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Federal Regulation of the Halogenated Solvents

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ABSTRACT: The chlorinated cleaning solvents have drawn the attention of regulatory agencies in recent years because of their popularity in a wide variety of industries. Initiation of regulatory review is sometimes viewed by chemical users and the public as the beginning of highly restrictive regulation or a ban. Consequently, an irreversible market impact can occur before a regulatory decision is made. The regulatory and market history of trichloroethylene and perchloroethylene are traced from the 1960s to the present. Current regulatory activities concerning methylene chloride, trichloroethylene, perchloroethylene, 1,1,1-trichloroethane, and trichlorotrifluoroethane (CFC-113) are reviewed, as are the prospects for future federal regulation. State regulation of the solvents also is discussed, focusing on regulation of air toxics and Proposition 65 in California and air toxics regulation in New York.

KEY WORDS: halogenated solvents, chlorinated cleaning solvents, methylene chloride, trichloroethylene, perchloroethylene, 1,1,1-trichloroethane, trichlorotrifluoroethane, air toxics, Proposition 65

The Halogenated Solvents Industry Alliance (HSIA) is a group of over 200 companies involved in the use, distribution, and production of chlorinated solvents. HSIA has been working for over a decade for the reasonable regulation and safe and effective use of these solvents in their many applications.

Because of their popularity in a wide variety of industries and the resulting potential for widespread exposure, the solvents have drawn the attention of regulatory agencies in recent years. This regulatory scrutiny has led to control measures that reduce human exposure to the chemicals while allowing their continued use. Initiation of regulatory review has sometimes been viewed by chemical users and the public, however, as the beginning of highly restrictive regulation or even a ban on the use of the chemicals under consideration. Users may choose alternative solvents processes in expectation of restrictive regulation and the potential for enhanced product liability.

The announcement of a regulatory review of a particular chemical, therefore, can affect the market for that chemical. This irreversible market impact can occur long before a regulatory decision is made, and even if that decision is not to regulate.

Solvent Demand

The apparent U.S. demand (production plus imports minus exports) for five chlorinated solvents since 1960 is shown in Fig. 1. The shapes of these curves are determined by several factors, including regulatory activity, and reflect the significant increase in recycling and reuse of the solvents in recent years. The interaction between solvent regulation and use can be demonstrated most clearly in the case of trichloroethylene (TRI) (Fig. 2).

Until the late 1960s, trichloroethylene was the most widely used solvent for metal cleaning and degreasing. Even today, it is often used as a standard by which the performance of other degreasing solvents is judged. Sales of the solvent were particularly strong in the mid-1960s as a result of rising aerospace and military use during the Vietnam War [*1*].

Use of TRI declined in the early 1970s as solvent users responded to concern over the chemical's photoreactivity. During this time, several states imposed controls on emissions of volatile organic compounds (VOCs) to meet the national ambient air quality standard (NAAQS) for ozone established in 1971. By the time the Environmental Protection Agency (EPA) announced a recommended policy on the control of VOCs in 1977, sales of TRI had essentially leveled off.

Concern over TRI in groundwater also increased as our ability to detect small amounts of organic compounds improved in the 1970s. The low levels of TRI found in ground and drinking waters heightened public awareness of the chemical, and reflect past disposal techniques that have since been vastly improved.

In 1975, the National Cancer Institute issued a Memorandum of Alert on trichloroethylene indicating that the preliminary findings of a bioassay on the chemical showed carcinogenic activity in mice. Additional study of the carcinogenic potential of the chemical, however, has produced inconclusive results in laboratory animals. In the early 1980s, the American Conference of Governmental Industrial Hygienists (ACGIH) lowered its recommended 8-h time-weighted average (TWA) threshold limit value (TLV) for workplace exposure to 50 parts per million (ppm).

Increased usage of 1,1,1-trichloroethane in the 1970s corresponded with the decrease in demand for TCE and demonstrates the interrelationship among the solvents. The conversion to 1,1,1-trichloroethane proceeded through the mid-1970s as companies responded to toxicity questions about TRI (Fig. 2).

The demand curve for perchloroethylene, or perc, follows a much different course than that for TRI. Since 1960, the perchloroethylene market has been primarily defined by the dry cleaning and chlorofluorocarbon (CFC) production industries.

Although perchloroethylene was introduced in the dry cleaning industry in the late 1930s, it did not replace petroleum derivatives as the dominant dry cleaning solvent until the 1960s. As a result, the use of perchloroethylene increased steadily throughout the decade. Demand for perchloroethylene leveled off between 1972 and 1980 and has been declining since then.

