

Response: EPA disagrees with this comment. Standards at or close to zero are not consistent with definition of hazard in TSCA section 401 which is conditions of lead in residential paint, dust, and soil that would result in adverse human health effects. Although there is no known no effects threshold for lead, there is considerable uncertainty associated with health effects at very low levels of exposure. Most of the physiological effects that have been documented at these levels occur at the molecular level. It is unclear how these effects manifest themselves in real human health outcomes. Furthermore, health effects at very low levels of exposure are less well substantiated because the evidence of these subtle changes comes from a limited number of studies and limited number of children. EPA, therefore, cannot conclude that levels of lead at or close to zero would result in adverse human health effects.

2.2.8 Several comments claimed they could identify children who have been poisoned associated with the weakened standards EPA has proposed.

Response: While assertions have been made that specific children have been poisoned at levels below the proposed standards, EPA does not believe that blood lead levels for any particular child can be directly attributed to causation by any particular lead levels.

2.2.9 EPA should strengthen the standards because unexplained violence, hyperactivity, diminished attention spans, and other aberrant behavior among children appears to be increasing.

Response: No evidence was provided that these problems are increasing. Even if one assumes they are, these problems are complex phenomena influenced by many factors. There is no evidence the lead exposure is helping to cause these problems to increase. In fact, declining lead exposure is likely having an effect in the opposite direction.

2.2.10 The proposed standards are overly broad, while the problem of lead exposure is increasingly focused in specific communities. NHANES data shows that there are far fewer children with elevated blood lead levels than there are homes that would be identified as having hazards using the proposed standards. According to the most recent NHANES data 890,000 children ages one to six have blood-lead levels equal to or exceeding 10 µg/dl (81,000 exceeding 20 µg/dl) while EPA estimates that 30 million homes would have paint, dust, and/or soil hazards. The standards would identify 25 million homes as having dust-lead hazards alone. One need go no further than these statistics to conclude that EPA has greatly overreached in its proposal.

Response: EPA believes that this analytical approach is flawed for several reasons. First, it is not appropriate to look at just the number of children who currently have elevated blood-lead levels (EBL), but at the number of children who will have EBL in the future if exposed to current environmental lead levels. At the current rate, 180, 000 one year olds will have an EBL each year or 3.6 million children over the next 20 years. Second, EPA is not recommending action in all these houses, only houses where young children reside. Third, EPA foresees that actions will be implemented over a long time frame, not immediately. Fourth, the Agency acknowledges that it cannot predict with perfection situations that will cause elevated blood lead levels; EPA cannot measure exposure perfectly and the relationship between environmental lead and blood lead is, in part, explained by factors such as hand-to-mouth behavior and the child's nutritional status which is highly variable. Therefore, to protect children adequately, EPA needs to cast the net somewhat more broadly than just to identify those properties where children with EBLs are currently found. Furthermore, national environmental data recently collected by HUD shows large declines in dust-lead levels and, consequently, that less homes are likely to be identified has having hazards than estimated by EPA using the 1989-1990 HUD National Survey data. These new data seem to corroborate EPA's position that the hazard standards are not overly inclusive.

2.2.11 Costly abatement actions triggered by the hazard standards will impose burdens that will be born disproportionately by the oldest, poorest inner city neighborhoods. The approach EPA has laid out in the proposed rule, fails to target the areas (such as the census tracts identified by NHANES or the records maintained by municipal health departments that identify the locations involved in lead-poisonings) in which the most vulnerable population will reside. This overly broad approach is not the most effective course to take in protecting children from lead poisoning.

Response: EPA notes that both the prevalence of elevated levels of lead in dust and soil and deteriorated lead-based paint as well as the incidence of children with elevated blood lead levels is greater in these communities. Therefore, it is appropriate that hazard standards identify problems in these communities. At the same time, EPA recognizes that a common sense approach is needed to implement the regulations in a manner that provides even greater focus. Therefore, EPA has developed guidance that provides important advice how these standards should be used. This guidance provides recommendations on when properties should be evaluated and types of interventions that should be considered. Furthermore, these standards will be implemented as part of a broader program that includes extensive public education and outreach as well as well trained risk assessors who will be the primary users of these standards. Not only will risk assessors use the standards to identify hazards, they will provide recommendations to property owners and other decision makers on the best way to address the problems effectively.

2.2.12 EPA's own risk analysis shows that little if any harm occurs if no changes are made from the existing HUD Guidelines (100 $\mu g/ft^2$ on floors, 500 µg/Ft2 on window sills, and 5 ft^2 of damaged lead-based paint). The following quotation appears in Chapter 6 of the Risk Analysis document -- "there is little reduction from baseline in the percentage of children predicted to have IQ below 70, in the percentage of children to have an IQ decrement greater than one, and in the average IQ decrement, over the range of example standards considered in this analysis."

Response: This comment reflects a significant misunderstanding about the role of the risk analysis in EPA's decision making process. The primary function of Chapter 6 of the Risk Analysis was to provide EPA with a risk reduction methodology to be used in the Economic Analysis to estimate the benefits of different options for the hazard standards. The Agency did not rely on it directly in making its regulatory decisions.

Examination of the measures presented in Chapter 6 reveals two limitations that make it inappropriate for assessing benefits. First, it estimates changes in the number of children with blood lead levels exceeding selected benchmarks. In contrast, the economic analysis looks at changes in the entire blood-lead distribution which is a more comprehensive measure of the impact of the standards. Second, the economic analysis estimates benefits that occur over time. This approach is especially critical because it recognizes that a single abatement action is likely to provide benefits to children who are about to live in that home as wells as to children who will live in that in the future. The Risk Analysis is a static analysis that focuses on the public health impacts for the current population of young children and does include benefits that occur in the future.

Moreover, the focus on the Risk Analysis estimate of the reduction in the number of children with blood leads equal to or exceeding 10 μg/dl at a single point in time is also inappropriate. The impact of the standards needs to be evaluated by applying this percentage to the number of children born each year in account for individuals who will be protected by the rule over time. Using the approach, the standards could prevent 800,000 to four million children from having elevated blood lead levels over twenty years. This is a significant public health benefit.

PART THREE -- GENERAL TECHNICAL ANALYSES

The Risk Assessment was designed to estimate the declines in children's blood lead levels that would result if abatement and other response actions were taken in housing units that exceeded candidate standards for paint, dust, and soil before a child resides in that unit. While certain details of the analysis are complex, the basic approach is straightforward. First, a baseline of environmental lead and blood lead levels was established. These represent the "pre-403" conditions.

For the pre-403 environmental lead levels, the Agency used the Department of Housing and Urban Development's National Survey of Lead-Based Paint in Housing (the HUD Survey). Conducted in 1989-1990, the HUD Survey measured the extent and condition of lead-based paint in housing, the amount of lead in dust within the housing, and the amount of lead in soil surrounding the housing. For the pre-403 blood lead levels, the Agency used Phase 2 of the third National Health and Nutrition Examination Survey (NHANES III). Conducted by the Centers for Disease Control and Prevention in 1991-1994, NHANES III included measurements of children's blood-lead levels.

Next, the Agency estimated the reduction in environmental lead levels that would result if abatements or other responses were performed in housing units that failed candidate standards for paint, dust, and soil. These levels represent the "post-403" environmental lead levels and rely upon estimates of the effectiveness and duration of the response actions.

The Agency then modeled the blood lead levels that would correspond to the pre- and post-403 environmental lead levels. This allowed an estimation the blood-lead reduction that would result from the standards (*i.e.*, the difference in the blood lead levels from the pre-403 environmental levels to the post-403 environmental levels). Here, the Agency used two different models–the Integrated Exposure Uptake Biokinetic (IEUBK) Model and an empirical model that was based upon the results of the Rochester Lead in Dust Study. Consequently, there are two different estimates of the blood-lead changes that would result from the 403 standards, one based upon each model. Finally, the two estimates of blood-lead changes were applied to the pre-403 blood-lead levels in NHANES III. This section responds to comments received on these steps of the Risk Analysis methodology.

3.1 Risk Assessment Fundamentals

3.1.1 CHOOSING WHICH HEALTH EFFECTS TO CONSIDER

Although studies have identified a wide range of adverse health effects associated with exposure to lead, EPA was able to develop monetary estimates for relatively few benefits. Specifically, the Agency evaluated foregone lifetime earnings associated with diminished IQ, special education costs for children with IQ less than 70 and medical intervention compensatory education costs associated with children with blood lead levels exceeding 20 μg/dl.

3.1.1.1 A State health department suggested that EPA should have looked at the benefits to children with blood leads equal to or exceeding 10 μg/dl rather than 20 μg/dl.

Response. This is a misunderstanding on the part of the commenter. The use of 20 μg/dl in the analysis was associated with the effort to estimate the avoided medical costs associated with declines in lead exposure. This level of 20 μg/dl was selected as the benchmark for estimating the change in the number of children who would require medical treatment because medical treatment is recommended starting at 20 μg/dl not 10 μg/dl. The analysis includes benefits for reducing exposure to children with lower blood-lead levels as part of the avoided IQ point loss measure. In fact, avoided IQ point loss estimates benefits for all changes in blood-lead levels, not only for children with blood-lead levels at or above 10 μg/dl.

3.1.1.2 Lead hazard control would also reduce exposures to other harmful substances and the benefits associated with that should be incorporated into the analysis.

Response: EPA acknowledged in the proposed rule (63 FR 30319) that the Agency was not trying to estimate a real value for risk reduction. Many benefits were not included in the analysis (e.g., those resulting from reduction in exposure to other harmful substances) because EPA lacks the tools and/or data because some benefits are subjective in nature. The Agency believes, however, that the failure to include all benefits in the analysis does not affect the selection of the standards because the objective of the analysis was to provide a basis for comparing options relative to each other. The omission of a specific type of impact is unlikely to have affected the relative performance of the options and, therefore, would not have provided substantively different information to Agency decision makers.

3.1.1.3 Even assuming the cost-benefit analysis is appropriate, EPA's analysis is flawed because it fails to consider the appropriate cost elements. The cost-benefit analysis should compare the benefits derived from the regulation with the costs that result from compliance with the regulation. The regulation and Title X do not mandate any activity other than the disclosure of the presence of lead hazards and the use of certified lead-workers if soil is removed, covered, or disposed. The cost of certified lead-workers is contingent on a property owner's decision to remove soil from the property. The proposed regulation does not mandate the removal of identified lead-based paint hazards and thus, the cost of a certified lead-worker is not mandatory. The only mandatory cost of the regulation is the cost of disclosure. Therefore, the cost-benefit analysis should only compare the benefit of the regulation with the cost of disclosure and not the cost of abatement.

Response: This comment misunderstands the reasons for using the cost-benefit analysis. The analysis is used as a tool to help the Agency establish a regulatory cutoff. EPA has decided that those conditions at which there is a higher level of certainty on a national level that abatement would provide risk reduction commensurate with the costs are those conditions that the Agency feels confident "would result" in adverse effects. The costs of regulation under the current statute are not relevant to the normative analysis that supports the risk determination for this rule.

3.1.1.4 The cost-benefit analysis is flawed because it fails to consider interim controls -- low cost measures, which may be sufficient to reduce exposure, such as covering bare soil, placement of washable doormats, and access restrictions. EPA's failure to take the costs of interim controls into account directly contradicts what Congress considered as an appropriate response to lead-based paint hazards. EPA's belief that interim controls may be sufficient to reduce exposure of children to lead in soil contradicts its justification for excluding interim controls in its cost-benefit analysis. Moreover, the recommended practice of The National Academy of Sciences, stated in the 1975 report noted above, is that agencies "identify and present information on the full range of alternatives the decision maker has, i.e., no action, partial control, or total ban." NAS 1975, at 169. This point was reiterated in the NAS report regarding Decision Making in the Environmental Protection Agency (NAS 1977, at 9-10). This should clearly include interim controls in this case.

Response: As stated repeatedly in the preamble to the final rule, EPA expects that interim controls would be used to reduce risks. Case specific cost-benefit analyses certainly could be used in those circumstances. However, EPA believes those conditions at which there is a higher level of certainty on a national level that abatement would provide risk reduction commensurate with the costs are those that should be designated as hazards under the regulation. EPA chose abatement as the option to evaluate for the hazard determination because those conditions that warrant abatement are those the Agency decided it could with confidence determine "would result" in adverse health effects within the meaning of the statute. Furthermore, as noted in the preamble to the final rule, EPA was not able to reliably quantify the benefits and costs of interim controls to use in the analysis.

3.1.1.5 There is a lack of symmetry or even-handedness in the analysis, for while the costs reflect remediation of every housing unit exceeding the standards, every time a child is born, the calculation of benefits associated with foregone medical interventions factors in the probability that many of these interventions will not occur.

Response: EPA justifies the inclusion of testing and medical costs for only some children, as opposed to all children, based on the fact that currently only some children are tested for elevated blood lead, even though many public health authorities, including the CDC, recommend such testing. Because, the only medical treatment costs that would be avoided by reductions in lead are those that would otherwise actually occur, it is the medical costs for these children that are included in the benefits. On the other hand, the IQ damage to all children is included in the analysis.

3.1.1.6 EPA's benefits calculations did not include the resultant future medical costs for diseases incurred as a result of the increased levels of exposure. While the analysis includes costs of screening young children for EBL and treating those found to have EBL as necessary (e.g., chelation), it does not include medical costs that may appear later in life due to adverse health effects from lead exposure as a child (e.g., hypertension).

Response EPA is unaware of any data that demonstrates a link between childhood lead exposure and adult health effects. Therefore, EPA did not consider these effects in its analysis.

3.1.1.7 EPA is incorrect in it's position that special education could compensate for the brain damage resulting from lead exposure.

Response: EPA agrees that special education costs do not capture the costs of severe brain damage, but notes that they are not intended to in this analysis. Special education costs and compensatory education costs are included as one quantifiable cost that society would avoid under the standards. They are not limited to severely brain damaged children, rather compensatory education costs are included for every child with a blood-lead level greater than 20ug/dl. Due to data limitations it is not possible to estimate the number of lead-exposure induced cases of severe brain damage that would be prevented by these standards.

3.1.1.8 EPA's analysis is inconsistent in its failure to include the increased earnings of parents whose children will not require screening and medical treatment.

Response: The Agency acknowledges that income is lost to care givers while caring for a sick child. However, it is unaware of any studies or other data that would allow for an estimation of lost parental wages as a function of specific exposure or blood-lead levels. Instead of introducing this source of uncertainty, EPA decided to exclude lost wages from that calculation. Even if data were available, however, the inclusion of other avoided costs, such as lost wages of parents, would increase net benefits of all standards without necessarily affecting the ranking.

3.1.1.9 Ecological benefits likely to arise due to reduced lead exposure have not been included in EPA's analysis.

Response: While ecological benefits are likely to result from the reduction of residential lead hazards, neither data nor exposure models are currently available to allow for these benefits to be directly incorporated into the analysis.

3.1.1.10 The Science Advisory Board stated that, because the 403 standards would result in fewer emergency inspections and abatements due to children with elevated blood-lead and this outcome would represent an additional benefit in the form of cost saving, the benefits in the analysis had been underestimated.

Response: Although is true that adherence to the proposed standards will reduce the number of emergency (and thus higher cost) inspections and abatements, to the EPA's knowledge, data on the number of such emergency actions are not available and thus cannot be incorporated into the analysis. In addition, the savings realized is likely to be small in relationship to the benefits from earning increases, which make up the bulk of the benefits.

3.1.2 PREVALENCE OF LEAD IN HOUSING

3.1.2.1 The data presented by EPA on the prevalence of lead-based paint by age of housing contradicts the Agency's statement that the likelihood, extent and concentration of lead-based paint vary with the age of the building. The commenter then cites data from the 1990 HUD report "Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately-Owned Housing" that shows that the probability of lead paint being present does indeed increase with building age.

Response: EPA believes that its statement is correct. The percentages presented by EPA (63 FR 30305), which comes from the Agency's analysis of the HUD survey data, shows that the likelihood of the presence of lead-based paint varies with age. Additional results from this analysis also show that the prevalence of paint higher levels of lead (i.e, ≥ 2 mg/cm^2) and the extent of lead-based paint increases with age of the building. The Agency also wishes to note that the Agency's analysis of the HUD survey is the most current evaluation of these data and was conducted in response to a request from HUD. HUD's original analysis, which was presented in the "Comprehensive and Workable Plan" was conducted within significant time constraints. Following publication of that report, HUD requested EPA to conduct a more thorough which HUD subsequently accepted.

3.1.2.2 EPA makes an incorrect assumption that the percentage of pre-1980 homes with non-intact lead-based paint that have young children is the same as the percent of pre-1980 homes with some lead paint that have young children. Instead deteriorated paint is distributed disproportionately with those with young children having more chance of living in hazardous conditions because these families with younger children tend to have lower incomes and less financial access to housing with intact paint. The effect of EPA's assumption is that the Agency may have underestimated the percentage of pre-1980 homes in the United States containing both non-intact lead-based paint and young children.

Response: EPA is not aware of any data, and none has been provided, that would support an alternate assumption. Given the lack of data indicating otherwise, the assumption used by EPA, equal distribution of children among homes with intact and deteriorated lead-based paint is still believed to constitute a reasonable approach.

3.2 Relating Environmental Levels to Blood Lead

3.2.1 Performance of the IEUBK Model Compared to the National Blood-Lead Distribution

As an argument against use of the IEUBK model, commenters pointed to the differences between the blood-lead distribution produced when the model was used with the HUD National Survey data and the blood-lead distribution reported in NHANES III. Applying the IEUBK model to the HUD National Survey data, the geometric mean blood-lead level is mean is 3.9 µg/dl and the geometric standard deviation (GSD) is 2.3. The model predicted that 12 % of children would have a blood-lead level exceeding 10 µg/dl. The geometric mean and GSD of NHANES III Phase 2 (which was used in the risk analysis) is 3.14 µg/dl and 2.1, respectively, with 5.75 percent of the children exceeding 10 µg/dl. Commenters cited this as another example of model's tendency to over predict blood-lead distributions.

Response: The Agency disagrees with this conclusion. First, the HUD survey was not designed to collect measurements that reflect children's typical exposures for the residences chosen. The survey emphasized soil near the dripline of the house, where soil lead levels tend to be highest within a yard, but no information concerning play areas was collected. Therefore, the soil lead input was an overestimate, contributing to higher blood lead levels than would have expected. Also, dust samples from each residence came from two randomly chosen rooms, including bathrooms and kitchens, regardless of children's likely (for residences without children) or actual activities. Consequently, dust inputs are not expected to accurately reflect the child's exposure either.

Secondly, the HUD survey was not designed to coincide, either in geographic area or in time, with NHANES III, phase 2. It is not clear that there was much overlap in communities between the two studies. Also, the HUD survey was conducted from 1989 - 1990, whereas NHANES III, phase 2 was conducted in 1991 - 1994. If the IEUBK/HUD survey results are compared to NHANES III, phase 1 which was more contemporaneous with the HUD survey (i.e., conducted in 1989 - 1991), the results are more similar: 12% predicted > 10 μg/dl vs. 11.5 % measured in NHANES III, phase 2.

3.2.2 The Rochester Data and Models

EPA used the Rochester Lead-In-Dust Study to develop one of the two models used to relate dust, paint, and soil lead levels to blood-lead levels (the other model was the EPA IEUBK Lead Model). The HUD national survey of environmental lead levels in housing was used for nationally-representative inputs into the two models to predict blood-lead levels from environmental lead levels. The NHANES III, Phase 2 survey data was used to characterize blood-lead levels in the U.S. As noted in the preamble to the proposed and final rules, both studies had limitations. EPA had no study that empirically related national environmental and blood lead levels. Rochester was a local study of environmental and blood lead; while the

IEUBK only modeled the relationship. Accordingly, EPA employed statistical methods in its risk assessment to judge the relationship between environmental levels found in the HUD survey of environmental levels and the blood lead levels developed both in the IEUBK model and the Rochester study. These relationships overlapped to a large extent, but there were differences between the IEUBK and the Rochester model that EPA needed to evaluate in order to arrive at a final decision.

3.2.2.1 A local health department commented that "the IEUBK model, which is peer reviewed, is the stronger of the two. The empirical model, which has as a base the multimedia model, is derived from questionable data from a non-peer reviewed study. The utility of the empirical model in determining acceptable levels of dust in soil is questionable."

Other commenters held the opposite view. A Federal agency commented that "At 63 FR 30318, EPA appears to imply that the Rochester study (proposed rule preamble reference 20) has not been subjected to rigorous review. The original study was in fact subjected to rigorous peer review before a distinguished panel of independent scientists. The findings of the study have been published in several peer-reviewed scientific journals."

A State agency commented that "The empirical model function of lead concentrations is a multiple regression model where blood leads are directly estimated as a function of lead concentrations in several environmental media. The model appears plausible although it has not undergone a full peer review.

A lead researcher commented that "... the Rochester data are relevant and appropriate. The Rochester dataset was derived from an excellent study, whose design and conclusions have been extensively peer reviewed by HUD and outside experts (of whom I was one). There is no cogent reason to reject it or to constrain its applicability for estimating risks of similar populations (especially poor urban children)."

Response. The Agency agrees with the latter commenters that the Rochester study has been subject to rigorous review. It its statements in the preamble to the proposed rule, the Agency was simply contrasting the degree to which the IEUBK and the Rochester-based Empirical Model had been reviewed and noted that the Empirical Model had not been subject to the same degree of review as had the IEUBK Model. The Agency recognizes that the Rochester Study itself was peer reviewed and notes that, in the context of this rulemaking, their use in the Risk Analysis was reviewed both by an external panel of experts and, more recently, by the EPA's Science Advisory Board. Consequently, the Agency believes that the Empirical model and its application in the Risk Analysis for this rule has been sufficiently reviewed.

3.2.2.2 Several industrial corporations commented on the limitations of the Rochester Study, primarily the fact that it is not representative of the population as a whole and that EPA did not establish that the characteristics of the Rochester population are similar to the nationwide population. They claimed that EPA ignored the following: (1) the study uses only 205 children and, therefore, is too small a sample; and (2) the blood-lead concentrations are generally higher than those for children of low-income families measured in Phase 2 of the NHANES III study. Specifically, (a) the geometric mean blood-lead concentration of children aged 1-2 years in Rochester is 6.4 μg/dl, whereas the nationwide geometric mean blood-lead concentration is 3.1 μg/dl as estimated by Phase 2 of NHANES III; (b) approximately 23 percent of the Rochester children had observed blood-lead concentrations above 10 μg/dl, whereas only 5.9 percent of children aged 1-2 years nationwide were estimated to have blood-lead concentrations above 10 μg/dl; and (c) the distribution of observed environmental lead levels were considerably different between the programs. For example, the geometric mean dripline soil concentration from the Rochester study was approximately 730 ppm, while the dripline soil concentrations from the HUD National Survey was 75 ppm.

The commenter then claimed that several general issues rendered the Empirical Model suspect, specifically (a) approximately 84 percent of the housing included in the Rochester Study consists of older homes built prior to 1940, when the use of lead-based paint was widespread. Only approximately 20 percent of housing nationwide was built prior to 1940; (b) other important factors known to influence blood-lead levels are not accounted for in the Empirical Model (which consists of only environmental factors), including diet, nutritional status, and socioeconomic factors; and that (c) these factors are particularly important because 55 percent of households in the Rochester Study consisted of low income families (incomes below $15,500).

Response. The commenter misunderstands the way in which the Rochester data was actually used. The Rochester data is used for estimating the *relationship* between environmental lead levels and blood lead levels and not for estimating what the actual environmental and blood-.ed levels were. The environmental levels were estimated from the nationally representative inputs– the HUD National Survey – and baseline blood-lead levels were estimated from the NHANES data. The Empirical Model based upon the Rochester data and the IEUBK Model were then implemented using the applied to the HUD and NHANES data to derive the national estimates. Care was taken to correctly use these inputs, as is extensively described in the Risk Analysis document and its appendices.

As for including non-environmental variables, such as diet and socioeconomic factors, this would be inappropriate for the purposes of setting environmental standards. The standards are needed for routine use, and to make extensive examination of diet, nutritional status, and socioeconomic factors for every home in the U.S. would be highly impractical.

3.2.2.3 Comments were also received pointing out the differences between the environmental variables (paint, dust, and soil) measured during the Rochester Study and those measured during the HUD National Survey, specifically:

1. The sampling scheme for environmental lead for the two programs are different. For example, soil samples were collected along the dripline during the Rochester Study, but EPA proposes to use weighted average concentrations collected from the dripline, entryway and remote locations to characterize the soil concentration term for the HUD National Survey. A local health department also disagreed with the use of dripline soil lead concentrations to predict average soil concentrations for the entire yard ("the highest lead reading is likely to be found at the dripline and that area may not be representative of play areas or exposure sources for many children").

2. The sampling collection devices are instruments used to measure lead are different between the two programs. For example, floor and sill dust loadings were measured using wipe samples during the Rochester Study. The HUD National Survey measurements were made using a Blue Nozzle Vacuum, which were subject to significant error and provide a significantly different dust measure from wipe sample.

3. The distribution of observed environmental lead levels were considerably different between the programs. For example, the geometric mean dripline soil concentration from the Rochester study was approximately 730 ppm, while the dripline soil concentrations from the HUD National Survey was 75 ppm.

