

EXHIBIT D

Report of
Thomas J. Hughes, Keller and Heckman
On International Developments
Prepared for SPI Food, Drug and Cosmetic
Packaging Materials Committee Meeting
Washington, D. C.
November 7, 1968

Gentlemen:

It is indeed a pleasure for me to have this opportunity to report on some items of interest that have come to our attention on the international scene.

As is the normal practice whenever the Committee discusses international developments, or any of the topics we cover for you, I invite you to interject yourselves during the course of my discussion as you "feel the urge" and/or the need so that we can develop and cross-pollinate as much information on the subject as is possible. I don't have to tell you that the international legislative and regulatory situation is so complex and expansive that we must rely on all of the members of the Committee who have occasion to deal with, or in, foreign countries in the food and food packaging areas to keep us apprised of the latest developments.

UNITED KINGDOM

To "get the ball rolling", I thought I would first touch on the present food packaging situation in the United Kingdom. Those of you who were at the last Committee meeting in New York, in April, will recall that following a lengthy discussion, then Chairman, George Ingle, appointed an ad hoc Subcommittee to consider the question of whether or not it might be desirable to draft a joint set of comments bearing on an inquiry, drawn up by the British Food Additives and Contaminants Committee, and circulated to industry by the British Plastics Federation, which requested industry's views on several alternative proposals for the establishment of a food packaging regulatory scheme in the United Kingdom. A May 10, 1968 comment deadline date had been set by the British Committee.

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After careful deliberation and discussion between the ad hoc Subcommittee and your Steering Committee, the Steering Committee decided that this Committee would not undertake to submit any comments on behalf of SPI. In keeping with the Committee's long-standing policy on such matters it was agreed that the question of whether or not to submit comments on the British Food Additives and Contaminants Committee's proposal should be left up to the individual companies that had an interest in the matter. Since this Committee has neither the capacity nor the facilities for effectively dealing with foreign problems from an "industry" point of view it was felt that the "individual company" approach to the British situation would be best for all concerned.

That brings me to the current status of the situation in the United Kingdom. Actually we were most fortunate to have had a very recent opportunity to spend the better part of a day with Trevor Wells, of the British Plastics Federation.

Mr. Heckman, Mr. Ingie and I took the opportunity of our delightful and highly informative get-together with Mr. Wells to question him on the chain of governmental authority over food-packaging in the United Kingdom and the force and effect of the laws and regulations presently in effect in the United Kingdom, that might have any bearing on food packaging. I think it might be helpful for purposes of putting the present efforts of the British Food Additives and Contaminants Committee in perspective if I digress for a moment and briefly describe the governmental and legislative machinery in Great Britain as it relates to food packaging.

The British Ministry of Agriculture Fisheries and Food is the governmental entity with primary responsibility over the administration and enforcement of the Food and Drugs Act of 1955. It was also the sponsor of the Act when presented to Parliament for consideration. The Ministry is comparable to our own Executive Department of Health, Education and Welfare.

Basically, the Food and Drugs Act provides, in substance, that "thou shalt not poison the people", and is interpreted to apply to food packaging materials or containers only in the event that some food is poisoned (i.e., adulterated or contaminated), by such material or container. The Act is an "Act of Parliament" and any amendments thereto require a new Act of Parliament with all of the many procedural steps required for the ultimate passage of such Acts.

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In addition to sponsoring legislative measures, such as the Food and Drugs Act, before Parliament, the Ministry also, from time to time, proposes the adoption of "regulations", on various subjects, to Parliament. Such proposals are made strictly on an ad hoc basis, as the need arises, but, once adopted by Parliament, they have the full force and effect of law. The main difference between Acts of Parliament and such "regulations", known as "Statutory Instruments", is that the latter are not formally debated in Parliament, but rather, are subjected to mere superficial, pro forma deliberations, the theory being that the Ministry's technical expertise in such matters need not, and should not be the subject of political debate.

A good example of this type of regulation is the Anti-oxidants in Food Regulation of 1966, with which some of you may be familiar, and which relates to permitted antioxidants for use as direct additives in foods.

The Food Additives and Contaminants Committee was established by the Ministry, under authority vested in it by Parliament, for the purpose of considering and ultimately reporting on, the leaching of packaging chemicals into food. It was in furtherance of this purpose that the Committee requested the views of industry, which was the subject of this Committee's deliberations at our last meeting, as I have already mentioned.

