

DRAFT

CONFIDENTIAL
April 1, 1981

DRAFT EPA TOXIC SUBSTANCES CONTROL ACT PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify responses to potential EPA regulatory activity under the Toxic Substances Control Act (TSCA) affecting VCM/PVC.

PRESENT
SITUATION:

1. EPA promulgates and enforces regulations which affect VCM/PVC under TSCA.
2. EPA is developing the following rules under TSCA: Section 4(a) (testing), Section 5(a) (Pre-Manufacturing Notification (PMN) and Significant New Use Regulations (SNUR)), Section 6(a) (labeling), Section 8(a) (reporting), Section 8(c) (allegations of adverse effects), Section 8(d) (health and safety studies), and Section 8(e) (substantial risks). Each of these has a potential impact on VCM/PVC.
3. Under Section 4(a), EPA may determine whether it has insufficient data to properly regulate VCM/PVC. Currently, the Agency is behind schedule in evaluating Interagency Testing Committee (ITC) recommended substances for testing. It is improbable that VCM/PVC would be subject to a Section 4(a) rule unless a correlation between VCM and a new human health hazard becomes apparent.
4. Under Section 8(b) (chemical inventory) EPA made an arbitrary two percent exemption for comonomers in a reaction formula that produces high molecular weight polymers, such as PVC. This exemption may not apply.
5. EPA has proposed PMN regulations under Section 5. SPI has commented on the proposals, and maintained that structural

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polymers should be considered articles even when they are in particle form. Present indication is that EPA may react favorably to SPI comments on this point. Final regulations are expected to be promulgated in mid-1981.

6. Due to the multitude of PVC uses, it is unlikely that PVC would be subject to a SNUR under Section 5(a).
7. Under Section 6(a), EPA can require labeling to warn of human health and environmental hazards. While EPA was coordinating its efforts with OSHA, in November 1980, EPA terminated its joint labeling effort with OSHA. Separate EPA rules on labeling are not currently expected. However, CMA has furnished EPA's Office of Toxic Substances with a proposed rule relating to labeling and is urging EPA action on this proposal.
8. Section 8(a) directs EPA to promulgate rules that require manufacturers or processors to furnish reports on chemical substances. SPI has commented on the proposed reporting rule, objecting to its burdensome nature and the sales and customer information provisions. EPA anticipates promulgation of a final rule in mid-1981.
9. EPA has issued a proposed rule under 8(c) that will require recording and reporting of allegations that products are harmful to the environment or human health. SPI has commented on the burden of the proposed regulation.
10. Guidelines under 8(e) concerning evidence of significant risk have been issued; the information that must be submitted and the mechanism of submission are described.
11. Under 8(d), the Agency can require manufacturers or processors to furnish available health safety studies. EPA promulgated final rules under Section 8(d), but withdrew them following legal action by industry. VCM/PVC were not included in the first rule; we can anticipate EPA requiring studies to be submitted at a later date.

ACTION
UNDERWAY:

1. Continued SPI participation in proposed rulemakings under 5(a), 8(a) and 8(c).
2. Health Committee continues to collect and summarize new health and safety studies.
3. Proposed labeling rules issued by OSHA in January, 1981, were withdrawn in February, 1981. They are treated under a separate contingency plan, and are currently being evaluated by SPI.

WHAT IF:

1. EPA proposes additional toxicological testing under Section 4(a) of VCM or PVC.
 - a. Impact on industry - high
 - b. SPI influence - medium
2. EPA requires a PMN for minor constituents in PVC reaction formulation, or SNUR for VCM/PVC under Section 5(a).
 - a. Impact on industry - high
 - b. SPI influence - medium
3. EPA promulgates a proposed rule under Section 6(a) requiring labeling of VCM/PVC.
 - a. Impact on industry - medium to high
 - b. SPI influence - dependent on proposed agency action
4. EPA requires production, sales and customer reports under Section 8(a) for VCM/PVC.
 - a. Impact on industry - very high
 - b. SPI influence - medium to high
5. EPA promulgates a final rule under Section 8(c) containing the onerous reporting requirement of the proposed rule on allegations of harm.
 - a. Impact of industry - high
 - b. SPI influence - medium

