

UNITED STATES GOVERNMENT

MEMORANDUM

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U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

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JUN 3 1993

TO : The Commission
Through: Sadye E. Dunn, Secretary
Eric C. Peterson, Executive Director
FROM : Jerry G. Thorn, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (504-0980)
SUBJECT: Regulatory Investigation Concerning Levels of Lead in Paint

BALLOT VOTE DUE

JUN 22 1993

Attached is a staff briefing package that discusses the status of the regulatory investigation concerning whether the Commission should lower the allowable levels of lead in the Commission's ban of lead-containing paint and certain articles bearing such paint, 16 C.F.R. Part 1303. This investigation was the result of new information indicating that children are more sensitive to the adverse effects of lead exposure than was previously believed. The Commission published a notice of "Regulatory Investigation" ("NRI") in the Federal Register on April 30, 1992, requesting information on this issue.

Based on the latest available information, the staff recommends that the Commission terminate this investigation because of the small risk of serious adverse health effects from currently-marketed paints. Please indicate your vote on the following options.

I. TERMINATE THE REGULATORY INVESTIGATION FOR LEAD IN PAINT.

(Signature)

(Date)

II. THE STAFF IS DIRECTED TO CONTINUE THE REGULATORY INVESTIGATION TO SEEK FURTHER DATA ON HUMAN EXPOSURE TO LEAD IN PAINT AND ON THE COSTS AND BENEFITS OF A LOWER LIMIT ON LEAD IN PAINT.

(Signature)

(Date)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial nh Date 6/3/93

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III. THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE TO PROPOSE TO LOWER THE LIMIT FOR LEAD IN PAINT, FOR THE COMMISSION'S CONSIDERATION.

(Signature)

(Date)

IV. IF THE COMMISSION VOTES TO TERMINATE THE REGULATORY INVESTIGATION, THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE ANNOUNCING THIS DECISION.

(Signature)

(Date)

V. OTHER (please specify).

(Signature)

(Date)

Comments/Instructions:

OS#5190

BRIEFING PACKAGE

**REGULATORY INVESTIGATION CONCERNING
LIMITS FOR LEAD IN PAINT**

For further information, contact:

Brian C. Lee, Ph.D., D.A.B.T.
Directorate for Health Sciences
301-504-0994

CPSA 6 (b)(1) Cleared

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EXECUTIVE SUMMARY

The Commission issued a notice of regulatory investigation (NRI) in the Federal Register on April 30, 1992, requesting information to address data gaps in its investigation of limits for lead levels in paint. The renewed concern about lead in paint resulted from the application, by CPSC staff, of new data on the adverse health effects of low level lead exposure. Using exposure assumptions similar to those applied in the development of the current 0.06 percent limit (by dried weight), the staff estimated a maximum allowable limit of 0.01 percent to prevent lead poisoning.

The staff conducted a study to determine the lead levels in paint currently representative of the national market. Of the 433 national samples, 90 percent were below 0.01 percent. All but one of the samples were in compliance with the present 0.06 percent standard. Thus, 90 percent of the market currently complies with a theoretical 0.01 percent limit.

Costs to the industry to achieve a greater percentage of compliance cannot be estimated. The source of lead contamination is believed to be the earthen paint pigments. It is not known whether changing raw material sources, blending batches, or disposal methods would be used to achieve a lower lead level.

The health benefits of a lower lead limit would be small since the average lead level in current paint is already well below 0.01 percent. The industry-wide average is 0.004 percent, which is lower than the 0.025 percent average measured by the staff in 1978-1979. Additionally, data submitted in response to the NRI implies that paints manufactured today are less dense than those in the past. Application of these data to the assumptions used in calculating the lead in paint limit would raise the theoretical target limit from 0.01 to 0.02 percent.

No data were received in response to the NRI regarding the amount of paint ingested each day by children. Obtaining this critical information was a major reason that the staff recommended issuance of the NRI. Since no information was obtained, it is difficult for the staff to determine a definitively safe limit for lead in paint.

Insufficient data exist to indicate that paints exempted from the current standard could produce a hazard with the finished product. Exempted paints include those used for mirror backing and art work. Data were also insufficient to develop adequate exposure scenarios for typical application or removal of architectural and exempted paints.

Due to the difficulty in supporting a lower limit and since most paint is already below 0.01 percent, the staff recommends ending activities to lower the limit for lead levels in paint.

OS# 5190

UNITED STATES GOVERNMENT
MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

TO: The Commission

JUN 3 1993

THROUGH: Sadye E. Dunn, Secretary *SD*
Jerry G. Thorn, General Counsel *JGT*
Eric C. Peterson, Executive Director *EC*
Bert G. Simson, Assistant Executive Director for Hazard
Identification and Reduction *Bert G. Simson*
James F. Hoebel, Acting Associate Executive Director
for Health Sciences *JFH*
Murray S. Cohn, Ph.D., Director, Division of Health
Effects *MSC*

FROM: Brian C. Lee, Ph.D., D.A.B.T., Manager, Lead Poisoning
Project, Directorate for Health Sciences
(301-504-0994)

SUBJECT: Regulatory investigation concerning limits for lead in
paint

I. Background

Paint is a major contributor to lead poisoning in children in the U.S. Because of this, the Commission limited the maximum allowable level of lead in dried paint to 0.06 percent by weight (16 C.F.R. Part 1303). Recent data on the adverse health effects of lead suggested the possibility that the 0.06 percent level may not sufficiently protect consumers and that 0.01 percent might be more appropriate. In the investigation of this possibility, CPSC reviewed existing data, published a notice of regulatory investigation (NRI) in the Federal Register, and conducted a national sampling of lead levels in currently marketed paint.

This briefing package discusses the results of the national lead in paint sampling and addresses comments submitted in response to the Commission's NRI published in the Federal Register on April 30, 1992 (Tab A). Options for consideration by the Commission and a staff recommendation based on the analyses in this package are also provided. "Paint" is defined as surface coatings, with or without coloring matter, that change to a solid film after application (16 CFR Part 1303.2).

Background information in support of the NRI was presented to the Commission in a previous briefing package (OS #4367) dated January 24, 1993. That briefing package noted new data on the adverse health effects of low level lead exposure. The most serious adverse effects were retarded mental and physical development of young children. A lower maximum allowable lead-in-paint level (0.01 percent) was suggested by using the new data, applying exposure assumptions similar to those used to develop the 0.06 percent level. Tempering the significance of

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the 0.01 percent level was the staff's recognition that certain of the exposure assumptions had little or no data to support them, which might substantially affect the result. The NRI requested information where data gaps existed. Comments were requested primarily on the exposure to paint, particularly for young children, and exempted uses of lead paint.

The staff was unable to find additional information to test or verify the assumptions. The staff felt that useful unpublished data might exist among the many lead poisoning programs or studies by private and academic entities in the U.S.

II. Discussion

A. Market information

Of the 500 paint manufacturing firms, the largest 20 constitute 60 percent of the market (Tab B). About 80 percent of the paint is custom-colored. Water-based paint accounts for three-fourths of the market and can be expected to increase in the near future due to concern over air pollution from volatile organic chemicals. Half of the paints marketed are designed for use on interior surfaces. Nearly all of the architectural (residential) paint sold in the U.S. is domestically manufactured.

Colorants allow for custom coloring of paints. The colorants were at one time concentrated earthen pigments. Lead was once used as a pigment in architectural paint and still is used in artist/graphic and roadway paints. It is also a natural contaminant of earthen pigments. Therefore, it was hypothesized that the colorants were responsible for the lead in presently marketed architectural paint. However, conversations with National Institute of Standards and Technology (NIST) staff and manufacturers indicated modern "universal" paint colorant systems rely mostly on synthetic dyes rather than earthen pigments. Therefore, colorants are not likely to be a source of lead contamination in paint.

B. Lead levels in currently marketed paint

The level of lead in currently marketed paint was not known at the time of issuance of the NRI. The previous national sampling was conducted by the Commission 15 years ago, soon after the 0.06 percent standard became effective.

As benefits would be related to the lowering of existing lead levels in paint, the staff felt that a more recent sampling was needed. For this reason and as a review of compliance to the present 0.06 percent standard, the staff conducted a nationwide sampling of the paint market. The sampling was designed to

conform to identified market characteristics and involved five geographic/population regions of the continental U.S. (Tab B).

Of the 433 samples tested by the Health Sciences Laboratory, 90 percent contained less than 0.01 percent lead (Tab C). The overall average was 0.004 percent, which is considerably less than the 0.025 percent average in 1978-1979. Greater than 99 percent of the samples were in compliance with the 0.06 percent standard. The one sample slightly over 0.06 percent was referred to the Office of Compliance and Enforcement for possible corrective action.

Lead levels in samples of paint marketed in the Northeastern U.S. (Region 1), were slightly higher (0.0076 percent average) than the other regions (0.0014-0.0076 percent entire range of averages). No differences in average lead levels were observed for interior vs. exterior paint, or large (greater than 2 percent market share) vs. small (less than 2 percent market share) manufacturers.

The results are consistent with a June 1992 report of a pilot study conducted by NIST for the U.S. Department of Housing and Urban Development (Tab D). NIST found all 31 samples of paint from the local area were less than 0.01 percent lead by dried weight.

Information provided by Consumer and Corporate Affairs, Canada, indicated all eight samples of colorants analyzed by their Scientific and Laboratory Standards Division were less than 0.01 percent lead. This supports a conclusion that modern colorants are unlikely to be a source of lead contamination in paint.

C. Economic analysis of lowering the limit for lead

The benefits of reducing the allowable level of lead in paint are a function of the reduction in the amount of lead to which the public is exposed. Because at least 90 percent of the paint currently on the market is already less than 0.01 percent lead, the potential for significant further reductions is low. Thus, the potential benefits of reducing the allowable level of lead in paint are probably low.

Insufficient information exists to estimate the costs that would be incurred to further reduce levels of lead in paint (Tab E). To consistently achieve a 0.01 percent level, manufacturers with paint presently above that level could choose to avoid raw materials with high amounts of lead contaminants, blend paint batches that exceed the limit with batches that are under the limit, or dispose of batches that are overly contaminated. These choices represent a wide range of costs. For example, a manufacturer could choose to blend a paint over 0.01 percent with

one under 0.01 percent to comply. A manufacturer may or may not have sufficient tank storage and plumbing capacity to achieve this. If a manufacturer does have sufficient capacity, the costs could be relatively low. On the other hand, if a manufacturer does not have sufficient capacity, then the firm might need to expand its capacity.

It cannot be estimated how many manufacturers would select each choice without knowing the exact source and nature of the lead contamination, and the equipment capacities at a representative number of plants. The staff believes that manufacturers would probably prefer to impose stricter purity requirements on the pigments used for paint. However, the staff could not determine which choice would be preferred if the variability of paint ingredients resulted in occasional noncompliant batches.

D. Comments and responses

The Commission received 15 comments in response to the NRI. Most of the relevant comments (Tab F) were associated with health effects. No comments provided information on the major information gap concerning the amount of paint ingested by a child per day. Information on other assumptions used to calculate a lower limit for lead in paint, such as including the number of coats in a paint chip, was also not received.

One of the comments provided critical information on exposure. A commenter provided supplemental information regarding the estimation of the weight of a coat of paint that prompted the staff to revise part of the exposure assessment. The weight of a coat of typical architectural paint is about half the weight assumed in the development of the 0.06 percent level. This reduces the estimated paint exposure of a child who might ingest the equivalent of about a square inch of paint per day. When the new paint exposure estimate is applied, the revised estimated recommended limit becomes 0.02 percent.

Several comments were received concerning exempted uses of lead paint. None provided exposure data to indicate that exempted uses of lead paint could produce a hazard with the finished product, such as a mirror or an oil painting. Furthermore, comments were received indicating that industry is seeking "no-lead" and low-lead alternatives for some of the exempted uses. Data were also insufficient to develop adequate exposure scenarios for the application or removal of architectural and exempted paints. It is possible that improper application or removal of exempted lead paint or even architectural paint close to the 0.06 percent level might result in lead exposure.

Comments recommending a lead in paint standard based on "bioavailable" lead, as opposed to the present total lead content of paint, were received. However, no data were provided to support the use of such a standard. Furthermore, factors such as weathering and aging may affect bioavailability. The existing bioavailability standard (European Common Market EN 71 for toys) does not address weathering and aging. The proposed ASTM revision of toy safety standard F963 recognizes the CPSC 0.06 percent standard and includes a 90 mg/kg bioavailable limit in harmonization with the EN 71 standard.

III. Options

As a result of the information received in response to the NRI and from the national paint sampling, the Commission may decide to close the investigation, to seek additional information, or to begin proceedings to lower the maximum allowable limit for lead in paint.

A. *Close the regulatory investigation*

Pro

O The staff considers the Commission's present standard to be sufficiently protective. Actions that manufacturers have taken in order to comply with the current standard have caused lead levels in paint to be low. Lead levels (0.004 percent average with 90 percent below 0.01 percent) in currently marketed paint are already well below the staff's revised recommended level of 0.02 percent.

O The small risk of serious, adverse health effects indicates no further staff resources should be expended on this investigation.

Con

O Most of the information gaps critical to the development of a revised limit still exist. It is possible that further data indicating that a hazard might exist might be generated or become available in the near future.

B. *Continue the regulatory investigation to seek further data to fill existing data gaps on human exposure to paint and costs/benefits of complying with a lower limit.*

Pro

O Most of the information gaps critical to the development of a limit still exist. It is possible that data indicating that a hazard might exist may be generated or become available in the near future.

Con

O The Commission and staff undertook efforts to obtain the needed information in the literature, from other agencies and professionals working in the area of lead poisoning, and from the public by the publication of the notice of regulatory investigation. There are no indications that further data that might justify a lower limit will be found or generated in the near future.

O The small risk of adverse health effects from current lead in paint levels would not justify the staff resources that would be needed.

C. *Direct the staff to begin proceedings to amend the current 0.06 percent limit for lead in paint to 0.02 percent by dried weight.*

Pro

O A lower limit would ensure that all paint is below 0.02 percent. This would protect against a possible hazard, that may turn out to be greater than currently believed, and protect against the lead content of paint increasing from below 0.01 percent to the current limit of 0.06 percent.

Con

O The data do not currently indicate that a hazard exists.