The Committee, which plans to issue its report sometime during 1969, is presently considering three Procedural proposals for the regulation of packaging materials, namely:

(1) The establishment of a list of permitted packaging materials, by trade name as well as chemical category, which would prohibit the use of packaging formulations unless the specific formulation to be used is approved by the Ministry. Needless to say, this type of approach would be highly undesirable from industry's point of view but, fortunately, according to Mr. Wells, it has the least amount of support on the Committee of any of the three proposals:

(2) The second proposal would be to establish a list of permitted migrants. This approach might be acceptable, except that the members of the Committee are talking in terms of setting a 0.05 ppm limitation, above which level a material would be considered to be

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a "migrant" requiring Ministry approval. This proposal has support on the Committee but is not necessarily considered to be "the leading candidate":

(3) The third proposal calls for the government to refrain from adopting any detailed legislation on the subject of food packaging as experiences in other countries, notably the U. S., have proven that such legislation is neither practical nor necessary. All that would be necessary to assure safety would be to require that the several packaging industries each adopt and adhere to a "code of practice", similar in design and scope to the Good Manufacturing Practices Regulations employed in this country. This approach is obviously the most desirable of the three, from industry's point of view, and we are told by Mr. Wells, that this proposal is picking up increasing support and momentum.

With this prospect in mind, the British Plastics Federation (BPF) which, as you know, is an organization similar to our own SPI, has circulated, to the British plastics industry, a draft "code of practice" for comment and approval by the BPF members. The draft, which was approved by the BPF Toxicity Committee before being circulated to the BPF membership, has been rejected by one British company, and efforts are presently underway to resolve the objections that have been raised; although, we are led to believe that the objections raised by the company in question, have seriously impaired the possible approval of a BPF Code of Practice at any time in the near future.

NETHERLANDS

Turning next to the present status of the Dutch regulatory situation, the Dutch Ministry of Social Affairs and Public Health published, on July 25, 1968, a third version of a Draft Packaging and Food-Utensils Regulation, with a twelve-month comment period ending July 25, 1969.

On May 6, 1968, the Ministry had promulgated "Directives For Making Application For the Approval of An Additive in Packagings and Food-Utensils", such Directives to be administered under the Packaging and Food-Utensils Regulation, when the latter is ultimately finalized and formally adopted. The Directives are, as we understand it, final and not open for comment. They are very similar in design and scope to the Procedural Regulations

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governing the filing of Food Additives Petitions in this country under Section 121.50 of the Code of Federal Regulations.

Of particular significance is Section 8 of the subject Directives which grants provisional permission for the use of plastics materials and components in the Netherlands that were subject to applicable U. S. Food Additive Regulations prior to January 1, 1967, unless subsequent toxicity data calls for a reappraisal of the substance.

Substances which have been regulated in the U. S. after January 1, 1967, would be independently evaluated by the Netherlands and data, as specified in the Directives, would be required for purposes of obtaining Dutch governmental approval.

Additionally Section 8 of the Directives provides that an additive could be placed on the list of acceptable additives without toxicity data having been supplied, provided that it could be demonstrated by appropriate extraction studies using water, 3% acetic acid, 15% ethanol and arachis oil as food simulating solvents, that not more than 0.01 ppm of the additive will migrate into packaged food. This, of course, is a sort of adoption of the U. S. approach implied in FDA's Guidelines For Chemistry and Technology Requirements of Food Additive Petitions. We are told that the Dutch are closely watching the rest of the world, particularly the U. S., to see how and to what extent the 'Frawley approach' will be implemented in other countries before the Dutch perhaps undertake to modify the 0.01 ppm criterion.

We have just recently received a copy of the Dutch Directives and will circulate copies to the Committee in the very near future. We have also received a copy of the third Draft Packaging and Food-Utensils Regulations, but without the schedules to the draft, which contain prescriptions on the various permitted additives and components and the methods of investigation for enforcement of the Regulation. Chapter 1 of the schedules relates to polystyrene, polystyrene copolymers, polyethylene, propoxylene, polyolefin copolymers, PVC, PVDC, anti-oxidants for plastics and General Analytical Methods, and may be obtained by writing directly to:

Food Law Advisory Commission
(Adviescommissie Warenwet)
Dokter Reijersstraat 10
Leidschendam Netherlands.

