

December 7, 1972

No. 7

ROUTE TO:
Department

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TOPICS: Lead in Point -- Recent Developments

- A. NPCA's Petition requesting amendment of FDA Lead Order published in the Federal Register
- B. Petition requesting exemption of certain product categories from Massachusetts Lead Law filed by NPCA

Executive Synopsis

This Bulletin reports recent developments on the following:

A. FDA publication in the Federal Register of NPCA's Petition requesting that the FDA Lead Order of March 11, 1972 be amended to prescribe that certain lead-containing products that do not present a lead hazard to children are not subject to the restriction on lead content. This publication (copy appended for information) suspends the December 31, 1972 implementation date of the Order -- as it applies to the product categories described in the petition -- pending review of comments and issuance of final order.

B. NPCA submission of a similar Petition to Massachusetts state officials seeking exemption of certain product categories from the Massachusetts lead law.

ACTION REQUIRED. Members should submit appropriate comments to FDA, as explained herein.

CONTACT AT NPCA. Office of Legal and Government Relations

A. NPCA's Petition Requesting Amendment of FDA Lead Order Published in Federal Register

As reported to you in earlier Legal and Legislative Bulletins (see "L&L" Bulletins No. 4, 5 and 6), NPCA filed with the Food and Drug Administration (FDA) a Petition asking the Commissioner to rule that certain product categories are outside the scope of the FDA Order of March 11, 1972 which classified certain paints or other similar surface coating materials as banned hazardous substances after prescribed dates. The final version of NPCA's petition was filed with the FDA Commissioner on October 24, 1972, with a request for a specific amendment to the March 11 Order which would prescribe that it did not apply to:

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1. Automotive, agricultural, and industrial equipment refinish coatings.
2. Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings.
3. Graphic art coatings (products marketed solely for application on billboards, road signs and similar uses, and for identification marking in industrial buildings.)
4. Touch-up coatings for automobiles, agricultural and industrial equipment, boats, outboard motors, motorized recreational vehicles, and appliances.
5. Exterior marine coatings for small craft application.
6. Exterior rubber-based roof coatings.
7. Exterior primer coatings for wood siding containing extractives (products marketed solely for application on redwood and cedar.)

If this amendment should be adopted by final FDA Order, the aforementioned product categories would have to bear certain prescribed labeling, as requested in the NPCA Petition. The placement, conspicuousness, and contrast of such labeling, if approved, would be in accordance with the requirements of the Federal Hazardous Substances Act and regulations issued pursuant thereto.

The publication -- in the Federal Register of December 5, 1972 (37 F.R. 25849), under the heading "Banned Hazardous Substances - Proposed Exemption of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials" -- means that the agency has, at least, initially recognized the merit of such exemptions. (Under the regulations issued pursuant to the Federal Hazardous Substances Act, the FDA Commissioner does not propose the issuance, amendment or repeal of a regulation unless reasonable grounds for such action have been demonstrated.)

This publication also means that the December 31, 1972 deadline to meet the .5% lead requirement for paints and similar surface-coating materials shipped in interstate commerce after that date no longer pertains to those products described in the NPCA Petition. Therefore, except as affected by certain state or local restrictions (e.g., Massachusetts lead law), these particular products still may be marketed in interstate commerce after December 31, 1972, even if they exceed the .5% lead level set by FDA.

This is clearly spelled out by the next-to-the-last paragraph in the Attachment. In this paragraph the FDA states that:

"Since this petition was received prior to the implementation date (December 31, 1972) of § 191.9 (a) (6) (i) (b), the publication of this proposed amendment shall have the effect of suspending said implementation date, only as it applies to those paints and similar surface-coating materials as described in this proposal, pending review of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.9 (a) (6) (i) (b) as it applies to other paint and similar surface-coating materials."

The FDA has allowed 60 days within which interested persons may submit written comments regarding this proposal. Since this comment period will run from December 5, 1972 until February 3, 1973, the earliest possible date by which the agency could issue a final order would probably be late February or early March. Hopefully, this final order will exempt permanently the product categories described in the proposal from all lead restrictions of the FDA's March 11 Order.

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****ACTION REQUIRED.** It is absolutely vital that interested members of the paint and coatings industry submit comments to FDA, not only voicing support for these exemptions, but providing substantive reasons why lead is a necessary component in these products and why its continued use in these products will in no way create a lead poisoning hazard to children. It must be made clear that it is in the public interest, as well as in the interest of our industry, that these products be exempted from lead content restrictions. NPCA members shortly will receive an action letter with guidance on submission of comments and offering suggestions as to what information would be useful to FDA in rendering its final decision.