O Benefits would be small since most paint is already well below 0.01 percent, and the staff is unaware of a reason that the lead level would increase.

O Additional staff resources needed to revise the current regulation would not be justified by the small risk of adverse health effects from lead in presently marketed architectural paints.

IV. Recommendation

The staff recommends Option A., closing of this regulatory investigation. Insufficient information exists to support a lower lead limit in paint. The average level of lead in current paint is already well below 0.01 percent and little or no health benefits would be gained by lowering the limit.

NRC that it has implemented a fitness-for-duty program that meets the requirements of 10 CFR part 26. The certification shall describe any licensee cut-off levels more stringent than those imposed by this part.

Appendix A—Guidelines for Drug and Alcohol Testing Programs

9. In appendix A, the title is revised to read as set forth above.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

10. The authority citation for part 70 continues to read, in part, as follows:

Authority: Sec. 161, 86 Stat. 948, as amended, (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

11. In § 70.20a, paragraph (d)(3) is revised to read as follows:

§ 70.20a General license to possess special nuclear material for transport.

(d) . . .

(3) Shall be subject to part 26 and § 73.80 of this chapter.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

12. The authority citation for part 73 continues to read in part as follows:

Authority: Sec. 161, 86 Stat. 948, as amended, (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

13. In § 73.8, the introductory paragraph is revised to read as follows:

§ 73.8 Exemptions for certain quantities and kinds of special nuclear material.

A licensee is exempt from the requirements of 10 CFR part 26 and §§ 73.20, 73.25, 73.26, 73.27, 73.45, 73.46, 73.70 and 73.72 with respect to the following special nuclear material:

Dated at Rockville, Maryland, this 24th day of April, 1992.

For the Nuclear Regulatory Commission,
Samuel J. Chalk,

Secretary of the Commission.

[FR Doc. 92-10014 Filed 4-29-92; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1303

Regulatory Investigation; Lead in Paint

AGENCY: Consumer Product Safety Commission.

ACTION: Regulatory investigation.

SUMMARY: The Commission is investigating the possible revision of its lead in paint regulations in light of recent findings regarding the effects of lead toxicity. Application of these findings in the estimation of a regulatory level indicates to the Commission's staff that the maximum allowable limit for lead in paint used as or on consumer products could possibly be reduced from the current 0.06% to 0.01%, as measured by weight in the dried paint film. Information and comments are requested on the maximum allowable limit for lead in paint, exposure to lead paint and on uses of lead paint that are now, or should be, exempted from the regulation.

DATE: Information in response to this notice should be received by the Commission by July 14, 1992.

ADDRESS: Information submitted in response to this notice should be captioned "Limits for Lead in Paint" and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207-0001, or delivered to room 429, 5401 Westbard Avenue, Bethesda, Maryland 20816-1469.

FOR FURTHER INFORMATION CONTACT: Brian C. Lee, Ph.D., D.A.B.T., Project Manager, Directorate for Health Sciences, Division of Health Effects, Consumer Product Safety Commission, Washington, DC 20207-0001; 301/504-0994, 961-0894 PTS.

SUPPLEMENTARY INFORMATION

1. Background

The Commission administers the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051-2084). The CPSA authorizes the Commission to establish consumer product safety rules when the Commission determines, among other findings, that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with [a consumer] product." If the Commission determines (among other findings) that a consumer product presents an unreasonable risk of injury and that no feasible safety standard would adequately reduce the risk, the Commission is authorized to ban the product.

For the purposes of this notice, "paint" means surface coatings with or without coloring matter, that change to a solid film after application (16 CFR 1303.2). It does not cover printing inks, electroplating, or ceramic glazing. This notice is concerned with paints meant for sale to consumers, used in residential housing and schools and on

furniture, toys, and other items meant for use by children.

The Lead Based Paint Poison Prevention Act (LBPPPA), 42 U.S.C. 4801 et seq., set the maximum allowable limit of lead in paint to 0.5% of the dry film weight, and effectively eliminated lead pigments from paint. The LBPPPA, as amended by the National Consumer Health Information and Health Promotion Act of 1978 (Pub. L. 94-317, 90 Stat. 705-706), directed the Commission to determine whether it could demonstrate that a level of lead greater than 0.06% but less than 0.5% was safe. The Commission determined that the available information and data did not support a finding that a level greater than 0.06% but less than 0.5% was safe. As a result, the congressionally-established definition of "lead-based paint" under the LBPPPA (0.06%) automatically became effective in 1977. The Commission then established a ban on lead-containing paint and certain consumer products bearing lead-containing paint (Tab A, 16 CFR part 1303) as a regulation under the CPSA, to reduce the unreasonable risk of injury associated with paint greater than 0.06% lead. The ban became effective in 1978.

1.A. Sources of Lead in Paint

Lead has occurred in paint as pigments, driers, and contaminants. Contamination is believed to be the remaining source of lead in paint, aside from manufacturing errors and intentional additions. Likely sources of contamination are the natural presence of lead in certain pigments derived from earthen materials, for example, zinc ore, and the accidental cross-contamination of lead-free paint by intentionally-leaded paint or other lead product manufacturing processes within the same facility.

1.B. Development of the Current 0.06% Limit

The 0.06% level was recommended by the American Academy of Pediatrics Committee on Environmental Health (AAP, 1972) and affirmed by the National Academy of Sciences (NAS, 1973). The American Academy of Pediatrics (1972) estimated that lead poisoning occurs when the lead intake from sources other than food exceeds 150 micrograms (ug) per day in children. Barltrop (1973) estimated an intake of 156 ug/day of lead from food, water, and air. Based on differences in body weight, Barltrop then reduced the daily permissible intake of 600 ug for adults to 180 ug for a two-year-old. He then added a caloric requirement correction which lowered it to 133 ug. Four major

assumptions were then made to derive the 0.06% limit:

(a) Lead paint exposure from inhalation is negligible compared to the ingestion route.

(b) Paint on a typical surface is six coats thick.

(c) A child eats the equivalent of about one square inch of paint per day.

(d) Absorption of lead from ingested lead paint is 10%, the same as for lead from food.

At the time of the National Academy of Sciences (1973) and the American Academy of Pediatrics (1972) assessments, lead "poisoning" was defined as blood lead greater than 60 ug/deciliter (dl). The National Academy of Sciences felt that a blood lead greater than 40 ug/dl was "considered evidence of undue absorption", referring to exposure from paint ingestion. The American Academy of Pediatrics used a determination by King (1971) that an intake of less than 300 ug/day would not significantly increase blood lead. An intake of 200 ug/day was selected as a target level which corresponds to the amount of lead in a six-coat-thick chip of 8.5 cm² (1.3 square inches) of 0.06% lead paint (NAS, 1973) or 10 cm² (1.4 square inches) of 0.05% lead paint (AAP 1972).

2. Information

Recent data indicate that humans, particularly young children and fetuses, may be more sensitive to the adverse health effects of lead than was believed in the early 1970s. Of critical importance is the retardation of mental development, which can be observed at blood levels as low as 10 ug/dl. While this blood level does not require immediate medical attention, these neurobehavioral effects can persist for several years (CDC, 1991). Several Federal agencies agree that 10 ug/dl is a level of concern for adverse health effects; these agencies include the Agency for Toxic Substances and Disease Registry (ATSDR, 1988, 1990), Centers for Disease Control (CDC, 1991), CPSC (1989), and Environmental Protection Agency (EPA, 1990). Other adverse health effects, such as prematurity, decreased birthweight and stature, and biochemical alterations, have also been observed at blood levels from 10 ug/dl upward.

When the 10 ug/dl blood level of concern, along with other recent data, such as the absorption of ingested lead in young children, is applied in a process similar to that used to develop the 0.06% limit, the resulting maximum allowable limit for lead in paint is estimated as 0.01% (CPSC, 1990).

However, there are certain data gaps concerning exposure, such as the amount of paint ingested daily and the absorption of ingested paint. These gaps also existed in the development of the 0.06% limit. The exposure assumptions originating from the early 1970's reports (NAS, 1973; AAP, 1972), which were used when the 0.06% limit was established, were applied when these data gaps occurred.

3. Request for Information and Comments

The Commission seeks additional information for the assessment of age-specific, nonoccupational exposure to lead in paint, including residential architectural paint and paint from toys and other consumer products. Such information may be useful in the verification of assumptions or filling of data gaps in developing and considering recommendations for lower limits for lead in paint. Technical information is desired to answer questions in the following categories:

3.A.i. Ingestion of Paint

What are the average age-specific amounts and ranges of variability of ingested paint chips and dust for nonoccupational exposures?

What are the age-specific absorption rates or absorption percentages of lead from ingested paint chips and dust?

What effect does degradation of the paint matrix from aging, weathering, household cleansers, etc., have on the absorption rates or absorption percentages of lead from ingested paint chips and dust?

3.A. Inhalation of Paint

What are the average age-specific amounts and ranges of variability of inhaled paint dust for nonoccupational exposures?

What are the age-specific absorption rates or absorption percentages of lead from inhaled paint dust and its contribution to blood lead?

What effect does degradation of the paint matrix from aging, weathering, household cleansers, etc., have on the absorption rates or absorption percentages of lead from inhaled paint dust?

3.B. Lead Levels in Paint

What is the average thickness and weight and ranges of variability, for coats of paint?

What sources of lead contamination of paint exist?

How much does each of these sources contribute to the lead level in paint?

Which types and colors of consumer paint are likely to be contaminated with lead?

What are the average levels and range of variability of lead, whether from contamination or intentional use, in the various types of paint currently used or available in the marketplace?

Which analytical and sampling procedures are used and what levels of accuracy and precision result from their practice?

What methods of control of lead sources are followed in the manufacture of paint?

Do these methods differ among manufacturing plants?

What measures or processes could be taken to reduce lead contamination of consumer paints?

What percentage of paint is tested before use or sale?

What additional steps, processes, equipment, or monitoring would be needed to ensure that the lead level of paint would be less than 0.01%?

3.C. Intentionally Leaded Paint

Which applications of leaded paint are currently used?

What new technologies and applications have been developed for lead in paint and other surface coatings?

What lead-free substitutes are available for currently exempted uses of leaded paint?

4. Policy Considerations

In addition to technical information described above, the Commission solicits the views of interested persons or organizations concerning a lower limit for lead in paint and the rationale for their views, including the health effects of blood levels from 10 ug/dl upwards. The Commission requests comments from national, state, and local governments concerning their laws or proposals that regulate lead in paint more stringently than the 0.06% limit. Information and comments that were considered in their enactment or submitted in their support are also requested.

5. Trade Secret or Proprietary Information

A Person or organization responding to this notice, who wishes to submit information believed to be a trade secret or proprietary information, should identify the trade secret or proprietary information at the time of submission. Information that is claimed to be a trade secret or proprietary information will be received and handled in a confidential manner and in accordance with section 6(a) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2055(a)). Such

information will not be placed in a public file and will not be made available to the public merely upon request.

If the Commission receives a request for disclosure of the information or concludes that disclosure is necessary to discharge its responsibilities, the Commission will inform the person or organization who submitted the information and provide that person or organization with an opportunity to present additional information and views concerning the confidential nature of the information. A determination regarding the release of information submitted in response to this notice, which is claimed to be trade secret or proprietary information, will be made in accordance with applicable provisions of the CPSA, the Freedom of Information Act (FOIA) (5 U.S.C. 552b), 18 U.S.C. 1905, the Commission's procedural regulations codified at 18 CFR part 1015 governing protection and disclosure of information under the provisions of the FOIA, and relevant judicial interpretations of these statutes and regulations. Information which has been submitted with a claim that it is trade secret or proprietary information will not be made public until its status as trade secret or proprietary information is resolved in accordance with applicable provisions of law.

6. References

- AAP, American Academy Pediatrics Committee on Environmental Hazards (1972)—"Lead content of paint applied to surfaces accessible to young children." *Pediatrics* 49: 918-921.
- ATSDR, Agency for Toxic Substances and Disease Registry (1988)—"The Nature and Extent of Lead Poisoning in Children in the United States: A Report to Congress. July.
- ATSDR (1990)—"Toxicological Profile for Lead. Prepared by Syracuse Research Corp. For ATSDR in collaboration with EPA. ATSDR/TP-88/17. June.
- D Barltrop (1973)—"Sources and significance of environmental lead for children." *Proceedings of an International Symposium on the Environmental Health Aspects of Lead*. EUR 5004 d-e-f. Comm. Eur. Communities, Luxembourg. In NAS (1973).
- CDC, Centers for Disease Control (1991)—"Statement on lead. September.
- CPSC, Consumer Product Safety Commission (1989)—"Review of low level lead toxicology." Memorandum to SC Eberle from BC Lee. Dated May 10, 1989.
- CPSC (1990)—"Revision of the CPSC 0.06% lead in paint standard (16 CFR part 1303)." Memorandum to SC Eberle from BC Lee. Dated June 22, 1990.
- EPA, Environmental Protection Agency (1990)—"Air quality criteria for lead: Supplement to the 1986 addendum. Office of Research and Development. EPA/800/8-89/049F. August.

BG King—"Maximum daily intake of lead without excessive body lead-burden in children." *Amer. J. Diseases Child.* 122: 337-340.

NAS, National Academy of Sciences (1973) Report of the ad hoc committee to evaluate the hazard of lead in paint. Prepared for CPSC, contract #FDA 70-22, task order Dated: April 24, 1982.

Sadye E. Dunn,
Secretary, Consumer Product Safety Commission.

[FR Doc. 92-10003 Filed 4-29-92; 8:45 am]
BILLING CODE 6350-01-2

SECURITIES AND EXCHANGE COMMISSION

17 CFR Chapter II

(Release Nos. 33-6825, 34-30630, 35-255 39-2283, IC-18674, IA-1367; File No. S7-1 82)

Regulatory Flexibility Agenda and Rules Scheduled for Review

AGENCY: Securities and Exchange Commission.

ACTION: Publication of regulatory flexibility agenda.

SUMMARY: The Securities and Exchange Commission is today publishing an agenda of its rulemaking actions, pursuant to the Regulatory Flexibility Act. The agenda is a general announcement to the public intended to provide advance notice of rulemaking actions which may have a significant economic impact on a substantial number of small entities. The Commission invites questions and public comment on individual agenda entries.

