

National Paint, Varnish and Lacquer Association

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August 30, 1961

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TO ALL MEMBERS:

Analysis of Final Regulations under the Federal Hazardous Substances Labeling Act

Enclosed is an analysis of the final regulations under the Federal Hazardous Substances Labeling Act.

This was prepared by our Labeling Subcommittee which has also worked out revised precautionary labels which will be submitted to the Legislative Committee for recommendations, and then to the Executive Committee for final approval.

The precautionary labels will be used as the basis for our discussion at a late September meeting of the Joint Government-Industry Committee with the aim of securing the Food and Drug Administration's approval of precautionary labels for our industry's products, as explained in my letter of June 28.

Sincerely,

Joseph F. Battle
President

JFB:jw
Encl.

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PAINT THE FUTURE WITH CONFIDENCE AND QUALITY

74th Annual Meeting • October 30—November 1, 1961 • Washington, D. C.

PROGRESS THROUGH COOPERATION

N 4171

NATIONAL PAINT, VARNISH AND LACQUER ASSOCIATION

LEGISLATIVE BULLETIN

Analysis of Final Regulations under the Federal Hazardous Substances Labeling Act

Our Legislative Committee's Labeling Subcommittee has made the following analysis of the final regulations for administration of the Federal Hazardous Substances Labeling Act for the information and guidance of Association members.

1. Effective Date

The effective date of the Act has been extended to February 1, 1962, for the substances for which the Act is not already effective. As members will recall, the Act became effective for "highly toxic", "extremely flammable" and "flammable" substances, February 1, 1961. Since then, those who have been following the NPVLA Recommended Labels issued April 12, 1960 for these categories have been in substantial compliance with the law. No reports of any complaints by FDA enforcement authorities have been received since the middle of February, 1961 when the NPVLA Recommended Labels were distributed to FDA field agents.

The final regulations under the Act also become effective February 1, 1962. The Food and Drug Administration cannot extend this date since it is the final date set by the law itself. The Association, however, will join with other interested groups in seeking Congressional action to provide for further extension of the effective date through an amendment of the law. Reports indicate that there will be no opposition by the Food and Drug Administration to such an amendment, although the initiative will be left to industry.

Procedure by the N.P.V.L.A.

The Labeling Subcommittee has drafted revised labels intended to meet the requirements of the Federal Hazardous Substances Labeling Act. These will be submitted to the full Legislative Committee and to the Executive Committee for approval. Then they will be the subject of discussion by a Joint Government-Industry Committee at the Food and Drug Administration in the latter part of September. It is expected that this Joint Committee will recommend that the Commissioner of Food and Drugs approve the revised labels and labeling procedures in a special regulation under Section 3 (c) of the Act. Problems caused by the short remaining time for relabeling also will be taken up at the meeting of the Joint Committee to the end that administrative steps may be taken to alleviate any hardship on industry, because of the physical impossibility to relabel within the prescribed time.

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The Final Regulations

In this analysis, the important and pertinent portions and sections of the regulations are discussed and those which are deemed by the subcommittee to be of no serious effect are not mentioned.

Definitions Section 191.1

Subsection (c):

Following vigorous protests by members and by the NPVLA, the Food and Drug Administration made several clarifying changes in this subsection defining "containers intended or suitable for household use" (the key covering words of the Act).

The proposed regulations included "containers of ... polishes and cleaners designed primarily for professional use but available to non-professional people". The final regulations clarified the underlined phrase by substituting for it the words "available in retail stores such as hobby shops for non-professional use".

The final regulations further clarified the definition of "containers suitable or intended for household use" by adding the following sentences:

"The term does not include industrial supplies that might be taken into a home by a serviceman."

"An article labeled as and marketed solely for industrial use does not become subject to this act because of the possibility that an industrial worker may appropriate a supply for his own use."

Note: These amendments provide a definite official distinction between industrial products not intended for resale which are exempt from the Act and trade sales or other products which are intended ultimately to be used in the household, which are covered by the Act. A question was raised concerning marine paints sold to ship or boat construction and repair yards for use there, which the subcommittee believes fall into the exempt class, and marine paints and other products sold for use by "do-it-yourself" boat owners which must be labeled in accordance with the Act.

