

REPORT ON
PUBLIC/GOVERNMENT RELATIONS ACTIVITIES
FOR
VCM - PVC PRODUCERS COMMITTEE

JULY - NOVEMBER 1974

CONFIDENTIAL



HILL AND KNOWLTON, INC. 633 THIRD AVENUE NEW YORK, N.Y. 10017

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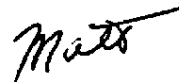
MEMORANDUM TO: Ralph L. Harding
The Society of the Plastics Industry

SUBJECT: Vinyl Chloride "Think Piece"

Attached is the vinyl chloride "think piece" which you, Jim Kiss, Jerry Heckman and I discussed two weeks ago in Washington. In order to make the piece more palatable for an "outside" audience, we have tried to view the problem from the perspective of OSHA rather than from that of the industry, pointing out the difficulties facing the agency and emphasizing those types of evidence that OSHA is likely to find persuasive in arriving at a final standard. As is stated at the outset, it is not an easy task.

In the final two pages of the piece, we felt it would be best if we did not try to anticipate OSHA's final decision on the standards, even though all indications to date are that "no detectable level" is out and something around 20-25 ppm is in. Jerry Heckman may have some thoughts on this.

After you have had a chance to look this over, let Jim or I know what you think.



Matthew M. Swetonic

/kk

Attachment

CC: E.S. Nuspliger, J.M. Kiss, J.H. Heckman, W.A. Durbin,
C. Thompson, J.D. Callaghan

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Occupational Safety and Health Administration and Vinyl Chloride

To the casual observer, the role of the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor seems straightforward enough -- to protect the health and safety of working men and women in the United States.

Behind this rather simple directive, however, lies one of the more complicated and perplexing tasks in all of government. Central to all OSHA activities is its mandate to develop and promulgate occupational safety and health standards that will assure "to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity" in his work.

In the area of safety, this mandate and its application have not created significant controversy. In the area of the development of occupational health standards, however, each standard thus far proposed by OSHA has been greeted with strong opposition, either from industry, organized labor or, in some cases, from both.

While most occupational health standards contain provisions regarding monitoring, respiratory protection, record keeping, medical surveillance, housekeeping, labeling, etc., the most controversy has been generated by whatever exposure limit OSHA has proposed for the toxic substance to be controlled. This controversy can usually be broken down into three essential elements:

1. Is the level proposed by OSHA sufficient to protect all employees?
2. Does the technology exist to achieve those levels throughout the workplace?
3. How much will it cost to achieve the proposed level and/or what will be the economic consequences if the proposed level is adopted?

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It was generally conceded by all interested parties that Congress specifically intended that questions of available technology were to be included in the definition of "feasibility" as contained in the OSHA Act. Organized labor bitterly opposed, however, any definition of feasibility that would include economic considerations.

This matter was brought to a head following the promulgation of the asbestos standards in June 1972. In a suit filed with the D.C. Court of Appeals, the Industrial Union Department of the AFL-CIO argued that OSHA had acted improperly in promulgating a standard based, at least in part, on the industry's ability to pay for the technology needed to achieve compliance.

Oral arguments on the case were heard in April 1973 and a decision handed down one year later. In its ruling, the Court stated that "it would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible,'" and later that "Congress does not appear to have intended to protect employees by putting their employers out of business -- either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible."

While the Court also warned that "it would appear to be consistent with the purposes of the Act to envisage the economic demise of an employer who has lagged behind the rest of the industry in protecting the health and safety of employees," the essential "concept of economic feasibility" was established.

The net effect of this landmark ruling has been to add yet another variable to the complicated set of factors which OSHA must evaluate and balance in arriving at a final occupational health standard.

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The first standard to be proposed following the Court of Appeals ruling was that on vinyl chloride monomer (VCM), an industrial chemical linked in recent months with angiosarcoma of the liver among previously heavily exposed employees.

