GENERAL COUNSEL'S REPORT
TO THE
PLASTIC BOTTLE INSTITUTE

November 6, 1981

TABLE OF CONTENTS

General Counsel's Report*/

To The

Plastic Bottle Institute

Ladies and Gentlemen:

Attendees of last year's semi-annual meeting of the Plastic Bottle Institute will probably remember the special guest speaker, Mortimer R. Feinberg and his discussion of "unfulfilled expectations." Although he used the phrase to discuss social relationships, it is apt to describe the regulatory situation of plastic bottles. Our expectations for positive Food and Drug Administration (FDA) action on a constituents policy and polyvinyl chloride (PVC) liquor bottles, and for positive Bureau of Alcohol, Tobacco, and Firearms (BATF) action regarding all types of plastic liquor bottles, remain unfulfilled; as reported below, however, our expectations are now running very high. On the brighter side, the unhappy expectation of some that FDA would require preparation of a new Environmental Impact Analysis Report for one-half liter plastic beverage containers will remain, quite happily, unfulfilled. We hope that the next six months will bring fulfillment of our desirable expectations without disturbing our record for nixing the undesirable ones.

PLASTIC BOTTLE REGULATORY ACTIVITY

BATF Reconsiders Rule Making on PET Liquor Bottle and Proposes Deregulation of Liquor Bottle Manufacturers

We have been advised by sources within the BATF that there has been a policy shift and that a rule making is no longer considered essential to the approval of polyethylene terephthalate (PET) plastic liquor bottles. An ill-conceived rule making had been under consideration as a means to obtain comments regarding environmental and international trade issues while at the same time raising several issues that BATF believes relate to consumer protection, mostly with respect to "proof-gain." While the rule making route could have consumed two years before any plastic bottles were approved, the current plan could clear the path for all plastic bottles by next spring and, perhaps, sooner.

We do not know whether the rumored potential dismantling of BATF may have influenced the change in policy, but we are told that the entire plastic

---

*/ Prepared on November 6, 1981, by Keller and Heckman, SPI General Counsel, for the November 19-20, 1981, meeting of the Plastic Bottle Institute in Scottsdale, Arizona.

liquor bottle matter is "far enough along" that the Agency will continue to move forward on the subject even though new projects are not being undertaken. Indeed, because new projects are on hold, plastic liquor bottles are receiving maximum attention. Our interpretation of this development is that a BATF policy decision will be one which either deregulates plastic liquor bottle materials cleared by FDA, or perhaps identifies objective criteria regarding such matters as "proof gain" so that if the criteria are met, any container permitted under FDA regulation could be used for alcoholic beverages without specific BATF action. (This is the case for wine containers now, of course.)

The most recent rumors around town suggest that reports of BATF's demise have been greatly exaggerated. While its regulatory functions are likely to be shifted to the Secret Service (Firearms) and Customs (Alcohol and Tobacco), it now appears that most BATF personnel will shift to these other agencies too and continue regulating as before. The spring forecast for plastic liquor bottle approval assumes that there will be no significant cut backs in personnel and, therefore, that the review process will not be hastened by the Agency's desire to settle this issue before losing those personnel familiar with this issue.

Prior to receiving the more recent reports on expected developments at the Bureau, we had been in contact with the Distilled Spirits Council of the United States (DISCUS) to seek its support for a meeting that we had planned to request with the Director of BATF, Mr. G. R. (Bob) Dickerson. We understand that DISCUS support of SPI in seeking prompt approval for plastic liquor bottles is due to be dealt with by the DISCUS Executive Committee on November 16, 1981. Thereafter, we plan to revisit the question of whether a meeting with Mr. Dickerson is still necessary or desirable.

As we have been saying for some time, BATF remains unwilling to take action with regard to PVC bottles until it gets a definitive ruling from FDA that it "approves" the use of PVC for packaging distilled spirits. FDA's constituents policy (see next item) should make the "definitive ruling" BATF has been waiting for on the PVC liquor bottle something more readily obtainable.

