GENERAL COUNSEL'S REPORT
TO THE
VINYL INSTITUTE EXECUTIVE BOARD

We are pleased to present this report to you on the status of matters involving our activity on issues which effect the Vinyl Institute. Recent developments on issues covered in our last report for the December 1992 Board Meeting are discussed here, as well as new issues that have come into focus subsequently.

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I. U.S. ENVIRONMENTAL PROTECTION AGENCY

A. Proposed Hazardous Organic NESHAP (HON) Establishes Maximum Achievable Control Technology (MACT) for Hazardous Air Pollutants

On December 31, 1992, EPA released its proposed rules for *National Emission Standards for Hazardous Air Pollutants for Source Categories; Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry and Seven Other Processes*, 57 *Fed. Reg.* 62,608 (Dec. 31, 1992) (commonly referred to as the "Hazardous Organic NESHAP" or "HON"). The proposed rule would regulate the emissions of certain organic Hazardous Air Pollutants (HAPs) from Synthetic Organic Chemical Manufacturing Industry (SOCMI) production sources and from equipment leaks at sources in the following processes: chlorine production; styrene/butadiene rubber production; pesticide production; chlorinated hydrocarbon use; pharmaceutical production; and miscellaneous butadiene use. The rules require sources to achieve emission limits reflecting the application of the Maximum Achievable Control Technology (MACT) consistent with Section 112(d) of the Clean Air Act Amendments of 1990 (CAA).

Keller and Heckman will be working with the VI Health Safety and Environment Committee to formulate comments in response to the proposed rules. Written Comments are due on or before March 31, 1993. The comments will conclude that the current vinyl chloride standard is more stringent than the HON proposal, and, therefore, the vinyl chloride standard, not the HON, will govern EDC/VCM/PVC production. This position is consistent with the draft comments of the Chemical Manufacturers Association (CMA).

B. EPA Releases Final Rule on Labeling of Ozone Depleting Compounds

The Environmental Protection Agency (EPA) recently released the Final Rule implementing the labeling requirements of Section 611 of the Clean Air Act Amendments of 1990 (CAA). A special *SPI Compliance Alert* has been circulated to all VI members which outlines the Rule in considerable detail. Section 611 of the CAA requires that containers of ozone-depleting chemicals, and products containing or manufactured with an ozone-depleting chemical, bear the following warning:

> WARNING: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms human health and environment by destroying ozone in the upper atmosphere.

All products containing or manufactured with "Class I" and "Class II" substances are subject to the labeling Rule. Class I substances include chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform; hydrochlorofluorocarbons (HCFCs) are Class II substances. Other compounds which are likely to be subject to labeling and phase-out

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regulations in the near future include methyl bromide and hydrobromofluorocarbons (HBFCs).

Under the new regulations, every container of a Class I or Class II substance must be labelled. Certain products which contain a Class I ozone depleting substance (*e.g.*, refrigerators, foam plastic insulation, medical products, *etc.*) must also bear a warning label. EPA followed the VI's suggestion and exempted from these labeling requirements products which contain "trace" quantities of a Class I substance as an impurity where the Class I substance serves no useful purpose in and of itself. As anticipated, EPA did not establish a specific exempt "trace" amount, but leaves this to the discretion of the manufacturer.

EPA did agree with the VI that products with trace quantities of unintended residues or impurities resulting from a chemical reaction in the manufacturing process are exempt from labeling. For example, trace quantities of carbon tetrachloride produced unintentionally in the chlorination of water, or in the manufacture of chlorine, are not covered by the rule. However, the exemption does not apply to a product containing a trace quantity of a controlled substance where the controlled substance is specifically and deliberately introduced during manufacture; if the use of the controlled substance is essential to the manufacture of that product, "such as with CCL4 as an explosion prevention measure in the manufacture of chlorine," the product is *not* exempt from labeling. Only those trace quantities associated with the inadvertent production of a controlled substance or unintended residues are exempt from labeling.