Based on recommendations from the National Institute of Occupational Safety and Health(NIOSH), in April OSHA proposed a "no detectable level" limit for worker exposure. The recommendation was primarily based on the scientific theory that, in the absence of evidence to the contrary, there is no safe exposure level for a carcinogen except zero.

As with many toxic materials, the first signs of the biological effects of vinyl chloride inhalation do not begin to show up until after many years of exposure. In the case of VCM, the latency period for angiosarcoma has averaged around 20 years.

Since exposure data going back more than a half dozen years is exceptionally rare in the industry, it has been extremely difficult to correlate known cases of disease with past levels of exposure that may have lead to those cases.

While mortality studies of previously exposed workers, such as that conducted by Dr. I. J. Selikoff of the Mount Sinai School of Medicine in New York, provide data on the incidence of the disease, without corresponding exposure data such studies are not useful in the setting of safe occupational levels. The only study to date that has compared exposure levels with disease, or the lack of it, has been that conducted by the Dow Chemical Company on VCM workers at its Midland Division. The results show a general cancer increase among heavily exposed workers (above 200 ppm), but none among workers below that level. No angiosarcomas were found.

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Some attempts have been made to compare current health effects with estimates of past exposure based on the odor detection level of VCM in air. Unfortunately, such estimates rely on the long term memory of employees rather than on hard scientific data. In addition, there is considerable controversy over the precise level at which the odor of VCM becomes detectable, estimates ranging between 250 and 4,000 ppm.

While the Dow data indicates that low levels of VCM exposure do not result in an excess of disease, it has been argued that the latency period at low levels is much longer than at high levels and that we will therefore not begin to see the effect of their exposure on the Dow employees for many years to come. Of course, if the latency period extends beyond the life span of the employee, a "safe level" has been achieved.

Which of these alternatives holds true will not be known for many years. OSHA, unfortunately, cannot wait and is required to act now -- "on the basis of the best available evidence."

For this reason, great importance has been placed on the animal studies of two Italian scientists, Dr. P. L. Viola and Professor Cesare Maltoni, and on the work being done under Manufacturing Chemists Association sponsorship at Bio-Test Laboratories. The essential results of this research can be summarized as follows:

... angiosarcoma is both dose and time related, i.e. the heavier the exposure, the more animals come down with the disease; and the longer they have been exposed, the more chance an animal has of contracting angiosarcoma. This would seem to correlate with human experience.

... angiosarcomas (but not deaths from angiosarcoma) have been detected in extremely old rats at 50 ppm. Deaths from angiosarcoma have been reported in mice at 50 ppm. At present, there is no correlation with known human experience.

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... other neoplasms in addition to angiosarcoma have been reported by Dr. Maltoni as being VCM related. There is some evidence of this in humans, but not necessarily the same neoplasms as reported by Maltoni nor have the excesses in humans been shown to be statistically significant.

Around this relatively small amount of hard data, great speculation has raged, the crucial issue being whether the animal results are translatable to the human condition, and to what extent. Generally speaking, animal experiments are not considered an adequate basis upon which to base a human exposure standard. In this situation, however, the absence of useful human data, with the exception of the Dow study, could make some qualified or limited use of the animal results attractive to OSHA.

The question whether the hazard of VCM exposure extends beyond the polymerization process into the PVC fabricating industry is one of great importance. In its testimony at the OSHA public hearings, the National Institute of Occupational Safety and Health included two "fabricator" angiosarcomas in its list of VCM induced cases.

NIOSH's intent was, of course, to demonstrate that even low levels of exposure can lead to angiosarcoma in humans. On the other hand, with the large number of employees engaged in the manufacture of PVC products, a certain "normal" incidence of angiosarcoma of the liver is to be expected. Whether these two cases are in reality an excess is therefore still an unanswered question.

It is likely, however, that OSHA will adopt a "prudent man" philosophy and assume that some risk exists in fabricating plants and that regulations of some type are thus required.