6. A rule is proposed under Section 8(d) requiring submission of health and safety studies relating to VCM/PVC.
 - a. Impact on industry - variable
 - b. SPI influence - minimal
7. A person submits a substantial risk notice under Section 8(e) including VCM/PVC.
 - a. Impact on industry - high
 - b. SPI influence on subsequent EPA proceedings variable

TRACKING:

Direct Agency contacts
 Keller and Heckman
 Trade and associated press
 Speeches and announcements by EPA
 Public news media
 SPI Washington office
 Other trade associations
 Non-SPI companies
 Federal Register

TRIGGERS:

1. EPA proposes rules which include VCM/PVC for: testing under 4(a), PMN or SNUR under 5(a), labeling under 6(a), or reporting under 8(a) or 8(c).
2. EPA requires health and safety studies under 8(d).
3. A notice of substantial risk is received by EPA under 8(e).

CONTINGENCY
 PLANS:

General

1. Alert PVC Safety Group.
2. Evaluate proposal or petition, or assess new health data.

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3. Coordinate with SPI Toxicology Committee.
4. Meet with Agency personnel.
5. Participate in administrative proceedings.
6. Seek favorable comments from OMB, other groups, and individual firms including non-SPI members.
7. Pursue court review if appropriate.

For Specialized What Ifs:

1. If EPA proposes a test rule for VCM or PVC under 4(a), SPI should join forces with CMA's Subcommittee on Testing for Improved Efficiency in formulating industry response.
2. If Agency proposes PMN's or SNUR's under 5(a), PVC Safety Group should identify SPI member companies which would be affected, and form appropriate task group to address issues raised by the proposed rule.
3. If EPA promulgates labeling rules under 6(a) which affect VCM/PVC, the appropriate SPI committee should share evaluations with established CMA committees that are currently tracking this activity.
4. If EPA requires volume and customer reporting under 8(a) the appropriate SPI committee should be divided, with part of the committee studying the regulations from the manufacturers point of view, and the remaining part of the committee studying the same proposed rule from a processors point of view.
5. If a notice of substantial risk is submitted under 8(e) that appears to affect other SPI members, an ad hoc committee should be formed to address the issues and industry actions resulting from this submission.

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DRAFT EPA RESOURCE CONSERVATION AND RECOVERY ACT PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify responses to potential EPA regulatory activity under the Resource Conservation and Recovery Act (RCRA).

PRESENT
SITUATION:

1. EPA promulgates and enforces regulations addressing chemical substances pursuant to five acts: Resource Conservation and Recovery Act (RCRA), Federal Water Pollution Control Act, also known as the Clean Water Act (CWA), Clean Air Act (CAA), Toxic Substances Control Act (TSCA), and the Safe Drinking Water Act (SDWA).
2. RCRA regulations must not be inconsistent with requirements for substances imposed under the CWA or SDWA and their implementing regulations.
3. EPA is intensifying regulation of toxic substances under all acts, and is focusing on chronic rather than acute toxicity.
4. In August 1979, EPA proposed to list waste PVC from the manufacture of coated fabrics and PVC sludge from the manufacture of polyvinyl chloride. SPI submitted extensive comments on these listings. EPA has not repropoed these two listings or taken final action.
5. Present RCRA listings include: (1) heavy end from the distillation of vinyl chloride in VCM production (K020), and (2) VCM as a commercial chemical product or manufacturing chemical intermediate which would be a toxic hazardous waste if discarded or intended to be discarded in its pure or off-spec form; (3) VCM is also listed in Appendix VIII to Part 261 as a hazardous constituent.

