Bulletin

1500 Rhode Island Ave., N.W. Washington, D. C. 20005

ROUTE TO:

Department		
Finance		
Administration		
Sales		
Technical		
Production		

No. 78
March 18, 1972

LEAD IN PAINT - CRITICAL DEVELOPMENTS

Executive Synopsis

This Bulletin reports on recent significant developments re use of lead in paint, particularly the FDA Regulation -- published in the Federal Register on March 11, 1972 -- which classifies "Certain Lead-Containing Paints and Other Similar Surface-Coating Materials as Banned Hazardous Substances" and reduces the maximum permissible lead level in many paints and coatings to 0.06%. With this and related actions, reported on herein, the industry truly is facing a crisis. A copy of the FDA Regulation and other relevant documents are attached for your information.

ACTION REQUIRED BY YOU: Tell your Congressmen and other government officials what this development will mean to your company. Time is running out for us on this issue!

OPERATIONS AFFECTED BY YOUR COMPANY: As this now stands, you must reformulate all household products and certain industrial products so that lead content does not exceed .06% (of total non-volatile content) by December 31, 1973. Those manufacturers marketing in the Chicago area must meet this deadline for interior paints by January 1, 1973.

ACTION BY NPCA: The Association has participated to the fullest extend possible in providing information and comments relevant to the matter to the responsible Federal Agencies, to the Congress and to officials of those other jurisdictions addressing this problem. Congress has not yet completed action on the Federal legislative proposal, however, FDA has rejected the industry views. All possible courses of action to challenge this unreasonable Regulation are being considered by NPCA, and -- appropriate steps will be taken upon guidance of the Executive Committee.

CONTACT AT NPCA: John M. Montgomery, General Counsel

A. BACKGROUND AND CHRONOLOGY OF DEVELOPMENTS

1. Legal Bulletin No. 73, dated February 16, 1971, reported the enactment of the Lead-Based Paint Poisoning Prevention Act (P.L. 91-695) which established, among other things, the definition of "lead-based paint" at the one-percent level, consistent with ANSI Standard Z66.1 - 1964. This was the first direct involvement of the Federal government on the use of lead in modern paints.

2. During the year 1971, pressures to reduce the lead level increased at an accelerated rate. A sampling by New York City authorities in the Summer of 1971 indicated that not all manufacturers were adhering precisely to either the voluntary standard (Z66.1 - 1964) or the New York City Health Code. Much bad press resulted, and Rep. William F. Ryan (20th District - N.Y.) began using the Congressional Record as a means of blasting the industry on this subject -- focusing unfairly on lead in modern paints, which were being blamed for the large numbers of lead poisoning cases resulting from the flaking and peeling chips of old lead-based paints. (The increasing numbers of reported cases today -- lead poisoning, as well as elevated blood lead levels -- are due to a greater awareness of the problem and improved methods of detection and identification of the symptoms.)

3. On November 2, 1971, the FDA published in the Federal Register a proposed regulation -- A Proposal To Declare Certain Heavy Metal-Containing Paints and Other Surface-Coatings "Hazardous Substances" and to Require Special Labeling for Child Protection. In the same issue, the FDA published -- a Proposal to Classify Paints Containing More Than Minute Traces of Lead as Banned Hazardous Substances.

4. Legal Bulletin No. 77 reported that, after due consideration by the NPCA Executive Committee, the Association had publicly supported the FDA proposed regulation and urged membership support, for the reasons that:

a. a consensus of the manufacturers had indicated that, with certain exceptions, the maximum permissible lead level (0.5%) was acceptable and would permit the continued use of necessary lead dryers;

b. without conceding any hazard at the 1.0% level, the reduced level (of 0.5%) would provide for an additional margin of safety; and, of greatest importance,

c. the prescribed mandatory labeling and pre-emption, under the Federal Hazardous Substances Act, would lead to uniformity of regulations and greatly reduce the burden of conflicting labeling and marketing standards for products in interstate commerce.

