PACKAGING CHALLENGES OF THE 1980s: LEGISLATIVE AND REGULATORY PROSPECTS

By

Jerome H. Heckman
Keller and Heckman
Washington, D.C. 20036*/

During March I was in Australia and Japan where I conducted seminars on the regulatory outlook for plastic packaging in the United States. When I returned, one of my colleagues promptly informed me that the Food and Drug Administration (FDA) had been vastly improved because the Bureau of Foods was no longer in existence. For an instant, I envisioned a small group of people in the Commissioner's office making the appropriate scientific and policy decisions with great dispatch. However, my momentary euphoria disappeared when I learned that the Bureau of Foods had merely been renamed the Center for Food Safety and Applied Nutrition. Then I began to fear that a longer name could only mean more delay and procrastination in decision making.

A. REGULATORY DELAY

Before reviewing specific FDA policies or the status of particular packaging materials, allow me to dwell a bit on some of the administrative process problems we face in seeking to clear the regulatory path for new materials and new applications. From my perspective, the single most serious problem we have, and the one that is the saddest commentary on how government can hamstring an important part of the American economy, is the almost interminable delay one encounters in seeking to obtain FDA action on a food additive petition or an opinion letter.

Some of this delay can be attributed to the nature of large bureaucratic organizations. The remainder stems from FDA attitudes and a sense on the part of the FDA staff that there

---

*/ This paper was prepared for presentation at a Regional Technical Conference (RETEC) of the Society of Plastic Engineers in Cleveland, Ohio on April 4, 1984.

is no penalty for inaction. In other words, the FDA staff perceives that they will not be reprimanded for failure to approve or act on questions before them. On the other hand, action which generates adverse publicity or other criticism of the Agency may be viewed as highly negative. A partial solution to this is food safety legislation, which I will address later.

Complaints with delay have surfaced on a fairly regular basis since the 1958 Food Additives Amendment was enacted. But, over the last few years the frequency and intensity of these complaints has grown enormously. The situation has deteriorated so significantly, that FDA itself is beginning to inhibit the development of new packaging materials and alternatives.

For example, within the past month an officer of one of the largest oil companies has flatly stated to our office that his company will forego a market opportunity rather than try to get FDA approval for a new substance or new application. In his view, to justify the cost occasioned by the Agency's "normal delays," the volume of the market would have to be extraordinary to justify a clearance effort. In contrast, the company view the premanufacture notification (PMN) requirements of the Environmental Protection Agency (EPA) as reasonable. Thus, while the company will continue to develop and market new substances, it will not normally work to seek FDA clearance for food contact applications that could be great breakthroughs.

Polyvinyl chloride (PVC) is a prime example of what FDA's inexplicable delays can do. The Agency's actions have affirmed the prior-sanctioned status of PVC consistently for more than two decades. Indeed, its 1975 proposal to ban rigid and semi-rigid PVC itself supports the prior-sanction status of rigid PVC containers. Without the prior-sanctioned status, rigid PVC could not have been used as a food packaging material because it was never the subject of a food additive regulation. Similarly, several food additive regulations refer to adjuvants for rigid vinyl chloride homopolymers. These regulations only make sense if PVC is acceptable for food contact use. In addition to this, at least as recently as February 1980, FDA has written letters stating that PVC bottles are acceptable if produced in accordance with good manufacturing practices. Yet, FDA has refused to take definitive regulatory action unequivocally clearing PVC use for liquor bottles, and the Agency's oblique manuverings have dampened marketability for no readily apparent reason.

From my recent discussions with Australian and Japanese packaging industry representatives, this FDA ambivalence is restraining the use of PVC in other countries because many countries follow FDA's lead. Thus, FDA action restrains the use of materials in other countries as well as the United States. It also inhibits or stops potentially significant U.S. exports of PVC resins and modifiers.