In a related matter, on September 2, 1981, BATF published a Notice of Proposed Rule Making which, if adopted, would deregulate the liquor bottle manufacturing industry (liquor bottle materials will still be regulated) and encourage the recycling of glass liquor bottles. On behalf of SPI's Plastic Bottle Institute and Plastic Beverage Container Division, we are now drafting Comments to file in this rule making which will remind the Bureau that plastics are a suitable material for packaging distilled spirits and that such bottles are recyclable. Specifically, the Comments will focus on the proposed change to the existing rules which will authorize an individual to possess used liquor bottles for the purpose of recycling glass. The Comments will request an amendment to this section to include plastics. We have already discussed this matter with the BATF staff and received a favorable preliminary reaction.

FDA's Constituents Policy Expected to be Published Soon

Despite the pessimistic reports emanating from the Food and Drug Administration in early September that the constituents policy was in "trouble," we have since reported that Commissioner Hayes has signed off on a Notice of Proposed Rule Making which should be published in the Federal Register as soon as the Department of Health and Human Services and the Office of Management and Budget review the proposed policy. According to our sources within FDA, the adoption of the constituents policy would permit the Agency to tolerate the possible existence of unwanted residual contaminants or constituents in either direct or indirect food additives provided they are not deliberately added and intended to accomplish some functional effect in either a package or a food additive; the amount involved is in the nature of a trace amount; and ,where possible, risk assessment techniques can be used to demonstrate that such a trace amount of an unwanted substance, even if it is a carcinogen, would present no real risk to public health. Presumably, FDA will use the 10^{-6} risk factor as an acceptable level.

If our understanding is accurate, the constituents policy could go a long way towards helping to clarify the beclouded status of PVC and should also provide a basis for affirming safe uses of materials like acrylonitrile (AN) polymers.*/ The constituents policy will not be of help in circumstances where a substance is deliberately employed as an adjuvant, such as a plasticizer, in a packaging material.

FDA remains anxious to publish the policy now because the Agency is faced with a need to do something to delimit a serious problem it is encountering with regard to a variety of food, drug, and cosmetic colors that are presently provisionally listed or ready for approval but which have been found by the newest analytical methodology to contain carcinogenic contaminants. At present, a consumer group is in court seeking to invalidate prior extensions of the provisional listings, and our understanding is that FDA believes its position in this litigation could perhaps be improved if it could say that it had a proposal outstanding that would establish a basis for permanent listing.

Whatever FDA's reasons, we are now more hopeful than we have been in quite some time that the constitutents policy might be formally proposed quite soon. Our latest "guesstimate" for publication of the policy is now mid to late

---

*/ As an interesting aside, the Canadian government recently rejected an outright ban of AN polymers and instead promulgated a regulation based on "none detectable" with an "official method" sensitive to about 15 parts per billion (ppb). The Canadians properly recognized that AN polymers are not a problem and appropriately focused its attention on whether or not AN monomer gets into food at a level that might be cause for concern.

November, 1981, based on FDA's need to take action with respect to the color additive D&C Green 6 since the provisional listing for that color--which FDA cannot approve except by using the constituents policy approach--is due to expire on November 28.

FDA Concludes Monsanto's L-600 Resin A Food Additive; Further Administrative Activity Underway

FDA finally issued its long-awaited Formal Advisory Opinion (Docket No. 80A-0190) on the status of Monsanto's Cycle-Safe® bottles on June 12, 1981. In the Agency's usual manner, the opinion is filled with bureaucratic doubletalk. While rejecting Monsanto's assertion that the beverage containers are not food additives because there is no migration, the Agency invited Monsanto to file a food additive petition and suggested its case could then be considered based on a risk assessment approach. Of particular significance in the response is FDA's openly inviting risk assessment for evaluating indirect food additives under its existing statutory authority.

On September 14, 1981, Monsanto responded to FDA by filing a renewed Request for an Advisory Opinion which provided point-by-point responses to the technical objections raised by FDA in its June 12 letter. At issue once more in Monsanto's renewed request is the amount of evidence FDA must have in order to properly conclude that a packaging material is subject to regulation as a food additive or, instead, might be ruled to present no food additive problem.