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In contrast with many other known toxic substances -- asbestos and lead, for example -- the amount of hard medical data available on VCM induced disease is quite limited and likely to remain so for some time to come. Thus, even if OSHA were permitted by its Congressional mandate to use health as its sole criteria for setting standards, it would find it very difficult to arrive at a specific exposure level between zero and 200 ppm which it could confidently claim is either safe or unsafe for humans "on the basis of the best available evidence."

For this reason the development of information relating to the technological and economic feasibility of the proposed standard was a major aim of OSHA throughout the course of the public hearings. With regard to technological feasibility, the essential facts brought out at the hearings were:

- ... The proposed OSHA standard of "no detectable level" is impossible to achieve with known technology, no matter how much money is expended.
- ... "Open" plants in the southern part of the country generally have lower levels than enclosed plants in the north.
- ... Newer plants generally have lower levels than older plants.
- ... Some companies have already achieved quite low levels for some operations but not for others, even in the same plant.
- ... Some companies are doing a far better job than others in controlling exposure levels.
- ... Temporary excursions beyond the peak limit are liable to occur at almost any time, even in the best controlled plants.

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In evaluating OSHA's reaction to the feasibility data presented by industry, it must be kept in mind that in the asbestos case the Court of Appeals ruled that if a "recalcitrant employer" is unable to comply with a standard as quickly as other employers, whether for economic or other reasons, his demise would probably be tolerated.

On the other hand, the Court did not want to see an industry concentrated in the hands of only a few companies. The most obvious solution would be for OSHA to seek some type of middle ground between what the best company has been able to achieve and that which the least progressive company has accomplished. Applying the principals of the asbestos case, if one or two manufacturers fell by the wayside as a result, OSHA and the courts might well consider this an acceptable price to pay for employee health.

While the industry has developed extensive data on the effect on the economy if a "no detectable level" standard resulted in a shutdown of the entire industry, little information was presented at the hearings relative to the cost in dollars and perhaps jobs of achieving a technologically feasible level, now or in the future.

As a result, OSHA has instituted its own economic and technological study to determine the feasibility of certain levels above zero and below 50 ppm. It can be anticipated that the results will generally support the industry position.

It is clear that OSHA now finds itself in what could be called a "no win" situation. It proposed a tough standard which, the indications get stronger every day, it is not going to promulgate. At the hearings, organized labor expressed its willingness to see the entire industry shut down to protect workmen. Even if it wanted to, OSHA cannot, on the basis of the Court of Appeals ruling, be so cavalier or simplistic in its approach to the problem. If the asbestos scenario is followed in the vinyl chloride situation, the final

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result will be a standard that will be labeled totally unsatisfactory, at least publicly, by organized labor; yet it will be stricter than anything the industry wanted. OSHA will, as usual, be the focus of criticism from both sides. The familiar charges of a conspiracy between OSHA and the industry will once again be raised. The case will probably end up in the Court of Appeals.

Despite the vast amount of testimony and evidence submitted at the public hearing and collected by OSHA and NIOSH since January, the full extent of the hazard of vinyl chloride exposure remains unknown. Except by relying heavily on the feasibility factors, OSHA cannot calculate a viable "acceptable risk" equation in arriving at a final standard. While it can no longer be argued persuasively that VCM is not a human carcinogen, the risk to employees at low levels of exposure (below 50 ppm) would appear to be very small but probably not nonexistent. This is complicated by the fact that some long term employees may have already accumulated enough exposure to result in disease in the future, or that any additional exposure, however minor, may be sufficient to push them over the line into a "high risk" category. It would appear, therefore, that additional cases of angiosarcoma of the liver will occur for many years to come, some small number of which may have been preventable if OSHA could adopt a standard based solely on health rather than one relying heavily on the substantive issues of technological and economic feasibility. This is the moral burden that the industry and OSHA will have to bear.

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