Response. In response to the first issue, the Agency notes that the play area soil lead levels were not available for many of the Rochester homes and thus the dripline levels were used. In the final rule, separate consideration is given to play areas in cases where they can be identified. In the implementation of the 403 rule itself, there are likely to be cases like those in the Rochester

Study where specific play areas are not identifiable. To the extent that this occurs, the Rochester case is not unique and so is not unrepresentative

With regard to the second issue, the Agency was fully aware that the dust sampling methods were different between the Rochester study and the HUD national survey. Consequently, the HUD measurements were converted to their equivalents of the Rochester study as described in the Risk Analysis, section 4.3.1. The converted levels from the HUD survey, when broken down by age of housing, were consistent with the Rochester data levels. Housing age was controlled for in the Risk Analysis, and thus is not a major source of concern for differences between the two studies.

The Rochester Lead-in-dust Study did target homes of children in a certain age group and where children spent the majority of their time in their primary residence. The children studied were in the population of interest for the 403 standards, and studying homes where the children spend the majority of their time in their primary home helps prevent against extraneous factors, such as condition of a second home or friend's home, adding uncertainty to the relationship observed.

3.2.2.4 A Federal agency commented that "the approach to adjusting the empirical model for measurement error, discussed on page 4-16 of reference 1 [referring to the EPA Risk Analysis report], requires an additional assumption to be valid. That is, that the post-intervention lead levels assumed in the table on page 6-8 and in figure 6-2 refer to measured, not actual, post-intervention levels."

Response. The Agency points out that the empirical model was developed to use measured lead levels (and not "actual" levels) and thus no additional assumption is necessary for the model to be valid. Page 4-17 of the EPA Risk Analysis, lines 1-2, states the fact that the model was developed "to use environmental variables as measured." Further details on this issue are found in chapter 4 of the Supplement to the EPA Risk Analysis.

3.2.2.5 The empirical model includes terms for both paint and dust lead to explain blood lead levels. A commenter stated that the model "erroneously implies that deteriorated paint has an independent effect on blood lead. It makes this implication because it inappropriately uses one variable that combines two distinct and different effects. Specifically, it uses a variable defined as either 0, 1, or 2, depending on compulsive eating behavior (pica) and the presence of deteriorated lead paint [EPA Risk Analysis, p. G-3]."

The commenter continues by stating that "the EPA uses the estimated coefficient to generate reductions in blood lead concentrations that are then valued at $5 billion [Proposed Rule, p. 30350. The IEUBK model gives benefits of $59 billion for paint abatement]. But deteriorated paint by itself does not adversely affect blood lead levels when dust levels are held constant. For example, as shown in table 2, the Rochester Final Report reported a negative coefficient for the independent effect of interior paint deterioration on blood lead. Similarly, Lanphear *et al.* also reported negative or statistically insignificant estimates of the effect of interior paint quality and lead concentration on blood lead [Environmental Research, A79:51-68]."

The commenter indicates that a paint variable should not be included in the multimedia model because he has found that "deteriorated paint by itself does not adversely affect blood lead levels when dust levels are held constant." This may be true for those children that do not exhibit paint pica, but for the few that do, the presence of damaged paint can be devastating. That paint pica does occur has been demonstrated by radiological study (McElvaine, et al, 1992, "Prevalence of Radiologic Evidence of Paint Chip Ingestion Among Children with Moderate to Severe Lead Poisoning, St. Louis, Missouri, 1989 through 1990"). Details on the Agency's analysis are found in Appendix D1 of the Risk Analysis.

Response. The key to interpreting the paint variable in the empirical model is that it represents the effect that the presence of deteriorated LBP had on the blood-lead concentration of a child who had some evidence of pica for paint. While it may be true that a child in general will be exposed to lead from LBP primarily through contact with dust (once the lead in paint finds its way into the dust), those children with paint pica tendencies are also likely to become exposed by directly ingesting paint chips that result from damaged LBP. This added effect for paint pica children is what the paint/pica variable in the empirical model is representing. The reason the two effects (presence of damaged LBP and paint pica tendencies) were combined into this one variable was that we recognized that any effect due simply to the presence of damaged LBP would likely be minimal once exposure to dust and soil was accounted for, and that any effect due simply to paint pica tendencies would be negligible if damaged LBP was not present. The two had to occur together to represent an important effect on PbB beyond what dust and soil exposure would explain. As very little paint pica was observed among children in the Rochester study (96% had either no or rarely-seen paint pica, cf. Table 3-3b of the 403 RA report), it is not surprising that a statistically insignificant correlation between paint condition and PbB would be observed in this study, especially after accounting for lead in dust.

Also, as noted in the risk assessment portion of the risk analysis, the paint/pica effect from the empirical model contributed to the predicted PbB for only those children in U.S. housing that exhibited paint pica in the presence of deteriorated LBP. This effect did not enter into the predicted PbB for any other children.

3.2.2.6 A commenter stated that the empirical model is unusual in that it separates the effects of lead dust on the floor from lead dust on windowsills, although these appear to have similar effects on blood lead. "Both the Rochester Final Report and the pooled analysis by Lanphear *et al.* assume that these two effects are identical. Using the EPA's data, we combine the measures of lead dust used by the EPA and find that the model performs nearly as well. In particular, we substitute a weighted average of the lead dust and windowsill lead wipe measures for the EPA's dust variables, using weights that reflect the percent of total surface areas wiped. The combined wipe measure has a statistically significant coefficient of 0.131, which is slightly less than the sum of those estimated by the EPA, 0.153. There is a slight decline of 0.0023 in the R^2 associated with the use of this simplified model. Thus there appears to be little empirical support for the notion that floor dust and windowsill dust have different effects on blood lead."

Response. The Agency, in determining whether a separate term in the model for window sills was appropriate, considered models both with and without the separate term for window sills. That is, the Agency wanted to determine whether window sills have an effect above and beyond that obtained from a floor measure alone. Statistically, the appropriate manner for testing for whether there is a statistically significant effect of window sills is through an F-test for a model with and without the separate term for window sills (cf. Draper, N and Smith, H., Applied Regression Analysis, second edition, New York: Wiley-Interscience, 1981, sections 2.7 and 2.10, or Seber, G.A.F., Linear Regression Analysis, New York: Wiley, chapter 4., etc). The effect of adding window sill dust-lead loading to the model was statistically significant at the 0.05 level ($p = 0.017$, $F=5.85$). Therefore, EPA included a separate term for window sills.

3.2.3 The Performance Characteristics Analysis

In addition to using dose-response models to characterize the relationship between environmental lead and blood lead levels, EPA also used a performance characteristics analysis to characterize the relationship between blood lead level. The performance characteristics analysis relied heavily upon the negative predictive value, which is one quantity for expressing how well the rule is likely to perform in practice.

3.2.3.1 An advocacy group commented that "EPA chose to ignore these results [from its modeling approaches] and instead relied on an untested 'negative predictive value (NPV)' 'approach that does not depend on a model' (FR Notice, at 30318). There are a number of limitations to this approach (FR Notice at 30318-30319). The most important limitation is that it does not incorporate dose-response relationships in a manner that adjusts for real world exposure. It presupposes a target level as an *a priori* assumption in the approach, which is highly questionable.

Response. Performance characteristics are widely used in statistics and other applied sciences to describe the performance of a rule or other system (see, e.g., Section 1.2 of Fleiss, J.L. (1981) "Statistical Methods for Rates and Proportions" (Second Edition. New York: John Wiley & Sons). A major *benefit* of this approach is that it doesn't rely upon determining the shape, or exact functional form, of the relationship between environmental lead levels and blood lead levels. Some of the performance characteristics analyses did include all environmental lead levels that will be measured and, thus, do reflect "real world exposure."

3.2.3.2 A private citizen commented "The mismatch between the EPA's proposed dust lead loading values and epidemiologic data is particularly confusing since the EPA estimates were derived from the same study we have cited, the University of Rochester Lead-in-Dust Study. [Lanphear, 1996] Moreover, in contrast with the results from these epidemiologic logic studies described above, I found that the description of the performance characteristic model (see page 30318], as described in the proposed rule, was unintelligible to most epidemiologists.

Response. The Agency believes that the differences between the proposed standard and the epidemiologic data come from two sources. EPA properly accounted for soil and paint in its analysis of dust lead levels. The commenter implicitly assumes that dust lead levels would be measured in isolation. However, EPA believes that this would be poor policy and explicitly states this in its final rulemaking discussion. EPA believes that the safest and most cost-effective approach is to measure soil and paint as well as dust and to set standards that are reflective of all three media. Elevated dust lead levels do not spontaneously arise -- there needs to be a source of that lead, and that lead usually comes from lead-based paint or lead in the soil. To set a level that would be identify potential risks from lead solely by dust lead levels would result in the majority of "elevated" readings to not result in a child with an elevated blood lead level. That is, it would be a very blunt and poor instrument for identifying conditions of concern. However, by considering which dust lead levels would pose a threat to human health when soil lead level and the condition/location of lead-based paint does not exceed the standards allows for much more precise identification of risks.

As for difficulty in explaining the performance characteristics analysis, the Agency believes its presentation of this approach in the proposed rule was clear and refers the commenter to page 30318 of the preamble to the proposal. Further discussion of the performance characteristics analysis can also be found in *Battelle Memorial Institute , Memorandum to Todd Holderman, U.S. Environmental Protection Agency, September 3, 1997* (Reference 64 to the preamble to the proposed rule) and in the Supplement to the Rule's Risk Analysis.

3.2.4 Other Dose/Response Comments

A Federal agency commented that "the risk analysis and the rationale provided for the proposed standard described in section IV [of the preamble] could be more clearly presented and includes some methodological errors. ...The lack of clarity could undermine confidence in the standard. For example, two models were developed from the Rochester Lead in Dust study, the multimedia model and the performance characteristics model. These yielded greatly divergent estimates of the relation of dust lead loading to the risk of elevated blood lead levels. The latter produces results more consistent with the proposed EPA standard for lead in dust, but no clear explanation of the divergent results or the rationale for choosing between them is provided. It appears that the multimedia model results were rejected by EPA on feasibility grounds, yet this is not as clearly stated as it could be. While we believe the multimedia model is probably more accurate (based upon other published studies), including feasibility considerations in the choice of a standard is consistent with good public health practice.

Another Federal agency was also concerned about the divergence in results between the two analyses and stated "the fact that the two types of analysis of soil in dust (multimedia and performance characteristics analysis) produce results that differ from each other by an order of magnitude [p. 30318 e of the preamble cited] makes it difficult to have any confidence in the results. Furthermore, the Agency indicates that other limitations of the analysis and the data including that the non-modeling analysis is based on data that may not be representative of the nation as a whole and that the data sample size is small. The types of data and analysis used seems highly suspect at best, and should probably undergo a thorough peer review, to ensure that the best available data is used in standards development.

A trade organization stated that "EPA has provided an inadequate rationale for use of the IEUBK Model to identify the 400 ppm soil lead initial candidate hazard level. The preamble states that the Agency used the IEUBK Model to identify the level of concern (which in the final rule has become the initial candidate hazard level) because the Rochester data relied on to develop the empirical model recorded soil lead concentrations at the dwelling drip line, rather than yard-wide average soil lead concentration values (63 *Fed Reg.* at 30317). For several reasons, this characteristic of the Rochester data should not disqualify use of the empirical model. First, because the statistical impact of drip line soil lead levels and interior dust lead levels is stronger than the impact of other soil in a dwelling's yard on interior dust lead levels (U.S. HUD, 1990; Bornschein, 1991), a model constructed using drip line soil lead concentration data will overstate the impact of yard--wide soil on interior dust lead levels. Second, it is clear that EPA itself sees no problem using the empirical model to predict the impact of soil lead on exposure since the Agency used the model (along with the IEUBK Model) to identify the soil lead hazard level of 2,000 ppm."

Response: EPA needs to correct possible misconceptions in this comment. In the first place, EPA has not determined that either of the basic models used is superior to the other. EPA applied equal weight to both models in making the decisions in this rule. In certain circumstances, however, EPA may have used different analyses based on the different models. This is true particularly in the case of the initial candidate hazard standards for dust and soil, where results of the modeling did not make sense to use directly as standards. EPA used both the performance characteristics analysis (based on the Rochester data) and the IEUBK to develop the initial candidate hazard level for soil. No greater weight was attributed to the IEUBK in this analysis. EPA did not use the empirical model for setting the initial candidate hazard level for reasons stated in the preamble.

EPA used the IEUBK model rather than the Rochester multimedia model to investigate ranges for the soil lead standard (at fixed dust lead levels) because that model considered yardwide average soil lead concentrations as inputs, and the Rochester model used dripline soil lead concentration as input. However, note that follow-up analysis of the proposed standards was done using a multimedia model based upon the Rochester data (e.g., see Section 5.1.2 of the Risk Analysis Supplement, including Table 5-4c which investigates ranges of yardwide average soil lead concentration based upon individual risk estimates obtained from fitting the modified Rochester model).

3.3 METHODOLOGY FOR CHOOSING INITIAL CANDIDATE HAZARD STANDARDS

3.3.1 EPA's blood-lead level of concern, which is used as a starting point to develop the lead-based paint hazard standards, should be lower than the 10 μg/dl that the Agency chose for the reasons discussed below.

A. EPA should have made a conservative judgement regarding the blood lead level of concern because it is authorized to do so under judicial precedent, which provides that agencies regulating health may make predictions based on extrapolations from limited data, may rely on inconclusive evidence, and may make conservative assumptions based on the best available evidence. Moreover, in the establishment of environmental standards, it is typical to include some safety factor; and if a safety factor is not applied, EPA should explain in the regulatory preamble why a safety factor was excluded from the lead risk modeling. Blood lead levels of concern should range from 2 to 5 μg/dl based on minimal safety factors of 2 to 5 applied to EPA's blood lead level of concern, which is the Agency's *de facto* lowest observed effect level (LOEL) – 10 μg/dl / 2 = 5 μg/dl; 10 μg/dl / 5 = 2 μg/dl.

Response: EPA disagrees with the "safety factor" suggested by this comment. It makes no sense for the Agency to use its usual safety factor of 100 or 1000 below 10 μg/dl. In this case, the blood lead level of concern would result in hazard standards much less than background environmental levels. The commenter, apparently, realizes that this kind of safety factor would not be appropriate, but then seems to arbitrarily choose safety factors of 2 and 5. EPA will continue to use 10 μg/dl, since it is commonly accepted by many scientific organizations and has been widely used for regulatory purposes.

In establishing 10 μg/dl, furthermore, EPA is not suggesting that there are no health effects below this level or that this level should be considered a level of safety. Quite the contrary, EPA has repeatedly stated that there is lack of evidence of a threshold health effects level for lead. EPA's intent in establishing a blood-lead level of concern, however, was not to establish a target safety level, but a target blood-lead concentration for establishing the basis of decisions for the national lead-based paint hazard control program.

B. The Agency's Science Advisory Board (SAB) refers to 10 μg/dl as a "maximum safe blood lead level" (Review of the OAQPS Lead Staff Paper and the ECAO Air Quality

Criteria Document Supplement). The National Academy of Sciences (NAS), in a 1993 publication Committee on Measuring Lead in Critical Populations, "Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations," stated that 10 µg/dl is "the maximum permissible concentration from the standpoint of protecting the health of children and other sensitive populations... Such a level is hundreds of times higher than estimated blood lead concentrations in preindustrial humans" (NAS 1993, at 1). NAS further noted that "at low-dose lead exposures, which induce effects that are of increasing concern, blood lead concentrations around 10 µg/dl or less must be monitored in various populations."

Response: EPA's decision to establish 10 µg/dl as the blood-lead level of concern is fully consistent with the position of taken by CASAC and by NAS. CASAC, after reviewing the 1990 supplement to the 1986 Air Quality Criteria Addendum and the staff position paper of EPA's Office of Air Quality Planning and Standards, stated that EPA should establish an "air standard that minimizes the number of children with blood-lead concentrations above a target value of 10 µg/dl." From this statement it is clear that CASAC agrees that 10 µg/dl should be the target blood-lead level. Otherwise, the Committee would have referenced a different level in its statement. Similarly, NAS concurs with the CDC's policy that 10 µg/dl serve as the blood-lead level of concern for public health programs. EPA's own analysis and decision, discussed in the risk assessment for this rule and the preamble to the proposed rule, is consistent with the independent SAB, CDC, and the National Academy of Sciences.

C. There is the potential for chronic lead exposure in childhood to bring the onset of the following adult diseases: a.) cancer; b.) increases in blood pressure and its associated effects including myocardial infarctions and stroke; c.) reproductive toxicity in both males and females, and, d.) neurotoxicity and its associated effects on learning ability. All of these potential effects have been suggested to occur at blood lead levels below 10 μg/dl.

Response: In its assessment of risks for this rule EPA has referred to some of the health effects associated with adult exposure (e.g., hypertension, myocardial infarction). The Agency, however, is unaware of any studies linking childhood exposure with adult health effects later in life and the levels of childhood exposure that are linked with those effects. Furthermore, no comment on this issue provided data or analysis to support the assertion that chronic childhood lead exposure leads to adult health effects.

D. Toxicologists inside and outside EPA believe 10 μg/dl is too high. Some toxicologists have indicated that the protective level should be 5 μg/dl.

Response: No substantive reasoning was provided for any of these assertions.

3.3.2 The exceedence probability for establishing the initial candidate hazard standards should be lower than the 1 to 5 percent used by EPA. When establishing standards under the Clean Air Act and Clean Water Act, EPA uses 0.5 percent. Another suggestion is a goal of 1 to 2 percent with an additional goal of 0.01 percent probability of exceeding 20 μg/dl. This lower probability, it is argued, would be consistent with other EPA programs and with the practice of using a safety factor.

Response: None of the comments have persuaded the Agency to select a different exceedance probability. The Office of Solid Waste and Emergency Response, the only other office that addresses lead in soil, uses five percent for the lead soil screening level. Thus this regulation is consistent with the other EPA program that addresses the same medium. The one to two percent level also falls within the one to five percent range selected by EPA.

The exceedance probability is based on the particular data available to EPA for lead and the limits of EPA's analytical tools, as explained in the preamble to the proposed and final rules. In general, EPA's assessment for this rule indicates that, as a practical matter, in the context of establishing on a national level the initial candidate for the hazard level, the probabilities that given environmental levels of lead "would result" in blood lead levels of concern, one percent is not distinguishable from five percent in estimating risks from soil and dust lead. This is because, within the context of the analyses for this rule, there was substantial overlap in estimates of risk within the one to five percent risk range. This overlap is due to the uncertainty and variability related to EPA's analyses to associate low levels of lead in a specific environmental medium to blood-lead concentrations and limited data. For example, results from models used to relate environmental levels to blood lead levels vary depending upon what is assumed about the interrelationship between dust and soil. Also, in the performance characteristics analysis the number of children was small, yielding similar results for a one percent exceedence as for a five percent exceedence. In effect, EPA is setting the exceedence probability as close to zero as it is able (within analytical limits of its analyses) for the effects of lead paint and lead in dust and soil.

3.4 Estimates of Risk Reduction

3.4.1. EPA UNDERSTATES BENEFITS

3.4.1.1 If the law had never been passed, the number of unprotected toddlers would be 458,000 toddlers. EPA's Empirical model concluded that EPA's proposed standards would fail to protect 75 percent of 1-2 year olds or 345,000 children each year that are at risk of having elevated blood-lead levels and adverse health effects associated with low levels of lead poisoning (e.g., IQ deficiencies, learning disabilities) identified in the congressional findings of Section 1002 of Title X. Over the next 50 years this would mean that at least 8 million people would suffer preventable lead-induced neurological and other health problems. More stringent standards would protect about 400,000 children per year on average, while the proposed standard will reduce exposure to soil lead for only 86,000 children. This would cause 8,000 to 26,000 children per year to require medical attention for the high levels of lead in their bloodstreams (20 ug/dl). Every year 48,000 to 68,000 children would likely suffer brain damage (at 10 ug/dl), manifest as IQ loss, attention deficits, problems with fine motor coordination, hearing loss, and other central nervous system problems.

Response: EPA takes serious issue with these numbers, but in any event he Agency has lowered its hazard standards from the proposal and believes, as elaborated upon in both the Dust and the Soil sections of this document, that the final regulations will be very protective of children.

3.4.1.2 In fact, the costs are very low for this rule when considered on a per child basis. Numbers in the *Economic Analysis* (Exhibit ES-1) suggest that abating soil, dust, and paint to the proposed standards would cost, on average, $24 per year for each child living in hazardous conditions. If we apply the average number of children (unspecified ages) per housing unit from Exhibit ES- 1 in the Economic Analysis, with the figures from the *Federal Register,* the average annual cost to remediate dust to the proposed standards would be $6 -$7 for each child affected by those standards. The numbers in the Federal Register indicate that the cost to remediate soil to the 2000 ppm standard would be $41 -$42 per affected child per year (for both the IEUBK and Empirical models, and for standards of 500 or 2000 ppm).

Response: The comparisons discussed in the comment are not useful in determining whether the proposed standards, or even the final standards are appropriate, in addition they are not valid and, thus, not meaningful in evaluating alternative standards.

As an overarching principle, it is meaningless for regulatory purposes merely to think in terms of total, or per person, costs of an activity or set of activities. The presumption of this exercise is that, if the costs appear to be low in absolute terms, we may feel comfortable that the resources are worth spending. This comment appears to be arguing this point.

However, costs in the sense of expenditure of resources are meaningless in a vacuum, without considering the benefits to be derived from those costs. No EPA decision in this case is based on considering benefits alone or cost alone. The comparison of expenditure of resources with the benefits to be derived from them is a major point of EPA's exercise in this rulemaking. If the benefits to be derived from the resource expenditure are negligible, we would be wasting resources. Another major point of EPA's exercise is to rank order various candidate standards in terms of their benefit cost rations, and to attempt to focus on those candidates with higher rations, again with the overarching objective of societal resource use efficiency.

We may think of this comparison in the following way. Of course, we cannot actually monetize all benefits in the real world, since there are many subjective benefits for which monetary value is meaningless. On the other hand, every benefit we derive comes at a cost and society as a whole (or individuals) has to be willing to pay for that benefit in some way. Even if a cost seems low in absolute terms, as this comment seems to imply is the case for the proposed standards, the inquiry is not over. Suppose the benefits in monetary terms for an activity that costs $6 per child is only worth one penny. If this same cost to benefit ratio is translated throughout society, to tens of millions of people, and to all other activities in which society may engage, the cost would be monumental. It would lead to billions or trillions of dollars in wasted resources and little to no societal benefits.

This is not to say that we can actually put a monetary value on a real health benefit. However, we need, in some way, to determine whether the resources to be spent in avoiding an adverse effect is commensurate with the risk of the adverse effect occurring. If the risk is a certainty and the effect very serious, we would spend substantial resources. Of course, any monetization of health benefits is subject to judgment and, in some sense, unreal. However, we weigh costs and benefits in almost all our daily tasks, however subjectively. For purposes of decisionmaking, in this case evaluating alternative standards, monetizing admittedly subjective benefits provides a useful tool.

In any event, this analysis is incorrect and underestimates the expected costs of this rule. Dividing the present value of 50-year costs by 50 is not a valid estimate of the annual costs. The number of interventions tends to decline over time (due to demolitions of pre-78 housing) and varies from year to year depending on the duration of the intervention (how often it needs to be repeated). Thus, interventions tend to be concentrated in the early years and in general the number declines with time. In addition, the present value over 50 years is a discounted value, and so the actual costs in any of the out-years will be greater than its current present value. Thus, using the present value divided by 50 produces a value that appears to underestimate costs.

3.4.1.3 The use of IQ points as the primary measure of benefits is a measure that is far too restrictive. Additional health effects from lead exposure include a wide range of developmental problems in children affecting heme and vitamin D synthesis, stature, altered nerve condition and brain activity, delays in cognitive and slowed sensory-motor development, as well as high blood pressure in adults and carcinogenicity in all ages.

Response: The EPA agrees that there are many important adverse health effects resulting from exposure to lead which affect adults as well as children. However, in support of its analysis two points need to be kept in mind. First, the EA focused on children because the goal of Title X is to protect children from exposure to lead. Furthermore, the focus on neurological damage in children was dictated by information limitations; the relationships between blood-lead levels and the incidence of these other health effects are not sufficiently well defined to permit an estimation of the number and severity of cases. Second, the objective of the EA was to rank alternative standards in a consistent fashion. Thus, it is not necessary to precisely estimate total benefits, nor total costs, as long as the same categories of costs and benefits were included for each potential lead hazard standard and the costs and benefits were sufficiently well estimated.

3.4.1.4 It is impossible to quantify the costs and benefits of cognitive functioning because the reduction in cognitive functioning does more than just reduce performance on standardized tests. Therefore, a simple IQ analysis does not begin to capture all the ways in which a child, family and society are impacted by the effects of lead poisoning.

Response: The EA uses IQ differentials as an indicator for the wider range of cognitive damage that can result from lead exposure. Likewise, the economic analyses that relate IQ level to annual earnings (which serve as the basis for valuing benefits) do not separate the impact of IQ from other cognitive functions. Thus the "value of an IQ point" includes cognitive performance that is correlated with IQ in the general population, not just narrowly defined.