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In summary then the Dutch are in the process of devising a regulatory scheme for food packaging materials which, with certain listed exceptions, will require the pre-clearance of additives and materials by the Dutch government before such substances are "listed" as acceptable for food-packaging applications in the Netherlands. It should also be noted that the Dutch proposal for the regulation of indirect additives migrating from packaging materials is separate and apart from the Dutch regulations bearing on direct food additives.

BELGIUM

Turning next to some recent developments in Belgium, the Belgian Ministry of Public Health and Families has promulgated a draft Royal Decree relative to the manufacture, trade and utilization of items and materials which come into contact with produce and food stuffs.

Unfortunately, the copy of the draft Decree we have been able to obtain makes no reference to comment deadline dates, nor, indeed to any desire on the part of the Belgian government to have industry submit its views on the draft, so I am unable to give you any specific information in this regard.

The draft Decree purports to apply only to those packaging materials which are "likely to become components of produce or food stuffs". Broad provisions are also made for requesting the Belgian government to list food packaging materials or components, which are likely to become components of food, on a positive list of approved materials. Here again, the copy of the draft Decree we have makes no reference to required extraction methods or other data that must be supplied to the government to establish safety but, from our past experience, we believe it very likely that the Belgians will ultimately follow the Dutch lead and probably will end up adopting the same, or very similar criteria, as the Dutch.

In general, the draft Decree seeks to prohibit the use of food packaging materials or components, which are likely to become components of food, if such material or component:

- (a) will contaminate the food with noxious substances in such quantity that the food becomes harmful or dangerous to health;
- or (b) will impart inoffensive substances to foods, but in undesirable quantities under the normal conditions of use; or
- (c) will change the organoleptic characteristics of the food when in contact with food stuffs under normal conditions of use.

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To summarize the situation in Belgium, we anticipate that the Belgians will ultimately adopt a packaging regulatory scheme similar in design and scope to the Dutch effort, so events in the Netherlands will have, we believe, a significant bearing on the ultimate position the Belgians take with regard to the regulation of food packaging materials.

ITALY

We have just recently been advised that, last April, the Italian Ministry of Public Health, in cooperation with a Committee established by the Italian National Association of the Chemical Industry, promulgated a positive list of ingredients acceptable for use in plastic food packaging materials. We have not seen the list as yet, but efforts are underway to obtain a translated version, and if and when we are able to procure the same, we shall be advising the Committee further in this connection.

I should note that our experiences with the Italian government, and, indeed, the information we have recently received, show a continuing spirit of cooperation between government and industry. It is no secret that we would certainly like to see the same type of cooperation in this country, and I think we have seen some hopeful straws in the wind as a direct result of the National Conference on Indirect Food Additives, as Jerry has already mentioned in his report.

EEC

In concluding my report, I would like to briefly touch on the current situation in the E.E.C. As most of you are probably aware, the interests of the plastic industry within the Common Market have generally been represented by the B.I.T.M.P. Some two years ago, in the interest of greater harmonization of the plastics industry within the E.E.C., a Comité Mixte[®] was established. The establishment of this Committee, which actually constituted the merger of several technical committees operating within the framework of the Common Market, coincided with the establishment, by the E.E.C.'s Agricultural Division, of a Committee to study the problem of instituting a common regulatory approach to food packaging in the Common Market.

The E.E.C. Committee, usually referred to as the Franck Committee in honor of its Chairman, Professor R. Franck of Berlin, has received several proposals for legislation on the

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subject, and is presently reviewing the procedures used by other countries in an effort to develop a workable and effective regulatory approach in the E.E.C.

The plastics industry, through the Comité Mixte, has submitted a proposal to the Franck Committee which calls for the listing, on a Common Market "positive list", of all plastic food packaging materials and components that are approved for use in at least two E.E.C. member countries, without further assessment. Plastic food packaging materials and components that have been approved in only one country will also be listed, but will be subject to removal from the list if objections are raised by a government toxicologist from any of the member countries within a six month period of the date of listing. The Franck Committee is presently studying this proposal.