Half-Liter Bottle Stirs Opposition, but Not From FDA

Test-market introductions by major soft drink manufacturers of the one-half liter PET beverage bottle have prompted the Glass Packaging Institute (GPI) to launch an extensive anti-plastics thrust. Early in June, GPI began an active public relations and advertising campaign to discredit the one-half liter plastic bottle. The ad campaign consists of Mailgrams to bottlers, full-page ads in beverage industry publications and thirty-second television spots in test market areas for the new size plastic container.

Rather than engage in a head-to-head advertising contest with GPI, SPI asked the National Advertisers Division (NAD) of the Better Business Bureau to investigate the basis for the claims made by the GPI ads. The Society has requested that NAD review the substantiation for the claim that appears in all of the promotional materials that "taste tests prove that more people preferred the leading cola in glass to one-half liter plastic . . . over 36% more." We have been

told that GPI is guarding the data from this so-called "taste test" very closely, and there are rumors that the "taste test" was so poorly conducted that it cannot properly be called a test.

While many are reasonably confident that the so-called "taste test" will not hold up to critical review, NAD has also requested GPI substantiate its other claims, including: (1) soft drinks lose carbonation in plastic; (2) plastics have an unacceptable shelf life of 8-12 weeks compared with one year for glass; (3) plastic bottles cost more than glass, and the price differential will increase; and (4) one in five consumers of a major brand in Ohio declared they would switch if it went to plastic.

Coinciding with GPI's vigorous advertising campaign, new rumors began circulating to the effect that PET or its components were carcinogens. A number of news organizations were known to be investigating these rumors when FDA issued its response to a 7 month old request by a so-called "public interest" group requesting that PET be banned for beverage applications. The FDA letter, dated June 23, 1981, unequivocally affirmed the safety of PET for all food applications. A Jack Anderson column on July 24, 1981, discussing the events that occurred before June 23, 1981, seems to have attracted little attention and no follow-up.

At the Plastic Beverage Container Division and Plastic Bottle Institute Meetings last May, there were reports that FDA might require the preparation of a new Environmental Impact Statement (EIS) because of the anticipated advent of half-liter beverage containers. This issue has now been laid to rest in what we consider to be a most satisfactory way. More explicitly, FDA stated very frankly in response to arguments made concerning the entire question "that an Environmental Impact Statement is not required for final Agency action on [a] petition" which would permit the use of another type of PET bottle for use in manufacturing all sizes of beverage containers, including the half-liter sizes.

The FDA statement, made in a letter to us, confirms that the EIS question remains where it always has been, as a non-issue which needs no further attention. FDA's 1976 EIS comprehensively dealt with all bottle sizes.

OTHER REGULATORY AND LEGISLATIVE ACTIVITIES

Status Report on the Food Safety Amendments of 1981

Senate hearings on the Food Safety Amendments of 1981 (S. 1442) are now scheduled by the Labor and Human Resources Committee and the Agricultural Committee on December 1, 2, and 3; at present, the House has no hearings scheduled on H.R. 4014 and is unlikely to do so during this session of Congress.

Both House and Senate hearings, initially scheduled for early October, were postponed because the Administration needed more time to formulate its position on the proposed legislation. A Sub-Cabinet Level Task Force which includes William McMillan, Assistant Secretary of the United States Department of Agriculature (USDA), Commissioner Hayes of FDA, and a Deputy Administrator of the Environmental Protection Agency (EPA) has been studying the amendments and was scheduled to make its recommendations to Health and Human Services' Secretary Schweiker by November 1, 1981. The Administration is committed to make its views public by November 15, 1981.

In the meantime, on October 6, 1981, SPI's Food, Drug, and Cosmetic Packaging Materials Committee met for a workshop and technical briefing during which the background leading up to the drafting of the bill was presented in detail. There was quite a full discussion of the meaning of S. 1442 and companion bill H.R. 4014 as they relate to the regulation of packaging. The workshop also included talks from various industry leaders on their expected impact of the legislation on various segments of the industry, i.e., resin producers, additive manufacturers, packaging fabricators and film producers. Although some language modifications to the bills may be necessary, an SPI statement in support of the principles in the proposed legislation was approved.