The perchloroethylene market leveled off in the 1970s as a result of a decline in domestic dry cleaning as American preferences

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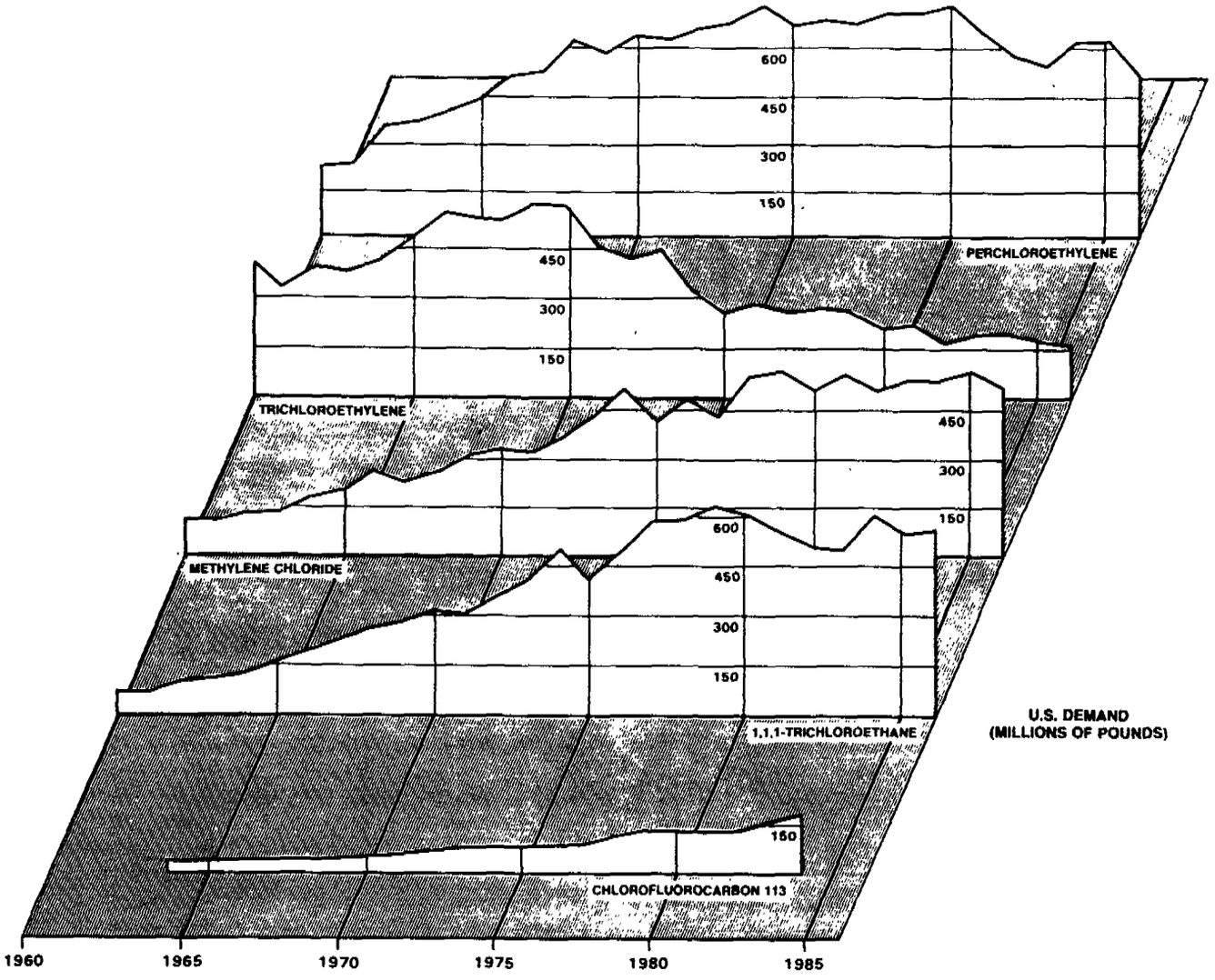

FIG. 1—*U.S. demand for the chlorinated cleaning solvents, 1960–1986. (Numbers are based on U.S. government statistics; numbers for CFC-113 are estimates of U.S. production.)*

shifted to wash-and-wear clothes. In addition, more efficient dry cleaning machines were being developed and installed. The increased use of fabrics requiring dry cleaning in the late 1970s did not result, however, in renewed sales of perchloroethylene. The reason for this appears two-fold [*1*]. Increased recycling of used perchloroethylene lowered demand for virgin solvent. At the same time, the Consumer Product Safety Commission (CPSC) was developing a carcinogen policy. The first chemical to be classified by the Commission was perchloroethylene. While CPSC withdrew its proposal to classify perchloroethylene as a carcinogen after its policy was overturned in court, the action may have had an effect on the market.