With respect to the labeling that may be required, it is recognized that manufacturers cannot, with confidence, prepare label copy and place orders prior to publication of the final order in this matter. However, each manufacturer is urged to study these proposals carefully and to be prepared for early compliance if and when ordered.

Note. The labeling prescribed in Attachment (at page 25849) and recommended in the NPCA Petition to FDA was approved by the Association's Labeling Committee and is consistent with the recommendations in the new LABELING GUIDE soon to be published.

B. Petition Requesting Exemption of Certain Products Filed in Massachusetts

In our Legal Bulletin of March 18, 1972 (No. 78), it was reported that a lead law for the Commonwealth of Massachusetts would become effective on January 1, 1973. To refresh your memory, this law, in pertinent part, provides that:

- a. No person shall apply or cause to be applied any lead-based paint, glaze or other substance to any toy, furniture, cooking, drinking, or eating utensil, or interior or exterior surface or fixture of any dwelling;
- b. No person shall sell, expose for sale, deliver, give away or possess with intent to sell, deliver or give away any toy, furniture, cooking, drinking or eating utensil to which any lead-based paint, glaze or other substance has been applied; and
- c. No person shall sell, expose for sale, deliver, give away or possess with intent to sell, deliver or give away any lead-based paint, glaze or other surface covering.

Note. Under the Massachusetts law, any paint, glaze or other substance is deemed to be lead-based when it contains more than one-half of one per centum lead by weight (calculated as lead metal) in the total non-volatile content of liquid paints or in the dried film of paint or glaze already applied, or when it contains a substantially equivalent amount of lead measured by such alternative reliable method of measurement as the director shall by regulation establish.

It should be noted that the Massachusetts bill is very broad in scope and could be interpreted to restrict lead content in any paint product or similar substance. The act did provide, however, that the lead poisoning control director for the State could, by regulation with the concurrence of a majority of an advisory committee (consisting of nine members, four either physicians or persons active in public health and two parents of children under six who reside in lower-income urban areas) exempt from the provisions of the law restricting the sale of lead-based paints those products that:

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"..... 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 he finds with substantial certainty that the sale or use of said paints will not result in the exposure of children younger than six years of age to said paints and will not result in an additional danger to life or health for such children or for the general public."

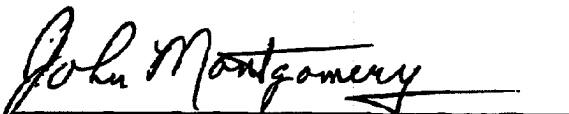
Although a lead poisoning control director has not been appointed, an advisory committee for the Massachusetts Lead Poisoning Prevention Program has been formed. The first meeting of this Committee was held in Boston on November 28, 1972, at which time industry and NPCA representatives were given an opportunity to discuss the need for exemptions for certain product categories. NPCA submitted to the committee a petition similar to that filed with the FDA. The Massachusetts petition, however, contained an additional category, "factory-applied, original finish coatings, not sold to the general public." This had to be added since, unlike the FDA March 11 Lead Order, the Massachusetts law, unless a specific exemption were granted, would cover such coatings. However, even if such an exemption were granted, it would not permit the continued use of such coatings (exceeding the .5% lead level) on toys, furniture or cooking, drinking, or eating utensils because the Massachusetts law prohibits both the application of such a coating on these articles and the sale of these articles if such a coating has been applied to them.

The Advisory Committee also was requested to expand the category of "exterior marine coatings for small craft application" to cover "Industrial marine coatings for use in construction, repair and maintenance work" since, as with factory-applied coatings, the Massachusetts law seems broad enough to cover such coatings. Furthermore, NPCA has asked the Committee to give consideration to exempting "artists' paints and related materials" since they also could be covered by the Massachusetts law.

Note. "Artists' paints and related materials" were not included in the initial NPCA Petition to FDA because they were deemed to be outside the scope of a regulation covering "paints and similar surface coating materials." However, as a result of numerous inquiries on the subject, it is understood that FDA may initiate a separate proposal.

Substantial questions were raised at the Advisory Committee meeting with respect to exemption of exterior primer coatings for wood siding containing extractives because this product, unlike the others for which exemptions were requested, is intended or suitable for use "on or within residential premises." The Massachusetts law, because of this, may be interpreted in a manner that would not allow for the total exemption of such a product. In view of this, it is understood that the Advisory Committee is considering the possibility of granting only a temporary exemption for such exterior primers in order to allow for the development of adequate substitutes.