The October 6 meeting lead to the formation of an ad hoc group to review the technical points in the proposed legislation and provide guidance to SPI's Legislative Task Force as to testimony which will be offered by The Society if it is invited to testify before the House or Senate, as is expected.

Meanwhile, a public interest group and others have submitted Comments to both House and Senate members which are critical of the proposed legislation. SPI, together with the American Meat Institute and the National Soft Drink Association, is preparing a joint response to these Comments. Because the joint response answers many common questions concerning the amendments, it should be an excellent tool for understanding the legislation.

MANUFACTURING AND PROCESSING

Amendment to OSHA Noise Standard Will Affect Many Processors

After three deferrals by the Agency, the Occupational Safety and Health Administration (OSHA) issued a revised and improved hearing conservation amendment to its noise exposure standard on August 22, 1981. It provides for initial monitoring to be completed by February 22, 1982, and baseline audiograms to be established by August 22, 1982. The rules that are now in effect are simpler than those originally promulgated on January 16, 1981. They apply where noise exposures are greater than or equal to 85 dBA on an 8-hour, time-

weighted average (TWA). While few processors were affected by the OSHA standard for occupational noise exposure when the threshold was at 90 dBA, many processors will be affected by the new regulations. As requested by SPI's Committee on Occupational Safety and Health, an explanation of the rules has been prepared and will be a supplement to an upcoming issue of Plastics News Briefs.

Meanwhile, the Agency is continuing its review of the overall approach of the rule to determine whether a specification or performance standard would be more appropriate. It is also reviewing the rest of those provisions of its current standard which remain subject to the administrative stay to determine whether their requirements are necessary to the establishment of an effective hearing conservation program. Reconsideration of the entire noise standard is expected to take at least three years.

Upate on EPA Activity Involving Vinyl Chloride Standard

The Environmental Protection Agency is still at work drafting an Advance Notice of Proposed Rule Making for revision of the vinyl chloride standard issued under the authority of § 112 of the Clean Air Act. While the Agency staff had indicated several months ago that the proposed changes would address only the administrative and housekeeping provisions of the standard, we have learned that some substantive changes are also under consideration. In addition, EPA has decided to proceed with Phase II of the Vinyl Chloride Standard Review which involves focusing on particular provisions of the standard and drafting proposed changes. Phase II will be conducted without the assistance of TRW, the outside consulting firm which did most of the work on Phase I. In part, the decision to continue without TRW was based on budget cuts at EPA and personnel turnover at TRW. We have also been informed that EPA's Carcinogen Assessment Group (CAG) is reviewing the risk assessment literature on vinyl chloride.

DISPOSAL/SOLID WASTE: LEGISLATION

Senate Schedules Hearings on Mandatory Deposit Legislation

The Senate Commerce Committee had scheduled hearings on federal mandatory deposit legislation on November 5, 1981. The hearings on S. 709, the Beverage Container Reuse and Recycling Act, marked the first time in more than three years that the Congress has had hearings on this issue. The proposed legislation calls for the labels of carbonated beverage containers to declare the

refund value of the container--which must not be less than five cents. In addition, the legislation proposes that distributors be required to pay the retailer two cents for each container returned to help defray handling costs. SPI was invited but was unable to testify; a written statement is being prepared for the record by SPI's Washington office. No hearings have been scheduled yet in the House on companion bill H.R. 2998.

DISPOSAL/SOLID WASTE: LITIGATION

A Final Postscript on the Minnesota Plastic Milk Container Case

At the end of any litigation, costs are always assessed to the loser. As the prevailing party in Minnesota v. Clover Leaf Creamery Co., the State of Minnesota is entitled to reimbursement for all reasonable costs and expenses, excluding attorney's fees, incurred in defending itself. It was no surprise, therefore, when the State petitioned the trial court, where this action began many years ago, to recover its costs and disbursements. We challenged the reasonableness of the claimed expenses and were pleasantly surprised when the court denied the State reimbursement for over half the amount it had claimed. The trial court judge refused to award the State payment for the services of one of its expert witnesses; the judge claimed the State's expert witness was the worst to ever appear in his court room. We thought that the judge's comments certainly seemed an appropriate postscript to this entire chapter in the history of misbegotten legislation.