One particular aspect of the rule which may have serious adverse consequences for VI member companies concerns the Agency's interpretation of who is the "manufacturer" of a product containing an ozone depleting substance. Wholly owned subsidiaries and parent corporations are considered to be a single manufacturer under the Rule. This could have significant consequences for vertically integrated manufacturers of chlorine. The VI and other industry groups will be asking EPA for further guidance on whether labeling is still required if a further "transformation" takes place.

Another issue drawing VI comments involved the production of Class I substances as coincidental, unavoidable by-products (CUBP) of other manufacturing processes. CUBPs are exempt from the labeling requirement under the new rule, but the definition of CUBP severely limits its application. According to EPA, CUBP is a "coincidental unavoidable by-product of a manufacturing process that is immediately contained and destroyed by the producer, using a maximum available control technology with a destruction efficiency of 99.99%." This is the definition of MACT destruction efficiency which was adopted in the EPA's final rule on *Protection of Stratospheric Ozone*, 57 *Fed. Reg.* 33754, 33788 (July 30, 1992) (phase-out rules).

VI and other industry commentors argued that the MACT definition should include any of the five destruction technologies recently approved by the parties to the Montreal Protocol on Substances that Deplete the Ozone Layer in the Copenhagen Amendments. The Agency did not adopt those suggestions, but has indicated that it will accept comments on whether it should exempt from the labeling requirements those five destruction technologies approved in the Copenhagen Amendments -- liquid injection incineration, reactor cracking, gaseous/fume oxidation, rotary kiln incinerators, and cement kilns.

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The labeling requirements for both products containing and products manufactured with ozone depleting chemicals, as defined by the rule, take effect May 15, 1993. The EPA has agreed that products which are "warehoused" should be "grandfathered" and not subject to labeling. Thus, no product manufactured before May 15, 1993 will be subject to the requirements of Section 611. In addition, the Agency has acknowledged that due to the short time frame involved between issuance of the final rule and the effective date of the rule, it will be "the Agency's policy to take no enforcement action for matters occurring within the first nine months following the publication of these regulations."

C. EPA Expected to Release Rules on Accelerated Phase-out of Ozone Depleting Chemicals and Significant New Alternatives in First Quarter of 1993

We are still awaiting publication of EPA's final rules governing the accelerated phase-out of ozone-depleting compounds (ODCs), and the Significant New Alternatives Program (SNAP). Last summer, EPA issued proposed rules to govern the phase-out of the production and consumption of ODCs, including carbon tetrachloride (CTC). Because of the broad wording of that proposal, the phase-out could be interpreted to apply to processes in which ODCs are unintended byproducts, and when present as catalysts or coincidental participants.

The VI submitted comments on last year's proposal, urging EPA to exempt from the ODC phase-out those processes in which ozone-depleting substances are created as an unintentional byproduct of the manufacturing process, as well as processes in which ODCs are created as an intermediate, and either consumed or destroyed. We have been told informally that the EPA staff believes that this issue will be resolved in an interpretation to be issued by the technical committee to the Montreal Protocol on Substances that Destroy the Ozone Layer. In November 1992, representatives from 80 countries (including the U.S.) met in Copenhagen to discuss various interpretations of the Protocol, and to adopt a stricter environmental policy on the phase-out of CFCs. Under the agreement which was made a part of the Protocol, the U.S. agreed to accelerate the deadline for ceasing production of CFC's from the year 2000 to December 31, 1995. No formal announcement of this meeting has yet been issued.

In a related issue, EPA continues to make slow progress in its SNAP program. SNAP is intended to encourage the rapid transition from the use of CFCs to substances thought to be less harmful to the stratospheric ozone layer while minimizing the hardship this transition will present to users and consumers of affected products. SNAP was developed to implement Section 612 of the CAA. That provision requires EPA to prohibit the introduction of any CFC substitutes that may have adverse effects on human health and the environment, if the Agency has determined that there are other more environmentally acceptable substitutes. SPI supports the broadest possible listing of acceptable substitutes to encourage the transition from CFC's.