Warning: Members are warned that they should read their label data carefully so that no directions placed on industrial products can be construed to apply to "do-it-yourself" application, and should see to it that no "industrially labeled" containers are put into channels for resale to the general public.

Observance of the Federal Act, moreover, does not relieve manufacturers from labeling industrial products as required by various states for the protection of workmen, using or handling the same.

Subsection (d): "Prominently and Conspicuously"

The proposed regulations declared that these words meant that the required information should be "visible, noticeable, and understandable to the purchaser, user, or to any other person except a young child".

In the final regulations, the underlined portion of that quotation has been deleted and in lieu the following words have been inserted: "in clear and readable English".

In this section under the listing of factors affecting prominence or conspicuousness of a warning, the proposed regulations referred to location on the main panel, but the final regulations have deleted reference to the main panel.

The proposed regulations, moreover, provided that the label "must be of such construction and finish as to withstand reasonably foreseeable spillage through foreseeable use".

This directive was substantially toned down in the final regulations, which preface the clause with the condition: "Unless impracticable because of the nature of the substance, the label shall be of such construction," etc.

Comment: The subcommittee draws attention to the desirability of placing warnings under the ears of gallon containers or any others equipped with handles, since the ears are adjacent to the front panel and help to prevent the warning statement from being obliterated by spillage. When placed on a back panel, the subcommittee recommends that the required information, as far as possible, be placed at the bottom of the panel.

Subsection (f) (1)

The following opportunity for exemptions from requirements of toxicity has been added as the final sentence to this subsection:

"Substances falling in the toxicity range between 500 milligrams and 5 grams per kilogram of body weight (of the test animals) will be considered for exemption from some or all of the labeling requirements of the act, under Section 191.82, upon a showing that, because of the physical form of the substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors, such labeling is not needed."

Note: Upon the basis of human experience with paints containing mineral spirits, turpentine and similar ingredients, the subcommittee recommends that, at the Joint Government-Industry conference, exemption for all paints be sought in accordance

with this paragraph on an industry-wide basis, with the understanding such exemption would not cover the type of clear liquids and removers currently identified under Group IV of the NPVLA Recommended Precautionary Labels. Not only the minor hazards demonstrated in human experience should be stressed, in the opinion of the subcommittee, but also the fact that the physical form of paints includes such a high viscosity as to make impossible the ingestion of hazardous amounts.

Subsection (o) Accompanying literature

By adding the clause "which provides directions for use" to the list of items of accompanying literature listed in the proposed regulations under this subsection, the final regulations brought this subsection into line with the Act and with Section 191.105 of both the proposed and final regulations.

Note: The subcommittee is of the opinion that the mere representation of a person wielding a brush or a roller is not a direction for use by means of a "graphic device". When directions for use appear on color cards or printed attachments to the container, the Act requires that precautionary labels appear on such accompanying material.

Section 191.4 Substances declared to be highly toxic

This section under the proposed regulations which would have given a definite right to those adversely affected to obtain a public hearing upon their objections and a Circuit Court review of any decision not based on the bulk of the evidence adduced at the hearing has been deleted in the final regulations. Section 191.7 (commented on below) is used to provide special labeling for the six substances involved or mixtures of them.

Section 191.6 (c) Listing of "strong sensitizer substances".
Epoxy resin systems.

A vigorous protest was made to this subsection in the proposed regulations on the ground that the general condemnation of such systems of the right to present tests or data on human experience contrary to the findings which the Commissioner proposed to make in this instance.

The final regulations completely revised this subsection and defined clear limits of a particular hazard in lieu of the generalized condemnation in the proposed regulations. The subcommittee finds the revision satisfactory.

Section 191.7 Products requiring special labeling under
Section 3 (b) of the Act

This supplants for labeling purposes the regulations for the six substances originally listed under Section 191.4 in which, in the proposed regulations, the Commissioner announced an intention to find "highly toxic" Carbon Tetrachloride, Diethylene Glycol, Ethylene Glycol, Kerosene, Methyl Alcohol and Turpentine. This, automatically, would have required the poison label with skull and crossbones symbol on all containers for these substances. Under this new section, none is declared "highly toxic", but poison labels are required for Carbon Tetrachloride and Methyl Alcohol. The other four substances (with "petroleum distillates" including kerosene, mineral spirits, etc.) are required to have highly cautionary warnings.

