The Vinyl Institute

A Division of The Society of The Plastics Industry, Inc.

May 19, 1989

TO: VI Legal Committee
VI Health, Safety & Environment Committee

RE: <u>EPA Radionuclides NESHAPs Rulemaking</u>

Enclosed are comments filed on May 15th on EPA's proposed rulemaking for radionuclide NESHAPs.

The comments, as you will notice, are largely similar to those we filed in the benzene rulemaking.

Meredith N. Scheck

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Assistant Director

MNS/pmb
enclosure

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May 15, 1989

Central Docket Section (A-130)
ATTN: Docket No. A-79-11
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Proposed Rule for National Emission Standards for Hazardous Air Pollutants; Radionuclides; 54 Fed. Reg. 9612 (March 7, 1989)

Dear Sir or Madam:

On March 7, 1989, the U.S. Environmental Protection Agency (EPA) published a notice of proposed rulemaking (NPR) for radionuclide National Emission Standards for Hazardous Air Pollutants (NESHAP). The proposed rule tracks the regulatory issues presented in EPA's proposed rule on emission standards for benzene (53 Fed. Reg. 284,496); namely, the radionuclide proposal examines four policy approaches in determining hazardous air pollutants emission standards to provide "an ample margin of safety to protect the public health." Although specifically addressing radionuclide emissions, EPA makes it clear that the "final policy approach and the relative weight it gives to the various risk measures and uncertainties may become the framework for future NESHAPs decisions." 54 Fed. Reg. at 9,613.

The policy approach selected is intended to make EPA's actions consistent with <u>Natural Resources Defense Council, Inc. v. EPA</u>, 824 F.2d 1146 (1987) ("<u>Vinyl Chloride</u>"). As a party to the <u>Vinyl Chloride</u> case, the

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Society of the Plastics Industry, Inc. (SPI)[1/] and its Vinyl Institute is pleased to submit comments on this Notice of Proposed Rulemaking. In general, SPI supports Approach A, the case-by-case risk assessment approach which considers all health information and risk factors as the only proposed approach consistent with the Vinyl Chloride decision and the mandates of the Clean Air Act.

A. SPI-Vinyl Institute Interest

Principally through the Vinyl Institute, SPI has extensively participated in the NESHAPs decision processes under Section 112 of the Clean Air Act. This included the initial National Emission Standard for vinyl chloride, 41 Fed. Reg. 465640 (Oct. 21, 1976); the proposed amendments to the vinyl chloride standard, 42 Fed. Reg. 29006 (June 7, 1977); and the EPA's notice withdrawing the 1977 proposal and simultaneously proposing a new set of revisions to the vinyl chloride standard, 40 C.F.R. § 61.60 et. seq., 50 Fed. Reg. 1182 (Jan. 9, 1985).

More significant to this rulemaking, the Vinyl Institute participated as an Intervenor-Respondent in Natural Resources Defense Council, Inc. v. EPA, 824 F.2d 1146 (D.C. Cir. 1987). The Vinyl Institute's comments and briefs submitted in the Vinyl Chloride proceedings addressed specific areas now under consideration by the EPA in this radionuclide emissions proposal, including: (1) risk determination, (2) acceptable level of risk, and (3) ample margin of safety.

[1/] SPI, the major national trade association of the plastics industry, is a corporation organized under the Not-for-Profit Corporation Law of the State of New York. Its 2,000 member companies and individuals and 49 operating units include those who supply raw materials; process or manufacture plastics or plastics products; and engineer or construct molds or similar accessory equipment for the plastics industry. The majority of SPI members are the processors and converters of plastic resins into end products which represent 75% of the dollar volume sale of plastics in this country.

Members of the Vinyl Institute include Air Products & Chemicals, the BFGoodrich Chemical Group, Borden Chemical, Certain-Teed, Dow Chemical U.S.A., Occidental Chemical, PPG Industries, Shintech and VISTA Chemical. Members of the Vinyl Institute account for approximately 82% of the domestic production of vinyl chloride and 85% of the domestic production of polyvinyl chloride.

The Court of Appeals remanded the _Vinyl Chloride_ case to the Agency for further action. Therefore, the Vinyl Institute and SPI have a particular interest in the outcome of this rulemaking which will ultimately influence the Agency's handling of _Vinyl Chloride_ remand.