A similar delay has enveloped FDA's regulation of acrylonitrile (AN). In 1977 and 1979, the United States Court of Appeals for the District of Columbia Circuit overturned two FDA decisions that effectively ended Monsanto's ability to market its Cycle-Safe® bottle, which had been on the market for several years. Since that time, FDA has failed to take any corrective action in response to a variety of Monsanto's requests. As you may have read in Food Chemical News, we were forced to write Acting FDA Commission Mark Novitch and demand action by the Agency to avoid further litigation. It is not the type of letter I enjoy writing and it is, in my judgement, a blotch on the record of the Agency that such a letter was required. Yet FDA's consistent course of promoting forced frustration often leaves American industry helpless and ripe only for the kind of commercial "drop-out" one oil company has made policy.

FDA would do well to look at the statutory direction given to the agencies regulating transportation and communications. Those statutes include a statement that the agencies have a duty to promote the advancement of the regulated industries while providing for the public welfare. FDA should do the same. The Agency must develop systems for ensuring that decisions are made in a reasonably prompt fashion. If it does not, as the currently popular book Megatrends so well indicates, local governing bodies will take even more of the food and drug laws into their own hands and FDA will become an empty bowl of anachronism.

Now, let me turn my attention to specific FDA policies, the Agency's treatment of particular packaging materials, and related matters. Perhaps by hearing about them you will get some ideas on how you can make your views known if you agree that something must be done to stop the denial of justice by FDA's simple refusal to act.

B. FDA CARCINOGEN POLICY

1. Advance Notice of Proposed Rulemaking

In April 1982, FDA published an Advance Notice of Proposed Rulemaking, officially titled "Policy for Regulating Carcinogenic Chemicals in Food and Color Additives." 46 Fed. Reg. 14,464-14,470 (Apr. 2, 1982). In large part, this proposal sprang from the decision in Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), and its de minimis concept. In other words, the court held that FDA had authority to disregard insignificantly small migration.

The proposed policy has three elements. First, it would attempt to clarify the statutory definition of a "food additive." Second, it would interpret the Delaney Clause as applying only when the additive itself has been shown to cause cancer, as opposed to some unwanted constituent or contaminant in the additive. Third, the policy would adopt risk assessment as one of the tools for determining whether an additive is safe under the general safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In clarifying the definition of an additive, FDA has proposed what it terms three different approaches which might be used separately or in combination. These are referred to as the constituents, de minimis and sensitivity of method (SOM) approaches.

2. Policy Application

a. Green No. 6: The same day that FDA issued the carcinogen policy, it issued a decision applying the policy to D&C Green No. 6, a color additive for externally-applied drugs and cosmetics. 47 Fed. Reg. 14,138 (Apr. 2, 1982). Green No. 6 is formed by reacting para-toluidine and quinizarin. Some para-toluidine remains in the purified color as an unwanted residual reactant. Animal studies have indicated that para-toluidine is a carcinogen in mice.

Applying the carcinogen policy, FDA found that para-toluidine is a constituent and not a color additive. Because

there is no evidence that D&C Green No. 6 as a whole causes cancer, the color was declared outside the coverage of the Delaney Clause. FDA then reviewed the safety of the color. It considered potential human exposure, determined the upper limit of individual life-time risk for exposure to the contaminant and held that "there is a reasonable certainty of no harm" from the color.

b. Green No. 5: FDA conducted a similar analysis in a June 1983 listing of D&C Green No. 5. Green No. 5 is produced from further reaction of D&C Green No. 6. Like Green No. 6, Green No. 5 also has trace quantities of para-toluidine as a residual reactant. However, the listing for Green No. 5 included applications which involve ingestion.

Again, FDA reviewed toxicological data and found that D&C Green No. 5 as a whole produced no significant adverse effects. FDA determined that para-toluidine was a constituent and that the risk presented was insignificant even though small amounts were ingested.

