In our discussions with FDA personnel close to the writing of the Preamble, we were informed that they did not intend the quoted statements to be read as broadly as indicated above. Rather, they said FDA intends only to deal explicitly with the colorants listed in the proposed regulation and the others added as a result of post-1972 food additive petitions. If this is the intention, the Preamble is written in an unnecessarily broad and extreme manner. The draft Comments we are circulating for your review are intended to bring about a revision of the obviously broad, sweeping generalizations set forth in the Preamble so as to limit regulatory treatment to those colorants which are food additives within the meaning of Section 201(s) of the Act.

Emergency Regulations Provide Temporary Relief from Proposition 65; SPI Joins Food Industry Suit Challenging Constitutionality of Law

On February 27, 1988, the California Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65, went into effect. On that date the consumer, workplace and environmental warning requirements of the law took effect for "significant," non-exempt exposures to any of the first 29 "known" carcinogens and known reproductive toxins listed by the Governor in February 1987. The discharge restrictions of the law and its private citizen enforcement provisions remain a problem for the plastics industry. Fortunately, with regard to plastic food, drug and cosmetic packaging, emergency implementing regulations issued by the state just 10 days prior to the initial compliance deadline for the time being have alleviated many of the Proposition 65 problems of suppliers of food packaging materials. However, we are not out of the woods yet. The emergency regulations are only interim standards as of this writing; worse, the no significant risk standards adopted therein, which presently virtually exempt FDA-compliant products, could be drastically revised as a result the state's ongoing review of risk assessments for the listed chemicals.

There have been many developments regarding Proposition 65 since our last report. The following account, divided into sections for the sake of clarity, is designed to bring you up to date on the most critical aspects of this subject.

Emergency Implementing Regulations. On February 17, 1988, the state issued emergency regulations dealing with, among other things, the warning requirements of the law, and "no significant risk" levels for exposures to listed carcinogens. Consistent with SPI's December 17, comments, as supplemented by our January 13, submission to the state, the regulations acknowledge that FDA-regulated products, including food and food packaging materials, complying with the FD&C Act are safe; that is, they pose "no significant risk" of cancer within the meaning of Proposition 65 and, therefore, are exempt from the consumer product warning requirement of the law. The regulations specifically exclude food additives covered by FDA regulations from the scope of Proposition 65.

For substances not subject to a specific FDA regulation, the California regulations provide that exposures to such chemicals pose "no significant risk" provided they comply with "all applicable administrative standards". The applicable administrative standards for food packaging materials are clearly the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the FDA regulations promulgated thereunder. Thus, the regulations provide an explicit basis for concluding, that FD&C Act compliance obviates the need for Proposition 65 consumer product warnings except in those cases where the reproductive toxin limitations cannot be met.1/

Assuming all goes well and the emergency regulations are not contested, they will remain in effect initially for 120 days and will be extended by the state for at least another 120 days. California will hold hearings on the emergency regulations and ultimately issue final regulations based on comments received. However, as noted at the outset, you cannot permit yourself to be tranquilized by the "no significant risk" standards California has adopted because they are only interim standards. The acceptance of existing regulatory standards as "no significant risk" levels is subject to revision depending on the findings of the state's own Scientific Advisory Panel, which is making independent quantitative risk assessments.

California Risk Assessments. In a March 16, 1988 memo to the State Department of Health Services (DHS), the California Health and Welfare Agency (HWA) requested DHS to review existing state and federal risk assessments for 49 Proposition 65 chemicals, and to conduct original risk assessments for two other substances on the "known" carcinogen list: aflatoxins and ethyl carbamate. The risk assessment reviews, scheduled to be completed by July 1, 1989, will be used to establish permanent "no significant risk" levels which will supersede the current interim "no significant risks" levels for the subject chemicals. According to the HWA memo, assessments for nine chemicals, including benzene, dioxin, and cadmium, are due by July 1, 1988. By October 1, 1988, existing risk assessments for acrylonitrile, vinyl chloride and 21 other chemicals are due to be reviewed.2/ Evaluations of risk assessments for a third set of chemicals are due by January 1, 1989, with the final group scheduled for review by July 1, 1989.