Perchloroethylene is no longer believed to contribute significantly to photochemical smog [*2*], although it remains classified as a non-exempt VOC. To meet VOC emission controls and as a matter of economy, dry cleaning equipment has become more efficient and the recycling of used solvent has increased considerably. The same is true, to a lesser degree, for the use of perchloroethylene in the metal cleaning industry. This decline in the use of perchloroethylene in dry cleaning and metal cleaning was somewhat offset by an increase in its use as an intermediate in the production of CFCs.

The use of perchloroethylene as a chemical intermediate in the production of CFCs, primarily CFC-113, has doubled over the last 10 years as production of CFC-113 has increased steadily (Fig. 3). Future demand for perchloroethylene to produce CFC-113 may be curtailed by the restrictions imposed by the Protocol on Substances that Deplete the Ozone Layer signed in Montreal in September 1987 [*3*] and the EPA regulations that will implement the Protocol's restrictions nationally [*4*].

Perchloroethylene also is used in the synthesis of CFC-114, CFC-115, CFC-116, and some of the alternative fluorocarbons. The production of CFC-114 and CFC-115 is restricted by the Montreal Protocol.

The foregoing examples illustrate the impact that public concern and regulatory review, regardless of its outcome, can have on the market for the chlorinated solvents. HSIA has been working actively in recent years to prevent premature, and often unneces-

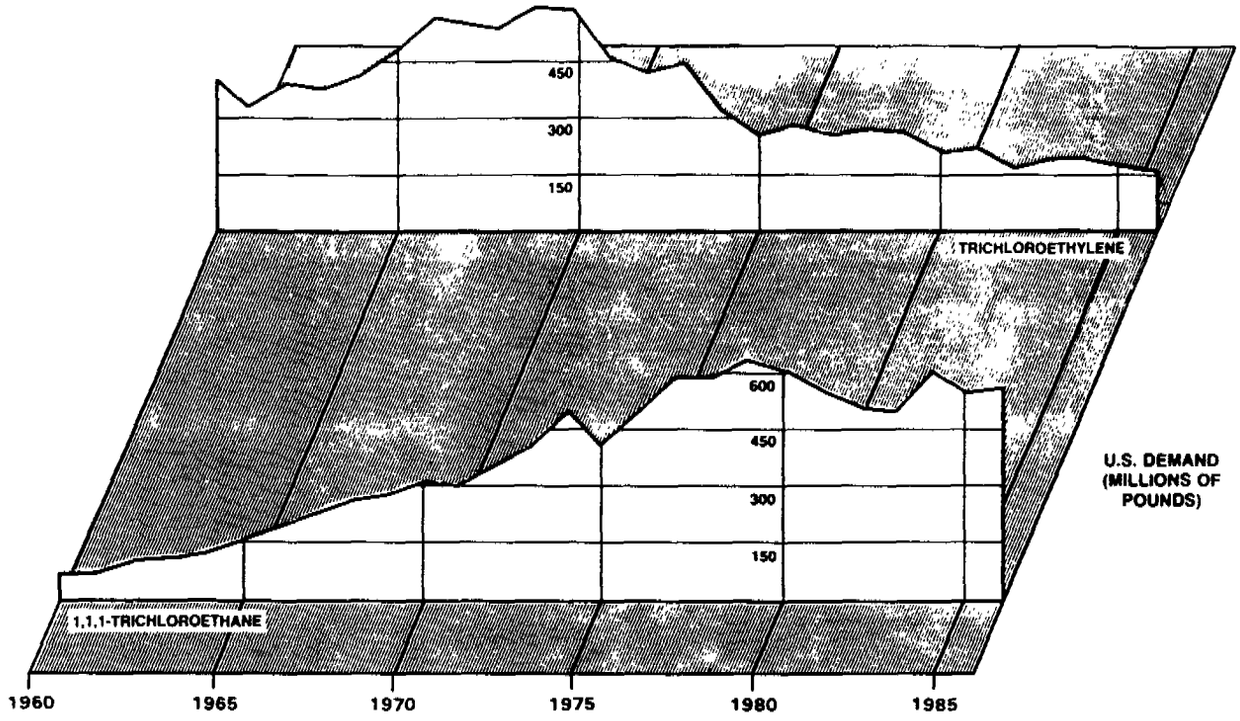

FIG. 2—*U.S. demand for trichloroethylene and 1,1,1-trichloroethane, 1960–1986.*

sary, movement away from these solvents as regulatory agencies review exposure to these common industrial chemicals. The remainder of this paper will describe current regulatory activities in the federal government and the prospects for future regulation. It also will briefly touch on regulation at the state level.

Federal Regulation of the Halogenated Solvents

Methylene Chloride

The results of a carcinogenicity bioassay performed by the National Toxicology Program (NTP) and released in 1985 indicated an increase in lung and liver tumors in mice and benign memory gland tumors in rats exposed to the chemical [5]. Following release of the NTP results, four federal agencies began rulemakings pertaining to exposure to methylene chloride in industrial or consumer use.

