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The Role of Threshold Limit Values in U.S. Air Pollution Policy

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This paper analyzes the role of threshold limit values (TLVs) in national air pollution policy during the 1980s, a period in which the Environmental Protection Agency (EPA) sought to delegate to individual states the authority to evaluate and regulate airborne toxic substances. We focus on 20 carcinogens and 11 substances with non-genotoxic health effects that were regulated by local air toxics programs using TLVs. Data from EPA's National Air Toxics Information Clearinghouse indicate that maximum TLV-based Ambient Air Level guidelines (AALs) frequently exceed minimum TLV-based AALs by a factor of >1,000. Cancer potency data from EPA's Integrated Risk Information System suggest significant risks remain at TLV-based AALs. Cancer risks at the median TLV-based AAL exceed 1,000 cases per million exposed persons for cadmium (1,040), nickel and its compounds (1,420), propylene oxide (1,550), coke oven emissions (1,860), benzene (2,500), arsenic and its compounds (7,300), *N*-nitrosodimethylamine (21,000), asbestos (21,500), and ethylene dibromide (55,000). We also summarize published studies that report non-genotoxic health effects in workers exposed at levels near the TLV for 11 substances whose AALs were based on TLVs. Contrary to the assumption frequently made by state air toxics program, TLVs cannot be taken to represent no observed effect levels (NOELs) for regulatory purposes.

Key words: Threshold Limit Values, air pollution, Clean Air Act, toxics, carcinogen, Environmental Protection Agency, regulatory policy

INTRODUCTION

During the 1980s, the Environmental Protection Agency (EPA) delegated to individual states the responsibility for controlling airborne toxic substances. A substantial fraction of states developed Ambient Air Level (AAL) guidelines based on the Threshold Limit Values (TLVs) of the American Conference of Governmental Industrial Hygienists (ACGIH). This embodied the assumption that TLVs were health-based limits that fully protected worker populations and would fully protect the general population when multiplied by an appropriate safety factor. Recent analyses of the TLVs have undermined this assumption, however, documenting strong cor-

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porate influence on the TLV-setting process and significant adverse health effects at occupational exposures at and below the TLV.

This paper evaluates the process and outcome of the trend toward reliance on TLVs in U.S. air pollution policy during the 1980s. The first section presents our materials and methods. The second section describes the political evolution of airborne toxics policy in the United States and the delegation of responsibility by the EPA to the state programs during the 1980s. The third section of the paper documents the consequences of federal reliance on state regulation, in terms of the variability in AALs and residual health risks. To illustrate the variability in air toxics control efforts, we focus initially on state and city AALs and residual cancer risks for acrylonitrile, the only substance officially delegated to the states by EPA. We then document the variability in AALs and residual health risks for 19 other substances that were regulated using TLV-based guidelines despite having been designated as probable or confirmed human carcinogens by the International Agency for Research on Cancer (IARC). Finally, we summarize published data on non-genotoxic health effects at worker exposure levels close to the TLV for 11 toxics regulated by states and cities under the assumption that TLVs represent safe levels of exposure for worker populations. Acrylonitrile, the 19 other carcinogens, and the 11 chemicals with documented non-genotoxic effects were all among the 189 substances whose regulation by EPA was subsequently mandated as part of the 1990 Clean Air Act Amendments. This paper concludes with a brief comparison of the role of TLVs in air pollution policy with their role in occupational safety and health policy.

MATERIALS AND METHODS

Information on state and city air toxics programs was obtained from the 1989 edition of the National Air Toxics Information Clearinghouse (NATICH), published by EPA to facilitate and encourage the development of local programs [EPA, 1989b]. The NATICH database provides data on each state and city air toxics program that has developed ambient air level (AAL) guidelines for each substance. These data include the AAL itself, averaging time (e.g., 8 hr, 24 hr, 1 year), quantitative basis [TLV, OSHA Permissible Exposure Limit (PEL), quantitative risk assessment], and safety factor applied to the basis. To facilitate comparisons, we adjusted all AALs to a 24-hr averaging time.