1/ Based on the exemption language in the emergency regulations, we have developed a draft Proposition 65 customer assurance format to help packaging material manufacturers and suppliers in advising customers on the status of their products in a way that is intended to satisfy them without providing broad "hold harmless" clauses or guarantees.

2/ There is some uncertainty regarding the timing of reevaluation of risk assessments for acrylonitrile since the chemical appears on both the list of chemicals to be evaluated by October 1, 1988 and on the list of chemicals due to be evaluated by January 1, 1989.

The List. To bring you up to date on the list of chemicals subject to Proposition 65, as of April, 1988, the total number of substances listed as known carcinogens under Proposition 65 stood at 209, including vinyl chloride, benzene, di(2-ethylhexyl) phthalate (DEHP), methylene chloride, trichloroethylene and acrylonitrile. Fifteen chemicals are now listed as known reproductive toxins. Chemicals placed on the state's "known" list become subject to Proposition 65's warning requirements 12 months after listing. The discharge prohibition goes into effect 20 months after a chemical is listed. At its most recent meeting, on April 22, 1988, the California Scientific Advisory Panel recommended the listing of alcoholic beverages per se, 2,4 dinitrotoluene and five pesticides as known carcinogens.3/

CURL Suit Contesting Constitutionality of Proposition 65. On February 26, the Committee for Uniform Regulation and Labeling (CURL), a coalition of food and packaging associations, of which SPI is a member, filed suit in the U.S. District Court for the Northern District of California challenging the constitutionality of Proposition 65 as applied to food and food packaging. CURL elected to file suit now despite the generally favorable emergency regulations to preserve its standing for a subsequent challenge to the law and to try to ensure that any litigation over the constitutionality of Proposition 65 will occur in an acceptable forum.

The CURL complaint alleges that the application of Proposition 65's warning requirement to food violates both the Supremacy Clause (Article VI, Section 2) and the Commerce Clause (Article I, Section 8) of the U.S. Constitution. The Supremacy Clause count charges that Proposition 65 stands as an obstacle to the accomplishment of the purposes and objectives of the basic FDA regulatory scheme because it adopts safety standards different than those adopted under the FD&C Act and, thus, would require warnings on many foods complying with federal safety standards. The Commerce Clause count claims that, for several reasons, the warning requirements of the law place an undue burden on interstate commerce. The complaint also alleges that Proposition 65 is impermissibly vague, discriminatory (because it exempts state and federal agencies), and a violation of the First Amendment right to freedom of speech because the law compels companies to make warning statements that are false and misleading.

3/ On April 14, the Panel's Subpanel on Reproductive Toxicity met to consider criteria for listing chemicals as reproductive toxicants where there is only "limited or suggestive" evidence of reproductive toxicity in humans. At that meeting, the Subpanel compiled a list of 29 possible candidates for listing as reproductive toxins. The Health and Welfare Agency will collect background information over the summer on these chemicals, which are not yet officially candidates for listing as known teratogens. Among the 29 chemicals on which the state is assembling information is styrene.

As of the date of preparation of this report, the CURL suit remains "on hold." CURL does not plan to file a motion for a preliminary injunction unless and until a suit is filed challenging the Emergency Regulations.

Attorney General, Consumerists Challenge 800-Number Warning System. Controversy continues to swirl around the Ingredients Communication Council's (ICC) 800-number consumer product warning approach. The ICC system, designed to satisfy the warning requirements of Proposition 65 without placing cancer and reproductive toxin warning labels on products, offers consumers product-specific messages about the Proposition 65 status of various food products via a toll-free number. The warning system, which has been under attack from the outset by consumer groups as not meeting the law's warning requirements, is now being investigated by the California Attorney General.

