

**BORDEN****INTER-COMPANY AND  
OFFICE CORRESPONDENCE**

TO C. A. Mills

DATE: September 29, 1988

FROM J. C. Lunn

DIV / DEPT Technical

ADDRESS: Geismar, LA

SUBJECT: Vinyl Institute Health, Safety & Environment  
Committee Meeting - San Francisco - 9/21/88

TELEPHONE 622

Highlights of the Vinyl Institute 9/21/88 meeting are as follows:

1. Safety Subcommittee Recommendations

The Safety Subcommittee has recommended to the VI Board that the following statement be added to the Mission Statement of the Vinyl Institute. The safety goal shall be "To promote the Vinyl Industry to be the safest segment of the Chemical Industry."

The objectives of the Safety Committee shall be to:

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- A. Share safety related information which can improve the overall Vinyl Industry safety record.
  - B. Promote safety programs for the Vinyl Industry.
  - C. When appropriate, review and prepare comments on Governmental/ Vinyl Industry safety issues.
  - D. Assist in recognizing and publicizing outstanding safety performance in the Vinyl Industry.

In order to assist in meeting the first objective, a proposal has been made to share incident reports concerning safety within VCM or PVC plants. A suggested format is attached for review and approval. Information would be transmitted to Keller & Heckman, the law firm representing the Vinyl Institute. The member company could, at their discretion, remain anonymous when this information is transmitted to other VI members.

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To meet the second objective, a series of "workshops" have been proposed to share safety information within the Vinyl Institute. The members agreed that this program would be more task oriented than the Vinyl Chloride Safety Association annual meeting. Workshops would be held on such topics as VCM fire fighting procedures, VCM loading/unloading operations, protective equipment practices, etc. The intent is to bring together the various disciplines in centrally located areas (such as Baton Rouge or Houston) for one day workshops to thoroughly review safety practices for one or two topics in a focused manner. Member companies concurred that it would be beneficial to share this type of safety information since one major VCM incident at any plant could seriously affect the vinyl industry as a whole.

BOR 009081

2. EPA PROPOSED BENZENE STANDARD

The EPA is currently revising its benzene standard based on the vinyl chloride standard settlement agreement. Essentially the agreement states that EPA must establish a safe level for a chemical prior to reviewing other impacts such as cost of compliance. Benzene is the first such review. EPA has proposed several methods of determining risk and are leaning toward a generic determination. Attached are comments to EPA from the Idaho Mining Association concerning the benzene standard generic approach. This Mining Association is concerned with radionuclides for which specific information on risk is available (similar to VCM) and that a generic approach may lead to a stricter standard. The Vinyl Institute also supports a case by case approach versus a generic risk determination.

3. CERCLA (SUPERFUND) HAZARD RANKING SYSTEM

EPA is sending its new proposal for updating the hazard ranking system (the method of determining which sites become Superfund sites) through internal channels for approval. The VI expects the new H.R.S. to be published in the Federal Register at any time.

4. TCLP RCRA REVISIONS

The toxic characteristic leaching procedure (TCLP) which is now called toxic characteristic (TC), standards are expected to be issued late this year or early next year prior to any administration change. The TC will set the standards for determining a hazardous waste. Of concern to VI members is that some metals such as lead may be a problem in certain PVC compounding resins. This standard could make waste-waters from chemical plants a hazardous waste under RCRA. For instance, the VCM standard as now proposed could be as low as 50 parts per billion VCM allowed in wastewater.

5. OSHA LABELING UPDATE

OSHA dropped the proposed PVC labeling violation against the Oxy Addis facility. The VI will send member companies updates on this issue.

6. CALIFORNIA PROPOSED MCLs

California's Department of Health Services has proposed maximum contaminant levels for VCM in drinking water systems which are much more stringent than EPA standards. Their proposal could seriously affect the use of PVC pipe in California since the California standard is 0.5 PPB versus the EPA current standard of 2 PPB and tests by the National Sanitation Foundation have shown that new PVC pipe with 2 PPM of residual VCM leached VCM into water at up to 0.78 PPB even after 30 days in service. The VI comments are attached.

