



Legal Bulletin

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ROUTE TO:

Department

Finance		
Administration		
Sales		
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FDA PROPOSES REGULATION OF LEAD AND CERTAIN OTHER HEAVY METALS

Executive Synopsis

This Bulletin reports on new developments concerning the use of lead, mercury and certain other heavy metals in paints and coatings. The most significant of these is the new proposed regulation of FDA which would, among other things, reduce the lead level to 0.5% from the 1% currently authorized by ANSI Standard Z66.1 and would declare products containing unacceptable levels of these heavy metals to be hazardous materials, thus requiring mandatory labeling. Copy of the FDA proposal is attached, as well as a copy of the "Ryan" petition to FDA asking that all lead in household paints be banned.

This bulletin also comments on the status of the "mercury review" presently being conducted by EPA. A copy of the Administrator's Order on certain algimycin products (attached) contains a number of "findings" relating to phenylmercuric acetate and, in that respect, reflects the government's views on the subject. EPA action on mercury uses across the board is expected in the near future.

ACTION REQUIRED BY YOU: Comments and views on the proposed FDA regulation are solicited.

OPERATIONS AFFECTED IN YOUR COMPANY: The reduced maximum allowable lead level could require many formulation changes and, when the regulation becomes effective, mandatory labeling on all trade sales products containing more than 0.5% lead would be required.

ACTION TAKEN BY NPVLA: Liaison maintained with all government agencies having regulatory and/or administrative responsibilities in these matters, with the objective of achieving uniform, reasonable and effective regulations; and, pursuant to policy decision at the NPVLA Executive Committee meeting on October 8, 1971, general objectives of the FDA proposal have been supported.

CONTACT AT NPVLA: John M. Montgomery, General Counsel

I. FDA PROPOSED REGULATION

A. What Does It Involve?

The Commissioner, Food and Drug Administration, U. S. Department of Health, Education and Welfare (HEW), has issued a proposed regulation which would declare "certain heavy metal-containing paints and other surface coatings to be hazardous substances that require special labeling for child protection." The impact of this proposal (Attachment A) is three-fold:

1. It would reduce the acceptable level of lead (as metal) from 1.0% to 0.5% in the non-volatile content of paints and coatings for toys, other children's articles, all interior surfaces and certain exterior surfaces accessible to children.
2. It would reduce the acceptable level(s) of antimony, arsenic, cadmium, mercury and selenium in the non-volatile coating to 0.05% individually or in total from the ANSI Standard (Z66.1 - 1964) of 0.06%, the acceptable level of water soluble barium at one percent of the barium present is affirmed.

Note. In addition to the percentage restrictions above, the proposed regulation makes it clear that the use of these heavy metals should be limited to that amount essential under good manufacturing practices.

3. It would declare that paints and other surface-coating materials are hazardous substances requiring special label warning, under the Federal Hazardous Substances Act, if they contain more than the acceptable levels prescribed in 1. and 2. above.

B. Why This Regulation?

Noting the one-percent lead level authorized by Z66.1 and prescribed by the Lead-Based Paint Poisoning Prevention Act (P.L. 91-695) earlier this year, the Commissioner, FDA has stated that this proposal is for the purpose of achieving "an additional margin of safety." Also, mandatory labeling requirements would be established, thus eliminating the expressed concern of some public officials that the voluntary labeling program for lead is not working.

The Commissioner does distinguish between the high lead levels which were used in the old paint formulations and the lead content of modern paints, and confirms that he is "unaware of any reports of serious injury or death as a result of ingestion of paints containing one-percent lead or less." Nevertheless, he states that small amounts of lead in excess of the proposed levels, when considered in conjunction with other sources of lead in the environment, do constitute "a substantial addition to the body burden that can reasonably be avoided through the application of available technology."

Notwithstanding the absence of human experience showing hazard from ingestion of paints containing one-percent lead or less, many doctors today have expressed the concern that the content of "one-percent" lead in several layers of dried paint film could exceed the safe limits, particularly for children. Because of this, efforts have been mounting to reduce the maximum allowable lead level in paints. Recently, because of this, Rep. William F. Ryan (D-N.Y.) joined in a "citizen's petition" to ban all lead (other than trace amounts) in household paints. (See Attachment B.)