The Attorney General's investigation is focusing on whether businesses are complying with the warning requirements of Proposition 65. As part of this investigation, on May 3, 1988, the Attorney General subpoenaed the ICC for documents revealing the identity of all products listed with the ICC, the message being provided for each product, the identity of the Proposition 65 chemicals contained in such products and the levels at which the chemicals are present. At this point it is uncertain whether the ICC is the exclusive target of the investigation, or if the Attorney General will seek to broaden the scope of his inquiry to include scrutiny of the warning practices of companies not participating in the ICC program.

* * *

Despite the temporary relief provided by the February regulations, it is far too soon to close the curtain on Proposition 65. There is still the possibility of a legal challenge of the emergency regulations by consumer advocates. If one is filed, it will be opposed and protracted litigation is likely. Also, there is uncertainty concerning both the outcome of the state's risk assessment reviews and the direction the California Attorney General's new warning investigation will take. Additionally, there is still no fool-proof approach for dealing with the bounty hunter threat. Meanwhile, the proponents of the Proposition 65 philosophy continue to spread word of the "success" of Proposition 65 up and down the map.

Proposition 65-type Legislation Appears in Massachusetts, Illinois, New York and Louisiana; Similar Bills Falter Elsewhere

Although Proposition 65-type bills introduced in Hawaii, Tennessee and Missouri this past winter are dead or dying, new California-style legislation has surfaced this spring in Massachusetts, Illinois,New York and Louisiana.

On April 11, 1988, State Representative Lawrence Alexander introduced a Proposition 65-type bill in the Massachusetts House of Representatives. The bill's discharge and public warning requirements are substantially the same as those of Proposition 65. Unlike Proposition 65, however, the Massachusetts measure places responsibility for developing a list of carcinogens and reproductive toxins in the hands of the State Commissioner of Public Health. The bill requires the Commissioner to publish the initial list of known carcinogens and teratogens on March 1, 1990. Although the bill permits enforcement by private citizens, such citizen enforcers are not entitled to collect a bounty, but they may recover attorneys' fees and costs. Civil penalties for violations of the discharge and warning provisions are set at $25,000 per day per violation. A hearing on the bill has not yet been scheduled.

On April 6, 1988, a bill was introduced in New York's State Assembly to amend that state's environmental conservation law. Like Proposition 65, the New York bill, A 10630, would require the listing of chemicals known to the state to cause cancer or reproductive toxicity, and provision of a warning before exposure to such chemicals. New York's legislation, however, contains no specific discharge or release restrictions. The bill requires the state Commissioner of Environmental Conservation to publish a list of chemicals known to the state to cause cancer or reproductive toxicity by March 1, 1990, and bars the knowing and intentional exposure of persons to such chemicals without warning. The warning provision takes effect 12 months after listing of a chemical. As presently drafted, the proposed law contains no enforcement provision, nor does it specify penalties for violations of the law. The bill is currently before the Assembly's Environmental Conservation Committee.

On April 8, 1988, the Illinois Safe Drinking Water and Toxic Enforcement Act of 1988 was introduced simultaneously in the Illinois Senate and House of Representatives. Illinois S. 2214, H.B. 3948. The Illinois legislation proscribes the knowing and intentional exposure of an individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual. Under the Illinois Act, the Governor of Illinois is required to publish "on or before July 1, 1989, a list of chemicals known to the state to cause cancer or reproductive toxicity." Like New York's legislation, the Illinois bills contain no discharge prohibition similar to Proposition 65's, although the warning requirement is applicable to exposures to listed chemicals from drinking water. The warning requirement takes effect 12 months after the state's listing of a chemical.

The Illinois legislation imposes civil penalties of $2,500 per day per violation in addition to any other penalties established by law. While the Illinois bills provide for citizen enforcement of the law, in addition to enforcement by the state, any person bringing a citizen's suit pursuant to the bills' requirements does not appear to be entitled to a percentage of any civil penalty assessed by a court. The Senate version of the Act is currently before the Rules Committee;

the House version was reportedly tabled by the House Energy and Environmental Committee on May 6.