B. The _Vinyl Chloride_ Case Requires Adoption of Approach A

The _Vinyl Chloride_ decision determined that the initial step in setting emission standards for hazardous air pollutants is determining whether a "risk" to health is posed by a particular emission level. (". . . the Administrator's decision must be based on an expert judgment with regard to the level of emission that will result in an 'acceptable' risk to health" _Vinyl Chloride_ at 1165.) To be consistent with the approach established under the _Vinyl Chloride_ decision, EPA must evaluate all scientific data in determining "acceptable risk to health" and then "decide what risks are acceptable in the world in which we live." _Vinyl Chloride_ at 1165. As the Agency acknowledges, Approach A, the case-by-case approach, is the only approach that permits consideration of all relevant health information, both qualitative and quantitative. The Vinyl Institute believes Approach A is the most consistent with the _Vinyl Chloride_ decision and is the most scientifically sound approach for determining acceptable risk.

In determining acceptable risk as outlined by the _Vinyl Chloride_ decision, the court concluded that Congress directed EPA to provide an "ample margin" of safety to account for any scientific uncertainties in deciding what constitutes a safe level. Congress provided the EPA with discretionary powers under the statute to deal with these scientific uncertainties. While the Court concluded that the Congressional mandate to provide "an ample margin of safety" "to protect public health" requires the Administrator to make an initial determination of what is "safe," the "decision does not require a finding that safe means 'risk-free' . . . ."[2] Moreover, the court's opinion, prior case

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[2] **Zero risk is not** required by Section 112. As the Supreme Court **has held:**

> "[S]afe" **is** not the equivalent of "risk-free." There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment;

(continued...)

law and common sense all suggest that EPA consider whatever credible health information is available at the time a decision is made.

> In this regard, the Administrator must determine that inferences should be drawn from available scientific data and decide what risks are acceptable in the world in which we live.

Vinyl Chloride, 824 F.2d at 1,165.

The other proposed approaches, B, C and D respectively, focus on a single parameter of risk that is extremely inflexible and creates risk values based upon boundary confidence limits. These approaches directly conflict not only with the approach set forth by the Vinyl Chloride decision, but with EPA's own Guidelines for Carcinogen Risk Assessment. 51 Fed. Reg. 33992 (1986). In August 1988, the Agency announced its intent to review the 1986 Guidelines for Carcinogenic Risk Assessment. 53 Fed. Reg. 32656 (Aug. 26, 1988). The Notice emphasized that one purpose of the Guidelines was to "encourage research and analysis that will lead to new risk assessment methods and data" which would be used to improve and revise the Guidelines. The Guidelines were developed and published with the understanding that risk assessment is an evolving scientific undertaking and that continued study would lead to change. Thus, reliance upon a fixed number or a single numerical risk criterion under this rulemaking is inappropriate.

2/ (...continued)
nevertheless, few people would consider these activities "unsafe." Industrial Union Dept. AFL-CIO v. API, 448 U.S. 607, 642 (1980). See also Ethyl Corp. v. EPA, 541 F.2d 1, 18 n.33 (D.C. Cir. 1976), cert. denied, 426 U.S. 941 (1976). Indeed, if zero risk were required, the Administrator would not have need to exercise any judgment in setting emission levels, which is specifically what Section 112 requires him to do. Perhaps for this reason, even the panel dissent rejected NRDC's zero risk argument. See NRDC v. EPA, 804 F.2d 710, 735-36 (D.C. Cir. 1986), vacated, 810 F.2d 270, 824 F.2d 1146 (1987).

C. Conclusion

SPI and its Vinyl Institute believe regulation of National Emission Standards for Hazardous Air Pollutants must be on a case-by-case approach. Given the inherent limitations of a single parameter of risk, in the face of evolving scientific information on the hazards associated with various substances and the high degree of uncertainty associated with absolute risk, a case-by-case approach and assessment of all available health information is the only appropriate approach in determining acceptable risk to protect public health.

SPI appreciates this opportunity to offer comments on this rulemaking. We would be happy to provide additional support for the comments that the Agency might need. Whatever the outcome of this proceeding, artificial limitations on the type of scientific or technical information that the Agency will consider for the remanded vinyl chloride standard must be viewed as arbitrary and improper.

Sincerely,

Margaret Rogers /CNR

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Director
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