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II. STATE ENVIRONMENTAL ACTIVITIES

A. Federal District Court Strikes Down Standard for "Recyclable" Claims in California's Environmental Advertising Law, and Limits Application of the Law to "Commercial Speech," but Upholds Remainder of Statute

On December 23, 1992, the United States District Court for the Northern District of California issued its decision in the labelling lawsuit in which SPI was a leading plaintiff along with a number of other trade associations representing the advertising, food, soap and detergent, and paper industries. *ANA, et al. v. Lungren*, No. C-92-0660 (N.D. Cal. Dec. 23, 1992). The suit was brought to challenge the constitutionality of California's environmental advertising law. Cal. Bus. & Prof. Code Section 17508.5. The industry association plaintiffs alleged that Section 17508.5 violates the First Amendment of the U.S. Constitution and is unconstitutionally vague in violation of the First Amendment and the Due Process Clause of the Fourteenth Amendment.

The Court found that the statute meets the First Amendment standard for permissible regulation of commercial speech, but ruled that the state's standard for use of the term "recyclable" is invalid because it is unconstitutionally vague. The Court noted that although the law defines a consumer good as "recyclable" if it can be "conveniently recycled" in all California counties with more than 300,000 people, "the statute offers no guidance as to what recycling programs satisfy the 'conveniently recycled' requirement." *ANA* slip opinion at 29. Therefore, the Judge concluded that "it is not sufficiently clear to a manufacturer or distributor of ordinary intelligence, what exactly the statute prohibits. Due to the potential for criminal sanctions, including incarceration, the absence of any standard for 'conveniently recycled' wrecks this portion of section 17508.5 on the shoals of vagueness." *ANA* slip opinion at 29.

The Court held that the statute can only be applied to representations by a manufacturer or distributor about a particular product and not to general "advertorials," "infomercials" or association-sponsored ads addressing attributes of general classes of products. Thus, "[p]laintiffs are free to encourage recycling, or to editorialize about the environmental benefits of biodegradable plastics or comment on the desirability of ozone friendly products." *ANA* slip opinion at 12. That holding resolved one of SPI's major concern, *i.e.*, that the law might unduly restrict the new institutional advertising being run by the industry's American Plastics Council (APC).

The District Court concluded that California's asserted interest in enacting the law, *i.e.*, ensuring truthful environmental advertising and encouraging recycling and environmentally sound packaging, is substantial. The Court held that the necessary "reasonable fit" (required by recent Supreme Court cases) between the legislature's ends and the means chosen to accomplish those ends did exist here. Finally, the Court concluded that Section 17508.5 directly advances the asserted governmental interest and was not unduly restrictive or broad in light of the state interest involved and the nature of the regulated speech. *ANA* slip opinion at 18.

The Court's ruling is quite troublesome in one respect, particularly from the viewpoint of those whose labeling or ads are designed in part to promote recycling. The

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Court implied that no amount of qualifying language would save a claim on a specific product or in an advertisement if the accessibility and extent of recycling for that product does not meet the standards set by the statute. Under this questionable interpretation of the statute, even carefully qualified claims that would pass muster under the Federal Trade Commission's (FTC) *Guides for the Use of Environmental Marketing Claims* could be deemed to violate California's law.

A detailed analysis of this decision is available upon request.

III. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

A. Court of Appeals Denies OSHA Request for Rehearing on PEL Rules; OSHA Considering Next Step

On July 7, 1992, the U.S. Court of Appeals for the Eleventh Circuit ruled that workplace exposure limits for 428 substances adopted by the Occupational Safety and Health Administration (OSHA) under its 1989 Air Contaminants Rule (54 *Fed. Reg.* 2332 (January 19, 1989)) are invalid because the Agency failed to give sufficient supporting evidence to justify the standards adopted. The Air Contaminants standards were challenged by the AFL-CIO as too lax while industry groups, including the Vinyl Institute, alleged that many of the standards were too restrictive, such as that for ethylene dichloride (EDC).

OSHA is now seeking approval from the U.S. Solicitor General to appeal to the Supreme Court. While a final resolution of this appeal is being decided, the court's order rescinding the standard is on hold, and OSHA's 1989 rule is in effect. If the Supreme Court hears an appeal of this ruling, it could be a year or more before any final decision is reached. If the government does not seek Supreme Court review or if the Supreme court does not accept the case, the permissible exposure limit (PEL) for ethylene dichloride (EDC) will revert from 1 ppm to the pre-1989 value of 50 ppm. However, there is a possibility the Congress will pass legislation enacting the 1989 limits later this year.