The NATICH database contains information on a vast number of substances. We selected the subset of substances that were regulated based on TLVs by at least one air toxics program and were among the 189 substances mandated for federal regulation in the 1990 Clean Air Act Amendments. Within this group, we focused on carcinogens plus 11 substances for which non-genotoxic health effects had been reported at or near the TLV. This sample represents substances that were regulated based upon TLVs but for which alternative sources of scientific information were accessible to both local air toxics programs and EPA.

Information on the health risks posed to community residents exposed at levels permitted under TLV-based AAL guidelines was obtained from several sources. Residual cancer risks at the TLV-based AALs were calculated using the EPA's cancer potency data in the Integrated Risk Information System (IRIS) [EPA, 1989a]. IRIS is a computerized database that contains summaries of published health effects literature and EPA's most recent evaluation of the weight of the carcinogenicity evidence for

each substance. Non-genotoxic clinical effects were obtained from the publications cited in the ACGIH TLV documentation [ACGIH 1986], as analyzed by Roach and Rappaport, [1990], or cited in a recent review [Ziem and Castleman, 1989].

We focus initially on acrylonitrile, the only substance officially delegated to the states. To illustrate the variability in AALs, quantitative bases, and residual risks, we present data from each of the 15 state and city air toxics programs that have acrylonitrile AALs, including those whose guidelines are based on something other than the TLV. We then present summary data on 19 additional substances designated as carcinogens by IARC. These substances were designated by IARC as either group 1 (sufficient human evidence) or group 2A (limited human, sufficient animal evidence) carcinogens. For these substances, we summarize the variability in AALs in terms of the ratio of the maximum TLV-based AAL to minimum TLV-based AAL. Residual risks are then presented for the median TLV-based AAL, using IRIS cancer potency data. Finally, we summarize the published non-genotoxic clinical data on each of 11 substances for which at least one city or state air toxics program developed a TLV-based AAL. For each substance we present the clinical effects, the exposure level causing those effects, the exposure level designated as the TLV by the ACGIH, and the median safety factor used by the state and city air toxics programs.

In describing the general evolution of U.S. air pollution policy from the passage of the Clean Air Act in 1970 to the Amendments of 1990, we rely upon previous analyses by ourselves and others. The chronology of EPA resistance to enforcing Section 112 has been analyzed in detail by legal scholars, including Doniger [1978], Graham [1984], Goldberg [1988], and Dwyer [1990], by the General Accounting Office [GAO 1983], and by ourselves [Robinson and Pease 1991]. None of these analyses of air pollution policy has focused on the EPA's attempt to delegate regulatory responsibility to the states during the 1980s. Calabrese and Kenyon [1989] highlight the role of TLVs in state air toxics programs. The General Accounting Office [GAO 1987] describes the EPA referral policy, but without considering the role of TLVs in state air toxics programs. In our presentation of the historical chronology, we refrain from repetitive citation of these secondary sources, limiting references to EPA documents, *Federal Register* announcements, and the weekly editions of the *Environment Reporter*.

EVOLUTION OF U.S. AIR POLLUTION POLICY

Section 112 of the Clean Air Act of 1970 established a rigorous structure for the regulation of hazardous air pollutants, defined as substances that cause "an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness" and that are not among the six "criteria" pollutants covered by other sections of the Act. The EPA was given the authority to list individual substances as hazardous and then impose emissions standards that guaranteed "an ample margin of safety" for the exposed population. These emissions standards were to be established based on considerations of health, without consideration of technological feasibility or economic costs. As recognized by both the Congressional authors of the 1970 Act and EPA, this regulatory structure could lead to the forced closure of individual factories and/or the ban of individual toxic substances.

The potential for economic dislocations from bans or stringent emissions limits

resulted almost immediately in efforts by the EPA to avoid enforcement of the law. The EPA sought to avoid, wherever possible, designating toxic substances as candidates for regulation. In those instances in which designation was unavoidable because of political pressure from Congress and/or environmental organizations, the EPA established emissions limits based primarily on economic considerations ("best available technology") rather than health considerations ("ample margin of safety"). The EPA's standard for vinyl chloride was challenged in court by the Environmental Defense Fund (EDF). The EDF reached an out-of-court settlement with the EPA, in which the Agency agreed to tighten the vinyl chloride standard and, more importantly, to accelerate the listing and regulation of other substances. This agreement was subsequently formalized in the EPA's proposed policy for identifying and regulating airborne carcinogens [EPA, 1979]. It embodied the same philosophy of "generic" approaches to environmental and occupational carcinogens that appeared in the carcinogen assessment guidelines of the Interagency Regulatory Liason Group [IRLG, 1979] and OSHA's generic carcinogen policy [OSHA, 1980].