6. Potential listings. The listing of VCM as a hazardous constituent in Appendix VIII means that additional listings of VCM-containing waste is probable. Generic listing of chlorinated hydrocarbon wastes have potential impact on the production of VCM, EDC, ethyl chloride and PVC. Potentially affected wastes include: reactor clean-up wastes, fractionation bottoms, distillation bottoms, spent catalysts, batch residues, and solution residues.
7. If EPA follows past practice any new listing will be in interim final form, effective in six months, but giving 60 days to comment before the listing is promulgated in final form.
8. Although not specified, the inclusion of VCM suggests that the basis will be the toxicity/carcinogenicity of VCM.
9. Potential listing of chlorinated hydrocarbon wastes could potentially drag a plant's entire waste water treatment system into the hazardous waste requirements. A formal rulemaking petition to delist one or all of these wastes would be required. Delisting would be difficult for VCM.
10. Disposal of PVC sludge on landfills presents both air and groundwater contamination concerns.
11. Recent animal studies suggest tumors for relatively low-level ingestion of VCM.
12. EPA developing national groundwater strategy.
13. The Reagan Administration is conducting a review of all RCRA regulations.

WHAT IF:

EPA lists chlorinated hydrocarbon wastes as a hazardous waste.

- a. Impact on industry - very high
- b. SPI influence - medium

TRACKING:

Direct Agency contacts

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Keller and Heckman

Federal Register

Other trade associations such as CMA, AIHC,
Chamber of Commerce and Business Roundtable

Trade and associated Press

TRIGGERS:

EPA lists a particular substance or class of substances related to VCM/PVC production as a hazardous waste.

A RCRA "citizen petition" is filed with EPA for rulemaking of concern to the PVC industry.

CONTINGENCY
PLANS:

1. EPA lists VCM/PVC-related waste under Section 261.11(a)(3) (individual determination that a particular substance is hazardous waste).
 - a. Alert PVC Group.
 - b. Mobilize SPI membership to compile relevant data to contest listing.
 - c. Utilize CMA comments on the May 1980 regulations.
 - d. Argue that more than simple presence of a substance in any quantity or form is required before a waste can be listed under Section 261.11(a)(3).
 - e. Encourage helpful comments from other associations and individual firms including non-SPI members.
 - f. Participate in administrative proceedings.
 - g. Consider petitioning for judicial review within 90 days from the date of the promulgation of the list.
 - h. Consider petitioning EPA for amendment or repeal of the listing.
2. In the event EPA lists VCM/PVC-related wastes under authority of Section 261.11(d) (generic listings) we should follow the plan listed under

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No. 1 above. In addition, the right of EPA to generically list waste under Section 261.11(b) has been challenged in the pending RCRA litigation, and intervention or an amicus brief by SPI should be considered.

3. Response to a citizen petition to EPA for a rulemaking of concern to the PVC industry should be similar to that listed in 1 and 2 above.
4. Recent VCM animal studies suggest tumors at relatively low levels using ingestion as route of exposure. These studies are being reviewed by the PVC Health Committee.
5. SPI should review and consider commenting on EPA's emerging nationwide ground water strategy, which will have an important impact on disposal methods for VCM-containing wastes.

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DRAFT EPA SAFE DRINKING WATER ACT PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify possible responses to potential EPA regulatory activity under the Safe Drinking Water Act (SDWA) that would effect VCM/PVC.

PRESENT
SITUATION:

1. EPA promulgates and enforces regulations under five relevant acts: Clean Air Act (CAA), Clean Water Act (CWA), Toxic Substance Control Act (TSCA), Resource Conservation and Recovery Act (RCRA), and Safe Drinking Water Act (SDWA).
2. Under SDWA, EPA identifies contaminants which may have an adverse effect, and sets maximum contaminant levels for drinking water.
3. In 1975, EPA and FDA signed a Memorandum of Understanding that FDA would exercise jurisdiction over bottled drinking water under the SDWA.
4. In setting standards, EPA considers exposure to contaminants in other media, including piping.
5. Current regulations establishing maximum contaminant levels for chlorinated hydrocarbons do not include VCM.
6. Ambient water quality criteria for vinyl chloride were published by EPA in October 1980.
7. Current information indicates that the quantity of VCM that migrates from PVC pipe into drinking water is well below the one in a million risk level identified in the EPA water quality criteria document.

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8. The Criteria and Standards Division of EPA's Office of Drinking Water is currently evaluating the need for a vinyl chloride standard under the SDWA.