7. SARA 313 RESPONSES

The SARA Title 313 member responses are being tabulated by the Vinyl Institute and will be distributed soon.

8. ENFORCEMENT UPDATE

BFG recently was fined \$50,000 for failure to follow the terms of a Settlement Agreement to the letter. BFG did not review the details but suggested that others review any agreements that they have outstanding and carefully follow. The enforcement agencies are giving little room for errors or omissions.

9. FEDERALLY PERMITTED RELEASES

EPA recently issued a definition of "Federally permitted release". The interpretation of Federally permitted release has been used by VCM/PVC manufacturers to exclude reporting certain VCM released to EPA. No one at this meeting had a copy of the proposed definition which supposedly was issued this past August. This definition will be passed on when a copy is available.

The next Committee meetings of the Vinyl Institute are scheduled for November 10 in Houston and December 6 in Kansas City.



J. C. Lunn

esr

Attachment

cc: W. P. Leonard  
J. L. Russ  
M. D. Owens  
W. B. Barton  
M. Thorsen  
G. T. Hennings  
H. J. Accardo  
P. West

VINYL INSTITUTE SAFETY WORKSHOPS HAVE BEEN PROPOSED AS ONE METHOD OF MEETING THE SAFETY GOAL "TO PROMOTE THE VINYL INDUSTRY TO BE THE SAFEST SEGMENT OF THE CHEMICAL INDUSTRY".

IF THE VINYL INSTITUTE DECIDED TO SPONSOR VCI SAFETY WORKSHOPS THE FOLLOWING THOUGHTS SHOULD BE CONSIDERED:

1. THE WORKSHOPS SHOULD NOT BE A DUPLICATION OF THE VCI'S ANNUAL MEETING.
2. THE AGENDA SHOULD BE TAILORED TO SUIT THE NEEDS OF PLANT PERSONNEL (SAFETY, PRODUCTION AND MAINTENANCE).
3. WORKING SESSIONS SHOULD BE CONSIDERED WHICH ALLOW ACTIVE PARTICIPATION OF THOSE IN ATTENDANCE.
4. THE MEETINGS SHOULD BE HELD IN CENTRAL LOCATION TO INSURE MAXIMUM PARTICIPATION BY EMPLOYEES OF THE MEMBER COMPANIES.
5. TO BE SUCCESSFUL EACH MEMBER COMPANY MUST AGREE TO ACTIVELY PARTICIPATE BY PROVIDING BOTH SESSION LEADERS AND ATTENDEES.

## TOPICS FOR PROPOSED VINYL INSTITUTE SAFETY WORKSHOPS

1. VINYL CHLORIDE HANDLING
  - A. VCM LOADING/UNLOADING
  - B. SAMPLING
  - C. STORAGE
  - D. CLEARING PROCEDURES
2. INCINERATION
  - A. SAFETY INTERLOCKS
  - B. FLAME ARRESTING
3. LABORATORY PRACTICES
  - A. PROTECTIVE EQUIPMENT
  - B. SAMPLE HANDLING
  - C. WASTE DISPOSAL
4. ACCIDENTS
  - A. INVESTIGATION PROCEDURES
  - B. FIREFIGHTING PROCEDURES
  - C. SPILLS AND CONTAINMENT
5. ENGINEERING DESIGN STANDARDS
  - A. RELIEF VALVE/RUPTURE DISC
  - B. FIRE PROTECTION
    - CRACKING FURNACE
    - TANKS
    - PVC REACTORS
    - EXPLOSIVE MONITORING SYSTEMS
  - C. TESTING PROCEDURES
    - NEW EQUIPMENT
    - RECERTIFICATION
    - TIMING
  - D. METALLURGY
6. SAFETY PROGRAMS
  - A. MOTIVATION/BEHAVIOR MODIFICATION
  - B. ORGANIZATION/RESPONSIBILITIES
7. INCIDENT REPORTS
8. INDUSTRIAL HYGIENE

BEVERIDGE & DIAMOND, P. C.