Finally, legislation creating a carcinogen list and restricting the discharge of listed chemicals into the environment was introduced in the Louisiana Senate on May 2, 1988. S.B. 487 would authorize the State Department of Environmental Quality to develop an initial list of carcinogenic chemicals by September 30, 1988 and make it illegal for any person to discharge any such chemical into the environment unless expressly authorized and permitted by the Department. "Discharge" is defined as "placing, releasing, spilling, percolating, draining, pumping, leading, seeping, emitting or other escaping of pollutants into the air, waters, subsurface water, or ground as a result of a prior act or omission." The proposed legislation also provides that wastes that can no longer be discharged due to their carcinogenicity be handled as harzardous waste.

Chemicals subject to S.B. 487 would include any substance designated as a carcinogen by the National Toxicology Program, or classified by the International Agency for Research on Cancer as a Group 1, 2A or 2B carcinogen (which would include styrene) -- as well as any substance regulated as a carcinogen "by a public health or environmental regulatory agency of the federal government or any state." Additionally, the bill stipulates that any person may petition the Department of Environmental Quality to amend the list f carcinogens.

S.B. 487 contains no warning requirements, nor does it provide for citizen enforcement. Penalties for violation of the discharge prohibition are n t specified. No hearings have been scheduled on the legislation, which is currently before the Senate Natural Resources Committee.

Meanwhile, the Hawaiian "Safe Drinking Water and Toxic Enforcement Act," which would have required consumer warnings not only for exposure to "known" carcinogens and reproductive toxins, but also for exposure to chemicals causing immune system damage, has reportedly died in committee. On January 20, 1988, a "Safe Drinking Water and Toxic Enforcement Act" was introduced in the Tennessee Senate. The Tennessee bill, with requirements virtually identical to those of Proposition 65, is languishing in committee. Another Proposition 65 clone, introduced in the Missouri House in January, has since been withdrawn by its sponsor.

[redacted] EPA's Views on Need for PVC EIS

FDA's 1986 proposed rule governing the use of polyvinyl chloride (PVC) food contact materials (51 Fed. Reg. 4173, Feb. 3, 1986) continues to twist slowly in the wind because of the environmental impact issue. On February 2,

1988, FDA requested the Environmental Protection Agency's (EPA) views on whether an environmental impact statement (EIS) is warranted before finalizing the PVC rulemaking. Although FDA asked for a response within 60 days, no answer has been forthcoming from FDA's sister agency to date and apparently FDA is not pressing for a speedy reply. We obtained a copy of FDA's letter to EPA, and, through a Freedom of Information Act request, we also received the attachments to FDA's letter, including FDA's PVC market projections.

FDA's letter contains a chronological summary of the environmental assessment issue and notes the comments EPA filed as well as additional issues raised by public commentors. FDA indicates that it has not yet decided whether an EIS is required, meaning that it has yet to determine whether promulgation of the final rule would cause significant environmental effects.

The letter concludes with six broad inquiries for EPA to answer. These include reviewing FDA's preliminary analysis and providing any new information that would reduce uncertainties in the analysis. FDA also sought assistance in evaluating any impact of municipal solid waste incineration including the generation of "HCl, CDD, CDF, chlorobenzenes, chlorophenols, organotins, and metallic chlorides." Since EPA announced last year that it intends to further regulate incinerator emissions, FDA asked whether action on the PVC rule would run counter to any regulation EPA plans to issue, or with the ability of municipalities to comply. Finally, FDA asked for EPA's views concerning whether promulgation of a final rule would substantially impact air and water emissions of vinyl chloride or industry's ability to comply with EPA regulations.

With regard to the market potential for PVC food contact applications, FDA's estimates of the current and future PVC resin usage (set forth in one of the appendices to its letter to EPA) are identical to our April 1987 submission on behalf of SPI with two exceptions. First, based on the SPI survey, we projected that 12 million pounds of resin would be used to bottle alcoholic beverages in 1991 if FDA promulgated the PVC rule in 1987. In contrast, FDA projected 12 million pounds for liquor bottles and, based on a market study by an independent company, an additional 7 million pounds for wine bottles.