ACTION
UNDERWAY:

The National Sanitation Foundation (NSF) has established standards and test methods for PVC pipes. NSF is aware of EPA's current activity and is submitting documents and background information on VCM migration into drinking water from PVC pipe. Keller and Heckman is coordinating the submission of information with NSF.

WHAT IF:

EPA proposes a maximum contaminant level for vinyl chloride in drinking water.

TRACKING:

Direct Agency contacts

Keller and Heckman

National Sanitation Foundation

Other trade associations

Federal Register

Trade and associated press

TRIGGERS:

EPA staff recommends regulation of vinyl chloride under the SDWA.

CONTINGENCY
PLAN:

EPA proposes regulation of vinyl chloride under the SDWA.

- a. Alert Group.
- b. Evaluate proposal; coordinate with SPI Plastics Pipe Institute and NSF. Compare proposal to known levels of VCM in PVC-piped water.
- c. PVC Group meets, discusses nature of comments to be presented to Agency.
- d. Meet with EPA personnel and submit comments.
- e. Seek favorable comments from OMB, other groups and individual firms including non-SPI members.

- f. If EPA adopts a regulation of VCM under the SDWA, consider judicial review.

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DRAFT CONSUMER PRODUCT SAFETY COMMISSION PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

- PURPOSE: To identify responses to potential Consumer Product Safety Commission (CPSC) regulation that may affect vinyl chloride or polyvinyl chloride.
- SITUATION:
1. CPSC is an independent regulatory commission with jurisdiction over consumer products. Its authority does not extend to motor vehicles, aircraft, boats, pesticides, foods, drugs or cosmetics.
 2. PVC is used in many consumer products.
 3. Under CPSC regulations, PVC used in wearing apparel is subject to a flammability standard under the Flammable Fabrics Act.
 4. Self-pressurized products intended or suitable for household use may not contain VCM as an ingredient or a propellant under CPSC regulations.
 5. In 1979, CPSC announced a program to identify carcinogens in consumer products. The policy statement was subsequently withdrawn, and no further CPSC action is presently expected.
 6. PVC is one of the plastics products involved in a CPSC study that will focus on the flammability and combustion toxicity of plastics. The study might result in proposals to regulate certain uses of PVC. Regulatory action may entail the development of a flammability test method or standard in conjunction with the National Bureau of Standards (NBS). SPI has been in liaison with the CPSC through the SPI Coordinating Committee on Consumer Safety (SPI-CCCS), some of whose members represent the PVC industry.

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ACTIONS
UNDERWAY:

1. SPI's Coordinating Committee on Consumer Safety maintains liaison with CPSC and NBS during flammability study.
2. PVC Group or outside Lawyer's Committee may collect and maintain flammability data in conjunction with pending fire litigation.

WHAT IF:

CPSC adopts a flammability test method or standard for PVC used in construction, electrical insulation, furnishings and other consumer products.

- a. Impact on industry - varies with test or standard
- b. SPI influence - medium to high

TRACKING:

Direct Agency contacts

Keller and Heckman

Other trade associations

Federal Register

Trade and associated press

TRIGGERS:

NBS proposes flammability test method.

CPSC considers endorsement of flammability test method.

CPSC considers establishment of a plastics flammability standard.

CONTINGENCY
PLAN:

CPSC or staff proposes adoption of flammability test or standard.

- a. Alert Group.
- b. Evaluate proposal; draw on SPI-CCCS analysis and PVC litigation data.
- c. Coordinate with SPI-CCCS.
- d. Submit comments to CPSC, if appropriate.
- e. Seek favorable comments from OMB, other groups and individual firms including non-SPI members.

- f. Consider judicial review if regulation is finalized.

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DRAFT OSHA PLAN

SPI PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify possible responses to potential OSHA action that would effect VCM/PVC.