In August 1986, CPSC began a rulemaking to review consumer exposure to products containing methylene chloride. At the same time, CPSC, the Consumer Federation of America (CFA), and several industry representatives, including HSIA, participated in a steering committee aimed at developing a consumer education program to lower exposure levels to methylene chloride. In September 1987, CPSC published a final enforcement policy which established labeling principles for products containing methylene chloride [6]. These new labeling principles became effective on 14 March 1988. As of 14 September 1988, all consumer products containing more than 1% methylene chloride will be required to conform with these labeling guidelines.

Because of the wide range of consumer products containing methylene chloride, CPSC did not attempt to develop a single product label. It instead established three general principles for labeling that provide product formulators with flexibility in developing product-specific labeling. The first principle established by CPSC is that the label indicate a potential cancer hazard. The policy statement provides the following example of language that meets the requirements of the Federal Hazardous Substances Act (FHSA):

> *This product contains methylene chloride which has been shown to cause cancer in certain laboratory animal tests.* [6]

The second CPSC labeling principle is that the label explain the factors that control the degree of risk. A statement such as "risk to your health depends on level and duration of exposure" meets FHSA requirements according to the CPSC statement [6]. The third principle requires that the label explain precautions to be taken when using the product. The CPSC statement of policy offers the following language, developed by the steering committee, as acceptable under the FHSA for paint stripping products:

> *Use this product outdoors, if possible. If you must use it indoors, open all windows and doors or use other means to ensure fresh air movement during application and drying. Do not use in basement or other unventilated area.* [6]

The CPSC policy statement is a significant step forward and can serve as a model for future industry/government interaction on controversial issues. In conjunction with the new labeling requirement, HSIA, the National Paint and Coatings Association, and CPSC are jointly undertaking a comprehensive consumer education program, including a point-of-purchase brochure and a how-to article. This program will greatly enhance the overall effectiveness of the new labels and will improve consumer awareness of the precautions that should be taken when using these products.

In December 1987, CFA and the State of New York sued the

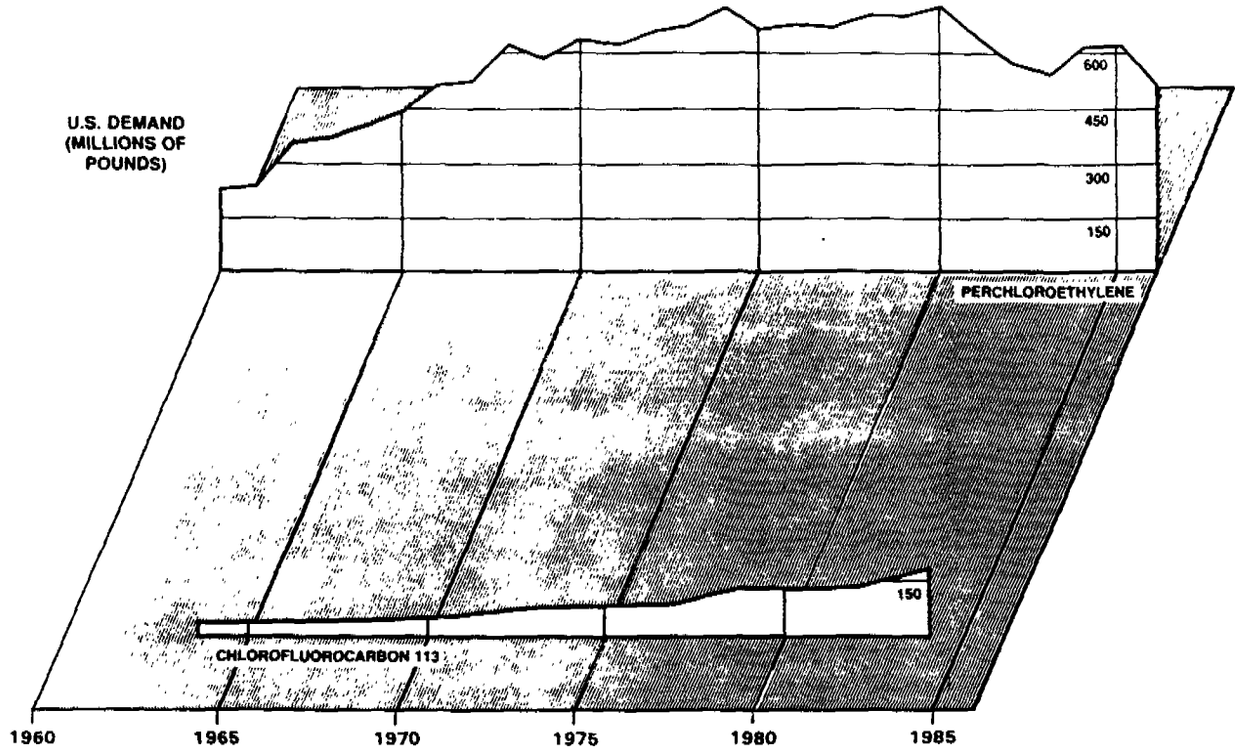

FIG. 3—*U.S. demand for perchloroethylene and CFC-113, 1960-1986.*

Commission for failure to respond to a 1985 CFA petition to ban the use of methylene chloride in consumer products. Following the Commission's formal denial of the petition for a ban on 14 June 1988, CFA and New York State withdrew their legal challenge. They have since filed suit challenging the Commission's decision.