The subcommittee makes the following comments:

Under 191.7 (a) (3) no labeling will be required on products with less than 10% diethylene glycol. (The product may require labeling under other provisions for other hazards).

The petroleum distillates category in Section 191.7 (a) (4) generally would cover trade sales solvent-thinned paints. Many house paints are on the border line and careful consideration of the requirements of this section are in order.

Coal tar solvents are not mentioned but in the interest of product liability, the same procedure for these solvents as followed for petroleum distillates is recommended by the subcommittee.

BENZOL is not listed. The subcommittee believes our industry should recommend for it the same labeling as for Carbon Tetrachloride and Methyl Alcohol.

Legal Note: Since this section:

- (1) is a substitute for Section 191.4, which was subject to petition for public hearing as a matter of right by those adversely affected, and
- (2) performs, as far as two of the substances are concerned, largely the same functions that Section 191.4 would have performed, and
- (3) is a regulation far beyond definition, or a procedural or interpretative regulation, being to some extent an extension of the substantive provisions of the law itself,

it is therefore believed that the contents of the section are still subject to the requirement of a public hearing as a matter of right by those adversely affected.

Section 191.7 (b) (3)

The subcommittee feels that thinners and solvents, clear liquids and similar products should be labeled as provided by Section 191.7 (b) (3), but recommends that exemption from such labeling of paint products of a viscosity greater than boiled linseed oil be made one of the objectives of the Government-Industry Committee based on human experience and on the ground that insufficient amounts of the thick paint could be ingested in the normal case to cause physical harm. Where the petroleum distillate percentage is abnormally high, a substantially higher tolerance than 10%, based on the paint as a whole, should be sought.

The subcommittee recommends that a further addition to the requirements of Section 173.1 (b) (1), be sought, whereby the following warning would be added to the others required for Carbon Tetrachloride:

"Avoid contact with flame or hot surface which may produce toxic gases".

Section 191.101 Placement, conspicuousness, contrast

Subsection (a)

It is noted that warning labels in the final regulations are no longer required to be in a "box" or square or rectangle with a borderline, as required in the proposed regulations.

Of vital importance is the provision under this section which requires on the main panel only the signal word, statement of hazard and a statement that cautionary information elsewhere on the label should be read carefully. This supplants a requirement in the proposed regulations that the whole warning must be on the main panel. Because of the minor hazard represented by paints, the subcommittee recommends that an exemption from this main panel requirement in its entirety be sought by industry representatives during the conference of the Joint Government-Industry Committee.

Subsection (c)

This subsection provides more liberal treatment of the type-size requirements, making the maximum of 18 points applicable for the signal word ("Danger", "Caution", etc.) and for "Poison", in lieu of the requirement for 30-point type for the signal word in the proposed regulations.

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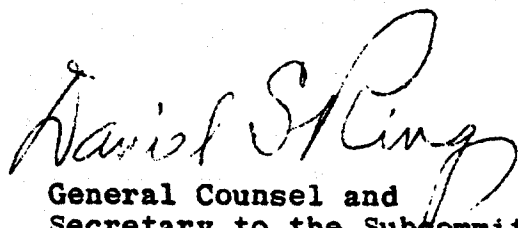
Subsection (d)

This subsection provides for 10-point type in the body of the warning. In all cases when the space permissible for labeling on the container requires a reduction in type size, such reduction may be made, provided that body type not less than 3 points be used. The subcommittee feels that gallon containers should carry the maximum size type and that for smaller containers the rule of reason should be the guide, with the signal word and the statement of hazard in type larger than the body of the warning.

General Note: In seeking the exemption from any labeling on the front panel, the subcommittee points out that it should be urged that all cautionary information on paint products should appear in one place, the rear or side panel, where through the years the public has been educated to look for warnings directly associated on the label with the directions for use of the product.

Section 191.109 Substances named in the Federal Caustic
Poison Act.

The subcommittee recommends that, with respect to the substances involved in this section, the word "Poison" be used in addition to the signal word: "Danger!"


General Counsel and
Secretary to the Subcommittee

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