FOOD AND DRUG ADMINISTRATION

November 30, 1971

SUBJECT: Lead Based Paint

REFERENCE: 21 CFR Part 191,
Federal Register
November 2, 1971

The American Academy of Pediatrics files the following comments on the matter at issue and now under consideration:

It is recommended that the Food and Drug Administration promulgate a final regulation pertaining to the lead content in paints and that the limit for lead be revised downward from the proposed .5% to "minimum traces" or $\leq 0.06\%$ of the total weight of the contained solids (including pigment, film solids and driers). This recommendation is based on the study of recently published materials[1,2,3,4], based upon an evaluation of data published after the 1% voluntary standard for lead was originally established in 1955 by the American National Standards Institute. The American Academy of Pediatrics recommends that paints containing more than minimum traces of lead be declared banned hazardous substances, if intended for use on children's toys, furniture, or interior surfaces.

Upon review and evaluation of available data in children and adults, an Ad Hoc Committee (B. G. King, Chairman)[1] recently concluded that for children the maximum daily permissible intake (DPI) of lead from all sources should not exceed 300 µg Pb/day.* If average daily intake is maintained below this

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*This DPI is concerned primarily with increments in oral intake of inorganic lead salts. In calculating this DPI, it was assumed that average daily respiratory exposure in most urban areas is approximately 2 µg Pb/m^3. Any significant increase in respiratory intake would have to be given added weight because respiratory retention is estimated at 35-40% of very small lead-bearing particulates in the lower respiratory tract. Assimilation in the GI tract is estimated at 5-10% of oral intake. It is understood that the comments which follow apply almost exclusively to increments in oral intake in the presence of constant but low levels of respiratory exposure (2 µg Pb/m^3 on the average).

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[illegible] blood concentrations are unlikely to exceed 40 μg Pb/100 G whole blood. At this level of intake, it is estimated that the amount assimilated by one to three year old children could probably be excreted, so that no net increment in total body lead burden would be anticipated. It is estimated that approximately one-half of this 300 μg Pb/day intake would be derived from usual food, water and air, so that intake from all other sources on the average should not exceed 150 μg Pb/day. In particular, average daily intakes below this DPI would not be associated with any significant increment in soft tissue lead content. It is this portion of the total body lead burden which appears to be responsible for the known toxic effects of lead.

Available data indicate that increments in total lead intake above this DPI increase assimilation (see Chapter 3 in Reference 2) and raise blood levels above 40 μg Pb/100 G whole blood. Such increments may be associated with increase in the soft tissue component of the total body lead burden. At blood lead concentrations of 40 to 50 μg Pb/100 G whole blood, some individuals may show minimal adverse metabolic response in the form of increased delta-aminolevulinic acid (ALA) excretion in urine (see reference No. 2, Chapter 4). Increased ALA excretion in urine is the metabolic response most specifically associated with rising concentrations of lead in the soft tissues. Increments in total assimilation of lead to levels five-fold to tenfold above that assimilated from usual dietary intake, if continued for several weeks or months, clearly can bring such persons into the range of adverse metabolic effects and can be statistically correlated with blood lead levels in the range of 60-80 μg Pb/100 G whole blood. In some instances, persons with blood lead concentrations in this range may show non-specific symptoms compatible with, but not diagnostic of, clinical

plumbism. At blood lead concentrations of 60 μg Pb/100 G whole blood or higher, x-ray evidence of abnormal skeletal mineralization at the ends of growing long bones occurs in some children when excessive intake persists for several weeks or months or longer. Such undesirable effects should be avoided in young growing children.

It is concluded, therefore, to preserve health, prevent adverse metabolic effects attributable to increased soft tissue lead content in growing children and to minimize the risk of serious poisoning, the total daily intake of lead should be limited to ⩽300 μg Pb/day. A policy statement recently approved by the Surgeon General of the U. S. Public Health Service similarly concluded that blood lead concentrations ⩾40 μg Pb/100 whole blood be considered indicative of undue exposure to lead and that children with blood lead concentrations in the 30-80 μg Pb/100 G whole blood range be considered as <u>possible</u> cases of lead intoxication and that such children require further medical evaluation.[4] In view of the prevalence of pica in one to three year old children, the permissible content of lead in paint should be considered with the foregoing in mind.

The content of lead in paint calculated as elemental lead and expressed as a percent of the total weight of the paint may be a good criterion by industry for the content of lead in paint per se. However, this is not a good criterion for evaluating the health hazard present in chips of paint from surface coverings of the walls, windows, doors, furniture, and other objects to which children may be exposed. It is the weight of lead in the chips that determines the health hazard. Recent studies[5] indicate that the weight of multilayer paint chips can be related to the number of layers of paint applied to a surface. In this way, the amount of lead in single and multiple layers