The Advisory Committee is expected to rule on the NPCA request for exemptions on or about December 12th. Such ruling will be promulgated to the membership without delay.



John M. Montgomery
General Counsel

JMM/ew
attachment

0007-SWP-036700

0007-SWP-000118017

NPCA Recommended Label 14

For lead-containing special-purpose coatings which may be declared to be outside the scope of the FDA Order of March 11, 1972. (See Note 1.)

RECOMMENDED LABELING:

(Front Panel)

WARNING!
CONTAINS LEAD
DRIED FILM OF THIS PAINT MAY BE
HARMFUL IF EATEN OR CHEWED

See Other Cautions on (Side or Back) Panel.*

(18 pt. caps)

(12 pt. caps)

(10 pt. type)

(Back Panel)

CAUTIONS**

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units, such as windowsills, porches, stairs, or railings, to which children may be commonly exposed.

KEEP OUT OF REACH OF CHILDREN.

(10 pt. caps)

(10 pt. type)

(10 pt. caps)

NOTE 1. This label has not yet been approved by FDA. However, FDA has published in the Federal Register (on December 5, 1972) the NPCA petition requesting that Section 191.9(a)(6)(i) of the FHSA Regulations be amended to provide that certain categories of special-purpose coatings are not subject to the ban established by the FDA Order of March 11, 1972. (See Appendix, Section 1.) The NPCA Petition further requested that the labeling statement recommended above, or its practical equivalent, be prescribed for such special-purpose coatings declared to be outside the scope of the FDA Order.

NOTE 2. If and when approved by FDA, the above recommended labeling would be used to caution for the single hazard of lead in any lead-containing special-purpose coating which may be permitted to be shipped in interstate commerce after December 31, 1972. Refer to other labels for suggested wording for additional hazards to combine with this label.

NOTE 3. See Label 14.1 for special requirements of City of Chicago re lead and certain other industrial (heavy) metals. See also Part IV of this Guide for additional comments concerning lead laws of other states (e.g. Kentucky and Massachusetts) and local jurisdictions which must be considered by manufacturer doing business in those areas.

*Identify panel with proper word.

**The word "Cautions" is optional.

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Label 14

0007-SWP-036701

0007-SWP-000118018

NPCA Recommended Label 14.1

For paints marketed in City of Chicago and containing more than specified percentage of lead and certain other industrial (heavy) metals in total non-volatile. (See Note 1.)

Example: Exterior House Paints

RECOMMENDED LABELING.

(Front Panel)

WARNING!
CONTAINS _____*
DRIED FILM OF THIS PAINT MAY BE
HARMFUL IF EATEN OR CHEWED.
Read Other Cautions on (Side or Back) Panel.**

(18 pt. caps)

(12 pt. caps)

(10 pt. type)

(Back Panel)

Do not apply on toys and other children's articles, furniture or interior surfaces of any dwelling or facility which may be occupied or used by children.
Do not apply on those exterior surfaces of dwelling units, such as windowsills, porches, stairs, or railings to which children may be commonly exposed.***
KEEP OUT OF REACH OF CHILDREN.

(10 pt. type)

(10 pt. type)

(10 pt. caps)

NOTE 1. This label is required by the City of Chicago on paints and coatings for exterior residential uses and for "non-residential uses such as business, commercial or manufacturing" and having (in their total non-volatile content) more than 0.06% lead or more than 0.05% antimony, arsenic, cadmium, mercury or selenium individually or in total. All paints, lacquers, other liquid surface coatings and putty "for use on interior surfaces of dwellings or on fixtures or other objects intended for use in dwellings, within the City of Chicago" are prohibited from sale or use in that City if they contain lead or the other metals named above in excess of the levels prescribed. Thus, this label would not apply nor be permitted for such products. (Refer Chapters 78-17.2 and 100-29.3 of the Municipal Code of Chicago, approved February 24, 1972.)

NOTE 2. This recommended label only addresses the single hazard of lead (and/or the other regulated industrial metals). Refer to other labels for suggested wording for additional hazards to combine with this label.

**List the name(s) of the regulated industrial (heavy) metals. In case of multiple ingredients, it is permissible to use the phrase "Contains Lead and Other Toxic Heavy Metals" or, if no lead, the phrase "Contains Toxic Heavy Metals."*

***Identify panel with proper word.*

****This paragraph is optional, since it is not required by the Chicago ordinances; however, its use would be consistent with Label 14.*

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Label 14.1

0007-SWP-036702

0007-SWP-000118019