In November 1986, the Occupational Safety and Health Administration (OSHA) issued an advance notice of proposed rulemaking to lower the 8-h TWA permissible exposure limit (PEL) for methylene chloride from the existing 500 ppm. OSHA is expected to issue a proposed rulemaking in late 1988 or early 1989. At present, OSHA has not indicated what the new occupational exposure limit will be. ACGIH's recommended TLV for methylene chloride was recently lowered from 100 to 50 ppm.

In December 1985, the Food and Drug Administration (FDA) proposed a ban on the use of methylene chloride as an ingredient in aerosol cosmetic products (i.e., hairsprays). While this proposal has not been made final, it appears that little or no methylene chloride is currently used in hairsprays or other cosmetic products. Also in this proposal, FDA indicated it would not prohibit the use of methylene chloride as a decaffeinating agent for coffee or lower the maximum permitted residue level for methylene chloride in decaffeinated coffee. This decision was challenged in a lawsuit filed by Public Citizen, the public interest group founded by Ralph Nader. The lawsuit was dismissed by the U.S. Court of Appeals in November 1987. Final action on the cosmetic part of the methylene chloride is expected in early 1989. Since the original 1985 proposal, FDA has significantly reduced its estimate of the health effects resulting from exposure to methylene chloride.

EPA also is interested in methylene chloride. Largely in response to the positive carcinogenicity tests of the National Toxicology Program, EPA initiated a priority review of methylene chloride under Section 4(f) of the Toxic Substances Control Act (TSCA). EPA subsequently announced that it intended to conduct, along with other federal agencies, an investigation to determine whether methylene chloride presents an unreasonable risk to human health. At the same time, EPA announced its intent to list methylene chloride as a hazardous air pollutant (HAP) under Section 112 of the Clean Air Act.

The Agency's Office of Air Quality Planning and Standards is currently collecting background information for a possible national emission standard for hazardous air pollutants (NESHAP) for the use of methylene chloride, perchloroethylene, and trichloroethylene in organic solvent cleaning (degreasing) equipment. The Agency is reviewing a variety of possible technological and work practice controls to determine their potential for reducing emissions of these three solvents from degreasers. It is not known if, or when, a NESHAP will be proposed. Regulation of methylene chloride and the other solvents under Section 112 is inappropriate in HSIA's view.

EPA subsequently established an interagency working group to look at methylene chloride and five other chlorinated solvents. The working group, chaired by EPA, includes representatives from CPSC, FDA, and OSHA, and is looking at four major use categories of the solvents including metal degreasing, dry cleaning, paint stripping, and aerosols. The working group is expected to release a draft strategy document for perchloroethylene use in dry cleaning in 1989. Similar documents for the other three applications also are being prepared.

Following release of the NTP results of the methylene chloride bioassay, EPA developed an Addendum to its Health Assessment Document (HAD) for the chemical [7]. At the same time, industry in the United States and Europe initiated a research program to

determine the reasons for the difference in response among laboratory animal species following methylene chloride exposure. The initial results of this research were submitted to EPA and the other agencies in 1986. Based on these new data, EPA developed a draft Update to the HAD Addendum for the chemical [*8*]. This new health assessment, while not final, will likely lower the previous upper-bound unit risk estimate for methylene chloride by at least a factor of ten. In reviewing the draft Update, the Agency's Science Advisory Board concluded that "the level of uncertainty is greater and that the hazard for [methylene chloride] may be less than that expressed by the Agency's classification system in its cancer risk assessment guidelines" [*9*]. The Agency recently announced its intent to review the cancer guidelines.

HSIA also has sponsored a study to investigate the potential for chronic (long-term) neurotoxic effects from methylene chloride exposure. The data collected from this study and subchronic studies were submitted to EPA and have been submitted for publication.

Perchloroethylene

In 1985, NTP released the results of a two-year inhalation study that indicated an increase in liver tumors in mice following exposure to perchloroethylene [*10*]. EPA staff subsequently drafted an Addendum to the HAD for perchloroethylene [*11*]. After reviewing the Agency's draft HAD Addendum, EPA's Science Advisory Board disagreed with the Agency's proposed listing of perchloroethylene as a "probable human carcinogen." The Board concluded that the evidence for carcinogenicity was limited and that the chemical should be considered a "possible human carcinogen." These conclusions were submitted to EPA Administrator Lee M. Thomas in January 1987 [*12*].

