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Re: Vinyl Institute Comments on California Proposed Rulemaking on Maximum Contaminant Levels

Dear W.C.:

Enclosed for your review are draft comments objecting to the California Department of Health Services' proposed rulemaking on a maximum contaminant level (MCL) for vinyl chloride. If you could return your comments and/or revisions to us by Monday, September 26, 1988, we should have enough time to incorporate your changes prior to the September 28, 1988 filing deadline. California's risk assessment is also enclosed. We would particularly appreciate comments on the State's approach.

While only one community water system well in California (an industrial well, used for non-potable purposes, and thus not subject to the proposed Rulemaking's standards) contains vinyl chloride at a level greater than California's proposed vinyl chloride MCL, the rulemaking has far-reaching implications, especially in light of California's testing requirements for contaminants. California's regulations governing domestic water quality and monitoring define "maximum contaminant level" as:

> The maximum permissible level of a contaminant in water which is delivered to a free flowing cold water outlet of the ultimate user of a public water system, except in the case of turbidity where the maximum permissible level is measured at the point of entry to the distribution system. Contaminants resulting from corrosion of piping and plumbing caused by water quality are included . . .

The regulations do not indicate where in the distribution system monitoring of maximum contaminant levels for volatile organic compounds is to occur, although the above definition of MCL seems to indicate that monitoring can occur anywhere within the system, whether at a point of entry into the system or a point of use. Were California to require monitoring at point of use, the proposed maximum contaminant level for vinyl chloride could conceivably cause some concern to producers of PVC pipe.

In 1986, the National Sanitation Foundation (NSF) conducted extraction testing of PVC pipe pursuant to Standard 14, a national, voluntary guideline on PVC pipe specifications. To establish levels of vinyl chloride monomer in NSF-listed products currently on the market, NSF tested every PVC sample shown to contain two or more parts per million (ppm) residual vinyl chloride monomer. NSF's test data demonstrated that new (freshly produced) pipe with residual vinyl chloride monomer of 2 ppm leached 2.5 parts per billion (ppb) vinyl chloride monomer to water when exposed under the conditions defined in the Standard. The exposure conditions, considered aggressive given expected end use, also resulted in seven day old pipe, with 2 ppm residual vinyl chloride monomer (RVCM), leaching less than 1.5 ppb. After 30 days, 0.78 ppb vinyl chloride was extracted from 2 ppm RVCM pipe. California's proposed maximum contaminant level for vinyl chloride monomer, however, is still less than this 0.78 ppb figure. Even with continued aging of the PVC pipe and its concomitant reduction in vinyl chloride monomer leaching, California's proposed vinyl chloride MCL is cause of some concern.

Because of the possible ramifications of California's proposed rulemaking, we think it worthwhile to submit the attached comments to the California Department of Health Ser-

vices. We welcome your comments and look forward to hearing from you soon. In the meantime, should you have any questions, please do not hesitate to call.

Cordially yours,

Peter

Peter L. de la Cruz

Enclosure

cc: Robert D. Luss, Esquire
Ms. Meredith M. Scheck
Mr. Larry Thomas (w/o enclosures)
Mr. Lewis R. Freeman, Jr. (w/enclosures)
Mr. Robert W. Sherman (w/o enclosures)
Mr. Stan Mruk

Before the

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

Maximum Contaminant Levels Proposed Rulemaking R-38-88 (June 23, 1988)

COMMENTS OF THE

VINYL INSTITUTE, a

Division of The Society of the Plastics Industry, Inc.

Vinyl Institute
Wayne Interchange Plaza II
155 Route 46 West
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September 28, 1988

VINYL INSTITUTE COMMENTS

I. INTRODUCTION AND STATEMENT OF POSITION

The Vinyl Institute appreciates the opportunity to comment on the California Department of Health Services' (CDHS) proposed Maximum Contaminant Levels rulemaking. Cal. R-38-88 (June 23, 1988). The Vinyl Institute, a Division of The Society of the Plastics Industry, Inc. (SPI),[1/] represents the major producers of vinyl chloride (VC) and polyvinyl chloride (PVC); members of the Vinyl Institute account for approximately 82% of the domestic production of vinyl chloride and 63% of the domestic production of polyvinyl chloride. While the Vinyl Institute does not oppose CDHS's proposed rulemaking in its entirety, we do have serious concerns with the maximum contaminant level (MCL) set for vinyl chloride. For the reasons set forth below, the vinyl chloride MCL should not be finalized as proposed.