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FOR YOUR INFORMATION.  
GARY BAISE

Public Hearing

National Emission Standards  
for Hazardous Air Pollution  
Benzene Emissions  
Proposed Rule  
53 Fed. Reg. 28496 (July 28, 1988)

U.S. Environmental Protection Agency  
Washington, DC

September 1, 1988

TESTIMONY of the IDAHO MINING ASSOCIATION

by

Don G. Scroggin  
Beveridge & Diamond, P.C.  
Washington, DC  
(202) 828-0200

BOR 009086

National Emission Standards  
for Hazardous Air Pollution  
Benzene Emissions  
53 Fed. Reg. 28496 (July 28, 1988)

Public Hearing  
Washington, DC  
September 1, 1988

TESTIMONY of the IDAHO MINING ASSOCIATION

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Members of the Idaho Mining Association include elemental phosphorus plants and phosphate mining operations in Idaho that are affected by EPA's hazardous air pollutant regulations for radionuclides, which were recently remanded to EPA for reconsideration in light of the recent Vinyl Chloride<sup>1</sup> decision of the DC Circuit Court. The extensive record in EPA's rulemaking for airborne radionuclides<sup>2</sup> and the related Science Advisory Board review<sup>3</sup> sheds considerable light on the central question regarding EPA's generic approach in regulating hazardous air pollutants, which is the subject of this hearing today. EPA has announced that the policy approach developed in response to Vinyl Chloride and used for benzene "will become the framework

1. Natural Resources Defense Council, Inc. v. EPA, 824 F.2d 1146 (DC Cir. 1987) ("Vinyl Chloride"). In Vinyl Chloride, the DC Circuit Court established that the first step in regulating hazardous air pollutants is the determination of whether a significant risk is posed by emissions of the particular pollutant. Pursuant to Vinyl Chloride, this first determination is to be made based solely on health risk information, without considering the cost or technical feasibility of pollution controls.
2. National Emission Standards for Hazardous Air Pollutants: Regulation of Radionuclides, 49 Fed. Reg. 43906 (October 31, 1984).
3. "Report to the Scientific Basis of EPA's Proposed National Emission Standards for Hazardous Air Pollutants for Radionuclides," Subcommittee on Risk Assessment for Radionuclides, Science Advisory Board, U.S. Environmental Protection Agency (August 1984).

for decisions on future NESHAP,"\* which will include that for radionuclides.

That central question concerns what risk assessment information EPA will consider in reaching the Agency's risk management decision regarding whether certain sources of hazardous air pollutants pose significant risks to public health and therefore warrant regulation. In particular, EPA has asked whether the Agency should consider all the scientifically relevant risk information -- including quantitative information on uncertainties and range of risk -- or, rather, whether EPA should rely upon only one particular piece of the risk assessment, such as the upper bound of risk to the most exposed hypothetical individual or the upper bound of excess cancers expected in the whole population.

This question is fundamental to the integrity of the process by which EPA incorporates scientific information into regulatory decisions on hazardous air pollutants. Specific guidance in addressing this question is provided by three independent authorities that EPA must consider. The validity of EPA's scientific basis for regulating cancer-causing substances is addressed first by EPA's own Cancer Risk Assessment Guidelines and second by specific guidance from the congressionally created Science Advisory Board. Third, the Clean Air Act itself specifically requires that the EPA Administrator review "all available relevant information"\* in considering whether to regulate certain hazardous air pollutants.