The presidential inauguration in January 1981 of Ronald Reagan derailed all these attempts at broad-based regulation of toxic substances. The proposed EPA carcinogen policy was never adopted. The proposed tightening of the vinyl chloride standard was never carried out and was officially revoked in 1985. EPA efforts to avoid listing and regulating airborne toxics under Section 112 during the early 1980s combined two quite different approaches. One focused on increasing the extent of scientific understanding of individual substances, exposures, and health effects prior to their being listed for possible regulation. By contrast, the other component of the EPA's evolving policy sought to delegate responsibility for the evaluation and regulation of airborne toxic substances to the individual states. This informal and then formal process of delegation was developed by EPA even while candidly acknowledging that the states had neither the technical expertise nor the political will to evaluate and regulate these substances comprehensively. It is at this point that ACGIH Threshold Limit Values began to play an important role in U.S. air pollution policy.

In 1984, the EPA began signing memoranda of intent with selected states, including Alabama, Florida, Ohio, and South Carolina, to allow them to assume responsibility for the evaluation and control of airborne toxic substances [BNA, 1984]. The principle underlying this pilot project was that emissions of many toxic substances are limited geographically to areas surrounding particular plants, hence do not pose national problems. The EPA claimed that individual states would be better situated to deal with state-specific problems. After delegating regulatory responsibility for a particular substance, the EPA would not challenge decisions by individual states not to evaluate or regulate the substance. The first substance chosen for referral was acrylonitrile.

This pilot project was one of the central components of the EPA's new policy for airborne toxics, published in June 1985 [EPA, 1985]. Two types of substances would be considered for referral to the states. The first category would be composed of substances such as acrylonitrile, which the EPA considered of limited geographic importance and which it therefore refused to list as hazardous air pollutants under Section 112. The other category would be composed of substances that would be listed under Section 112 but that were emitted by industrial sources that the EPA believed could be more efficiently regulated by individual states. This category,

according to the EPA, potentially included some sources of benzene, butadiene, ethylene oxide, ethylene dichloride, chloroform, cadmium, methylene chloride, and chromium [BNA, 1985c,e]. Health risks posed to populations living near sources of these pollutants could be quite high in individual cases, according to EPA calculations. The maximum lifetime cancer risks for neighbors of a Texas plant emitting butadiene sulfolane, for example, was 34 chances in 1,000 [EPA, 1985c; BNA, 1985e].

As part of its new proposed federal-state "partnership," EPA would provide limited funding and technical expertise to state air toxics programs. The technical support would include information on emission factors, monitoring methods, risk analysis, and threshold limit values [BNA, 1985c]. A major component of the EPA's support for state initiatives was the newly established National Air Toxics Information Clearinghouse (NATICH) database, which included information on state initiatives for individual toxic substances [EPA, 1989b].

The proposed federal-state partnership incurred immediate opposition from state air pollution authorities, environmental organizations, and selected federal legislators, albeit for somewhat different reasons. The state and local air pollution authorities often welcomed the enhanced authority but decried the meager level of federal funding offered by EPA [BNA, 1984, 1985c,d]. They were also concerned about the EPA's unwillingness to question state decisions not to regulate particular substances. The state officials believed that they needed EPA support when faced by local political opposition to stringent air toxics regulation. By late 1985, these state officials were demanding that referrals be limited to substances produced in less than five states and that posed a lifetime cancer risk of less than 1 chance in 1 million. This clearly excluded acrylonitrile, which the state officials said should be subject to federal regulation. They also demanded that EPA ensure federal scrutiny of states that do not regulate a particular substance that had been "delegated" [BNA, 1985g].