PRESENT
SITUATION:

1. OSHA established the current workplace standard of 1 ppm 8-hour TWA (and 5 ppm 15-minute TWA) in October, 1974, on the basis that the standard was feasible, although possibly technology-forcing.
2. There is no current movement at OSHA to tighten the standard. OSHA did request information on VCM and PVC in December 1979. SPI filed voluminous comments. OSHA has taken no action stemming from this.
3. PVC respirable dust is regulated as any other dust. A British study suggests that excessive exposure may cause adverse effects on the lungs.
4. OSHA proposed labeling regulations for hazardous chemicals on January 16, 1981, but the proposal was withdrawn on February 12, 1981.
5. In December 1978, OSHA requested information on ethylene dichloride (EDC) (1, 2-dichloroethane). Since that time, EDC has appeared on OSHA's Candidate List for further review pursuant to the Generic Cancer Policy.
6. The OSHA Generic Cancer Policy is being reevaluated by the Reagan Administration. Meanwhile, review proceedings in the court of appeals have been stayed.

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7. Regulation in other countries: 1977 British standard of 10 ppm 8-hour TWA; 1978 EEC alarm threshold of 15 ppm for mean values measured over a one hour period.
8. Post-1974 health data shows that the actual incidence rate for cancer in workers exposed to VCM is lower than projected rate.
9. Update of VCM Mortality Study by CMA will be underway in 1981.

ACTION
UNDERWAY:

SPI, together with AIHC, is pursuing court review of the Generic Cancer Policy.

WHAT IF:

1. OSHA attempts to lower the vinyl chloride standard or apply the generic cancer policy to EDC or VCM through rulemaking.
 - a. Impact on Industry - medium to high
 - b. SPI Influence - medium to high
2. OSHA begins investigation or rulemaking regarding PVC respirable dust.
 - a. Impact on Industry - varies with regulation
 - b. SPI Influence - medium to high
3. OSHA repropose labeling regulations.
 - a. Impact on Industry - medium
 - b. SPI Influence - medium
4. OSHA proposes additional regulations on PVC additives.
 - a. Impact on Industry - varies with regulation
 - b. SPI Influence - medium to high

TRACKING:

Direct agency contacts
 Keller & Heckman
 Daniel P. Boyd and Co.
 Federal Register

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Trade and associated press

NIOSH

Other associations - CMA, AIHC, Chamber of
Commerce and Business Roundtable

ACGIH

OSHA priority lists under Generic Cancer Policy

Contacts with non-SPI companies

TRIGGERS:

New health data produced

OSHA requests information

OSHA announces a proposed rulemaking

OSHA amends Cancer Policy

CONTINGENCY
PLANS:

General

1. Alert PVC Safety Group.
2. Assess health data.
3. Evaluate proposal. Assess economic and technological feasibility; prepare cost/benefit analysis.
4. Lobbying activities as appropriate.
5. Meet with OSHA personnel.
6. Participate in administrative proceedings.
7. Seek favorable comments from OMB, other groups, and individual firms including non-SPI members.
8. Pursue court review if necessary.

For Specified What Ifs:

1.
 - a. Challenge revision to VCM standard by focusing on lack of need; support by worker health records.
 - b. Use Maltoni data and latest information on angiosarcoma world-wide.

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- c. Utilize Health and Lawyers Committees.
- 2. a. Evaluate critically any health hazard allegation for PVC dust and recommend appropriate action.
- b. Verify dust exposure levels in all segments of the PVC industry.
- c. Evaluate possible dust exposure reductions.
- d. Recommend that producers advise customers.
- e. Evaluate acceptability of regulation.
- 3. a. Coordinate with CMA on labeling proposal. Ensure protection of proprietary information.
- b. Consider filing SPI comments.
- c. Enlist support of other groups, i.e., food, rubber, specialty products.
- 4. a. Coordinate with CMA on application of Cancer Policy to EDC. Solicit more individual companies to respond.
- 5. a. Compare PVC additive regulation proposal with other standards such as lead.
- b. Build a library of information on substances such as heavy metals, phthalates, etc., to be prepared with the facts.

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DRAFT EPA CLEAN WATER ACT PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify responses to potential EPA regulation of vinyl chloride or PVC under the Clean Water Act (CWA).