DATE: Public comments are due by July 26, 1992.

ADDRESSES: Persons wishing to submit written views should file three copies with Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 5th Street, NW., room 8104, Stop 6-Washington, DC 20549. All submissions should refer to File No. S7-11-92, and will be available for public inspection and copying at the Commission's Public Reference Room, room 1020, at the same address.

FOR FURTHER INFORMATION CONTACT: Thomas M. Selman, Special Counsel, Office of the General Counsel, Securities and Exchange Commission, 450 5th Street, NW., room 8148, Stop 6-Washington, DC 20549 (202-272-2428). The names of persons to contact concerning particular rules are identified with each entry.

SUPPLEMENTARY INFORMATION: The Regulatory Flexibility Act ("RFA") (Pub

U.S. GOVERNMENT
MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

23 SEP 1992

TO: Brian Lee, Project Manager Lead Poisoning, Health Effects Division

THROUGH: James Hoebel, Acting Associate Executive Director, Health Sciences

FROM: Warren K. Porter, Jr., Director Health Sciences Laboratory
Bhavi K. Jain, Chemist, Health Sciences Laboratory

SUBJECT: Lead in Paint Survey

Introduction:

One task in the Lead Poisoning Project was to find the lead content in a typical selection of domestic retail sales paints. Since the Consumer Product Safety Commission (CPSC) is considering reducing the allowable amount of lead in paints, knowing the lead content of new paints would allow the staff to evaluate the need for amending the current regulation. In addition the staff would find out if domestic manufacturers were meeting the current regulations. The Health Sciences Laboratory (HSHL) provided the CPSC data by analyzing 433 paint samples collected throughout the United States. The geographical collection regions were the North East (1), South East (2), North Central (3), South Central (5), and West Coast (6) areas of the United States. Due to other work assigned to resident posts in the CPSC Central Region, some samples from the Central States (Geographical area four) were reassigned and collected in other areas within jurisdiction of the CPSC Central Regional Office. The paint samples represented both large and small manufacturers. Also of interest to the staff was the distribution of lead concentrations in distinct concentration ranges. The ranges chosen were less than 0.01 percent lead, a possible new regulatory limit; 0.01 to 0.06 percent, the range between the current CPSC regulation of 0.06 percent and the possible new limit; and greater than 0.06 percent, the concentration that exceeds the current CPSC regulation.

Methods:

The HSHL used the Association of Official Analytical Chemists' (AOAC) Official Method 5.009 to analyze the paints. Prior to analysis, a commercial paint shaker thoroughly mixed all paints. After four hours of nitric acid digestion of accurately weighed samples, an inductive coupled plasma spectrophotometer (ICP) measured the lead content.

Quality assurance consisted of daily calibration of the ICP and 26 repeat analyses of a 10 parts per million standard solution of lead. If the lead determination fell outside two standard deviations of the known value, corrective actions were taken. Corrective actions consisted of recalibration, cleaning and realigning the torch assembly, or requesting outside service. Analysis of a random selection of five percent of the samples provided a statement of the precision of the analytical method (Appendix 1).

Results and Discussion:

The 433 samples, collected from 5 regions of the country, represented a selection of white and non-white paints, interior and exterior paints, and large and small manufacturers. The data show nearly total compliance with the current CPSC regulation. The average lead content of the 433 paints analyzed was 0.004 percent. The distribution of lead concentrations was 91 percent less than 0.01 percent lead, 8 percent between 0.01 and 0.06 percent lead, and 0.2 percent (only 1 sample) over 0.06 percent lead (Figure 1). Table 1 shows the distributions by percentage of paints with lead contents in the above ranges. The table also shows the average lead content, the number of samples, and standard deviation of the lead content for the 433 samples of paint. The table shows the distributions by region, for all paints, for manufacturer size, interior and exterior paints, and white and non-white paints. The data show that Region 1 has a larger proportion of lead concentrations in the 0.01 to 0.06 percent range than the other regions. In spite of the higher lead concentrations in paints from Region 1, none exceeded the current 0.06 percent lead regulations. The difference between Region 1 and the other regions was statistically significant ($p < 0.05$). A statistical comparison of all non-white and all white paints showed non-white paints to be significantly higher in lead concentration than white paints ($p < 0.05$) (Figures 2 and 3). Comparisons of large and small manufacturers, and interior and exterior paints showed no significant differences ($p < 0.05$).

Table 1. Average Percent Lead Concentrations and Ranges in Paints

	Region					
	1	2	3	5	6	All Paints
Category						
All Paints						
< 0.01%	66.67	100.00	94.87	98.72	96.36	91.22
0.01%-0.06%	33.33	0.00	4.62	1.28	3.64	8.55
> 0.06%	0.00	0.00	0.51	0.00	0.00	0.23
Number	75	30	195	78	55	433
Average	0.0076	0.0014	0.0039	0.0028	0.0028	0.0040
Standard Deviation	0.0070	0.0011	0.0101	0.0028	0.0030	0.0078
Manufacturer Size						
Large						
< 0.01%	86.21	100.00	98.00	97.14	95.65	95.68
0.01%-0.06%	13.79	0.00	2.00	2.86	4.35	4.32
> 0.06%	0.00	0.00	0.00	0.00	0.00	0.00
Number	29	25	50	35	23	162
Average	0.0053	0.0016	0.0031	0.0035	0.0029	0.0033
Standard Deviation	0.0049	0.0012	0.0024	0.0037	0.0040	0.0035
Small						
< 0.01%	54.35	100.00	93.79	100.00	96.88	88.56
0.01%-0.06%	45.65	0.00	5.52	0.00	3.12	11.07
> 0.06%	0.00	0.00	0.68	0.00	0.00	0.37
Number	46	5	145	43	32	271
Average	0.0090	0.0008	0.0042	0.0022	0.0027	0.0044
Standard Deviation	0.0077	0.0007	0.0117	0.0015	0.0022	0.0094

Table 1. Continued
Paint Type

	Region					
	1	2	3	5	6	All Paints
Exterior						
< 0.01%	60.00	100.00	96.92	96.67	95.45	92.00
0.01%-0.06%	40.00	0.00	3.08	3.33	4.55	8.00
> 0.06%	0.00	0.00	0.00	0.00	0.00	0.00
Number	20	13	65	30	22	150
Average	0.0080	0.0012	0.0033	0.0033	0.0033	0.0037
Standard Deviation	0.0072	0.0009	0.0033	0.0026	0.0037	0.0045
Interior						
< 0.01%	69.09	100.00	93.85	100.00	96.97	90.81
0.01%-0.06%	30.91	0.00	5.38	0.00	3.03	8.83
> 0.06%	0.00	0.00	0.77	0.00	0.00	0.35
Number	55	17	130	48	33	283
Average	0.0074	0.0016	0.0042	0.0025	0.0025	0.0042
Standard Deviation	0.0070	0.0013	0.0121	0.0028	0.0025	0.0090
Paint Color						
White						
< 0.01%	80.00	100.00	96.43	97.78	100.00	95.42
0.01%-0.06%	20.00	0.00	3.57	2.22	0.00	4.58
> 0.06%	0.00	0.00	0.00	0.00	0.00	0.00
Number	35	23	140	45	41	284
Average	0.0054	0.0017	0.0030	0.0030	0.0021	0.0031
Standard Deviation	0.0057	0.0011	0.0037	0.0023	0.0012	0.0035
Non-White						
< 0.01%	55.00	100.00	90.91	96.97	85.71	82.55
0.01%-0.06%	45.00	0.00	7.27	3.03	14.29	16.78
> 0.06%	0.00	0.00	1.82	0.00	0.00	0.67
Number	40	7	55	33	14	149
Average	0.0094	0.0006	0.0060	0.0025	0.0050	0.0058
Standard Deviation	0.0075	0.0005	0.0181	0.0033	0.0052	0.0121

Lead in Paint Survey

All Paints by Region

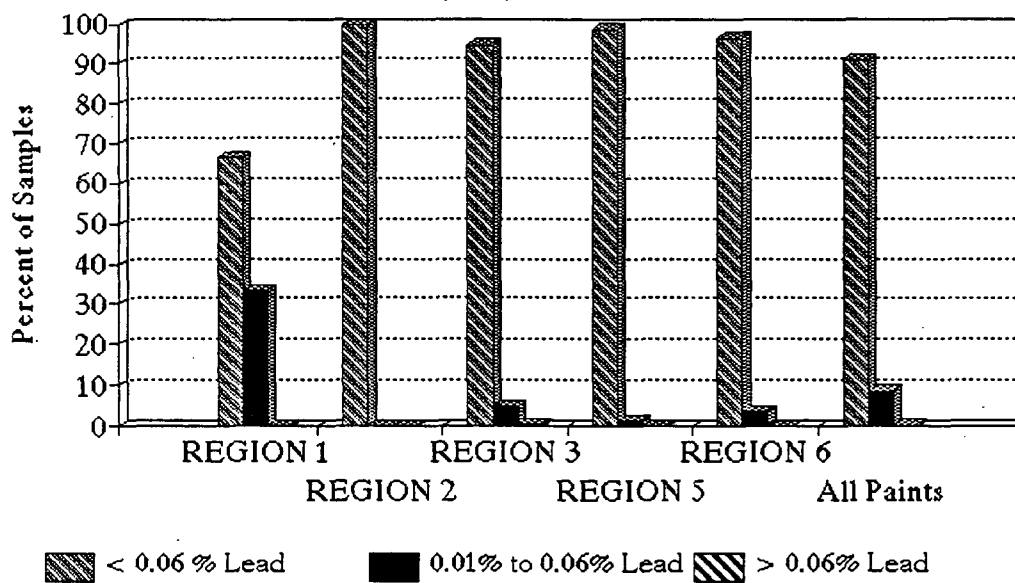


Figure 1. Distribution of lead contents for all paints by region.

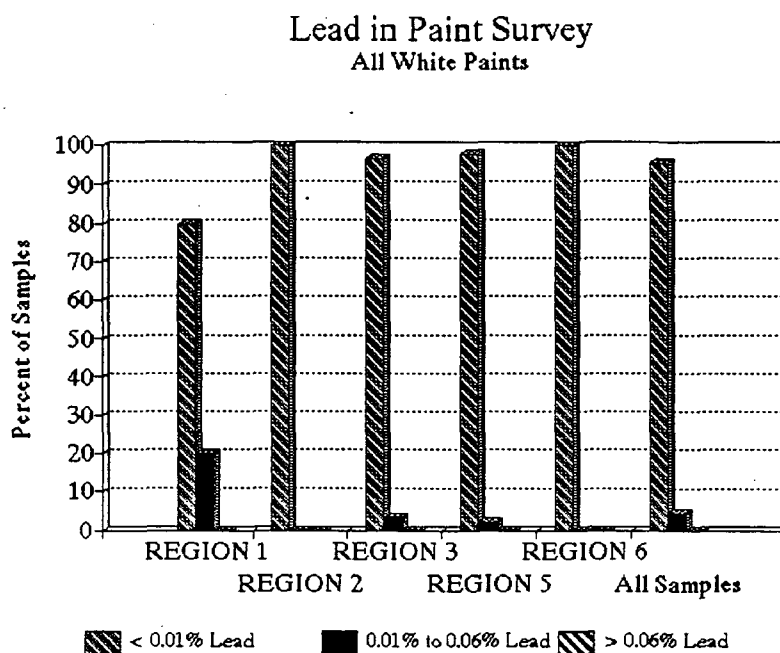


Figure 2. Distribution of lead contents for all white paints by collection region.

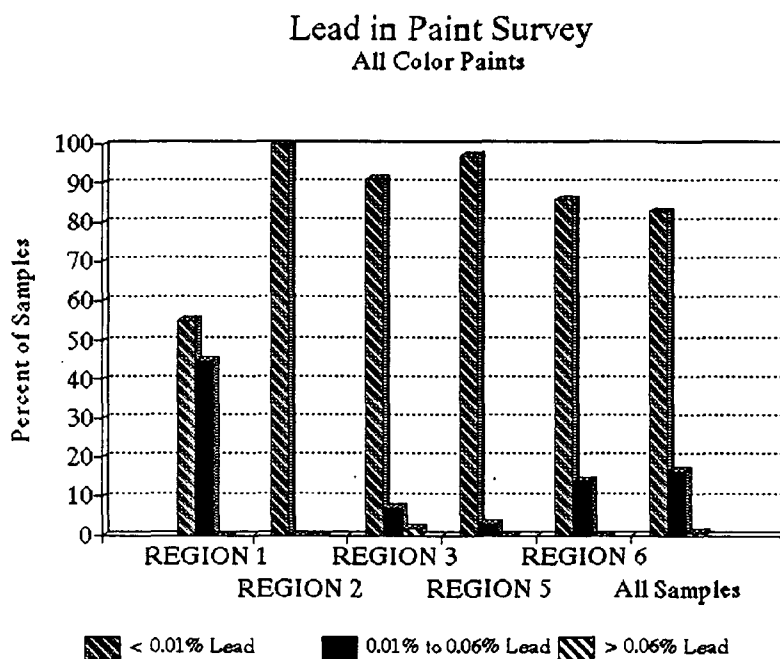


Figure 3. Distribution of lead contents for all non-white paints by region.

Appendix 1 Quality Assurance

Repeat analyses of a blind standard and a random selection of 21 samples provided an estimate of precision and accuracy of the method. For accuracy of data, a 10.0 ppm lead control solution was used as a blind standard and analyzed 26 times during the course of the survey. The average lead concentration found was 10.4 ppm with a standard deviation of 0.62 ppm or 5 percent. The data indicate a four percent bias toward higher than actual concentrations. Repeat analysis of 21 randomly chosen paint samples provided an estimate of the precision of the analytical method. The Standard error of the method was 0.0003 ppm, a Students t-test between repeat analyses showed no significant difference at the five percent confidence level.