The "Ryan" petition is considered by NPVLA Staff to be unreasonable and without foundation. Nevertheless, it must be given due consideration by FDA. The new proposed regulation serves, in part, as the FDA reply to the petition.

C. New Labeling Requirements

The proposed regulation would require special labeling for any paint or other surface coating containing more than the acceptable limits of lead or the other named heavy metals and packaged in a container intended or suitable for household use.

The special labeling would include on the main panel the signal word "WARNING", a statement of the hazard "CONTAINS _____" (the blank being filled in with the name(s) of the applicable heavy metals) and instructions to read cautionary information elsewhere on the label.

The proposed regulation prescribes the language for this additional cautionary statement (or its practical equivalent) to be placed elsewhere on the label. The FDA proposal, set forth hereafter, is the precautionary statement recommended by the NPVLA Labeling Committee:

CONTAINS _____

Dried film of this paint may be harmful if eaten or chewed.

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 THE REACH OF CHILDREN.

Note. The above is a modification of the "lead" statement currently included in the NPVLA Recommended Precautionary Labels (e.g. Label No. 14). The new recommendation will be incorporated in the updated Labeling Pamphlet, scheduled to be published by NPVLA in the near future. And, of course, statements of any other hazards in that particular product should be included, as appropriate.

D. How About Inventories?

The proposed regulation (Sec. 191.5 (a) (2)) would apply to "...paints and other surface-coating materials, produced or shipped in interstate commerce after the effective date of this regulation,..." Under such provision, shelf stocks would not have to be relabeled, but -- goods shipped in interstate commerce from a warehouse to a dealer might be covered. Since this could pose a hardship, a request will be made that the proposal be modified to delete the words "or shipped".

E. Comments are Invited

The proposed regulation was published in the Federal Register on November 2, 1971, and -- comments are invited for a period of sixty (60) days. Those wishing to express views on this proposal should ensure that written comments reach the Hearing Clerk, Department of HEW (at the address shown on Attachment A) prior to December 31, 1971. Comments on the "Ryan" petition also may be submitted, if desired. Please send NPVLA a copy of your comments if you forward same directly to HEW, or if you prefer, you may send your comments to NPVLA prior to December 10th, to be incorporated in the Association's position paper. (See G. below.)

F. Timetable For Implementation

With the 60-day period for comments and another 30 days for review and analysis of these comments by FDA, the final regulation should not be published before February 1972. We will request that the industry be granted an additional 90 days before compliance would be required. In any event, it would appear that the regulation could become operational by July 1, 1972.

G. Industry Support Urged

At a special meeting of the NPVLA Executive Committee on October 8, 1971, a policy decision was made that the general objectives of the FDA proposal should be supported. This decision was reached after careful consideration of all factors, particularly confirmation that technological developments of recent years would permit the industry to adjust to the reduced lead content (0.5%) without forcing the consumer to accept major sacrifices in quality and durability. Therefore, it was believed to be in the public interest to assist in achieving this "additional margin of safety" for children, desired by the FDA. Furthermore, due notice was taken of the fact that the pre-emption and mandatory labeling, provided by 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.

For the above reasons, industry support of the general objectives of this FDA proposal is deemed to be appropriate and warranted, and -- is so urged.

In this regard and because of the great public interest in the matter, NPVLA issued a News Release on October 29th (immediately upon receipt of an official copy of the proposal) declaring its support of the objectives of the FDA proposal. It was emphasized in this News Release, however, that:

1. No human experience or other finding has shown that the 1% lead level presents any hazard to the public.
2. Proper uses of lead-based paints and coatings should continue to be allowed -- for primer coats and to protect metal structures against rust and corrosion.
3. Old "white-lead" paint is the recognized primary cause of lead poisoning in children.

II. OTHER HEAVY METAL CONTROLS

A. Lead

While the most significant development concerning the use of lead in our products was covered in detail in Part I, other actions and the activities of other agencies have had substantial impact on the industry. These are addressed briefly below:

1. Lead-Based Paint Poisoning Prevention Act (P. L. 91-695)

The Secretary of HEW has assigned regulatory responsibilities for this 1970 Federal law to the Bureau of Community Environmental Management (BCEM). (See Legal Bulletin No. 73.)