In August 1987, Administrator Thomas asked the Science Advisory Board to provide the Agency with further scientific advice on issues pertaining to the classification of perchloroethylene. The results of this second review were submitted to the Administrator in March 1988 [*13*]. The Board's Halogenated Organics Subcommittee, responsible for reviewing the laboratory evidence for perchloroethylene, apparently continues to believe that it should be considered a possible carcinogen. The Board's letter to the Administrator concluded, however, that the evidence for the chemical "lies on the continuum between [the probable and possible carcinogen categories] of EPA's risk assessment guidelines for cancer." Consequently, the Board recommended that EPA re-evaluate its classification system and its method for characterizing uncertainty. (A review is now underway.) The Board further recommended that the Agency review the possibility of revising its classification system to be more consistent with the terminology now used by the International Agency for Research on Cancer (IARC). Perchloroethylene is considered "possibly carcinogenic to humans" by IARC [*14*].

In December 1985, EPA announced its intent to list perchloroethylene as a hazardous air pollutant under Section 112 of the Clean Air Act. National emission standards for the use of perchloroethylene in dry cleaning and degreasing are currently under development. Perchloroethylene is one of the six solvents under review by the interagency chlorinated solvent working group. A regulatory strategy document on perchloroethylene dry cleaning is expected to be released in 1989.

Both CPSC and EPA have expressed concern over indoor air exposure to perchloroethylene, although no rulemaking has been initiated. Such exposure is believed to result from dry cleaning products brought into the home. HSIA has organized preliminary discussions with EPA and the dry cleaning industry regarding indoor air exposures to perchloroethylene. It is generally felt that exposure to perchloroethylene can be reduced by removing solvent residual before the clothes leave the dry cleaning establishment. Under discussion is the conduct of studies designed to examine and develop methods for reducing perchloroethylene residual in clothes.

In a June 1988 proposal to revise the PELs for a large number of compounds, OSHA has proposed lowering the 8-h TWA for perchloroethylene from 100 to 50 ppm and to establish a short-term (15-min) exposure limit, or STEL, of 200 ppm for the chemical. The levels proposed by OSHA are the TLVs recommended by ACGIH and are supported by HSIA.

Trichloroethylene

EPA announced its intent to list trichloroethylene as a hazardous air pollutant in December 1985 and currently is developing a national emission standard for its use in solvent degreasers. Trichloroethylene is among those solvents under review by the interagency chlorinated solvent working group, chaired by EPA.

EPA staff recently prepared a draft Addendum to the HAD for trichloroethylene which considered the results of several studies completed since EPA's initial health assessment [*15*]. The Agency's Science Advisory Board reviewed the trichloroethylene draft Addendum and concluded, as it did for perchloroethylene, that the evidence for carcinogenicity falls between the possible and probable carcinogen categories of EPA's risk assessment guidelines [*16*]. The Board further concluded that, because of the moderateness of tumor responses in laboratory animals and the uncertainties of most of the end points of the laboratory tests, the animal evidence for the carcinogenic potential of trichloroethylene falls "between sufficient and limited evidence." In its review of the same evidence, IARC concluded that trichloroethylene was "not classifiable as to its carcinogenicity to humans" [*14*].

In June 1988, OSHA proposed lowering the PEL for trichloroethylene from 100 ppm to the 25 ppm level recommended by the National Institute for Occupational Safety and Health (NIOSH). HSIA opposes lowering the PEL to 25 ppm and has urged OSHA to adopt the TLVs recommended by ACGIH: 50 ppm for the 8-h TWA and 200 ppm for a 15-min STEL.

1,1,1-Trichloroethane (Methyl Chloroform)

1,1,1-Trichloroethane is not listed as a VOC under the Clean Air Act and is therefore exempt from all but a few State Implementation Plans to achieve the NAAQS for ozone. Furthermore, EPA announced its intent not to list the chemical as a hazardous air pollutant under Section 112 of the Clean Air Act in December 1985. In many applications, 1,1,1-trichloroethane has served as a substitute for other solvents.

A long-term carcinogenicity bioassay conducted at the Dow Chemical laboratories was negative. Studies conducted by NTP have been seriously flawed or inconclusive. To supplement the existing data base on the chemical, HSIA sponsored developmental toxicity studies of inhaled 1,1,1-trichloroethane in response to an EPA test rule issued under Section 4 of TSCA. Results of these studies indicate no adverse effect in the offspring of pregnant females exposed to high concentration levels. Moreover, HSIA cur-

rently is involved in discussions with EPA concerning an HSIA-planned series of neurotoxicity tests on 1,1,1-trichloroethane.

