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April 10, 1972

RECEIVED

T. P. M.

Hearing Clerk
Department of Health, Education, and
Welfare
Parklawn Building, Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Re: Classification of Certain Lead-
Containing Paints and Other Similar
Surface-Coating Materials as Banned
Hazardous Substances - 37 F.R. 5229

Dear Sir:

This firm is counsel to the National Paint and Coatings Association, Inc. (formerly the National Paint, Varnish, and Lacquer Association), 1500 Rhode Island Avenue, N. W., Washington, D.C. 20005. The Association represents the manufacturers of more than ninety (90%) percent of the value of paints, varnishes, lacquers and allied products produced in the United States. The majority of its more than 900 members are engaged in the manufacture, marketing and distribution of these products for general household use.

The Association fully supports the Commissioner's

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objective -- limiting the exposure of children to lead to a safe level. Members of the Association, however, have indicated that they believe that many of the issues raised by the Commissioner's Order of March 11, 1972 are of such a grave nature as to merit explication in a situation where evidence can be presented.

The Association is concerned, on behalf of its members, with the implementation of the Federal Hazardous Substances Act (74 Stat. 372), as amended by the Child Protection Act of 1966 (80 Stat. 1303), and the Child Protection and Toy Safety Act of 1969 (83 Stat. 187). In its representative capacity, it is concerned with the marketing and distribution, for general household use, of lead-containing paint and related products. Therefore, it is an interested person that will be adversely affected by the Order of the Commissioner of Food and Drugs classifying certain lead-containing paints and other similar surface-coating materials as banned hazardous substances, 37 F.R. 5229; 21 C.F.R. 191.9(a)(6). See Toilet Goods Ass'n v. Celebrezze, 235 F. Supp. 648 (S.D.N.Y. 1964), aff'd sub nom. Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967). The Association, therefore, requests that a hearing be held on the following objection to the Order, as provided in 21 C.F.R., Subpart 2F:

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The objection of the National Paint and Coatings Association is to the provision of the Commissioner's Order that would classify as banned hazardous substances any paint or other similar surface-coating material intended, or packaged in a form suitable for use in or around the household that is shipped in interstate commerce after December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film. [21 C.F.R. 191.9(a)(6)(i)(a)]

No sufficient factual basis has been established, either from a medical or toxicological standpoint, or from human experience, to support a finding by the Commissioner that paints and other similar surface-coatings exceeding the 0.06% level of lead content are hazardous substances. ^{1/} The Commissioner's conclusions appear to be based, in part, on comments

1/ Implicit in a classification of paint and other similar surface-coatings which contain lead above a specific level as banned hazardous substances is a declaration by the Commissioner of Food and Drugs, under authority delegated by the Secretary, that these products are in fact hazardous substances under the provisions of the Federal Hazardous Substances Act since these products are not hazardous by traditional test methods. See 15 U.S.C. 1261(f)(1)(q).

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received in support of a notice published in the Federal Register (36 F.R. 20986) on behalf of petitioners Joseph A. Page, et al. These comments urge 0.06% as the critical level for lead content for the products in question, as reflected by the Commissioner's Order. However, these comments are not based on responsible scientific research involving dried paint films containing small amounts of specific kinds of lead compounds. Instead, they are drawn from remote and entirely inconclusive evidence. Therefore, they are open to serious question.

The "preponderance of medical opinion" is not a valid basis for a required finding unless the opinion is based upon relevant research. The discussion in the preamble to the proposed amendment to Section 191.9 does not reference data which support a modification of the acceptable level of lead to 0.06%.

The study of Gage and Litchfield -- not referenced by the Commissioner -- supports a finding that lead compounds of the type used in modern paints may not assimilate into the GI tract to the same degree as lead acetate. ^{2/} Further, the study

^{2/} J.C. Gage and M.H. Litchfield, "The migration of lead from paint films in the rat gastro-intestinal tract," J. Gil Colour Chemists Ass'n, 52, 236 (1969).

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raises the equally important question of whether the absorption rates of lead compounds are drastically reduced as a result of encapsulation in a resinous dried paint film. As Gage and Litchfield indicate, based on studies of dried paint film (the product actually being regulated), only about one-half of the lead in lead naphthenate, or one quarter in lead chromate, can migrate into the body content. ^{3/}

The work of these authorities indicate acceptable lead limits that are conservatively from 4-1/2 to 9 times greater than the limits on which the position of the American Academy of Pediatrics, et al., is based. From these more related studies (since they were founded on actual testing and animal feeding studies of dried paint films), it could be properly concluded that limits of 0.54% of lead in paint would be safe values even for daily feeding. In fact, Gage and Litchfield indicate that the hazardous dose may be 50 times the safe dose.

England and Canada, each having strong health and safety programs, approve the sale and distribution of children's toys and furniture coated with materials containing 0.50% lead in the

^{3/} Even these proportions may be excessive because in Gage's work, the paint films were finely ground to a powder before feeding, which is a more drastic treatment than mastication by young children:

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total weight of the contained solids.

(1) Schedule I of the Canadian Hazardous Products Act prohibits the sale of:

2. Furniture, toys and other articles intended for children, painted with a liquid coating material containing lead compounds of which the lead content (calculated as lead) is in excess of 0.50 percent of the total weight of the contained solids, including pigments, film solids and driers.

2) The Toys (Safety) Regulations issued pursuant to the British Consumer Protection Act provide in relevant part:

2.(1) A toy shall not have any coating of paint which contains lead, or any compound of lead, so that the proportion (by weight) of lead calculated as the element (Pb) exceeds 11,000 parts, or, after 31st October 1958, 5,000 parts in 1,000,000 parts of the dry paint film.

* * *

(4) In this Regulation, 'paint' includes lacquer, varnish and other similar substances.

Paints produced in England which contain more than 1% (with a tolerance of + 0.5%) of lead or which contain known toxic compounds of other metals are labeled with the cautionary statement, ^{BS#3/D} "Do not apply on surfaces which might be chewed by children." A comprehensive method for determining the lead content of dry paint film is published by the British Standards Institution.

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The above demonstrates that there are grounds from which it is reasonable to conclude that facts can be established by reliable evidence which will adequately support a higher level of lead than proposed by the Commissioner. The burden of proof rests with the proponent of the regulation (21 C.F.R. 2.63). The Commissioner's discussion of the material submitted in response to the Federal Register notice (36 F.R. 20986) does not reference with sufficient particularity the studies and data relied upon to permit a more detailed response than the foregoing. A regulation having such a broad impact should rest only upon a careful inquiry, cross-examination of the purported evidence, and a complete record developed by all interested parties.

Request for a Public Hearing

A finding as to the hazardous nature of paint containing more than 0.06% lead should be supported by medical and toxicological data and by properly-documented human experience. The Order in this instance is not supported by competent evidence in either regard to justify such a conclusion. The specified level is substantially below a predictable safe level based on the available evidence.

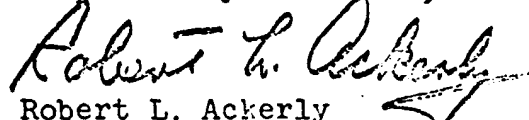
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WHEREFORE, it is respectfully submitted that a public hearing be convened, pursuant to 21 C.F.R., Subpart 2F, for the purpose of establishing on the record all of the evidence relevant to the Commissioner's Order, and that the effective date of the regulation be stayed until a complete record can be made to test the validity of the Commissioner's findings.

Respectfully submitted,


Robert L. Ackerly
Counsel to National Paint
and Coatings Association, Inc.

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