The theoretically preferable measure of willingness to pay (WTP) is not used because WTP values for cognitive damage are not available. The WTP value of avoiding cognitive damage, however, would be no less than the objective measure of the present value of avoided reductions in income. This underestimate of the benefits occurs across all standards and thus consistently affects the net benefits for each potential standard. Since the objective of the economic analysis is to rank alternative standards in terms of net benefits, exact estimates of benefits are not required as long as all standards are treated in the same way.

3.4.1.5 The economic analysis should have used the adjusted factor for the value of an IQ point that Salkever presents as the most inclusive and accurate. In his article, Salkever concludes that on average every point of IQ preserved through reduced lead exposure increases lifetime earnings by 2.094% for men and 3.631% for women, while the economic analysis uses the unadjusted figures of 1.931% and 3.225% that reflect according to Salkever, a downward bias that does not capture non-IQ effects of lead exposure on schooling. HUD, held a similar opinion and suggested an upward revision of the value of an IQ point from the $8,346 used in the analysis to $9,663.

Response: EPA is confident that the EA uses the best data currently available, since it relies on peer reviewed articles for the relationships between blood-lead and IQ damage, and between IQ and earnings. These studies are widely known and have undergone intense public scrutiny. EPA acknowledges that the comment about the choice of factors from the Salkever analysis is correct, and it has used the factor that represents the value of an IQ point (including both its direct affect and indirect affect through schooling) in terms of earnings. This was a conservative choice on the part of the Agency, which focused on IQ differentials. However, as the Salkever article supports, there are other lead-induced problems that adversely affect earnings, and in the re-analysis EPA uses a higher value that reflects these additional adverse impacts. This revised value for an IQ point based on the EPA's calculation is $ 9,318 and it includes the Schwartz coefficient to account for the non-IQ affects of lead on earnings. This revised IQ value differs from the one suggest above by HUD. Because the latter did not specify how their estimate was derived, the reasons for this divergence cannot be explained.

3.4.2. EPA OVERESTIMATES BENEFITS

3.4.2.1 EPA underestimated costs and overestimated benefits because it used a single medium approach for analyzing costs and benefits and this leads to a double counting of benefits.

Response: EPA acknowledges that presenting results for each medium individually will result in some double counting. The magnitude of the double counting, however, is very small, however does not materially affect the results or EPA's decisions. On the other hand, the single medium approach for presenting results gives EPA decision makers a more direct basis for comparing options for each medium. Therefore, EPA has continued to rely on the single medium approach for presenting results.

3.4.2.2 EPA used an unrealistic "birth trigger" instead of a more realistic real estate transaction trigger and thus overstates the benefit to cost relationship because the birth trigger only incurs costs when there are benefits to an intervention

Response. The "birth trigger" model is an appropriate tool to support these regulatory standards.

As envisioned by Congress, the §403 lead hazard standards are intended to tell people when they should act for the safety of their children. In other words, the standards would tell people when interventions should take place. Thus, the goal of the analysis is to rank potential standards to determine which one would maximize net benefits for children. Therefore, the birth of a child is used as the event that triggers intervention activities in the analysis used to rank the alternative standards. In economic terms, this is referred to as a normative analysis. If the objective of the analysis were to estimate the total costs and benefits of particular actions, then it should model activities as occurring when they are most likely to occur, as opposed to when they should occur. This is referred to as a positive model, and would not assume all inspections and interventions occur at the birth of a child.

Furthermore, it is unclear that costs under a "birth trigger" model would be significantly smaller than under a "transaction trigger" model, especially for multifamily rental property where states and/or financial institutions could impose their own requirements. In a multi-family property, soil remediation for the entire structure occurs when a newborn is introduced into any unit in the building, which is usually in the first year of the model. Therefore, soil remediation costs and benefits would probably be the same under either model. In addition, for unit-specific actions (e.g., paint stabilization or abatement), EPA has endorsed the recommendations of the Federal Advisory Task Force on Lead-Based Paint Hazard Reduction and Financing, which calls for hazard control plans that would phase in action over time. Implementation of such a plan would result in costs and benefits similar to those estimated by the birth trigger model.

In addition, even if one were to accept the possibility that EPA overestimated benefits as a result of the "birth trigger" model, any overestimate in benefits will be partially offset by an underestimate because the analysis does not include benefits to children who are already living in the unit at the time of the inspection and/or intervention.

3.4.2.3 EPA should not have used a 3 percent discount rate, but should have used the 7 percent recommended by OMB. The value used by EPA leads to an overstatement of the benefit to cost relationship because costs are incurred before benefits are generated and are, therefore affected less by discounting.

Response. EPA believes that three percent is the appropriate rate by which to discount the future costs and benefits under this rule. The choice of the correct discount rate involves answering two questions: what type of discount rate is appropriate, and what is the magnitude of that discount rate. One type of discount rate measures the rate of return that would be received if the funds were invested in a risk-free investment. The second type, called the social rate of time preference, measures the willingness of people to postpone consumption. It can be thought of as expressing how much more money people would need in the future in order to be just as satisfied as they are with a dollar today. The type of discount rate used depends in large part on whether the regulations will simply affect consumption at various points in time (in which case the social rate of time preference is relevant), or will reduce investment by diverting funds away from investments that would otherwise occur (in which case the investment rate of return would be appropriate).

In the case of the §403 standards, best practice suggests that both benefits and costs should be measured in terms of foregone consumption, and thus the social rate of time preference be used for discounting. The benefits are measured in consumption terms since they are in terms of increased income due to higher IQ levels. This higher income represents the higher potential for consumption in the future. In the case of costs, the rationale for discounting by the social rate of time preference is based on the expected means for financing the interventions that will be performed under the standards. Most property owners will reduce consumption not investments to pay for these actions. Home owners are likely to view expenditures on improving their home as a consumption expenditure and would not divert funds from investments to lead reduction activities. While landlords may view these expenditures as investments, the actions are voluntary and landlords will not make them unless their rate of return (increased rents and/or increased property values) is at least as great as the landlord would realize on the alternative investment. Thus there would be no net reduction in societal investment levels, i.e. no displacement of investment only a change in the specific investments. In addition, expenditures on rental properties make up a small proportion of the total costs of the rule, and thus the discount rate of homeowners should dominate.

Having determined that the social rate of time preference is the appropriate discount rate, the second question is what is its value? The rate most often used by EPA is the three percent used in this analysis. However, three percent may actually be too high. The Government Accounting Office (GAO) guidelines recommend the use of a very low discount rate when analyzing policies with large intergenerational effects involving human life. The guidelines note that if the rule increases human productivity, the effective discount rate for evaluating the present value of future is roughly zero. The Congressional Budget Office (CBO) generally requires the use of a social rate of time preference for social welfare analysis. They have set this rate to be two percent, and suggest a sensitivity analysis using zero and four percent.

Even if one does not accept the argument that the social rate of time preference should form the basis for setting the discount rate, the rate still should be around three percent. Recent economic analyses show that regulations do not displace capital to the degree once thought. The displaced investment concept depends on a closed economy with a fixed supply of available capital. With the open economies of today, increased demand for investments in the United States will attract funds from other parts of the world. This relatively elastic supply of capital reduces the difference between the rate of return on investments and the social rate of time preference.

In addition, estimates of real financial rates of return are lower than many people believe. The real rate of return on U.S. government bonds has been near zero for most of this century, while the annual return on a broad portfolio of stocks has averaged near 4 percent. In general, stocks have done better since 1980 than in other parts of the century, but many analysts feel that rates of return may return to historical levels in the future. Thus real rates of return on investments range from near zero to 4 percent. This conclusion that the social rate of time preference and the real rate of return are not much different is supported by the work of Moore and Viscusi (1990) who found no evidence that the rate of time preference for environmental-related health effects differs from financial rates of return. They recommend the use of a two percent discount rate, while Lind (1990) recommends a range of one to three percent, and Freeman (1993) recommends two to three percent.

For all of the reasons presented above, EPA agrees with the Science Advisory Board and other commenters that three percent is the appropriate discount rate for this analysis. However, in order to provide a basis for comparison, net benefits using a seven percent discount rate have also been calculated and presented in the sensitivity analysis section of the EA.

3.4.2.4 In the risk analysis for the 403 rule, EPA uses an estimate of the relationship between IQ and blood-lead level that was developed and published by Schwartz. In the sensitivity analysis for the risk analysis, EPA considers the effects if the relationship were different (section 5.4.2 of the risk analysis). The scientific evidence related to IQ does not support the selection of overly stringent hazard levels under TSCA section 403. Schwartz's estimate of IQ reduction due to lead exposure is high relative to Pocock's estimate of no more than 1-2 points over the same range. While this may appear to be a small difference, it is a difference of 25-50% in IQ points lost and thus a difference of 25-50% in economic loss or gain estimated. Furthermore, since the soil model (IEUBK) is roughly linear in this range, using the Pocock estimate would make a roughly 25-50% difference in the resulting soil standard as well; the standard of 2,000 ppm would become 3,000 ppm. This in turn would make far more than a 50% difference in the money that could be paid to remediate affected soil. This result occurs because soil lead levels are lognormally distributed, and highly skewed.

The risk assessment that relates IQ to blood lead uses a meta-analysis by Schwartz (1994). This analysis uses the results from three longitudinal and four cross sectional studies. Each study relates blood lead concentrations to full-scale IQ scores in school age children. Of the seven studies, three employed log-linear models, i.e., where IQ is associated with the natural log of blood lead. The other studies employed linear models. The log-linear models indicate a steeper slope at lower blood lead levels. This phenomenon may reflect blood lead saturation at higher blood lead levels. The same paper by Schwartz (1995) uses a locally weighted smoothing analysis to demonstrate that the blood-lead to IQ slope appears to be steeper at lower blood lead levels. Despite this evidence, the risk assessment assumes a linear model which would reduce the estimated effect of a given increase in lead exposure. In addition, subsequent analysis using the large prospective cohort studies undertaken in Boston, Port Pirie and Cincinnati have been conducted. These studies demonstrated larger effects (relative to the studies used in the Schwartz meta-analysis) on IQ per µg/dl of blood lead when the age at the time of IQ test and the age at the time of blood leads measurement are greater (or if cumulative measures of blood lead are used). Again, ignoring these later studies reduces the estimated impact of soil, dust or paint exposure.

Response: As described in 4.4.1 of the Risk Analysis, and in more detail in Appendix D2 and section 2.3 of the Supplement to the Risk Analysis, EPA believes that the approach of Schwartz (which is based upon the random effects modeling approach suggested by DerSimonian and Laird, 1986, "Meta-analysis in Clinical Trials," Controlled Clinical Trials. 7: 177-188) is a more reliable approach, and thus uses this as the primary estimate. However, the Risk Analysis considers other estimates (in section 5.4.2 of the risk analysis) as well as part of the sensitivity analysis (one of those other estimates is the Pocock estimate of 0.185). Although the Schwartz-approach slope is used, the actual model is linear and not log-linear, which results in net benefits not quite as great as if a log-linear model were used. This makes it less likely that EPA is overstating net benefits. However, the possibility of other estimates is considered in section 5.4.2. Thus, in summary, EPA believes that its approach is the most reliable, but does consider the possibility of estimates that are higher or lower.

As for the comment on the log-linear model, EPA believes that there is some evidence for a log-linear model at lower doses. However, the evidence is limited. If EPA were to use a loglinear model approach, it would result a larger estimate of the effect of blood-lead level on IQ at lower blood-lead levels. We would then be estimating near the largest reasonable effect of low blood lead levels on IQ and the possibility of overestimating benefits of preventing relatively low blood lead levels would be larger than underestimating benefits. The sensitivity analysis of section 5.4.2 considers the effects of a steeper relationship between blood lead and IQ to evaluate the possibility of underestimating the relationship between blood lead and IQ.

3.4.2.5 While lower IQ scores are clearly associated with lower educational attainment and lower lifetime earnings, the health endpoints used to determine the potential effect of this standard were ≥1, ≥2, and ≥3 IQ points. These small effects are not considered meaningful, as the standard deviation associated with IQ testing is usually 5 points (Section 6, page 24). To base a risk assessment on IQ impairments in less-than-meaningful ranges is cause to question the scientific validity of implementing these standards. The results of the EPA risk analysis suggest that implementation of the standard would have little or no impact on IQ decrement.

Response. Small changes in IQ in an individual child may not be statistically significant in comparison to the variability of the IQ measure. However, it would be completely unsound to apply that reasoning to a population at large. For example, where the variability as measured by the most common measure, standard deviation may be 5 IQ points, the corresponding standard error for the mean in a population would be 5 divided by the square root of the number of individuals in the population group. If the population group were even only 10,000 children, the standard deviation of the population mean would be 0.05, a very small number. Thus, uncertainty applicable to an individual is not applicable to population means.

3.4.2.6 The Department of Defense commented on the number of significant digits used in the analysis: "The proposed rule estimated the benefit of implementing the standards by computation of IQ point loss based on an average decrease of 0.257 IQ points per increase of one µg/dl in blood-lead concentration. Furthermore, the proposed rule assigns a monetary value of $8,346 per

IQ point loss in 1995 dollars. In using these numbers, it is not clear that the Agency has used the best available data, used the data appropriately or characterized the variability, uncertainties or limitations of the data. The Agency cites a single reference, a meta-analysis, which combines the results of other studies to support both numbers, and is therefore subject to greater uncertainties. The IQ value has three significant digits while the monetary value has four significant digits, and yet the numerical uncertainty (presumably in the last significant digit) is not discussed. By using such uncertain IQ and monetary values, the results are highly likely to be not only uncertain, but possibly unsound.

Response. The commenter would seem to suggest that use of more significant digits than are really present is not justified. However, just because there is uncertainty in an estimate does not mean that the intermediate calculations should round off to the last significant digit. Rounding would not improve the certainty of the final answer, but could introduce rounding error. EPA reviewed its statements on uncertainty for the final rule preamble and Supplement to the Risk Analysis to make sure that no unrealistic estimates of certainty were implied; however, rounding the intermediate steps would not have helped that at all; it would have just added more uncertainty. The commenter also seems to imply that combining a variety of studies will result in more error. However, the reverse is true. Considering all of the relevant studies and including them in the (meta-)analysis is far superior than simply ignoring all but one so that no combination is needed. By its nature, the meta analysis combines several studies to provide a best estimate given all of the data. EPA considered uncertainty directly through its sensitivity analysis to convey the uncertainty in the estimates.

3.4.2.7 The Agency is relying on benefits that are ascribed to children's whose blood lead levels are below 10μg/dl and whose blood lead levels are expected to decrease as a result of the actions taken under the proposed rule. Studies performed by Dr. Marjorie Smith of the University of London and presented at a September, 1998 conference entitled, "Environmental Policymaking: A Workshop on Scientific Credibility" sponsored by the Massachusetts Institute of Technology suggest that other variables in a child's environment are more likely (by a factor of 2) to influence a child's IQ than is a blood lead level under 10-15 μg/dl. According to a series of investigations conducted in Edinborough, these factors include among others: mother's IQ and the frequency with which stories are read to a child by both parents, but especially by the child's father.

Furthermore, correlational analyses have predominated the children's lead-IQ literature, and results of correlational studies should not be used to infer causality in children, regardless of the results of pertinent animal research. As Pocock et al. (1994) note in their meta-analysis, "Observational epidemiology cannot distinguish between this direction of effect and the more important issue, 'does lead cause a deficit in IQ?' However, this review provides some implicit evidence that reverse causality is plausible" (p. 1196). In addition, "Epidemiological studies, even when design flaws are minimized, have limitations in establishing cause and effect links" (Banks et al., 1997, p. 255). The trade association continued by commenting that "these societal implications derive, first, from the assumption that low doses of lead level really do produce IQ loss (which may or may not be true); second, from the notion that IQ is the sole determinant of special education placement; third, with the implicit assumption that a person's IQ is somehow an unchangeable, absolute construct; and, fourth, from the perspective that the loss of a few IQ points is surely related to diminished functioning within society. None of these assumptions or notions is true.

Response: The Agency notes that the fact that there are other factors besides lead that affect a child's IQ does not mean that lead doesn't affect IQ. The effects of lead have been demonstrated by epidemiological data which control for other effects. The estimates in the risk analysis are for effects above and beyond those due to other factors.

3.4.2.8 EPA's justification for the rule rests principally not on the predicted decrease in the fraction of children with blood lead levels exceeding 10 µg/dl, but on the avoided loss of IQ points among children whose blood lead levels are already below 10 µg/dl. The estimated magnitude of this benefit depends on the assumption of a linear relationship between IQ and blood lead levels all the way down to zero exposure. This assumption lacks adequate scientific support. Indeed, EPA concedes in the preamble that "the evidence of health effects below 10 µg/dl is not sufficiently strong to warrant concern," (63 *Fed Reg.* at 30305, 30316-17). Similarly, the Centers for Disease Control prescribe no action for blood lead levels below 10 µg/dl. (CDC, *Preventing Lead Poisoning in Young Children, p.* 3 (Oct. 1991). Moreover, even if it were appropriate to assume IQ effects below 10 µg/dl, the evidence does not support EPA's assumption of linearity at those levels. (See Kaufman report at pp. 22- 23). It appears that two of EPA's peer reviewers also have registered concerns about this point to which EPA did not respond (see comments of Victor Hasselblad and William Richards at pp. 36-37 and 48 of the "Risk" Peer Review comments).

Thus the calculation of benefits from reduction of lead exposure is highly uncertain, since there is no empirical evidence that reducing already low (< 10 µg/dl) blood lead levels to even lower blood lead levels will have any positive impact on IQ. EPA does not quantify the fraction of benefits associated with expected IQ increases among children whose baseline blood lead levels are below 10 µg/dl. However, this fraction is likely to be large since for one to two year old children, the baseline geometric blood lead level is 3.14 µg/dl, and the baseline geometric standard deviation is 2.09, according to Table 3-36 in EPA's Risk Analysis. If EPA's modeled baseline blood lead levels are approximately lognormal, these assumptions imply that 94 percent of the blood lead levels are below 10 µg/dl for which benefits are claimed for the rule.

Moreover, even if it were appropriate to assume IQ effects below 10 µg/dl, the evidence does not support EPA's assumption of linearity at those levels [footnote: Statement of Dr. Alan Kaufman, pp.22-23. Submitted to Docket FR-3482-p-01]. The data from the pertinent lead-IQ studies are, indeed, more consistent with a threshold effect than with a linear relationship between lead level and alleged IQ loss. If there were in fact a linear relationship extending to zero, one would expect to see consistent signs of it in the studies that have low detection limits. In any event, the data are available to answer the question, but researchers simply have not focused on this essential distinction.

Among the animal studies, the evidence that low doses of lead are associated with cognitive impairment is meager or, perhaps, nonexistent. Even when impairment is shown in some studies, it is clear that the impairment does not seem to generalize, but is task-specific. In the investigation in which steady-state levels of 11 or 13 µg/dl were observed, the monkeys had some difficulties when they were introduced to new tasks, but lead-treated monkeys in this latter study were not impaired on the acquisition of any of the three tasks. Rice, 1996, p. 344). At best, results are inconsistent.

Dietrich et al. (1993, Figure 2) presented a line graph that shows the mean adjusted and unadjusted Performance IQ for four lead-level groups (0-10 µg/dl, >10-15 µg/dl, >15-20 µg/dl, and >20 µg/dl. Only the adjusted values are interpretable, and these show no meaningful difference among the first three groups (each averaging a Performance IQ of 90 ± 2). Only the most extreme lead group deviated from the other three (averaging about 85 on Performance IQ), suggesting a threshold effect (at about 20 μg/dl) rather than a linear relationship.

Bellinger et al. (1992, p. 858), offer a bar graph that presents adjusted WISC-R Full Scale IQs and K-TEA Battery Composite (Kaufman & Kaufman, 1985) standard scores for the following groups: 0-4.9 μg/dl, 5.0-9.9 μg/dl, 10.0-14.9 μg/dl, and ≥15.0 μg/dl. The two groups with the lowest lead levels were indistinguishable from each other, averaging IQs of 118-120 and standard scores of about 119-122. Similarly, the two groups with the highest lead levels were indistinguishable from each other, each earning mean IQs of about 112 and mean standard scores of about 110. Again, a threshold effect (this time at about 10-15 μg/dl) is a more realistic explanation of the relationship than is a linear one.

Hatzakis et al. (1987, Figure 5) included a line graph that presents unadjusted and adjusted WISC-R Full Scale IQs for the following groups: ≤ 14.9 μg/dl, 15.0-24.9 μg/dl, 25.0-34.9 μg/dl, 35.0-44.9 μg/dl, and ≥45.0 μg/dl. The lowest two groups did not differ meaningfully from each other, averaging adjusted IQs of 90 ± 1. Likewise, the highest three groups earned similar mean IQs of 85 ± 2. Once more, there was an apparent threshold, this time at about 25.0-34.9 μg/dl, considerably above the lead levels that define "low doses.". Although the graph suggested linearity for the four groups with lead levels of 15 and above (adjusted mean IQs of about 91, 86, 84, and 83 with increasing lead level), there was decidedly no linearity for children with lead levels below 15 μg/dl.

Fulton et al. (1987, Figure 1) presented a scatterplot for 10 lead-level groups that are defined by the log blood lead. The mean adjusted British Ability Scales (Elliott, Murray, & Pearson, 1983) score difference from the school mean is presented for each group. Although the authors draw a line of best fit through the points, visual inspection suggests no meaningful difference in the means for any of the samples; the values for nine samples (all but the lowest lead-level group) seem virtually identical to each other. These data suggest neither a threshold effect nor a linear relationship.

The graphs shown by the authors of the aforementioned studies indicate quite dramatically that if lead level truly affects IQ negatively, then there is likely a threshold effect to explain the relationship; there does not, however, appear to exist a documented linear relationship between lead level and adjusted IQ. Or if such a linear relationship exists, then it does so only at the higher levels of blood lead.

As indicated in the critique of lead-IQ studies that was provided to the SAB, one common flaw in lead-IQ studies with children is the use of a "shotgun approach"–making multiple comparisons and just focusing on the ones that are significant and support the researchers' position while ignoring the comparisons that fail to provide support. That same flaw seems to be true with the animal studies, where non-significant comparisons are ignored in favor of the few comparisons that distinguish between lead-exposed and non-exposed animals. And it seems to be true with the SAB, who has focused on the atypical studies that marginally used low lead doses while ignoring the bulk of evidence that was based on animals literally saturated with lead. Furthermore, even well-designed animal studies that are above reproach on psychometric or research-design grounds cannot unilaterally address the issue of causality in children. Animals differ from children in fundamental and crucial ways in the size and functioning of the cerebral cortex; what is considered a low level of lead in humans may not truly be low in primates or other animals.

Response: The fact that EPA and CDC are not recommending action for individual children when their blood lead levels are below 10 μg/dl does not imply that there is no risk. There are practical reasons for not recommending specific actions. The evidence for health effects is less strong below 10 μg/dl and it is important to consider such as considering costs and benefits and the importance of recommending action for children at the most risk. However, it would be inappropriate to exclude estimates of benefits to children with blood lead levels below 10 μg/dl since benefits accrue to those children.

In the Supplement to the Section 403 rule Risk Analysis, section 2.3 provides a detailed analysis of this issue and sections 2.1 and 2.2 provide additional information. EPA believes that it is most appropriate to assume that the threshold is likely well below 10 μg/dl and more likely than not below 1 μg/dl. Most studies have failed to find sufficient evidence of a threshold and when claims of a non-zero threshold have been made, these have not been consistent. Furthermore, in looking across studies or combining the studies through meta analysis, it appears that the slope increases and not decreases at lower levels. The observed trend toward higher slopes at lower concentrations discounts the likelihood of a threshold. Also, Schwartz (1993) performed a quite reasonable nonparametric smoothing approach on McCarthy index data collected at age 57 months and blood-lead concentration data collected at 24 months (in the Boston prospective lead study, Bellinger, et al, 1991). After adjusting for potential confounding variables, a definite relationship was observed below 10 μg/dl, and a regression model with different slopes connecting at an inflection point looking for a potential threshold estimated that a threshold would be less than 1 μg/dl.

As for the animal studies, EPA recognizes that not all animal studies demonstrate neurological impairment in all functions. However, they add to the causal link found in the epidemiologic studies and demonstrate once again that lead is a neurotoxin. Note that EPA is basing its dose-response relationship upon the extensive epidemiologic data.

3.4.2.9 In its analysis, EPA estimated the increased percentage of children with IQ scores less than 70 due to having increased blood lead levels. Part of EPA's analysis used a paper by Wallsten and Whitfield (1986). An industrial corporation commented that EPA used Wallsten and Whitfield (1986) to provide an estimate of the increased percentage of children having IQ scores less than 70 due to having blood lead levels in specific ranges. This study was not a typical study or even a mathematical analysis, but a compilation of the opinions of six lead experts. Much scientific evidence has been developed since the Wallsten and Whitfield study was conducted, but no additional evidence has been brought forth to support estimating IQ reduction below 70. It appears that including such estimates, and basing selection of lead standards on these estimates, is unsupportable at this time.

The Science Advisory Board commented that the Risk Analysis 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 SAB continued "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? 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. 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. 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).