5. Immediately after the 92nd Congress convened in January 1972, Senator Edward M. Kennedy of Massachusetts and Rep. William F. Ryan of New York introduced legislative proposals (S. 3080 and H.R. 12466, respectively) to amend the Lead-Based Paint Poisoning Prevention Act (P.L. 91-695) in order to obtain the authorization for additional funds to continue the programs established by Titles I, II and III of that Act and to change the definition of "lead-based paint" from 1.0% to 0.6%. A substantial number of other members joined as sponsors of these legislative proposals.

0.06%

6. Association members -- having been kept apprised of these significant developments by Memoranda and other Notices -- were urged to write their Congressmen concerning the impact of these legislative proposals, particularly if they were sponsors of either bill or members of the Senate Labor and Public Welfare Subcommittee on Health, which had scheduled early hearings on S. 3080. Members also were urged to write to Commissioner Edwards of the Food and Drug Administration concerning the pending regulation, and particularly if it were found impossible or impractical to comply with the Notice -- published by FDA in the Federal Register on February 19, 1972 -- asking that all manufacturers of paint and/or other surface-coatings submit data regarding formulations and actual heavy-metals content of their products. (Forwarded to all Class A Members by NPCA Memorandum of February 26, 1972.)

7. Hearings on S. 3080 were held during the week of March 6 - 10, 1972. (No hearings yet have been scheduled by the House Banking and Currency Subcommittee on Housing, which has jurisdiction over this subject.) On the last day of the Senate hearings on S. 3080, the HEW witness announced the FDA decision on the subject, which was published in the Federal Register as a Regulation on the following day, March 11th.

8. Concurrently with the above- mentioned developments at the Federal level, several states and other local jurisdictions had initiated actions leading to reduced levels of lead in paint. Notwithstanding strong efforts by the Association staff, working in close cooperation with local industry officials, Massachusetts approved House Bill No. 6266 on November 15, 1971, which established the maximum permissible level at 0.5%, and an Ordinance was adopted by Chicago on February 24, 1972 which established this level at .06%. A related Chicago Ordinance provided for specific precautionary labeling. Other proposals currently are known to be pending in Kentucky and Delaware, and Philadelphia is understood to be contemplating an ordinance similar to that of Chicago.

B. THE FDA REGULATION

1. General. A copy of the FDA Regulation, published on March 11, 1972, is attached. The text material on the first two pages represents an effort on the part of FDA to explain the developments which caused that agency to reject its earlier proposed regulation (of November 2, 1971) and, in spite of industry pleas that unnecessary restrictions not be prescribed prematurely, adopt the extreme views of the consumer groups, Public Health Officials and the medical community. We feel strongly (and have substantial evidence to support our belief) that this "turn-around" resulted principally from political pressures. Recognizing the very great emotional issue and the need for action by government agencies to take steps to correct the major problem of old lead-based paints, it is regrettable that the FDA has taken this precipitous action, which will have such a serious impact on the industry but -- does nothing to alleviate the current problem of lead poisoning from old lead-based paints!

NPCA had contended that the reduction of the maximum permissible lead level in paints to .06% should not be directed until shown necessary and justified by federally-funded, independent research and animal-feeding studies, based on dried films of modern paints. The rationale for this position is contained in the Statement of NPCA's Executive Vice President, Robert A. Roland, at the Senate hearings on S. 3080 (copy attached).

2. Analysis of the FDA Regulation. The Regulation provides for an effective date 45 days after publication (or April 25, 1972) and the following, with respect to paints and other similar surface-coating materials coming under the purview of the Federal Hazardous Substances Act (FHSA):

a. Such products, shipped in interstate commerce after December 31, 1972, must not contain more than 0.5% lead (in total non-volatile content).

b. Such products, shipped in interstate commerce after December 31, 1973, must not contain more than .06% lead.

c. Similar restrictions apply to "any toy or other article intended for use by children...."

And, of greatest concern --

d. Products, containing lead in excess of the prescribed levels and on dates specified, are declared "banned hazardous substances."

Note. This step has been taken by FDA without such products ever having been declared hazardous under prior FHSA regulations and with an acknowledgement by that agency that there is no imminent hazard!

e. The Regulation applies only to lead in paints; the other heavy metals -- addressed in the proposed regulation, published on November 2, 1971 -- are expected to be the subject of additional regulations by FDA at a future date.