Meanwhile, as an adjunct to this proposal, the B.I.T.M.P. has completed a draft listing of plastic food packaging materials and components it would recommend be included on such a positive list. As we understand it, the B.I.T.M.P. has circulated the draft to the member countries for comment and approval before submitting the same to the Franck Committee. Apparently, West Germany has raised some objections to the draft listing, not on the substance of the list, but rather on the grounds that neither the Comité Mixte proposal nor the B.I.T.M.P. proposed list have "national" status as is normally required under the Rome Treaty for E.E.C. consideration.

Therefore, it appears as though the biggest roadblocks in the way of any E.E.C. effort to regulate food packaging are in the nature of "political" rather than "technical" hurdles.

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That completes my report. I thank you for your attention and, again, if any of you have any additional information on these, or other countries of interest, I know that the Committee will appreciate hearing it.

Thank you.

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THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

250 PARK AVENUE • NEW YORK, NEW YORK 10017 • 212/687-2675

M I N U T E S

MEETING OF SPI FOOD, DRUG AND COSMETIC
PACKAGING MATERIALS COMMITTEE

Shoreham Hotel
Washington, D. C.

February 26, 1970
9:40 a.m.

Present:

Robert M. Miller, Chairman, Hercules, Inc., 910 Market St., Delaware Trust Bldg., Wilmington, Delaware 19898
Taylor W. Hanavan, Vice Chairman, E. I. du Pont de Nemours & Co., Inc., 1007 Market St., Film Dept., Wilmington, Delaware 19898
Watson B. Ackart, Union Carbide Corp., Chemicals & Plastics, One River Rd., Bound Brook, New Jersey 08805
Nelson Allen, E. I. du Pont de Nemours & Co., 910 Market St., Wilmington, Delaware 19898
Robert H. Anderson BASF Corp., 866 Third Ave., New York, New York 10022
Robert C. Asam, The Goodyear Tire & Rubber Co., Chemical Materials Dept., 1485 E. Archwood Ave., Akron, Ohio 44316
James Asbeck, B. F. Goodrich Chemical, 3135 Euclid Ave., Cleveland, Ohio 44115
Ralph P. Blodgett, Northern Petrochemical Co., 2223 Dodge St., Omaha, Nebraska 68102
Norman D. Bornstein, W. R. Grace & Co., Converted Plastics Group, P. O. Box 464, Duncan, South Carolina 29334
Sal M. Cannavo, L. A. Dreyfus Co., P. O. Box 500, South Plainfield, New Jersey 07080
Kenneth C. Conley, Development Division, Borg-Warner Corp., Washington, West Virginia 29181
Paul F. Cundy, American Can Co., Box 702, Neenah, Wisconsin 54956
Richard A. Dannells, Dart Industries, Inc., P. O. Box 37, Paramus, New Jersey 07652.

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Laverne J. De Corte, Sinclair-Koppers Co., Product Development, Frankfort Rd., Monaca, Pennsylvania 15061
Harry R. Dittmar, IMCO Container Co., Div. Ethyl Corp., 4240 Blue Ridge Boulevard, Kansas City, Missouri 64133
Daniel S. Dixler, AIRCO, Inc., Central Research Laboratory, Murray Hill, New Jersey 07971
R. J. Dowling, Uniroyal Chemical Division, Spencer St., Naugatuck, Connecticut 00770
George W. Ferner, The Goodyear Tire & Rubber Co., Research Division, 1144 East Market St., Akron, Ohio 44316
Robert A. Ferrell, KLC Corp., Prospect & Hodell Sts., Shelbyville, Indiana 46176
Gerhard Fuchs, Allied Chemical Corp., P. O. Box 405, Morristown, New Jersey 07960
P. R. Ginnings, Goodyear Tire & Rubber Co., Research Div., 142 Goodyear Blvd., Akron, Ohio 44316
S. F. Goodheart, Levey Div., Cities Service Co., 630 Glendale-Milford Rd., Cincinnati, Ohio 45215
Earl C. Haag, Jr., Mobay Chemical Co., Penn Lincoln Parkway W., Pittsburgh, Pennsylvania 15205
Richard H. Haas, The Goodyear Tire & Rubber Co., 1144 East Market St., Akron, Ohio 44316
Robert M. Hagins, Mobay Chemical Co., Penn Lincoln Parkway W., Pittsburgh, Pennsylvania 15205
Jerome H. Heckman, SPI General Counsel, Keller & Heckman, 1712 N St., N.W., Washington, D. C. 20036
Karl A. Hochschwender, American Hoechst Corp., P. O. Box 2500, Somerville, New Jersey 08876
Thomas J. Hughes, Keller & Heckman, 1712 N St., N.W., Washington, D. C. 20036
George W. Ingle, Monsanto Co., 1101 17 St., N.W., Washington, D. C. 20036
John F. Jones, The Standard Oil Co. (SOHIO), Midland Bldg., Cleveland, Ohio 44115
James R. S. McCartney, Standard Packaging Corp., 111 Prospect St., Stamford, Connecticut 06904
Gordon L. McIntyre, Cities Service Co., Drawer #4, Cranbury, New Jersey
Kenneth Morgareidge, Food & Drug Research Laboratories, Inc., Maurice Ave. & 58 St., Maspeth, New York 11378
Peter Morison, Eastman Chemical Products, Inc., Chemical Sales Div. & Technical Service, Kingsport, Tennessee 37562
Francis J. Nadolski, American Cyanamid Co., Building #3, Bound Brook, New Jersey 08305
James N. O'Connor, The Dow Chemical Co., Legal Dept., 47 Bldg., Midland, Michigan 48640
B. Newell Olson, Reynolds Metals Co., Tenth & Byrd Sts., Richmond, Virginia 23219
I. Frank Peake, E. I. du Pont de Nemours & Co., Inc., Film Dept., 1007 Market St., Wilmington, Delaware 19898