California has assumed primary enforcement responsibility for its public water systems under the Safe Drinking Water Act.[2/] On June 23, 1988, the California Department of Health Services proposed maximum contaminant levels in drinking water for nine compounds, including vinyl chloride. The Department has proposed a level of 0.0005 mg/l, which it contends is the current limit of detection, as the maximum permissible level of vinyl chloride in drinking water.

The California Department of Health Services' proposed rulemaking followed the U.S. Environmental Protection Agency's (EPA) July 1987 promulgation of final maximum contaminant levels for eight volatile organic compounds by nearly a year.[3/] Among the eight compounds regulated by EPA in that 1987 rulemaking is vinyl chloride, for which EPA set an MCL of 0.002 mg/l. CDHS's proposed vinyl chloride MCL of 0.0005 mg/l is far more stringent than that recommended by EPA. CDHS's rationale in lowering the maximum contaminant level to equal the limit of detection is based in CDHS's unfounded criticism that EPA's risk assessment underestimates the health risks of vinyl chloride. CDHS's risk assessment, however, [develop and insert critique of CDHS risk assessment if possible].

We question whether California's standard is supported by available scientific evidence on the potential health effects associated with vinyl chloride. Whether technological issues were adequately considered by the Department of Health Services is also uncertain. Since EPA's administrative record supporting its promulgation of maximum contaminant levels is based upon conservative risk assessment methodology and feasible, analytical capabilities, there is no rational basis for the Department of Health Services to establish maximum contaminant levels below EPA's safe recommendations. To do so, simply because on occasion it is analytically possible, using procedures that have

not been shown to be consistently reproducible, is likewise unjustified. We recommend that California's Department of Health Services adopt a vinyl chloride MCL consistent with EPA's 0.002 mg/l level.

II. EPA'S REGULATION OF VINYL CHLORIDE

EPA's final rule promulgating a maximum contaminant level for vinyl chloride of 0.002 mg/l requires analysis of vinyl chloride in groundwater systems only where one or more of the following two-carbon organic compounds are also detected: trichloroethylene, tetrachloroethylene, 1,2-dichloroethane, 1,1,1-trichloroethane, cis-1,2-dichloroethylene, trans-1,2-dichloroethylene, or 1,1-dichloroethylene.[4/] If one of the above compounds is present, vinyl chloride analysis must occur at each distribution or entry point;[5/] if no vinyl chloride is detected at a 0.002 mg/l level, a state need only monitor the location for vinyl chloride once every three years.[6/] Vinyl chloride analysis of surface water systems is left to the discretion of each state.[7/]

The former requirement, applicable to ground water systems, is based on the rationale that any detectable quantity of vinyl chloride in drinking water likely results from the degradation of trichloroethylene and similar solvents, rather

than the actual disposal of vinyl chloride or polyvinyl chloride. As EPA stated in its proposed rulemaking in November, 1985, "EPA has concluded that the most likely explanation for vinyl chloride detection in groundwaters is from in situ transformation."[8/] As to a state's discretion in analyzing surface water for vinyl chloride, EPA stated "[N]o requirements would be set for vinyl chloride monitoring in surface water systems because vinyl chloride is not expected to be found due to its high volatility."[9/]

While only one community water system well in California currently contains vinyl chloride at a level higher than CDHS's proposed MCL,[10/] the ramifications of California's vinyl chloride standard are far-reaching. Under California's proposed rulemaking, all community water systems will be required to monitor for vinyl chloride, regardless of the technical feasibility of analyzing for the chemical at such a low level, and regardless of the presence of halocarbon solvents indicating VC's possible presence.

Community water systems in California are required to test for vinyl chloride, and other organic chemicals, pursuant to the following schedule. All systems are considered by the state to be initially vulnerable. Following quarterly monitoring during the first year, a system must monitor thereafter

every other year. This monitoring schedule is far more onerous than that required by EPA, and is simply unnecessary given the unlikelihood of vinyl chloride's presence, and given the negligible risk factors presented by the compound at the extraordinarily low maximum contaminant level designated by EPA.

III. EPA DETERMINATION OF MAXIMUM CONTAMINANT LEVELS

In its initial statement of reasons for lowering vinyl chloride's MCL, CDHS identified what it perceived as inadequacies in EPA's risk assessment for the organic compound. Nevertheless, we submit that EPA's risk assessment procedures are sufficiently "conservative" to protect the public safety even if, arguendo, the CDHS criticism is justified.

Carcinogenic risk assessment is a complicated science, at best. Any number of factors enter into the analysis of a particular chemical's human cancer effect; whether one relies on epidemiological or long- or short-term animal studies, or a combination of the three, may significantly alter one's conclusions. Equally competent scientists differ in their interpretation of pathology slides; they must also choose from among several alternative dose response models for projecting low-dose risks because of a fundamental absence of definite data on cancer induction and development mechanisms. And a risk

assessment may well be hampered by a simple lack of or gap in sound available data.

