



CHEMICAL MANUFACTURERS ASSOCIATION

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OCT 17 1988

Geraldine V. Cox, Ph.D.
Vice President-Technical Director

October 7, 1988

Docket Officer
Docket No. H-020
Room N-3670
U.S. Department of Labor
200 Constitution Ave, N.W.
Washington, D.C. 20210

Dear Sir:

The Chemical Manufacturers Association (CMA) is pleased to present post-hearing evidence on OSHA's proposed rule on permissible exposure limits (PEL) for Air Contaminants. 53 Fed. Reg. 20960 (June 7, 1988). CMA is a non-profit trade association whose member companies represent 90 percent of the production capacity of basic industrial chemicals within this country. Because many chemical industry employees are potentially exposed to substances covered by the proposed rule, CMA has an active interest in the rulemaking.

CMA's evidence falls into two categories: one deals with the operations of the American Conference of Governmental Industrial Hygienists, the other focuses on vinylidene chloride.

The evidence concerning ACGIH deals with that organization's philosophy in developing Threshold Limit Values. The two articles detail ACGIH's commitment to worker protection and its uncompromising independence.

The material on vinylidene chloride (VDC) consists of a list of studies on that chemical. The National Institute for Occupational Safety and Health recommended in its testimony that VDC be designated as a carcinogen. The attached list of studies show that NIOSH's recommendation is not supported by the scientific evidence. CMA believes that since OSHA did not cover vinylidene chloride in the present rulemaking proposal, the agency could not legally adopt a standard for this chemical without a new proposed rule and opportunity for comments.

If you have any questions concerning CMA's evidence, please call Timothy O'Leary at 202/887-1278.

Sincerely,

Geraldine V. Cox

**POST-HEARING EVIDENCE OF THE
CHEMICAL MANUFACTURERS ASSOCIATION
RELATING TO OSHA'S PROPOSED
AIR CONTAMINANTS RULE**

Docket No. H-020

SL 061865

POST-HEARING EVIDENCE OF THE
CHEMICAL MANUFACTURERS ASSOCIATION
RELATING TO OSHA'S PROPOSED AIR CONTAMINANTS RULE

Docket No. H-020

Attachment II consists of materials bearing on the question whether vinylidene chloride ("VDC") (also referred to as 1,1-dichloroethylene) poses a cancer risk to humans. Since OSHA did not propose to regulate VDC on the basis of carcinogenicity, CMA did not address this issue in its Comments. In testimony presented on August 1, 1988, however, the National Institute for Occupational Safety and Health ("NIOSH") recommended that VDC be designated a carcinogen and be "controlled as specified for vinyl chloride in 29 CFR 1910.1017 with eventual goal of zero exposure."^{2/} Although we believe that the NIOSH recommendations could not lawfully be adopted unless OSHA issues a new (or revised) rulemaking proposal and provides an opportunity to comment thereon, we are submitting in Attachment II materials that supplement the record by providing a more complete picture of the studies that have been conducted on VDC. These studies provide additional information showing that the NIOSH recommendations are not supported by the scientific evidence.

^{2/} Testimony of NIOSH on the Occupational Safety and Health Administration's Proposed Rule on Air Contaminants, Docket No. H-020, August 1, 1988 at 8-9 and NIOSH Table N6B at 4.

Message from the Chair

During the latter part of 1987, the American Conference of Governmental Industrial Hygienists (ACGIH) received a number of copies of a manuscript accepted for publication in a journal serving the industrial medical profession. This manuscript offers what I feel to be an unfair attack on the Threshold Limit Values (TLVs) for Chemical Substances and the process whereby they are established; it questions the professional ethics of some of the past and present members and consultants of the committee. I would like to thank our colleagues in the various professions who were asked to comment on the manuscript and who were kind enough to supply us with copies, since the journal to which the manuscript was submitted did not.

Although the copy of the manuscript which we have received contains some facts, it also contains a generous amount of innuendo and misrepresentation of information. Some of this information, which the uninformed reader would interpret as fact, is actually unsubstantiated opinion by the authors. It is not my desire to undertake a point-by-point rebuttal at this time. The ACGIH will reserve that as an option after we have seen the published article.