PRESENT
SITUATION:

1. Current effluent limitations for PVC waste water only address the pH level.
2. EPA is developing effluent guidelines under Sections 301, 304 and 307 of the CWA on an industry-by-industry basis.
3. In 1975, effluent guidelines for some plastics manufacturing operations were proposed, but they were withdrawn in March, 1981. The proposals included standards for TSS, BOD, COD and pH.
4. Ambient water quality criteria for vinyl chloride were published by EPA in October 1980.
5. Effluent guidelines for the chemical and plastics industries were scheduled for proposal in August 1981. However, the entire guidelines program is being critically evaluated by new Administration.
6. Effluent guidelines will specify best available technology (BAT), best conventional technology (BCT), new source performance standards (NSPS), and pre-treatment standards for publicly owned treatment works (POTW).
7. Ethylene dichloride (EDC) is listed as a hazardous substance under EPA rules implementing the oil and hazardous substance spill provisions of CWA § 311.

WHAT IF:

1. EPA's effluent guideline document sets allowable VCM levels at unrealistically low levels.
2. Water quality criteria issued in October 1980 are used to write water quality discharge permits.
3. New scientific data on the health effects of vinyl chloride in ambient water is reported.

TRACKING:

Direct Agency contacts, including Effluent Guidelines Division

Keller and Heckman

Other trade associations, such as CMA and SOCMA

Beveridge and Diamond

Federal Register

Trade and associated press

Member companies having water quality criteria used in their permit negotiations

TRIGGERS:

EPA proposes effluent guidelines.

Water quality criteria used to write permits.

EPA requests information.

New health data reported.

CONTINGENCY
PLAN:

1. EPA proposes effluent guidelines.
 - a. Evaluate proposal
 - b. Mobilize membership to compile relevant data.
 - c. Compare guidelines to actual effluent levels of vinyl chloride.
 - d. SPI Group meets and prepares comments for the administrative proceedings.
 - e. Meet with EPA personnel.
 - f. Seek favorable comments from OMB, other groups and individual firms including non-SPI members.

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- g. Consider ultimate judicial review plan.
- 2. Water quality criteria used to write discharge permits.
 - a. Advise Group
 - b. Evaluate suggested discharge limit; assess economic and technological feasibility; prepare cost/benefit analysis.
 - c. Compile relevant data through membership and submit to permit writers.
 - d. Consider preparing a "briefing" package in advance of the use of the water quality criteria in permit writing.
 - e. Consider judicial review if permitting negotiations fail.
- 3. New scientific data on the health effects of vinyl chloride in ambient water reported.
 - a. Advise Group
 - b. Assessment of data by Health Committee.
 - c. Group meets to consider Health Committee assessment and recommend course of action.

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DRAFT FDA PLAN

SPI-PVC SAFETY GROUP

ALTERNATIVES COMMITTEE

PURPOSE: To identify possible responses to potential FDA action that affects PVC Polymers.

PRESENT
SITUATION:

1. PVC polymer use presently permitted on basis of "prior sanctioned" status.
2. In 1973, based on information reported by Schenley Distillers that it was finding up to 25 ppm VCM in alcoholic beverages packed in PVC containers, BATF terminated experimental use of PVC packaging for distilled spirits.
3. In September, 1975, FDA proposed to remove the "prior sanctioned" status with respect to all rigid and semi-rigid food packaging applications, while reaffirming prior sanctioned status for film, cap and can liner and medical applications.
4. Residual VCM content in PVC resins dramatically reduced since 1975. In February, 1979, Ethyl Corporation submitted data to support no migration of RVCN from a bottle resin with a test method sensitive to approximately 2 ppb.
5. In 1979, the United States Court of Appeals for the District of Columbia Circuit held that FDA must determine with a fair degree of confidence that a substance actually migrates into food in more than insignificant amounts before it becomes a food additive, and that FDA has latitude to find migration insignificant. FDA is now planning to issue a new "constituents policy" in light of this decision.
6. The uncertain status of FDA regulation of PVC food packaging has confused and bewildered food packagers.