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Robert E. Rutherford, Gulf Oil Corp., 439 Seventh Ave., Pittsburgh,
Pennsylvania 15230

E. H. Schaeffer, Shell Chemical Co., 2525 Marworth Dr., Houston, Texas 77025

A. Merrill Schnitzer, Phillips Petroleum Co., Research and Development Dept.,
356 Chemical Laboratories, Bartlesville, Oklahoma 74003

William W. Sederlund, National Starch & Chemical Corp., 1700 W. Front St.,
Plainfield, New Jersey 07470

C. Boyd Shaffer, American Cyanamid Co., Berdan Ave., Wayne, New Jersey 07470

Marc K. Shaye, Keller & Heckman, 1712 N St., N.W., Washington, D. C. 20036

Arthur W. Sheldon, M & T Chemicals, Inc., Woodbridge and Randolph Aves.,
Rahway, New Jersey 07067

Anthony C. Signore, Monsanto Co., Packaging Div., Box 1019, Hartford,
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Matthew E. Smith, Owens-Illinois, Plastics Products Div., 14th & Adams Sts.,
Toledo, Ohio 43624

Charles J. Spiegl, Continental Can Co., Inc., 7622 South Racine Ave., Chicago,
Illinois 60620

M. C. Stone, Eastman Chemical Products, Inc., P. O. Box 431, Kingsport,
Tennessee 37662

Donald F. Thompson, AviSun Corp., R & D Div., Post Rd., Marcus Hook, Pennsyl-
vania 19061

Harry S. Turpack, Diamond Shamrock Corp., P. O. Box 191, Painesville, Ohio
44077

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Edward J. Vendermark, Northern Petrochemical Co., 2223 Dodge St., Omaha,
Nebraska 68102

Harold Warp, Flex-O-Glass, Inc., 1100 N. Cicero Ave., Chicago, Illinois 60611

Willard M. Westveer, The Dow Chemical Co., Quality Assurance, Dow Center,
2040 Bldg., Midland, Michigan 48640

George F. White, Jr., Reynolds Metals, Co., Tenth & Byrd Sts., Richmond,
Virginia 23219

Heinrich Wirth, BASF Corp., Central Ave., South Kearny, New Jersey

David L. Wolfe, U.S. Industrial Chemicals Co., Polymer Service Laboratories,
Tuscola, Illinois 61953

Einar T. Wulfsberg, American Paper Institute, 1835 K St., N.W., Washington,
D. C. 20006

Leo W. Ziemlak, Foster-Grant Co., Inc., Research & Development, 289 N. Main
St., Leominster, Massachusetts 01453

Charles L. Condit, Secretary, SPI, 250 Park Ave., New York, New York 10017

Under the direction of General Chairman Robert M. Miller, Hercules, Inc.,
a full meeting of the SPI Food, Drug and Cosmetic Packaging Materials Com-
mittee convened in the Shoreham Hotel, Washington, D. C., on February 26,
1970, at 9:40 a.m.