The overall thrust of this manuscript is that corporate consultants have had an undue influence on the development of TLVs. The inference is that these professionals have ridden roughshod over the better judgment of the voting members. Most of this historical perspective related to events in the 1960s and 1970s. Although the manuscript does admit to the paucity of peer-reviewed information on a number of compounds during much of that era, it goes on to charge that corporate consultants manipulated the available data to the perceived advantage of industry without regard to human health.

This message was prepared in early January 1988. At that time, the publication date of the manuscript in question was unknown.

Obtaining data on which to base a TLV was a formidable task in the early years of the committee. The fact that much of the needed information had been generated by, and was in the hands of, industry is acknowledged in the manuscript. The committee could have very well taken the easy way out and done nothing to obtain the needed data. To argue about industry's position on releasing these data to the public during that time is not now germane. In my opinion, it is to the committee's credit that it brought in industrial consultants to provide this source of information. As an added point of information, an effort has been underway for some time to remove references from the TLV Documentation for which there is no complete report on file when a TLV is reviewed or updated. The committee hopes to complete this process in the near future.

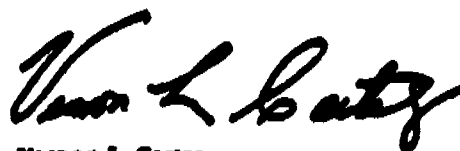
I would also like to draw upon my five years (1980-1985) experience as Chair of the Chemical Substances TLV Committee. Debate among and between members and consultants was many times very intense over the value of scientific data to be used in establishing a TLV. This is as it should be because I have yet to see the perfect scientific study that is not open to some question. However, without question, I can say that when debate had ended, voting members based their decisions upon valid scientific reasoning.

One unchallenged fact remains. The ACGIH TLV Committee stepped into a vacuum and filled a need in helping to provide worker health protection. If you are to believe the vast majority of occupational health professionals, this process has made a very significant contribution to industrial health programs. The criteria for development of TLVs and the limitations and directions for their use as guidelines have been a matter of record for years. The Notice of Intended Changes invites input to proposed changes in, or development of, new values. The TLV Documentation, although not as complete

presently as we would like on atomic compounds, is a published basis for each value.

Challenges of individual TLVs from various sources as being too high or too low are welcome, and have strengthened the process, especially when accompanied with new scientific data. Disagreement with the concepts of "protection of nearly all workers" and of "thresholds" is to be expected due to well known philosophical and political differences concerning these issues. Published scientific commentary by informed and qualified people on the proper use of TLVs for health professionals as well as an informed critique on their misuse is appreciated. However, attempts to discredit the TLV process through unfounded attack on the professional ethics of committee members and consultants are difficult to tolerate.

The ACGIH does not apologize for the way the committee operated in the past or present. In fact, we take great pride in its accomplishments. Published elsewhere in this issue for your review are the current TLV Operational Guidelines and the TLV Documentation Outline (see "Technical Briefs") and a paper given at the 1986 Professional Conference on Industrial Hygiene in Savannah by the current TLV Chair, Ernest Mastromarino, MD, on "TLVs: Changes in Philosophy (see "Invited Commentary"). The TLV and Biological Exposure Indices (BEI) Committee will continue to respond to the need for guidelines to assist the industrial hygienist until a better and more accepted process comes along. They will then gladly take their rightful place in history.



Vernon L. Carter
Chair, ACGIH

Invited Commentary

TLVs: Changes in Philosophy

Ernest Mastromatteo

When Ed Baler first approached me about speaking at this Professional Conference on Industrial Hygiene, I readily agreed to talk on TLVs. I became Chair of the TLV Committee for Chemical Substances in June 1985, after having served as a member and consultant to the committee since 1963.

The word philosophy is derived from Greek roots with "philin" meaning loving and "sophy" meaning science or wisdom. The *Random House College Dictionary*¹ defines philosophy as follows:

- The rational investigation of the truths and principles of being, knowledge, conduct.
- A system of philosophical doctrine, e.g., the philosophy of Spinoza.
- A critical study of the basic principles and concepts of a particular branch of knowledge, e.g., the philosophy of science.
- A system of principles for guidance in practical affairs, e.g., a philosophy of life.
- A philosophical, calm or stoic attitude.