The inescapable conclusion is that if EPA's regulatory decisions on hazardous air pollutants are to be scientifically valid and legally defensible, they must consist of case-by-case considerations of all relevant scientific information. Thus, a determination of significant risk based solely upon consideration of a particular isolated fragment of the risk assessment, would be scientifically inadequate and legally vulnerable. Of the four regulatory approaches EPA has proposed for comment, only the first, Approach A, satisfies these requirements. As EPA explains in the benzene proposal, Approach A "is the only approach in which all the health information, risk measures, and potential biases, underlying assumptions and quality (i.e., uncertainties) of the information are considered together in the acceptable risk decision."\*

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4. 53 Fed. Reg. 28496, 29487 (July 28, 1988); National Emission Standards for Hazardous Air Pollutants (NESHAP), Clean Air Act, Section 112; 42 U.S.C. 7412.
  5. Clean Air Act, Section 122; 42 U.S.C. 7422.
  6. Benzene Proposal, 53 Fed. Reg. 28497 (July 28, 1988).

EPA's Cancer Risk Assessment Guidelines

First, EPA Administrator Lee Thomas has emphasized that EPA's Cancer Risk Assessment Guidelines require that "risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information."<sup>7</sup> These Guidelines, which apply uniformly to all risk assessments performed by EPA, require that all EPA's risk assessments "describ[e] uncertainties, assumptions, and limitations" inherent in the risk assessment.<sup>8</sup>

Science Advisory Board Guidance

Second, EPA's Science Advisory Board, an independent scientific review panel established by Congress, has stressed the critical importance of a risk assessment's disclosing specific information on the quantitative range of risk estimates and on comparative risks to which society is exposed. For example, the SAB has emphasized the importance of full disclosure to the public and the decisionmaker the information that cancer risk estimates are specifically designed to be estimates of the upper limits of cancer risk, rather than estimates of the "real risk" and that "for many [cancer-causing] substances, the lower bound estimate of risk is zero."<sup>9</sup> EPA's Cancer Risk Assessment Guidelines reflect these fundamental scientific requirements for full disclosure of the risk uncertainties and the nature of the upper bound numbers and require that this information be explicitly stated in the risk assessment.<sup>10</sup>

The Clean Air Act's Requirements

Finally, Congress has specifically addressed the breadth of information EPA must consider in regulating hazardous air pollutants. In the 1977 Clean Air Act Amendments, Congress added Section 122, which requires EPA to address four specific pollutants<sup>11</sup> to determine if they are hazardous and should be regulated under Section 112. Section 122 provides that "the

7. 51 Fed. Reg. 88992 (September 24, 1988).
8. Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992 (September 24, 1986).
9. "Report by the SAB Carcinogenicity Guidelines Review Group," Science Advisory Board, U.S. Environmental Protection Agency (June 1985).
10. 51 Fed. Reg. 88998 (September 24, 1986).
11. Radionuclides, cadmium, arsenic, and polycyclic organic matter.

Administrator shall review all available relevant information"<sup>12</sup> in determining whether these pollutants endanger public health and should be regulated as hazardous air pollutants.

These considerations lead inescapably to the conclusion that EPA should assure that all cancer risk assessments used for regulatory purposes disclose fully the quantitative uncertainties and range-of-risk information to the public and the decisionmaker. EPA acknowledges that Approach A (Case-by-Case Approach) "is the only approach in which all the health information, risk measures, and potential biases, underlying assumptions, and quality (i.e., uncertainties) of the information are considered together in the acceptable risk decision."<sup>13</sup>

The other three options put forth for comment would be easier for EPA to administer, for they consider only one fragment of the risk information, such as total cancer incidence in the regional population or maximum individual risk. However, these approaches conflict with the requirements of sound science prescribed by the Risk Assessment Guidelines and the Science Advisory Board and with the procedural requirements of the Clean Air Act.