B. OHEIC Drafts Guidelines to Assist Members in Preparing Material Safety Data Sheets for Plastics

The Occupational Health and Environmental Issues Committee's (OHEIC) MSDS Task Force is preparing materials to guide SPI members in drafting material safety data sheets (MSDS) for plastics and plastics products. The guidelines are intended to supplement the Chemical Manufacturer Association's (CMA) MSDS Manual and the American National Standards Institute (ANSI) standard. The project was also undertaken in anticipation of revisions to OSHA's Hazard Communication Standard expected to be issued late this year. That rule is expected to attempt to clarify the MSDS requirements applicable to complex mixtures and products that release hazardous chemicals during processing and use; it is also expected to clarify the definition of an "article" subject to MSDS requirements and may include a standardized MSDS form in response to comments by industry last year. Many aspects of the long-pending proposed rule are addressed by the CMA MSDS Manual, but the focus of CMA's efforts has been on chemical substances and mixtures, not plastics.

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C. OSHA Issues Final Rule on Permit-Required Confined Spaces Standard

On January 14, 1993, OSHA issued its long-awaited Confined Spaces Standard, to be codified at 29 C.F.R. 1910.146. The final rule becomes effective April 15, 1993. A memorandum summarizing the requirements of the Standard is available from Keller and Heckman upon request; it explains important aspects which may not be readily apparent from the language of the Standard.

Appendix A of the Standard provides a useful flow chart on implementation of the Standard. By April 15, 1993, the employer must:

1) identify all permit-required confined spaces ("permit spaces") in its facilities;
2) inform exposed employees and contractors of those spaces by signs or other effective means;
3) institute measures to prevent unauthorized entry into those spaces; and
4) develop and implement a written permit space entry program to protect authorized entrants from permit space hazards.

Initial training, commensurate with the individual's duties, must be provided before the individual is first assigned duties covered by the Standard. Before allowing entry into a permit space the employer must, pursuant to the permit space entry program:

1) identify and evaluate the hazards of the space;
2) develop and implement appropriate entry, monitoring and rescue procedures;
3) train and equip affected employees; and
4) inform contractors of the hazards identified and any procedures developed for dealing with them.

Less stringent requirements apply in two situations:

1) where the atmospheric hazard is controlled by continuous ventilation; and
2) where the non-atmospheric hazard is eliminated prior to entry.

Finally, the employer must review the effectiveness of its program at least annually.

The Standard requires practices and procedures to protect individuals in General Industry from the hazards of entry into a subcategory of "confined spaces" known as "permit-required confined spaces." The term "confined space" means a space that:

1) is large enough and so configured that an individual can make a full body entry and perform assigned work;
2) has limited or restricted means for entry or exit (for example, tanks, vessels, silos, storage bins, hoppers, vaults, and pits); and
3) is not designed for continuous employee occupancy.

The term "permit-required confined space" or "permit space" means a confined space with one or more of the following characteristics:

1) contains or has a potential to contain a hazardous atmosphere;

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2) contains material that may engulf an entrant;
3) has an internal configuration likely to trap or asphyxiate an entrant; or
4) contains any other recognized serious safety or health hazard.

IV. PROPOSITION 65

A. California Environmental Protection Agency Agrees to Repeal Food and Drug "Safe Harbor" Provision

The California Environmental Protection Agency (Cal EPA) announced on December 28, 1992, that it has reached an agreement to settle the 1988 lawsuit challenging the regulation that exempts foods, drugs, cosmetics and medical devices containing Proposition 65 carcinogens that comply with Food and Drug Administration standards from the warning requirements of the law, pending the adoption of permanent "no significant risk levels" (NSRL's) for the carcinogens. *AFL-CIO, et al. v. Deukmejian*, No. 502541 (Sacramento County Super. Ct., filed May 31, 1988) (*"Duke II"*). Cal EPA Administrator James Strock announced that under the terms of the settlement agreement, the state will repeal Section 12713 effective July 1, 1993. The state has agreed to pay $800,000 in attorneys fees to the Environmental Defense Fund, Natural Resources Defense Council (NRDC) and other environmental and labor groups, who collectively brought the *Duke II* lawsuit.