Note. The use of mercury in paints and other surface-coatings will be subject to restrictions expected to be published shortly by the Environmental Protection Agency. (Refer Legal Bulletin No. 77, Part B.)

3. Impact of the FDA Regulation. In addition to the massive reformulation of products and related testing which will be required by most manufacturers, the greatest impact relates to the declaration of certain paint products -- for the first time -- as banned hazardous substances. This declaration carries with it the problems of possible "repurchase" of large numbers of products, and -- the problems are compounded because of the uncertainties in this matter. (e.g. No regulations as to repurchase of products declared to be banned hazardous substances have been promulgated by FDA to implement the relevant provisions of FHSA.)

Furthermore, in this Regulation the FDA has made a finding that precautionary labeling is inadequate to protect against the hazard of lead in paints. Thus, without mandatory precautionary labeling having been prescribed, it would appear that we do not obtain the pre-emption we had been seeking to provide relief against the proliferation of conflicting requirements from other jurisdications.

4. Challenging the FDA Regulation? NPCA is studying the FDA Regulation in detail to ascertain what legal challenge or other action(s) may be appropriate. Such action will be initiated promptly by the Association after evaluation and approval by the NPCA Executive Committee, and -- the members will be kept informed of such developments.

C. THE LEAD-BASED PAINT POISONING PREVENTION ACT (P.L. 91-695)

1. Title IV Regulations. As reported in Legal Bulletin No. 73, this Act became effective on the date signed by the President, but the specific impact on the industry was subject to promulgation of regulations implementing Title IV thereof. These final regulations were published in the Federal Register on March 7, 1972. These regulations (copy attached) became effective upon the date of publication in the Federal Register. However, their impact on the industry is lessened considerably now because they are based on the one-percent definition of "lead-based paint" contained in the Act.

2. Action of the Federal Agencies.

a. Department of Housing and Urban Development. HUD has published an Instruction for guidance of its field offices -- to ensure compliance with the provisions of the Title IV regulations.

b. General Services Administration. The Federal Supply Service of GSA is known to be reviewing all of its specifications in order that necessary changes (to conform with the Title IV Regulations) can be made. However, it is understood that -- after the publication of the proposed regulation by FDA in November 1971 -- the 0.5% level was used as a guideline. Now, we would expect the FSS to give due consideration to the greatly-reduced level (0.06%),looking to compliance by January 1, 1974 for those specifications relating to paints and other surface-coating materials covered by the new Regulation.

3. Amendments to P.L. 91-695. As previously discussed, Senate hearings already have been held on S. 3080 which would, among other things, change the aforementioned definition of "lead-based paints" in the Federal law to .06%, the same arbitrary level established by the FDA Regulation of March 11th.

In addition to the NPCA Executive Vice President, six other industry witnesses appeared before the Senate Labor and Public Welfare Subcommittee on Health at the hearings on March 9, 1972. This select group was believed to be representative of the industry -- both as to company size and geographical location. Although the Statements of all witnesses were submitted for the record, time did not permit all witnesses to testify; and, unfortunately, because of conflicts, very few Subcommittee members heard any part of the week's hearings. Regrettably, the focus of the hearings related more to reducing the level of lead in modern paints than to the existing and identified problem of the old lead-based paints.

NPCA had hoped and specifically asked that the Congress not legislate to reduce the maximum permissible level of lead in paints but -- that this be left to the regulatory agencies having statutory responsibilities therefor. It was urged that the Congress provide funds for and indicate its interest in having proper research and studies conducted in order that the decision of the regulatory agency could be based on a responsibile scientific finding.

It was pointed out that such aetion would permit a proper determination to be made as to which surfaces of existing structures should receive attention and correction. This was deemed imperative after Assistant Secretary Finger of HUD had testified earlier in the hearings that it had been estimated that the elimination of the hazard of old lead-based paints from existing structures today (by removal or coverage) might cost as much as $70 billion. NPCA witnesses pointed out this cost would be increased substantially if the standard were to be reduced from the present one percent to the .06% announced by the FDA; and, that adequate research on the subject might reduce this figure dramatically.