However much we might desire a more simple world, science cannot answer some questions to which all of us would very much like simple answers. Foremost among these questions is whether human exposure to certain hazardous pollutants is "safe." It is frustrating that there is no single index for cancer risk, such that a single number or consideration can serve as the sole guide to whether human exposure to certain pollutants is "safe." But failing to recognize the inherent complexity of such regulatory decisions will not change the scientific reality -- it will only compromise the integrity of EPA's regulatory process. That is precisely why Congress mandated that the EPA Administrator use his "judgment" in determining what pollutants pose significant risks to public health. If a single number extracted out of context from a risk assessment could suffice for such a decision, there would be no need for any exercise of judgment by the Administrator, for the decision would be easy.

As former EPA Administrator Ruckelshaus said in adopting the risk assessment/risk management framework for EPA's decisionmaking, "We must take great pains not to mislead people

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12. Clean Air Act, Section 122(a); 42 U.S.C. 74422(a).

13. 53 Fed. Reg. 28497 (July 28, 1988).

regarding the risks to their health."<sup>14</sup> The integrity and legal defensibility of the process by which EPA protects public health from significant risks depends on full consideration of the uncertainties in which that regulation occurs. And public confidence in the Agency's commitment to its obligation to protect public health depends on accurate and candid disclosure of the difficult judgment calls the Agency must make in the face of complex information and uncertainties. As former Administrator Ruckelshaus emphasized, only with such honesty and full consideration of all relevant information can EPA set priorities and allocate its resources efficiently by focussing on those risks that are the most urgent.<sup>15</sup>

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14. William D. Ruckelshaus, "Science, Risk, and Public Policy," Address before the National Academy of Sciences (June 22, 1983) at 11.
  15. U.S. Environmental Protection Agency, Risk Assessment and Management: Framework for Decision Making (December 1984); see also William D. Ruckelshaus, "Risk, Science, and Democracy" 1 Issues in Science and Technology 19 (Spring 1985).

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September 19, 1988

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W. C. Holbrook, Manager  
Environmental Control Engineering  
The BFGoodrich Company  
6100 Oak Tree Boulevard  
Cleveland, Ohio 44131

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:

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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-

W. C. Holbrook, Manager  
September 19, 1988  
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KELLER AND HECKMAN

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 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

BOR 009094

Befor 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  
Wayne, New Jersey 07470

September 28, 1988

BOR 009095

## 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),<sup>1/</sup> 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.<sup>2/</sup> 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.<sup>3/</sup> 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.<sup>4/</sup> If one of the above compounds is present, vinyl chloride analysis must occur at each distribution or entry point;<sup>5/</sup> 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.<sup>6/</sup> Vinyl chloride analysis of surface water systems is left to the discretion of each state.<sup>7/</sup>

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."<sup>8/</sup> 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."<sup>9/</sup>

While only one community water system well in California currently contains vinyl chloride at a level higher than CDHS's proposed MCL,<sup>10/</sup> 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.<sup>11/</sup> 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.<sup>12/</sup> According to EPA, such evidence is an indication, although limited, of potential carcinogenicity, and therefore should be considered.<sup>13/</sup>

To develop its MCLs, EPA used the most conservative of extrapolation models, the linearized multi-stage model.<sup>14/</sup> 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."<sup>15/</sup> 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.<sup>16/</sup> Because the multi-stage model is linear at the low-dose region, its risk estimates are generally regarded as very conservative.<sup>17/</sup> 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.<sup>18/</sup> PQL is a measurement concentration independent of time and independent of specific laboratory,<sup>19/</sup> and is itself based on another estimated measurement, the method detection limit (MDL).<sup>20/</sup> An MDL is the minimum concentration of a substance that can be measured with 99% assurance that the true value is greater than zero.<sup>21/</sup> While laboratories can achieve MDLs of 0.0005 mg/l or lower,<sup>22/</sup>

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."<sup>23/</sup> 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.<sup>24/</sup> 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.<sup>25/</sup>

The PQLs developed by the EPA for vinyl chloride equal 0.002 mg/l (2 ug/l).<sup>26/</sup> 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."<sup>27/</sup> 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  $\pm 40\%$  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  $\pm 40\%$  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  $\pm 40\%$  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

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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.