In response to the inherent uncertainty found in any study of potential carcinogens, the carcinogenic risk assessment procedures adopt "conservatisms" to provide ample margins of safety. For example, the initial stage of EPA's MCL development, the recommendation that maximum contaminant level goals be set at zero, is rooted in the notion that a so-called "threshold" for carcinogens does not exist, or if it does, cannot be demonstrated by current science.[11/] Proponents of such a view hold that the reaction of a single molecule of a carcinogen with a sensitive cell can initiate a cancer response -- that there is no threshold. Since science is unable to demonstrate unequivocally such a threshold effect for all potential carcinogens, they argue that any exposure to a carcinogen presents a finite level of risk. However, scientific evidence does exist that, at certain exposure levels, no carcinogenic effect can be observed. Despite this, EPA assumed the "worst" scenario in drawing the conclusion that a "no effect" level does not exist in order to ensure human health is properly safeguarded by the final MCLs.

EPA builds into its risk assessments other safety factors. EPA not only factors into its analysis the increased incidence

of malignant tumors initiated by the dosage, but also considers increased occurrence of benign tumors.[12] According to EPA, such evidence is an indication, although limited, of potential carcinogenicity, and therefore should be considered.[13]

To develop its MCLs, EPA used the most conservative of extrapolation models, the linearized multi-stage model.[14] In its general guidelines to assess human cancer risk, EPA notes that the choice of a particular low-dose extrapolation model can have a "pronounced influence on the estimated low-dose risk."[15] The multi-stage model recognizes that a developing tumor goes through several stages, all of which can be affected by the particular carcinogen before it is clinically detectable.[16] Because the multi-stage model is linear at the low-dose region, its risk estimates are generally regarded as very conservative.[17] One further safety factor is EPA's use of a 95% confidence level for resulting carcinogenic risk. This very cautious statistical measure results in a significantly higher calculated risk of cancer incidence than observed in the animals and thus errs on the side of safety. Finally, EPA relates the experimental animal exposures to equivalent human exposure by utilizing body surface areas instead of weight -- another approximately ten-fold safety factor.

The extreme conservatism created by these risk modeling assumptions may be demonstrated in the following example. Assume

fifty laboratory animals (rats) are exposed to a putative carcinogen at a dosage of 1,000 parts per million (ppm); suppose further that no tumors of any kind are observed resulting from that dosage. A 95% confidence level will assume that 5.8% of those rats actually contracted cancer from that exposure to the 1,000 ppm dosage. The 5.8% value is then used to calculate the one in a million risk of cancer, resulting in a safe dosage of approximately 2.9 parts per billion (ppb). In other words, the observation that none of the fifty rats showed any incidence of cancer at a dose of 1000 ppm (0.1%) leads to a "safe dose" of only 2.9 ppb, a safety factor of more than 340,000.

Risk assessment values were never intended to measure actual cancers (i.e., one in one million) produced by exposure to a substance. Rather, at the calculated dose, the risk may well be zero, but is virtually certain not to exceed 1 in one million. Despite EPA's extremely cautious approach, California rejected EPA's methodology and established a vinyl chloride MCL at an unnecessarily low level.

IV. DISCUSSION OF CALIFORNIA RISK ASSESSMENT

[Insert critique of California risk assessment if possible.]

V. EPA'S STANDARDS PROVIDE FOR A CONSISTENT LEVEL OF DATA QUALITY FROM A DIVERSE GROUP OF LABORATORIES

In light of EPA's extreme conservatisms in setting health effects levels, it is appropriate to recognize that practical considerations can enter into the setting of enforcement levels without adverse health consequences. In the present case, it is necessary to recognize the inherent variability experienced by good laboratories conducting routine, periodic tests for substances present at very low concentrations. In this light, the MCLs set by EPA are those that can regularly be achieved by good laboratories working under good procedures; the California limit requires extreme analytical care that cannot be achieved regularly -- and that is not necessary to protect the public health.

