

FDA Confirms .50% Lead Level; Defers Action on .06%

The Food and Drug Administration (FDA) has confirmed the .50% lead level for lead in paint to become effective December 31, 1972.

Published August 10 in the Federal Register, the new Order implements the .50% provision contained in the March 11 FDA Order which classified certain paint products as "hazardous" substances. The new Order does not, however, take any action on the .06% provision also contained in the March 11 Order, but states that this issue will be the subject of a separate ruling.

In issuing the new Order, FDA noted a number of comments and objections filed in opposition to the March 11 Order. Of the 10 objections received, the majority concerned the .50% level and will be ruled upon at a later time. Of the objections concerning the .06% level, the FDA ruled as follows:

1. The Agency rejected requests for additional time (up to 18 months) to comply with the .50% provision because it was not a sufficient supply of paint at lead levels which exceeds the .50% level.

2. Requests from retailers and distributors for an additional 18 months to

dispose of existing inventories was refused on the grounds that these groups had known since March 11 that paint above the .50% lead level would be banned and thus had sufficient opportunity to eliminate non-comforming paint from their inventories.

3. The Agency ruled that the comments filed by the Georgetown University Law Center (Professor Page et al) on repurchase were not supported by grounds legally sufficient to justify a public hearing. This action leaves the repurchase issue still in question since no implementing regulations to Section 15 of the Federal Hazardous Substances Act (FHSA) have yet been issued.

According to NPCA General Counsel John M. Montgomery, "in the absence of more restrictive language in the most recent Order or any amplifying comments, the qualified repurchase requirement contained in the March 11 Order should control." This provision is being interpreted to mean that only those products exceeding the .50% lead level which are shipped in interstate commerce after the December 31, 1972 deadline date should be subject to repurchase.

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Recently there has been much legislative activity with regard to the use of lead in paint products. Although the outcome of this is uncertain, it is nevertheless appropriate that I report to you what we at The Sherwin-Williams Company are doing to provide you with products which will be in compliance with these laws.

On March 11, 1972, FDA issued an order which declared that paints containing more than .1% lead after December 31, 1972 and more than .06% lead after December 31, 1973 were declared to be a banned hazardous substance and could not be shipped in interstate commerce. As of this date, FDA has not implemented this order although they are expected to do so very soon.

The Senate has adopted an amendment to the Lead-Based Paint Poisoning Prevention Act which would prohibit the use of paints containing more than .5% lead after December 31, 1972 and .06% lead after December 31, 1973 on surfaces of Federally funded housing. The companion bill introduced by Representative Ryan in the House of Representatives is still in committee, so the outcome of this legislation is uncertain although it is expected to be adopted by the Congress.

In addition to the Federal legislative activity, various states and municipalities have adopted ordinances relating to the sale and use of coatings containing lead. Chicago recently passed two ordinances which prohibited the sale and use of coatings intended for use on interior household surfaces and containing more than .04% lead and more than .05% other toxic heavy metals (selenium, cadmium, mercury, arsenic, and antimony) after July 1, 1972. Other states are expected to adopt similar legislation.

The Sherwin-Williams Company recognized several years ago that legislation restricting the use of lead in paints would probably be adopted. As a consequence, we began to routinely reformulate our products to remove the lead content. As a result of this foresight, I can report to you that all interior coatings currently manufactured by The Sherwin-Williams Company contain less than .06% lead and less than .05% other toxic heavy metals. In addition, all other Trade Sales products, including those designed for exterior surfaces on dwellings, are being reformulated to less than .06% lead. We expect to be down to less than .5% lead content by October 1, 1972 and to less than .06% lead content soon thereafter.