I would like to think that the term philosophy, when applied to TLVs, refers to the rational investigation of the knowledge of the effects to workers of chemicals to which they are exposed in the workplace for the purpose of making recommendations which will then serve as guidelines for good industrial hygiene practice, primarily by governmental industrial hygienists but also by other occupational health professionals.

With the definition of philosophy as applied to TLVs, my presentation will cover the early history of the development of TLVs, the philosophy of the TLV Committee as reflected through the previous chairs, and finally, some of my own philosophy in relation to new developments.

The American Conference of Governmental Industrial Hygienists (ACGIH) was first organized in 1938. From its inception, a major concern of ACGIH was the assessment of health hazards of workers and the

provision of recommendations as guidelines for the control of occupational health hazards.

Bloomfield² has described the first annual meeting of ACGIH which was held in June 1938. The objectives of the conference were affirmed in the constitution of 1938 and re-affirmed in 1951. The objectives were to "promote industrial hygiene activities ... by official federal, state, local and territorial industrial hygiene activities; to encourage the interchange of experience among industrial hygiene personnel in such official organizations; to collect and make accessible to all governmental hygienists such information and data as may be of assistance to them in the proper fulfillment of their duties. ..."

The ACGIH has become an independent organization with membership limited to federal, state, local, and territorial governmental occupational health professionals. Membership is also open to members of the academic community. ACGIH is financed entirely by its membership dues, the sales of its publications, and revenue from the sponsorship of conferences and symposia. The Conference receives no subsidies from governments, industries, or unions. Only governmental or academic workers were eligible to serve on ACGIH Committees. In 1971, the Chair of ACGIH, Herbert Stokinger, added non-voting consultants to the TLV Committee from industry and trade unions.

History of TLVs

The late William G. Fredrick,³ Director of the Bureau of Industrial Hygiene, Department of Health for Detroit, attended the third annual meeting of ACGIH in 1940 and asked this question "May I inquire what committee, if any, in this organization is responsible for the establishment of safe limits of threshold limits and concentration?" In 1941, a subcommittee on TLVs was established under the Committee on Technical Standards with Fredrick in the Chair. Fredrick commented to his subcommittee: "I feel that our Subcommittee should assume an active position in the establishment of working limits and should issue a list annually, to be revised each year so

conform with newer information. ... Then as medical or toxicological information appears which clearly indicates the need for revision, this can be done with ease in the annual report."⁴

In 1944, the TLV Committee became an independent standing committee. The 1946 report of the TLV Committee recommended 150 maximum allowable concentrations (MACs). The MACs became the TLVs in 1948.

Fredrick noted that ACGIH clearly resolved to separate TLVs from legal codes. In 1968, he went on to outline his philosophy as the first Chairman of the TLV Committee: "The philosophy of the TLV, as established by ACGIH in those early days of our profession, has remained substantially unchanged and despite copying, criticism, misunderstanding and abuse, today, its values, for better or worse, are accepted on an international basis as the best available guides for providing healthful occupational environments for the workers of the world.

"Although the perfect TLV, like the will-o'-the-wisp or the pot of gold at the end of the rainbow, cannot ever be realized, it remains the backbone of successful industrial hygiene practice. Eventually we will know enough to refine the value, to take into account the susceptibilities of numerically important genotypes, the effects of synergism, and the adverse influence of concurrent environmental stress, but I doubt if we can eliminate the need for the experiential judgment of the Industrial Hygienist for more effective application."⁴

Stokinger served as a member of the TLV Committee for 27 years from 1951 to 1978 and as Chair from 1962 to 1977. Stokinger's biggest assets were his deep knowledge and experience in toxicology, his organizing ability, and his determination to get the job done. Stokinger developed the operating procedures of the TLV Committee.⁵ He pulled together a TLV Committee representing professionals with hands-on experience in industrial hygiene, toxicology, pathology, epidemiology, and occupational medicine. As noted earlier, Stokinger added non-voting consultants from industry and organized labor on the TLV Committee.

¹Presented at the Professional Conference on Industrial Hygiene sponsored by the American Academy of Industrial Hygiene, Hyatt Regency, Savannah, Georgia, October 31, 1986.