In August 1987, EPA's Office of Air Quality Planning and Standards requested information to review the need for a new source performance standard under Section 111 of the Clean Air Act for degreasers using 1,1,1-trichloroethane and CFC-113. Whether regulations will ultimately be developed is uncertain.

While 1,1,1-trichloroethane is not included in the group of chemicals regulated under the Montreal Protocol on Substances that Deplete the Ozone Layer or in EPA's regulations to implement the Protocol, it was included in Senate proposals to establish national CFC controls. These bills have not progressed beyond Committee consideration, and both EPA and the Department of State are opposed to unilateral action to control production of CFCs and related compounds beyond international restrictions. Methyl chloroform is an effective alternative to CFCs in certain applications.

Chlorofluorocarbon 113

Trichlorotrifluoroethane, or chlorofluorocarbon 113 (CFC-113), is included in those chemicals subject to the restrictions of the Montreal Protocol on Substances that Deplete the Stratospheric Ozone Layer. The Protocol, developed under the auspices of the United Nations Environmental Programme, calls for a freeze on the use of CFCs at 1986 levels by 1989. By 1994, the Protocol requires that CFC production and consumption be reduced to 80% of 1986 levels. By 1999, production on consumption would be reduced by 50% of 1986 levels. Somewhat higher levels of production (but not consumption) would be permitted in certain circumstances. The Protocol took effect on 1 January 1989.

In December 1987, EPA proposed regulations that would implement the Montreal Protocol nationally. The regulations do not go further than the controls called for in the Protocol. Restrictions would be imposed on companies producing and importing CFC-113, but would not be imposed on individual users. The regulations were finalized in August 1988.

While demand for CFC-113 has grown steadily in the last ten years, primarily for use in the electronics industry, controls on production of CFCs may restrict future use of the chemical. It is possible, however, that CFC producers may adjust their production of other controlled CFCs to accommodate CFC-113 demand in this high value application. Methylene chloride and 1,1,1-trichloroethane also are used in the electronics industry [*17*].

State Regulation of the Halogenated Solvents

While we expect any future federal controls on solvent use to be reasonable, some of the responsibility for pollution control has been transferred to, or assumed by, the states. As previously noted, perchloroethylene and trichloroethylene are subject to VOC controls under State Implementation Plans implementing the NAAQS for ozone. Methylene chloride and 1,1,1-trichloroethane are excluded from VOC controls in all but a few states.

EPA's 1985 strategy for regulating air pollutants, often referred to as "air toxics," calls for greater state responsibility in implementing Section 112 of the Clean Air Act. There has been increasing political pressure on the states to regulate air toxics. EPA's strategy is leading to some significant problems, the foremost of which is the absence of an overall strategy for states to follow in regulating chemical emissions. As the General Accounting Office of the U.S. Congress concluded in March 1987, there is no mechanism for assuring consistency among the resulting state programs [*18*].

Very few state and local governments have the resources to properly assess the potential health effects of a chemical. Consequently, regulatory agencies at these levels of government have attempted to use the simplest approach possible. While some states regulate all toxic chemicals using the same procedure, many are treating chemicals listed as known, probable, or even possible carcinogens differently from chemicals that are not listed. When a state determines that a chemical is to be treated as a carcinogen, the regulations for that chemical are often much more stringent.

While a number of examples of efforts to impose stringent controls on solvent use on the state level could be used, this paper focuses on two of the leaders, California and New York.

California

Under California's Health and Safety Code, the Air Resources Board (ARB) is required to submit a list of candidate toxic air contaminants to the Department of Health Services (DHS) for health effects review. In developing this list, ARB staff use the identification of a chemical as a "probable human carcinogen" or as having "sufficient evidence of carcinogenicity" by EPA or IARC as criteria for candidacy. Methylene chloride, perchloroethylene, and trichloroethylene are under review for identification as toxic air contaminants. ARB and DHS staff are currently preparing health and exposure assessments for methylene chloride, and will be preparing reviews of the health effects data for perchloroethylene and trichloroethylene in the future. ARB placed 1,1,1-trichloroethane in the category of chemicals for which health effects data are not sufficient to support review.

As a result of concern over emissions of chemicals that have not yet been evaluated by ARB, the California Air Pollution Control Officers Association has developed an air toxics source assessment manual [*19*]. The manual, developed in conjunction with the EPA regional office, is intended to be used by the state's 44 air management districts in reviewing permits for these chemicals. While intended as an interim source of information, the manual would establish strict controls on new source emissions.