Lead Concentration in Consumer Paints: A Pilot Study

**Mary E. McKnight
Willard E. Roberts**

**Building and Fire Research Laboratory
Gaithersburg, Maryland 20899**



**United States Department of Commerce
Technology Administration
National Institute of Standards and Technology**

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June 1992
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U.S. Department of Commerce
Barbara Hackman Franklin, *Secretary*
Technology Administration
Robert M. White, *Under Secretary for Technology*
National Institute of Standards and Technology
John W. Lyons, *Director*

ABSTRACT

A pilot study was conducted for the U.S. Department of Housing and Urban Development (HUD) to measure the lead concentrations in a small sampling of new consumer paints. Although a Consumer Product Safety Commission Regulation requires that the lead concentration be no greater than 0.06 percent (600 parts per million, ppm or 600 $\mu\text{g/g}$) by mass of paint solids, the actual lead concentration is not usually measured and reported. Estimates of expected lead concentrations in new paint are needed in HUD's lead-paint abatement program. Thus, the objective of this pilot study was to determine whether the lead concentration in a small sampling of new paints tended to be near the regulatory limit. The lead concentration in each of 31 consumer paints was measured using laboratory x-ray fluorescence spectrometry. All concentration estimates were less than 100 ppm. The lead concentration of most samples was below the detection limit of the procedure used of 30 ppm.

KEYWORDS: Consumer paint; Lead concentration; X-ray fluorescence spectrometry

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1. INTRODUCTION

At the request of the U.S. Department of Housing and Urban Development, the lead concentrations in a small sampling of new consumer paints were measured. Although the Consumer Product Safety Commission (CPSC) Regulation, 16 CFR 1303 [1], requires that the lead concentration be no greater than 0.06 percent (600 parts per million) by mass of paint solids in paint, there is little information on the actual lead concentration in consumer paints. The objective of this pilot study was to determine whether the lead concentrations of new paints tended to be near the regulatory limit. This information is needed to help refine abatement procedures and recommendations. A description of the paints, the test method, and the results of the lead concentrations measurements are presented below.

2. MATERIALS

In this pilot study, a small sampling of consumer paints was selected at random for determining lead concentration. The paints were manufactured by nine major producers of paint and were obtained from local retail stores. Interior and exterior, and water-based and oil-based paints were included. Since more water-based than oil-based paints are used by consumers, the number of water-based paints selected was about twice that of the oil-based paints. Interior paints tested were white or tint bases. For the most part, exterior products were deep-tone earth colors with the colored pigments incorporated into the paints at the factory. The gloss varied from flat to high. The selection procedure was based on an incomplete random block design. The blocks or groups were oil-based paint, interior water-based paint and exterior water-based paint. This design provided for one paint of each type from each manufacturer being included in the study. Since each manufacturer makes many types of paint, further procedures for selecting a specific product were needed. It was assumed that each company had at least two quality grades and four tint levels (or colors for exterior paints) for each type of paint. Within each block (group) of paints, the grade and tint level of each paint to be purchased from a manufacturer were randomly chosen from this group of eight expected products. In addition, an additional interior water-based and exterior water-based paint were obtained from each of two larger manufacturers. For the oil-based paints, an arbitrary decision was made to sample five exterior paints and four interior paints; for a given manufacturer, the type of paint (interior or exterior) was chosen at random. Thus, the total number of paints tested was 31 (nine oil-based paints - five exterior and four interior, and 22 water-based paints - eleven exterior and eleven interior).

The merchant's recommendations were used to rank the quality of a particular manufacturer's paints and to select an appropriate tint base. In some situations, the manufacturer did not supply the complete range of paints. In these situations, the paint closest to the one described in the design was selected. For example, if the manufacturer did not have a deep-tone tint base, a medium-tone tint base was selected. Descriptions of the paints tested in this study are given in Table 1.

Table 1. Description of Paints Included in the Study

Sample Number	Generic Type	Description
1	Latex	White interior tint base
2	Latex	Green exterior, factory colored
3	Oil	Pastel interior tint base
4	Latex	White interior tint base
5	Latex	Deep-tone exterior tint base
6	Oil	Deep-tone interior tint base
7	Latex	Green exterior, factory colored
8	Latex	White interior tint base
9	Oil	Brown exterior, factory colored
10	Latex	Green exterior, factory colored
11	Latex	Pastel interior tint base
12	Latex	Intermediate interior tint base
13	Latex	Brown exterior, factory colored
14	Oil	White exterior tint base
15	Latex	Deep-tone interior tint base
16	Latex	Intermediate exterior tint base
17	Oil	White interior tint base
18	Latex	Intermediate interior tint base
19	Latex	Exterior intermediate tint base
20	Latex	Interior intermediate tint base
21	Oil	Exterior intermediate tint base
22	Latex	Deep-tone interior tint base
23	Latex	Brown exterior, factory colored
24	Oil	Green exterior, factory colored
25	Latex	Brown exterior, factory colored
26	Latex	White interior tint base
27	Oil	White interior tint base
28	Oil	Green exterior, factory colored
29	Latex	Dark exterior tint base
30	Latex	Brown exterior, factory colored
31	Latex	Pastel interior tint base

3. EXPERIMENTAL PROCEDURE

3.1 Mass Fraction of Solids

The mass fraction of solids in each of the paints was determined from the mean of triplicate specimens using ASTM D 2369 [2]. In this method, the paint is first thoroughly mixed and then a small amount placed in a tared aluminum dish. The dish with the paint is weighed and the paint is diluted with an appropriate solvent. The diluted paint is distributed over the bottom of the pan to form a smooth thin film. The specimen is baked at 110°C in an air-circulating oven for 1 hour. After cooling to room temperature in a desiccator, the sample is weighed to determine the solids content.

3.2 XRF Measurement of Lead Concentration

The lead content of each paint was measured in duplicate using a wavelength-dispersive x-ray fluorescence (XRF) spectrometer with a Mo tube operated at 60 kV, 50 mA; a LiF (200) crystal; and fine collimators. Measurements were made in helium. X-ray intensities were measured at three angles, at the lead L_{α} and on either side. Angles for each of the measurements were selected from data obtained from scans over the appropriate range of a paint sample to which lead nitrate had been added. The lead peak intensity was corrected for background by subtracting the background intensity. This background intensity was calculated from the straight line drawn between the intensities on either side of the peak and evaluated at the lead L_{α} peak position. Counting time for both background and peak intensities was 100 s.

Specimens for the XRF analyses were prepared by pouring well-mixed samples of paint into liquid XRF cups, having a depth of 20 mm. This sample depth provides a sample having essentially infinite thickness (defined in this paper as a sample that yields at least 99% of the fluorescence of an infinitely thick specimen). This thickness can be calculated from the mass attenuation coefficient, the density of the specimen and the instrumental parameters [3]. For the paints used in this study, this thickness is about 2 mm.

The spectrometer was calibrated using samples of a paint to which known masses of a 1000 parts per million (ppm or $\mu\text{g/g}$) standard lead nitrate solution had been added. Four samples were prepared; one with no added lead and three having lead concentrations of about 25, 50, and 100 ppm by mass of the liquid paint.

4. RESULTS

4.1 Calibration

The calibration curve obtained from a linear regression of XRF measurements of known masses of lead added to a paint is shown in Figure 1. Data taken on three successive days were used in the regression. The abscissa is the concentration of added lead in the liquid

paint, while the ordinate is the number of kcounts/s in the lead peak (corrected for background). The parameters of the linear regression are: slope = 14.1 kcounts/s/ppm, estimate of standard error of the slope = 0.860 kcounts/s/ppm; intercept = 58.3 kcounts/s, estimate of the standard error of the intercept = 58.3 kcounts/s; and square of correlation coefficient = 0.993.

4.2 Lead Concentration in New Paints

The lead concentrations in the paints included in this pilot study based on mass of paint solids are shown in Figure 2. The lead concentration based on mass of paint solids was determined for each paint by obtaining the lead concentrations of the duplicate liquid paint specimens from the calibration curve (Figure 1), calculating the mean and dividing it by the fraction of paint solids. The best estimates of lead concentration are shown for all samples, even though many are below the analyte detection limit, which was estimated to be about 30 ppm for the specific measurement procedures used in this study [4]. (The estimate was based upon the calibration data and the mathematical procedures described in the appendix of Currie's paper [4] using a limit of 0.05 for false-negative and false-positive decision probabilities.)

The major experimental error of this measurement method is associated with the assumption that the matrix effect of all the paints included in the study was similar to the paint used in the calibration. This error is much larger than those related to the random nature of the XRF interaction process, inhomogeneity of the paint sample, and determination of mass of solids of the paints. The matrix effect includes attenuation of primary x-rays and fluoresced lead x-rays by the matrix and depends upon the mass attenuation coefficient of the material. The mass attenuation coefficient is defined as

$$\mu(E) = \sum W_i \mu_i(E),$$

where W_i is the weight fraction of element i in the specimen, and $\mu_i(E)$ is the total mass attenuation coefficient of element i at energy E . The summation over i includes all elements in the specimen such that $\sum W_i = 1$.

To obtain an estimate of the size of the error associated with the matrix effect, it was assumed that the x-ray fluorescence intensity is inversely proportional to the mass attenuation coefficient. (This approximation is based on the assumption that the mass attenuation coefficient of the material at the energy of the Pb (lead) L_α is much greater than at the energy of the Mo (molybdenum) K_α [3]). Thus, attenuation coefficients were calculated for 10 kV, near the Pb L_α energy, for the paint used in the calibration and for each of the paints included in this study, for which the composition was described on the label. In addition, the attenuation coefficients were calculated for several raw-material suppliers suggested formulations [5, 6, 7]. Data from McMaster was used in calculating the mass attenuation coefficients [8]. A range of values of mass attenuation coefficients from 0.5 to 1.7 of the paint used in the calibration was obtained. Mass coefficients for model formulations [6,7,8]

were also in the above range for paint formulations having no barium and limited amounts of zinc. (Based upon the label information and energy dispersive x-ray analysis of the paints having no label information, none of the samples contained barium, and only two contained even a small amount of zinc.) Since the fluoresced x-ray intensity is approximately proportional to the mass attenuation coefficient, the change in the intensity due to possible matrix effects can vary by as much as a factor of 3.

This estimate of the possible error associated with the matrix effect and the uncertainty associated with the calibration curve [4] were used to estimate the 95 percent confidence intervals for the lead concentrations as shown in Figure 2. The intervals were determined by calculating the lead concentration corresponding to the greatest potential matrix affects (i.e., 0.5 and 1.7) and subtracting 20 ppm from the lower limit and adding 20 ppm to the upper one.

As a partial check of some of these values, a different paint was used for the calibration specimens, and three paints were reanalyzed. A comparison of values for lead concentration obtained for these paints is shown in Table 2. In each case the measured value fell within the confidence interval of the results shown in Figure 2.

Table 2. Comparison of Repeated Measurements of Lead Concentrations of Four Paints

Sample Number	[Pb], ppm 1st meas.	[Pb], ppm 2nd meas.
24	103	82
27	49	58
10	nd(0)	nd(7)
7	nd(0)	nd(0)

nd = not detected; the best [Pb] estimate is in parentheses

5. CONCLUSIONS

The laboratory x-ray fluorescence method is suitable for determining lead concentrations in the range of the CPSC regulatory limit in liquid paint samples. Variabilities in the results due to the matrix effect would be reduced by using an internal standard, e.g., strontium, and the use of an internal standard is recommended for further measurements of this type.

The lead concentrations in all the paints included in this pilot study were considerably less than the regulatory limit of 600 ppm (0.06%). All of the lead concentrations were less than 100 ppm and many were below the detection level, 30 ppm, of the specific method used. Further, based upon the analysis of errors, the 95 percent confidence intervals for the lead concentrations in all the paints was less than 100 ppm, except for one paint, Number 24.

The true lead concentration of this paint is likely less than the amount based on the calibration curve. This is because the mass attenuation coefficient for the paint, calculated using label information, is lower than that of the paint used in the calibration.

6. ACKNOWLEDGEMENTS

This investigation was conducted for the U.S. Department of Housing and Urban Development, Office of Policy, Development and Research. The authors gratefully knowlege the encouragement of Mr. Ronald Morony, HUD, and the technical assistance provided by Dr. Peter A. Pella, Chemical Sciences and Technology Laboratory, National Institute of Standards and Technology.

7. REFERENCES

1. 16 CFR 1303, Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint, Part 16, Code of Federal Regulations, Government Printing Office, Washington, DC.
2. ASTM D 2369, Test Method for Determining Volatile Content of Coatings, Annual Book of ASTM Standards, Vol. 6.01, American Society for Testing and Materials, Philadelphia, PA 19103, 1991.
3. Jenkins, R., Gould, R.W., and Gedcke, D., Quantitative X-ray Spectrometry, Marcel Dekker, Inc., New York, 1981, p. 37.
4. Currie, L.A., "The Many Dimensions of Detection in Chemical Analysis, with Special Emphasis on the One-Dimensional Calibration Curve," in Trace Residue Analysis: Chemometric Estimations of Uncertainty and Error, ACS Symposium Series No. 284, ed. by D.A. Kurtz, American Chemical Society, Washington, DC 1986.
5. Flick, E.W., Exterior Water-Based Trade Paint Formulations, Noyes Data corporation, Park Ridge, New Jersey, 1980.
6. Flick, E.W., Interior Water-Based Trade Paint Formulations, Noyes Data corporation, Park Ridge, New Jersey, 1980.
7. Schurr, G.G., "Exterior House Paint," and Volk, O. and Abriss, M., "Interior House Paint," in Treatise on Coatings, Volume 5, Formulations, Part I, ed. by R.R. Myers and J.S. Long, Marcel Dekker, New York, 1975.
8. W. H. McMaster, N. Kerr Del Grande, J. H. Mallett, J. H. Hubbell, Compilation of X-ray Cross Sections, UCRL - 50174, Sec II Rev. I, University of California, Livermore, California, May 1969.