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7. FDA has announced intentions to:
 - a. Withdraw the September 1975 Proposed Regulation.
 - b. Propose a new regulation based on "constituents policy."
 - c. Both events to occur in June 1981.
 - d. Announcement made in Regulatory Reporter, Vol. II, Issue II, Interagency Regulatory Liaison Group, December 1980.
8. On January 13, 1981, FDA responded to the BATF inquiry concerning the use of PVC to package distilled spirits. While the letter was apparently intended to maintain the status quo, the Agency did not find documentation indicating a prior sanction for PVC use in alcoholic beverage packages. FDA stated its intention to issue a PVC regulation in the future, but indicated that none would be forthcoming prior to its reassessing its overall policies regarding indirect additives. FDA will not take administrative action against rigid and semi-rigid PVC food containers unless there is a compelling public health reason based on new information.
9. In addition to impact on food packaging, an FDA decision has the potential to affect cosmetic, toiletry and household chemical packaging based on consumer and product manufacturer reaction. FDA policy may influence other governmental agencies such as EPA and OSHA, and possibly regulation in other countries.
10. The constituents policy appears to be the preferred solution to the dilemma created by the Delaney Amendment and ever-improving analytical technology.

ACTION UNDERWAY:

1. Continuing contact with FDA
2. Contact with Presidential Task Force on Regulatory Relief and OMB Director Stockman to obtain helpful reform of FDA constituents policy.
3. Participating with other leading industry lawyers in drafting and pressing for passage of constructive amendments to FD&C Act.

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WHAT IF:

1. FDA finalized the 1975 proposal.
 - a. Impact on Industry - very high
 - b. SPI influence - high
2. FDA proposed to limit VCM extractable to non-detectable level.
 - a. Impact on industry - varies with sensitivity of authorized test method. Method sensitive to 5 ppb would have a positive influence on use.
 - b. SPI influence - high
3. FDA proposes to regulate migratable VCM in food products to non-detectable levels by analytical method having sensitivity derived from dietary exposure calculations.
 - a. Impact on industry - high/positive
 - b. SPI influence - high
4. Legislation introduced that would modify Delaney Clause and/or remove packaging materials from preclearance as food additives.
 - a. Impact on industry - high/positive
 - b. SPI influence - high

TRACKING:

Contact with FDA officials.

Federal Register

Food Chemical News

Keller & Heckman

Trade and associated press

TRIGGERS:

New health data reported

FDA requests information

FDA issues constituents policy

FDA finalizes 1975 proposal

FDA proposes new regulations

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CONTINGENCY
PLANS:

General

1. Alert Group.
2. Evaluate proposal; assess impact.
3. Coordinate with Food, Drug and Cosmetic Packaging Materials Committee and other SPI groups.
4. Meet with FDA personnel.
5. Lobby if appropriate.

For Specified What Ifs:

1. FDA acts on 1975 proposal.
 - a. Inform FDA of the need to repropose the regulation given the passage of time.
 - b. Update the record with new information on residual VCM levels.
 - c. If FDA finalizes 1975 proposal assess legal options: stay, court review.
 - d. Encourage participation by individual firms together with SPI.
2. FDA proposes to limit extractable VCM to non-detectable level.
 - a. Determine sensitivity of official method of testing.
 - b. Individual companies assess impact.
 - c. Meet with Keller & Heckman to prepare comments.
 - d. Encourage favorable comments from OMB, other groups and individual firms.
3. FDA proposes regulation based on risk assessment and dietary exposure.
 - a. Individual companies assess proposal.
 - b. SPI Group meets with Keller & Heckman to prepare comments indicating proposed compliance schedule if proposal is reasonable.

4. FDA issues constituents policy.
 - a. Assessment by individual firms.
 - b. SPI Group meets with Keller & Heckman to develop coordinated response and prepare comments if appropriate.
 - c. SPI Group should establish subcommittee to prepare industry case assuming "most likely" regulatory proposal.
 - d. If appropriate, encourage favorable comments from OMB, other groups, and individual firms including non-SPI members.
 - e. Consider judicial review, and pursue if necessary.
5. New legislation introduced.
 - a. Monitor legislation introduced.
 - b. Organize industry support.