FDA action on Green No. 5 drew objections from a citizen group, the Health Research Group (HRG), and from a Mr. Glen M. W. Scott. Both HRG and Scott contended that the FDA action was at odds with the language and intent of the Delaney Clause. In November 1982, FDA rejected these objections and confirmed the listing of D&C Green No. 5 for general use in drugs and cosmetics. Although HRG did not seek judicial review, Mr. Scott filed an appeal with the United States Court of Appeals for the Sixth Circuit.

The court of appeals affirmed FDA's decision. Scott v. FDA, Nos. 82-3544 and 82-3759 (6th Cir. Feb. 23, 1984). It agreed with FDA that the Delaney Clause only prohibits the use of an additive where the additive as a whole has been shown to induce cancer. Thus, the presence of a carcinogenic constituent in an additive does not trigger the Delaney Clause.

After holding that the Delaney Clause did not prohibit FDA approval of the color additive, the court reviewed FDA's conclusion that the risk presented by the color did not offend the general safety clause of the Act. In addressing this question, the Sixth Circuit noted that FDA's decision was consistent with the holding in Monsanto Company v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979). The court agreed with the Monsanto decision and FDA's position that the Agency "has discretion to find

that low-level migration into food of substances in indirect additives is so insignificant as to present no public health or safety concern (and) it can make a similar finding about a carcinogenic constituent or impurity that is present in a color additive." Slip opinion at 6 quoting 47 Fed. Reg. 24,280 (1982).

In sum, the court held that the Delaney Clause did not prohibit the use of a color additive when the additive as a whole, as opposed to its constituents, was not a carcinogen. Moreover, the Agency could disregard de minimis risks under the general safety provisions of the Act.

c. Indirect additive application: While the color additive questions were being addressed, FDA also used the constituents policy when it issued a final Food Additive Regulation for an indirect food additive. 48 Fed. Reg. 37,615 (Aug. 19, 1983). This antioxidant/stabilizer, whose scientific name is 2,2'oxamidobis (ethyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate), represented the first use of the carcinogen policy when no two-year feeding study was conducted on the additive "as a whole" to establish that the substance was not carcinogenic. Here again, vocal opposition has been expressed by self-proclaimed guardians of the consumer. Although legislative reform is necessary to solve the problems created by FDA regulation of carcinogens, the development and application of the Agency's carcinogen policy is a significant step in the direction of good science and good administration.

C. POLYVINYL CHLORIDE

We all know of FDA's 1973 proposal to ban the use of PVC containers for alcoholic beverages and the even broader 1975 proposal which would have revoked the prior sanction and banned all food-contact use of rigid and semirigid PVC containers. 38 Fed. Reg. 12,931 (May 17, 1973); 40 Fed. Reg. 40,529 (Sept. 3, 1975). The 1975 proposal arose from concern with residual vinyl chloride monomer (RVCM) in rigid packaging materials. Since 1975, the RVCM level of rigid PVC plastics has been reduced dramatically. In other words, the basis for the 1975 proposal has been invalidated. FDA has openly acknowledged this in correspondence with concerned members of industry.

Today, PVC remains a prior-sanctioned food-contact material provided it is made and used in accordance with good manufacturing practices (GMP). Consequently, the use of PVC for food-packaging does not require the promulgation of a Food Additive Regulation. Nonetheless, the current status of PVC presents two difficulties. First, the 1975 proposal to ban rigid and semirigid PVC--an unfinished cacophony--has left a "little black cloud" hindering marketing. Second, the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms (ATF) has refused to approve the use of PVC liquor bottles until it receives a clear statement from FDA indicating that PVC is suitable for that use.

FDA's carcinogen policy provides a vehicle to solve both these problems. The Agency could clarify its position by confirming the prior-sanctioned status of PVC or, as is more likely, by issuing a regulation specifically authorizing the use of PVC. The same review would provide a basis for FDA to inform ATF that PVC is suitable for liquor bottles.

Using conservative risk assessment procedures, FDA has calculated that a dietary intake of 0.22 micrograms of vinyl chloride per day will be "very safe." Because the Agency considers the average diet to consist of 3 kilograms (kg) of food (both solid and liquid combined), the safe concentration of vinyl chloride in food is 0.073 ppb by weight assuming that the entire daily diet is packaged in PVC.