Moreover, individual California air districts are considering controls on new sources of certain chemicals, including the three solvents. In the Los Angeles area, the South Coast Air Quality Management District (SCAQMD) has proposed an air toxics regulatory program directed at 37 chemicals for which the State of California or EPA have developed cancer risk estimates. SCAQMD has delayed additional consideration of a proposed rule until a later date. Further north, the Bay Area Air Quality Management District is considering an air toxics risk screening policy for several chemicals and sources.

The major area of activity in California is the listing of chemicals "known to the state to cause cancer or reproductive toxicity" under the Safe Drinking Water and Toxic Enforcement Act (Proposition 65) and the resulting warning and notification requirements. Methylene chloride (inhalation only), perchloroethylene, and trichloroethylene were officially added to the Proposition 65 list of chemicals on 1 April 1988, based on evidence for carcinogenicity in at least one animal test. In testimony before the Proposition 65 Scientific Advisory Panel, HSIA had questioned whether these data indicated that the solvents were likely to be human carcinogens.

The "clear and reasonable" warning requirements for these chemicals will become effective on 1 April 1989. Prohibitions on

discharge will take effect on 1 December 1989. The Act provides for exemptions for discharges that are in compliance with applicable permits or regulations, and that will not cause listed chemicals to enter drinking water sources in "significant amounts," defined as exposures that can be shown to pose no significant risk. Determinations by DHS of significant risk levels for these chemicals were issued in late 1988.

Also included on the Proposition 65 list are a few chemicals found in commercial formulations of the HSIA solvents as stabilizers or contaminants. HSIA and its members are currently seeking clarification of the applicability of Proposition 65 to the small quantities of these chemicals found in solvent formulations.

New York

New York's Department of Environmental Conservation plans to revise its acceptable ambient levels (AALs) for several chemicals, including four chlorinated solvents. The new AALs would be used as guidelines for reviewing emission permits. For those facilities that do not meet the new guidelines, control requirements would be necessary to reduce emissions. The severity of the technological control would be determined by the chemical's weight-of-evidence classification by EPA. Controls would range from reasonably available control technology, or RACT, for Category C substances ("possible human carcinogens") to best available control technology, or BACT, for Category B substances ("probable human carcinogens") to the lowest achievable emission rate, or LAER, for Category A substances ("human carcinogens"). Thus, the higher the EPA category, the greater the cost to the business for the control of the emissions.

For the chlorinated cleaning solvents, acceptable levels would be drastically reduced. For methylene chloride, the acceptable average annual concentration would be reduced from 1167 to 0.37 $\mu g/m^3$. That is a three thousand-fold reduction in emissions of methylene chloride. Sources unable to meet the new AAL would be required to install BACT. For trichloroethylene, the proposed guideline revision amounts to an almost four thousand-fold reduction in allowable emissions. For perchloroethylene, a two thousand-fold reduction would be required, and for methyl chloroform a reduction of 100-fold is proposed.

There is no doubt that these new levels, if implemented, would adversely impact businesses in the state of New York. The new guideline for methylene chloride, for example, would affect 660 businesses in New York as permits are renewed. The state, however, currently is revising its assessment for the chemical based on EPA's latest health assessment.

Summary

HSIA strongly supports the incorporation of the latest scientific and technical information in developing reasonable regulations, where regulation is appropriate. HSIA, and its member companies, have established themselves as leaders in the promotion and conduct of metabolism, pharmacokinetic, and neurotoxicity testing of the solvents to provide federal and state regulators with an enhanced scientific understanding. This leadership has vastly improved the ability of regulators to assess the potential health effects resulting from exposure to the solvents. Consequently, it has resulted, and will continue to result, in regulatory controls that will protect human and environmental health while allowing continued safe and effective use of the solvents.

Future demand for virgin quantities of the chlorinated cleaning solvents is expected to continue to decline as a result of the recycling and reclamation of solvents prompted by regulatory and economic factors. Federal and state review of the use of, and exposure to, the solvents is likely to continue. HSIA has made considerable progress, however, in our discussions with the regulatory agencies. Most importantly, EPA has begun to consider pharmacokinetic and metabolic data in performing its health assessments, information that ultimately will be reflected in any regulatory controls. This is demonstrated most clearly in the case of methylene chloride.

Continuing questions about the significance of laboratory animal data to human risk for certain chemicals has prompted EPA to re-evaluate its method of assessing carcinogenic risk to humans. This re-evaluation should affect existing federal rulemaking initiatives impacting the solvents and may be reflected in state regulatory activities.

New regulatory frontiers for the solvents appear to be neurotoxicity and indoor air exposure. HSIA is leading the way in both areas. We have performed neurotoxicity studies of methylene chloride and have submitted the results to EPA. Similar studies of 1,1,1-trichloroethane may be conducted.

In conjunction with EPA and representatives of the dry cleaning industry, HSIA will be involved in evaluating methods to reduce exposures to the solvents in the home. This study should result in a substantial reduction in indoor air exposure to perchloroethylene.

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