- a. The proposed regulation to implement Title IV of P. L. 91-695 has been completed and is awaiting the Secretary's approval and promulgation in the Federal Register. In accordance with the directive in Title IV of the Act, this regulation is expected to prohibit the use of "lead-based" paints in "any residential structure constructed or rehabilitated by any Federal Agency directly or under any Federally-assisted program." The definition of "lead-based" paints in the regulation is expected to remain at one percent, consistent with the Federal law.

Note. In view of the reduction (from 1.0% to 0.5%) proposed by FDA, BCEM plans to review measures for reduction to 0.5% in the interest of uniformity. Copy of the BCEM proposed regulation will be promulgated to the membership as soon as it becomes available. Appropriate comment on any variance in authorized lead levels will be made.

- b. Quite apart from the above, we are confident that efforts will be made to have the authorized lead level (1%) in P. L. 91-695 reduced by amendment to the law later this year or at the beginning of the next Session of the 92nd Congress.

Note. Such an amendment might be sought in conjunction with the necessary requests for additional funds to support the programs provided for by Titles I, II and III of P. L. 91-695. Much controversy and complaint were voiced over failure of the Executive Agencies to request and the Congress to provide adequate funds for the above-mentioned programs in fiscal years 1971 and 1972.

- c. Meanwhile, in response to letters addressed to the Secretaries of HEW and HUD, NPVLA has been assured that both Departments are devoting maximum effort, consonant with available resources, to the programs addressed by Titles I, II and III of the Federal law. These, of course, relate to the real problem of lead-paint poisoning of children.

One of the principal efforts at this time, coordinated by HEW and HUD, is the establishment of a program for testing and evaluation of the lead content of paint products currently on the market. This program is being conducted by the National Bureau of Standards. Industry representatives were invited to participate and are participating to the extent practical in this program.

2. Federal Specifications

The Federal Supply Service, General Services Administration, is continuing its review of all existing specifications with respect to lead content, looking to elimination or reduction of lead insofar as practical. However, GSA has assured us that lead will be retained in paint specifications where its uses are deemed beneficial and its hazard to children minimal.

3. Government Agencies Updated on Lead Uses

Because of the rapid developments in recent weeks and because of some uncertainties and misinformation, NPVLA convened a meeting at Headquarters in Washington on November 4, 1971 for the purpose of clarifying the issues. The meeting was attended by representatives of all key government agencies in Washington involved in specification writing and having responsibilities under the current laws and regulations relating to lead uses.

B. Mercury

1. The Environmental Protection Agency has not yet issued its findings and orders concerning the use of mercury compounds as fungicides and bactericides in paint products. The review -- initiated by the Pesticide Regulations Division of USDA last December (F. R. Mercurial Notice, dated December 3, 1970) -- has been completed and is being staffed. Action by the Administrator is expected in the near future.

Note. The Pesticide Regulations Division now is a part of the Environmental Protection Agency (EPA), having been transferred from USDA upon the establishment of EPA earlier this year.

2. In this connection, a preview of the EPA position on mercury uses is reflected in the Order of the Administrator which was published in the Federal Register on October 19, 1971. (A copy of this Order is provided -- Attachment C -- for your advance information.)
 - a. This Order was published in connection with a petition of the Great Lakes Biochemical Co., Inc. to continue the use of several "algimycin" products registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
 - b. The Order Contains 27 "findings of fact" regarding mercury uses, and these findings confirm our fears that phenylmercurials will be treated no differently than the alkyl mercury compounds.
 - c. However, in this Order, the registrations of the algimycins were suspended immediately because of "imminent hazard to the public." We do not believe such imminent hazard can be determined for the mercury uses in most paint products.

Note. On November 1, 1971, the Administrator refused to suspend all registrations of DDT, stating that such action was not justified on the basis of imminent hazard, and that he believed all the facts should be considered before a decision was made.