As we see it, FDA should be concerned only with actual migrants. In other words, rather than focusing on RVCM levels, attention should be on migration, as the law requires. Therefore, we have recommended that any FDA regulation set a limitation on extractables, not on residual monomer. Further, the use of an extraction test procedure sensitive to 1 ppb appears most reasonable.

In late November 1983, FDA received two Italian feeding studies using PVC powder. The test protocols were somewhat unusual and employed a small number of animals. It was our position that FDA should not be concerned with PVC powder since it is not a food additive. Rather, FDA's concern should be with substances that actually migrate into the food. Moreover, we suspect that the reported effects attributed to PVC that passes through the intestinal wall into the body would be no different from any other fine particle.

Although we have conveyed this view to the FDA staff, the studies were referred to FDA's Cancer Assessment Committee (CAC) for evaluation. Recently, we were informed that CAC met, reviewed the studies, and concluded that neither were of any value in determining the safety of PVC as a food packaging material. In other words, CAC agreed with our analysis that the studies were irrelevant.

At this time, there is a draft regulation in FDA's Center for Food Safety. While we see no reason standing in the way of action, the Agency is manifesting an irresistible and inexplicable attraction to delay.

D. ACRYLONITRILE

When FDA requested market data on PVC in 1982, it also requested data on AN. Because FDA used one letter to SPI requesting information on both substances, there was speculation that FDA would act on PVC and AN together. This, in fact, seems unlikely. We are reasonably certain that PVC and AN will be considered separately by the Agency.

FDA should act soon on Monsanto Company's petition seeking approval of its acrylonitrile bottle. The petition is based on data showing that, using a method sensitive to 0.1 ppb, there will be no extraction of AN from the Monsanto bottle into carbonated beverages. When FDA does act, it will be an unconscionably overdue response to the the 1979 decision in Monsanto Co. v. Kennedy.

After dealing with the Monsanto petition, FDA can address the broader issue of AN's general use for food-contact applications. Indeed, an interim Food Additive Regulation for acrylonitrile is also pending before FDA. The great difference between PVC and AN, without regard to the Monsanto bottle, is that the use of AN for other packaging applications does not seem to be increasing at this time. In the view of many, it would be best for FDA simply to state that there should be no detectable level of AN migration using a specified, generally accepted test methodology. Government regulators have done precisely this in Canada where the official test method has a sensitivity between 20 and 30 ppb.

E. PET LIQUOR BOTTLES

1983 marked the introduction of polyethylene terephthalate (PET) liquor bottles in the United States market although their regulatory status is slightly marred by a pending lawsuit brought by the Glass Packaging Institute (GPI). The PET situation merits a brief introduction on the regulation of alcoholic beverages by both FDA under FD&C Act and ATF under the Internal Revenue Code. Under this dual statutory plan, ATF has deferred to FDA decisions concerning the health and safety of beverage containers. After FDA clears a packaging material, ATF will then determine whether the material is "suitable" for packaging distilled spirits. ATF's prime concern is with revenue collection.

Acting on a petition filed by a PET resin manufacturers, FDA amended the Food Additive Regulations in 1973 to expand the permissible food-packaging uses of PET to include the manufacture of articles, including bottles, for food with up to 50% alcohol. 21 C.F.R. 177.1630; 38 Fed. Reg. 13,557 (1973).

In 1980 and 1981 two distillers requested ATF clearance for the use of PET containers. After conducting a notice and comment proceeding leading to the preparation of an environmental assessment of PET as a material for use in the manufacture of liquor bottles, ATF issued a decision on November 12, 1982 concluding that PET liquor bottles would adequately protect government revenue if they met certain conditions. These conditions were simply that PET liquor bottles comply with applicable FDA regulations and be rigid or semirigid with a wall thickness that is as uniform as possible. Approval contains no limitations as to container size, nor is it restricted to PET manufacture by any particular resin manufacturer, or fabrication by any particular converter.