Certainly, as stated, IQs below 70 are not sufficient to place a child in a special education class. Mental retardation, by legal definition and diagnostic practice, cannot be diagnosed without evidence of retarded intellectual functioning <u>and</u> retarded adaptive functioning

(Kamphaus et al., 1999). Low IQs, by themselves, do not qualify a person for special education services; low adaptive behavior must accompany the cognitive retardation. I have seen no lead study that has examined a child's social-adaptive behavior with an instrument such as the Vineland Adaptive Behavior Scales (Sparrow et al., 1984), much less that has shown any relationship between low doses of lead and diminished adaptive behavior. Additionally, there is no true notion of the kinds of cognitive behaviors that define IQs of 70 or 75 or 80. The IQ concept is not an absolute; it is not determined by a specific set of skills that indicate that a person is deficient in this or that type of mental functioning. Rather, low IQs are relative concepts. What defines an IQ of, say, 75 changes over time. As indicated in the discussion of generational changes in IQ, Americans are getting smarter at the rate of about 3 points per decade."

Response. EPA agrees that further analysis would be interesting to conduct, and that there is additional data on the subject. However, the prevalence of IQs below 70 is not a particularly important part of the analysis and thus no additional analysis was performed on this topic.

In response to the comment on the use of an IQ of 70 as requiring special education, the use of an IQ of 70 as requiring special education is not always fixed. As the comment points out, it is a combination of " retarded intellectual functioning and retarded adaptive functioning." However, on average, an IQ of 70 is what requires special education.

3.4.2.10 EPA should have used a lower 0.185 relationship for disadvantaged communities which would receive most of the benefits of this rule. EPA used a higher 0.257 relationship which applies to the whole population, and this would overstates IQ point loss.

Response. The Agency believes that the use of the average IQ point loss is appropriate for this rulemaking. EPA's analysis is based on the average child. Therefore, the Agency should use average parameter values. If EPA were to use the IQ point loss for disadvantaged populations, the Agency should also use the blood lead distribution for the same population (which is significantly higher than the distribution for the whole population) and the environmental lead data for the housing stock where disadvantaged populations reside (which is not available but presumably higher than the environmental lead data for the entire housing stock). Even if EPA wanted to conduct the analysis in a way that uses data that focuses on disadvantaged communities, it could not because the data is not available. If the data were available, it would likely show higher benefits because any given hazard control intervention would result in a greater amount of risk reduction.

3.4.2.11 The value of an IQ point is overstated. The statement that EPA has overstated the value of an IQ point is based on a three part argument: EPA incorrectly combined gender-specific values to calculate the population average; EPA based lost earnings on population-wide earnings rather than earning for disadvantaged populations which are lower; and the value used by EPA is significantly higher than the value used by the Agency in its report to Congress on the costs and benefits of the Clean Air Act.

Response. The comment is incorrect in its description of how the population weighted average present value of life time earnings, and thus the value of an IQ point, is calculated in the §403 Economic Analysis. The procedure described in the comment as the "correct" method is equivalent to the procedure used in EPA's analysis. To simplify the discussion, the §403 Economic Analysis presented the calculation as if the averaging were performed on each part and then the parts multiplied together. In fact, the value of an IQ point was calculated separately for men and for women and then the average taken, as suggested by the comment. The revised Economic Analysis that accompanies the final regulation shows the calculation as it was actually performed.

The apparent discrepancy in the value suggested by the commenter ($8,714) and the value used by EPA ($9,360) is due to the commenter's comparison of a value calculated in 1992 dollars to a value calculated in 1995 dollars. These being estimates for the value of an IQ point that have not yet been adjusted for additional education costs. The calculation presented in the §403 Economic Analysis is in 1992 dollars because the data used in the calculation are in 1992 dollars. Then the final value is converted to 1995 dollars for use in the Economic Analysis. The difference of approximately $646 is simply the difference between 1992 and 1995 dollars.

EPA's response to the second part is the same as the response to the preceding comment that EPA should have used the IQ parameter value for disadvantaged populations. EPA's analysis is based on the average child.

The third part of the argument is somewhat confusing because the Clean Air Act Section 812 Report does not use a value of $5,550 per IQ point. The value used in the Section 812 report is $2,957 (as presented in Appendix G of the Section 812 report) and rounded to $3,000 for the analysis (as presented in the main body of the Section 812 report). There are three reasons for the difference between this value and the $8,346 value of an IQ point used in the §403 Economic Analysis. Each of these differences results in a lower value per IQ point in the Section 812 analysis, as compared to the §403 economic analysis.

First, the Section 812 analysis used a five percent discount rate, as opposed to the three percent used in the section 403 Economic Analysis. EPA previously presented its rationale for using three percent as the discount rate. A discount rate of 5 percent was used in the Section 812 analysis as a compromise between three percent and seven percent discount rates. Second, the Section 812 analysis calculates the effect of IQ on earnings using two alternative approaches and then averages the two values, while the section 403 Economic Analysis uses only one of the two methods. One approach used in the Section 812 analysis was chosen because it was used in a previous analysis. It is based on several older studies (including articles back to 1977). The other approach is based on the 1995 Salkever article. Because the Salkever approach is more recent and considered to be a better estimator, the section 403 economic analysis used only this approach.

Also, the Section 812 value is reported in 1992 dollars, while the §403 Economic Analysis value is reported in 1995 dollars. To summarize the differences: using the Salkever approach only, increases the value from $2,957 to $3,410; using a 3 percent discount rate further increases the value to $7,765; and adjusting to 1995 dollars brings the value of an IQ point to $8,346, the value used in the §403 economic analysis. However, as reported above, the value of an IQ point has been revised to $ 9,318 in the re-analysis in order to include the non-IQ affects of lead on earnings.

PART FOUR Dust Standards

4.1 Floor Standards

A number of comments maintained that the proposed dust hazard standard of 50 $\mu g/ft^2$ for floors was not adequately protective and recommended standards ranging from 5 to 40 $\mu g/ft^2$. EPA has chosen 40 $\mu g/ft^2$ as the dust-lead hazard for the final rule. EPA responds to relevant comments on that issue in the preamble. In this section of the Response to Comment document, accordingly, EPA is explaining why it rejects those comments that support a standard lower than 40 $\mu g/ft^2$ or higher than that level.

4.1.1 One comment stated that according to its modeling and reading of the literature, the dust hazard standard should be between 5 and 15 $\mu g/ft^2$.

Response. This comment does not provide further detail on the this modeling or literature review effort and EPA was unable to identify the modeling and literature review to which the comment referred. Consequently, EPA is unable to evaluate the merits of the recommendation.

4.1.2 An advocacy group stated that "studies demonstrate that blood lead levels below CDC's definition of lead toxicity or a blood lead level 'of concern' (10 $\mu g/dl$) are associated with house dust loadings below 20 $\mu g/ft^2$. ...Additional studies help to establish a dose-response relationship between housedust loadings and blood lead levels. Clark et al. (1985) and Succop et al. (1987) [two papers from the Cincinnati lead study] analyzed the effect of environmental lead measures associated with housing quality criteria and its effect on children's blood lead levels. These children resided in the same type of housing continuously from birth to over 27 months. Peak mouthing behavior is thought to occur at around 18-30 months of age. The studies demonstrated that decreasing quality of housing is associated with increasing dust loading, dust concentration, dust deposition, exterior soil concentrations, and hand- lead levels. Blood lead levels are highest in deteriorated housing and (in declining order) are lower in satisfactory housing, rehabilitated housing, public housing, and private housing ... when dust loadings exceed about 20 μg/ft^2, blood lead levels exceed 10 μg/dl at age 18 months." Rabinowitz et al. (1985) [a paper from the Boston lead study] measured the dose-response relationship between housedust loadings and blood lead levels in young children...as floor dust lead concentrations approach 30 μg/ft^2, blood lead levels exceed 8.8 μg/dl. This study, undertaken in the white suburbs of Boston, represents a minimum effect of housedust loadings on blood lead levels, since many of the covariates influencing uptake and absorption of lead were likely to minimize blood lead levels. Therefore, the dose-response relationship of about 2 μg/dl per 6 μg/ft^2, as the change in blood lead associated with the middle two values on the scale, is similar to the relationship demonstrated in the Cincinnati lead studies for 24 months at the low end of the loading scale.

The advocacy group continued by stating that "Clark's data indicates that blood-lead levels exceed 10 μg/dL whenever housedust loadings exceed 20 μg/ft2. By 200 μg/ft2 blood lead levels exceeded 20 μg/dL. Rabinowitz's study indicates that blood lead levels exceed 10 μg/dl whenever housedust loadings exceed 30 μg/ft2. Taken together, these studies establish that housedust loadings in excess of 20-30 μg/ft2 are associated with blood lead levels in excess of 10 μg/dl.."

Response: EPA does not agree with these conclusions. While EPA acknowledges that elevated blood lead levels do occur in children where floor dust-lead levels are below 50 μg/ ft^2, the Agency believes that, since the section 403 rule is a three-media rule, covering lead in soil and paint as well as dust, the consequences of the standards must be evaluated in the context of all three standards simultaneously. Although cases of elevated blood-lead levels occur where dust lead levels are below 50 μg/sq ft, many children in environments with dust-lead levels below 50 $\mu g/ft^2$ do not have elevated blood lead levels at or above 10 μg/dL. Most children with blood-lead levels at or above 10 μg/dl and that have dust lead levels below 50 $\mu g/ft^2$ have high soil lead levels and/or damaged lead-based paint as well. In fact, using the final rule's dust hazard standards of 40 $\mu g/ft^2$ for floors and 250 $\mu g/ft^2$ for sills, if the soil and paint standards are assumed to be in place, just over 95% of the elevated-blood-lead level children in the Rochester Lead-in-Dust study were identified.

Further, using a dust-lead level below 40 $\mu g/ft^2$ would increase the number of homes identified as lead hazards without identifying more truly hazardous environments. In addition, since dust does not spontaneously generate lead, the Agency believes that identifying hazards closer to the source is likely to be more effective in this gray area below 40 $\mu g/ft^2$. A standard for lead loading in floor dust, used alone and without soil and paint sampling, would need to be at most 20 $\mu g/ft^2$, to be protective, as the commenter points out, and perhaps much lower, such as at 5 $\mu g/ft^2$, the level at which 95% of children would be protected from the Empirical model based upon the Rochester lead-in-dust study data.

4.2 More Stringent Dust Hazard Standards are Feasible. The interim results of the evaluation of HUD's abatement grant program show that, on average, initial floor dust--lead levels are below 20 $\mu g/ft^2$. The new data show that median dust-lead levels on floors continue to drop for at least the first year following the hazard control work, from 19 $\mu g/ft^2$ to 14 $\mu g/ ft^2$ twelve months later. The average dwelling unit undergoing lead hazard control had a median floor dust-lead level of 17 $\mu g/ft^2$ immediately following hazard control work. That level declined to 14 μg/ft^2 six months later and remained at the same level one year following the work.

Based on the HUD national evaluation data and other data sets, it is feasible, on a national level, to attain floor dust lead levels and window sill lead levels considerably lower than 50 μg/ft^2. First, there is considerable evidence that, on a national level, dust lead levels are considerably lower than 50 μg/ft^2. The HUD national survey for lead in U.S. housing in 1989 and 1990 shows that the national average in floor dust lead loading was approximately 5 μg/ft^2 after converting from the blue nozzle vacuum sampling technique (the method used in this survey) to wipe equivalent (the method commonly used by lead risk assessors.

Second, in the national HUD evaluation, median floor lead loading in 764 housing units undergoing lead hazard control was 22 μg/ft^2 before abatement. [NCLSH, 1997] The median floor lead level following abatement was 17 μg/ft^2 - 90% were below 48 μg/ft^2 indicating that dust lead loading below 20 μg/ft^2 can be achieved after lead hazard controls. Lower levels arguably would have been achieved if a lower standard was promulgated because dust clean up is halted once a dust clearance test is less than 100 μg/ft^2 (the current dust clearance level in guidance). These levels were collected in high risk older housing which is often in poor condition or housing that was occupied by a lead-poisoned child. New housing or older housing that is well maintained will have dramatically lower levels.

Third, geometric mean floor lead loading in the 1,297 housing units included in the HUD-sponsored pooled analysis was 13.5 μg/ft^2. In 9 of the 12 studies, representing 77% of 1297 housing units, the geometric mean floor dust lead levels were less than 10 μg/ft^2. These studies were done in specific populations because lead exposure was thought to be a problem. Other communities with a larger proportion of newer housing or without an industrial source of lead will have lower levels of lead- contaminated house dust.

Fourth, measuring levels of lead in the 5 $\mu g/ft^2$ or 10 $\mu g/ft^2$ is feasible. Until about 5 years ago, flame atomic absorption (AA) was the predominant method used to assay house dust for lead. Currently, flame AA is often used as a screen and, if lower lead levels are present (i.e., < 10 μg per sample), graphite furnace is utilized. (Roda S, University of Cincinnati, personal communication). Although the cost for graphite furnace was previously more expensive, the cost for these analyses is now comparable with flame AA.

Nevertheless, there is still a great deal of uncertainty. Questions remain, however, about what proportion of housing would fail a specific standard. Once data from a national survey of lead in housing are available, it may be possible to lower it further. Until lower dust standards are promulgated or research is conducted to specifically assess levels of lead-contaminated dust that can be achieved following lead hazard controls, it will be difficult to know the extent to which lower dust lead levels can be achieved in high-risk housing.

Questions also remain about the duration of various lead hazards controls. Indeed, there are limited data about the duration of abatement or other lead hazard controls. While citing work performed by Mark Farfel (another lead researcher) that "lower" dust lead levels can be sustained following various forms of lead hazard controls, the commenter notes that it is difficult to infer the results from this research since dust sampling was conducted with a modified cyclone dust sampler, not a wipe sampling method. There are clear differences in dust lead loading as measured by these two different sampling methods.

Response. EPA recognizes that lower dust-lead loadings are feasible in the short-term, but in its estimate of risk reduction the Agency was more concerned about the long-term effectiveness of dust cleaning. The data provided does not alter EPA's assumption that lead will reaccumulate and dust-lead levels will rise resulting in a long-term expected dust-lead level of 40 $\mu g/ft^2$ or the pre-intervention dust-lead level, whichever is lower. This assumption is based on an analysis which can be found on page 6-8 of the Agency's Risk Analysis document. However, as is explained in the preamble to the final rule, the Agency has, based in part upon these comments, reconsidered the floor-dust hazard level and chosen to lower that hazard from the proposed value of 50 $\mu g/ft^2$ to 40 $\mu g/ft^2$.

4.3 Dust Hazard Standards are too Stringent.

4.3.1 EPA did not relate the proposed dust levels to any known evidence of health hazard associated with dust exposure.

Response. EPA disagrees with the commenter's assertion that the Agency did not relate the proposed standard to known health effects. EPA's risk analysis establishes a link between dust-lead and blood lead. The performance characteristics analysis performed by EPA, which accounts for exposure to paint and soil, finds that there is a one to five percent risk of a child having a blood-lead level equaling or exceeding 10 $\mu g/dl$ at floor dust-lead levels as low as 50 $\mu g/ft^2$ in the proposal and 40 $\mu g/ft^2$ for the final rule. As summarized below in the discussion of the dust-lead initial candidate hazard level, other commenters have provided analyses showing significant risks at even lower levels, even though the Agency doesn't find those levels convincing for this rule. EPA's analysis for the hazard determination further shows that risk reduction is achievable at dust-lead levels as low as 40 $\mu g/ft^2$. Thus, regardless of any comment's views on the relative risks of any of the levels chosen, EPA has certainly linked lead dust exposure to some level of risk.

4.3.2 EPA did not even attempt to justify the proposed dust standard on grounds of risk reduction and stated that "based on the assumption that 'the costs of reducing risk from residential dust is relatively low,' EPA acknowledges that its selected standard would not result in much risk reduction. See 63 Fed. Reg. 30315.

Response. This comment distorts the Agency position on the relationship between risk reduction and cost for the dust analysis. In its presentation of how cost-benefit balancing should be implemented, the Agency stated that if the costs of standards are relatively low, the level of risk reduction and the strength of evidence could be less compelling than in a situation where the standards require a relatively high expenditure of resources. See preamble to proposed rule at 30315. This describes a situation in which EPA is faced with a range of possible regulatory outcomes based on varying degrees of uncertainty of the evidence. Under a cost-benefit analysis, the Agency could choose a more stringent standard, even if the evidence is relatively weak, provided the costs are commensurate with the benefits of achieving the lower standard. This formulation of the legal/policy basis for the cost-benefit analysis clearly contemplates risk reduction considerations contrary to the views of the comment. With specific reference to this rulemaking, EPA stated that "because the cost of reducing risk from residential dust is relatively low, EPA could select a dust-lead hazard standard that would not result as much risk reduction" as standards associated with higher cost of risk reduction (emphasis added). This excerpt makes clear that EPA stated that risk reduction for standards that are associated with lower costs could be lower. This does not mean it has to be low; it merely means it can be lower relatively to standards associated with higher costs. Nevertheless, contrary to the comment's assertion EPA has never claimed that the risk reduction associated with the proposed dust standard was in any sense trivial, since risk reduction in terms of monetary benefits could run into the billions of dollars under either modeling approach used.

4.3.3 The thorough cleaning envisioned in the proposed rule is not the inexpensive cleaning that is achievable by the ordinary homeowner, but instead can only be achieved by professionals with HEPA vacuums and other expensive tools and professional methods. Clearly Congress did not envision armies of professional house cleaners swarming over one-third or more of the nation's housing stock. Instead of targeting the rule to the greatest risks, it appears that EPA is proposing a standard based on what the Agency finds to be the most stringent achievable level of risk reduction.

Response. EPA strongly disagrees that the kind of cleaning contemplated in the Agency's analysis can only be accomplished with excessively expensive methods. While the specialized cleaning is more costly than routine housecleaning, it is inexpensive compared to the resulting risk reduction.

4.3.4 There appears to be a consensus in the lead hazard reduction industry supporting the current levels in the HUD guidelines. Moreover, the HUD standards are consistent with standards in Maryland and Massachusetts, two states that have been leaders in this issue.

Response. EPA disagrees with the commenter's perspective on views of the lead hazard reduction industry. While the lead hazard evaluation/control industry may have supported the dust standards in the HUD Guidelines when they were published, hazard evaluation/control industry commenters (including individual firms and the industry's trade association) support the more protective dust standards proposed by EPA. Even HUD has reduced the standards in its guidance over the years and has issued a rule further reducing the standards.

With respect to consistency between the HUD Guidelines and the standards from Maryland and Massachusetts, EPA notes that these levels are based on data from the 1980's.

Moreover, the standards are clearance standards and are technology-based; they are not based on analysis of health risk. The current rulemaking represents the first time an effort has been made to set dust standards based on human health risk.

EPA used data from the Rochester Lead-in-Dust study, which as specifically designed to support this rulemaking, as well as the best available national blood lead data (NHANES III) and residential environmental lead data (the HUD survey). Analyses of these data helped EPA select the hazard standards. In fact, based on the Rochester data, some commenters have recommended even more stringent standards than those proposed by EPA. For example, relying on an analysis of the Rochester data and 11 other data sets, HUD set 40 µg/ft2 for floors and 250 µg/ft2 for window sills as interim standards in its regulations promulgated under authority of Title X sections 1012 and 1013.

Moreover, EPA constantly reevaluates lead standards. Prior to 1991, the maximum contaminant level for lead in drinking water was 50 ppm. Regulations issued in 1991 established a goal of 0 ppm and an action level of 15 ppm. Despite good faith efforts that have been made in the past, additional action could be warranted if new data and analysis indicates that properties present excessive risk to young children.

4.4 Sills

4.4.1 The proposed window sill standard of 250 $\mu g/ft^2$ must be clearly dangerous if EPA supports a 50 $\mu g/ft^2$ standard for floors.

Response. EPA disagrees with this comment because it focuses on the presence of lead rather than exposure. Young children tend to have much less contact with window sills than with floors and this results in less exposure. Consequently, a higher level of lead in dust on sills is required to present a hazard. This relationship is borne out both by the Rochester Lead-in-Dust Study and by the Agency's Empirical model (based on the study data), which EPA used to estimate risk reduction.

4.4.2 EPA was incorrect in setting a sill standard using only the model based on the Rochester data.

Response. EPA does not recognize reliance on the Rochester-based empirical model to support development of the sill standard as a weakness. EPA had to rely solely on the empirical model to set the sill standard because the IEUBK was not appropriate for sills in that it did not have a sill parameter. Moreover, the empirical model has been determined to be technically sound and appropriate by EPA's SAB. As a result, the Agency is confident that this model provides a reliable basis for supporting its decision regarding the sill standard.

4.5 Levels at Which 1-5% of Children Will EBLs Are Lower Than 40 μg/ft^2

4.5.1 To support the development of its regulations under Title X sections 1012 and 1013, HUD conducted a study pooling the data from virtually all available epidemiological studies that examined the relationship between dust-lead and blood-lead levels, taking into account differences across the studies. After combining data from each study, a cohort of 1,861 children aged 6 to 36 months was created. This age group has been found to have the clearest relationship between dust lead and blood lead. The pooled analysis excluded children who had been individually selected for study on the basis of high blood lead, due to the bias this could introduce. Environmental lead measurements and other variables (such as season, presence of industrial sources of exposure, year of study, race, sex, socioeconomic status and measurement error) were standardized across all studies. The pooled analysis estimated the expected prevalence rate of blood lead levels greater than or equal to 10 and 15 μg/dl in young children using a number of different candidate dust-lead standards and holding all other environmental variables and other covariates at their national averages. The pooled analysis concluded that at floor dust-lead loadings of just over 5 $\mu g/ft^2$, a child would have a 5 percent risk of having an elevated blood lead level exceeding 10 μg/dl.

In addition, data from the Rochester Lead-in-Dust study shows that the floor lead level of 50 $\mu g/ft^2$ is associated with 20% of children having an elevated blood lead of 10 μg/dl or higher [Lanphear 1996, Lanphear 1998] and that at a floor lead level of 5 $\mu g/ft^2$, 5% of children are estimated to have a blood lead level of 10 μg/dl or higher. [Lanphear 1996, Lanphear 1998]. Similarly, an interior window sill lead level of 250 $\mu g/ft^2$ is associated with approximately 15% of children having a blood lead of 10 μg/dl or higher [Lanphear 1996]. These estimates, the commenter asserts, account for the independent contribution of dust lead loading.

Response. After review of these comments, EPA has determined that the evidence documented in Lanphear et al., 1996 and 1998 does not provide adequate support for a lower dust-lead level at which 1-5% of children will be predicted to have elevated blood lead levels. This conclusion is based on the following reasons. EPA takes a multimedia approach with respect to standard setting because lead in paint, dust and soil are interrelated. The Agency does not focus on control of exposure to lead in one medium alone to reduce risk to children, but instead recommends that all lead exposure in all media be evaluated and controlled when indicated.

The 1996 analysis included soil-lead concentration, whether the child directly ingests soil, and parent's level of education as covariates. While the authors indicate that the analysis is "adjusted for (these) other covariates," it is not clear what the values of these covariates were when making the 5% likelihood prediction at a floor dust-lead loading of 5 $\mu g/ft^2$. For example, EPA cannot determine whether the authors fixed each covariate at a single value (e.g. median value) or considered only values that did not exceed candidate values for standards (e.g., only considered soil values below 400 ppm). The Agency believes that the latter approach is the more appropriate way of analyzing the relationship between dust-lead and blood-lead when controlling exposure to lead in other media. In the absence of information about how the authors controlled for the values of covariates, EPA is unable to make a complete evaluation of this analysis and determine the extent to which levels of lead in dust on window sills, lead in soil, and condition of lead-based paint were controlled.

The 1998 analysis is characterized by another set of issues that, from EPA's perspective, limits its usefulness. Most significant of these in determining how well exposures from other media are being controlled is the treatment of lead in soil in the "pooled analysis." Specifically, there seems to be a great deal of difference in how soil samples were collected and analyzed across the 12 studies in the analysis. Furthermore, it is unclear what material these samples actually represent. For example, in some studies, exterior dust, not soil, was reported. Additionally, section 3 of this document identified other limitations of the pooled analysis. As a result, EPA does not find that this analysis provides a reliable basis on which to make the regulatory decision in this case.

Furthermore, as illustrated below, when looking directly at the raw Rochester data, it is difficult to ascertain why a loading of 5 $\mu g/ft^2$ would be the correct dust-lead level when exposure to lead in paint and soil and lead in window sill dust are being controlled within their own corresponding standards. A level of 5 $\mu g/ft^2$ would identify 45 of the 47 children with elevated blood-lead levels when considering only dust-lead on floors. However, with a dust-lead level of 40 μg/ft^2 and the final rule's hazard standards for soil (400 ppm in the play areas, 1200 ppm for the rest of the yard), along with the other standards, 42 of the 44 children would be identified with the hazard levels (see Table J-2 of the Risk Analysis Supplement for more details).

4.5.2 Analysis on a number of studies, described below, indicated that house dust loadings in excess of 20-30 μg/ft^2 are associated with blood lead levels in excess of 10 μg/dl. Five studies that included house dust loadings as an environmental measure when examining various cohorts of young children demonstrate that blood lead levels below 10 μg/dl are associated with floor dust-lead loadings below 20 μg/ft^2.

Papers from the Cincinnati lead study analyzed children who resided in the same type of housing continuously from birth to over 27 months (peak mouthing behavior is thought to occur at around 18-30 months of age). The studies demonstrated that decreasing quality of housing is associated with increasing dust-lead loading, dust-lead concentration, dust deposition, exterior soil-lead concentrations, and hand- lead levels. Blood lead levels are highest in deteriorated housing and (in declining order) are lower in satisfactory housing, rehabilitated housing, public housing, and private housing. When dust-lead loadings exceed about 20 μg/ft^2, blood lead levels exceed 10 μg/dl at age 18 months.