of paint can be calculated from the percentage of lead contained in the paint. Such calculations are shown in Table 1. For example, studies at the U.S.P.H.S. Injury Control Laboratory, Providence, R.I.[5] indicate that 1 sq. cm. of one layer of interior paint may weigh 5.2-8.0 mg (avg. = 6.5 mg) and that six layers of paint may weigh 37.0-40.6 mg (avg. = 38.8). Sixty-nine samples of multilayer paint chips obtained from old dwellings in Philadelphia were found to weigh 89±33 mg per sq. cm. of exposed surface. (The term "sq. cm. of exposed surface" is used here because of the difficulty in sampling a precise and reproducible volume of paint under field conditions). Forty mg of interior paint (6 layers) containing 1% of lead in the final dried solids would contain 400 μg Pb. Using the same calculation, a 10-layered paint surface containing 1% lead might contain 650 μg Pb/sq. cm. of exposed surface. The calculated dose in either instance is in excess of the calculated DPI (daily permissible intake). One sq. cm. of 6 layers of paint on a surface containing 0.1% lead would contain 40 μg Pb; whereas at 0.05% lead, 1 sq. cm. of a 6-layered surface would contain 20 μg Pb. In this last instance, ingestion of a paint chip with 1 sq. cm. (6.25 cm^2) of exposed surface per day on the average can be calculated to provide a dose of 125 μg Pb. Thus, 125 μg of lead from paint, together with an allowance of 150 μg of lead from the usual lead content of food, water, and air approaches the DPI of 300 μg Pb from all sources but would make little allowance for such other non-dietary sources as the child may encounter[2,6].

Also to be considered is the prevalence of pica in young children. It is estimated that approximately 50% of children between one and three years of age repetitively ingest non-food substances. Abdominal x-rays obtained in the diagnostic evaluation of children suspected of having lead poisoning indicate that very large quantities of foreign substances such as paint, putty,

and plaster may be ingested, often without the parents' awareness.

A federal standard for lead to $<0.06\%$ is needed in order to minimize this particular health hazard to future generations of children. At the present time, lead poisoning as seen in children is related to old, deteriorated housing so that a federal standard is unlikely to have a significant impact on plumbism as now seen. Nevertheless, as this old housing is replaced or rehabilitated, safe surface covering should be used in order to minimize hazards to the health of future children. Because pica has been a well-recognized habit among humans for many centuries, it appears unlikely that this behavioral pattern will quickly change.

The American Academy of Pediatrics endorses the principle contained in the petition filed with the Commissioner that paints containing more than minute traces of lead be declared as banned hazardous substances, if intended for use on children's products or interior surfaces. It appears that cautionary labeling will not adequately protect the public health and safty.

It should be further noted that therapy is not effective in reversing or preventing permanent brain damage associated with severe forms of acute lead poisoning such as acute encephalopathy. It is currently estimated that 40% or more survivors of encephalopathy sustain permanent brain damage. In order to provide a margin of safety against such occurrences, which are not reversible by current methods of chelation therapy, it is essential that the level of exposure be reduced. Promulgation of a federal standard with respect to lead to minimum traces and certainly to $<0.06\%$ .b probably would provide a safety factor of five with respect to doses unequivocally associated with demonstrable adverse metabolic responses in

virtually all individuals and clinical toxicity in some. Except in instances of voracious pica for paint, it would probably provide a safety factor of at least 20 with respect to the average daily intake, which is probably necessary to cause encephalopathy and fatalities in children. Such a safety factor would appear to be a minimum requirement.

REFERENCES

1. King, B. G.: Maximum daily intake of lead without excessive body lead-burden in children. Amer. J. Dis. Child. 122:337, 1971.

2. Airborne Lead in Perspective, report of Committee on Biologic Effects of Atmospheric Pollutants of the Division of Medical Sciences, to be published by the National Research Council, National Academy of Sciences, Washington, D.C., 1971.

3. Chisolm, J. J., Jr.: Increased lead absorption: Toxicological considerations. Commentary in Pediatrics 48:349, 1971.

4. Medical aspects of childhood lead poisoning; Statement approved by surgeon general, U.S.P.H.S. Pediatrics 48-464, 1971.

5. King, B. G.: Personal Communication

6. Hunt, W. F., Jr., Pinkerton, C., McNulty, O. and Creason, J.P.: The 77 mid-western city study: A study of trace element pollution of the air. Presented at Fourth Annual Conference on Trace Substances, University of Missouri, Columbia, Missouri, June 23-24, 1970.

TABLE I

Amount of Lead in Single and Multiple Layers of Paint vs. Per Cent Lead Content in Paint

Painted Surface Covering		Calculated Lead Content of Paint Chip With 1 cm.^{2} of Exposed Surface	
No. Layers	Rounded Average Wgt. of Paint Chip† (Milligrams)	Per Cent by Weight	Amount (Micrograms)
1	6.5 mg	1.0%	65 µg Pb
6	40.0 mg	1.0%	400 µg Pb
10	65.0 mg	1.0%	650 µg Pb
1	6.5 mg	0.1%	6.5 µg Pb
6	40.0 mg	0.1%	40.0 µg Pb
10	65.0 mg	0.1%	65.0 µg Pb
1	6.5 mg	0.05%	3.2 µg Pb
6	40.0 mg	0.05%	20.0 µg Pb
10	65.0 mg	0.05%	32.0 µg Pb

†Same area; e.g., 1 sq. cm. of 1, 6 and 10 layers of paint.