**Note. These valid arguments should be incorporated in your letter to the Congress. Remember -- even if we were to challenge successfully the .06% level contained in the FDA Regulation, the problem would be compounded greatly if the .06% figure should be incorporated in P.L. 91-695 by the pending amendment.

D. THE MASSACHUSETTS LAW

The new lead law in Massachusetts, previously mentioned, becomes effective on January 1, 1973. It provides, among other things and in pertinent part, as follows:

a. the sale, exposure for sale, delivery or use of any lead-based paint, glaze or other surface covering after effective date is prohibited.

b. a paint, glaze or other surface covering is considered to be "lead-based" when it contains "more than one-half of one-*percentum* lead by weight (calculated as lead metal) in the total non-volatile content...."

c. exemptions for certain products may be approved by an advisory committee if it can be shown that they are not "intended or suitable for use on or within residential premises, and are not advertised or labeled as intended or suitable for such uses, and are not sold to the general public on a retail basis, when .... with substantial certainty .... the sale or use .... will not result in the exposure of children younger than six years of age .... and will not result in an additional danger to life or health for such children or for the general public."

Does industry have to make application for exemption .... to whom ... how?

Another provision of the Massachusetts law, which is of significant impact to its citizens, is the requirement for removal of all lead-based paints from any residence wherein a child under six years of age may be living or, upon change of ownership, a child younger than six years of age may reside.

NPCA is continuing to study the Massachusetts law to determine if there might be any constitutional grounds for industry challenge.

E. THE CHICAGO ORDINANCES

The Chicago Ordinances, previously referred to, provide for reductions in the maximum permissible lead level for paints and for mandatory precautionary labeling. These are of particular significance to those manufacturers located in or doing business in the Chicago area because the amendments to these Ordinances become effective on July 1, 1972.

These provide, in pertinent part, for:

a. Effective July 1, 1972, all paints containing more than 0.06% lead (except varnishes, oil stains, floor paints and coatings in aerosol cans) must be labeled as prescribed.

b. Effective January 1, 1973, the exclusions granted with respect to varnishes, oil stains, floor paints and coatings in aerosol cans will end.

c. Labeling prescribed is generally consistent with that presently being used by the industry (both as to format and type size), with minor modifications patterned after the Recommended Label for lead contained in the FDA proposed regulation of November 2, 1971 and promulgated to the membership by Legal Bulletin No. 77.

d. Stickers (self-adhesive) are permitted.

Note. Althought the Ordinances address all paints, it is our understanding that the City of Chicago has indicated that its principal concern at this time is with interior paints. There is no ban.

?

Further details of these Chicago Ordinances are not included in this Legal Bulletin because the Chicago PVLA has promulgated requisite information to its members, and most manufacturers, located in or doing business in the Chicago area, or believed to be cognizant of such details. Additional information, if desired, may be obtained from NPCA Headquarters. Questions from members located in the Chicago area can be addressed to Edward F. O'Toole, General Counsel for the Chicago PVLA, who has coordinated the activities on this matter for the industry.

F. SPECIFIC ACTIONS RECOMMENDED

It should now be obvious to all members that the lead-in-paint problem is indeed a crisis. It is not only a problem at the Federal level, but in many states and other jurisdictions. We particularly need timely alert to any additional legislative or regulatory proposals -- at the local level -- which may come to your attention.

Again, we urge that you:

1. Write to your Congressmen and let them know how these proposals impact on your company. Emphasize the need for adequate research and animal-feeding studies and, particularly, the economic impact of actions which are deemed to be unnecessary and unduly restrictive.

2. Write to the Commissioner of the Food and Drug Administration and apprise him of the impact of the actions of his agency. It should be noted especially that the FDA action was taken before the deadline date (of April 7th) for the manufacturers to provide him with the substantial data requested by his Notice of February 19, 1972.

   Although recognizing that it was not feasible for many manufacturers to provide the data requested by the February 19 Notice (and many manufacturers have so advised the Commissioner), we believe that the promulgation of the FDA Regulation on March 11, 1972 was not only precipitous but premature.

John M. Montgomery
General Counsel

JMM/ew
Attachments - 3