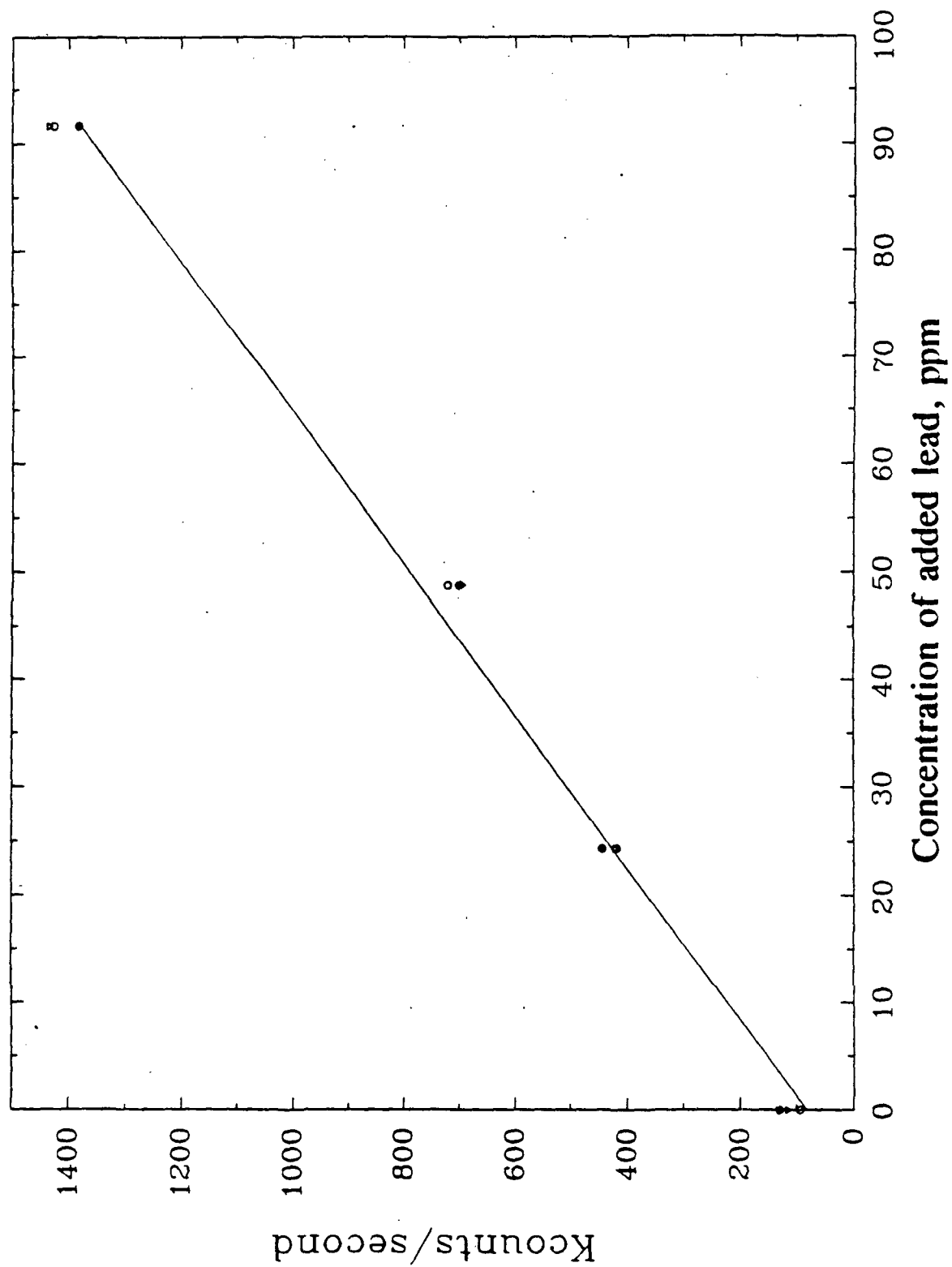


Figure 1. Concentration of added lead in parts per million (ppm or $\mu\text{g/g}$) of liquid paint vs x-ray intensity. Specimens were analyzed on each of three days, ● - Day 1, ▼ - Day 2, and ○ - Day 3. The solid line is the linear regression of all the points.

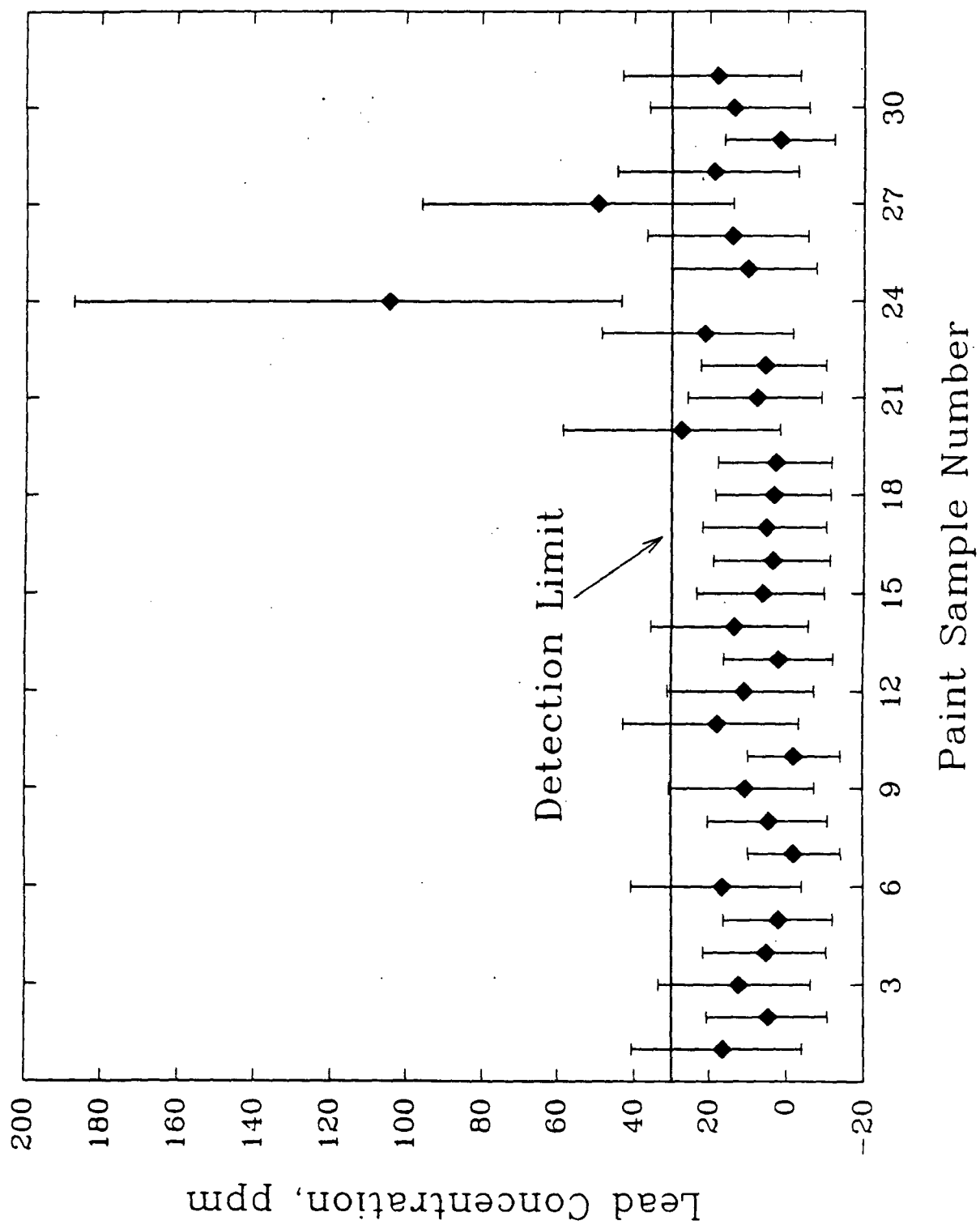


Figure 2. Lead concentration in a small sampling of consumer paints by mass of paint solids; the brackets indicate 95 percent confidence intervals.

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10. SUPPLEMENTARY NOTES

11. ABSTRACT (A 200-WORD OR LESS FACTUAL SUMMARY OF MOST SIGNIFICANT INFORMATION. IF DOCUMENT INCLUDES A SIGNIFICANT BIBLIOGRAPHY OR LITERATURE SURVEY, MENTION IT HERE.)

A pilot study was conducted for the U.S. Department of Housing and Urban Development (HUD) to measure the lead concentrations in a small sampling of new consumer paints. Although a Consumer Product Safety Commission Regulation requires that the lead concentration be no greater than 0.06 percent (600 parts per million, ppm or 600 $\mu\text{g/g}$) by mass of paint solids, the actual lead concentration is not usually measured and reported. Estimates of expected lead concentrations in new paint are needed in HUD's lead-paint abatement program. Thus, the objective of this pilot study was to determine whether the lead concentration in a small sampling of new paints tended to be near the regulatory limit. The lead concentration in each of 31 consumer paints was measured using laboratory x-ray fluorescence spectrometry. All concentration estimates were less than 100 ppm. The lead concentration of most samples was below the detection limit of the procedure used of 30 ppm.

12. KEY WORDS (6 TO 12 ENTRIES; ALPHABETICAL ORDER; CAPITALIZE ONLY PROPER NAMES; AND SEPARATE KEY WORDS BY SEMICOLONS)

Consumer paint; Lead concentration; X-ray fluorescence spectrometry

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U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

MEMORANDUM

TO : Brian C. Lee, Ph.D., Lead Poisoning Project Manager, HSHE MAY 7 1993

Through: James F. HoebeI, Acting AED, HS *James F. HoebeI*

Through: Warren J. Prunella, AED, EC *WJP*

Through: Fay H. Dworkin, Ph.D., Director, ECSS *FH Dworkin*

FROM : Robert L. Franklin, Economist, ECSS, 504-0962 *RLF*

SUBJECT: Economic Analysis of Reducing Lead in Consumer Paints

Introduction

The Directorate for Economic Analysis has studied the likely economic impact of reducing the allowable level of lead in paint. The analysis is based upon material submitted in response to the Notice of Regulatory Investigation (NRI) published in the Federal Register on April 30, 1992, and from conversations with representatives of a paint industry association and several paint and pigment manufacturers. This memorandum discusses what was learned from the limited available information regarding the economic impact of reducing the allowable level of lead in paint from 0.06 percent by dry-weight or 600 parts per million (ppm) to 0.01 percent or 100 ppm.

Sources of Lead in Paint

Even though consumer paint manufacturers have not intentionally added lead to consumer paints since 1978, most consumer paints contain traces of lead. Usually, lead is present in consumer paints at levels of less than 100 ppm. However, lead levels over 100 ppm but less than 600 ppm, the current legal limit, are not uncommon. The consensus among paint manufacturers is that most of the lead in consumer paints comes from lead impurities that naturally occur in many paint raw materials.

The primary paint raw materials that contain lead impurities are the various inorganic pigments. Inorganic pigments are produced from minerals which are mined from the earth's crust. Because lead is a ubiquitous element in the earth's crust, the minerals from which the inorganic pigments are produced naturally contain small amounts of lead which may end up in the manufactured paint.

One paint manufacturer that submitted comments in response to the NRI supplied the "typical" lead levels of several commonly

used pigments. The commenter indicated that the actual level of a particular lot could be higher or lower depending on the pigment involved, the geographic location of the mine, and the type and amount of processing. The levels reported by the manufacturer follow.¹

<u>Pigment</u>	<u>Lead Content (ppm)</u>
titanium dioxide	1.0
red iron oxide	50.0 - 600.0
yellow iron oxide	10.0 - 50.0
magnesium silicate (talc)	10.0
barium sulfate	22.0
aluminum silicate	12.0
kaolin clay	4.0 - 40.0
diatomaceous silica	2.0
silica	1.0

Reducing Lead Contamination

If pigments and other inorganic raw materials are the major source of lead contamination in paints, then the most effective way of reducing lead in consumer paints is to reduce the lead content of the pigments used. Reducing the lead content of the pigments would involve paint manufacturers determining the levels of lead contamination they can tolerate for each pigment and then specifying to their suppliers that all shipments must be below this level.²

The lead content of a particular pigment is influenced by the lead content of the raw ore or feedstock from which the pigment is derived and the type and amount of processing performed. Pigment suppliers routinely monitor the lead levels of their products due to the fact that for some applications they are required to meet strict purity standards. For example, both calcium carbonate and zinc oxide are used as pigments in the paint industry and as dietary supplements in the food and drug industry. When used as dietary supplements these products can contain no more than 10 ppm lead. However, when used as pigments in consumer paints the only constraint is that the final paint contain no more than 600 ppm lead when dried.

Because pigment suppliers would have to meet more stringent specifications, it is expected that their costs, and therefore, their prices would increase. The magnitude of the increase is dependent upon several factors. Suppliers whose product is already very low in lead may have to take few, if any, actions to meet the new specifications. On the other hand, suppliers of pigments with higher lead contents may have to take more severe actions. These actions may include changing the source of the raw ore or feedstock that they use or changing the process used

to refine the pigments. The costs of these actions will be passed on the paint manufacturers and eventually to the consumers.

An authority at a paint manufacturing company, contacted by telephone, said the current lead-in-paint limit allows manufacturers some leeway in the use of inorganic pigments. The authority expressed a particular concern that a lower limit may make it more difficult to use zinc oxide in consumer paints.³ Zinc oxide is a pigment frequently used in exterior house paints to inhibit mildew growth. Zinc oxide often has a high level of lead contamination. However, zinc oxide is occasionally used as a dietary supplement and so it seems likely that relatively pure zinc oxide can be obtained. Whether the purer zinc oxide would be an economical alternative for the consumer paint industry has not been determined. Therefore, while a lower lead-in-paint limit may not rule out the use of zinc oxide in consumer paints, its use may have to be considered with more care in formulating paints. The same may be true of other pigments or raw materials that paint manufacturers currently use.

It is possible that some manufacturers may not be able to adjust the formulations of some particular paints sufficiently to insure that all batches produced meet a more stringent lead standard. In these cases the manufacturers would either have to drop the particular lines of paint involved or more closely monitor their lead levels. If excess lead is found in some batches the manufacturers would have to take some form of remedial action. For example, the noncomplying batches could be blended with batches containing lower levels of lead. Alternatively, manufacturers may simply dispose of the noncomplying batches of paint. Costs would be incurred by the manufacturer in each of these alternatives. The costs would include the cost of labor and materials needed to monitor the lead levels and blend the noncomplying batches of paint or to produce extra batches of paint to replace batches that had to be disposed. The manufacturers may also incur capital costs if storage or manufacturing capacity has to be expanded. If the manufacturers simply drop these lines of paint then consumers may experience costs in the form of reduced utility.

Thus, although it is probable that paint manufacturers can make adjustments that would enable their products to meet more stringent lead-in-paint requirements, some cost would be involved. The magnitude of the cost is difficult to estimate with available information. The cost may be modest if the only action manufacturers must take is to change their sources for a few pigments. The cost may be more significant if manufacturers are no longer able to use certain key pigments or if reducing the lead content of pigments proves costly.