Current Philosophy of TLV Committee

Under Seidinger's Chairmanship, the philosophical principles of the TLV Committee were summed up in the written preface to the recommended values. These philosophical principles were:

- TLVs are health-based recommendations derived from assessment of the available published scientific information from studies in exposed humans and from studies in experimental animals. For each TLV, there is to be a published documentation supporting the Committee recommendation.
- TLVs are based on a belief in a threshold or thresholds of response below which no adverse health effects would occur in workers—including the so-called "practical" thresholds for carcinogens.
- TLVs refer to airborne concentrations to which "nearly all" workers may be exposed for 8 hours per day, 40 hours per week for a working lifetime without adverse effect. Some workers with individual susceptibility may not be protected by the recommended TLVs.
- TLVs are not to be regarded as fine lines between safe and unsafe conditions. They are guidelines for use in the practice of industrial hygiene and should not be used by anyone untrained in the field of industrial hygiene.
- TLVs are derived in an open process. Recommended additions or amendments to current TLVs are placed in a provisional list, the Notice of Intended Change (NICs), for a minimum period of two years to allow for input by all interested parties. NICs are given public notice in professional publications. The TLV Committee meets with interested groups wishing to present a point of view. Finally, as noted above, the recommendations of the TLV Committee are published in a special documentation which provides the scientific basis for the judgment by the Committee.

The TLV Committee defined three categories of TLVs:

- **TLV-TWA**—the time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, in which nearly all workers may be repeatedly exposed, day after day without adverse effect.
- **TLV-STEL**—A 15-minute time-weighted average exposure which should not be

exceeded at any time during a work day even if the 8-hour time-weighted average is within the TLV. Exposures at the STEL should not be longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL.

- **TLV-C**—The concentration that should not be exceeded during any part of the working exposure.

Excursion Factors and STELs

In the earlier editions of the TLV list, excursion limits for the TLV-TWAs were based on the value of the TLV-TWA. The 1963 list contained this range of permitted excursions:

TLV-TWA	Excursion Factor
0-1	5
1-10	2
10-100	1.5
100-1000	1.25

The TLV Committee interest in STELs was sparked by the publication of Pennsylvania's Short Term Limits (STLs) in 1964. Pennsylvania adopted 38 STLs in 1964 and an additional 50 in 1965. Pennsylvania published a list of STLs for about 100 substances for exposures of 5, 15, and 30 minutes. In 1971, the Executive Board of ACGIH requested the TLV Committee to consider STELs to give guidance to industrial hygienists in the management of brief exposures for airborne agents, especially those which cause irritation, irreversible tissue damage, and narcotics. The TLV Committee set up an ad hoc group to study STELs. After its review, the TLV Committee assigned STELs to 425 TLVs; 95 were considered to need further evaluation.

In 1976, the STELs were added to the TLV list under the Notice of Intended Change. In general, the documentation for these STELs was inadequate and many questions of interpretation were raised by industrial hygienists in the field. In 1983, the TLV Committee carried out another review. All STELs for which the published data were weak or lacking were recommended for deletion. Today, STELs will only be recommended where there is need for them and where scientific documentation is available to support them.

The current TLV list provides the present concept for the new excursion limit recommendations as follows:

"Short-term excursions should exceed three times the TLV-TWA for no more than a total of 30 minutes during

the work day and under no circumstances should they exceed five times the TLV-TWA, provided that the TLV-TWA is not exceeded."

Whenever the toxicologic data for a specific substance are available to establish a STEL, this value takes precedence over the excursion limit regardless of whether it is more or less stringent.

Other Principles

The "skin" notation was added to the TLV list as an attention-drawing device. This notation refers to the potential contribution to the overall skin exposure contact with the chemical agent. The notation is added on the basis of the Committee's judgment based on the published literature.

The TLV list also provided information on:

- Occupational exposure to mixtures of two or more substances. An appendix gave examples of how to apply the formulas for mixtures.
- Nuisance dusts.
- Simple asphyxiants.

Uses and Misuses of TLVs

The preface of the TLV list contained a number of recommended prescriptions in the use of TLVs. TLVs are not intended for use in the following cases:

- In the evaluation or control of community air pollution nuisances.
- In estimating the toxic potential of continuous uninterrupted exposures or other extended work periods.
- As proof or disproof of an existing disease or physical condition.
- For adoption in countries whose working conditions differ from those in the United States and where substances and processes differ.