Since its adoption in 1987, the food and drug "safe harbor" has served a valuable purpose in reducing the uncertainty and complexity of establishing compliance with Proposition 65 in cases where a product complies with FDA requirements and is, therefore, safe, even in the absence of a second safety evaluation by California. Cal EPA has narrowed the scope of the exemption considerably in the last year. The demise of the safe harbor provision will make it more difficult for some companies to establish compliance with the law and, if need be, defend that determination, particularly in light of the burden on the accused party to prove the exposure is safe.

In a December 28, 1992 press release, NRDC declared that as a result of the settlement "[d]ozens of carcinogens will now be forced out of foods, cosmetics and other consumer products, as the people intended." Thus, there is at least the potential that repeal of the exemption will trigger a certain amount of "bounty hunter" activity.

B. State Sets Exposure Limits for 177 Proposition 65 Carcinogens, Including Vinyl Chloride; Vinyl Institute Comments on Limit for Vinyl Chloride

The California Office of Environmental Health Hazard Assessment (OEHHA) has amended Section 12705 of the Proposition 65 regulations to establish permanent "no significant risk" levels (NSRL's) for 177 Proposition 65 carcinogens, including vinyl chloride (3.0 micrograms (μg)/day for all routes of exposure).[1] As part of the amendment, the state

[1] Among other notable chemicals for which NSRL's have been set are cadmium (0.05 μg/day -- by inhalation), methylene chloride (200 μg/day -- by inhalation), arsenic (0.06 μg/day -- by inhalation), trichloroethylene (50 μg/day -- by ingestion, 80 μg/day by

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has transferred all chemicals (37) that previously had interim NSRL's under Section 12711 to Section 12705. At the same time, NSRL's have been set under Section 12705 for 140 substances based on the state's so-called expedited risk assessment procedure.[2] The effect of the amendment is to remove 177 chemicals, including vinyl chloride, from the scope of the food and drug "safe harbor" provided in Section 12713, since the safe harbor is an interim measure and does not apply to substances that have a permanent NSRL under Section 12705.

The amended Section 12705 now contains a three-tiered hierarchy of NSRL's. First, levels based on *de novo* risk assessments by California or preexisting assessments reviewed by the state are set forth in Section 12705(b). Vinyl chloride is in this category. Second, exposure levels based on previous state or federal risk assessments are listed in 12705(c). Third, exposure limits based on expedited risk assessments by California are contained in 12705(d). A level set under Section 12705(b) supersedes a subsection (c) or (d) level. A Section 12705(c) NSRL supersedes a subsection (d) level.

On July 16, 1992, the Vinyl Institute filed comments on the proposed NSRL for vinyl chloride. In the comments, the Vinyl Institute expressed concern that the state's approach to risk assessment does not afford a complete or adequate review of the toxicity of individual chemicals. The Institute argued that the 3.0 μg NSRL is far below the appropriate exposure limit needed and that California's level unduly exaggerates the cancer risk posed by vinyl chloride.

OEHHA has also announced that it might consider listing vinyl chloride and several other significant chemicals as reproductive toxins during 1993.[3]

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inhalation), 2,3,7,8-tetrachlorodibenzo-p-dioxin (0.000005 μg/day), hexavalent chromium (0.001 μg/day -- by inhalation) and butylated hydroxyanisole (BHA, 4,000 μg/day).

[2] These levels were determined through the state's application of an expedited procedure to derive cancer potency values for certain listed substances. The procedure relies on a Carcinogen Potency Database on 1050 chemicals developed by Gold et al.

[3] The other potential reproductive toxins include acrylamide, benzene, carbon tetrachloride, ethylene thiourea, methylene chloride, and trichloroethylene. Although all of these substances are regulated as carcinogens under Proposition 65, in light of the statutorily required thousand-fold safety factor for reproductive toxins there is the potential that the permissible daily exposure limit for them as reproductive toxins would be lower than their no significant risk level as carcinogens.

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