ATF approval came after several hectic weeks of activity relating to the status of the containers. Some confusion arose as a result of an ATF rule issued on October 5, 1982 that largely deregulates liquor bottle manufacturers. 47 Fed. Reg. 43,944 (Oct. 5, 1982). The confusion cleared rapidly as a result of the filing of a lawsuit by the GPI on November 3, 1982. We intervened in GPI's suit against ATF on behalf of SPI.

The order sought by GPI would have enjoined approval of PET liquor bottles by ATF until after a notice and comment

rulemaking on the subject was conducted. The pleadings filed by GPI and its oral argument contained a variety of allegations about the potential health hazards posed by residual quantities of dimethyl terephthalate (DMT) and terephthalic acid (TPA). GPI's attorneys also raised the spectre of tampering tragedies by claiming that liquor in plastic bottles is more readily susceptible to adulteration by syringe injections than it is in glass bottles.

In orders entered on November 4, 1982 and February 28, 1983, the United States District Court in Washington, D.C. rejected GPI's arguments. GPI appealed this decision to the United States Court of Appeals for the District of Columbia Circuit on two grounds: (1) that ATF could not approve PET liquor bottles without conducting a notice and comment rulemaking, and (2) that the environmental assessment was inadequate because it failed to consider the risk of criminal tampering.

Oral argument was held on November 16, 1983. As always, it is impossible to predict the outcome of a case based on oral argument. Nevertheless, we think it fair to say that the three-judge panel gave GPI's counsel a very difficult half-hour.

The judges focused on a "standing" question that was not briefed by the parties, that is, whether GPI was the proper party to bring this case before the court. Because protection of the revenue is a purely governmental interest rather than one affecting private parties, the judges suggested that GPI could not raise the notice and comment issue. The court also seemed aware that GPI had had many opportunities over the years to comment on the issues of broad public concern, such as the health and environmental issues. Finally, one judge noted that glass bottles could be tampered with as well as plastic bottles.

While we are hopeful of a favorable decision by the ourt of appeals, we feel certain that the ultimate outcome will favor PET liquor bottles. In the court of appeals, GPI's complaints only focused on the procedural aspects of the ATF proceeding and not on any substantive problems with PET liquor bottles. Therefore, we believe that ATF will reach the same conclusion, that PET is suitable for liquor bottles, even if it is required to conduct a notice and comment rulemaking. In the interim, PET bottles may be and are being used as liquor bottles.

F. ASEPTIC PACKAGING

The use of hydrogen peroxide as a direct food additive at low levels is considered generally recognized as safe (GRAS). 21 C.F.R. 184.1366. Thus, its low-level use as a sterilant on food-packaging materials is also GRAS. 21 C.F.R. 186.1(a). When Brik Pak sought to introduce an aseptic packaging system using a 30% to 35% hydrogen peroxide solution, FDA advised the company that that level, or its application, was not GRAS and a regulation was required. Given this background, it is not surprising that the current FDA regulation defines the term hydrogen peroxide solution as an aqueous solution containing 30-35% hydrogen peroxide by volume. 21 C.F.R. 178.1005. In its one significant provision, the regulation further provides that there may be no more than 0.1 ppm of residual hydrogen peroxide immediately after packaging.

Based on a public remark by an FDA staff member, there is a perception that this regulation requires the use of a 30% to 35% hydrogen peroxide solution for any aseptic system. Efforts are underway to correct this misunderstanding so that it will remain clear that less concentrated but adequately effective hydrogen peroxide solutions can be used. Keller and Heckman submitted a petition to FDA on January 4, 1984 seeking to clear the use of all H_2O_2 concentrations. This Petition has now been accepted for filing as FAP 4B3777. Informal discussions with the FDA staff indicate that favorable FDA action is likely in the near future.