The second and more significant difference is in FDA's estimate for the potential for non-alcoholic PVC bottles. We projected a 1991 figure of 50 million pounds for all non-alcoholic bottle applications. FDA projected 50 million pounds for the edible oil market and an additional 147 million pounds for other [redacted] including edible oils. This figure is derived from SPI's 1983 projection, supplemented by trade journal articles indicating the potential market in PVC bottles for water, juices and other foods. In addition, recent developments suggest that the heat-distortion temperature for bottle compound will be raised above the temperature required for hot-filling. This would allow jams, jellies, puddings and similar foodstuffs to be packaged in rigid PVC containers.

In sum, FDA estimates that if the PVC rule were to have been promulgated in 1987, total PVC food contact application in 1991 would be approximately 402 million pounds. If there is no FDA action, both SPI and FDA predict that the total food contact resin market will be 223 million pounds. The difference between these two numbers, that is 179 million pounds, "represents the effect of the regulation" in FDA's view.

While FDA's market analysis is not totally unreasonable, industry sources do not agree with what it foresees and certainly not that favorable FDA action will have anything approaching a significant environmental impact. According to SPI figures, 7.256 billion pounds of PVC were produced in 1986. Facts and Figures of the U.S. Plastics Industry, page 4 (1987 ed.). Assuming an increase of 179 million pounds in food packaging applications based on FDA's estimate, this would reflect an increase of approximately 2.5 percent over 1986 production. Naturally, the 1991 estimate for total PVC production would be substantially higher than the 1986 figure and thus the percentage increase is likely to be less than 2.5 percent.

The EPA staff has informed us that a response to FDA's letter is anticipated within a few weeks. Unfortunately, the "holding action" on the PVC rulemaking is having an impact on several pending petitions for PVC modifiers as well. The Agency is now once again expressing an unwillingness to act on any petition even tangentially related to PVC until the PVC rulemaking is resolved.

FDA Opposes Supreme Court Review of De Minimis Colorants Decision and Certiorari is Denied; Agency Rethinking De Minimis Position on Methylene Chloride

On March 18, 1988, FDA and the Justice Department filed a joint brief opposing Supreme Court review of the decision by the U.S. Court of Appeals for the District of Columbia Circuit which struck down FDA's use of risk assessment and the de minimis doctrine to clear carcinogenic color additives under the Delaney anticancer Clause. Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987). On April 18, the Supreme Court denied certiorari (Cosmetic, Toiletry and Fragrance Association v. Public Citizen, No. 87-1194) so the Court of Appeals' decision will stand unchanged.

Public Citizen involved an appeal by Public Citizen of FDA's clearance of D&C Orange No. 17 and D&C Red No. 19 as color additives for external drug and cosmetic applications. Despite tests on both Orange No. 17 and Red No. 19, indicating some carcinogenic effects in test animals fed very high doses, FDA cleared the colorants. FDA's clearance was based on a judgment that although the colors have been found to induce cancer in animals under laboratory conditions, they do not "induce cancer in man or animal" within the meaning of the Delaney Clause.

Fine line here - Could mean the suc
OR PVC line in Packaging = S/M
blister PKGS, bottles, ect. -

As we reported in December, the D.C. Circuit ruled in Public Citizen that the Food, Drug, and Cosmetic Act's Delaney Clause prohibits FDA from clearing color additives that FDA has determined to be animal carcinogens, even if they are to be used at levels so low as to pose an insignificant, or de minimis cancer risk to humans. Delaney Clauses were enacted as part of the Food Additive Amendment of 1958 and the Color Additive Amendment of 1960. The court, however, distinguished the application of the Delaney Clause in the food additive context. Thus, the decision does not affect FDA's use of de minimis principles to clear non-carcinogenic food additives or color additives that contain minute quantities of carcinogenic impurities, its so-called constituents policy. Furthermore, the court's ruling upheld the teaching of Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), that the de minimis concept may be used to determine that a non-carcinogenic substance that migrates into food in trivial amounts is not a food additive.