We currently are putting the following letter suffix after the manufacturing date on all containers to indicate the lead and other toxic heavy metal content of the coatings:

- X less than .06% lead and .05% other toxic heavy metals
- V less than .5% lead and .05% other toxic heavy metals
- Z more than .5% lead and .05% other toxic heavy metals

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Lead-in-Point Rules, Legislation Finally Moving Toward Resolution

Stagnant for the past few months while industry leaders conducted quiet negotiations in an attempt to provide for fair and equitable treatment for both the manufacturers and retailers, the lead-in-point question is finally moving toward resolution in both the Food and Drug Administration (FDA) and in the Congress.

A small victory for the paint industry can be claimed in the recently published FDA regulations implementing its March 31 order banning lead-containing paints, while the fight continues in the Congress as the National Paint and Coatings Association (NPCA) attempts to change some language within Sen. Edward (Ted) Kennedy's amendment to the Lead-Based Paint Poisoning Prevention Act, passed by the Senate in mid-June 1973, and currently being considered by House Committee on Housing as part of its Omnibus Housing Bill.

According to the FDA notice in the Federal Register in early August, the repurchase of paint will not be required under the FDA regulation. The agency took the position that repurchase of products containing more than .5 percent lead which are banned effective Dec. 31, cannot be enforced by the federal agency and is therefore inappropriate for the government to include in its formal order. This doesn't mean, however, that the matter is entirely resolved. Consumers can and may challenge the FDA ruling in the federal courts, although no such movement is visible at this time.

What does this mean to retailers? Simply stated, dealers will not be required to buy back from consumers any paints manufactured before Dec. 31, regardless of the lead content. It also means that retailers need not expunge their shelves of paints containing more than .5 percent lead, the products were purchased prior to Dec. 31.

Rudy Vignone, director of the Office of Compliance for the FDA's Bureau of Product Safety, states that individual retailers need not expect on-site inspections by FDA inspectors. Instead, he continues, "our field force will go to the points of production to determine whether or not there are violations. In the case of violations, seizures will be the first step taken by Vignone's office. Should this fail, violators would face fines and jail sentences ranging from \$400 and 90 days or both, to \$3000 and a year, or both. WARNING — This FDA order does not supersede or replace local or state lead laws.

Still the center of controversy is the .06 percent lead limit which is scheduled to take effect Dec. 31, 1973.

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The FDA order confirming the end-of-1973 deadline at the .5 percent level added fuel to industry demands for some changes in this ruling pursuant to a proposed HEW eight-month study which is contained in Sen. Kennedy's bill. The FDA's position is that it will shelve industry requests for hearings and its implementation of the .06 percent lead level until such a study is completed by HEW.

The paint industry is, for the most part, pleased with the FDA's approach to the .06 percent question, noting that such a study should establish once and for all solid data on what lead levels are really proper.

There are, however, some problems which revolve around the proposed HEW study and the Kennedy bill as passed by the Senate. While waiting for the study, the Kennedy bill does not defer action on the banning of lead-based paints at the .06 percent level after Dec. 31, 1973. NPCA is attempting to amend the Kennedy amendment while it's being considered in executive session of the House Committee on Housing to at least conform to the Senate bill.

In addition to the conforming language, NPCA has requested additional changes, including a provision to defer the .06 percent standard until the research called for under the Kennedy bill has been conducted by HEW and then fully evaluated by both the government and the paint industry. The point, according to NPCA Executive Vice President Robert Roland is that to enact the .06 percent standard before research is completed would negate the practical value of the research, "especially if the data shows a higher standard to be safe in residential paints."

Another significant change Roland states, is the inclusion of a full pre-emptive section in the federal law. The industry, he points out, has been plagued by state and local lead ordinances at differing levels of lead content and with different timetables for enactment than that proposed either by the FDA or by the Congress.

Under the Kennedy amendment to the Lead-Based Paint Poisoning Prevention Act, an appropriation of some \$100 million in preventive and study funds will be authorized. HEW is directed by the Kennedy bill to conduct its study and report back to the Congress on its findings no later than eight months after its enactment. This, according to highly placed Congressional authorities, is considered to be sufficient time by Sen. Kennedy and his followers to change the .06 percent lead level should it be determined that a higher level is safe.

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