Lead in Artists' Paints

The Arts and Craft Materials Institute (ACMI) submitted comments to the Commission supporting the continued exemption of artists' paints. Lead is often used in artists' paints as pigments and as driers. The ACMI reported that the average cost of reformulating artists' paints to remove the lead would be \$50,000. ACMI also suggested that there was no guarantee that a reformulated product would be equal to the original product in either performance or quality.⁴

Current Industry Efforts to Reduce Lead in Paints and Coatings

The use of lead is legal in many types of paints and coatings including traffic paint, mirror backing, marine paint, and various industrial coatings. The increased attention focused on lead by health professionals and government agencies is leading manufacturers to seek ways to reduce their use of lead. The National Association of Mirror Manufacturers reports that substantial progress has been made towards developing low-lead and no-lead mirror backings. Currently, these backings have acceptable performance qualities at time of manufacturer but their durability is not known at this time.⁵ Another firm that specializes in industrial protective coatings reports that it is undertaking an effort to make the firm "lead-free" in the near future.⁶

Estimating the Benefits

Given that lead has adverse impacts on human health at very low levels, any action that reduces human exposure to lead will have a positive impact on public health. However, in order to estimate the value of these benefits, more information is required concerning the magnitude of the expected reduction in exposure to lead. The magnitude of the reduction would be dependent upon the specific changes made. For example, it is possible that the use of pigments would be adjusted in such a way that the only paints affected are those that otherwise would have had excessive lead levels. The result would be a modest reduction in the public's exposure to lead. However, it is conceivable that the use of pigments would be adjusted in such a way that the average lead levels of all paints are reduced. The result in this case would be a more significant decrease in the public's exposure to lead.

Notes

1. Public Comment CH92-2-3.
2. The information under this heading is based upon information obtained in telephone conversations with authorities at two paint manufacturers and pigment suppliers. The conversations took place on December 3, 1992; January 29, 1993; and February 5, 1993.
3. Telephone conversation of January 29, 1993.
4. Public Comment CH92-2-10.
5. Public Comment CH92-2-3.
6. Telephone conversation on December 5, 1992.

UNITED STATES GOVERNMENT
MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

MAR 17 1993

TO: Murray S. Cohn, Ph.D., Director, Division of Health Effects

FROM: ~~SV~~ Brian C. Lee, Ph.D., D.A.B.T. and Laureen E. Burton, M.P.H., Directorate for Health Sciences *MSC*

SUBJECT: Health-related responses to comments received from the April 30, 1992 Federal Register notice of regulatory investigation on limits for lead levels in paint.

I. Introduction

The Commission's Federal Register notice requesting information on limits for lead in paint resulted in comments from 15 respondents. Most of the significant comments were related to health effects, consistent with the health effects-driven nature of the investigation. Legal aspects of the comments are addressed in the memorandum from the Office of the General Counsel.

Some of the comments were unrelated or peripherally related to this regulatory investigation, for example, those related to lead figurines, heat guns, and blood lead testing facilities. A few commenters included informational copies of reports or comments submitted to other agencies on other matters. Some commenters misinterpreted the notice as a proposal to lower the limit of lead in paint to 0.01 percent instead of a request for information.

No new data were received regarding the absorption and consumption of paint chips and dust by young children. A couple of commenters believed that the absorption and consumption assumptions were too high, but did not provide data supporting lower values. One commenter provided critical information that prompted the staff to further revise one part of its exposure estimate.

The one critical comment and the staff response will be presented first. This will be followed by other relevant comments and staff responses. Summarized comments are referred to by the comment number assigned by the Office of the Secretary, identification of document (if necessary to distinguish between multiple documents in the same submission), and page number. The list of commenters from the Office of the Secretary is attached.

II. Critical comment and staff response

COMMENT

The weight of a coat of paint can be estimated from the wet weight of the paint, the dried weight, and surface area covered. [report from 6, Tables 1 and 2].

RESPONSE

The following estimates used the factors mentioned by the commenter for currently marketed architectural paint. Common house paint covers 400 ft²/gal according to the labels. A gallon of common paint is about 10 lb wet weight and 30 percent non-volatile materials. One coat of current paint is therefore $30 \text{ percent} * 10 \text{ lb/gal} / 400 \text{ ft}^2/\text{gal} = 0.0075 \text{ lb/ft}^2$, or in metric units, 3670 ug/cm²/coat dry weight.

This suggests that typical paints are lighter in weight than those measured 20 years ago. Data from King (1971) indicated paint was 6500 ug/cm²/coat dry weight, which is about twice as heavy as current paint. Thus, the 0.01 percent level estimated in the notice of regulatory investigation should be revised to a recommended maximum allowable limit of 0.02 percent.

Reference: BG King (1971)- "Maximum daily intake of lead without excessive body lead-burden in children." Amer J Diseases Child 122 337-340.

III. Other comments and staff responses

A. OTHER SOURCES OF LEAD EXPOSURE

COMMENT

The primary reference used to determine the 0.06 percent limit for lead in paint (King, 1971) is biased against paint and blind to gasoline as the overwhelming source of child blood lead. Literature citations since then as well as information on bioavailability differences for various types of lead (i.e. high for gasoline lead chloride and low for paint driers), indicate that the limit can be restored to 0.5 percent. [1, Weaver memorandum to Lee, 7/13/92, p.1]

RESPONSE

Other sources of lead were not explicitly considered in the development of the 0.06 percent level because no data existed at that time. Although the entire blood lead level was not attributed solely to a paint source, the American Academy of Pediatrics (AAP, 1972) and the National Academy of Sciences (NAS,

1973) estimated that paint was a major contributor to blood lead levels considered hazardous at that time (40-60 ug/dl).

Leaded gasoline exhaust was also a major contributor to blood lead levels prior to the EPA ban on leaded gasoline. The reduction of average blood lead since the 1970s from 15-20 ug/dl in some cities to 3-4 ug/dl is attributed primarily to this ban. However, other sources of lead exist since blood lead levels continue to be excessive (>10 ug/dl) in an estimated 15 percent of American children six years old and under (previous briefing package Tab C).

Lead paint is still a major contributor to blood lead levels and therefore is of high concern to the Federal government. The intent of the CPSC ban on lead paint was to prevent future excessive contributions of paint to blood lead levels. It did not concern paint which was already applied.

The staff's current consideration of a maximum allowable lead in paint level (previous briefing package Tab C) includes the contribution of blood lead levels from "background" sources other than paint. Based on present knowledge, the staff believes it would be unsafe to return to the previous 0.5 percent level.

References:

AAP (1972)- "Lead content of paint applied to surfaces accessible to young children." Pediatrics 49 918-921.

NAS (1973)- Report of the ad hoc committee to evaluate the hazard of lead in paint.

COMMENT

Better environmental source identification and risk assessment methodology is needed to determine sources of the genuine lead exposure hazard. CPSC should investigate other sources of lead exposure, and take appropriate actions to reduce those exposures. [9, p.9; 12, p.5; 15, p.2]

RESPONSE

Blood lead levels may result from exposure to multiple sources including dust (from leaded gasoline exhaust, paint, industrial activities, and soil), paint, water, food, and art/crafts materials. Effective prevention of excessive blood lead levels involves reducing exposure to each of these multiple sources, not just a single source. Several Federal agencies, including CPSC, currently coordinate efforts to prevent lead poisoning by reducing exposure from various sources of lead.

COMMENT

Before changing the 0.06 percent limit for lead in paint, CPSC should await the results of the US Environmental Protection Agency (EPA) 1992 Three City Urban Soil Lead Demonstrations. The preliminary findings from this research indicate that the source of environmental lead could be something other than paint, such as soil contaminated by lead additives in gasoline. [1, Weaver memorandum to Lee, 7/13/92, p.1; 3, p.2]

RESPONSE

At two technical lead poisoning conferences (Brophy, 1992; Bornschein, 1992), results of the Three City Urban Soil Lead Demonstration studies were reported. In these studies, soil with high (>1000 ppm) lead levels was removed or covered. The blood lead levels of the residents were not affected by the soil abatement. Dust levels in soil-abated homes fell immediately, but then recovered to pre-abatement levels in about a month. Thus, soil lead was not the only significant contributor to the residents' blood lead levels. The rapid recovery of interior dust lead levels suggests other sources, such as paint, play a role.

References:

R Bornschein (1992)- CDC National Childhood Lead Poisoning Prevention Conference, Ravinia, Atlanta, GA. 8 Dec.

M Brophy (1992)- Lead Tech '92, Bethesda, MD. 1 Oct.

B. LEAD DUST FROM PAINT**COMMENT**

The primary vector of lead poisoning in children is surface dust. Lead dust is released from paint as a result of deterioration, abrasion, or disturbance (i.e. through home repair, renovation, or abatement).[8, p.1; 15 p.1]

The issue of untrained or improperly trained abatement professionals should be addressed. The improper work practices of these individuals may increase lead dust exposure levels. [9, p.8; 12, p.6]

To reduce exposure to lead dislodged during renovation, CPSC should evaluate and regulate paint removal products (i.e. heat guns, chemical strippers, scraping and sanding tools, etc.).[8, p.1]

RESPONSE

The development of the 0.06 percent standard or the 0.01 percent estimate (previous briefing package Tab C) reflects information that ingestion of deteriorating paint is known to be a major route of lead exposure in children. Improper removal of lead paint can result in lead poisoning of the workers, occupants, neighbors, and pets. However, insufficient data are available to estimate contributions to blood lead levels resulting from the removal activities on current paint (<0.06 percent). The Commission issued a safety alert in 1990 indicating that removal of lead paint should be done by professionals (CPSC, 1990).

The staff believes that reduction of lead in paint levels would result in less exposure during future removal/remodeling activities, whether done by consumers or professionals. The US Navy is moving toward a 0.005 percent standard for architectural paints to eliminate future problems associated with worker protection and hazardous waste disposal of paint.

Reference:

CPSC (1990)- "What you should know about lead-based paint in your home." Safety alert.

C. INTERNATIONAL STANDARDS**COMMENT**

The lead level limit for paint applied on toys in Brazil is 90 mg/kg, according to specification ABNT EB-2082. [2, p.1]

The choice of a level of 100 ppm is particularly appropriate in that it would bring the United States into line with European countries which currently require that children's toys and related materials have bioequivalency lead levels of 90 ppm or less. [11, p.3]

The Danish legislation has no ban on lead in paint (pigments and driers). However, for private use a lead content greater than 0.15 percent (w/w) has to be labelled. [14, p.1]

RESPONSE

The Brazilian specification for paint on toys of 90 mg/kg (90 ppm) relates to a leaching level (bioavailable) rather than the total lead in paint. It conforms to the EN-71 European Common market specification for toys. The current CPSC and EN-71 standards do not conflict. Both levels are used in the ASTM F963 Toy Safety standard proposed revisions.

The 0.15 percent level stated as part of the Danish legislation is greater than the Commission's 0.06 percent standard. The commenter provided no data to support the 0.15 percent level.

D. REGULATORY ACTIVITIES

COMMENT

A provision of the current House bill designed to reduce lead exposure limits the lead-content in industrial coatings to the current CPSC maximum level of 0.06 percent by dry weight. We assume that if this House bill passes and CPSC lowers the maximum lead level to 0.01 percent, industrial coatings could not exceed this new level. Therefore, any decision your office makes may impact industrial as well as consumer paints. [3, p.1]

It is recommended that the Commission await the enactment of current legislation in the House and Senate which will within a period of time result in lead being eliminated from many products including mirror backing paint. [4, p.2]

RESPONSE

The final legislation referred to by the commenters was not passed. One compromise bill passed at the end of the last session of Congress (Title X, H.R. 5334, "Residential Lead-Based Paint Hazard Reduction Act of 1992") did not address industrial coatings or mirror backing paint.

COMMENT

Some cities and states require rehabilitation of building with interior paint with lead levels above the nationally recommended or mandated levels. Lowering the level may cause such entities to lower their intervention threshold and thereby expend major funds and dislocate families. [15, p.2]

RESPONSE

Government entities prioritize abatement activities to address the worst situations first. Top priority is logically given to areas with the most urgent lead paint hazards -- heavily leaded paint that is deteriorating. In parts of the US, there are insufficient resources to abate paint above 0.5 percent, which is the action level recommended by the U.S. Department of Housing and Urban Development (HUD, 1990). Therefore, government-sponsored abatements are less likely to occur for paint below 0.5 percent.

Reference:

HUD (1990)- Lead-Based paint: Interim guidelines for hazard identification and abatement in public and Indian housing. Sept. 1990.

E. SOURCES OF LEAD IN PAINT

COMMENT

In producing consumer housepaints, manufacturers do not utilize lead. However, most paints contain pigments which are mined from the earth and may be naturally contaminated with lead. Depending on the type of pigment and the geographical location of the mine, addition of the pigment may cause the lead level of the paint to naturally exceed 0.01 percent. [3, p.1; 9, p.13]

RESPONSE

The natural occurrence of a toxicant in the earth's crust can not be considered justification for allowing its existence at hazardous levels in a consumer product. As an analogy, aflatoxin is a potent carcinogen produced by a naturally occurring mold that grows on peanut and grains. Peanut butter containing aflatoxin above a specified level (1 ppb) is unsafe for human consumption. Just as peanut butter manufacturers test peanuts for aflatoxin, paint manufacturers could test pigments for lead.

The commenters acknowledge that the pigments refined from mined earths are the likely source of lead in current day paints. The paint industry can discern and avoid raw materials for pigments and extenders that would result in greater than, for example, a 0.01 percent lead in paint level. Some paint manufacturers include a maximum lead level in specifications for pigment materials.

COMMENT

The CPSC should investigate potential paint substitutes prior to reducing the level of lead in paint. This substitute should be proven to be less harmful than lead and not be prohibitively expensive. [12, p.4; 15, p.1]

RESPONSE

Substitutes may be needed only for the currently exempted uses of lead paint; none are needed to achieve a lower level in residential paint. No data were provided regarding substitutes for currently exempted lead paint.