3. In view of the foregoing, we are hopeful that EPA will see fit to allow our industry the time necessary for adequate testing and evaluation of substitutes (for efficacy and hazard), as requested by the Association. In any event, it would appear that we would have a period of several months to change formulations and dispose of current stocks while any cancellation of registrations ordered would be held in abeyance pending prescribed administrative proceedings!

4. Conclusion

In light of all developments of the past year, the Administrator's Order in the Great Lakes case (Attachment C) and the continued concern over the buildup of mercury levels in the environment, we must conclude that EPA will, in due time, cancel the registration of all mercury compounds. Such action would, of course, deny to our industry, the phenylmercurial compounds for use as fungicides and bactericides. Thus, Association members are advised to prepare now for such eventuality.

C. Other Heavy Metals

In addition to lead and mercury, many other heavy metals are being studied with respect to environmental hazard. Some already have been earmarked for future control and others have been named as likely candidates in the following actions:

1. Pesticide Regulations Division, EPA Study

In addition to the review of all mercury uses in paint products (see B. above), EPA announced on June 25, 1971 a review of all uses of lead and arsenic, naming specifically such uses in anti-fouling paints. This review has not been completed.

2. FDA Proposed Regulation

As previously discussed (see Part I), the other heavy metals covered by ANSI Standard Z66.1 - 1964 (antimony, arsenic, cadmium, mercury, selenium and water-soluble barium) already are covered by the new proposed regulation of FDA.

3. Clean Air Act Amendments of 1970

In addition to the six pollutants originally named (sulfur oxides, particulate matter, carbon monoxide, photochemical oxidants, hydrocarbons and nitrogen oxides), mercury, beryllium and asbestos were declared air contaminants by the 1970 amendments, and proposed emission standards on the latter are being developed. Also, EPA has indicated that lead, cadmium, selenium, molybdenum and arsenic should be declared air contaminants.

4. Federal Water Pollution Control Act Amendments of 1971

This strict, far-reaching water pollution control bill -- designed to stop all pollution of the nation's waterways by 1985 -- could have an impact on our industry equal to or, possibly, even exceeding that of the Air Pollution Control laws. The Senate approved this legislative proposal (S. 2770) on November 2nd by a vote of 86-0. A similar bill is pending before the House, but -- action by that body may not be completed until early next year.

S. 2770 is the successor bill to S. 523 and numerous other similar bills which were considered for many months by Chairman Muskie's Senate Public Works Subcommittee on Air and Water Pollution. Its stated policy is "to restore the natural chemical, physical and biological integrity of the Nation's Waters" by eliminating the discharge of pollutants by 1985. This is to be accomplished principally by effluent limitations.

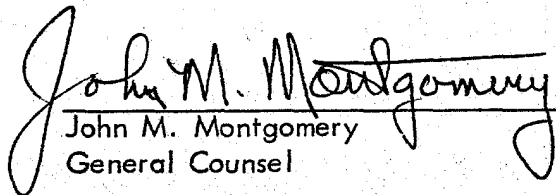
One of the key provisions of S. 2770 is Section 307 (Toxic and Pre-Treatment Standards) which would require EPA to publish, within 90 days of enactment, a list of pollutants that are determined to be toxic. Six months later EPA must publish proposed effluent limitations, which could be a prohibition of a discharge, for these pollutants. Hearings and regular administrative proceedings are prescribed, but -- the potential impact should be clear!

The Senate Committee, in its report (No. 92-414), indicated that "arsenic, cadmium, mercury and beryllium, as well as certain chlorinated hydrocarbons, had been identified as pollutants which could be subject to effluent standards or prohibition of discharge."

D. Summary

At the present time, lead and mercury are receiving principal attention and most of the significant developments, addressed in this Bulletin, relate to these two ingredients. However, the various agencies are looking at many other heavy metals -- antimony, arsenic, (water-soluble) barium, beryllium, cadmium, molybdenum, selenium) -- and all seem to be potential candidates for some regulatory controls.

Individual manufacturers must keep informed of these developments in order that program planning may provide for appropriate substitutes and necessary reformulations. NPVLA will attempt to provide the timely and authoritative information on these developments which you need to keep your scorecard up to date!


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JMM/ew
attachments