The Natural Resources Defense Council (NRDC) took the lead among environmental organizations in denouncing the new EPA policy. The NRDC claimed that referral of substances to the states violated the statutory language of Section 112 and constituted a "shirking of federal responsibility" for protecting the national public health [BNA, 1985f]. In January 1986, the NRDC sued the EPA, seeking to force it to list acrylonitrile, butadiene, cadmium, carbon tetrachloride, chloroform, chromium, ethylene dichloride, and ethylene oxide as hazardous air pollutants and to commence the development of national emissions standards [BNA, 1986a]. The NRDC claimed that the EPA's own data proved that acrylonitrile was produced in at least 24 states [BNA, 1985c].

Legislative opposition to the proposed delegation policy built on a longstanding skepticism among selected Senators and Congressmen concerning the EPA's degree of good faith in carrying out the provisions of the Clean Air Act. Congressional impatience over the slow rate of listing toxic substances had begun during the 1970s, as evidenced most prominently by the requirements in the 1977 Clean Air Act Amendments for the EPA to evaluate four specific substances for possible listing. By 1981, Democratic legislators were proposing bills that would eliminate EPA discretion altogether by statutorily listing various toxic substances as hazardous air pollutants. By 1985, Representatives Wirth, Waxman, and Florio had a list of 85 substances, including acrylonitrile, that they wanted to require the EPA to regulate [BNA, 1985a]. Waxman, chairman of the Health and Environment subcommittee of

TABLE I. Acceptable Ambient Air Level (AAL) Guidelines for Acrylonitrile by State and City, 1989 (24-hr Averages)*

Agency	Acceptable AAL ($\mu\text{g}/\text{m}^3$)	Basis for AAL	Residual risk: cancers per 1 million
Connecticut	8	PEL	544
Indianapolis, IN	0.25	PEL	17
Kansas City	0.25	TLV	17
Massachusetts	0.25	NA	17
Nevada	38	TLV	2,584
New York	258	TLV	17,544
North Carolina	2.6	NA	177
North Dakota	BACT	NA	NA
Philadelphia, PA	194	NA	13,192
Rhode Island	1.2	TLV	82
South Carolina	23	NA	1,564
South Dakota	0.8	PEL	54
Tampa, FL	16	NA	1,088
Vermont	0.3	NA	20
Virginia	45	TLV	3,060

*BACT, best available control technology; PEL, OSHA permissible exposure limit = $4.5 \text{ mg}/\text{m}^3$; TLV, ACGIH threshold limit value = $4.5 \text{ mg}/\text{m}^3$; NA, not available.

the House Energy and Commerce committee, was particularly vociferous in denouncing the EPA's new air pollution policy. Senators Lautenberg and Moynihan of the Senate Environment and Public Works Committee announced their intention to introduce legislation blocking the referral of regulatory authority to the states, declaring it would start a race by communities to "steal jobs from areas which have imposed public health controls" [BNA, 1985b]. Faced with this opposition, the EPA retreated from its new air toxics policy. By February 1986, the referral policy had been placed "on hold," citing opposition from state and local air pollution control officials [BNA, 1986b].

EXTENT AND EFFECTS OF RELIANCE ON TLVs

Table I presents Ambient Air Level guidelines and residual cancer risks per million exposed persons for acrylonitrile from 15 state and city air toxics programs. Of these 15 programs, five officially designated the TLV as the basis for their AAL. Another three programs designated the OSHA PEL, which in this case is identical to the TLV. The AALs vary widely depending on the averaging period and safety factor. For ease of comparison, the 15 AALs are standardized in terms of 24-hr averages. A safety factor of 4.2 is routinely applied to TLVs by state and city air toxics programs, under the assumption that the TLVs indicate safe exposure levels for a 40-hr workweek, while community residents are exposed to air pollution for the full 168-hr week. Additional safety factors, which vary considerably, are applied under the assumption that the TLVs indicate safe exposure levels for healthy, working populations while air pollution programs must protect more susceptible populations such as children, the elderly, and persons with chronic diseases.