For many years, the TLV Committee published a statement in the TLV list about the use of TLVs in legal codes. Before 1971, the preface contained this statement: "The Conference does not consider that TLVs are appropriate matter for adoption in legal codes and regulations and recommends against such use. If the TLVs are used (in legal codes) the intent and concepts contained in the preface should be maintained and provisions made to keep the list current." In 1971, the Occupational Safety and Health Administration (OSHA) promulgated its permissible exposure limits—the great majority of which were derived from

the 1968 TLVs. Currently, the TLV booklet contains no recommendation about the use of TLVs in legal codes. In retrospect, it may have been unwise to delete this statement from the preface.

Carcinogens

In 1972, the TLV list included Appendix A which listed occupational carcinogens. Carcinogens were categorized as follows:

- A1 Human carcinogens:
 - a) with an assigned TLV.
 - b) without an assigned TLV—no exposure permitted by the most sensitive measure.
- A2 Experimental carcinogens: These chemicals are capable of causing tumors in animals and should be regarded as potential human carcinogens. Exposure should be reduced to a minimum.

In recommending TLVs for carcinogens, the TLV Committee was, in effect, giving recognition to its belief in the existence of "practical" thresholds to these carcinogens. The risk to workers exposed to concentrations below the TLV are considered negligible.

In 1976, in addition to appendix A provided the TLV Committee guidelines for the classification of the potency of animal carcinogens.

In the 1986 TLV list, the number of carcinogens in each group was as follows:

- A1 (a) 8 substances (including 4 forms of asbestos) which are assigned a TLV.
- A1 (b) 4 substances without an assigned TLV
- A2 40 substances, 13 without an assigned TLV

In 1983, an ad hoc Committee was setup under Dr. Robert L. W. This ad hoc Committee considered that TLVs were justified for some carcinogens. They recommended that two categories of occupational carcinogens be included in the TLV list:

- A1 Confirmed human carcinogens
- A2 Suspect human carcinogens

In future editions of the TLV list, Appendix A will be removed. Individual carcinogens will be identified in the main list with the A1 or A2 designation as appropriate. All substances listed as A1 or A2 carcinogens will be listed in the published Documentation of the TLVs. In addition, the classification of the TLV Committee will be compared in a tabular fashion to that of the International Agency for Research on Cancer, the MAK Commission of the Federal

Republic of Germany, the National Institute for Occupational Safety and Health (NIOSH), and the National Toxicology Program. The TLV Committee is aware that these classifications are not comparable. Nevertheless, those using TLVs may be able to review the TLV classification and recommended exposure limits in comparison with those made by other agencies. This change in the handling of carcinogens represents a major new approach.

As practical philosophy, TLVs are guidelines to be used by occupational health professionals. In essence, the TLV Committee members carry out a critical review of the literature for a specific chemical covering such points as:

- Hazard identification.
- Exposure assessment—both human and animal.
- Dose-response assessment
- Recommendations for workplace exposure.

One could say that the TLV Committee applies a risk assessment approach in applying its professional judgment for a recommended TLV. It is up to regulatory agencies to apply the appropriate social, economic, political, and other factors in applying the recommendations of the TLV Committee in legal codes.

Biological Exposure Indices

In 1967, Hervey Elkins, a former member and Chairman of the TLV Committee, published a paper on biologic TLVs.¹⁷ In this paper, he described a primary biological threshold—the biological concentration of an agent at which workers would not incur any disability over a working lifetime. A secondary threshold was defined as that biological concentration which, if maintained, will invariably lead to disease. Elkins listed the 395 TLVs in the 1967 list, showing those for which he felt urinary biological TLVs and those for which blood B TLVs would be appropriate.

In 1973, the TLV booklet made reference in the preface to biological TLVs but none was listed.

In 1980, the ACGIH Executive appointed a 15-member working group to make recommendations on biological monitoring of workers. This working group reported in 1982 and recommended that the ACGIH should develop biological TLVs but should not become involved in medical surveillance.