Acting on a petition filed by the National Food Processors Association (NFPA), FDA has amended the aseptic regulation to permit the use of all olefin polymers as the food-contact surface. Previously, only polyethylene was approved. We anticipate that FDA also will revise the aseptic regulation in response to petitions submitted for other polymers, such as SURLYN and PET.

G. IRRADIATION

In response to a letter from the Dow Chemical Company, FDA clarified its position on the use of irradiated packaging materials. The good news is that the Agency has confirmed that it will not require food additive petitions if a manufacturer

wishes to irradiate packaging materials to obtain some technical effect. FDA views this as part of the manufacturing process for producing the packaging material. So long as the material is otherwise cleared for the intended use and the irradiated packaging material does not differ in a significant way from the non-irradiated material, its use is permissible.

Manufacturers must ensure that irradiation causes no changes that would produce unsuitable impurities and that no detectable radioactive nuclei are induced in the packaging material. In general, according to the FDA letter, packaging materials may be irradiated at a dose up to 100 kiloGray (kGy) (10 megarads (Mrad)).*/

Besides this general guidance, some existing regulations address the irradiation question. For example, the polyolefin regulation, 21 C.F.R. 177.1520, permits the irradiation of polyethylene from a source not exceeding 2.3 million volts to cause molecular cross-linking and thus increase the material's strength or heat shrink properties.

On February 14, 1984, FDA published a proposed rule governing the use of irradiation in the production, processing, and handling of food. The proposed regulations would permit food to be irradiated to inhibit the growth and maturation of fresh fruits and vegetables and to disinfect food of insects at doses not to exceed 1 kGy (0.1 Mrad). Doses up to 30 kGy (3 Mrad) may be used to disinfect spices of microbes. The proposed regulations require that records be kept for one year past the expected shelf-life of the product and that the records be available for FDA inspection.

Doses at the 1 kGy (0.1 Mrad) level may be used, for example, to control insect infestation and are sufficient to inhibit the sprouting of onions and potatoes. This can be contrasted with a 1981 report of the Joint FAO/IAEA/WHO Export Committee on the wholesomeness of the radiated food. That report recommended unconditional clearance for food irradiated

---

*/ Recently FDA has begun to use the System Internationale (SI) Unit for expressing the amount of absorbed radiation dose, that is the Gray (joules/kilogram). The older term, used in prior FDA proposals, was the rad (100 rad = 1 Gy). For consistency, we use the Gray unit with the older term in parenthesis.

with up to 10 kGy (1 Mrad). One of FDA's concerns was that there were not enough data to permit the use of radiation above the 1 kGy level under conditions where spoilage microorganisms might be destroyed but where spore-forming organisms, such as C. botulinum, can grow and produce toxins. However, following the development of more data, it is conceivable that FDA may one day permit higher irradiation levels.

A major regulatory question is FDA's power to require special labeling for irradiated food. Under existing regulations for wheat and potatoes which would be replaced by the new proposal, retail packages must contain the statement "treated with ionizing radiation" or "treated with gamma irradiation." Wholesale packages and invoices must carry similar statements. 21 C.F.R. 179.22 and 179.24.

At the wholesale level, special labeling can reasonably be required to prevent processors from irradiating food ingredients again and raising corresponding safety questions concerning any additional radiolytic products. It is not at all clear that requiring special labeling is wise or fair at the retail consumer level. There is little that the average consumer could do to irradiated food that would significantly effect the radiolytic composition of the food.

Quite properly, FDA's proposal does not require any special labeling of irradiated foods sold at the retail level. Food which is shipped to a food manufacturer or processor for further processing, labeling, or packaging must bear the statement: "Treated with ionizing radiation--do not irradiate again" on the label and invoices.

While the labeling portion of the proposal is favorable, FDA did solicit comments on whether labeling should be required on the retail package. Given the confusion about food which has undergone irradiation and the misimpression that such products contain radioactive materials, we certainly hope that FDA avoids consumer labeling requirements.

