

The Regulatory Status of
Vinyl Chloride and Polyvinyl Chloride */

EPA

The Environmental Protection Agency's National Emission Standard for Vinyl Chloride is due to be published in the Federal Register soon. With the requisite hearing and Comment period complete, the final document is known to be circulating at the Assistant Administrator level prior to final presentation to EPA Administrator Russell Train.

Since we first described its provisions, the EPA Standard has not been altered substantially. It still exempts the compounding and fabrication segments of the industry but calls for strict limits on both point and general emission sources in plants manufacturing monomer and/or resin. However, because EPA worked closely with the industry during the development of its Regulations for vinyl chloride, the final text will probably be as reasonable as could be expected under the circumstances.

Once the Regulation appears in the Federal Register, it will go into effect 90 days later, except to the extent that individual applicants have during that time been granted statutory waivers of up to two years duration. Additionally, we now expect the Preamble to the Standard to contain a notation that the research and development portion is subject to further review and, perhaps, revision by the addition of an alternate control strategy. The Agency has at last become convinced that some "solid questions" still remain to be answered in this area, and, as a result, requests for further information have been sent out by EPA in anticipation that the new data will justify waivers while the additional control strategy is developed.

OSHA

In the past we noted that, with the approach of the April 1, 1976 date upon which the Occupational Safety and

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Health Administration (OSHA) Standard went into full force and effect with regard to respirator usage, five members of the Vinyl Chloride/Polyvinyl Chloride Producers Group had filed with OSHA seeking temporary variances based on the non-availability of certain types of respirators, insufficient time to complete engineering modifications, the effects of other regulatory action (viz., FDA and EPA activity), and other grounds.

We also reported that all of these temporary variance requests were mooted by the publication in the April 1, 1976 Federal Register by the Mining Enforcement and Safety Administration (MESA) of the Department of the Interior of its retroactive (to January 1, 1976) extension to September 30, 1976 of the previously established December 31, 1975 deadline for development of an "end-of-service-life indicator" for canister and cartridge respirators in vinyl chloride service. Prior to this, the failure to develop the requisite indicator had made use of canister and cartridge respirators inadequate for compliance with the OSHA Standard during 1976; only air-supplied respiratory protective devices were approved. With MESA on its own motion having extended the deadline for the end-of-service-life indicator requirements, the resultant canister and cartridge mask availability made it possible for OSHA to deny all requests for variances.

Of late, we have had occasion to be in touch with the responsible officials at OSHA, NIOSH and MESA concerning the status of an end-of-service-life indicator and to determine, were such an indicator not approved by the deadline, whether an extension of the September 30, 1976 cutoff could be expected.

The NIOSH laboratories responsible for investigating the end-of-service-life indicator for vinyl chloride informed us that the only applicant's device was rejected and had not been resubmitted. We were told that it would now be impossible to approve any indicator device prior to the cutoff date.

Having already addressed ourselves to MESA and OSHA officials about a time extension with no success, we inquired

of the appropriate NIOSH officials as to whether they were going to take any action. We received something in the nature of a "no--that is your problem" response.

Only two companies have so far expressed to us any desire for an extension of time. Nevertheless, with only a little time left, we are still prepared to proceed if sufficient interest exists to support a request for an extension of time by the VCM/PVC Producers Group.

FDA

We have previously reported to you that the Food and Drug Administration (FDA) had scheduled its priority for finalizing the PVC Regulations into the fourth quarter of 1976 but that, as a result of internal objections to the timing schedule, the Agency began to state it was committed to finalizing the Regulations by June, 1976. At this juncture, our characterization of that time schedule as "improbable" has certainly proven correct. In fact, the most the Director of the Division of Food and Color Additives has been willing to say recently is that the Regulations "might be promulgated some time in the fall."

We do know that the Bureau of Foods' evaluation of the scientific data was completed in April, 1976, and that a preliminary draft of regulatory language is now circulating within the Bureau. At least two issues are holding up further progress: one involves a question of a basic regulatory philosophy for PVC, while the other was brought on by the difficulties inherent in regulating potable water pipe.

Speaking at a recent American Chemical Society Symposium in San Francisco, Mr. Richard Ronk, Director of FDA's Division of Food and Color Additives stated that biostatisticians working with the available data have informed him that a level of 2 parts per billion (ppb) in food is a "safe" level with respect to vinyl chloride. Nevertheless, he cautioned that no Regulation could set a "tolerance" in the conventional sense, even at the 2 ppb level, since to do so would violate the Delaney Clause as that section of the Food, Drug and Cosmetic Act is presently interpreted by staff

attorneys at the Food and Drug Administration. He implied that the staff in the Bureau of Foods is presently wrestling with the problem of just how to regulate materials which are recognized to be safe without at the same time setting any number which could be interpreted as a tolerance. This is a problem we have long recognized and took into account in SPI's PVC Comments.