In the study of lead in Boston, Rabinowitz et al. (1985) (Table 17 in the comment), measured the dose-response relationship between house dust-lead loadings and blood lead levels in young children. As floor dust lead loadings approach 30 μg/ft^2, blood lead levels exceed 8.8 μg/dl. By 200 μg/ft^2 blood lead levels exceeded 20 μg/dl. Rabinowitz's study indicates that blood lead levels exceed 10 μg/dl whenever house dust-lead loadings exceed 30 μg/ft^2. This study, undertaken in the white suburbs of Boston, represents a minimum effect of house dust-lead loadings on blood lead levels, since many of the covariates influencing uptake and absorption of lead were likely to minimize blood lead levels. Therefore, the dose-response relationship of about 2 μg/dl per 6 μg/ft^2, as the change in blood lead associated with the middle two values on the scale, is similar to the relationship demonstrated in the Cincinnati lead studies for 24 months at the low end of the loading scale.

At a floor dust-lead loading of 20 μg/ft^2, according to the Lanphear analysis of Rochester study data, the risk of blood lead levels exceeding 10 μg/dl rises to 15 percent and that risk flattens out in the 20 to 25 μg/ft^2 range.

The literature reveals two recommendations for a house dust-lead loading standard. Milar and Mushak (1982, at 150) concluded that when house dust loadings exceeds 50 μg/ft^2 "a definite hazard exists to children and that decontamination of the home environment is indicated." Chisolm concluded in a discussion of clearance standards for house dust after paint abatement that a house dust-lead loading standard should be less than 100 μg/ft^2 (HUD 1989, at 50).

Another model based on a so-called "SEGH" soil model suggests a floor dust-lead loading standard of less than 0 μg/ft^2 under certain conditions.

Response. For the following reasons, EPA did not find the data and analysis presented by this comment to be useful.

First, these comments reported statistics (assumed to be arithmetic means) on floor dust-lead loadings and blood-lead concentrations within five different studies (and certain subgroups of these studies), observing that the statistic for blood-lead concentration occasionally exceeded 10 μg/dl when the statistic for floor dust-lead loading was below 20 μg/ft^2. Because no further information on the distributions of the blood-lead and dust-lead levels and their relationships with each other was provided, it cannot be determined from the information provided by the commenters as to the precision and accuracy of these statistics (e.g., no standard errors associated with these statistics were reported, and no indication was given whether the reported statistics were heavily influenced by very low or high observations).

Second, the extent to which dust-lead loading influences the value of blood-lead concentration in a particular child, after taking into account the effects of other important parameters, cannot be determined.

Third, while the comment uses information from the Cincinnati lead study to imply that blood-lead concentrations exceed 10 µg/dl within certain specified child age groups when dust-lead loadings achieve approximately 20 $\mu g/ft^2$ (it is assumed that the statistics they present are averages), their results also show that blood-lead concentrations increase with the decreased condition of the house. In addition, other effects on blood-lead concentration, such as the likely increase in soil-lead concentration that occurs with decreased condition of the house, are not accounted for when the commenters present these results. Therefore, it is uncertain from the information presented by the commenters as to the role that dust-lead loading actually contributes to the observed increases in blood-lead concentration.

Fourth, the same concerns are raised when results are presented from the Boston lead study that group children according to blood-lead concentration and show increased (assumed) average dust-lead loadings are associated with increased blood-lead concentration. Again, only an increasing relationship is seen, with no attempt to characterize the role that dust-lead loadings may actually contribute to the increased blood-lead concentrations relative to other important measures (e.g., soil).

Fifth, EPA is uncertain how to use the finding that the commenter's "SEGH" model predicts a dust-lead loading standard that is not significantly different from 0 $\mu g/ft^2$ (i.e., an unachievable result) and somewhat disingenuous, since it would make no sense to find all homes with any lead dust in them to be hazardous. In addition, more must be known about the mechanics and statistical properties of this model (and the correctness associated with replacing the soil variable with the dust variable) before it's findings can be utilized to inform EPA's decisions in this rulemaking.

4.5.3 The Centers for Disease Control (CDC) stated that the multimedia model and the performance characteristics model yielded greatly divergent estimates of the relation of dust lead loading to the risk of elevated blood lead levels. However, no clear explanation of the divergent results or the rationale for choosing between them is provided. CDC also offered the opinion that the multimedia model is probably more accurate based upon other published studies that CDC says indicate a relationship between measured lead loading on floors and blood lead levels in children that continues at levels well below the proposed lead dust standard of 50 $\mu g/ft^2$.

CDC further stated that it believes EPA rejected multimedia model results on feasibility grounds and that including feasibility considerations in the choice of a standard is consistent with good public health practice.

Several other comments agreed with CDC, stating that EPA's justification for rejecting the multimedia model results were vague and confusing to the public. They were not convinced by EPA's argument that the results of the multi-media model were rejected because the "values are far below current clearance standards" and stated that EPA's action appears wholly arbitrary, especially considering that the Agency later feels comfortable enough with the multimedia model to make it a major component in its cost-benefit analysis to develop hazard standards. A well-known lead researcher added that the difference in results between both analytical approaches was particularly confusing because both were derived from data from the Rochester Lead-in-Dust Study.

Response. There were several critical differences between the multimedia model approach and the performance characteristics analysis approach presented in the preamble to the §403 proposed rule. First, the former approach used Rochester study data to construct a model that can predict a geometric mean blood-lead level for children exposed simultaneously to specified lead levels in floor-dust, window sill-dust, and soil-lead concentration. Assumptions regarding the form of the model are required in order to develop a model that fits the data adequately. The latter is a non-modeling approach which simply determines whether households are above or below specified thresholds (e.g., candidate dust standards, 10 μg/dl blood-lead level in resident children). Unlike the model-based approach, the performance characteristics analysis approach requires no assumptions on the underlying distribution of the environmental-lead and blood-lead data, nor does it focus on the distribution of blood-lead concentrations under specific exposure scenarios. (The performance characteristics analysis approach is further detailed below.)

The public comments provided EPA with useful input in its review of the results of the multimedia model approach and performance characteristics analysis approach presented in the §403 proposed rule (63 FR 30318). EPA did this review in an attempt to better explain why such a discrepancy existed in results between the two approaches and with the results of other researchers who analyzed the Rochester study data.

As a result of this review, EPA modified its use multimedia model to make the results of both approaches more comparable from a statistical standpoint and to improve on the extent to which these results can be used to address the key objective of identifying dust-lead standards that would result in fewer than 5% of children with elevated blood-lead concentrations living in homes that do not exceed the standards. The following paragraphs discuss the reanalyses that EPA performed.

EPA's objective in the re-analysis was to have the definitions of the data inputs (i.e., household environmental-lead measures) be more consistent between the two analytical approaches presented in the §403 proposed rule (63 FR 30318). Specifically, inputs to the multimedia model approach included average floor dust-lead loadings (carpeted and uncarpeted), soil-lead concentration at the foundation, and an indicator of the presence of deteriorated lead-based paint and a child with paint pica tendencies in the house. In contrast, inputs to the performance characteristics analysis included average uncarpeted floor dust-lead loading, yard-wide average soil-lead concentration, and the percentage of painted surfaces with deteriorated lead-based paint. As EPA chose to make decisions based on the environmental measures used in the performance characteristics analysis, the Agency examined a revised implementation of the multimedia model to use a similar set of floor-dust, soil, and paint data inputs similar to the performance characteristics analysis.

Specifically, the Agency modified the way in which the model was applied to have the multimedia model analysis characterize the likelihood of blood-lead concentration being at or above 10 μg/dl for children residing in homes whose lead levels do not exceed any of the candidate standards (methods are provided in chapters 5 and 6 of the Risk Analysis Supplement, which was peer reviewed). Therefore, rather than characterizing this likelihood only under conditions represented by the given set of candidate standards (as was done in 63 FR 30318), EPA characterized this likelihood for that group of housing whose environmental-lead measures are all below the candidate standards. This was done by determining average environmental-lead measures across those homes in the Rochester study that do not exceed any of the candidate standards, then using these average measures as input into the multimedia model.

To illustrate how the revised multimedia model approach is applied to data from the Rochester study, consider the following candidate standards for the soil and dust-lead levels of concern and hazardous lead-based paint:

- (uncarpeted) floor dust-lead loading = 50 µg/ft^2;
- window sill dust-lead loading = 250 µg/ft^2; and
- yard-wide soil-lead concentration = 400 µg/g
- hazardous lead-based paint = <5 percent deterioration (smallest level observed in Rochester data)

According to the performance characteristics analysis (and ignoring paint at the moment), 24 of the 184 Rochester study homes have dust-lead and soil-lead data that do not exceed any of these three thresholds. Of these 24 homes, one (4.2 percent) contains children with blood-lead concentrations at or above 10 µg/dl. Across these 24 homes, the following averages are calculated:

- household average (uncarpeted) floor dust-lead loading: 12.1 µg/ft^2
- household average window sill dust-lead loading: 72.0 µg/ft^2
- yard-wide average soil-lead concentration: 82.4 µg/g
- average area of deteriorated lead-based paint: no deteriorated paint

When using these averages as input into the model, the estimated percentage of children with blood-lead concentration at or above 10 µg/dl is 3.9 percent. Note that in this example, when taking into account their variability, these two results compare very favorably (4.2 percent for the performance characteristics analysis versus 3.9 percent for the model-based analysis). These analyses illustrate that at least under the scenario considered, likelihoods of less than 5 percent for standards that approximate the proposed dust-lead and soil-lead levels of concern are estimated using the multimedia model. Therefore, the revised multimedia model analysis supports the decisions made in the proposed rule regarding dust-lead levels of concern.

4.5.4 Several commenters stated that EPA's explanation of the performance characteristics analysis was difficult to understand. Others stated that the performance characteristics analysis was not presented for peer review, the method has no track record in epidemiological literature, and EPA does not provide any standard reference for further information.

Response. In the preamble to the §403 proposed rule (63 FR 30318), EPA provided a brief description of what performance characteristics analysis is, as well as the particular performance characteristic, negative predictive value (NPV), that EPA emphasized when evaluating the performance of a specific set of candidate standards. While the basic approach to performance characteristics analysis is relatively simple, EPA recognizes that some who may not have been previously familiar with the approach would likely have benefitted from a clearer, more detailed, but non-technical explanation of performance characteristics analysis. Therefore, this additional explanation is now provided in the Preamble to the Final Rule.

Table 2 of the proposed rule (63 FR 30318) illustrated that when a performance characteristics analysis is applied to a specified set of candidate standards, each household whose data are used in the analysis is placed into one of four categories according to whether or not its average lead levels (in specified media) exceed any of the candidate standards and whether or not it contains a child with elevated blood-lead concentration. (In the performance characteristics analysis presented in 63 FR 30318, candidate standards were specified for uncarpeted floor dust-lead loading, window sill dust-lead loading, average soil-lead concentration, and percentage of painted surfaces containing deteriorated lead-based paint.) The numbers of homes is determined within each of the four categories, and the statistic known as "negative predictive value" (NPV) is calculated from these numbers. Specifically, NPV equals the percentage of those homes that do <u>not</u> exceed any of the candidate standards that do <u>not</u> contain a child with elevated blood-lead concentration. The performance characteristics analysis is applied independently for each set of candidate standards, and NPV is calculated within each analysis. As it was desired to identify those candidate standards for which no more than 5 percent of the homes not exceeding a standard would contain a child with elevated blood-lead concentration, the objective of the performance characteristics analysis was to identify those sets of candidate standards for which NPV was at least 95 percent (this was generally a range of levels for a particular medium based upon the values of the other media, or "variables").

Some of the terminology used in a performance characteristics analysis is described in statistical texts on discrete data analyses, such as in Section 1.2 of Fleiss, J.L. (1981) "Statistical Methods for Rates and Proportions" (Second Edition. New York: John Wiley & Sons). Other books on statistics, epidemiology, engineering, and other fields describe approaches like performance characteristics analysis that involve basic analyses of raw data without the use of statistical modeling techniques.

4.5.5 The performance characteristics analysis does not incorporate dose-response relationships in a manner that adjusts for real world exposure. It presupposes a target risk level as an *a priori* assumption in the approach, which is highly questionable.

Response. EPA notes that this approach looks at the relationships among empirical data and controls for exposure from other media (i.e., paint and soil). Selecting a risk level is a necessary part of both the multimedia model and the performance characteristics analysis approaches. It would not be possible to evaluate candidate standards for lead in dust, or any other media for that matter, without first identifying a target blood-lead level. The selection of the target blood-lead level, itself, is a part of the regulatory decision making for this rulemaking and is the basis of which is fully discussed in the preamble to the proposed rule.

4.6 Other Dust Issues

4.6.1 EPA should include a trough standard in the regulation for the following reasons: First, children are exposed to dust-lead in troughs. Second, the cleaning history for troughs may be different for sills and troughs casting doubt on the degree of correlation between the two surfaces. Third, troughs pose a greater risk because they frequently exceed guidance levels. For example, a state lead program reported that from the results of 40 home inspections picked at random, 95 percent of troughs exceeded 800 µg/ft2 while only 35 percent of window sills exceeded 500 µg/ft2. Fourth, troughs may be a good indicator of potential lead exposure from exterior lead paint. Fifth, a standard is needed because of the high lead levels often observed in this surface. Sixth, troughs are sometime the only source of lead that can be identified. Seventh, dust on troughs can migrate to floors.

Response. EPA has determined that its proposed approach is appropriate, and the Agency will not issue a hazard standard for window troughs. Although the highest dust-lead levels are usually found in window troughs and children are exposed to lead in window troughs, these observations are irrelevant to the question of whether a dust hazard standard for troughs is needed in addition to the standards for floors and sills. What matters is whether lead in window troughs help improve a risk assessor's ability to predict exposure above and beyond floor and sill dust measurements. EPA's data indicates that window troughs do not.

The only data offered by commenters relevant to this issue does not refute the Agency's conclusion. While it is true that window troughs exceeded the current guidance far more frequently than did window sills, the analysis offered by this commenter contains three deficiencies. First, it does not include the rate at which home exceed either the floor or sill standard. Under EPA's regulations (both proposed and final), a dust lead hazard exists if either floor or sill measurements exceed the relevant standard. Second, the commenter presents the failure rate for sills based on EPA's 1994 guidance level (i.e, 500 $\mu g/ft^2$) rather than the proposed (and final) standard of 250 $\mu g/ft^2$. Presumably, a significantly higher percentage of homes would exceed the new sill standard. Third, the commenter presents the failure rate for troughs based on EPA's 1994 guidance level of 800 $\mu g/ft^2$ which is a technology-based standard. There is no evidence that this would be an appropriate health-based standard. In fact, performance characteristics analyses conducted by the National Center for Lead-Safe Housing, which were presented at EPA's Dialogue Process meetings, suggests that a health-based standard for troughs should be significantly higher, if it were appropriate to have one.

In making this decision, EPA wishes to emphasize three points. First, having a trough standard is not the best way to protect children. Although there may be a rare situation where a window trough is the only source of exposure that can be identified, EPA believes its approach will protect more children. By avoiding the costs associated with trough sampling, resources can be directed to sampling more floors and sills to better characterize dust hazards, to sampling more units, or to controlling hazards. Second, State, Tribal, and local governments are encouraged to establish standards that are appropriate for their specific needs. If window troughs seems to be an independent source of exposure in a jurisdiction, the responsible agency should establish a separate trough hazard standard. EPA's analysis, however, indicates that a separate hazard standards for lead-dust in window troughs is not warranted. Third, EPA is issuing a clearance standards for troughs. Consequently, following any abatement action, troughs would have to be cleaned to pass clearance. Troughs, therefore, would not become an independent source of exposure.

4.6.2 The 800 $\mu g/ft^2$ proposed through level should also apply to exterior horizontal surfaces such as porches, patios, and balconies. This standard was included in previous EPA guidance. The porch also often is used as a play area by young children who may be permitted to play there unattended by adults; and preschoolers frequently will involve themselves in imaginary play that includes playing on the rails, hanging from the rails, and jumping off the porches and steps. Even more than windows, porches serve as an entry way, not only for humans, but for lead-contaminated dust into the building.

Response. The Agency considers enclosed porches to be indoor rooms for purposes of this rule based on input received from stakeholders during the dialogue process. In light of their design and use of these rooms, EPA's data and analysis for dust are applicable. The floor and sill dust standards, therefore, apply to the appropriate surfaces in these rooms.

With respect to dust on external surfaces, EPA is concerned that the extent of the data linking it to health effects beyond the sources already identified is limited. More details on the sources of data on other surfaces is found in Section 3.5 of the Supplement to the Section 403 Rule Risk Analysis.

4.6.3 Lead loading standards should be established for sofas and upholstery. Small children spend much time on plush furniture which can be large sources of dust, lead and allergens (Roberts et al. 1996a, Battelle 1997).

The duct work and the [furnace] system itself in forced air heating systems may be an overlooked important means of spreading dangerous lead-based paint dust after renovation. The dust could be transferred to carpeted or uncarpeted areas. These and similar potential recontamination sources should be designated in new regulations. According to one study, lead in dust within air ducts represented nearly one-third of lead in household dust. Another study showed lead levels in ducts correlated strongly with lead loading on floors (EPA 1997)."

Response. For air ducts, furniture, and other interior surfaces not covered in the regulation or the guidance mentioned above, EPA is not convinced that sampling these surfaces would provide significant additional information beyond what is already conducted in a risk analysis. EPA also does not believe that it would have enough information to set meaningful standards at this point even if these surfaces provided additional information.

4.6.4 Further study is needed before accepting lead dust loading as the best predictor of blood lead levels.

Response. Numerous empirical studies show a statistically significant relationship between dust-lead and blood-lead, including the Rochester Lead-in Dust Study, which was designed specifically for the purpose of developing the TSCA section 403 standards. As noted in the preamble to the proposed rule, some studies show that dust-lead concentration is the better predictor and other studies show that dust-lead loading is the better predictor. Ideally both measures would given an assessor the most complete picture of the nature and extent of dust-lead contamination at a property. EPA decided to use dust-lead loading as the basis for the standard not because it is the best predictor of blood-lead, but because loading is yielded by wipe samples, the most widely employed sampling technique.

4.6.5 Composite sampling allowed by this rule is not appropriate because it misses hot spots, particularly at the dust-lead hazard levels proposed by EPA. Composites would be reasonable if the standard were lower because hot spots would cause the composite to exceed the standard. **Response.** EPA is still permitting composite sampling, although it is making some changes to the comparison. In addition, the Agency has already stated (63 FR 30339) that a risk assessor should use the results of individual samples in developing a hazard response strategy for the property that targets specific areas of a home.

With respect to the concern that averaging masks exposure to hot spots, EPA has determined that hot spots should not be over emphasized but considered as part of overall exposure. When determining appropriate dust sample locations, the risk assessor should be identifying rooms where children are likely to spend most of their time. Assuming the risk assessor identifies these locations correctly, the average of the samples taken should reflect a good approximation of the child's exposure to lead in dust. Making a hazard determination for each sample separately, in contrast, would overemphasize the exposure represented by that sample.

EPA is providing the following analogy to help illustrate this point. A person is exposed to sun during the summer for one hour a day. This hour is an aggregate measure that includes 20 minute at 7 am, 10 minutes at 10 am, 10 minutes at 1 pm and 20 minutes at 5:30 pm rather than one hour straight between 12 and 1. Because, exposure is spread out and most exposure takes place when the damaging ultraviolet rays are not a dangerous levels, this exposure does not present a risk to the individual and the individual would not need to apply sun screen to help prevent skin damage. This situation is similar to a child that may be exposed to loadings in the 5 $\mu g/ft^2$ range 75 percent of the time and 145 $\mu g/ft^2$ 25 percent of the time. Although 145 $\mu g/ft^2$ would clearly be a dangerous level of exposure if that level was maintained for long periods of time, it is unlikely to be dangerous when it occurs for brief periods. A child would not have the opportunity to ingest enough dust and lead to contribute to adverse levels of exposure.

PART FIVE -- Soil Standards

5.1 EPA's Determination That 400 ppm is the Soil-Lead Level That Correlates with 1-5% of Children Having Elevated Blood Lead Levels.

5.1.1 The Level is Lower. The Rochester Lead-in-Dust study shows that at 400 ppm 15 percent of children had elevated blood-lead levels. Data from the evaluation of HUD's abatement grant program show that 77 percent of children aged 6 to 36 months with elevated blood lead levels live in homes with soil-lead levels equal to or exceeding 400 ppm. Data from San Francisco show that 61 percent of children with elevated blood lead levels live in homes where soil-lead levels equal or exceed 400 ppm. Data from California's lead poisoning prevention program show that 42 percent of children with elevated blood lead levels live in homes where soil-lead levels equal or exceed 400 ppm.

Response. The Agency believes that these comments support its position that the most accurate way to determine the effectiveness of standards for multiple media (in this case paint, dust, and soil) is to identify the children that would be protected when all of the standards are in place. Presentation of data such as that provided by the commenters did not address the potential for dust or paint to be the major contributors to elevated blood lead in addition to, or instead of, soil lead. While the commenters did not provide sufficient date to establish what is actually occurring in these cases, there likely are other factors at play including exposure to paint and dust as well as soil. As described earlier in response to Comment 4.1.2 and 4.5.1, the Agency believes that the hazard standards, when considered in total, are very effective at identifying, and thus protecting, those children who are most at risk of an elevated blood lead due to paint, dust, and soil sources.

5.1.2 The Level Is Higher. An analysis conducted by the Gradient Corporation shows that by the early part of the next decade, the risk of exceeding 10 μg/dl will be 5 percent at 2,000 ppm based on EPA's empirical model.

Response. A review of the Gradient report shows that EPA's empirical model was discussed but not used in this analysis. The conclusion rests on predictions of future national blood-lead distributions based on the most recent NHANES III data and several state and local data sets. EPA has concluded that it is not appropriate to draw any conclusions about national blood-lead trends based on limited local data. First the data is contradictory. Second, it may not be nationally representative. The fact that this data was collected suggests that the jurisdictions involved have more active lead-poisoning prevention programs which may in part be responsible for the declines observed. Third, it may be that blood leads are declining because environmental lead levels are also declining in which case the environmental lead – blood lead relationship underlying EPA's analysis remains valid.

5.2 General Criticism of the IEUBK Model's Use At All In Determining the Soil Hazard Standard

5.2.1 There is no strong or consistent correlation between soil lead levels and blood lead levels and the IEUBK model greatly overpredicts blood lead levels. One commenter submitted the following summary of IEUBK model results:

		Geometric Mean PbB (µg/dl)		Proportion of Children with PbB>10 µg/dl	
Community	Model Version	Measured	Predicted	Measured	Predicted
Aspen, CO	0.4	2.6	4.9	0%	0.9%
Leadville, CO	0.5	4.8	9.5	8.2%	41%
Butte, MT	0.61	3.7	4.9 to 5.9		
U.S. EPA, 1993					
Butte, MT					
U.S. EPA, 1992	0.6	3.7	9.1		
Palmerton, PA	0.99(d)	6.8	7.5	29%	31%
ASTDR					
Palmerton, PA					
University of	0.99(d)	4.5	8.1	7.2%	34.2%
Cincinnati					
Sandy, UT	0.99	3.1	6.0	0%	11%

Data from these same sites, as well as others, support the claim that the proposed soil-lead standard cannot be reconciled with recent empirical studies that conclude that there is no strong or consistent correlation between soil-lead levels and blood-lead levels. The following studies are specifically cited:

1. A report by the Colorado Department of Health and the U.S. Department of Health and Human Services (ATSDR 1992) concerning the Smuggler Mountain Superfund site in Colorado which concluded that there was no relationship between soil lead levels and blood lead levels in the community. At that site, the mean soil lead levels was 1,370 ppm and ranged from 135 to 11,676 ppm but there was no increase in blood lead levels in the community as compared to the general population. (The average blood lead level in the community was less than 3 μg/dl.)

2. The same trend in blood lead levels was seen in the vicinity of a former battery recycling facility in Pennsylvania (Taylor and Forslund 1991), where matched data for blood and soil lead values were collected among children living near the battery recycling plant. There, surface soil lead levels ranged from less than 500 ppm to more than 13,000 ppm and blood lead levels were not elevated, with average blood leads less than 10 μg/dl in screenings performed in 1988, 1989, and 1990. The data from this study established that soil lead levels were not correlated with blood lead levels in the vicinity of the smelter.

3. There was a similar situation at Granite City, Illinois (TRC 1990). A blood lead study was performed in 1982 and the blood-lead levels among children living close to the smelter were compared with soil lead levels in an overlapping area. The soil lead values ranged from less than 500 ppm to more than 4000 ppm, whereas the blood lead levels

were found to be consistent with those seen in other urban areas, with the average being less than 10 μg/dl.