H. PRODUCT TAMPERING

Following several tragic deaths from poisoned Tylenol capsules in 1982, FDA issued tamper-resistant packaging regulations for certain over-the-counter (OTC) human drugs, cosmetic products and contact lens solutions and tablets in November,

1982. 47 Fed. Reg. 50,442 (1982). The FDA regulations do not apply to food, and every indication from the Agency suggests that the regulations will not be extended to cover food. Jerry Heckman reviewed these regulations in his presentation to this group in March 1983.

While state criminal law can be applied in tampering cases, new federal anti-tampering legislation was signed into law on October 13, 1983. The legislation makes it a federal crime to tamper with or attempt to tamper with any consumer product, its labeling or container, with "reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk." It is also illegal to communicate false information that tainting has occurred if such tainting, had it occurred, would have created a high risk of death or bodily injury to another person. Conspiracies to commit a tampering offense and threats of tampering are also covered. Maximum punishments range from $10,000 to $100,000 in fines and from one year to life imprisonment depending on the severity of the injury that occurs as a consequence of the crime.

I. FOOD SAFETY LEGISLATION

On June 8, 9 and 10, 1983, the Senate Committee on Labor and Human Resources held hearings on the need for food safety reform. The Committee heard testimony from past and present FDA officials, the United States Department of Agriculture (USDA), distinguished scientists, a panel of consumer groups and industry representatives. The hearings successfully established a congressional record to support the position that advances in science mandate changes in the law. SPI testified at the hearings.

Legislative momentum continued with the introduction of the Food Safety Modernization Act (FSMA) of 1983 on October 6, 1983. Identical bills were introduced in the House and Senate by Representative Madigan and Senator Hatch. The bills, S. 1938 and H.R. 4121, include provisions addressing: (1) indirect additives, (2) the definition of "safe," (3) modification of the Delaney Clause, (4) consideration of an additive's health benefits, (5) scientific peer review, (6) phase-out authority, (7) informal rulemaking for food contaminant tolerances, and (8) conforming amendments to the Federal Meat, Poultry, and Egg Inspection Acts.

In its present form, the legislation would direct FDA to issue regulations clarifying when a food-contact substance shall be deemed a food additive. In particular, this should establish a common framework for "no migration" determinations.

Since over 75 food safety issues have been identified during the last two or three years in conjunction with this legislative effort, we were pleased that indirect additives were one of the select items chosen for inclusion in this streamlined bill. This is especially true since some draft bills have not included an indirect additives provision. Nonetheless, we are deeply disappointed that the bills did not have additional language directing the development of a premarket notification (PMN) system as an alternative to the current food additive petition process. However, Senate staff members have stated that changes to the indirect additive provision are not foreclosed, and appropriate amendments will be sought.

In December 1983, SPI pursued the Senate staff's indication of receptiveness by writing to Senator Hatch and Representatives Madigan and Gore. The SPI letter noted the critical need for a premarket notification (PMN) system as an alternative to the food additive petition process. Several typical problems under the current system that PMN's would rectify were discussed. Proposed statutory language to accomplish this end was also presented. The suggested provision is brief and general, but, if successful, we anticipate that more detailed congressional guidance for FDA will be included in accompanying congressional reports or other legislative materials.

Current efforts to promote enactment of food safety legislation continue. However, because 1984 is an election year and there are few legislative days scheduled unless Congress acts within the next few months, it is highly unlikely that food safety legislation will be seriously considered until after the November 1984 elections and the convening of a new Congress in 1985.

J. Conclusion

The enactment of food safety legislation represents the most promising path for meaningful improvement in FDA's operation. The PMN provisions would help because they would not require FDA to take positive action on acceptable materials or

applications. Instead, FDA would only need to review PMN submissions internally. The recent court decision on the carcinogen policy and the development of refined risk assessment techniques should provide a comfort margin for FDA safety determinations and application of the carcinogen policy. However, the Agency's seeming inability to act is a cause for serious concern which needs to be battled continually in any forum where an opportunity is presented.