Biological monitoring was defined as the evaluation of workplace exposures to po-

tionally toxic chemicals by the measurement of

- 1) Specific chemical substances normally found in the body, but which can increase from work experience.
- 2) Substances normally absent from the body.
- 3) Substances resulting from or associated by a biochemical response to exogenous influences.

Biological monitoring is not necessarily a measure of toxicity but a measure of absorption and metabolism of any industrial chemical.

The working group recommended that a new Committee be established to develop biological TLVs, which were called Biological Exposure Indices (BEIs); the Chair was Dr. Vera Thomas. In the 1986-87 TLV list, there are six adopted BEIs and are placed on the "Notice of Intended Change." The BEI Committee defined BEIs as follows: "workers are not expected to suffer any ill effect as long as the described measurement of the determinants are maintained within the limits of the recommended BEIs."¹⁸

Current Issues in Relation to TLVs

- The use of TLVs in deriving air quality standards is widespread despite the TLV Committee recommendation against their use as air pollution guidelines or standards.
- There is some pressure to develop emergency exposure limits for community residents in cases of industrial accidents, e.g., spills, fire fighting, etc.
- The ACGIH TLVs had received wide international recognition. In recent years, however, many countries, particularly in Western Europe, had begun to develop national committees to recommend occupational exposure limits. The ACGIH maintains a liaison member of the German MAK Commission. In 1985, ACGIH sponsored an international meeting to discuss occupational exposure limits. This meeting stimulated much interest and an international steering committee of such organizations was set up with Dr. D. Henrichler of Germany as Chair.
- The TLV Committee is moving towards particle-size-selective sampling criteria (PSS-TLVs). Particles will be divided into three categories determined by their locale of action:
 1. In respirable particulate mass TLVs (IPM-TLVs); particles from > 10 to $50 \mu\text{m}$

aerodynamic diameter.

2. Thoracic (T_{PM}-TLV) with a mean aerodynamic diameter of $10 \mu\text{m} \pm 1 \mu\text{m}$.
3. Respirable (R_{PM}-TLV) with a mean aerodynamic diameter of $3.5 \mu\text{m} \pm 0.5 \mu\text{m}$.

This aspect is now under study by the TLV Committee.

- Alternate work schedules are commonly used in the workplace. Brief and Scala⁸ recommended a simple approach to a TLV reduction factor for an alternate workshift as follows:

$$\frac{8}{\text{hours worked}} \times \frac{\text{hours off work}}{16}$$

For a 12-hour day, the TLV Reduction factor would be

$$\frac{8}{12} \times \frac{12}{16} = \frac{1}{2} \text{ TLV for 8-hr day}$$

The TLV Committee is reviewing this question.

- Many of the TLVs for soluble and insoluble compounds are listed without any definition of soluble and insoluble. A definition of solubility as greater than 5 percent in water is not completely satisfactory. The TLV Committee is reviewing this and will probably list the soluble and insoluble compounds intended to be covered by this term in the documentation.

Conclusion

The overall philosophy of the TLV Committee has remained unchanged from that outlined by its founders. TLVs are intended for the guidance of occupational health professionals to assist them in the control

of adverse health effects from exposure to airborne chemicals in the workplace. TLVs will be health based.

The TLV Committee will continue to be independent and representative of the professional skills (industrial hygiene, toxicology, occupational medicine, and epidemiology).

The process of developing TLVs will continue as an open process. The TLV Committee publishes an appendix, "Chemical Substances and Other Issues Under Study," which lists the substances and areas it is interested in and requests input by interested groups. Revisions and new additions are put on a "Notice of Intended Changes" for a minimum of two years for comment. There is a published documentation giving the basis for the recommendation of the TLV Committee.

The TLV Committee is currently comprised of 15 eligible members from government and academia and 9 consultants from government, industry, and organized labor. As noted above, the members are representatives of various disciplines and expertise in occupational health. There are 5 Subcommittees in addition to special working groups. The full Committee meets twice yearly. The Subcommittees also meet twice yearly. All work is done on a volunteer basis with administrative and clerical support from ACGIH. Members are assisted in travel costs, but no honoraria are paid. A major role for the Committee member is in the preparation of documentations for new or revised substances. This requires a major effort as there are currently about 750 substances listed.

There are current problems in the misuse of TLVs over which the Committee has

no control. There is, of course, disagreement sometimes with the judgment of the TLV Committee based on its interpretation of the literature.

The current philosophy of the TLV Committee remains unchanged from that outlined by Fredrick. Despite the carping, criticism, misunderstanding, and misuses, the recommendations of the TLV Committee are still of value to the practicing industrial hygienist in protecting the health of workers in the United States and abroad. ♦

References

1. The Random House College Dictionary, L. Urden, Ed. The Random House Inc., New York (1975).
2. Bloembergen, J.J.: What the ACGIH Has Done for Industrial Hygiene. *Am. Ind. Hyg. Assoc. J.* 19:538 (1958).
3. Fredrick, W.O.: The Birth of the ACGIH Threshold Limit Values Committee and its Influence on the Development of Industrial Hygiene. *Trans. 50th Annual Meeting of ACGIH, May 12-14, 1968, St. Louis, MO*; pp. 40-43. ACGIH, Cincinnati (1968).
4. Seikinger, H.E.: Modus Operandi of Threshold Limits Committee of ACGIH. *Am. Ind. Hyg. Assoc. J.* 25:589 (1964).
5. Pennsylvania State Health Department: Short Term Limits (1965).
6. American Conference of Governmental Industrial Hygienists: Threshold Limit Values and Biological Exposure Indices for 1965-67. ACGIH, Cincinnati (1966).
7. Ellena, H.B.: Excretion and Biologic Threshold Limits. *Am. Ind. Hyg. Assoc. J.* 28:305 (1967).
8. Brief, R.S.; Scala, R.A.: Occupational Exposure Limits for Novel Work Schedule. *Am. Ind. Hyg. Assoc. J.* 36:467 (1975).

Dr. Matsuromi is Chair of the ACGIH Threshold Limit Values for Chemical Substances Committee.

Attachment II

SL 061873

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

CHEMICAL MANUFACTURERS ASSOCIATION
VINYLIDENE CHLORIDE PROGRAM PANEL
POST-HEARING EVIDENCE
(Docket No. H-020)

In its testimony in this docket the National Institute for Occupational Safety and Health ("NIOSH") recommended that vinylidene chloride ("VDC") (also referred to as 1,1-dichloroethylene) be designated a carcinogen and be "controlled as specified for vinyl chloride in 29 CFR 1910.1017 with eventual goal of zero exposure."^{1/} CMA believes that these NIOSH recommendations are not supported by the extensive existing data base regarding the potential carcinogenicity of VDC.

While action on the NIOSH recommendations would require an entirely new rulemaking proceeding pursuant to Section 6(b) of the Occupational Safety and Health Act, it is important that the record in this proceeding contain a more complete collection of existing studies on this issue.

^{1/} Testimony of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration's Proposed Rule on Air Contaminants, Docket No. H-020, August 1, 1988, at pp. 8-9 and NIOSH Table N6B, p. 4.

Accordingly, CMA submits th attached data and valuations, together with a bibliography of other studies that must be considered before OSHA may make an evaulation of the carcinogenicity of VDC.

EXHIBITS

- Exhibit A Norris, J.M. and R.H. Reitz, Interpretive Review of the Animal Toxicological, Pharmacokinetic/ Metabolism, Biomolecular and In-Vitro Mutagenicity Studies on Vinylidene Chloride and the Significance of the Findings for Man (November 5, 1984).
- Exhibit B Quast, J.F., M.J. McKenna, L.W. Rampy and J.M. Norris. Chronic toxicity and oncogenicity study on inhaled vinylidene chloride in rats, Fundam. Appl. Toxicol. 6:105-144, 1986.
- Exhibit C Quast, J.F., M.J. McKenna, L.W. Rampy and J.M. Norris. A chronic toxicity and oncogenicity study in rats and subchronic toxicity study in dogs on ingested vinylidene chloride, Fundam. Appl. Toxicol. 3:55-62, 1983.
- Exhibit D NTP Technical Reports on the Carcinogenesis Bioassay of Vinylidene Chloride in F344/N Rats and B6C3F1 Mice (Gavage Study), NTP NO. 80-82.
- Exhibit E Bibliography