Response. The Agency disagrees with these comments because, in the case of many of the submitted summaries, the exposure inputs to the model have been overestimated and, when more likely inputs are used, the model's predictions reasonably approximate the measured blood-lead levels. In the other cases, for reasons that are explained below, it is not reasonable to expect the model predictions to match the reported blood-lead measurements. More specifically, EPA has examined the available data at these sites, and believes that the predictions were generated primarily through:

- *Uncritical use of environmental measurements collected for hazard assessment rather than actual exposure assessment.* Most often, soil-lead inputs to the IEUBK model were averages of all available soil lead measurements, including street dust and building dripline samples, without consideration of where the studied children actually spent their time. In more than one instance, *only* dripline soil lead measurements were used in generating IEUBK predictions, which therefore tended toward high end risk estimates. These high end estimates are useful for characterizing the risks for children whose main exposure is in these areas, but are not relevant to the majority of children with less extreme exposure patterns. Thus, it is misleading to compare these predictions with the actual blood lead levels outside of the context of the individual assessments.

Disproportionate emphasis on children with incomplete exposure evaluations. Approximately 50% of children documented in most of the studies considered to date spend appreciable time away from their homes, where the exposure data in these hazard assessment studies were exclusively collected. Predictions based only on residential measurements for these children with other activities are too uncertain for model evaluation purposes.

For good quality studies with environmental measurements corresponding to children's typical exposure patterns, the use of the IEUBK model has generally resulted in predictions that are concordant with observed blood-lead levels--that is, within 1 µg/dl of observed geometric mean blood lead levels or within 7% of the proportion of children exceeding 10 µg/dl, without alterations of the model algorithms or default media-specific intake rates (Hogan et al., 1998).

In the absence of studies designed specifically for model evaluation, the opportunistic use of data collected for other purposes must also take into account study goal conflicts, such those between assessing actual exposure and reasonable maximal exposure assessment, and other study design issues concerning the generalizability of the results. These study design issues include, but are not limited to, representativeness of the study group, seasonality of blood lead levels, quality of environmental sampling, and the impacts of community education and awareness of lead risks.

EPA maintains, however, that there is useful information to be gained from all of the available studies, including the weaker ones included in the comments, since the studies targeted residential exposures, many with lead-based paint present. Among the adequately conducted studies cited, the apparent discrepancies make sense given study-specific data collection procedures. Furthermore, the Agency believes that an integrated weight-of-evidence analysis of the results available from most of these studies supports the use of the IEUBK model for multi-media and multi-source (e.g., mining, smelting, and lead-based paint) lead risk assessment in typical residential settings. The following sections discuss relevant issues for each of the highlighted sites in more detail.

Smuggler NPL Site (Aspen, CO) Lead Study

The Smuggler Mountain study cited in the comments (Colorado Department of Health, 1992) did not have an exposure assessment adequate for model validation purposes. As described in the IEUBK Validation Strategy (USEPA, 1994a), any studies considered for an empirical comparisons analysis of predictions should have data of sufficient quality and quantity to characterize the children's typical sources and amounts of lead exposure adequately. This means that for each child in the study, he or she would have had a blood lead measurement taken, and concurrent soil, interior dust, and tap water samples (from areas the child frequents) collected and analyzed for lead. The commenter noted that the prediction it provided for Smuggler Mountain used default values for house dust, and water lead levels, since site-specific lead levels are not available for all relevant sources. Since the IEUBK model is intended to be used with site-specific exposure information, extensive reliance on default inputs available as place-holders is misleading. Clearly, such a prediction cannot be expected to be accurate, and is unsuitable for drawing conclusions about model performance.

Most importantly, however, the comments did not include the Smuggler Mountain Technical Advisory Committee report (1993) statement that

> "the outdoor soil measurements were not made in conjunction with the blood lead survey. As a result, the design for the soil sampling had a different purpose in mind. Thus, the type of sample and the way in which it was taken was different than for the other blood lead-soil lead studies done in Colorado and other similar sites. For this reason, it was probably inappropriate to perform correlation analysis between the blood lead and soil lead data."

As detailed in the CO/ATSDR report, the soil samples were taken from the centers of 25 ft x 25 ft area segments, apparently without regard to where particular children in the study played. Since the soil samples did not represent the children's exposures, there were no exposure measurements for generating IEUBK predictions suitable for this comparison.

Leadville, CO

The Leadville/Lake County Environmental Health Lead Study (conducted 1992; University of Cincinnati (UC), 1997) included extensive environmental sampling. The IEUBK prediction reported in the comments apparently relied on higher end exposure measures, especially the average of all available outdoor measurements (including street dust) and a composite indoor dust measurement that included the area just inside the front door. As pointed out earlier, high end exposure estimates are useful for understanding the upper limits on plausible risk levels, but would not be expected to provide reasonable estimates of risk of elevated blood lead for most children. In addition, several study design issues also contributed to a likely underestimate of the blood lead distribution suitable for characterizing long term risks at the site.

As noted above under the discussion for Smuggler Mountain, studies considered for an empirical comparisons analysis of predictions should be able to characterize the children's typical sources and amounts of lead exposure adequately in addition to representative blood lead measurements.

- Play area soil measurements should be given more weight than other soil samples, because play areas were identified as the outdoor areas where these children were likely to spend their time. The averages used in the reported prediction included drip line measurements and street dust, which on average tended to be higher than the play areas. Note that play area composites included samples from sandboxes, when present in individual yards and it is not clear how lead from these areas should be incorporated into a child's total exposure.

- Floor dust samples included a sample of dust from directly inside of the main entry to the residence. This area often can have relatively higher loadings or concentrations of lead among indoor areas, since it is the point of entry for track-in from exterior sources. Of course, this area can an important source of lead which is then dispersed throughout the residence. More significantly, however, it is not clear that most children routinely play in this area, since it would be dangerous to be where the door swings open. Consequently, measuring areas that children do not directly contact misrepresents their actual exposure.

- It is not clear that the drinking water lead measurement represented typical exposure levels. According to the UC report, water samples were collected after a 3-minute flush and 30-minute stagnation period. This is neither first flush nor fully flushed, but would tend to overestimate actual exposure EPA recommends a weighted average of this measurement with a measurement representing fully flushed systems.

The factors summarized above contributed to an overestimate of typical lead exposures, and, consequently, to an overestimate of predicted blood-lead levels. At the same time, several other factors related to the conduct of the study contributed to underestimating the risk of elevated blood lead levels. First, the blood samples were drawn in October, after the annual peak is expected (USEPA, 1995). Strong seasonal effects were observed in the Boston longitudinal study, for example. In that study, peak blood levels were seen in June and exceeded minimum blood levels seen in winter by more than a factor of two. It is noteworthy that by September blood lead levels were already much reduced from their summer peak. This study also noted seasonal patterns in measured environmental lead levels including air and dust lead. The analysis suggested that the variability in the environmental levels contributed to the observed seasonality in blood lead levels. At this time, however, it is not possible to ascribe the observed seasonality in blood lead levels to any single factor and it is likely that a number of factors contribute. These factors may include changes in children's behavioral patterns such as time spent outdoors, changes in dust lead or other environmental lead measures, and physiological changes with season, including, for example, an effect of sunlight on vitamin D synthesis (increased levels of vitamin D are known to contribute to increased absorption of ingested lead). While the complex and multifactorial nature of seasonality in blood lead levels is not yet well understood, the existence of the pattern is well documented.

Second, while the default IEUBK soil ingestion rates were based on data from a relatively cold area, it was probably not as cold as Leadville. This suggests that Leadville children could have had less outdoor contact with soil in early winter and late spring than in more temperate areas. Otherwise, soil ingestion should be similar to the sites where the model was calibrated, with near-default dirt ingestion in warm weather, low to no outdoor soil ingestion in winter. Further, the default ingestion rates were measured at the same warm time of year as the Leadville data (near the end of Summer) when soil ingestion rates would have been expected to be at a relative maximum for several months. So, the climate seems to explain a slight reduction in dirt ingestion and blood lead levels. Also, it is likely that the Leadville community was generally aware of the lead problem there. At the time of the UC study, parents were probably more likely to minimize children's lead exposure through more frequent hand washing, avoidance of contaminated areas, *etc.* This factor could account for substantially lower dirt ingestion rates and lower blood lead levels for some children during the period of the study. For risk assessment purposes, however, use of a lower soil ingestion rate in the IEUBK model is not recommended, since such behavior alterations may only be temporary whereas long-term risk reduction for families yet to have young children is an important concern as well.

Finally, other relevant information is not currently available. A somewhat wide range of relative bioavailabilities has been determined for a number of lead-containing compounds in Leadville soils, ranging from lower to much higher than the IEUBK model default. In order to take advantage of this information, the distribution of characterized soils in the play area of at least some of the children in the study would need to be known.

Butte, MT

The geometric mean blood lead levels reported in the commenters' letters were taken out of context, and presented in an illogical order. The prediction provided last was actually generated the earliest of those presented. It was quoted from a USEPA report, "A TRW Report: Review of the EPA Uptake Biokinetic Model for Lead at the Butte NPL Site" (USEPA, 1992), which reviewed the derivation of an IEUBK prediction of 9.1 µg/dl calculated by a contractor, and detailed a number of reasons why this prediction was not supportable:

- The environmental data input to the model were not representative of actual exposures, involving soil lead measurements only from residence driplines and drinking-water lead measurements which emphasized first flush concentrations and lead-lined drinking water fountains, which were only hypothesized to be of particular concern.

- Public awareness of ongoing Superfund activities in the area may have influenced people's behavior and artificially (temporarily) reduced blood lead levels.

- The subset of children used in the comparison most likely was not adequately representative since it had focused on only one neighborhood when others had been studied as well.

Subsequently, a USEPA/Region 8 report, "Butte Priority Soils: Development of Preliminary Remediation Goals (PRGs) for Lead in Soils: Comparison of Paired Data Sets from the Environmental Health Lead Study and the Integrated Uptake/Biokinetic Model, Version 0.61," (USEPA, 1993) followed the recommendations of the 1992 report summarized above. The assessors added children from other areas of Butte who had been included in the same public health study. They also changed the soil lead inputs to an average of soil lead measurements within each residential yard, which included play area, garden, and bare area soil samples, in addition to the perimeter/dripline samples. There are several factors which help to explain the remaining difference between observed and predicted geometric mean blood lead levels. In experience gained with working with subsequent data sets with additional information available (Hogan et al., 1998), the Agency has learned that there is substantial within-yard variability among all of these locations. Consideration of just the play area soil samples for assessing current exposure is important since these areas generally have lower lead concentrations than at the dripline. Indeed, the sites evaluated in the ATSDR Multisite Study (ATSDR, 1995) only sampled yard areas where children played frequently, and otherwise avoided perimeter/dripline samples. Omission of the dripline measurements from the averages would provide more typical estimates of actual exposure.

In addition, there was no information available concerning the amount of time Butte children spent away from the residences studied. In all studies EPA has examined where this information is available, approximately 50% of children spend sufficient time away from their homes, which is where the available exposure data in these hazard assessment studies were exclusively collected. Predictions based on residential measurements for these children with other activities are too uncertain for model evaluation purposes.

Bingham Creek, UT

While no citation was provided for the Bingham Creek statistics cited in the comments, EPA notes that the difference noted, between 2.5 μg/dl observed and 2.9 μg/dl predicted, is adequate for risk assessment purposes. The difference in proportions of children with elevated blood lead levels, between 0.7% and 2.0%, is similarly insignificant. This is more than adequate for risk assessment purposes.

Palmerton, PA

Empirical comparisons of the IEUBK model using the ATSDR Multisite Lead and Cadmium Exposure Study (ATSDR, 1995) have been reported (Hogan et al., 1998). The first comparison noted by the commenter-- 6.9 μg/dl observed vs. 7.5 μg/dl predicted, and 29% observed to exceed 10 μg/dl vs. 31% predicted--does not appear in the references cited by the commenter, but is the same as that reported by Hogan et al. (1998). These differences are within a practical range for site-specific risk assessment. Furthermore, when the age range is limited to that targeted by the Title X/§403 risk assessment (children 12-31 months old), the geometric mean IEUBK prediction is approximately 1 μg/dl *lower* than the geometric mean observed blood-lead level.

The University of Cincinnati study (UC, 1996) differed in design from the earlier Multisite study and, as a result, is not directly comparable with the earlier blood-lead study. Two major disadvantages were that the UC study was conducted in the fall months when blood levels are likely to have been well off peak (see earlier discussion for Leadville, CO), and that only perimeter soil samples were collected. As noted earlier, perimeter soil samples are generally not a recommended input for IEUBK model risk calculations, as most children cannot be assumed to have contact primarily with perimeter soils. If calculations with perimeter soil levels are made, they need to be interpreted as applying to children whose primary contact with soils is in the drip line area. Data from the Palmerton portion of the Multisite study indicate that perimeter soil lead concentrations were well in excess of lead concentrations for other yard samples. Under these circumstances, concordance should not be anticipated between the UC blood lead measurements and IEUBK runs made using perimeter soil concentrations.

Sandy, UT

The IEUBK predictions provided by the commenters were evidently generated using the average of all available soil measurements, one composite dust measurement, and "at-tap" water measurements. Other factors which limited the usefulness of the predictions provided by the commenters included: use of partially flushed water in IEUBK Model simulations; a focus on children with variably representative lead exposure inputs; and incomplete quality assurance data and analytical variability. When changes were made to the analysis so that the environmental measurements could be reasonably expected to correspond to children's actual exposure, with all other non-site-specific inputs left at default levels, IEUBK predictions were within 1 μg/dl of measured geometric mean blood lead concentrations, with concordant exceedance probabilities.

The changes in the analysis were

- Use of play area soil measurements, rather than average of all available measurements: The play areas were identified as areas where these children were likely to spend their time.

- Use of representative water-lead measurements: According to the work plan, water samples were collected after a 3-minute flush and 30-minute stagnation period. This is neither first flush nor fully flushed. It also seemed unusual that water lead concentrations were reported only at 5 µg/L or 10 µg/L; it seemed possible that some of the reported concentrations actually were below the detection limit. IEUBK Model simulations were run assuming that daily water intake consisted of 50% of this partially flushed measurement, using 2.5 µg/dl as half of the limit of detection where appropriate, and 50% flushed water, assuming that flushed water had a lead concentration of 1 µg/L (U.S. EPA, 1992). These assumptions decreased the predicted blood lead levels by ~0.5 µg/dl for the 15 children with10 µg/L measurements. Although water lead appeared not to be a major concern in Sandy *(i.e.*, children exposed to higher water-lead concentrations had slightly lower blood lead levels than children exposed to lower water lead concentrations, ignoring other sources), the use of the unadjusted measurements as input to the IEUBK Model contributed to overestimation of predicted blood lead levels, especially in view of the much lower water-lead levels inferred from the later EPA study.

- Focus on children who spent less than 2 hours/day away from home: Children who spend several hours each day away from home have less exposure to the lead measured at their homes. Overall, about 50% of the 105 children sampled spent more than 2 hours each day away from home, including traveling, and playing in other parts of their neighborhoods. This is similar to the results of surveys at other sites (ATSDR-managed: Madison County, Galena/Jasper County, West Dallas; University of Cincinnati: Leadville CO, Midvale UT, Palmerton PA; and the Rochester Lead-in-Dust Study).

Based on the above considerations, subgroup geometric mean blood lead levels that apply to children who are exposed to the measured play area soil lead levels, and who play outside are consistent with other empirical comparisons of IEUBK Model predictions with site-specific data (Galena/Jasper, Granite City, Palmerton, Rochester). In those analyses, use of input values for children who were exposed in play areas and who were away from home less than 10 hours/week (roughly equivalent to 2 hours/day) yielded predicted geometric mean blood lead levels that were within 1 µg/dl of the observed geometric mean observed blood lead levels (U.S. EPA, 1996).

Granite City, IL

The commenter reported comparison statistics for the Granite City, IL, portion of the ATSDR Multisite Lead and Cadmium Exposure Study (ATSDR, 1995): geometric means of 5.6

μg/dl observed *vs*. 6.1 μg/dl predicted and percentages with blood lead greater than 10 μg/dl of 15.2% observed *vs*. 19.0% predicted. These statistics were derived from an earlier comparison (USEPA, 1994c) which included all studied children. Hogan et al. (1998) have reported a comparison of results from the 333 children who spent no more than 10 hours/week away from home to be 5.9 μg/dl observed geometric mean vs. 5.9 μg/dl predicted geometric mean; and 19% observed with blood lead levels greater than 10 μg/dl, vs. 23% predicted. In both cases the differences are adequate for risk assessment purposes. It is important to note that the concordance of observed blood lead levels with predictions was better within the group with more representative exposure assessments, those away from home no more than 10 hours/week.

References

ATSDR. 1995. Multisite Lead and Cadmium Exposure Study with Biological Markers Incorporated. April 1995.

Colorado Department of Health, and ATSDR. 1992. Final Report: Clear Creek/Central City Mine Waste Exposure Study, Part I: Smuggler Mountain Site. September 1992.

Hogan K, A Marcus, R Smith, P White. Integrated Exposure Uptake Biokinetic Model for Lead in Children: Empirical Comparisons with Epidemiologic Data. Environmental Health Perspectives. 106:1557-1567.

Smuggler Mountain Technical Advisory Committee. 1993. Final Report. January 27, 1993.

University of Cincinnati. 1996. Palmerton Lead Exposure Study. Final Report. October.

University of Cincinnati. 1997. Leadville/Lake County Environmental Health Lead Study. Final Report. April 1997.

USEPA. 1992. Technical Review Workgroup for Lead (TRW). A TRW Report: Review of the EPA Uptake Biokinetic Model for Lead at the Butte NPL Site. October.

USEPA. 1993. Butte Priority Soils: Development of Preliminary Remediation Goals (PRGs) for Lead in Soils: Comparison of Paired Data Sets from the Environmental Health Lead Study and the Integrated Uptake/Biokinetic Model, Version 0.61. March.

USEPA. 1994a. Validation Strategy for the Integrated Exposure Uptake Biokinetic Model for

Lead in Children. EPA/540/R-94/039.

USEPA. 1994b. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. EPA/540/R-93/081.

USEPA, 1994c. Statistical Analysis of Data form the Madison County Lead Study and Implications for Remediation of Lead-Contaminated Soil. US Environmental Protection Agency, Environmental Criteria and Assessment Office: Research Triangle Park, NC.

USEPA, 1995. Seasonal Rhythms of blood lead levels: Boston, 1979-1983, USEPA September, 1995. EPA 747-R-94-003.

USEPA. 1996. Baseline Human Health Risk Assessment, California Gulch superfund Site, Leadville, Colorado. Prepared for USEPA Region VIII by Roy F. Weston, Inc. Prepared for USEPA, Region VIII by CDM Federal Programs Corporation. January.
Weis, C. 199 .

5.2.2 Comments also criticized the IEUBK model in light of the data sets used for its calibration, claiming that the sites used (East Helena, Montana, Omaha, Nebraska, and Bunker Hill, Idaho) were "settings that are or once were mining or smelting sites, which have little relevance to typical contemporary residential settings." Additionally, comments noted the following statement from the Agency's Risk Analysis document to support their criticism:

> The IEUBK Model was developed and calibrated for children at certain large area lead sites identified in the Superfund program. In general, these are children in housing for which lead in soil contributes significantly to lead in house dust, and this lead is accessible and bioavailable. It is not clear that the default parameters, which were selected as appropriate for Superfund sites, are applicable to all US children. Conditions at general residential sites have not been investigated to the same level of detail.

Response. The Agency believes that this criticism in invalid for several reasons. First, the sites used in the calibration included many homes with lead-based paint, in addition to other sources of lead. Consequently, the Agency is not convinced that children's exposures to lead from paint, dust, and soil would be substantially different at these sites as compared to residential sites that are not Superfund or other corrective action sites. While the bioavailability of the portion of environmental lead that originates from a mining or smelting operation may be different from the portion of lead that originates from sources more traditional sources (*e.g.*, lead-based paint, previously deposited lead from gasoline, *etc.*), the Agency does not believe that this would disqualify the model's use at residential sites where these industrial sources are not present. In fact, many of the model's parameters are not likely to be dependent upon the source of the lead in a child's environment (*e.g.*, dirt ingestion rate, dietary lead intake, and water intake).

As to the quotation from the Risk Analysis document, this statement was made as a general caveat on comparing the results from the IEUBK model using the HUD National Survey data to the results from the empirical model using the HUD data or to the results from the NHANES survey. It was not intended to convey any concern that the IEUBK model could not perform adequately for the purposes of the risk analysis underlying the proposed rule. Rather, the Agency believes that, as detailed in the response to the previous comment in this section, the model has produced results that are reasonable approximations of measured blood lead distributions in those cases where the environmental measurements used as input truly reflect the environments to which the children are exposed.

5.2.3 Comments pointed to the differences between the blood-lead distribution produced when the model was used with the HUD National Survey data and the blood-lead distribution reported in NHANES III. Applying the IEUBK model to the HUD National Survey data, the geometric mean blood-lead level is mean is 3.9 µg/dl and the geometric standard deviation (GSD) is 2.3. The model predicted that 12 % of children would have a blood-lead level exceeding 10 µg/dl. The geometric mean and GSD of NHANES III Phase 2 (which was used in the risk analysis) is

3.14 μg/dl and 2.1, respectively, with 5.75 percent of the children exceeding 10 μg/dl. Commenters cited this as another example of model's tendency to over predict blood-lead distributions.

Response. The Agency disagrees with this conclusion. First, the HUD survey was not specifically designed to collect measurements that reflect children's typical exposures for the residences chosen. The survey emphasized soil near the dripline of the house, where soil lead levels tend to be highest within a yard, but no information concerning play areas was collected. Therefore, the soil lead input was an overestimate of soil-lead than would have been expected if samples were more indicative of the average of the yard. Also, dust samples from each residence came from two randomly chosen rooms, including bathrooms and kitchens, regardless of children's likely (for residences without children) or actual activities. Consequently, dust may not be especially indicative of the dust to which a child is predominately exposed.. While these factors are relevant in terms of evaluating how accurately the HUD Survey reflects actual nationwide distribution of environmental lead levels to which children are exposed (which would be the ideal input for purposes of the Risk Analysis for this rule), it is, nevertheless, the best national survey of environmental lead levels available to the Agency and is believed to reflect a reasonable representation of those levels.

Secondly, the HUD survey was not designed to coincide, either in geographic area or in time, with NHANES III, phase 2. It is not clear that there was much overlap in communities between the two studies. Also, the HUD survey was conducted from 1989 - 1990, whereas NHANES III, phase 2 was conducted in 1991 - 1994. If the IEUBK/HUD survey results are compared to NHANES III, phase 1 which was more contemporaneous with the HUD survey (i.e., conducted in 1989 - 1991), the results are more similar: 12% predicted > 10 μg/dl vs. 11.5

% measured in NHANES III, phase 1.

5.3 EPA's Proposed Soil-Lead Hazard Standard Was Inappropriate

5.3.1 The Hazard Standard Should Be More Stringent

EPA should select 100 ppm for the soil hazard standard for the following reasons. First, the adverse effect blood lead level of concern is at least as low as 10 µg/dl and perhaps as low as 5 µg/dl for reductions in IQ, growth and stature, hearing loss, etc. and the potential for chronic disease conditions. Second, blood-lead levels increase at the rate of 1 µg/dl per 100 ppm lead in soil between 100 ppm and 600 ppm. Third, lead may contribute to chronic disease conditions (including cancer and heart disease) for which there is no known safe level, and childhood lead exposure could contribute to chronic disease years later. Fourth, children with habitual pica for lead in soil can ingest a substantial amount of lead when soil lead concentrations exceed those associated with natural background. Fifth, lead researchers have been steadily reducing their recommendations for soil lead standards and are now establishing soil lead standards at or below 100 ppm.

Response. EPA rejects this recommendation for the following reasons. First, the conclusions regarding dose-response for lead in soil are not consistent with the results of analyses conducted by EPA. For example, a review study by Elias and Marcus (1994) reported dose-response relationships for urban studies higher than 3.6 µg/dl per 1000 ppm. Excluding Cincinnati, the highest slope factor was 2.4 µg/dl per 1000 ppm or one fourth the slope factor reported by the comment.

Second, when the person who submitted the comment used its dose-response relationship as an input into its own lead model, the resulting standard for soil was less than zero. Such as result calls into question the reliability and validity of model and its inputs including the assumed dose-response relationship.

Third, the standards should not be based primarily on children who exhibit habitual pica for soil. EPA's analysis already accounts for pica for soil to the extent it occurs. While these individuals need to be protected, implementation efforts rather than national regulatory standards based primarily on children who exhibit habitual pica for soil is the best approach.

Fourth, the conclusions regarding the recommendations of lead researchers are problematic. The table submitted with the comment reports recommendations ranging from 80 ppm to 1000 ppm.

5.3.2 The Hazard Standard is Too Stringent

5.3.2.1 Comments opposed the EPA's proposed choice of 400 ppm as a "level of concern" for residential soil lead. This proposed "level" was below the soil-lead hazard, but at the time of the proposal EPA felt that it was a useful communication tool for the public. EPA no longer believes that a "level of concern" is appropriate.

However, the 400 ppm level still has relevance to the final rule. EPA determined its initial candidate hazard level based on the same analysis used to determine the "level of concern." This analysis showed that at 400 ppm soil-lead concentration on a yard-wide basis, on a national level, 1-5% of children would be predicted to have blood lead levels above 10 µg/dl. Earlier in this section, EPA responds to comments received on whether 400 ppm lead in soil was the appropriate level (for regulatory purposes) at which 1-5% of children would be predicted to have blood lead levels above 10 µg/dl. In addition, EPA has established 400 ppm in play areas as a residential soil-lead hazard standard. The Agency's reasons for this are explained in the preamble to the final rule.

