

## 1.0 INTRODUCTION

On June 3, 1998, the U.S. Environmental Protection Agency (EPA) proposed regulation to establish standards for lead-based paint hazards in most pre-1978 housing and child-occupied facilities (40 CFR Part 745, “Lead; Identification of Dangerous Levels of Lead; Proposed Rule”). EPA proposed these standards in accordance with Section 403 of the Toxic Substances Control Act (TSCA), as amended by Title X, the Residential Lead-Based Paint Hazard Reduction Act of 1992. The proposed standards are as follows:

- Dust-lead hazards: Household average dust-lead loadings equal to or exceeding 50  $\mu\text{g}/\text{ft}^2$  on uncarpeted floors and 250  $\mu\text{g}/\text{ft}^2$  on window sills, assuming wipe collection techniques for dust;
- Soil-lead hazards: Total lead levels equal to or exceeding 2,000 ppm based on a yard-wide average soil-lead concentration
- Hazardous lead-based paint: Lead-based paint in poor condition, defined as follows:
  - More than 10  $\text{ft}^2$  of deteriorated paint on exterior components with large surface areas
  - More than 2  $\text{ft}^2$  of deteriorated paint on interior components with large surface areas
  - Deteriorated paint consisting of more than 10% of the total surface area of exterior or interior components with small surface areas.

These standards, a focal point of the Federal lead program, identify the presence of lead-based paint hazards, defined within TSCA Section 401 as the condition of lead-based paint and the levels of lead-contaminated dust and soil that “would result” in adverse human health conditions.

To provide a scientific basis for selecting the §403 standards, EPA conducted a risk analysis to assess the health risks to young children (aged 1-2 years) from exposures to lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil in the nation’s housing. This risk analysis also documented EPA’s approach to estimate the reduction in these risks following promulgation of the §403 standards and applied this methodology to evaluate example options for the §403 standards. Finally, the risk analysis provided estimates of the numbers of homes and children that would be affected by various example standards. EPA published this risk analysis in June, 1998, in a document hereby referred to as the “§403 risk analysis report” (USEPA, 1998a).

A period of public comment followed publication of the §403 proposed rule, extending to March, 1999. Several comments received during this period requested additional analyses and investigation. In addition, the Environmental Health Committee of EPA’s Science Advisory Board (SAB) performed a review of the technical aspects of the §403 risk analysis, the §403 economic

analysis, and the proposed rule. While the SAB concluded that many approaches taken in the §403 risk analysis were technically sound and scientifically defensible, their final report provided detailed comments and recommendations for additional investigation and analysis to be considered when preparing a final rule (USEPA, 1998b).

This report is a supplement, or addendum, to the §403 risk analysis report. It contains additional information obtained since the report was published that further supports the findings and conclusions made in that report. It also contains the results of additional analyses requested by the SAB and by key public comments. This supplement does not replace any parts of the original risk analysis, but rather supplements the original risk analysis with more detailed analyses on selected topics.

Reflecting its close ties to the original §403 risk analysis report, this supplement contains the same chapters as those found in the §403 risk analysis report. These chapters represent the different components of the risk analysis: Hazard Identification, Exposure Assessment, Dose-Response Assessment, Risk Characterization, and Analysis of Example Options for the §403 Standards. The additional analyses and investigations presented in this supplement are found within the specific chapters to which their findings contribute. Each analysis or investigation is presented as an independent module within each chapter. See the chapter introductions for the contents of each chapter and the motivation for each analysis being presented. Furthermore, the reader is referred to the §403 risk analysis report for details on the risk analysis approach and findings.

## **1.1 PEER REVIEW**

This report was reviewed independently by members of a peer review panel who, together, had considerable knowledge on the subject areas addressed in this report. The three reviewers on this panel who provided EPA with comments on this report were:

Dr. Ruth Chen, Tennessee Department of Health  
Joseph Schirmer, M.S., Wisconsin Division of Health, Bureau of Public Health  
Nellie K. Laughlin, Ph.D., Harlow Center for Biological Psychology, University of Wisconsin-Madison.

Two of these reviewers (Dr. Chen and Mr. Schirmer) also provided peer review comments on the §403 risk analysis report prior to its 1998 publication. Therefore, they were previously aware of the issues addressed and approaches taken in the original §403 risk analysis. The third reviewer (Dr. Laughlin), while not involved in the review of the §403 risk analysis report, was provided a copy of this latter report for reference while reviewing the present report. Dr. Laughlin was selected primarily based on her involvement in research to investigate the health effects of lead exposures in various animal species, which is addressed in Section 2.1 of this report.

EPA asked the peer reviewers to provide general comments and suggestions concerning this report. In addition, EPA suggested that the reviewers provide more detailed comments on those sections of the document addressing specific components of the risk analysis in which the reviewer had a particular technical expertise.

The peer reviewers were appreciative in regard to the additional information being provided in this supplement report. They did provide some useful suggestions for additional additions and revisions, however, which were considered when finalizing this report. The remainder of this section discusses how the peer review comments led to report modifications.

One reviewer questioned the usefulness of measuring IQ decrements greater than 1, 2, or 3 resulting from lead exposure, which the risk analysis has included among the health effect endpoints that were estimated. This reviewer pointed out that in an individual child, the variability associated with a measured IQ score is generally greater than the decrement measures of 1, 2, or 3 being considered in the risk analysis. While this may be true, the risk analysis is targeting the decrement in IQ score that occurs on average, across an entire population of children, rather than in an individual child. The variability associated with estimating the mean IQ in a population of children is much smaller than the variability of an individual child's IQ score, thereby allowing the risk analysis to consider these types of IQ decrements. To emphasize and clarify this point to the reader, initial introductions of these health effect endpoints in this report have been revised to refer to "IQ score in the population of U.S. children."

Peer reviews of Section 2.1 of this report, which addressed the adverse health effects associated with lead exposure as observed in animal studies, resulted in considerable revision to this section. Suggestions were followed to re-format Section 2.1.2 to resemble the format of Section 2.1.3, where detailed results of specific studies were incorporated within the general discussion of observed health effects across studies. Additional published articles on specific studies that were suggested and/or provided by the reviewers were obtained and reviewed, and their relevant results were added to the discussion within Section 2.1.2. The articles suggested by the reviewers tended to focus on the effects of lead exposure on the visual and auditory systems and on social development and behavior. Requests for additional information on selected discussion items were addressed by re-reviewing the relevant references that had previously been cited and augmenting the discussion. Finally, general clarification points raised by the reviewers on the content of the section were incorporated when revising the section.

EPA has established a public record for the peer review of this report under administrative record AR-188, "Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil: Peer Review." The record is available in the TSCA Nonconfidential Information Center, which is open from noon to 4 PM Eastern time Monday through Friday, except legal holidays. The TSCA Nonconfidential Information Center is located in Room NE-B607, Northeast Mall, 401 M Street SW, Washington, DC.