In November, 1985, EPA introduced the concept of practical quantitation level (PQL), the lowest level that can "reliably be achieved" within specified parameters of precision during "routine" laboratory conditions.[18/] PQL is a measurement concentration independent of time and independent of specific laboratory,[19/] and is itself based on another estimated measurement, the method detection limit (MDL).[20/] An MDL is the minimum concentration of a substance that can be measured with 99% assurance that the true value is greater than zero.[21/] While laboratories can achieve MDLs of 0.0005 mg/l or lower,[22/]

these detection levels "are not necessarily reproducible over time in a given laboratory even when the same analytical procedure, instrumentation, and sample matrix are used."[23/] Because MDLs result from laboratory performances under ideal conditions, PQLs are better described as models of what normal good laboratory practices can achieve. Usually set at five to ten times the MDL, EPA characterizes the PQL as a "relatively stringent target" for everyday performance.[24/] While EPA recognizes that a number of laboratories have reported data at levels below EPA's PQLs, EPA has explicitly found that the data is insufficient upon which to base national standards.[25/]

The PQLs developed by the EPA for vinyl chloride equal 0.002 mg/l (2 ug/l).[26/] California not only has established a maximum contaminant level far below this level and far below what most laboratories can identify, it has set an MCL equal to the method detection limit for vinyl chloride -- 0.0005 mg/l. In setting this level, CDHS has ignored the fact that even good laboratories are incapable of consistently performing at such a level.

In its proposed maximum contaminant level rulemaking in November 1985, EPA stated that the "effectiveness of the proposed regulations is dependent upon the ability of analytical laboratories to produce reliable data at relatively low levels

for these contaminants."[27/] EPA thus established performance requirements for laboratories analyzing compliance samples for the various compounds; the final acceptance limits for laboratories for vinyl chloride analysis were based on a ± 40% of the true value of vinyl chloride levels found in a sample. EPA found that, for vinyl chloride, only 8 out of 18 laboratories (or 44% of the laboratories) were able to analyze three varying levels within the ± 40% acceptance limits. When the lowest concentration (0.0015 mg/l, far greater than California's proposed MCL of 0.0005 mg/l) was not considered, the laboratories found within the acceptance limits increased to 13 of 18 (or 72% of the laboratories). In other words, analyzing samples at the 0.0015 mg/l level posed significant problems in accuracy for the laboratories. A second study by EPA confirmed these initial results. Twenty-nine out of 44 laboratories (or 66% of the laboratories) analyzed vinyl chloride within the ± 40% limits, when the lowest level of 0.0015 mg/l was not considered. In light of these figures, California's proposed maximum contaminant level for vinyl chloride stands out as an unachievable regulatory standard for even highly competent laboratories. The proposed MCL will inevitably lead to arbitrary and confusing test results rendering the regulation itself invalid as it applies to vinyl chloride.

The rationale offered by the EPA in rejecting lower standards is equally applicable to California's standards;

unlike California's MCL for vinyl chloride, the federal standard provides for a consistent level of data quality from a diverse group of laboratories and hence, an enforceable standard.

VI. CONCLUSION

In summary, the Vinyl Institute strongly urges the California Department of Health Services to adopt a vinyl chloride MCL consistent with the U.S. Environmental Protection Agency's maximum contaminant level, issued July 7, 1987. EPA has carefully considered all currently available scientific data on vinyl chloride, and has carefully weighed all pertinent factors in making its recommendations. Any lower levels will only unjustifiably burden California's communities with no concomitant gain in public safety.

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FOOTNOTES

1/ The Society of the Plastics Industry, Inc. is a trade organization of more than 2,000 members representing all segments of the plastics industry in the United States. SPI's operating units and committees are composed of resin manufacturers, distributors, machinery manufacturers, plastic processors, mold makers, and other industry-related companies and individuals.

2/ 42 U.S.C. § 300g-2 (1982, as amended, 1986).

3/ See 52 Fed. Reg. 25690 (1987) for federal standards.

4/ 52 Fed. Reg. 25690, 25703.

5/ Id. at 25713.

6/ 52 Fed. Reg. at 25713.

7/ Id.

8/ 50 Fed. Reg. 46902, 46919-46920.

9/ Id.

10/ According to CDHS, the well is used only for industrial purposes; there is currently "no known exposure [in drinking water] to vinyl chloride." California Department of Health Services, Proposed Rulemaking for Maximum Contaminant Levels, Initial Statement of Reasons pp. 1 and 8.

11/ 50 Fed. Reg. 46880, 46884 (1985).

12/ 51 Fed. Reg. at 34002.

13/ 50 Fed. Reg. at 46884.

14/ 50 Fed. Reg. at 10438.

15/ 50 Fed. Reg. at 10441.

16/ 50 Fed. Reg. at 10438.

17/ 50 Fed. Reg. at 10438.

18/ 50 Fed. Reg. 46902, 46906 (1985).

19/ 52 Fed. Reg. at 25699.

20/ Id.

21/ Id.

22/ 50 Fed. Reg. at 46906.

23/ 52 Fed. Reg. at 25700.

24/ Id.

25/ Id.

26/ 50 Fed. Reg. at 46970.