Allowable risks of cancer per million persons exposed to acrylonitrile range considerably, from a low of 17 per million in Indianapolis and Kansas City to highs

TABLE II. Cancer Risks From Environmental Exposure to IARC-Designated Carcinogens Whose Acceptable Ambient Air Level (AAL) Guidelines Are Based on Threshold Limit Values*

Substance (TLV-based AAL/total AAL)	Ratio of maximum to minimum TLV-based AAL	Residual risk at median TLV-based AAL: cancers per 1 million	EPA carcinogen designation
4-Aminobiphenyl (1/5)	1	NA	NA
Arsenic and compounds (5/13)	2,609	7,300	A
Asbestos (3/12)	555,556	21,500	A
Benzene (5/13)	680	2,500	A
Benzidine (1/11)	1	0.23	A
Beryllium (4/12)	5	23	B2
Cadmium (4/15)	275	1,040	B1
Coke oven emissions (1/2)	1	1,860	A
Dimethyl carbamoyl chloride (1/4)	1	NA	B2
Epichlorohydrin (8/15)	340	13	B2
Ethylene dibromide (3/12)	44,118	55,000	B2
Ethylene oxide (7/15)	941	NA	B1
Formaldehyde (10/18)	71	208	B1
Nickel and compounds (4/7)	80	1,420	A
N-Nitrosodimethylamine (2/9)	2500	21,000	B2
Polychlorinated biphenyls (3/11)	2,050	NA	B2
Propylene oxide (6/12)	20,714	1,550	B2
Vinyl bromide (3/8)	575	NA	NA
Vinyl chloride (6/15)	40	391	A

*EPA cancer classification: A, sufficient human data; B1, limited human data; B2, sufficient animal data; NA, not available.

of 13,192 per million in Philadelphia and 17,544 per million in New York state. This represents a thousandfold variability around a sample median of 177–544 cases per million exposed. The TLV-based AALs include both the lowest (Kansas City) and highest (New York state) AALs. These estimates correspond not to actual risks faced by residents of these states and cities, which depend on actual exposure levels, but rather to the risks that were permissible in these states and cities under the TLV-based guidelines. The air toxics program in North Dakota does not have a numerical AAL for acrylonitrile but requires that emission sources adopt the best available control technology (BACT).

Table II presents measures of variability in Ambient Air Level guidelines and residual cancer risks at the median TLV-based AALs for 19 IARC-designated carcinogens. For most substances, the number of states and cities with AALs is modest, with a maximum of 18 in the case of formaldehyde. TLVs were adopted by five or more air toxics programs for the regulation of arsenic, benzene, epichlorohydrin, ethylene oxide, formaldehyde, propylene oxide, and vinyl chloride. The figures on AAL variability and residual cancer risk at the median AAL in Table II reflect solely those state and city AALs based on TLVs.

The ratio of maximum to minimum AAL is quite large for TLV-based AALs, ranging from 5 in the case of beryllium to >500,000 in the case of asbestos. These ranges are sensitive to the presence of a single very high or low AAL. More relevant for grasping the overall degree of regulatory stringency stemming from the use of TLVs is the median AAL for those state and city programs that based their AALs on

TLVs (multiplied by a safety factor). These median AALs can best be evaluated and compared when translated into the number of cancer cases expected to occur among the exposed population. The third column of Table II presents residual risks in terms of expected cancer cases per million persons exposed over a lifetime at the median TLV-based AAL. These residual risks exceed 1,000 cancers per million persons exposed for cadmium (1,040), nickel and its compounds (1,420), propylene oxide (1,550), coke oven emissions (1,860), benzene (2,500), arsenic and its compounds (7,300), *N*-nitrosodimethylamine (21,000), asbestos (21,500), and ethylene dibromide (55,000).

Considerable controversy surrounds attempts to estimate risks of cancer stemming from environmental exposure to toxic substances such as those listed in Table II. Particularly controversial are cancer risk assessments for substances where data are available only from animal experiments to the exclusion of epidemiological evidence from humans. The quality of the evidence for the substances listed is quite good, however. These substances are all considered probable or confirmed human carcinogens by IARC based on an evaluation of available epidemiological studies. The last column presents the EPA's own cancer classification for each of the 19 substances; these classifications are very similar to their IARC counterparts. For seven of the 19 substances, the EPA assigned a classification of "A," indicating confirmed human carcinogen based on high-quality epidemiological evidence. Another three substances were classified as "B1," indicating the presence of limited human evidence, combined with sufficient animal evidence of carcinogenicity. Another seven are classified as "B2," indicating insufficient evidence of carcinogenicity in humans but with sufficient evidence in animals. Two substances were not ranked insufficient in the EPA classification system despite having been classified by the IARC.