The comments on the "level of concern," accordingly, may be somewhat moot now since EPA no longer uses that formulation. In view of the relevance of the 400 ppm level, however, EPA is responding to comments on 400 ppm as a "level of concern," to the extent they are relevant to the final hazard determination.

The relevant comments argue that there is no evidence that abatement at 400 ppm would have any impact on blood lead levels. According to the comments, the Boston phase of the Urban Soil Lead Abatement Performance ("Three City") Study, which was cited by EPA, shows at best a minimal decline in blood lead levels following soil removal. In Boston, where pre-abatement soil lead concentrations averaged 2,400 ppm, the principal investigators concluded that (Weitzman *et al.*, 1993, p.1647):

> The magnitude of the [blood lead level] decline independently associated with soil abatement ranged from 0.04 to 0.08 µg/dl (0.8 to 1.6 µg/4L) when the impact of potential confounders, such as water, dust, and paint lead levels, children's mouthing behaviors, and other characteristics, was controlled for.

According to this comment other findings published by Weitzman *et al.* (1993) indicate, moreover, that the observed decrease in blood-lead levels in the Boston phase of EPA's Three City study may reflect factors other than soil abatement. Weitzman *et al.* noted that (p. 1651), "no dose-response relationship was observed between the mean change in blood lead level and the starting soil lead level or the size of the excavated area." According to the comment, this result is not consistent with the hypothesis that soil abatement affects blood lead levels since, if it was, one would expect a larger decrease in soil lead concentrations to have a larger impact on blood lead levels.

Also, an outside review conducted by Dr. Kenny Crump (1997) identified substantial flaws in EPA's analysis of the Boston Three City Study data (U.S. EPA, 1996), which U.S. EPA (1998a) relies on for the purpose of conducting its cost/benefit analysis. In the context of this analysis, the following were among the most important flaws that Dr. Crump identified. First (Crump, p. 3), the recorded decrease in house dust was the same in the study group (soil abatement together with interior loose paint removal and interior dust abatement) as it was in the two control groups (interior loose paint removal only, and interior loose paint removal together with interior dust abatement). These results were believed to indicate that soil abatement does not improve dust lead levels beyond the improvement gained through the dust lead and paint lead abatement measures.

Second, Crump states that, because the Boston analysis restricted attention to children with blood lead levels ranging from 7 μg/dl to 24 μg/dl, its results overstate the impact of soil abatement on childhood population blood lead levels. The arithmetic mean blood lead level among children in the Boston study group was 13.1 μg/dl, far greater than the NHANES III phase 2 geometric mean blood lead levels (3.14 μg/dl for one to two year olds and 2.74 μg/dl for one to five year olds). By excluding children with blood lead levels below 7 μg/dl, the Boston study limited its analysis to those children whose blood lead levels are likely to be affected by environmental lead to the greatest extent. As a result, the blood lead levels of the children included in the Boston study would have responded to soil abatement to a greater degree than would the blood lead levels among other children. In any case, the average pre-abatement soil lead level of 2,400 ppm far exceeds 400 ppm, rendering invalid any inferences drawn from the Boston study about the potential impact of abatement at levels as low as 400 ppm.

The risk analysis for the section 403 regulation also mentions data taken from the Level III dwellings that were part of the Baltimore Repair and Maintenance (R&M) study in support of the Agency's contention that lower soil lead levels would decrease blood lead levels. U.S. EPA (1996). As detailed on p. 3-48 of the Agency's Risk Analysis (U.S. EPA, 1998b, Table 3-19), there were twenty-eight dwellings for which soil lead measurements are available, and this small sample is unable to offer useful information for several reasons:

> the "Previously Abated Group" of dwellings is far too small to draw any inferences from (N=2); the "Units Slated for R&M Intervention" have soil lead levels that are too high (geometric mean of 1,260 ppm and a geometric standard deviation of 2.0) to serve as a basis for evaluating the potential benefits of abating soil with soil lead levels that are approximately 400 ppm; finally, the "Modern Urban Units" had soil lead levels that are too low (geometric mean of 61.1 ppm, geometric standard deviation of 1.7) to offer a comparison for assessing the potential benefits of abating soil with soil lead levels that are approximately 400 ppm.

Of greater relevance, according to this comment, is the failure to identify a statistically significant impact of soil abatement on blood lead levels in the Baltimore phase of the Three City Study (U.S. EPA, 1996). The Baltimore dwellings, although selected because they were thought to subject occupants to a relatively high level of lead exposure, had soil lead levels in the vicinity of 400 to 500 ppm.

Similarly, a recent study in Toronto, conducted jointly by the Texas and Toronto Departments of Public Health, found greater blood lead reductions over an eight-year period in the study cohort that received no soil lead abatement than in the soil abatement group.

Response. In the first place, EPA notes that these comments would have been totally irrelevant had the Agency decided to keep a "level of concern." This is because the comments consistently argued that various studies do not support soil-lead abatement at 400 ppm and EPA did not recommend abatement at 400 ppm. In the proposal, EPA recommended interim controls (e.g., ground cover) to reduce exposure to lead in bare soil at 400 ppm on a yard-wide basis. In fact, EPA specifically rejected 400 ppm, yard-wide, as a hazard standard.

For the final rule, EPA continues to believe that 400 ppm would not be appropriate as a yard-wide hazard standard, or for yard-wide abatement. Moreover, the Agency clarifies in the final rule that public and private organizations should evaluate both interim control and abatement strategies in determining the most effective course of action when dealing with dust and soil hazards.

In the final rule, EPA does identify 400 ppm as a soil-lead hazard standard, on a nationwide basis, in children's play areas. However, this is not to be interpreted as a blanket recommendation for abatement. Instead, for its determination in the final rule, EPA tried various options to partition children's expected exposures from soil in play areas and soil in the rest of the yard in an approach that indicated focusing primarily upon a child's play area would likely be preferable in terms of protectiveness, risk reduction, and cost-effectiveness. These analyses indicated that, in situations where the play area is small, an approach which establishes a more stringent standard for the play area can be more optimal in terms of cost effectiveness (and obviously more protective) than a less stringent standard applied to the yard as a whole. These analyses are indicative of the benefits of separate standards for the play area and the rest of the yard.

Nevertheless, these comments still would not convince EPA to issue a different final soil-lead hazard. This is because these comments generally refer to the inappropriateness of abatement as the approach to controlling soil-lead levels at 400 ppm and the final section 403 rule(and its proposal for that matter) does not suggest abatement as the general approach to control of soil-lead at 400 ppm.

5.3.2.2 EPA should set the soil hazard standard no lower than 2,000 ppm and preferably at

5,000 ppm.

1. The 5,000 ppm standard is consistent with recent epidemiological data (e.g., Palmerton, PA; Smuggler Mountain, CO; Granite City, IL; Boston, MA) showing no strong correlation between soil-lead and blood-lead. Moreover, the empirical model shows negative incremental net benefits as the standard is lowered from 5,000 ppm to 2,000 ppm.

Response. EPA disagrees with this comment and cites the reasons stated in the preambles to the proposed and final rule for rejecting 5,000 ppm as the soil-lead hazard standard. EPA has responded, above, disagreeing with the extensive comment regarding the lack of correlation between soil and blood lead. In addition, Soil-lead concentrations well below 5,000 ppm are associated with significant risks to young children as shown both by a review of the epidemiological data and the predictions of the IEUBK model. Furthermore, EPA's analysis predicts that significant risk reduction can be achieved by abating lead in soil at lower concentrations.

2. The choice of 2,000 ppm is not supported by the Boston Three-City study which did not find significant public health benefit from removal of soils averaging in excess of 2,000 ppm lead. Furthermore, the Rochester Lead-in-Dust Study shows that the 2,000 ppm standard would yield negligible public health benefits. Finally, 2,000 ppm is far too stringent given the built-in conservatism of the IEUBK model.

Response. EPA also disagrees that 2,000 ppm would be the appropriate soil-lead hazard level for the reasons stated in the preamble to the final rule and further explained below. EPA also disagrees with any analysis that uses one particular study or model to either refute the Agency's decision or argue for an alternative. The fact is that the Agency balanced a number of different analyses and models to arrive at its lead-based paint hazard determinations.

With respect to the Boston Three-City Study, the evaluation by Crump, discussed in the previous general comment in this section, was not cited by one of its principle proponents, the Lead Industry Association (LIA), for the proposition that soil-lead should not be abated at 2,000 ppm. In fact, LIA advocated a soil-lead hazard standard of 2,000 ppm.

In addition, as noted in the preamble to the final rule, EPA's own evaluation of the Boston study showed just the opposite of what the comments claim. That is, EPA found that abatement of soil in the Boston study resulted in a measurable, statistically significant decline in blood lead concentrations in children, and that this decline continued for at least two years.

Nevertheless, the Three City Study has been cited by many commenters as evidence that soil-lead abatement is not an effective means of reducing blood-lead levels, especially in the absence of paint abatement. To the extent that comments have cited the study this proposition, EPA disagrees with the comments. The study certainly does not refute a 2,000 ppm standard, and as stated in the preamble to the final rule, can be used to support a non-play area hazard standard of 1200 ppm. The study, as noted above, shows a measurable decline in blood lead levels after abatement at the relatively higher levels.

EPA, however, believes that, if it were not for certain weaknesses in the study, it would show even greater benefits from soil abatement, particularly at the higher levels. In the first place, the Boston Study measures the effectiveness of secondary prevention and not primary prevention. As discussed in the preamble to the proposed regulation (63 FR 30319), primary prevention is thought to be more effective than second prevention because, with primary prevention, exposure is prevented and children's risk remains at pre-exposure levels. With secondary prevention, risk does not drop to pre-exposure levels because some lead is stored in bone tissue, which continues to release lead into blood for come period of time even after environmental levels decline. Consequently, studies that focus on secondary prevention will underestimate the effectiveness of any hazard control interventions implemented.

Second, the criteria for selecting children in the Boston City Study tend to minimize the soil-lead blood lead relationship. Children with blood lead levels exceeding 25 (probably the group that could benefit the most from soil abatement) were excluded from the study. Likewise, children with very low blood lead levels were also excluded. The selection criteria limits the variability in blood-lead data, which will reduce the magnitude of the relationship between soil lead and blood lead.

EPA, as stated in the preamble to the proposed and final rules, also disagrees the Rochester Lead-in-Dust Study shows that the 2,000 ppm standard would yield negligible public health benefits. Under some aspects of the Agency's analysis, 2,000 ppm could be a viable soil-lead hazard standard. While net benefits fluctuate slightly in 2,000 to 5,000 range, they are relatively constant. Given the uncertainties in EPA's predictions, the Agency considers net benefits in this range to be equal. In light of this and the other factors that EPA considered in whether to establish a 2,000 ppm standard, it would not have been unreasonable for the Agency to choose 2,000 as a standard for the non-play areas of the yard.

Finally, with respect to the so-called "built in conservatism" of the IEUBK model, EPA notes that the empirical model was the one that tended to support the 2,000 ppm hazard standard and that the Agency weighed both models equally in arriving at its decision. EPA refers the commenter to the preambles to the proposed and final rules for a more complete discussion of the viability of the 2,000 ppm standard.

3. Health effects are speculative and uncertain at 400 ppm.

Response. EPA concurs in part with the comment, in that the Agency does not believe that 400 ppm would be an appropriate yard-wide standard on a national basis. The explanation for this is in the preambles to the proposed and final rules. However, for reasons stated in the preamble to the final rule, EPA has decided that 400 ppm is an appropriate hazard standard for play areas.

5.3.2.3 Under the proposed hazard standard, lead abatement could lead to excessive housing abandonment, and could seriously impact the availability of affordable housing according to an analysis by Lutter and Frass.

Response. The analysis by Lutter and Frass is based on the housing market response to increased property taxes. An earlier analysis cited by the authors concluded that some owners will abandon their properties in response to property tax increases. By analogy, the authors conclude that owners will abandon their properties when faced with the cost of abatement. This analysis, however, is characterized by several significant deficiencies. First, the entire analysis is a hypothetical based on an analogy, not on empirical data. Second, the analogy is not appropriate. Unlike taxes, abatement is not mandated by any EPA regulation. Third, it is not appropriate to make a comparison between a world with abatement and one without. Even in the absence of the section 403 regulations, abatements will occur, some ordered by local health departments and some by juries in liability trials. Unfortunately most of these abatements will be performed after a child has been injured. It is EPA's objective that any abatements that are performed in response to the Section 403 standards are conducted to prevent injuries. In addition, to these deficiencies, EPA wishes to note that this study has never been peer reviewed.

5.3.2.4 It would be arbitrary and capricious not to select 5,000 ppm as the hazard standard because it was the consensus recommendation of EPA's stakeholder process.

Response. The dialogue process was not a consensus process or a negotiated rulemaking. EPA was seeking the input of individual participants. Even if there were unanimous recommendations, the Agency was under no obligation to incorporate these recommendations into the rule. Most importantly, however, no analysis was done to determine the 5,000 level in the dialogue process. Therefore, it could not serve as a basis for a rule. In fact, if EPA were to issue a standard of 5,000 solely based on the dialogue process, the Agency would be acting in an arbitrary and capricious manner.

5.3.2.5 The impact of 2,000 ppm is overly broad because an estimated 2.5 million homes have lead in soil at this level but less than 900,000 children have elevated blood lead levels.

Response. The argument that the regulation is overly broad has been made and responded to with respect to the standards in their entirety and the dust standards alone. To summarize, EPA has concluded that this comparison is inappropriate and irrelevant. One must compare the number of children with elevate blood lead levels over the next generation and compare that to the number of homes with hazards. Furthermore, EPA's recommendations concerning implementation of the hazard standards call for targeting older homes where very young children live and conducting this work over a number of years.

5.4 Effect on Disclosure

Only hazards have to be disclosed under section 1018 and, therefore, the proposed soil hazard level of 2,000 ppm is not protective, since soil-lead levels between 400 and 2,000 ppm would not have to be disclosed as hazards even though these levels are associated with risks that should be communicated to the public.

Response. The final 403 rule designates 400 ppm as the soil-lead hazard level for play areas and, therefore, makes much of this comment moot. Levels below 1200 ppm in the rest of the yard do not have to be disclosed as hazards either. However, EPA clarifies that the section 1018 regulations also require property owners and landlords to provide prospective buyers or tenants testing results regardless of the dust, soil or paint lead levels. This is because the section 1018 regulations require disclosure of all reports "pertaining to" lead-based paint hazards. See 24 CFR 35.88(a)(3) and (a)(4); 24 CFR 35.92(a)(3) and (b)(3); 40 CFR 745.107 (a)(3) and (a)(4); 40 CFR 745.113(a)(3) and (b)(3). Thus, even though a "hazard" does not exist, evaluations of residential dust, soil or paint that show lower levels still "pertain to" a hazard. EPA believes this is consistent with its lead program in general to ensure that members of the public are fully informed about the existence of lead on residential property.

PART 6 – PAINT STANDARDS

6.1 Because 83 percent of pre-1978 housing contains lead-based paint, the section 403 regulations should contain a presumption that all paint in pre-1978 housing is lead-based unless determined to be otherwise by a certified risk assessor. Given the widespread prevalence of lead-based paint, the onus should be on the property owner to prove that lead-based paint is not present. The New York City lead ordinance presumes that deteriorated paint in the residence of a child under seven in a building erected before 1960 is a hazard.

Response. EPA disagrees with the conclusions drawn from the statistic that 83 percent of homes built prior to 1978 contain lead-based paint. Many homes that contain lead based paint, only contain it on limited number of surfaces. Most components in these homes do not contain lead-based paint. In fact, according to the National Survey, only 12 percent of the interior paint tested was lead-based; only 5 percent of interior paint in housing built between 1960 and 1978 was lead-based. These data do support this recommendation in this comment. Furthermore, such a recommendation, if implemented would lead to unnecessary abatement of surfaces covered paint that is not lead-based, wasting limited resources that should be used to address hazardous lead-based paint, dust-lead hazards, and soil-lead hazards.

6.2 EPA should provide better justification for its interpretation that "lead-contaminated paint" means the same thing as "lead-based paint." Also, a question was raised regarding the statement that "lead-based paint is not a risk-based term" but "only a benchmark that identifies material subject to the jurisdiction of various authorities of TSCA and Title X." This statement makes it problematic to use "lead-based paint" to define a health hazard.

Response. The term "lead-contaminated paint" does not appear anywhere else in the statute. In contrast, "lead-based paint" is the term used throughout the statute. EPA, therefore, has concluded that it is reasonable to define the two terms synonymously.

With respect to the second part of the comment, lead-based paint in itself is not a hazard and is not a risk-based term under the statute. For lead-based paint to be a hazard, it must be deteriorated or deteriorated or abraded and located on a friction or impact surface. Lead in dust and soil at levels equal to or exceeding the standards identified in the statute are also hazards. The risk-based term that refers to these media and conditions is "lead-based paint hazard."

6.3 EPA should not have a separate standard for paint. This recommendation is based on data from the Rochester Lead-in-Dust study which shows that interior lead-based paint has no independent effect on expected blood lead levels when dust levels are held constant. The proposed paint hazard standards, therefore, lacks an empirical basis. Given the lack of empirical evidence relating paint condition to blood lead, paint abatement is not a cost-effective way to reduce blood lead levels, provided that lead dust is adequately controlled.

Response. EPA disagrees. While this point may have some validity if there is a single paint chip, it would make no sense if there are very large amounts of deteriorated paint. Surely, EPA could not ignore that as a hazard. EPA has, for reasons discussed in the preamble to the final rule, adopted a standard that identifies any deteriorated lead-based paint as a hazard, but does not impose restrictive certification or work practice standards for low levels of deteriorated paint. Thus, all deteriorated paint must be controlled.

Part 7 -- Regulatory Assessment Requirements

Impacts of the Regulation -- Executive Order 12866 and the Unfunded Mandates Reform Act (UMRA)

7.1 The Unfunded Mandates Reform Act of 1995 (104 P.L. 4, 109 Stat. 48) and Executive Order No. 12866 require the Agency to prepare an analysis of costs and benefits of regulation and, unless the law directs otherwise, to adopt regulations "only upon a reasoned determination that the benefits of the intended regulation justify its costs." Exec. Order No. 12866. Nothing in Section 403 overrides this requirement and accordingly the Agency must use this approach in setting hazard standards in this rule.

Response: EPA disagrees with this comment to the extent it argues that either UMRA or E.O. 12866 requires the Agency to issue a regulation based on a determination that benefits are justified by costs unless a statute specifically overrides that approach. As a preliminary matter, the comment is not suggesting that EPA has failed to comply with either UMRA or E.O. 12866.

Under Title II of UMRA, the Agency is required to assess, unless otherwise prohibited by law, the effects of its regulatory action on State, local, and tribal governments, and on the private sector, other than to the extent that such actions incorporate requirements specifically set forth in the law (section 201). If the regulatory action is estimated to result in a "Federal mandate" involving annual expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector in any one year, section 202 of the UMRA requires an agency to prepare a written statement, including a cost-benefit analysis. Before promulgating a regulation for which a written statement is needed, section 205 of UMRA generally requires an agency to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows an agency to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the agency head publishes with the final rule an explanation on why that alternative was not adopted. Before an agency establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of the agency regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Under E.O. 12866, whenever an action is designated as a "significant regulatory action" under section 3(f)(1) of the E.O., an agency must provide the Office of Management Budget (OMB) with an opportunity to review the regulatory action. Included in the material the agency submits to OMB for review under the E.O., is an assessment of the potential costs and benefits associated with the action (section 6(a)(3)(B)). Under section 1(b), the E.O. enumerates several principles that agencies are asked to adhere to, to the extent permitted by law and where applicable. Among the twelve principles articulated is the principle that agencies "assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." (Section 1(b)(6)).

Other principles in the E.O. ask the agencies to consider such factors as the risks posed, available alternatives to direct regulation, cost-effective alternatives that achieve the regulatory objective, and that decisions are based on the "best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation." In specifically describing the many agency responsibilities under the E.O., it does not require agencies to adopt regulations only if the benefits justify the costs. (Section 6).

As indicated at the proposal, EPA has determined that UMRA is not applicable to this regulation because the regulation does not contain any Federal mandates or impose any enforceable duty on State/Tribal, or local governments or on the private sector. Nevertheless, the Agency has prepared the analyses described by UMRA, and also consulted with affected entities during the development of this regulatory action. In addition, since this rule may result in behavioral changes that involve increased expenditures by owners of target housing and child-occupied facilities with a potential annual effect on the economy of $100 million or more, OMB designated this rule as a "significant regulatory action" under E.O. 12866, even though the establishment of the standards in this rule do not, in and of themselves, mandate any action. As such, EPA submitted this rule to OMB for review under E.O. 12866, along with an assessment of the potential costs and benefits associated with this action, the alternatives considered, and the explanation for the Agency's final decisions.

Finally, neither UMRA nor E.O. 12866 subjects the Agency to judicial scrutiny for not adopting the regulation based on a cost-benefit approach. Of course, EPA has chosen to consider a cost-benefit methodology to assist it with establishing the hazard standards in this rule, but that is a decision within EPA's discretion and is in no way mandated by statute or Executive Order.

7.2 Comments offered opinions on whether EPA's analysis should have included adverse impacts on property values.

A task force of a national tenant advocacy group argued that little empirical evidence exists to support the notion that a standard for hazard disclosure for soil will inevitably lead to further depressed property values in already depressed areas. On the contrary, it is necessary to provide this information in order to stimulate the market, and force the remediation of contaminated properties. The comment questions whether disclosure of dust hazards has affected property values or bank loans. Furthermore, as contaminated properties are identified, and the public and real estate communities gain confidence in the status of the remaining properties, the aggregate worth of all but the most heavily impacted areas will increase because people will better understand the risks and costs associated with developing properties with probable lead paint contamination. Financial institutions will also be better equipped to lend money to problem properties as the hazard standards provide increased protection from liability, and a better picture of how occupants could be protected from identified hazards.

National rental property trade associations have expressed different conclusions. These comments cite the real costs that other types of contaminated properties have had (due to asbestos or leaking underground storage tanks), in the form of devaluation and potential stigmatization. They argue that it was inappropriate for the economic analysis to dismiss the costs already shown to exist for similar situations.

Furthermore, properties needing lead-based paint remediation have been devalued by a factor at least equal to the costs necessary to remediate the contaminated site. Values are depressed further because these properties are often located in communities where there are ongoing sources of contamination and will be subject to additional costs to address additional contamination. The negative stigma attached to a property can cause even greater devaluation, although it is difficult to place an exact value on the impact of stigmatization.

The Science Advisory Board commented that it is necessary that the presence of lead be incorporated into value of a property. Failure to do so would constitute a real estate subsidy for those properties containing lead. The cost of lead in a property should be viewed in the same light as pollution for a business; both are real, and need to be reflected in the property's value.

Response. EPA agrees that the promulgation of lead hazard standards may have an impact on residential property values, but the inclusion of property values in the economic analysis would be inappropriate for several reasons. First, the extent of the price changes is unknown. As the first comment described above says, the information provided by the section 403 standards will help rationalize the market for older housing and housing in depressed areas by reducing uncertainty and providing a workable basis for lenders and purchasers to easily and reliably identify the level of risk associated with the presence of lead-based paint. The extent to which property values for homes without lead hazards might increase due to the publication of these standards, the degree to which these increased property values will off-set the decreases in other property values, and the time period it will take the market to adjust are not known at this time, and would be difficult, if not impossible, for the Agency to predict.

Even it this information were available, however, the Agency does not believe that it should be included in the economic analysis. The risks posed by the presence of these lead hazards are unchanged by the standards themselves. Children living in these units are exposed to the lead, regardless of the standards, until some action is taken. The reduction in property values that may result from buyers and renters knowing about this situation is simply a shift of the costs from the occupants to the owners, or in the case of owner-occupied units, a shift from an implicit to an explicit cost. Since it is not an additional cost to society, it is not included in the calculation of the costs of the regulation. If the value that purchasers and renters place on avoiding these lead hazards is greater than the cost of the abatement or other interventions, then the reduction in property values will exceed the cost of fixing the problem. This situation presents a strong incentive to the property owner to remove the hazard because the resulting increase in the value of their property will exceed their outlay.

The section 403 standards distinguish situations where lead is present but does not constitute a hazard from situations where the presence of lead would result in adverse health effects and remediation actions should be taken. The intent is to provide information so that individuals are better able to determine when they should act to reduce their exposure and when such actions are not warranted. Section 403 and the rest of Title X presents a very measured response to the problem of childhood lead poisoning. The standards identify those properties that present a lead hazard and separate them from properties that do not present hazards. Although an action can be taken to mitigate or eliminate an identified hazard, this regulation does not mandate any such actions.

7.3 The hazard standards proposed by EPA would impose significant costs on owners of low-income rental housing and result in abandonment of some units, reducing the supply of affordable housing. A paper by two economists at the Office of Management and Budget (OMB), Fraas and Lutter (1996), estimated the impact of hypothetical paint abatement requirements. Their calculations indicate that increasing annual expenses associated with ownership of a rental dwelling by an amount equal to 1 percent of the annual real estate tax increases the number of dwellings that are abandoned by 2 - 2.5 percent per year.