The Cosmetic, Toiletry and Fragrance Association (CTFA), an intervenor in the case, petitioned for Supreme Court review, filing a Petition for a Writ of Certiorari on January 19, 1988. In asking the Court to deny CTFA's writ, the government stated that it was "in the process of giving further consideration to the issues raised" by the case and that Supreme Court review "should wait until that process comes to a rest."

In its Petition for Certiorari, CTFA argued that the D.C. Circuit's interpretation of the Delaney Clause vis-a-vis color additives would apply to food additives as well and conflicted with both Monsanto and Scott v. FDA, 728 F.2d 322 (6th Cir. 1984), the leading case involving the constituents policy.

The government's brief acknowledged that Scott and Monsanto "lead to anomalous results when considered along with the ruling in this case," but denied that there is an express conflict between the D.C. Circuit's holding in Public Citizen v. Young and either of those decisions.

In a related development, FDA has announced in its semi-annual regulatory agenda that it is "reconsidering" its decision to permit the use of methylene chloride to decaffeinate coffee under its de minimis policy. As you may recall, FDA's decision to permit the continued use of methylene chloride to decaffeinate coffee stemmed from its December, 1985 Notice of Proposed Rulemaking concerning the use of the solvent in aerosol cosmetic products. In that Notice, FDA concluded that despite carcinogenicity bioassay studies indicating that methylene chloride is an animal carcinogen, the use of the substance to decaffeinate coffee was not automatically precluded by the Delaney anticancer Clause to the Food Additives Amendment, because, at the levels remaining in the coffee, the risk posed is so minuscule as to be de minimis. Now, FDA says cryptically that "in light of a recent appeals court decision [i.e., Public Citizen v. Young] that struck down a similar interpretation of the color additive Delaney Clause," it is "reconsidering" its decision regarding methylene

chloride. The announcement, which appeared in the April 22 Federal Register, does not indicate when FDA will reveal the results of its reassessment.

Appropos the Agency's rethinking the status of methylene chloride, it should be borne in mind, as noted above, that while the Court denied that there is a de minimis exception to either the food additive or color additive Delaney Clause, it acknowledged that FDA may use de minimis principles in determining whether or not a substance is, in fact, a food additive and thus subject to Delaney. Thus, the Court's holding leaves the Agency with some leeway to conclude that the use of methylene chloride in certain indirect additive food packaging applications falls under the de minimis or constituents policy exceptions to the food additive definition and is thus outside the scope of the Delaney Clause.

FDA Scrutinizing "Susceptor" Microwave Packaging; Will Call in Manufacturers for Meeting

FDA is becoming increasingly concerned about "susceptor" microwave food packaging because of the possibility that packaging materials near the susceptors may reach significantly higher temperatures than those contemplated when these materials were cleared. Susceptor packaging uses foils or metalized substrates (the susceptors) to create hot spots in the container to facilitate browning, crisping or frying of foods in the microwave oven. Unlike traditional microwave packaging materials, which are "transparent" to microwaves and, thus, during brief microwave exposures do not reach temperatures much above that of the heated foods, i.e., 212°F, susceptors both focus and absorb microwave energy to produce temperatures which may range as high as 400-500°F within certain parts of the package.4/

The Agency recently became aware of new extraction studies indicating that the temperatures the susceptors reach during microwaving may lead to increased migration of volatile compounds from the package. In fact, in cases where the metal is coated on a substrate of polyethylene terephthalate (PET), the heat can be so great as to cause the PET to crack. This could cause serious regulatory concerns in situations where the PET layer of the package is intended to serve as a functional barrier to the migration of adhesives or other components not cleared for use in direct contact with food.

4/ A detailed discussion of the nature and regulatory status of susceptor packaging is contained in a recent paper by Dr. Charles Breder, formerly with FDA and now a member of Keller & Heckman's scientific staff. Dr. Breder's paper, entitled "Microwave Packaging: Too Hot for Comfort?" is available upon request.