Table III presents nongenotoxic health effects for 11 substances whose AALs were based on TLVs by at least one state or city air toxics program. These clinical effects were reported in published studies of workers whose exposure levels were at or below the TLV (seven cases) or above but not far above the TLV (four cases). The seven cases with adverse health effects at or below the TLV clearly demonstrate that TLVs cannot be assumed to approximate no observed effect levels (NOELs). A NOEL is the highest tested exposure level at which no effect is observed in toxicological studies of a particular substance. The four other cases are less conclusive but indicate that the TLVs in these cases provide at best a modest margin of safety. Particularly striking are the reports of asthma in workers exposed to styrene at one third the TLV, and to 2,4-toluene diisocyanate at one-half the TLV, and of foggy vision, corneal edema, and eye irritation among workers exposed to triethylamine at less than half the TLV. All the state and city air toxics programs applied safety factors to the TLVs for these substances. The median safety factor applied to the TLV-based AALs for these substances range from a low of 50 to a high of 300, with most below 60. It is impossible to ascertain the actual degree of risk posed to community residents caused by exposure at the TLV once it has been divided by one of these safety factors.

DISCUSSION

Threshold limit values were originally developed to control workplace rather than community exposures to toxic substances, and played an important role in early efforts to control work-related illness [Paull, 1984]. The ACGIH provided a forum for

TABLE III. Non-Genotoxic Health Effects of Exposure to Selected Substances Whose State and/or City Acceptable Ambient Air Levels (AAL) Are Based on Threshold Limit Values***Acetonitrile (5/8)**

Bronchoconstriction observed in 1 of 3 workers exposed to 40 ppm and on 1 of 2 workers exposed to 160 ppm for 4 hr. (TLV = 40 ppm = 70 mg/m³.) [Pozzani et al., 1959]. Median AAL safety factor: 50.

Carbon disulfide (6/10)

Objective neurological signs were found in 39 of 100 workers exposed for long periods to less than 10 ppm and in 16 of 16 workers exposed to 20 ppm. (TLV = 10 ppm = 30 mg/m³.) [Kleinfeld and Tabershaw, 1955; Rubin et al., 1950.] Median AAL safety factor: 80.

Carbon tetrachloride (5/15)

Liver dysfunction and headaches were reported in 15 of 17 workers exposed to 45 to 97 ppm and in workers exposed to 20 ppm. (TLV = 5 ppm = 30 mg/m³.) [Elkins, 1942.] Median AAL safety factor: 300.

Methyl chloroform (9/12)

Behavioral performance deficits were observed after exposure for 3 hr to 175 and 350 ppm. Narcosis and anesthesia were reported after exposure to 450–560 ppm. (TLV = 350 ppm = 1,900 mg/m³.) [Mackay et al., 1987; Stewart et al., 1969.] Median AAL safety factor: 50.

Nitrobenzene (8/11)

Methemoglobin was found in 39% of workers in a plant with exposures averaging nearly 6 ppm. (TLV = 1 ppm = 5 mg/m³.) [Pacseri et al., 1958.] Median AAL safety factor: 90.

Phosphine (7/9)

Bronchoconstriction, cough, nausea, diarrhea, and dizziness occurred in workers intermittently exposed to 3–35 ppm (averaging below 10 ppm). (TLV = 0.3 ppm = 0.4 mg/m³.) [Jones et al., 1964.] Median AAL safety factor: 50.

Styrene (8/14)

Asthma was observed in workers exposed to 62.7 mg/m³. (TLV = 50 ppm = 215 mg/m³.) [Moscato et al., 1987.] Median AAL safety factor: 130.

Tetrachloroethylene (9/18)

Narcosis was observed in 4 of 14 workers exposed to 100 ppm. (TLV = 50 ppm = 340 mg/m³.) [Stewart et al., 1970.] Median AAL safety factor: 100.

Toluene (10/14)

Decreased muscular coordination, pulse rate, and systolic blood pressure, and prolonged reaction time, fatigue, and sleepiness were observed in 3 of 3 workers exposed to 100 ppm and in 1 of 2 workers exposed to 50 ppm for 8 hr. Neurasthenic problems, including fatigue, short-term memory loss, and concentration problems, were observed in 30 workers respectively. (TLV = 100 ppm = 375 mg/m³.) [von Oettingen et al., 1942; Orbaek and Nise, 1989.] Median AAL safety factor: 55.