F. EXEMPTED USES OF LEAD PAINT

COMMENT

The exemption for mirrors--Sec. 1303.3(c)(1) of the current regulation should not be amended. The rationale presented in support of the exemption for mirrors is the fact that consumers do not get exposed to the lead backing paint on mirrors because the back of the mirror is always either affixed to the wall or is in a frame with a backing. In addition, the industry has reduced the lead used in mirror backing and is continuing its efforts to confirm the effectiveness of the technology used in producing low-lead or no-lead mirror backings. [4, p.1]

RESPONSE

If the mirror backing paint is sealed or enclosed, then this exempted use would not contribute to consumer exposure. If it is not sealed or adequately enclosed, then the deteriorating paint could become a source of lead exposure. No information is available on exposures from mirror backing paint.

COMMENT

The current exemption for artist paints and related materials should be maintained. The rationale for this exemption is that they perform a valuable role to artists, there are no adequate substitutes, and they do not present a risk of ingestion by small children. Lead can occur in artist paints as a raw material or as a contaminant. Lead in certain artists' products can occur at levels above the current 0.06 percent limit and is allowed under the current exemption for artist paints and related materials. It would be impossible to reformulate these materials to meet either the current 0.06 percent or the proposed 0.01 percent level and retain the same properties of these materials. [10, p.5; 13, p.1]

RESPONSE

Information provided by the commenter indicates some artist paints are well above 0.06 percent. Under the present exemptions, a wall-filling mural or sign could be created with lead paint. Its deterioration could present a significant lead hazard to the consumer. However, the staff is unaware of any consumer incidents related to such situations. It is possible that leaded artist paints are too expensive or otherwise unsuitable for architectural purposes. Art materials are covered under the Labeling of Hazardous Art Materials Act (LHAMA).

COMMENT

The current definition of paint should continue to exclude materials that are bonded to the substrate of the finished product, such as ceramic glazes. Lead is contained in ceramic glazes, overglazes and underglazes which are regulated by CPSC under FHSA/LHAMA and by the Food and Drug Administration (FDA) for lead-release in food-safe glazes. These products are not within the scope of the current regulation because they are bonded to the resulting artwork through kiln firing. [10, p.12]

RESPONSE

Ceramic glazing before application is subject to FHSA/LHAMA regulations. Once it has been fired, the glazing is no longer considered paint.

G. EXPOSURE ASSUMPTIONS

COMMENT

Exposure resulting from ingestion of paint "chips" from modern day paints is not reliably quantifiable in a manner consistent with that shown in historical studies involving old lead based paint. [9, p.4]

RESPONSE

It is not known if there are differences in the ingestion of modern vs. old paint because there are no data for either. The Commission's Federal Register notice requested information regarding ingestion of paint chips and dust, especially by young children. No data were received regarding ingestion.

COMMENT

Biological indicators of toxic exposure, while lower than in previous studies, are not so low as to preclude any increased concern for modern paints as a source of exposure. [9, p.4]

The new threshold for identifying toxic levels of lead (in adolescent populations) should result in increased concern about environmentally dispersed lead, not residual lead in products which have already been regulated. [9, p.4]

RESPONSE

This investigation arises from the Commission's concern about currently marketed paint as a possibly significant source of lead exposure, in light of the recent toxicological information on lead poisoning. The Federal Register notice was issued to request information where certain data gaps existed.

Blood lead levels are used as a biological indicator since the associations to adverse health effects in humans are known. The 10 ug/dl level of concern issued by the Centers for Disease Control and Prevention (CDC, 1991) is based mainly on toxic effects in young children, not adolescents. However, the CPSC staff also identified toxic effects on the fetus and adults which can occur above that level.

Blood lead levels alone can not identify specific sources of exposure. The lead from products, whether previously regulated, can contribute to lead in the environment.

Reference:

CDC (1991)- Preventing lead poisoning in young children. Oct.

COMMENT

The estimated incidence of pica at 50 percent seems high. Based on a poll of four [unidentified] prominent pediatricians, the estimated prevalence of pica is between five and ten or fifteen percent or less. [15, p.2]

RESPONSE

The incidence of pica was not a factor in the staff review of the limits for lead in paint. The definition of "pica" varies in the scientific literature (CPSC, 1990). Some researchers used it to describe mouthing activities, some use it to mean ingestion of non-food items, and others use it to refer to excessive dirt eating. As a result, the reported incidence of "pica" vary widely.

Reference:

CPSC (1990)- "Project on playground equipment- Transmittal of estimate of risk of skin cancer from dislodgeable arsenic on pressure treated wood playground equipment." Dated August 2, 1990. Informational package containing: BC Lee (1990)- "Estimation of hand-to-mouth activity by children based on soil ingestion for dislodgeable arsenic exposure assessment." Memo to EA Tyrell, EXPM, from BC Lee, Ph.D., HSHE. Dated January 26, 1990.

COMMENT

Based on 0.01 percent lead contamination and standard assumptions for paint of 11 lb/gal, 60 percent solids, and coverage area of 400 ft²/gal, the ingested dose would be 6.76 ug/day. The EPA Biokinetic Uptake Model for lead exposure demonstrates the inappropriateness of setting 6.76 ug/day (which

is a trivial level when compared to other common sources of exposure) as the maximum exposure level which would assure reduction in the incidence of childhood lead poisoning from paint ingestion. [9, p.16]

The EPA Biokinetic Model indicates that lead exposure through the inhalation route is extremely small in comparison to the ingestion route and therefore does not warrant further concern. [9, p.16]

RESPONSE

The EPA biokinetic model was intended for estimating blood lead levels and risk due to hazardous waste exposures. It was not intended for application to consumer paint exposure. Nevertheless, if the default assumptions are changed to appropriate values for lead paint absorption and the intent to protect 90 percent of young children, the model verifies the estimates (previous briefing package Tab C) made by CPSC staff.

Absorption of inorganic lead by inhalation is less significant than by ingestion in the usual everyday consumer situation (previous briefing package Tab B). However, inhalation might become a significant source in certain situations, such as during paint removal.

No inhalation data exist for children, so the model assumes absorption to be the same as in adults. This might possibly be an inappropriate assumption since absorption by ingestion is age-dependent (previous briefing package Tab B). EPA is revising the model due to newly developed data on exposure and resultant blood lead changes. Users of the model should be aware of its assumptions, defaults and proper application.

COMMENT

The following should be considered when applying the exposure assumptions used to determine the current 0.06 percent and the proposed 0.01 percent levels to artists' paints:

1. Inhalation is negligible in comparison to ingestion, both in the application process and from the resulting product. Furthermore, the amount of paint applied at any one time is limited: there is less opportunity for exposure, even by ingestion, than from commercial or household paints.
2. Lead-containing paint on a typical painting is only two coats thick. Upon complete drying, the surface may be sealed by varnish, which reduces the likelihood of deterioration.

3. The amount of lead containing paint a child could ingest from a finished painting is negligible since the paint on a painting does not normally chip off, nor do children usually put paintings in their mouths.
4. The absorption of lead from ingested lead paint will generally be less than absorption of lead from food. [10, p.8]

RESPONSE

Lead exposure from using artist paints is considered under FHSA/LHAMA. Children of artists could be exposed to lead from paint splatters or dust in the children's living or play area, or from the washing of protective clothing with the children's clothing and linens. The staff's scenario used to recommend a maximum limit of lead in paint considered only ingested paint, not inhaled paint. No data were received on exposure from inhalation.

Although the staff agrees with the commenter that an artist's oil painting is typically two coats thick, the coats can be thicker, heavier, and more heavily pigmented than ordinary architectural paint. Varnish should not be considered an adequate encapsulant since it would probably fail to meet most of the ASTM E06.23.30 task group's [draft] performance criteria for encapsulants. However, the staff agrees that an overcoating, such as varnish, may retard paint deterioration by reducing contact with oxidants in the air.

The staff agrees that certain consumer practices may minimize exposure to artist paint. Paintings are normally not placed in locations prone to abrasion or mouthing by young children. Although deteriorating paintings can chip, the staff feels that a chipping painting would probably be discarded or repaired due to its unsightly appearance.

H. BIOAVAILABILITY

COMMENT

Ingestion of paint "chips" involves different lead compounds with different bioavailabilities. Therefore, the CPSC lead in paint level should reflect actual risk and should be based on testing for bioavailable levels of lead not total lead. A number of tests including a European standard [CEN's EN-71.3 (1988)] and a test currently under consideration by ASTM give surrogate measures of the bioavailability of lead in paints and other consumer products. [9, p.4,16; 10, p.9; 11, p.1]

CPSC specifically notes in the proposed guidelines for LHAMA that bioequivalency testing should be utilized for evaluating the

toxicity of an art material. The same concept should be extended to other consumer products. [11, p.1]

RESPONSE

Bioavailability is an important toxicological parameter describing the amount of a substance that is released and "available" for absorption by the body. The concept is embraced in the FHSA/LHAMA guidelines, ASTM standard D-4236 for art materials, and proposed revisions for ASTM standard F-963 for toys. The staff agrees that the form of lead can affect bioavailability. Several different forms, including oxide, carbonate, tallate, stearate, chromate, and chloride, exist in paints.

The staff agrees that there are large differences in the water solubility among the forms of lead. In general, bioavailability increases with water solubility for inorganic lead salts. However, it is not known if this is valid for lead fatty acids or "soaps" that were used as drying accelerators in oil-based paint.

Data from rodent ingestion models cited by some commenters do not reflect absorption of lead ingested by human children. EPA is presently funding an absorption study with young pigs having metal absorption characteristics more closely resembling the young children.

The "matrix" or substance that contains the lead also affects bioavailability. If the matrix binds the lead loosely, then more lead can be liberated than with a tightly binding matrix. The composition of paint varies among the presently marketed types and brands of paint. The wide range of paint matrices plus the different forms of lead in the paint may result in an even wider range of associated bioavailabilities.

In addition, a coat of paint may vary within itself. For example, the matrix characteristics of the shiny top of a high gloss paint differs from the lower part attached to the substrate. This difference in matrix characteristics and thus bioavailability within a coat of paint is significant to the determination of bioavailable lead. Different bioavailabilities could occur depending on the type of deterioration process and the paint involved.

Aging/weathering effects are not addressed by FHSA/LHAMA and ASTM art or toy standards. However, the CPSC staff and ASTM paint and lead abatement/encapsulant committees recognize that aging/weathering substantially affects aesthetic and physical properties of surface coatings. Bioavailability could increase as the matrix deteriorates from aging/weathering.

Considering the variability of forms of lead, matrices, and aging/weathering conditions, insufficient data are available to reasonably propose incorporation of a simple bioavailability test for lead in residential paint. Although the CPSC regulation (16 CFR 1303) specifies total lead, a 40 percent absorption of an ingested amount was assumed in the staff's review of the lead in paint level (previous briefing package Tab C). This assumption was based on data from studies with young children and infants ingesting lead in milk or water (previous briefing package Tab C).

I. LEAD POISONING SYMPTOMS

COMMENT

The association between low lead levels and neurobehavioral deficits is questionable. The primary reference used to determine these associations (Needleman, 1979) has been questioned. There are reports that contradict his results that effects are related to other lifestyles and socioeconomics. The effects from early exposure are temporary. [9, p.20; also mentioned in comments by 7, p.18 to another agency]

RESPONSE

The permanence of lead-induced retarded mental development is unknown (previous briefing package Tab B). Results presented by McMichael (1988) found retardation continued to age four, which was the end of the study. Other studies cited by the commenters indicate the developmentally delayed children may be able to "catch-up" after four years. At the least, neurobehavioral effects may be long-term.

The commenters supplied informational copies containing comments to another agencies on a related area. Attempts to discount neurobehavioral effects of low level lead exposure migrate toward reporting suspected fraud and scientific misconduct against the work of pediatric researcher, Dr. Herbert Needleman. These were initiated by Dr. Claire Ernhart, a social scientist and Virginia Scarr, a psychology professor. The National Institutes of Health Office of Scientific Integrity asked the University of Pittsburgh to determine the need for an investigation.

The staff briefed the Commission in March 1992 regarding the controversy. The staff's 10 ug/dl blood lead level of concern (previous briefing package Tab B) is consistent with the CDC's level of "community-wide concern" (CDC, 1991). Needleman (1979) examined tooth lead, which was not used by the CPSC staff. The 10 ug/dl level was identified by the staff after considering data on the adverse effects on the physical and mental development of children, and biochemical, reproductive, and blood-forming

systems that increased in incidence and/or severity above 10 ug/dl. Retarded mental development was not the sole critical effect. If the Needleman data were eliminated from consideration, sufficient data exist to continue to support a 10 ug/dl level.

Since that Commission briefing, the University of Pittsburgh panel found "no evidence of fabrication, falsification, or plagiarism" (Science, 1992). Dr. Needleman (1992) responded that Dr. Ernhart and Scarr ignored three meta-analyses (a statistical pooling of several studies that reduces experimenter bias) which show an association of lead exposure (usually blood levels) and decreased mental development. The 10 ug/dl blood lead level continues to be solidly supported by EPA, CDC, and other Federal agencies, as well as the CPSC staff.

References:

CDC (1991)- Preventing lead poisoning in young children. Oct. AJ McMichael, PA Baghurst, NR Wigg, GV Vimpani, EF Robertson, & RJ Roberts (1988)- "Port Pirie cohort study: environmental exposure to lead and children's abilities at the age of four years." New Engl J Med 319 (8) 468-475.

HL Needleman, C Gunroe, A Leviton (1979)- "Deficits in psychologic and classroom performance of children with elevated dentine lead levels." New Engl J Med 300 689-695.

HL Needleman (1992)- "Effects of low levels of lead exposure." Science 256 294-295.

Science (1992)- "Panel clears Needleman of misconduct". Science 256 1389.

V. Conclusion

Given the exposure assumptions used to develop the existing 0.06 percent standard and new information on the density of dried paint, the recommended maximum allowable limit for lead in paint would be 0.02 percent by dried weight. This limit is based on exposure by ingestion and adverse health effects. It may be prudent to use paints with levels lower than 0.02 percent since inhalation of paint dust is not considered and situations involving remodeling or removal of paint may generate a greater exposure than estimated here. Due to the lack of data for these situations, a lower allowable limit can not be estimated.

However, no data were received in response to the NRI concerning the validity of these exposure assumptions, especially regarding the ingestion of paint by children. Therefore, the correctness of using these assumptions to support a lower standard cannot be ascertained.