Using Fraas and Lutter's methodology, it was calculated that soil removal for yards greater than 400 ppm of lead could result in an incremental abandonment of rental housing ranging from 0.2 – 1.0 percent, depending on the number of units per dwelling. The commenter also contends that soil abatement costs are higher than estimated by EPA. If the higher soil abatement costs were compounded over the period ten years, losses would range from 2 - 10 percent. Losses among owner-occupied dwellings would be similar.

A rental property owner trade association also use this methodology to estimate that EPA's proposed standards will lead to an increase in abandonment of as much as 43 percent annually, or a decline of roughly 70,000 units per year. [These estimates are based on elasticities of abandonment calculated by Arsen 1992 and presented in Fraas and Lutter. LIA also assumed an average annual abatement cost of $100 (calculated by annualizing the EPA's estimated $52.8 billion present value of total costs over 50 years at 3 percent), and 20.6 million units requiring abatement.]

A city community development agency agreed with the argument that some groups and individuals have made that the adoption of a more stringent soil hazard standard - given the substantial costs of soil abatement - may influence the decisions or actions of owners of target housing in unintended ways.

Lutter also cites his 1996 article with Fraas that estimated the effects of mandatory abatement on the housing supply by assuming that regulatory costs needed to comply with lead standards have the same affect on abandonment as property taxes. Lutter estimated that total incremental abandonment could be as high as 2 million units over 10 years. Lutter states that the abatement costs presented by the EPA are close enough to those proposed by Fraas and Lutter to suggest that their argument is correct.

Response. EPA disagrees that this rule will result in any significant abandonment of housing. In the first place, there is no requirement to abate any soil or even an absolute recommendation to perform abatements as a result of this rule. Thus, any analysis that assumes that abatements will occur as a result of this rule is skewed toward the absolute worst case approach.

Affordable housing in this country falls into three categories, depending on its funding: publicly-provided, publicly-assisted, and private-sector housing. Although the section 403 standards do not require any action, housing in the first two groups will be required under other regulations to control hazards as defined by these standards. Thus the impact of the standards on the availability of affordable housing will differ between public and private housing.

In the case of publicly-provided and publicly-assisted housing, the concern is not so much with abandonment, but with the potential constraints on hazard control and other upgrading/modernization efforts due to budget limitations. On the one hand, the promulgation of the section 403 standards may provide a basis for increasing these budgets to cover some of the costs. In the absence of sufficient budget increases, housing authorities will need to make choices among the competing needs. With this in mind, EPA carefully considered the costs of hazard control actions, along with the benefits when setting the final section 403 standards.

On the private-sector side, actions are not required under section 403, and the supply of affordable housing is largely affected by market forces including the interplay of these standards with other market forces and liability concerns. While economic theory suggests that introducing awareness of a new factor in evaluating housing quality may have an impact on the market for housing, and that on the margin some housing stock that would otherwise be viable property may get squeezed out of the market, the comments greatly exaggerate the extent of this impact. In the only study which attempts to directly measure the impact of abatement costs on abandonment, Ford and Gilligan ("The Effect of Lead Paint Abatement Laws on Rental Housing Values," Deborah Ann Ford and Michelle Gilligan, *AREURA Journal*, Vol. 16, No.1, 1988) show that abandonment due to lead paint abatements will occur infrequently. This is further supported by data they present from the Baltimore City Health Department which found no cases of abandonment in response to their mandatory abatement program.

Using the results of the Fraas and Lutter paper to estimate the likely number of abandonments is inappropriate in this situation and likely to overestimate the impact on abandonment rates for three important reasons. First, property tax payments are not analogous to lead interventions under section 403 because property tax payments are mandatory while the interventions are not. If the owner is unwilling or unable to pay increased property taxes, then she can be forced to relinquish the property to the municipality. On the other hand, if the owner is unwilling or unable to pay the cost of the lead intervention, the property is not necessarily abandoned; the intervention does not take place.

Second, the Fraas and Lutter study relies on elasticities (published in an article by Arsen) which were estimated using data on the number of properties in tax default foreclosure. As previously discussed by EPA in response to similar comments on their section 402/404 regulations tax default foreclosure is not the same as abandonment, and is likely to overstate the actual rate of abandonment. Property can be in foreclosure and still be in use or available for use.

Third, one of the results of a lead-based paint intervention is the possible increase in the value of the property due to the improvement, offsetting the cost of the intervention at least in part. There is no similar increase in property values associated with increases in property taxes, if the increase is due to the higher cost of providing services, as opposed to an increase in services. This offsetting increase in property values provides an incentive for owners to perform interventions, not walk away from their properties.

7.4 EPA's conclusion that the regulation will not have a significant impact on housing supply is based on an analysis with four serious deficiencies. First, the EPA assumes that no multi-family units will incur soil abatement costs. This is inconsistent with other parts of the EPA's cost analysis and is implausible, especially if the standards become effectively mandatory.

Second, the EPA assumes that all units will incur average abatement costs. In fact, abatement costs will vary among different homes. Some rental units may have costs far above the average, and some will have costs far below the average. It is among these non-typical units that abandonment is especially likely.

Third, the EPA conducts this analysis assuming births trigger abatements. Impacts would be better estimated by assuming compliance is triggered by promulgation of the rule, at least for landlords.

Finally, the Property Owners and Managers Survey used by the EPA excludes owner-occupied dwellings, although older two-family owner-occupied dwellings represent the dominant residential structure in large portions of northeast cities like Rochester and Buffalo, New York.

Response. EPA disagrees with these comments.

The first deficiency mentioned, that the analysis assumes that no multi-family units have soil lead levels that exceed the proposed standards of 2000 ppm, is moot. Under the final regulations the soil standard is set at 400 ppm for play areas, and 1200 ppm for non-play areas.

At the soil hazard level for non-play areas, over 280 thousand multi-family units are estimated to exceed the standard and are assumed to potentially become the subject of a soil abatement in the analysis. Although this rule does not mandate an abatement, in assessing the potential costs associated with this rule, the Agency assumes that hazards will be addressed through abatements. The Agency recognizes that other response actions are possible, but believes that using an abatement assumption in the economic analysis provides the potential maximum costs.

With respect to the second claimed deficiency, data are not available which allow for a matching of rent streams to the incidence of lead as suggested by the comment. Instead, the average incidence of lead is used in the analysis. The analysis does, however, take into account the various sizes of buildings (in terms of number of units) and their actual rent streams. Thus the cost per individual building is based on the number of units in the building and the average incidence of lead – buildings with more units are more likely to have to perform abatements. Since the analysis assumes that there is a single abatement cost for each medium (for multi-family units and another for single family housing units), once a building exceeds the standards, the costs are a function of the number of units in the building, not the severity of the lead levels. While the use of averages does underestimate the number of buildings with larger than average abatement costs to revenue ratios, it also underestimates the number with smaller than average ratios. Offsetting any potential underestimate of the impact on landlords is the assumption that all landlords will have interventions performed whenever the building exceeds the standards and a newborn child is introduced into the building. Such abatement actions are not required under section 403 and landlords are likely to consider their alternatives, the associated costs of those alternatives, and other relevant factors, taking that action which makes the most economical and practical sense to them.

On the third point, consistent with the rest of the analysis, and with the recommendation that lead interventions be done whenever a young child is present, the analysis assumes that interventions will occur at the birth of a child. This is discussed earlier in this Response To Comment document. Moreover, because a variety of factors may affect the decision and timing of the interventions, there is no reason to assume that the entire building will be addressed at the time the standards are promulgated. If the landlord were to decide to abate the entire building at one time, however, it is likely that he/she would finance these costs over several years. In such a case, the costs should be amortized over the life of the loan, and this annualized amount compared to the annual revenues of the building, which is similar to the estimation procedure used in the analysis.

On the fourth point, the comments address the small business analysis, which by definition did not analyze owner-occupied housing. Owner-occupied, two-family housing presents a special case, with the owner both the occupant (of one unit) and landlord (of the other unit). While data limitations prevent our directly analyzing these cases, as with the second set of comments above, lead-based paint interventions are not required and presumably will not be undertaken unless profitable.

7.5 The City of Cambridge, Community Development Department argues that because the soil hazard regulations apply to all pre-1978 residential housing units that receive federal funds, project costs will be increased significantly. An additional cost of several thousand dollars for each federally funded housing rehabilitation project in Cambridge would dramatically reduce the number of low income residents that their programs could serve each year. Cambridge was concerned that the Home Improvement Program moderate rehabilitation projects may no longer be cost-effective give the additional costs of soil abatement and disposal.

Another city housing agency expressed concern that the failure of the standards to focus on units with children could make it difficult to respond to other repair needs in residential property, which may also impact the well being of tenants. This commenter also stated that a mandate to perform building-wide assessments could adversely impact ongoing renovation and disposition programs due both to financial impact and potential liability issues.

Response. The standards serve as guidance to the general public by providing property owners and other decision-makers with the Federal government's best judgement concerning lead dangers in residential paint, dust, and soil. To promote cost-effective approaches to risk reduction, EPA intends also to publish guidance that explains to the public why efforts should be focused on older poorly maintained properties. Combined with this guidance, these standards are intended to help the public determine when properties should be evaluated for the presence of those hazards or levels of concern and what the most appropriate response action is.

On the other hand, the standards are not intended to replace local decision-making. Individuals on-site are in the best position to judge what actions should be taken and to assess the tradeoffs among possible actions. These lead-hazard standards do not mandate actions to be taken at the local level; decisions about the relative importance of various repairs will continue to be made at the local level.

Regulatory Flexibility Act

7.6 The National Multi-Housing Council (NMHC), a trade association of apartment owners, challenged EPA's conclusion that the proposed rule will not have a significant economic impact on a substantial number of small entities. NMHC argued that the proposed rule will affect a substantial number of small entities and will have a significant economic impact on these small entities. According to NMHC, costs of this order of magnitude are highly significant across the spectrum of rental housing and will exacerbate the shortage of affordable housing. NMHC further argued that, according to data in the 1992 Census of Finance, Insurance, and Real Estate, 98 percent of the 40,455 firms that reported their business as "operator of apartment building" are small businesses under the economic definitions used by the Small Business Administration.

NMHC analyzed the expected costs of complying with the §403 proposed regulations and found a much higher cost of complying with the proposed regulations and a much higher frequency of intervention. However, even using the Agency's analysis the group questioned EPA's conclusion that "...no property owners experience a cost to rent ratio larger than 3%.... The §403 rule [if finalized as proposed] will not have significant economic impact on a substantial number of small entities." Based on data from national surveys by the Institute of Real Estate Management and other organizations, total operating expenses of apartment properties average 40 to 50 percent of rental revenues and thus, as a percentage of operating costs, 3 percent becomes at least 6 percent. NMHC argues that costs of this order of magnitude are highly significant across the spectrum of rental housing and that the proposed regulation will exacerbate the shortage of affordable housing particularly for low income households.

Finally, the industry group provides qualitative evidence that small property owners may be significantly affected by the proposed rule. The 1995 Property Owners and Managers survey reported that small property owners are very concerned about the implicit financial burdens associated with federal lead-based paint requirements.

Response. EPA finds no reason to change its certification pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), that this rule will not have a significant economic impact on a substantital number of small entities based on the fact that the rule does not mandate any action or directly impose any costs. See Preamble to the proposal at 30351.

It is important to first note that any effect of other lead rules on small entities was evaluated in the context of those rules when they were promulgated under Title X. See section 1018 regulations at 61 FR 9064, 9081 (March 6, 1996), section 402 regulations at 61 FR 45778, 45810-11 (August 29, 1996), and section 406 regulations at 63 FR 29908, 29917-18 (June 1, 1998). In promulgating each of those rules, the Agency assessed the related small entity impacts, explored and adopted options to reduce adverse economic impacts on small entities, and provided a complete explanation of the Agency's decisions in those final rules. Since this rule does not impose any requirements, it is not necessary to revisit those assessments.

The purpose of the RFA is to ensure that, in developing rules, agencies identify and consider ways of tailoring regulations to the size of the regulated entities when appropriate. The RFA does not require an agency to minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. When applicable, the RFA generally requires that agencies:

s) determine, to the extent feasible, the rule's potential economic impact on small entities directly and adversely impacted,

t) explore regulatory options for reducing any significant economic impact on a substantial number of such entities, and

u) explain the agency's ultimate choice of regulatory approach in the rule.

Although the establishment of the standards in this rule does not, in and of itself, mandate any action, or directly impose any costs, the Agency recognizes that the existence of the hazard standards may influence the decisions or actions of owners of target housing, and that the standards may also be used or relied on in other regulatory programs, both at the federal level and by States or Tribes. As a result, the Agency considered the potential costs and benefits associated with the various regulatory options proposed and the related possible actions that a small entity could or might take based on the hazard standard established under this rule. As noted in the Economic Analysis (EA) the section 403 standards are designed to inform decisionmakers about what conditions constitute a hazard and recommend potential actions. See the EA section 9.1. The only extent to which section 403 standards may be enforced would occur if state or local governments decide to impose their own requirements based on the standards. Nevertheless, EPA conducted an analysis of the potential impact of the 403 standards on small entities as they may work within the market. The Agency acknowledged that these standards might influence mortgage lenders and that they might have indirect effects in tort liability suits as guidance for courts in determining whether a property owner's decision not to intervene may be an act of negligence. See the EA section 9.1.2. It is this incidental analysis that is actually addressed by these comments.

To the extent that the comment challenges the market, as opposed to the regulatory, implications of this rule, EPA disagrees that this rule will have a significant effect on a substantial number of small entities. The data used by EPA in the analysis indicate that an estimated 2 million firms (99.6%) in this industry are small businesses using the Small Business Administration's threshold, and thus any regulation of this industry will affect a substantial number of small firms. However, EPA's findings indicate that these impacts will not be significant. EPA's analysis shows that approximately 99% of these small firms will have less than a 1% impact on revenues due to this rule. Approximately 1% of small firms will experience impacts in excess of 1% but less than 3% of rental revenue. EPA's estimates indicate that no small firms will experience impacts greater than 3% of rental revenue and NMHC gives no indication that such greater impacts will be felt. Instead, NMHC merely asserts that these costs "could" be significant and "could" be the difference between profit and loss.

Part of the difference between the EPA analysis and the NMHC interpretation of impacts is that NMHC argues that the transaction trigger model, presented in EPA's sensitivity analysis, more accurately portrays behavior than the birth trigger model used by EPA in the economic analysis. EPA's continued support for use of the birth trigger model is discussed earlier in this Response to Comment document. Even if property owners chose to intervene in all units regardless of whether a child is present, they are not likely to always chose the more expensive response of abating the lead hazard, which the analysis assumes, and instead may chose one of the other available options for mitigating or reducing the lead hazard.

While NMHC alludes to the fact that some firms are marginally profitable, thus implying that profits could be lower than the 3% of revenues that this rule could cost, they provide no indication of how many firms would be affected at this level, and EPA could not identify any other data regarding such firms. Certainly, compliance costs of any magnitude may cause firms that are only marginally profitable to cease operation. However, the question for RFA purposes is not whether there are any small businesses that may experience a significant adverse impact, but whether there will be a **substantial number** of small businesses that will experience a **significant direct and adverse** impact. As with many industries EPA analyzes for small business impacts, data on the distribution of profit margins are not available for the rental property management industry and NMHC supplies no data on this. Therefore, the range of revenues for an average-sized firm (average in terms of number of housing units owned) is used on the assumption that smaller revenues for a given number of units is associated with smaller profits. The idea is to provide an indication of the ability of firms to absorb compliance costs and not to assess the magnitude of these costs compared to other costs the firm faces, and the 3% benchmark was developed to apply to annual revenues.

These impacts must be evaluated in terms of the risk reduction that will result from the rule. The benefit cost analysis approach was employed to ensure that the rule was reasonable in terms of the amount of risk reduction obtained. In compliance with the RFA requirements, EPA has estimated, to the extent feasible, the rule's potential economic impact on small entities directly and adversely impacted; explored and chosen regulatory options that minimize, to the extent feasible, those potential economic impacts on small entities; and has thoroughly explained its decisions.

Environmental Justice Executive Order

7.7 The proposed section 403 Standards do not address the disproportionate exposure to lead among disadvantaged children who have a higher prevalence of elevated blood-lead levels because uniform national standards based on average exposure scenarios do not adequately protect children who have greater exposure to lead from residential paint, dust, and soil as well as exposure from other sources. Reliance on program implementation to protect these children, as suggested by EPA, is not sufficient.

Response. The Agency believes this comment is a misunderstanding of its analysis to establish these standards and offers the following explanation. While the analysis uses statistical averages, it nonetheless incorporates a measure of variability (geometric standard deviation or

GSD) to account for a variety of behavioral and other differences among children. Thus, the consideration of children who are at greater risk are, in fact, incorporated into the decision-making process.

EPA believes that it has selected standards that are likely to identify hazards in properties in the same communities where children with elevated blood lead levels live, focusing resources on vulnerable populations. This is particularly true given the final standards, which target play areas as soil-lead hazards at 400 ppm of lead, sets the rest of the yard standard to 1,200 ppm, set the dust lead hazard at 40 ug/sq.ft, set a paint-lead hazard at any deterioration of lead-based paint, and include carpeted floors in its dust-lead hazard.

Furthermore, disadvantaged children will benefit from implementation efforts such as EPA's education and outreach program, HUD's abatement grant program, and CDC's new screening guidelines. The guidance focuses on older properties that are not well maintained, which will also help target efforts on the most vulnerable children.

EPA believes that it would be inappropriate to set standards by only using the most vulnerable children as the average situation. The result of such an approach would be to spread resources across a significantly greater number of properties, leaving fewer resources to help protect the children at greatest risk. In fact, this very concern was expressed by advocates for at-risk children at a stakeholder dialogue meeting.

7.8 EPA received a significant number of comments related to the regulatory development process. Several persons who submitted requests to extend the public comment period criticized the Agency for limiting public notice to the Federal Register, stating that this fails to provide the public with adequate notice.

Response. EPA respectfully disagrees and points out that the Agency provided public notice in a variety of ways, including the Federal Register, press statements, mass mailings, communications via interested stakeholders such as trade associations and citizen groups, and on EPA's Internet site where nearly 4,000 "visits" were counted. EPA also held several public meetings designed to elicit comment from at-risk communities. A review of the record suggests that EPA has been successful in its outreach efforts. The agency received over 500 comments from national and local advocacy groups, state and local governments, community-based organizations, industry, private citizens, military base closure advisory boards, and other Federal Agencies.

As explained in the preamble to the proposal (63 FR 30307), EPA solicited public input through a stakeholder dialogue process. The Agency held five meetings with this stakeholder group. These meetings were open to the public and each meeting included an opportunity for the public to offer oral comments. In addition to the dialogue process, EPA provided updates on the rulemaking process at conferences and other events. Agency staff also met occasionally with interested parties to obtain information on specific issues of concern.

7.9 EPA's decision-making was biased because it consulted with a variety of groups but failed to seek input from tenants and families with small children and representatives of the environmental justice community.

Response. Again, EPA respectfully disagrees. Both groups were represented in the Agency's Dialogue Process, established to support this rule. Among the 25 representatives on the Dialogue were two members of the National Environmental Justice Advisory Council (NEJAC), a member of United Parents Against Lead, and several other advocates who represent environmental justice interests. Moreover, this input has been supplemented by numerous written comments raising environmental justice concerns and oral presentations at two public meetings.

7.10 A number of persons requested that EPA hold public meetings to discuss the proposed rule, and suggested that EPA affirmatively seek input from low-income communities, communities affected by closing military bases, local health departments, and other interested parties.

Response. In response to these comments EPA held two public meetings. The first was held in San Francisco on December 4, 1998. The first third of this meeting was a panel discussion on EPA's risk management choices. Panel members were national lead experts representing a range of perspectives. The remainder of the meeting was a public hearing in which members of the public could offer comment. Most persons who commented were members of communities affected by high levels of lead exposure.

EPA held a second public meeting on February 16, 1999 in Washington, DC focusing on environmental justice issues. Four members of NEJAC offered oral comments. Several members of the public also spoke.

7.11 One person who requested a public meeting on the rule, objected to the public meeting held by EPA in San Francisco on December 4, 1998, because it was not accessible to low-income groups from urban areas in the east and Midwest. This person also criticized the "panel of experts" assembled by the Agency for this public meeting, asserting that it was monolithic, could not represent the issues and concerns of those affected by lead poisoning, and most of the individuals on the panel were clearly in favor of the proposed regulations.

Response. Although the location of this particular meeting could not accommodate everyone interested, the Agency believes that it did make a considerable effort to reach out to as many interested parties as possible as noted above. In addition, the panel of experts assembled by the Agency represented a broad range of perspectives, from the lead industry's trade association to a lead researcher who focuses on the exposure to soil and environmental justice concerns. Although EPA would have been pleased if all panelists supported the rule, that was certainly not the case, since a number of panelists were clearly critical of the proposed rule.

7.12 NEJAC claimed that EPA failed to provide adequate notice for its second public meeting and, therefore, only four of its members and no representatives of environmental justice communities attended.

Response. Again, this is rather unfortunate. However, the Agency believes that it made a considerable effort to involve as many stakeholders as possible. In fact, EPA even sent individual invitations to all members of NEJAC to attend the February 16, 1999 meeting. Nevertheless, EPA believes that there have been many opportunities for stakeholders interested in environmental justice issues to participate and provide comment to the Agency during the development of this rule, and, as evident by the protective standards established in the final rule, that the Agency has considered environmental justice issues in its final decision-making.

7.13 Private citizens and community groups criticized EPA for what they perceived to be a violation of Executive Order 12898, which states that "... each Federal Agency shall work to ensure that documents relating to human health or the environment are concise, understandable, and readily accessible to the public." These persons felt that the economic analysis of the proposed rule was confusing and did not meet this accessibility criterion. The Atlantic States Legal Foundation stated that the regulations fail miserably, by proposing a framework that is too complicated for people to understand or implement.

Response. EPA has attempted to make the final rule as simple to understand as possible and believes it has succeeded. However, underlying these standards is a complex and comprehensive analysis of the risks and economics associated with lead-based paint hazards and their identification and control. This analysis is based on complicated issues including analysis of epidemiological data, modeling, and evaluating health effects. The complexity of the analysis is an inherent part of the subject matter and environmental standard setting. In attempt to make the analysis more accessible to disadvantaged populations, EPA has revised the Economic Analysis to improve clarity. Both the preamble to the proposed rule and the preamble to the final rule, contained units that provide an overview of the standards free of complicated analytical discussion. In addition, the Agency has developed outreach materials and intends to issue specific guidance documents to help ensure that the public is informed about the dangers of lead exposure and suggested interventions.

Children's Health Protection Executive Order

7.14 EPA failed to comply with Executive Order 13045 (Protection of Children form Environmental Health Risks and Safety Risks) because the proposed standards are associated with excessive levels of risk. As pointed out by NEJAC, EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) for lead in children indicates that even at 1200 ppm lead in soil, the risk of exceeding 10 μg/dl is 30 percent or higher.

Response. E.O. 13045 applies to any rule that: (1) is determined to be "economically significant" as defined under OMB's guidance related to section 3(f)(1) of E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA's analysis includes all the factors required to be considered in the E.O., including evaluation of alternative options, and why the selected standards are preferable to other options.

Furthermore, EPA points out that its final rule establishes a soil-lead hazard standard of 400 ppm for play areas and 1,200 ppm for the remainder of the yard, thus, mitigating the comment's concern. In addition, while the comment presents a correct statement about EPA's modeling, the Agency notes that its analysis had to consider a variety of models that suggested a variety of standards and other models showed that standards should be higher, as noted elsewhere in the preambles to the proposed and final rules and in this Response to Comment document. Moreover, the 1,200 ppm discussion in the proposal would be an overestimate of the effects of the final rule because the analysis in the proposal was derived without consideration of a play area. With separate consideration of a play area, the overall individual risks will likely be lower.

7.15 EPA violated the Executive Order because it did not consider pica for soil in its analysis and, therefore, the standards would not protect children who exhibit pica for soil.

Response. EPA disagrees, as noted earlier in the Response to Comment document, the analysis accounts for children with pica. The empirical model is based on data from approximately 200 homes in Rochester, New York, and reflects a range of pica behavior from little to no ingestion to higher rates of ingestion. In addition, EPA applies a standard deviation that accounts for variation in factors such as soil ingestion. The IEUBK model uses a default soil ingestion rate and applies a standard deviation which accounts for variation of factors such as soil ingestion. Furthermore, as indicated previously, given the focus of this rulemaking the Agency is not required to conduct a separate analysis under this E.O. Nor does this E.O. require the Agency to take any other specific actions as implied by the comment.

National Technology Transfer and Advancement Act

7.16 EPA received a number of comments stating that EPA should have referenced voluntary consensus standards in the rule. All of the standards referenced by commenters address sampling collection and analysis (e.g., methods for collecting a dust wipe sample).

Response. As stated in the preamble to the proposed rule (63 FR 30353), Section 12(d) of the National Technology Transfer and Advancement Act of 19995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. In the proposal (63 FR 30353), the Agency determined that the regulation did not involve any technical standards that would require consideration.

The standards being set by today's action are hazard standards for residential lead-based paint and lead-containing dust and soil. There are no relevant voluntary consensus standards involving these hazard standards and, therefore, NTTAA does not apply.

With respect to standards involving sampling collection and analysis, EPA notes that the regulations promulgated today, as well as applicable guidance documents, do identify a number of voluntary consensus standards for sampling collection and analysis, such as those developed by ASTM.