2,4-Toluene diisocyanate (6/10)

Asthma developed in 9 workers exposed to 0.002 ppm for less than 1 yr and in 12 workers exposed over 5 yr. (TLV = 0.005 ppm = 0.04 mg/m³.) [Venables, 1987.] Median AAL safety factor: 55.

Triethylamine (4/6)

Blue haze (foggy vision), corneal edema, and eye irritation were observed following exposures to 18 mg/m³. (TLV = 10 ppm = 40 mg/m³.) [Akesson et al., 1988.] Median AAL safety factor: 55.

*The ratio in parentheses after the name of each substance is the number of TLV-based AALs divided by the total number of AALs.

collecting and evaluating the meager epidemiological, toxicological, and exposure data that existed at the time. The Occupational Safety and Health Act of 1970 was in part designed, however, to provide a more scientifically based and publicly accountable alternative to private sector initiatives such as the ACGIH TLV committee. Bureaucratic inertia and industry resistance subsequently limited OSHA's standard setting, producing a void that the ACGIH was able to fill.

What was acceptable in the pre-OSHA era proved an anachronism after 1970, however. As documented by Castleman and Ziem [1988] using minutes from the TLV committee, TLVs for particular substances were heavily influenced by corporations with direct financial interests in the substances being evaluated. More recently, these investigators have identified 123 substances whose TLVs were assigned to representatives of the corporations who manufactured them [Castleman and Ziem, 1990]. Despite the claim that the TLVs represent "conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effect" [ACGIH, 1988], numerous epidemiological studies report adverse health effects at exposures equal to or less than the TLV. An analysis of the TLV documentation by Roach and Rappaport [1990] found widespread divergence between the findings of studies cited in the documentation and what the ACGIH TLV committee inferred from those same publications. Roach and Rappaport found that the TLVs often represent the exposure levels actually prevalent in major firms rather than levels at which no adverse health effects are reported. Ziem and Castleman [1989] surveyed four scientific journals and found 30 articles published between 1987 and 1989 that report adverse health effects among workers exposed at levels equal to or less than the TLVs.

The deficiencies of the TLVs would be of less public importance had not the governmental agencies responsible for control of toxic substances not increasingly relied on TLVs during the 1980s. The meager record of official standard-setting by OSHA during the early 1980s constituted an informal reliance upon TLVs, since the vast majority of existing OSHA standards had been adopted in 1971 explicitly based on TLVs [Mintz, 1984]. This reliance on TLVs by OSHA was formalized later in the decade when OSHA based its Air Contaminants Standard largely on TLVs [OSHA, 1989]. In so doing, OSHA consciously rejected the more stringent recommended exposure limits (RELs) developed by the National Institute for Occupational Safety and Health (NIOSH), despite OSHA's statutory mandate to rely on NIOSH recommendations. The ratio of TLV-based PELs to NIOSH RELs ranged up to 1,000, with a median of 2.5 and a mean of 71.4 [Robinson et al., 1991]. The Air Contaminants Standard largely ignored the carcinogen evaluations and recommendations by the IARC, the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services, and the EPA, in addition to NIOSH. A total of 67 substances were regulated under the Air Contaminants Standard based on non-cancer health effects despite having been designated as carcinogens by NIOSH and/or NTP [Paxman and Robinson, 1990].

As documented in this paper, the turn to TLVs during the 1980s was not limited to OSHA. The EPA informally encouraged states to develop air toxics programs during the early part of the decade knowing that this often implied reliance upon TLVs. By 1984, the EPA was signing memoranda of intent with individual states for referral of toxic substances. While acrylonitrile was the only substance actually referred to the states before the formal referral policy was shelved in 1986, the EPA discussed possible referral for some emission sources of benzene, butadiene, ethylene oxide, ethylene dichloride, chloroform, cadmium, methylene chloride, and chromium. This policy of referring toxic substances to TLV-based state air toxics programs occurred despite official ACGIH warnings against use of the TLVs for controlling environmental exposures. The ACGIH booklet containing the TLVs asserts: "These limits are intended for use in the practice of industrial hygiene as guidelines

or recommendations in the control of potential health hazards and for no other use, e.g., in the evaluation or control of community air pollution nuisances. . . .” [ACGIH, 1988].