UNITED STATES GOVERNMENT

RECEIVED-OFFICE
OF THE SECRETARY

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

MEMORANDUM

'93 AUG 24 A10:03

TO : The Commission

AUG 18 1993

Through: Sadye E. Dunn, Secretary *S Dunn*
for Eric C. Peterson, Executive Director *TM*

FROM : Jerry G. Thorn, General Counsel *JG*
Stephen Lemberg, Asst. General Counsel *SL*
Harleigh Ewell, Attorney, GCRA *HE*

SUBJECT: Federal Register Notice to Announce the Termination of the
Regulatory Investigation for Lead In Paint

BALLOT VOTE DUE: SEP 9 1993, 1993.

The Commission recently voted by ballot to terminate the regulatory investigation for lead in paint and directed the staff to prepare a draft Federal Register notice to announce that determination. A draft Federal Register notice is attached for the Commission's consideration. Please indicate your vote on the following options.

I. APPROVE THE ATTACHED FEDERAL REGISTER NOTICE AS DRAFTED.

(Signature)

(Date)

II. APPROVE THE ATTACHED FEDERAL REGISTER NOTICE WITH THE CHANGES NOTED BELOW.

(Signature)

(Date)

III. OTHER (please specify).

(Signature)

(Date)

Comments/Instructions:

NOTE: This document has not been
reviewed or accepted by the Commission.
Initial nh Date 8/18/93

CPSA 6 (b)(1) Cleared
8/18/93
No Mfrs/PrvtLbrs or
Products Identified
Excepted by Rubens

16 CFR Part 1303

Termination of Regulatory Investigation; Lead in Paint

AGENCY: Consumer Product Safety Commission.

ACTION: Termination of regulatory investigation.

SUMMARY: The Commission announces that it has terminated its regulatory investigation of whether its lead-in-paint regulations should be revised to lower the allowable lead content in paint and other articles subject to the regulations. The Commission terminated this investigation because the information obtained to date shows that there is only a small risk of adverse health effects from the lead content of currently marketed paints. In addition, there is insufficient information showing that the benefits of further reductions of lead in paint would bear a reasonable relationship to the costs of that action.

FOR FURTHER INFORMATION CONTACT: Brian Lee, Ph.D., D.A.B.T., Project Manager, Directorate for Health Sciences, Division of Health Effects, Consumer Product Safety Commission, Washington, DC 20207; telephone (301)504-0994.

SUPPLEMENTARY INFORMATION:

A. Background

Since 1976, the Commission has had a regulation banning (1) "lead-containing paint," (2) toys and other articles intended for use by children that bear lead-containing paint, and (3) furniture articles for consumer use that bear lead-containing paint. 16 CFR part 1303. The regulation defines "lead-containing paint" as "paint or other similar surface coating materials containing lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent by weight of the total nonvolatile content of the paint or the weight of the dried paint

film.” 16 CFR 1303.2(b)(2). A number of non-consumer coatings and low-risk products are exempted from the ban. 16 CFR 1303.3.

The maximum allowable lead content of 0.06 percent was established by the Lead Based Paint Poison Prevention Act, 48 U.S.C. 4801 *et seq.*, as amended by the National Consumer Health Information and Health Promotion Act of 1976 (Pub. L. 94-317, 90 Stat. 705-706). The 0.06 percent level had been recommended by the American Academy of Pediatrics and affirmed by the National Academy of Sciences, based on an estimate of the amount of lead required to cause lead poisoning in children and on a number of assumptions about the potential exposure of children to lead in paint.

Recent data, however, indicate that humans, particularly young children, may be more sensitive to the adverse health effects of lead than was believed when the 0.06 percent level was recommended in the early 1970’s. The Commission’s staff determined that applying the new toxicity data to the exposure assumptions used to derive the 0.06 percent level would result in a lead-limit level of 0.01 percent. Although the 0.06 percent level has had the effect of eliminating intentionally-added lead from paint, the Commission’s staff became concerned about whether the 0.06 percent level still provided adequate protection of the public, and especially children, from the risk of lead poisoning.

On April 30, 1992, the Commission published a Notice of Regulatory Investigation (“NRI”) in the **Federal Register** announcing that the Commission was investigating whether to revise its lead-in-paint regulations in view of the recent findings regarding the effects of exposure to lead. 57 FR 18418. The NRI explained the issues in more detail and cited relevant source documents. In the NRI, the Commission solicited comments and information concerning a number of topics that would have to be addressed if it was found necessary to amend the ban of lead-containing paint.

B. Lead Levels in Currently-Marketed Paint

In order to determine the lead levels in currently-marketed paints, the Commission's staff conducted a nationwide sampling of the paint market. Of the 433 samples tested by the Commission's Health Sciences Laboratory, 90 percent contained less than 0.01 percent lead and 98.6 percent contained less than 0.02 percent lead. The average lead content was 0.004 percent. Only one sample was found to be over the current 0.06 percent limit, and this was referred to the Commission's Office of Compliance and Enforcement for possible corrective action.

These results were consistent with tests of 31 samples from the Washington, DC, area reported by the National Institute of Standards and Technology ("NIST") in 1992. The results are also consistent with the analysis of eight samples of paint colorants conducted by Consumer and Corporate Affairs, Canada.

C. Comments Received on the Notice of Regulatory Investigation

The Commission received 15 comments on the NRI. Most of these related to the health effects of exposure to lead. No information was received that would allow an estimate of the number of children who ingest lead paint or of the amounts of lead ingested.

One comment provided valuable information about estimating the amount of lead to which children are exposed with a currently marketed anticorrosion coating. This comment provided a calculation procedure for estimating the weight of a coating. Using the procedure with typical application rates for currently marketed architectural paint, the staff estimated that the weight of currently marketed paint was about half the weight that was assumed in the development of the 0.06 percent level. Application of this estimate and the more recent information on the health effects of lead to the methodology used to compute the 0.06 percent level resulted in an estimated allowable level of 0.02 percent. No other information was received that would allow any further refinement of the allowable level. Additionally, no other information was received that confirmed or invalidated the appropriateness of exposure assumptions used in the computational methodology.

No comments were received that would justify any change in the types of products that are currently exempted from the lead-in-paint regulations. Comments were received recommending that the standard should be based on “bioavailable” lead, rather than on the total amount of lead in the dried film. There is insufficient information about the various factors that might affect bioavailability to justify such an approach.

D. Conclusion

The Commission concludes from the information discussed above that there would be very little benefit from a reduction of the allowable level of lead in paint from the current level of 0.06 percent to the revised recommended level of 0.02 percent. As noted above, the lead content of 98.6 percent of currently marketed paint already is below the 0.02 percent level, and the average level is 0.004 percent. In addition, the significance to the health of children of the slight percentage of marketed paint that exceeds the recommended level is not known. The statute under which the lead-in-paint regulation was issued (the Consumer Product Safety Act, 15 U.S.C. 2051-2084) requires that, in order to lower the level of paint by regulation, the Commission would have to obtain substantial evidence showing that the benefits of the regulation bear a reasonable relationship to its costs. This would require at least a minimum estimate of the benefits resulting from lowering the allowable limit. The sorts of assumptions used to arrive at the Congressionally-directed level of 0.06 percent would not provide this type of estimate, and other information that would enable such an estimate is not expected to be available in the foreseeable future.

For these reasons, the Commission concludes that the available information does not show that there is an unreasonable risk of lead toxicity associated with currently marketed paints. In addition, the available information does not show that the benefits of further reductions of lead levels in paints would bear a reasonable relationship to the costs required to achieve the reductions. Significant additional information on these topics is not expected to be able to be obtained in the foreseeable future. Accordingly, the Commission is terminating its investigation of whether to change the allowable limit of lead in paint. If information becomes available in the future

showing that Commission action is needed to reduce an unreasonable risk of injury to consumers, however, the Commission will take appropriate action.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 93-????? Filed ??-??-??;8:45 am]

BILLING CODE 6355-01-F

UNITED STATES GOVERNMENT
MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

'93 JUN 15 09:11
JUN 3 1993

TO : The Commission
Through: Sadye E. Dunn, Secretary
Eric C. Peterson, Executive Director
FROM : Jerry G. Thorn, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (504-0980)
SUBJECT: Regulatory Investigation Concerning Levels of Lead in Paint

BALLOT VOTE DUE JUN 22 1993

Attached is a staff briefing package that discusses the status of the regulatory investigation concerning whether the Commission should lower the allowable levels of lead in the Commission's ban of lead-containing paint and certain articles bearing such paint, 16 C.F.R. Part 1303. This investigation was the result of new information indicating that children are more sensitive to the adverse effects of lead exposure than was previously believed. The Commission published a notice of "Regulatory Investigation" ("NRI") in the Federal Register on April 30, 1992, requesting information on this issue.

Based on the latest available information, the staff recommends that the Commission terminate this investigation because of the small risk of serious adverse health effects from currently-marketed paints. Please indicate your vote on the following options.

I. TERMINATE THE REGULATORY INVESTIGATION FOR LEAD IN PAINT.

(Signature)

(Date)

II. THE STAFF IS DIRECTED TO CONTINUE THE REGULATORY INVESTIGATION TO SEEK FURTHER DATA ON HUMAN EXPOSURE TO LEAD IN PAINT AND ON THE COSTS AND BENEFITS OF A LOWER LIMIT ON LEAD IN PAINT.

(Signature)

(Date)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial rh Date 6/3/93

CPSA 6 (b)(1) Cleared

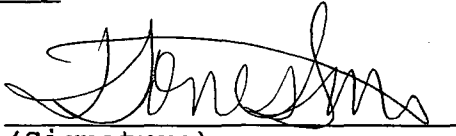
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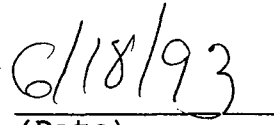
III. THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE TO PROPOSE TO LOWER THE LIMIT FOR LEAD IN PAINT, FOR THE COMMISSION'S CONSIDERATION.

(Signature)

(Date)

IV. IF THE COMMISSION VOTES TO TERMINATE THE REGULATORY INVESTIGATION, THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE ANNOUNCING THIS DECISION.


(Signature)


(Date)

V. OTHER (please specify).

(Signature)

(Date)

Comments/Instructions:

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT

RECEIVED-OFFICE SAFETY COMMISSION
OF THE SECRETARY WASHINGTON, D.C. 20207

'93 JUN 15 9 08 3 1993

TO : The Commission

Through: Sadye E. Dunn, Secretary
Eric C. Peterson, Executive Director

FROM : Jerry G. Thorn, General Counsel
Stephen Lemberg, Asst. General Counsel
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Based on the latest available information, the staff recommends that the Commission terminate this investigation because of the small risk of serious adverse health effects from currently-marketed paints. Please indicate your vote on the following options.

I. TERMINATE THE REGULATORY INVESTIGATION FOR LEAD IN PAINT.

Mary Galt
(Signature)

06/18/93
(Date)

II. THE STAFF IS DIRECTED TO CONTINUE THE REGULATORY INVESTIGATION TO SEEK FURTHER DATA ON HUMAN EXPOSURE TO LEAD IN PAINT AND ON THE COSTS AND BENEFITS OF A LOWER LIMIT ON LEAD IN PAINT.

(Signature)

(Date)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial nh Date 6/3/93

CPSA 6 (b)(1) Cleared

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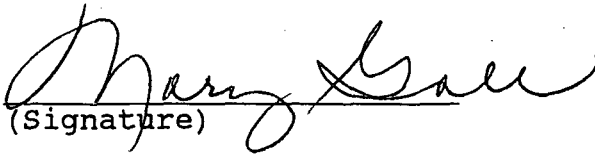
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III. THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE TO PROPOSE TO LOWER THE LIMIT FOR LEAD IN PAINT, FOR THE COMMISSION'S CONSIDERATION.

(Signature)

(Date)

IV. IF THE COMMISSION VOTES TO TERMINATE THE REGULATORY INVESTIGATION, THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE ANNOUNCING THIS DECISION.


(Signature)

06/18/93
(Date)

V. OTHER (please specify).

(Signature)

(Date)

Comments/Instructions:

UNITED STATES GOVERNMENT
MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

93 JUN 15 A9 JUN 3 1993

TO : The Commission

Through: Sadye E. Dunn, Secretary
Eric C. Peterson, Executive Director

FROM : Jerry G. Thorn, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (504-0980)

SUBJECT: Regulatory Investigation Concerning Levels of Lead in
Paint

BALLOT VOTE DUE JUN 22 1993

Attached is a staff briefing package that discusses the status of the regulatory investigation concerning whether the Commission should lower the allowable levels of lead in the Commission's ban of lead-containing paint and certain articles bearing such paint, 16 C.F.R. Part 1303. This investigation was the result of new information indicating that children are more sensitive to the adverse effects of lead exposure than was previously believed. The Commission published a notice of "Regulatory Investigation" ("NRI") in the Federal Register on April 30, 1992, requesting information on this issue.

Based on the latest available information, the staff recommends that the Commission terminate this investigation because of the small risk of serious adverse health effects from currently-marketed paints. Please indicate your vote on the following options.

I. TERMINATE THE REGULATORY INVESTIGATION FOR LEAD IN PAINT.

Carol G. Damer
(Signature)

6-28-93
(Date)

II. THE STAFF IS DIRECTED TO CONTINUE THE REGULATORY INVESTIGATION TO SEEK FURTHER DATA ON HUMAN EXPOSURE TO LEAD IN PAINT AND ON THE COSTS AND BENEFITS OF A LOWER LIMIT ON LEAD IN PAINT.

(Signature)

(Date)

NOTE: This document has not been
reviewed or accepted by the Commission.
Initial nh Date 6/3/93

CPSA 6 (b)(1) Cleared

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III. THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE TO PROPOSE TO LOWER THE LIMIT FOR LEAD IN PAINT, FOR THE COMMISSION'S CONSIDERATION.

(Signature)

(Date)

IV. IF THE COMMISSION VOTES TO TERMINATE THE REGULATORY INVESTIGATION, THE STAFF IS DIRECTED TO PREPARE A DRAFT FEDERAL REGISTER NOTICE ANNOUNCING THIS DECISION.

Carol G. Dawson
(Signature)

6-28-93
(Date)

V. OTHER (please specify).

(Signature)

(Date)

Comments/Instructions: