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Corporate Influence on Threshold Limit Values

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Investigations into the historical development of specific Threshold Limit Values (TLVs) for many substances have revealed serious shortcomings in the process followed by the American Conference of Governmental Industrial Hygienists. Unpublished corporate communications were important in developing TLVs for 104 substances; for 15 of these, the TLV documentation was based solely on such information. Efforts to obtain written copies of this unpublished material were mostly unsuccessful. Case studies on the TLV Committee's handling of lead and seven carcinogens illustrate various aspects of corporate influence and interaction with the committee. Corporate representatives listed officially as "consultants" since 1970 were given primary responsibility for developing TLVs on proprietary chemicals of the companies that employed them (Dow, DuPont). It is concluded that an ongoing international effort is needed to develop scientifically based guidelines to replace the TLVs in a climate of openness and without manipulation by vested interests.

Key words: unpublished corporate communications, TLV committee, carcinogen, conflict of interest, industrial experience, OSHA standards

INTRODUCTION

The Threshold Limit Values (TLVs) published by the American Conference of Government Industrial Hygienists (ACGIH) have been widely adopted as workplace exposure standards. The ACGIH values have been very influential over the past 40 years in Belgium, West Germany, Austria, Italy, The Netherlands, Portugal, Denmark, Sweden, Finland, Norway, Spain, Switzerland, the United Kingdom, and Japan [Toyama, 1985; Vigliani et al., 1977]. In the developing countries as well, the TLVs have been relied upon by governmental occupational health authorities [Noweir, 1986].

However, it has nonetheless been widely recognized that the TLVs for chemical substances are in most cases poorly supported by scientific evidence. This is clear from even a casual review of the *Documentation of the Threshold Limit Values and Biological Exposure Limits* (5th Edition, 1986). West Germany adopted the ACGIH values in 1955 and has been influenced by the ACGIH in setting exposure limits ever since. But the German authorities, upon review of the documentary adequacy of their MAKs, concluded that less than 10 percent of the limits were based on "sufficient

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animal tests and/or field experience" [Henschler, 1984]. This finding, based initially on a review of 150 substances, has been more recently corroborated by review of 300 more substances on the German MAK list [Henschler, 1985]. ACGIH's TLVs have been directly criticized by both industry and labor representatives for scientific inadequacy [Henderson, 1975; Samuels, 1981].

This report examines the historic role of industry in the development of the TLVs.

Role of Industry in TLV Process

The American Conference of Governmental Industrial Hygienists established a Committee on Threshold Limits which issued annual reports starting in 1946. ACGIH was and continues to be a voluntary organization with no formal ties to the U.S. government despite its name. Its members were initially federal, state, and local officials, and within a few years, academics and well-known industry consultants were also included.

From the beginning, the TLVs were acknowledged to involve a balancing of health considerations and cost to industry [Report, 1948]. Industry data were invited. In order to understand this interaction, it is necessary to appreciate the dependence of the TLV committee on information from industry, especially prior to the 1970s.

In the United States, government toxicologists and industrial hygienists of this era had very limited access to knowledge of dose-effect relationships in industry. There was no federal regulation of general industry workplace hazards until 1971; and state and local agencies were thinly staffed and minimally funded. These agencies had little if any regulatory power and lacked laboratory and other technical resources so vital to the surveillance of hazards in industry.

At U.S. universities, faculty occupational health professionals depended upon industry goodwill for research funding, consulting, and field experience and jobs for their students. Government funding for occupational health research was virtually nonexistent.

Dr. John Knox, medical officer for Turner and Newall, an asbestos-based multinational corporation headquartered in Britain, recorded his impressions in notes of a 1960 visit to his company's U.S. subsidiary [Knox, 1960]:

> "The legislative framework under which industries operate in the U.S.A. makes it difficult for me here to follow the lines of thought which prompt action over there in the matter of standards of industrial practice. In many industries, the employers seem so far in front of legislation as to have created a special code of practice for themselves."

It was well recognized that, to the extent that data existed on exposures to toxic agents and ill health in industry, they had been mostly developed by industry. Industrial concerns in the U.S. were in no way compelled to share what they knew.

Under the chairmanship of toxicologist Herbert Stokinger, the TLV committee first tried the approach of prodding industry by issuing a "Notice of Intent" to change some TLVs in 1964. A number of companies responded, supplying data, leading to 9 of 23 new additions that year [Notice of Intent, 1965]. Stokinger wrote to the Manufacturing Chemists' Association (now Chemical Manufacturers Association) [Stokinger, 1964]:

> "This was particularly encouraging in view of the fact that the committee has never had a significant amount of voluntary contributions from (industrial sources) as long as I can recall (13 years), despite annual exhortations welcoming such information."

By 1966, a committee of the Industrial Medical Association (now American Occupational Medical Association) expressed concern over the growing impact of the TLVs on industry. At the same time, it was acknowledged that industry had data on file and the means to develop more data that could "contribute constructively to the establishment of realistic TLVs" [Golz et al., 1966].

Over the years, Stokinger had had a number of meetings with industry groups at the Mellon Institute/Industrial Hygiene Foundation to discuss proposed changes in TLVs. The TLV committee's 1968 "Notice of Intent" even invited industry data via the Industrial Hygiene Foundation "Repository of Anonymous Occupational Health Data" [Committee, 1968]. However, little if anything of value was ever obtained in this way [Stokinger, 1986–87]. From the time the idea was first suggested, the Industrial Medical Association had apprehensively observed that documents in a data repository might be subject to subpoena in damage suits [Minutes, 1967].

In 1969, Stokinger described the lack of appropriate industrial hygiene data as the greatest problem facing the TLV Committee. Describing the American chemical industry's contribution of data on new substances to the TLV committee as "pathetic", Stokinger, who was employed at the U.S. Public Health Service, addressed industry's responsibility directly [Stokinger, 1969]:

> "The TLVs are industry's values. . . industry has the sole responsibility to develop data on its own products; government is not in a position to develop the facilities to handle the problem *in total*, nor should it, when reliable toxicologic consultants are now available." (Original emphasis)

Regarding chronic animal exposure data, Stokinger commented [Stokinger, 1969]:

> "The data are in short supply because industries either do not develop long-term studies, or if they do, more often than not, do not see fit to release the data in the open literature. Various reasons are given for this: legal protection of their products, lack of staff time to put data in publishable form. Whatever the reason, the data are not forthcoming."

The following year, (1970), the Occupational Safety and Health Act was passed by the U.S. Congress, and virtually the entire 1968 list of TLVs became enforceable federal standards. In future OSHA standards development, the TLV committee could well have been expected to have a considerable influence.

In the chemical industry, the Dow Chemical Company had developed some rapport with the TLV committee in the 1960s. Dow had provided unpublished data on at least 5–10 products, commented on the committee's documentation for specific TLVs, and discussed work published by Dow toxicologists and others around the world. In 1970, this relationship deepened, with the enlistment of Dow toxicologist V.K. Rowe as a "liaison member" of the TLV committee and his co-worker Theodore

TABLE I. TLV Documentation Assignments

Substance (trade name)	Person assigned	Year first assigned
2,4,5 -T	Rowe	1970
ethylene glycol	Torkelson	
vinyl chloride	Torkelson	1971
methyl bromide		
propylene glycol methyl ether ("Dowanol PM")		
methyl chloride	Torkelson	1972
1,2 dibromoethane (ethylene dibromide)		
1,2 dichloroethane		
o-chlorostyrene		
methylene chloride		
1,2,4 trichlorobenzene		
vinylidine chloride		
dicyclopentadiene		
clopidol ("Coyden")		
tricyclohexyltin hydroxide ("Plictran")		
chlorpyrifos ("Dursban")		
picloram ("Tordon")		
dimetholate		
3,5 dinitro-o-tolamide ("Zoalene")		
dimethyl sulfate	Morgan	1972
tris(2,3-dibromopropyl phosphate)	Morgan and Torkelson	1973
styrene	Torkelson	
bis-chloroethyl ether		
1,2,3 trichlorobenzene		
chloroform		
dipropylene glycol methyl ether ("Dowanol DPM")		
ethanolamine		
2-chloro-6-trichloromethyl pyridine ("N-Serve")		
crufomate ("Ruelene")		
chlorodifluoromethane	Morgan	1973
chromates		
methomyl ("Lannate")		
perfluoroalkanes		
cyclopentane		
m-xylene, α,α' -diamine		
bromacil ("Hyvar X")		
diuron ("Karmex")		
dioxane	Torkelson	1974
calcium hydroxide		
cyclopentadiene		
dibromochloropropane		
cyanamide	Morgan	1974
azodrin	Zavon	1975
dicrotophos ("Bidrin")		
m-phthalodinitrile		
isophthalonitrile		
dioxin	Torkelson	1975

(continued)

TABLE I. TLV Documentation Assignments (Continued)

Substance (trade name)	Person assigned	Year first assigned
phosgene	Morgan	1975
m-toluene diamine		
hexamethyl phosphoramide		
formamide	Morgan	1976
dimethyl sulfoxide		
dichloromonofluoromethane		
4,4'-methylene bis (2-chloroaniline) ("MOCA")		
tetramethyl thiourea	Zavon	1976
hexachlorobutadiene	Torkelson	1976
3-amino, 1,2,4 triazole ("Amitrol")		
deodorized kerosene		
toluene concentrate		
acrylonitrile		

Torkelson as alternate industry liaison member. Dupont industrial hygienist James Morgan joined the committee in 1972, and together with Torkelson, he played an active role in the work of the committee for the rest of the 1970s and into the present decade. Torkelson and Morgan became two of the four members of the new subcommittee on carcinogenic substances established in 1972 [Minutes, 1972].

The minutes of the TLV committee in 1972–1976 show that primary responsibility for reviewing documentation in developing TLVs was borne by corporate representatives for major products of their own companies and new products about which little or nothing had been published.

Torkelson was well situated to know about the toxicity of Dow Chemical's halogenated hydrocarbons and pesticides ("Tordon", "Ruelene", "Dursban", and "Plictran"). By the same token, Morgan would appear to have been well placed to know about DuPont's carcinogenic products (dimethyl sulfate, lead chromate, "Moca", hexamethyl phosphoramide), chlorofluorocarbons ("Freon" products), and pesticides ("Lannate", "Hyvar X", and "Karmex"). Dow and DuPont also had substantial economic reasons for wanting to influence the TLV committee on these and other products. But these economic considerations were adverse to the free and full flow of information from the companies.

The 1970s would see government regulators charged with the protection of workers, the environment, and consumers very busy with some of the chemicals in Table I. The demonstration of vinyl chloride's carcinogenicity cast a shadow over a large number of halogenated hydrocarbons. A reference point for regulators in every case would be the currently accepted limit for maximum human exposure, namely workplace exposure. And since most of OSHA's limits were from the aging 1968 list of TLVs, regulators looked to the current TLV lists and designations of carcinogenicity by the TLV committee for guidance. The chemical companies and trade associations contesting standards at OSHA, the Environmental Protection Agency, and the Consumer Product Safety Commission included Dow and DuPont. High TLVs tended to reduce the costs of regulation to the chemical industry.

Moreover, there were liability considerations in addition to regulatory ones. Manufacturers of products involved in damage suits before juries readily resort to the claim that the use of the product was not expected to exceed the TLV and was thus

considered "safe." The "TLV defense" offers manufacturers the plausible deniability that any harm sustained was foreseeable. Where a manufacturer has evidence that the exposure involved was in fact below the TLV, this may even be used to support a denial that the product caused health impairment.

Duplicity of corporate representatives clearly angered longtime Massachusetts occupational health official and TLV committee member Hervey Elkins, who, writing a letter of retirement to Chairman Stokinger in 1975 [Elkins, 1975], stated:

> "In looking over the new documentation I was taken aback by that for ethylene glycol; the limit of 100 ppm was found intolerable by sedentary volunteers in a few minutes (or seconds). I believe that {industry representative} recommended this figure. In spite of his knowledge he seems to come up with some recommendations for TLVs that are way too high, in my judgment. The same can be said for most of the other industry representatives we have had. In many cases they recommend a TLV much above the action levels used in their own plants."

By the time of Elkins' complaint, Dow Chemical had long been assigning internal corporate exposure limits for toxic substances. Other firms, including Rohm and Haas, had also decided to adopt this practice. Corporate workplace exposure limits have served as a managerial tool both for substances with assigned TLVs and others for which TLVs had not been adopted [Paustenbach and Langner, 1986]. Regulatory and liability concerns appear to have deterred corporate management from publishing these lists and supporting rationales—despite their obvious practical value and potential importance in preventing occupational disease.

MATERIALS AND METHODS

The 1986 *Documentation of the Threshold Limit Values and Biological Exposure Indices* was reviewed for all chemical substances. Where reference appeared in the text to unpublished communications and internal corporate reports, etc., a determination was made as to whether such information had been important in setting the TLV or classifying the substance's carcinogenic status. This was a matter of judgement based on the full text for each chemical substance listed. Due to the wide variation in type and quantity of information used as a basis for the various TLVs, rigid criteria could not be used; it is presumed that different experts conducting such a review would come up with slightly different lists of TLVs for which unpublished corporate communications would be judged important.

The important communications can be generally described as animal data, data from tests on human volunteer subjects, and "industrial experience."

Communications coming from corporations and trade associations are in many cases so identified in the *Documentation*. However, in many other cases only the names of individuals are published in the *Documentation*. The institutional affiliations of these people at the times they sent information to the Committee on Threshold Limits have been investigated in various ways. The sources checked included: contemporary publications by the same people; past directories of professional associations (American Industrial Hygiene Association, American Occupational Medical

Association, ACGIH); and retired members of the TLV committee contacted by telephone for their recollections.

Attempts were made in several ways to obtain copies of unpublished material cited in the *Documentation*. The New Jersey Department of Health requested copies of specific references on 67 substances in 1985 from ACGIH and companies named in the *Documentation* for the purpose of developing chemical fact sheets (later, as a pattern of irretrievable unpublished corporate statements emerged, the information was reanalyzed for this paper). An examination was also made of the historic TLV Committee files at the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati. The surviving files kept there by United States government employees who had served on the TLV Committee, covering years from the late 1950s through the 1970s, contained a small number of letters and reports cited in the *Documentation*.

Though ACGIH has copies of TLV committee minutes for the last 10 years, the Board of Directors would not grant access to them [Kelly, 1986–87].

RESULTS

For a total of 89 substances, the 1986 TLV *Documentation* placed important reliance on unpublished corporate communications (Table II). Another 15 substances were assigned TLVs *solely* on the basis of unpublished corporate studies and reports (Table III). This investigation was able to locate written copies of far less than half of the above unpublished corporate material from the NIOSH files, ACGIH, and the corporations.

Of the 89 substances in the first group above, corporate affiliation of the referenced source person was not published for 25. For the 15 TLVs based solely on unpublished corporate communications, the companies providing information were all identified in the *Documentation*.

There was thus a total of 104 substances for which important or total reliance was placed on unpublished corporate communications. This accounts for over one sixth of the number of (less than 600) chemical substances listed in the 1986 *Documentation*.

Of the 17 corporations asked for documentation they had provided to the TLV committee, nine sent old documentation or commented on their work to the New Jersey Department of Health. The unpublished documentation in most cases was unobtainable from the companies (Table IV) and the historic TLV committee records in NIOSH files. There were no files available from ACGIH itself; nor did former longtime committee members (Stokinger, Elkins) have personal files on the chemicals. Stokinger admits that some of the information was never conveyed in writing but came over the telephone [Stokinger, 1986-87]. In any event, most of these important unpublished corporate communications are now unobtainable in written form for independent scientific examination.

Industrial Experience

The TLV committee's reliance upon unpublished corporate communications included reports of "industrial experience" on dozens of chemical substances. The content of these reports rendered in the *Documentation* often appears in just the space of a sentence or two (Table V). The scientific community is left unable to determine whether there was more information originally conveyed; and where there was, no

TABLE II. TLVs for Which Unpublished Corporate Data was Important*

Substance	
acrylic acid	fonofos
acrylonitrile	hydroquinone
asphalt fumes[a]	isooctyl alcohol[a]
benomyl	isophorone
benzene[a]	2-isopropoxyethanol
n-butyl acrylate	lead chromate
sec-butyl alcohol[a]	manganese and compounds
n-butyl glycidyl ether	manganese tetroxide
caprolactam[a]	methacrylic acid
carbon disulfide[a]	methomyl
catechol	4-methoxyphenol
chlorinated camphene (60%)	methyl n-butyl ketone
chlorinated diphenyl oxide	methyl chloride
chloracetaldehyde	methyl 2-cyanoacrylate
chloracetyl chloride	methylene bis-4-cyclohexyl-isocyanate[a]
chlorodifluoromethane[a]	methylene bisphenyl isocyanate
o-chlorostyrene	methylene chloride
o-chlorotoluene	4,4′ methylene dianiline
chlorpyrifos	methyl isocyanate
copper[a]	metribuzin[a]
cyclopentadiene	monocrotophos
cyhexatin	paraquat[a]
dibutyl phthalate	piperazine dihydrochloride
dichlorodifluoromethane	propionic acid
dichloroethylene	quinone[a]
dichlorofluoromethane	resorcinol
2,2 dichloropropionic acid	rosin core solder pyrolysis products[a]
dichlorotetrafluoroethane	silicon tetrahydride
dicrotophos	silver and compounds[a]
dicylopentadienyl iron	sulfuryl fluoride
diethyl phthalate	sulprofos[a]
diglycidyl ether	tetraethyl lead[a]
dimethyl acetamide	tetramethyl lead[a]
dimethylamine	tetrahydrofuran[a]
dimethylformamide	thioglycolic acid
dimethyl sulfate	1,2,4 trichlorobenzene[a]
diphenylamine[a]	trichlorofluoromethane
di-sec-octyl phthalate	1,1,2 trichloro 1,2,2 trifluoroethane
endrin[a]	trimethyl phosphite
ethion	tungsten compounds[a]
ethylene dichloride[a]	vinylcyclohexene dioxide
ethylenimine	xylidine[a]
n-ethyl morpholine	zinc stearate
fenamiphos[a]	

*Includes substances' assigned carcinogenicity status. Does not include papers presented at scientific conferences.

[a]Corporate affiliation of correspondent not published in Documentation of TLVs.

TABLE III. Documentation of TLVs Solely by Unpublished Corporate Communications

Substance	Animal data, acute	Animal data, subacute or chronic	Human data	Source, year
n-butyl lactate			x	Philips Endoven 1969 British Petroleum 1972
o-sec-butylphenol	x		x	Dow/1977
clopidol		x (2 yrs;teratol)		Dow/1973
dinitolmide		x (2 yrs;teratol)		Dow/1973
divinylbenzene	x		x	Dow/1977
ethyl amyl ketone*	x		x	Shell/1958, 1965
2-hydroxypropyl acrylate	x	x (30 da.)		Dow/1977
isophorone diisocyanate	x	x (4 wks)		Vera-Chemie
n-isopropyl aniline	x			Dow/1977
methyl acetylene-propadiene mixture		x (4 mos.)		Dow/1964
nitrapyrin		x (93 days)		Dow
phenylphosphine	x	x (90 day)		DuPont/ 1970
tetrasodium pyrophosphate			x	Dow/1977
triphenyl amine	x		x	Kodak/ 1973
m-xylene α,α' diamine	x			Dupont/ 1973 Sherwin-Williams 1978

*Includes an industrial hygiene bulletin by Shell Chemical Corporation claiming no systemic effects in workers exposed to concentrations above the TLV recommended by the company.

way exists to look up the original source and resolve questions about the basis of statements published in the *Documentation*, including methodology utilized and whether the statement was based on any study or merely an impression.

Because of the weight given to these reports and the great value of studies industry could perform on the workers exposed to these agents, special attention to these communications is warranted.

The information provided by companies and published by ACGIH in the *Documentation* raises obvious and fundamental questions. What exactly did Dow's "routine" medical examinations and any analysis performed on them show to establish that "no evidence of over-exposure" occurred at the reported concentrations of methyl chloride? What tests were conducted and what analysis was carried out by Dow? What was the scientific content and methodology of the unpublished negative mortality studies on acrylonitrile, benzene, dimethyl sulfate, and ethylenimine? What were

TABLE IV. Requests of Data from Corporations

Corporation	Number of Chemicals	Results
Dow	33	No information received.
Hooker	2	The company provided a report for one (chlorotoluene) of the two requested chemicals. Study methods and results were described (animal study).
Hercules	2	For one chemical (chlorinated camphene), Hercules stated they had sold the operation to Nor-Am and stated any toxicologic information "must now come from Nor-Am." (Hercules did not say they no longer had the information.) Nor-Am stated they no longer produced it, and that much of the correspondence and reports had been discarded. For the other chemical (Rosin core solder pyrolysis products), the study was provided with detailed methods and results. However, inflammation and hyperemia in multiple organs for both controls and exposed animals causes one to wonder about (inadvertent) exposure of "controls."
Crown Zellerbach	1	The Documentation states, "industrial experience has been good over the years." Crown Zellerbach's correspondence describes 3 yr experience manufacturing the chemical (catechol), with only "a few mild toxic reactions." CZ notes "no physical abnormalities . . . noted by observation" (not stated whether all workers had physical exams) or in "multichannel blood tests" (type, frequency, other methods unspecified). While catechol is an irritant, there is no mention of the use of symptom questionnaires or lung function tests in this 1975 communication.
FMC	1	No information received (carbofuran).
Rohm and Haas	2	Significant material sent describing study methods and results for animal studies on both chemicals. Study report noted "Squamous metaplasia" of nasal mucosa, thought secondary to irritation (ethyl acrylate). This effect not noted in Documentation.
American Cyanamid	2	The company provided information on one (phorate) of the two chemicals requested. This was an inhalation study (level unspecified) for 8 hr involving 12 animals observed for 7 days after exposure. The report merely says "there was no evidence that they were affected in any way." There is no mention of whether pathologic studies or biologic monitoring were conducted let alone reporting of such findings. The criteria for no effects were unspecified.
DuPont	7	Some information (not always complete) was sent for all 7 chemicals. The Documentation states that there were "no complaints of illness" and no abnormal liver function tests in employees exposed at roughly half the TLV for several years (dimethyl formamide). The information provided by the company to NJDOH does not appear to be a reference upon which such a statement could have been based; the original basis for the statement not be located. An epidemiological study of 143 workers exposed to dimethyl sulfate showed that few deaths from respiratory cancer occurred among them while employed by DuPont. The work force was not broken down in terms of either time elapsed from onset of exposure or duration of exposure to DMS. No follow-up of ex-employees and retirees was done.

(continued)

TABLE IV. Requests of Data from Corporations (Continued)

Corporation	Number of Chemicals	Results
		No data were provided to substantiate Zapp's communication (1970) to the ACGIH that methylene bis (4-cyclohexyliso-cyanate) was less toxic on inhalation than TDI.
		Dupont's subacute study on dogs, found to have no skin irritation or sensitization effects, unlike "results. . . previously reported" (tetrahydrofuran), was given greater credence than the published positive studies by the TLV committee "because of the greater number of animals involved". The DuPont study used 4 dogs.
		A 90-day study of phenylphosphine contained adequate discussion of methods and results. DuPont's study of m-xylene α,α' diamine found "generally mild" sensitization in all 10 guinea pigs tested. This is mentioned in the Documentation as "evidence of sensitization" without noting that all animals were affected.
		The Documentation refers to a subacute study by DuPont in 6 rats as one which "caused no fatalities" (dicyclopentadienyl iron). The Documentation omits data showing that in addition to irritability and weight loss, all 6 rats showed testicular atrophy. It is unclear whether these effects were ever communicated to the TLV committee (report was obtained from the company but not in the TLV files).
Western Electric	1	Western Electric did not provide the correspondence for isophorone, but it was obtained from the TLV committee files and consisted of five sentences noting two symptom complaints, urinanalysis and "kidney function checks." No methods discription was given, nor was the number of employees noted, nor whether questionnaires were used or if they waited for employees to complain. No medical surveillance data was provided even in summary form.
Sherwin Williams	1	No response to request for information (m-xylene α,α' diamine).
Mobil Oil	1	Epidemiologic study conducted on employees (for eye effects only) with exposure levels evaluated, study methods described. Unclear whether study was ever published (trimethyl phosphite).
Ethyl C	1	No response to request seeking information (tetraethyl lead).
Koppers	1	The Documentation states that "a surveyj of 180 men employed in work involving resorcinol revealed that none complained of irritation or discomfort at exposure levels of 10 ppm." The company provided no information about any study but merely sent a safety data sheet on the chemical. No discussion of methods was provided in Koppers' letter to the TLV committee, which was located in the committee's files.
Eastman Kodak	4	Letters on animal studies were located for 2 chemicals (o. chlorotoluene, triphenylamine). Observations on workers could not be located for the other 2 (dibutyl phthalate, di-sec-octyl phthalate).
Union Carbide	4	No response to request for information.
Shell Oil	3	Shell no longer makes the 3 chemicals and states that correspondence concerning them is no longer available.
B.F. Goodrich	1	The Documentation states "observations in the rubber industry have revealed no adverse effects from many years of inhalation of zinc stearate dust." The company had discarded the correspondence but stated that there was no "organized study of workers exposed to zinc stearate."

TABLE V. Unpublished Industrial Experience Cited in TLV Documentation

acrylonitrile	Monsanto, 1981, epidemiology negative on carcinogenic effects.
asphalt fumes	Hammond (Humble Oil) 1968—opinion of industrial hygienists that conditions were satisfactory at 10 mg/m^3
benzene	Ott et al. (Dow), 1975, epidemiology "revealed no excess mortality."
sec-butyl alcohol	Banks (Shell Chemical Company) 1966—hygienist reports that "many years of industrial experience (at 100 ppm) have resulted in no difficulties."
n-butyl lactate	Turner (British Petroleum), 1972, reported that 7 ppm was not found to be objectionable or injurious.
caprolactam	Ferguson (Allied Chemical), 1972, reports on 143 workers, "some of whom were exposed up to 17 years to vapor concentration as high as 5–10 ppm without any evidence of damage to health."
carbofuran	Tobin (FMC Corporation), undated, given as source: "Workers exposed to concentrations approaching 0.1 mg/m^3 per day have not shown any effects."
carbon disulfide	Calhoun (American Viscose), 1968, reports no cases of carbon disulfide poisoning since 1942, when exposures averaged below 2.5 ppm.
catechol	Crown Zellerbach, 1975, referenced as reporting industrial experience has been good under adequately controlled conditions.
chlorinated camphene (toxaphene)	Hercules, Inc., 1969, reports that review of records of 137 employees, "some" exposed up to eighteen years, "failed to reveal any adverse effects that could be associated with toxaphene."
chlorodifluoromethane	Reinhardt (DuPont), undated, reports that cardiac arrythmias are not considered a possibility "under currently recommended industrial hygiene practices."
o-chlorotoluene	Hopton (Hooker Chemical), 1962, reports that no cases or dermatitis or poisoning from this compound had been encountered.
dibutylphthalate diethylphthalate di-sec-octylphthalate	Raleigh (Kodak), undated, reports workers exposed to 1–6 ppm of mixed phthalates had no phthalates in their blood and had no peripheral polyneuritis.
diglycidyl ether	White (Shell Chemical Company), 1962, recommends a ceiling limit of 0.5 ppm "on the basis of a no-effect level in animal studies and industrial experience." (TLV-TWA: 0.1 ppm)
dimethylformamide	DuPont, undated, reports no complaints of illness and no abnormal liver function tests at about one half the TLV.
dimethylsulfate	DuPont, 1972, epidemiology "covering a period of 15 years" and an update in 1976 show no excess of lung cancer in exposed workers.
diphenylamine	Dernehl (Union Carbide), 1967, cites "industrial experience" in recommending a satisfactory operating level. On this basis, the same value was selected as the TLV (10 mg/m^3).
endrin	Jager (Shell): no medical effects seen with 233 workers, comparing them before and after 10 years' exposure to endrin and related pesticides (body weight, blood pressure, WBCs, and SREs).
ethylene dichloride	Fassett (Kodak), 1964, "Experience in one plant indicated that concentrations in the range of 25 to 50 ppm were safe for prolonged exposure."
ethylenimine	Dow report of BASF, 1973, epidemiological study "revealed no evidence" of carcinogenicity in 144 workers "some of whom had 40 years' experience."
hydroquinone	Fassett (Kodak), undated, reports that clinical and environmental studies of workers "confirm that no systemic effects arise at (the TLV)."

(continued)

TABLE V. Unpublished Industrial Experience Cited in TLV Documentation (Continued)

manganese and compounds	Whitman (Bethlehem Steel), 1976, reports no cases of manganism in workers exposed for years to 1 to 5 mg/m^3 of manganese dioxide dust.
methyl n-butyl ketone	Raleigh (Tennessee Eastman Co.), 1976, reports "no history of muscular weakness, parathesia, loss of coordination or clinical evidence of neuropathy in 37 employees engaged for 3 years in the manufacture of (methyl n-butyl ketone)."
methyl chloride	Dow, undated, reports that a "routine periodic medical program did not identify evidence of overexposure to methyl chloride" at concentrations averaging 30 ppm.
methylene bisphenyl isocyanate	Imperial Chemical Industries, 1962, reports no cases of skin irritation during early industrial experience handling this compound.
4,4' methylene dianiline	Dow, 1977, reports "no morbidity findings" for exposures ranging from 0.03 to 0.4 ppm over 26 years.
monocrotophos	Shell Chemical, undated, reports no decrease in field workers' cholinesterase concentrations following exposure.
paraquat	Gage (Imperial Chemical Industries), 1968, is cited as reporting that "no serious injury or illness resulted from eight years' agricultural use of paraquat."
propionic acid	Dow, 1977, reports that, at reported exposure levels, no irritation was noted. Medical reports include mild eye redness and one case of mild cough and asthmatic response.
resorcinol	Koppers Company, 1974, reports that none of 180 men exposed to 10 ppm complained of irritation or discomfort.
tetraethyl lead tetramethyl lead	Linch (DuPont), 1968, reports that exposures averaging about 20% over the TLVs produce average urinary lead concentrations "not significantly elevated above a high normal" (no values above 0.15 mg/l). Ethyl Corporation, undated, reports that 3/4 of the TLV for tetraethyl lead "is a rough guideline for an allowable (TLV)."
trimethyl phosphite	Mobil Chemical Co., 1980 reports no ocular changes among 179 workers with exposures reported. "Plant exposure data could be interpreted to indicate that concentrations of 1 ppm certainly, and very likely 2 to 4 ppm, are without significant adverse effect." TLV raised from 0.5 to 2 ppm in 1982.
tungsten compounds	Dernehl (Union Carbide), 1966, reports that "long industrial experience" has indicated workers exposed to solely tungsten and its insoluble compounds do not develop pneumoconiosis.
vinyl cyclohexene dioxide	Dernehl (Union Carbide), 1973, referenced as source: "In the U.S., industrial experience over the past 10 to 20 years has been good."
zinc stearate	B.F. Goodrich Rubber Co., undated, referenced as source: "Observations in the rubber industry have revealed no adverse effects from many years inhalation of zinc stearate dust." (no concentrations given)

the parameters and data underlying Hercules' unpublished communication to the effect that a review of employee medical records "failed to reveal any adverse affects that could be associated with toxaphene?"

Similar questions arise over the nature and quality of industrial experience relied upon by the TLV Committee for 32 other chemical substances (see Table V). An even larger number of TLV substances were assigned exposure limits after significant reliance on unpublished corporate communications about animal experiments.

In this survey, a TLV *Documentation* reference was counted as "published" even if it was from a manufacturer's safety data sheet or an unsupported statement published in a text by a corporate health professional. The brevity, age, and obscurity of such documentation raises serious questions of reliability despite the fact of such references being "published."

Manufactureres' safety data sheets, while briefly noting chemicals' health effects or lack of effects, are not generally useful as primary sources for detailing the scientific basis of health effects statements. Safety data sheets are not written to convey the important data underlying statements like, "no health problems have been attributed to the use of this agent in industry"; or "it is an irritant but not a sensitizer." Yet TLVs are still based on such statements by manufacturers on safety data sheets issued in the 1950s (e.g., ethyl ketone, methylamine, nitromethane). The use of corporate safety data sheets of even recent vintage is inappropriate for documenting TLVs.

Some reports of "no adverse industrial experience" in the 1986 *Documentation* originally appeared in classical texts but were unsubstantiated by data and are now very old. In the case of morpholine, the text refers to the 1963 edition of Patty's toxicology text as a basis for saying that "no chronic effects have been reported." The primary source cited was a 1948 review on morpholine issued by the American Petroleum Institute. Patty's text was in large part written by industry professionals; and some of the statements appearing in the text, though unexplained there, went on to be cited as the basis for TLVs. Patty himself reported on ethyl acetate concentrations he had measured during a period of "several months" during which time "no adverse symptoms or illnesses were observed." Patty, who was an industrial hygienist at General Motors, did not explain whether the observations made were those of physicians, himself, or other medically untrained management officials (supervisors, foremen, personnel managers).

TLVs for Carcinogens

The case studies of six carcinogenic materials will be considered next, in order to examine in some detail the work of the TLV committee in this important area. These summaries illustrate a number of ways in which the committee was informed and influenced by industrial parties.

Some of the materials on the first lists of MACs, as they were called in the early years, were known or suspected of being human carcinogens. These agents included asbestos (1946), arsenic (1947), and chromates (1950). Threshold limits for these materials appear not to have been based on their carcinogenic effects, however.

Arsenic

In the case of arsenic and its compounds, the 1947 value was 100 $\mu g/m^3$. The following year, Hill and Faning produced strong epidemiological evidence of a lung and skin cancer hazard in a factory making sodium arsenite sheep-dip [Hill and Faning, 1948]. Median room air concentrations of arsenic measured in the chemical plant were 71, 254, 373 and 696 μg As/m^3. Average urinary arsenic concentrations of the workers were in the range of 0.09 to 0.24 mg/liter [Perry et al., 1948].

For reasons not explained at the time, the threshold limit for arsenic was *raised* in 1948 from 100 to 500 $\mu g/m^3$. In the first published documentation of the TLVs in 1962, the "subsequent experience" of the American Smelting and Refining Company

was cited as supporting 500 $\mu g/m^3$. The source of this information was the company medical director [Pinto, 1961; Documentation, 1962]. In acknowledging Pinto's confidential report, Stokinger replied, "It was surprising to see what a clean bill of health you were able to produce, in view of the many implications of arsenic and lung cancer." [Stokinger, 1961].

Pinto's work was published in 1963, showing that both employees exposed to arsenic and employees with "non-arsenic exposure" had a greater incidence of lung cancer than males in the state of Washington. The "exposed" group had urinary arsenic levels of 0.82 mg/liter, and the "unexposed" smelter employees had urinary arsenic burdens averaging 0.13 mg/liter [Pinto and Bennett, 1963]. Pinto later conceded that the latter group in this controversial report was in fact exposed to "low arsenic levels," but denied a suggestion published by the Occupational Safety and Health Administration (OSHA) that there had been under-reporting of lung cancer cases in the 1963 study [Pinto and Nelson, 1976].

The National Institute for Occupational Safety and Health evaluated Pinto's 1963 report as showing an increase in lung cancer mortality, contrary to the conclusions of the authors [Inorganic, 1975]. A 1974 mortality study on the workers at the same Asarco copper smelter confirmed their lung cancer hazard [Milham and Strong, 1974]. In 1975, OSHA responded to mounting reports of lung cancer in arsenic-exposed workers by proposing a reduction in the workplace standard for arsenic, from 500 to 4 $\mu g/m^3$. (The original standards was 500 because the 1968 TLV values for most substances were adopted en masse as enforceable standards with the passage of the Occupational Safety and Health Act of 1970).

The Threshold Limits Committee of ACGIH followed by adopting two TLVs for arsenic trioxide in 1977: 50 $\mu g/m^3$ at smelters and 250 $\mu g/m^3$ in non-smelting environments. This aroused bitter resentment at NIOSH and OSHA, where the actions of the TLV Committee were seen as aiding the industry challenges to the government standard. The government researchers and regulators were especially piqued at Dr. Stokinger, who was then Chairman of the TLV Committee while drawing a government salary at NIOSH. Referring to the actions of the TLV Committee on arsenic, OSHA said: "The detailed basis for arriving at these levels is not clear on the record" [Occupational Exposure, 1978]. OSHA's final standard for inorganic arsenic, issued in 1978, was 10 $\mu g/m^3$ of air, averaged over an 8-hr period [Occupational Exposure, 1978].

The TLV Committee first listed "arsenic trioxide production" as a human carcinogen in Appendix A of the TLV booklet in 1975. In 1980, arsenic trioxide production was reclassified as a suspect human carcinogen; and numerical TLVs for this process and for insoluble arsenic compounds were completely eliminated.

Asbestos

The TLV adopted by ACGIH in 1946 to 1970 for asbestos was based upon the "tentative" recommendations of a Public Health Service study published in 1938 [Dreessen et al., 1938]. The P.H.S. survey showed that workers exposed to more than 5 million particles per cubic foot (MPPCF) of total dust in the air of asbestos plants clearly developed asbestosis. But the P.H.S. survey also found "early to moderate" asbestosis in workers with less than 50 MPPCF—years of cumulative exposure. The P.H.S. findings and those of an earlier medical survey by Pennsylvania

labor authorities strongly indicated that workers eventually would develop asbestosis from exposures under 5 MPPCF [Fulton et al., 1935].

Lung cancer among asbestos workers was first reported in the mid-1930s, and by 1939, German state insurance carriers were compensating lung cancer in combination with even slight asbestosis as an occupational disease [Baader, 1939]. Pathologists around the world continued to contribute data and comments on the coincidence of those two diseases through the 1940s. In 1949 the British government published powerful confirmatory statistical evidence: in 235 deaths in which asbestosis had played a role, fully 31 (13.2 percent) also involved cancer of the lung or pleura [Annual Report, 1949].

The old 5 MPPCF threshold was never regarded as safe by leading asbestos industry consultants (Drs. Leroy Gardner, Arthur Vorwald, and Anthony Lanza). A similar lack of faith in this TLV as an index of safety was expressed publicly and privately in the 1940s, 1950s, and 1960s by executives and health professionals of the leading asbestos companies in the United States and the United Kingdom, as well as health authorities in these and other countries [Castleman, 1986]. In 1964, the old TLV for asbestos was repeatedly criticized by government and industry speakers at a widely publicized conference on asbestos held by the New York Academy of Sciences [Ann. N.Y., 1965]. By this time, it was evident that nearly half of all asbestos insulation workers, whose average exposure was of the same order of magnitude as the TLV, were dying from occupational cancer and asbestosis.

The ACGIH Threshold Limits Committee had included asbestos industry consultants from its earliest years. Industrial hygienist Manfred Bowditch, who was on the Committee in 1946 and 1947, was then also trying to fulfill contracts the Saranac Laboratory had made with the asbestos industry [Castleman, 1986]. Bowditch's deceased predecessor at Saranac, Leroy Gardner, had performed studies in confidence for asbestos manufacturers, and the manufacturers wanted to publish some of the results (not the animal studies showing asbestos causing lung cancer, however.

Dr. Arthur Vorwald, the next director of the Saranac Laboratory, accommodated asbestos industry sponsors with his publication of Gardner's non-cancer related research in 1951 [Castleman, 1986; Vorwald et al., 1951 and Vorwald, 1948]. That year, he joined the Threshold Limits Committee, on which he served until 1956. During these years, Vorwald evaluated at least 30 cases of suspected and proven asbestosis and cancer, many of which were the subject of compensation claims, for companies in the United States and Canada. He also conducted a confidential animal inhalation study which appears to have re-confirmed asbestos' carcinogenicity in the early 1950s; however, this was never discussed in Vorwald's publications [Castleman, 1986; Vorwald, 1952].

Dr. Paul Gross, at the Industrial Hygiene Foundation (since 1971, Industrial Health Foundation), became a member of the Threshold Limits Committee from 1964–1983. Gross' consulting work on asbestos included case pathology reviews for Johns-Manville in the 1950s and confidential animal research on brake drum dust for Johns-Manville in the 1960s [Castleman, 1986]. As a member of a U.S. Public Health Service committee in 1969, Gross secretly provided draft copies of a report to three asbestos companies. Dr. Robert deTreville, President of the Industrial Hygiene Foundation, inviting comment, explained: "(W)e will attempt to see that needed corrections are introduced by Dr. Paul Gross, a member of the Committee" [deTreville, 1969]. In 1976, Gross resigned from a committee of the National Academy

of Sciences, amid charges of improperly sharing information with a company he consulted for — the issue was health effects of asbestos in drinking water [Wade, 1976]. Upon joining the Threshold Limits Committee, Gross became chairman of the subcommittee on insoluble respirable dusts [Minutes, 1965].

ACGIH's Threshold Limits Committee briefly considered having a separate, more stringent TLV for the crocidolite variety of asbestos. A 1968 Notice of Intent was circulated, "so that industry-connected individuals principally, but others also, may have an opportunity to help shape the deliberations of the Committee prior to its (published) recommendation of tentative changes in the 1967 Threshold Limits List." Commenters were asked to write either to Dr. Stokinger at the Public Health Service, or to the "Repository of Anonymous Occupational Health Data" in care of Dr. deTreville at the Industrial Hygiene Foundation (Committee, 1968). "Revisions under consideration. . . proposed for 1968 List (of TLVs)" included the following for asbestos:

> A limit of 5 MPPCF, based on impinger samples counted by light-field technics (sic), is satisfactory to control exposures to most forms of asbestos. Crocidolite, however, has been shown to produce, in addition to the asbestotic inflammation, also mesothelioma. Since no safe limit can be established for this form of asbestos at this time, until more definite data are obtained, it is recommended that workers exposed to crocidolite be equipped with air-supplied helmets.

This idea of stringently controlling exposure to crocidolite asbestos dust was dropped before the publication of the 1968 book of TLVs.

Over the next few years, the ACGIH published notices of intent to lower the TLV for all varieties of asbestos and change the method of analysis to phase contrast microscopy, but the formally adopted value remained 5 MPPCF through 1970. Finally, in 1974, ACGIH listed an adopted TLV of 5 f/cc for asbestos (using phase contrast microscopy), two yr after OSHA had established a standard at that level through formal rulemaking. In 1980, ACGIH lowered its TLV for chrysotile asbestos, the most abundant variety, to 2 f/cc, and set lower limits for crocidolite and amosite. By this time, government standards for chrysotile had been in effect at the 2 f/cc level for 4 yr in the United States and 11 yr in Britain. The TLV for crocidolite asbestos only (0.2 f/cc) is equal to the current (1986) OSHA asbestos standard for all types of asbestos. No notice of intended change for asbestos has been published by ACGIH since 1980.

It is noteworthy that, despite the comparatively slow process governments must follow in developing standards under their laws and despite the reluctance of conservative governments to regulate industry in the 1980s, ACGIH has lagged behind both OSHA and the British government in lowering limits for workplace exposure to the leading recognized cause of occupational cancer.

Vinyl Chloride

Upon the recommendation of Dr. Robert Scala at Esso, the TLV committee proposed lowering the limit for vinyl chloride gas to 50 ppm from 500 ppm [McFarland, 1965]. This was largely based on animal tests published by Torkelson in 1961, where effects were noted at 100 ppm and a TLV of 50 ppm was recommended

[Torkelson et al., 1961]. Following the circulation of the committee's 1966 Notice of Intent, Chairman Stokinger was invited to the Industrial Hygiene Foundation (IHF) in early 1966 to discuss the proposed changes in the TLV list. There, he met with 50 representatives of companies with membership in IHF in Pittsburgh. Stokinger was told that, "industrial experience suggests that (50 ppm) may be too low" [Report, 1966].

Consequently, the proposed change of vinyl chloride's TLV was "put off, on suggestion of Dr. Torkelson, that the Committee await further accumulating experience" [Stokinger, 1966]. The committee lowered the TLV to 200 ppm in 1971, based on unpublished Dow findings of liver dysfunction in workers exposed to 300 ppm (vinyl chloride combined with 5 ppm vinylidine chloride) [Documentation, 1971]. Dow representatives maintain that the company reduced its internal employee exposure limit to 50 ppm in 1961; but in practice this limit was knowingly exceeded, as Dow first reported the above data in 1968 [Documentation, 1971; Paustenbach and Langner, 1986].

The first U.S. workplace standard for vinyl chloride was 500 ppm, the 1968 TLV. It was revealed in 1974 that vinyl chloride workers had died from angiosarcoma of the liver and that similar tumors had been produced in experimental animals at 50 and 250 ppm. OSHA issued a proposed standard for vinyl chloride, specifying that exposures be below detectability using instrumentation sensitive to 1 ppm. But official U.S. government statements that the safety of the gas had not been demonstrated at any level were publicly denounced by Stokinger as "irrational" and "unfortunate" in a letter to the National Cancer Institute. In an interview with the *New York Times*, Stokinger went on to say that there was "ample and increasing evidence that there are threshold levels for carcinogens below which there is little risk" [Official, 1974].

OSHA issued a 1 ppm standard for vinyl chloride later in 1974, and the U.S. industry not only met that goal but promptly resumed its growth [PVC, 1976].

In the meantime, the TLV committee had taken on members from industry, including Torkelson of Dow Chemical, a major manufacturer of vinyl chloride. Torkelson had primary responsibility for TLVs for vinyl chloride and a number of other high-volume, halogenated hydrocarbons, starting in 1971 [Minutes and Agenda, 1970–1976]. It was not until 1977 that the committee issued a new TLV for vinyl chloride, 5 ppm, which still stands.

The TLV for vinyl chloride was thus set at one tenth the concentration carcinogenic to animals for a proven human carcinogen. This conflicts with the current TLV committee claim that safety factors of 100 to 1,000 have "traditionally" been used to determine TLVs for carcinogens [Identification, 1986].

Dimethyl Sulfate

The TLV for this vapor, used as a war gas in World War I, was originally set at 1 ppm in 1946. German reports in the late 1960s showed that DMS was carcinogenic in rats and probably also in workers; and the Germans lowered their MAK for this vapor to 0.01 ppm in 1971, as animal studies revealed serious lung damage at 0.5 ppm [Henschler, 1975].

The TLV committee had published its first listing of carcinogens as an appendix to the TLV booklet in 1971, consisting of only nine entries (mostly dye intermediates) In early 1972, the committee's annual Notice of Intended Changes informed readers that this list was being expanded, with separate groupings of human and "experimen-

tal" carcinogens. The listing of DMS in the former category prompted inquiries from five chemical companies. Stokinger replied to them, sending copies of underlined articles and saying: "a sufficient number of human cancers of the lung have been observed to make it highly probable that dimethyl sulfate is a carcinogen for man" [Stokinger, 1972].

A few months later, DuPont provided Stokinger with a copy of a letter from a doctor at BASF, a German manufacturer of dimethyl sulfate. The writer pointed out that the German MAK list denoted dimethyl sulfate as an experimental animal carcinogen but not a human carcinogen [Morgan, J.F., 1972]. The next month, DuPont sent Stokinger an epidemiological report "which formed the basis of our conclusion that dimethyl sulfate is not known to have produced human cancers among potentially exposed persons." Stokinger was asked to limit distribution of the study to persons having a need to see it [Morgan, J.F., 1972].

The DuPont study examined employee lung and larnyx cancer rates at three plants where DMS had been handled. However, "usable data" identifying the employees exposed to DMS before 1961 were available for only one plant. During 1932–1970, 97 wage roll workers and 46 salaried employees had worked at some time in the DMS area. There were two deaths each from lung and larynx cancer among the DMS workers between 1956–1970, with retirees and ex-employees clearly *not* followed up.

When OSHA issued an Emergency Temporary Standard for carcinogens in 1973, Stokinger argued for a distinction to be made between "*known* human carcinogens" and others on the OSHA list. Writing as Chairman of the TLV committee, Stokinger relied on the unpublished DuPont report to assert that no excess of respiratory cancers had occurred among DMS workers: "Manufacturing exposure control was completely effective, without the requirement for air-pressurized suits: . . ." Stokinger cited other unpublished reports from DuPont and Dow to argue that two of these companies' products covered by the OSHA standard (MOCA, ethylenimine) also were not human carcinogens [Stokinger, 1973].

The TLV committee member with responsibility for DMS in the period 1972–1976 was James Morgan of DuPont (sole U.S. manufacturer of DMS) [Minutes and Agenda, 1970–1976]. The committee assigned a TLV of 0.1 ppm in 1977, ten times the limit previously accepted in Germany.

Benzene

The TLV for benzene was adjusted downward from 100 ppm in 1946, 50 ppm in 1947, 35 ppm in 1948, to 25 ppm in 1957. The TLV committee adopted 25 ppm as a ceiling exposure limit in 1963. An industry consensus "standard" of 10 ppm (with daily 10-min peaks of 50 ppm) was issued in 1969 by the American National Standards Institute. Consequently, 10 ppm was the first benzene limit adopted by OSHA (NIOSH, 1974).

British industry and government writers urged Stokinger to abandon the 25 ppm ceiling in favor of a 10 ppm average value as early as 1966 [King, 1970; Stokinger, 1966]. The TLV committee first proposed this change in 1968, but deferred its adoption until 1977.

Hueper had assessed benzene as almost certainly a proven cause of leukemia in 1942 [Hueper, 1942]. The German MAK commission had listed benzene in 1971 among nine human carcinogens, "for which zero concentration values are given

because the objectionable concentration is not yet known" [Morgan, L., 1972]. Benzene was classified by the TLV committee as a "suspected" human carcinogen in 1975.

The 1986 *Documentation* contains no references less old than 1977 and relies on one report whose findings were reversed in 1977. That year, OSHA issued an emergency temporary standard and proposed a permanent standard of 1 ppm for benzene. An adverse Supreme Court ruling in 1980 based on the record of the benzene standard issued in 1978 prompted OSHA to conduct quantitative cancer risk assessment and again propose a 1 ppm limit in 1985.

The 1986 *Documentation* refers to unpublished work by Ott in 1975 as showing no excess mortality among benzene-exposed workers. However, Ott concluded that this same cohort of Dow Chemical employees demonstrated a significant excess of myelogenous leukemia cases—prompting Dow to announce a new corporate ceiling limit of 10 ppm in 1977 [Benzene, 1977; Ott et al., 1978]. Dow epidemiologists have now seen 4 deaths from myelogenous leukemia in this work force, versus 0.9 expected; a fifth worker with leukemia was listed as dying with pneumonia [Bond et al., 1986]. Infante at OSHA notes that average benzene exposure of these workers was 5.5 ppm [Infante, 1987].

Similarly, the 1986 *Documentation* makes no mention of dose-related chromosomal abnormalities among Dow workers exposed to benzene concentrations below 10 ppm [Infante and White, 1983]. These findings were withheld by Dow during the OSHA benzene hearings in 1977, prompting the researcher involved to quit in 1978 in order to release his results. Because of the company's delay in releasing these findings, the researcher denounced Dow as "unethical" and "immoral" [Picciano, 1979; Scott, 1978].

The TLV committee, which adopted a companion short-term exposure limit of 25 ppm to go with the 10 ppm average for benzene in 1980, is discarding the short-term limit in 1987. Exposure at even 10 ppm for eight min is illegal under the OSHA benzene standard published September 11, 1987. The standard requires that exposures average no more than 1 ppm, with 15-min peaks no more than 5 ppm.

The committee's position in 1987 thus resembles that of the American Petroleum Institute in its 1978 court challenge to the overturned benzene standard. The past decade of benzene toxicology research has not been incorporated into the TLV *Documentation*. The research and policy at Dow Chemical (whose senior toxicologist was an active member of the TLV committee), if known to the committee, have been disregarded without mention.

Acrylonitrile

Following the reports of positive animal studies by inhalation and ingestion, as well as positive epidemiological findings, OSHA regulated acrylonitrile as a carcinogen in 1978. Acrylonitrile was also classed by ACGIH as a human carcinogen in 1978. Following the publication of an inconclusive epidemiological study in Britain and the receipt of epidemiological "communications to the TLV committee" from Monsanto Company in 1981, acrylonitrile was reclassified under "industrial substances suspect of carcinogenic potential for man." The Monsanto conclusions were quoted by the TLV committee; no published study is yet available for scrutiny by the scientific community.

Ethylenimine

When OSHA proposed to regulate this compound as a carcinogen in 1973, Dow's Dr. D.J. Kilian provided the basis for the TLV committee observation, that despite this chemical's toxic and carcinogenic effects in animal studies, "industrial experience has been good." The entire basis for this was the following second-hand report of a telephone conversation between two major manufacturers: [Kilian, 1973]

> "Today, I talked by telephone to Dr. Theiss, medical Director of Badische Anilin and Soda-Fabrik in Germany (the only other major manufacturing site of ethylenimine) and he stated that they had just finished an epidemiological study of 144 of their EI workmen. The exposure time on some was 40 years and they found no evidence that EI was a human carcinogen."

Dr. Kilian also wrote that he and Dr. Theiss planned to combine their companies' experience "in a medical publication in the near future." It does not appear that any study was subsequently published. Ethylenimine was removed from the TLV booklet's appendix list of "experimental carcinogens" after 1974, presumably upon the recommendation of the subcommittee on carcinogens, which included Torkelson of Dow Chemical (sole U.S. producer of the material).

Carcinogens in General

The TLV committee has now stated its intent to "formally" evaluate chemicals classified as carcinogens by other organizations but not ACGIH [Spirtas et al., 1986]. ACGIH has published a table listing the carcinogenic status of more than 300 substances, according to five national and international organizations [Identification, 1986]. The most appropriate comparison is with the list of the German Research Society maximum workplace concentrations (MAK) Commission.

The ACGIH classifies 11 materials in the aforementioned table as human carcinogens; the MAK Commission's total is 17. The ACGIH classifies 40 other entries as suspected human carcinogens; the corresponding MAK commission totals are 42 compounds proven carcinogenic in animal experimentation only, and 61 more "justifiably suspected of having carcinogenic potential" [Identification, 1986; Maximum, 1984].

The TLV committee avoided listing animal carcinogens of major industrial importance, including trichloroethylene and dioxane. These and other unnamed compounds were exempted by the "Committee Guidelines for Classification of Experimental Animal Carcinogens" published in 1976. The guidelines are unique in that they set maximum carcinogenic dosages, above which no "practical importance" is attributed for positive animal experiments.

Lead

Because of their enormous significance in occupational health and the manner in which their TLVs emerged, the story of inorganic and organic lead compounds could hardly be overlooked in this review.

Inorganic Lead

From 1946 through 1956, the TLV for lead and its inorganic compounds was 0.15 mg/m^3. This followed earlier recommendations of the U.S. Public Health

Service and an American Public Health Association committee on lead. Later editions of the Documentation observed that this limit proved "difficult to achieve in many industries."

Explaining the 1957 decision to raise the lead TLV to 0.20 mg/m^3, the first edition of the Documentation said: "Long industrial experience with the 0.15 mg/m^3 limit, however, showed that. . . lead absorption, as measured by urinalysis, were (sic) not indicative of harmful exposure." No reference for this was given. The 1966 Documentation went on to describe the blood lead concentration of 80 micrograms per 100 ml as "normal", and noted that repeated exposures above 0.20 mg/m^3 could cause higher blood lead burdens "indicative of incipient lead poisoning."

Pressure for lowering the TLV developed in November, 1968, when an international commission on occupational health recommended 0.15 mg/m^3. In preparation for discussions with industry, the TLV committee summarized recent developments on lead toxicity and reviewed the "Basis of Present TLV." Under this last heading were three items, all unpublished corporate communications, from: Bowditch (Lead Industries Association); Dooley (Texaco); and Nelson (Asarco) [Review, 1970]. Neither Stokinger nor Elkins can now recall what information was provided by these individuals over 30 years ago, and no primary written documentation has been found in Stokinger's old files at NIOSH.

On May 1, 1970, a meeting was held by TLV committee members Stokinger and Frederick with representatives of the automotive and lead industries, state health officials, and others. Industrial representatives said they used blood lead analyses for health control measures, and urged that air sampling be advised only as an engineering guide. General Motors hygienist Vincent Castrop acknowledged that his company used 0.15 mg/m^3 as its guideline [Stokinger, 1970].

The TLV committee then readopted the former value of 0.15 mg/m^3, which has remained unchanged since 1973. A short-term (15-min) exposure limit of 0.45 mg/m^3 was also adopted in 1976, later to be discarded in 1986. The current Documentation includes an attack on NIOSH for recommending a standard of 0.10 mg/m^3 and rejects the OSHA standard of 0.05 mg/m^3 promulgated in 1978.

Organic Lead Compounds

When tetraethyl lead was introduced as a gasoline additive in the 1920s, lead poisoning was a major by-product of the industry. About 80% of the workers at DuPont's New Jersey production facility were believed to have been lead poisoned; and the plant was known to workers as "the House of the Butterflies" because of the hallucinations afflicting employees there. DuPont was accused of suppressing information from the press even in cases where workmen were hospitalized and died from lead poisoning [Rosner and Markowitz, 1985].

Tetraethyl lead (TEL) and tetramethyl lead (TML) were given TLVs of 0.075 mg/m^3 in 1963 and 1967, respectively. The main basis for the tetraethyl lead TLV consisted of statements by industry representatives that this limit was observed by Ethyl Corporation without apparent ill effects on the workers [Documentation, 1966].

Publication of the second of these TLVs brought forth a "Confidential" letter of protest in 1967 from Dr. Robert Kehoe, the lead industry's foremost medical expert, its consultant and a defender of the tetraethyl lead industry since the 1920s [Rosner and Markowitz, 1985]. Kehoe urged that both TLVs be discarded, "with the least possible fanfare." His "Dear Herb" letter concluded: [Kehoe, 1967]

> "I would not take the risk of subjecting a group of men to working conditions represented by this atmospheric standard for any reason whatever, and yet this level is being adopted on a worldwide basis, and I have little doubt that it will be applied literally by someone, sometime, as being authoritative. It is not so applied in any part of the industry at present."

Kehoe invited Stokinger to be his lunch guest at the Queen City Club, a private club in Cincinnati catering primarily to businessmen [Kehoe, 1967]. Stokinger accepted, and recalls that Kehoe "pontificated" without supplying any data. Stokinger was aware that Kehoe had become a wealthy man over decades as the principal U.S. industry expert on lead poisoning. Though Kehoe presumably represented industrial interests in this matter, no firms were specifically named [Stokinger, 1986–87].

The most influential members of the TLV committee rejected the idea of dropping the limits for TEL and TML, and instead cautiously challenged the responsible industries to produce some dose-response data. In its January, 1968 "Notice of Intent", the committee wrote that a *downward* revision of the TLVs for both lead alkyls was being considered. No new proposed limits were given [Committee, 1968].

At least one manufacturer of these compounds found that operations involving each of these chemicals exceeded even the then-current TLV of 0.075 mg/m^3. But organic lead air concentrations averaging as high as 0.121 mg/m^3 for TEL and 0.179 mg/m^3 for TML reportedly corresponded to average urinary lead concentrations "not significantly above a high normal" — meaning, less than 0.15 mg/l. The source of this encouraging news was A.L. Linch, whose employer (never noted in the Documentation) was DuPont. The date of this communication to the TLV committee chairman is recorded as April 1, 1968.

The TLV committee held its semiannual meeting over the next two days, April 2–3, 1968, and decided to *raise* the TLVs to 0.10 mg/m^3 for TEL and 0.15 mg/m^3 for TML [Stokinger, 1968]. These limits were formally adopted in 1970, and remain the same to this day. No written communication from Linch to Stokinger has been found; and given the rapid sequence of events here, the cited report from Linch appears to have been a telephone call [Stokinger, 1986–87].

It has been proposed recently that OSHA try to adopt current TLVs to "update" the exposure limits for hundreds of substances. While this would yield stricter limits for many substances whose OSHA limits are still the 1968 TLVs, the opposite would result for the lead alkyls. This is especially worrisome in view of the fact that the OSHA standard for organic lead compounds is now more permissive than that for the inorganic lead compounds, which are less toxic; this anomaly will be worsened if OSHA adopts the current TLVs for the lead alkyls.

Bias of TLV Committee Membership

Dr. Hector Blejer, resigning from the committee in 1980 after 10 years as a member, protested what he called "an increasingly stronger pro-industry bias. . . particularly among almost all the Committee consultants and among the members who consult privately for private industry." Blejer went on to blame this pro-industry bias and repeated "unnecessary" disagreements with NIOSH and OSHA for having made the TLV committee and ACGIH appear "anti-NIOSH, anti-OSHA, and anti-labor" [Blejer, 1980].

To its discredit, the committee has long turned a blind eye to conflicts of interest, both overt and subtle. Health and safety professionals tend to view policy issues from a spectrum of opinions: from those who would resolve the benefit of doubt in assuring the fullest worker protection to those who are more sensitive to corporate financial priorities where health and safety is in practice regarded as an expenditure to be controlled as much as possible. It is no accident that professionals with the latter point of view are more likely to consult for or be employed by corporations, and those closer to the former viewpoint are more likely to be independent of corporate funding, perhaps working in government or for labor unions, public interest groups, etc.

The TLV committee never acknowledged this reality or attempted to achieve a balance between corporate- and union-affiliated health professionals. Only occasional token efforts were made to get a union industrial hygienist on the TLV committee. There, the union person could expect to be marginalized at least as badly as was Dr. Blejer (a NIOSH expert on lead, arsenic, cadmium, and asbestos), by the sheer force of numbers and adversaries with vastly superior technical resources. The TLV committee never offered unions and other strong advocates of worker protection a chance to participate on a fully equal basis. The occasional token offers for participation in effect only gave unions the "choice" of participating in an unequally balanced arena and depleting their resources with little chance of being heard — or of no participation at all.

CONCLUSIONS AND RECOMMENDATIONS

While earlier reviews of the TLVs themselves have been critical, the process of TLV development has not been critically examined in the past. The unavailiabity of unpublished corporate "documentation" precludes scientific scrutiny of the primary basis for nearly one sixth of the "documented" TLVs. At the same time, the TLV committee's uncritical acceptance of industry assertions based on scant, unpublished "data" raises yet greater concern.

The documentation of TLVs for their own companies' products by industry members of the TLV committee constitutes a major conflict of interest. This happened on a large scale in the 1970s, with the Dow Chemical representative primarily responsible for TLV development for major Dow products (vinyl chloride, vinylidine chloride, chloroform, methyl chloride, ethylene dichloride, ethylene dibromide, trichlorobenzene, dioxane, ethanolamine, dipropylene oxide methyl ether, styrene, ethylene glycol,dibromochloropropane, "Tordon", "Ruelene", "Dursban", and "Plictran"); and the DuPont representative doing the same for major DuPont products (dimethyl sulfate, "MOCA", lead chromate, formamide, dichloromonofluoromethane, "Lannate", "Karmex", and "Hyvar X") [Chemical Week, 1975; Minutes and Agenda 1970–1976].

The listing of dominant corporate TLV committee members as "consultants" and the issuance of statements to the effect that they did not officially vote on the TLVs were deceptive [Lee, 1987]. The concealment of industry influence on the TLVs is a serious matter, quite apart from the exercise of that influence itself.

Aside from the participation of industry-employed health professionals, the TLV committee has extended full membership to full-time industry consultants as early as 1951 (Dr. Arthur Vorwald of the Saranac Laboratory). To this day, TLV

committee members can and do earn a substantial fraction of their incomes as industrial consultants, while publishing only their university affiliations in the TLV booklet. ACGIH has no policy either restricting TLV committee membership in such cases or requiring public disclosure of consulting work for financially interested parties. Similarly, there is no policy restricting the chemicals assigned to TLV committee members because of conflicts of interest through employment, consulting, and research grants [Kelly, 1986–87].

The TLV committee's lack of adequate resources is evident from its finances. As part of the ACGIH, a volunteer organization, the committee now has an annual budget of $30,000, most of which goes for travel and lodging expenses to conduct meetings [Kelly, 1986–87]. The members of the committee must rely on whatever technical resources and support services are available to them as individuals (computer searches, libraries, research assistants, clerical assistants), and borne by them and/or their employers for their unpaid committee work (e.g., long-distance telephone calls). Over the years, this has meant that committee members have had to work on TLVs on their own time and their own expense, with their own resources, unassisted. As a result, documentation on many chemicals seems to have been prepared with minimal review of the literature.

The TLVs have nonetheless been widely represented and accepted as scientifically based limits that would protect virtually all workers from health impairment over a lifetime of exposure on the job [Lee, 1987]. The TLVs are assumed by many to be first world, "first class" guidelines for worker protection. The consequences of such misplaced confidence in the TLVs are profound and global. The credibility of the ACGIH limits as scientifically, independently, and verifiably determined persists as an obstacle to a better standard of worker protection.

Industrial hygienists need clear instruction regarding the limited nature of the TLVs. Hygienists too often assume or convey to workers that exposure below the TLV can be regarded as safe. They need training which would enable them to assess more adequately the scientific grounds upon which the TLVs are based. They also need increased training in eliciting and evaluating worker complaints of illness during field inspections. This approach should replace the technician approach of simply "cranking out numbers" with monitoring, comparing them to a table, and then assuming all is well if exposures measured are less than the TLVs.

OSHA is now considering adopting current TLVs to replace its exposure limits from the 1968 TLV list (Z table). While for some chemicals this may represent an improvement, it is clear that we cannot assume that the current TLVs are scientific or adequate. Since more rigorous and thorough documentation has been done for the chemicals for which NIOSH recommends specific maximum exposure levels, OSHA should adopt NIOSH levels where these are stricter than those of the ACGIH. Finally, since many chemicals have not been assessed by NIOSH and others need updating, OSHA should consider the adoption of TLVs or NIOSH values as a stopgap measure, not a substitute for ongoing rigorous assessment of chemical exposure values.

With the more recent emergence of better trained and equipped groups issuing workplace exposure limits and supporting documentation in North America, Europe, and elsewhere, it now seems appropriate for an international effort to be mounted to gradually replace the TLVs. This can be done under the auspices of an internationally respected organization, with the participation of leading experts from around the world, with sufficient financing. Corporations with their own internal lists of occu-

pational exposure limits can contribute to this process by publishing these lists and supporting data without further delay.

Openness of the process is essential, as is the exclusion of financially interested parties from having leverage in the deliberations. Policies regarding disclosure of income and conflicts of interest must be accepted by the participants so that the highest level of credibility maintained. Policies regarding making any use of and maintaining public repositories for unpublished documentation will also be needed. Public access to minutes of meetings should be assured and provided for.

Yet even a panel of the best technical experts would not overcome all obstacles inherent to the process of setting worker exposure limits.

There are implicit assumptions in any process of establishing some "acceptable" level of chemical insult to which humans may be exposed. Many scientists reject "safe" exposure levels for carcinogens and certain reproductive hazards. The concept of "safe" exposure limits for other chemicals is less often questioned however, even though scientists are unable in practice to determine "safe" exposures. They can only determine levels below which their limited measurement tools are unable to detect effects in a finite and often very limited number of workers. Thus the very concept of "safe" exposures to any chemical is inherently unscientific. Indeed, the term "threshold limit" embodies this unproven and probably unprovable concept that there is some known level of exposure which does not adversely affect the organism. Discarding the term "threshold limit" is a necessary first step in correcting this false ideology of the past.

Rather, the numerical values for exposure limits selected as "acceptable" by one social group (scientists) for another social group (workers) is very much a political as well as a scientific process. The Norwegian Administrative Norms, for example, explicitly acknowledge that the chemical exposure limits reflect economic as well as medical and technical considerations. The Norwegian authorities consider that while writing the documentation for chemicals is ideally a scientific process, the setting of numerical limits is a political process. It is time that we all openly acknowledge the political nature of decisions by unexposed scientists and regulators regarding maximum levels of chemicals to which other humans can knowingly be exposed. The decision process therefore must not only be freed from undue corporate influence; it must also include substantial participation by representatives of exposed persons.

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