One can only speculate as to the extent of referrals that would have taken place if there had not been such strong opposition from state air toxics programs, environmental organizations, and selected federal legislators. Insights can be obtained, however, by examining the Ambient Air Level guidelines developed by state and city programs using TLVs during the 1980s. State and city programs developed widely varying AAL guidelines for the same toxic substances. The ratio of maximum TLV-based AAL to minimum TLV-based AAL frequently exceeded 1,000. The risks to health posed by these TLV-based AALs were significant by any standard. Expected cancer cases for persons exposed to TLV-based AALs for acrylonitrile ranged from a low of 17 per million to a high of >17 per 1,000 (see Table I). Residual cancer risks exceeded 1000 cases per million persons exposed to the median TLV-based AAL for arsenic and its compounds, asbestos, benzene, cadmium, coke oven emissions, ethylene dibromide, nickel and its compounds, *N*-nitrosodimethylamine, and propylene oxide (see Table II). In contrast to the common assumption that TLVs represent NOELs for non-carcinogens, significant clinical effects have been reported in workers exposed at levels near the TLV for 11 substances whose AALs were based on TLVs and safety factors (see Table III).

The supreme irony in this delegation of responsibility to TLV-based state air toxics programs was that it occurred during the same period that the EPA's air toxics program was emphasizing the need for policy reliance on more rigorous scientific analysis. Regulatory policy during the late 1970s had sought to circumvent the lengthy delays associated with re-debate of basic scientific principles by proposing generic guidelines for evaluating toxic substances and, in particular, suspected carcinogens. Beginning during the 1980s, however, EPA began to advocate thorough discussion of basic scientific principles in each rule-making process. This policy reversal was most dramatic in the case of formaldehyde, where EPA considered opening case-by-case adjudication for such fundamental risk assessment principles as the relevance of experimental animal data for predicting human carcinogenesis [Ashford et al., 1983]. Other delays were engendered when EPA decided that all emissions standards must be approved, rather than simply reviewed, by its independent Science Advisory Board [GAO, 1983; Dwyer, 1990]. The 1986 EPA carcinogen policy abandoned the earlier interest in generic guidelines in favor of case-by-case re-evaluation of risk assessment principles for each suspect chemical [Latin, 1988].

The Clean Air Act Amendments of 1990 bring to a close this era of substantial reliance on Threshold Limit Values in U.S. air pollution policy. The 1990 Amendments require EPA to establish national emissions standards for 189 prominent toxic substances, including those discussed in this paper, over the coming decade. These new standards are to be based on “maximum achievable control technology” (MACT) rather than on the assurance of “an ample margin of safety,” embodying an exchange of regulatory depth for regulatory breadth [Robinson and Pease, 1991]. A similar exchange was made for toxic water pollutants in the 1977 amendments to the Clean Water Act [Hall, 1978; Schroeder, 1983]. Some observers have proposed a technology-based approach as a means of accelerating the pace of standard-setting for occupational exposures to toxic substances [Shapiro and McGarity, 1989].

There exists a strong possibility, however, that TLVs will continue to play a

part in public policies towards toxic substances. Technology-based emissions standards such as those mandated under the Clean Water Act and the Clean Air Act Amendments do not guarantee that residual risks are socially acceptable. A need remains for a health-based standard against which residual risks can be compared.

The Water Quality Act of 1987 amended the Clean Water Act to require that EPA develop a methodology for evaluating residual risks for toxic water pollutants [Liebesman and Laws, 1987]. The Clean Air Act Amendments of 1990 similarly mandate an evaluation of post-MACT residual risks. In both cases a clear Congressional preference is indicated for quantitative risk assessment as distinct from TLVs. Nevertheless, the possibility remains that EPA will set a low priority on the evaluation and control of residual risks. This would constitute an implicit policy of reliance upon state initiatives. It remains to be seen whether states continue to rely on TLVs or rather switch to quantitative risk assessment and other methodologies for establishing socially acceptable risk levels.

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