We understand that the present draft is attempting to finesse the problem by proposing a maximum residual monomer limit for rigid and semi-rigid PVC finished plastics. This limit will be set at a level sufficiently low so as to assure there will be no reasonable expectation that VCM can become a component of food. We have not been able to obtain any firm insight as to what level is being considered but our best (and paltry) information leads us to believe that a level below 0.100 ppm in the plastic is being discussed.

On the PVC potable water pipe front, you will recall that the Food and Drug Administration and the Environmental Protection Agency set up a joint Task Force to resolve, among other jurisdictional questions, the potable water pipe issue which was highlighted when FDA proposed an Interim Food Additive Regulation for PVC potable water pipe as a part of its proposed PVC package. SPI filed vigorous Comments pointing out that, in our opinion, EPA rather than FDA has exclusive federal jurisdiction in this area. Partly in response to these Comments and partly because other areas of apparent overlapping jurisdiction also exist, the Task Force has been meeting to develop a Memorandum of Understanding (MOU) to set inter-agency jurisdictional ground rules.

We have been informed that an agreement in principle has been reached between EPA and FDA working level representatives on the Task Force; that a preliminary MOU prepared by EPA was sent to FDA for review; that FDA found that draft to be satisfactory in general content but has prepared its own rewrite to include more details; and that the FDA version has been favorably received by the EPA Task Force representatives.

Although we have not had any access to the various working drafts, we believe that the present proposed Task Force Agreement is along the following lines: EPA will exercise primary jurisdiction over potable water piping systems (FDA will presumably withdraw the proposed Interim Regulation as it relates to piping systems in due course) but EPA will not recommend the use of any components that pose food additive problems. Should EPA determine there may be migration of an uncleared component of piping systems into potable water, the MOU presumably provides for it to notify FDA of the need to take enforcement action under the Food, Drug and Cosmetic Act's provisions barring adulteration of food (water).

We understand that the FDA draft MOU is now circulating among the upper echelons of both EPA and FDA. Based upon our understanding of past attitudes and positions, we would suspect little or no opposition will be encountered at EPA, but the concepts in the MOU could encounter significant resistance in the Office of the Commissioner or Chief Counsel of FDA. In particular, the new Associate Commissioner for Compliance, Paul J. Hile, has traditionally been reluctant to yield FDA jurisdiction in any area and if our understanding is correct, the MOU will propose that FDA "give up" something, i.e. general jurisdiction over potable water piping systems.

If the Memorandum of Understanding that is finally approved coincides with our current information, we believe that part of the reason why FDA will have agreed to cede jurisdiction and EPA to assert it will have been because of the very responsible way in which the PVC piping industry acted to assure both Agencies that the levels of residual monomer in PVC piping can and will be controlled so that there will be no reasonable expectation that vinyl chloride can enter the potable water supply system.

It is still too early to be sure that the ultimate outcome will be in the directions indicated but we do feel cautiously optimistic.

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As a final note about the status of vinyl chloride, we thought you might be interested to know that in the July 29, 1976 edition of the Federal Register, NIOSH (that is, the National Institute for Occupational Safety and Health) announced a "request for information on certain chemical/physical agents."

Curiously, although the Notice only requests the submission of new information regarding vinyl chloride, among other substances, the Agency is interested in more than updating the criteria document for vinyl chloride. In fact, we have learned that NIOSH has employed a contractor that is actually sending investigators into vinyl chloride and PVC plants. The information we have received is that, ultimately, all the information accumulated by NIOSH will be used to determine whether the Agency should recommend that OSHA revise its Vinyl Chloride Standard.

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The California bill aimed at requiring special permits, standards, and inspections for the "use" of any carcinogen has now passed through both Houses of the California Legislature and is on Governor Brown's desk where it is expected to be signed.

This OSHA-type bill, originally a "special use permit" bill which we vigorously contested, now provides for specific state enforcement of its almost mirror-image vinyl chloride exposure regulation but it adds a few procedural twists with which the PVC producers in California will have to wrangle. Specifically, the bill mandates certain duplicative inspections and fees, reports, medical examinations in some cases and "civil" penalties with minimums ranging from \$500 to \$5,000. It also fails to distinguish a level below which a carcinogenic effect is not expected or regulated; this, combined with a more restrictive definition of "fabricated product", will probably cause some problems where operations had been taking advantage of the "not...melting...the polyvinyl chloride

resulting in the release of vinyl chloride" exemption-type language. Although the language in the bill does not explicitly apply to compounders and fabricators, the author of the bill has stated that it is his intent that both the reporting and inspection provisions should apply to all elements of the industry.