Association, who presented the following formal report:

"The June 19, 1969 report of this committee indicated that the methodology for testing polyolefin containers would be published in the next edition (XIII) of the National Formulary but would be limited to ophthalmic products only. This is proceeding on schedule.

"Mr. Elmer O. Krueger of the National Formulary Board and also of Abbott Laboratories contacted me last month with regard to the inclusion of a method for measuring light transmission. Although our group had recommended that this test be omitted from any write-up on the basis of unreproducible results obtained in our round-robin study, nonetheless it was now proposed that the original method be resurrected.

"Our committee was circulated and a brief statement was prepared describing the problem of measuring scattered light transmitted through translucent plastics with a reference to ASTM-D-1003-61 and ASTM-D-791-61T and the so-called 'light integrating sphere.' Mr. Krueger was convinced of the inadvisability of publishing the original method and our statement will be substituted in the published procedures.

"The June 1969 report also indicated that a proposal would be prepared covering the regulation of polyolefin containers for dry pharmaceuticals. A task group met in Detroit last August and prepared a draft of such a proposal which then went through one revision by mail. Several questions were raised which necessitated another meeting of the task group which was held yesterday in Washington and which resulted in another draft. It is hoped that this draft can be circulated to the FD & C Packaging Materials Committee of the Society as a separate mailing in the near future.

W. B. Ackart"

Commenting on the objective of the joint effort between the PMA and the SPI, Mr. Miller said that essentially it is one of starting out with the polyolefins and developing methodology for their use in packaging dry drug products; that following completion of this first phase of methodology, the PMA would be asked to approve its content and then consideration would be given to giving it to FDA for its consideration.

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The ultimate objective of this entire program is to attempt to convince the Food and Drug Administration to include in Section 130.9 of the Drug Regulations a provision which would make it permissible for drug companies to substitute one plastic bottle, or other container, for another provided that the materials used in manufacturing the bottle could be said to be essentially equivalent when they are tested by the prescribed methodology. This cause would, of course, be materially aided if the test methodology and limits included in the draft SPI report could be made the subject of a National Formulary or U.S. Pharmacopoeia coverage. It is hoped that the Pharmaceutical Manufacturers Association might find the proposal suitable for such inclusion in its official publications and that the Food and Drug Administration might then be in a receptive frame of mind to amend Section 130.9 so that substitutions of containers might be more readily made. The Liaison Committee's draft report spells out the objectives, as well as the methodology and limits, in great detail so all members of the full Committee will be fully informed about the matter when the draft is circulated in the next few weeks.

SPI Food and Drug Bottling Committee
of the Plastic Bottle Division

Chairman Miller next called upon M. E. Smith, Owens-Illinois, to deliver his regular report. Mr. Smith reported as follows:

"The Bottle Division committee has met three times since our last June 19 meeting. Of interest to the Food, Drug and Cosmetic Packaging Materials Committee would be:

"Food Bottle Seminar: The Plastic Bottle Division is conducting a seminar on food bottling at the Hotel Commodore, New York, on March 18, 1970. From all indications there should be about 350 people in attendance.

"SPI - MSDI: The task group of the bottling committee working with the Mayonnaise Salad Dressing Institute members have distributed over 13,500 containers for a round-robin testing of spoonable and pourable dressings in PVC bottles. Because of the number of containers required the initial testing is limited to PVC. All containers have been coded and identified only as octyl tin or calcium zinc stabilized PVC. Containers will be stored and tested over a six month period. Rather than go into the details of the tests here I suggest if anyone wants to know about the program, he should let me know and I'll go over the whole program with him.

"U.S. Public Health Service: The U.S. Public Health Service has published its third edition of its list of single service milk containers manufacturing plants that have been certified as meeting the USPFS sanitary guidelines. A new listing will be published again in January in which over 50 plants should be listed.

"PMA Seminar: At our last meeting we discussed plans for a two day seminar with the pharmaceutical people in the New York, New Jersey, and Philadelphia area. Hopefully we will be better able to learn more of their problems as they switch to plastic packaging and at the same time give them better knowledge of plastics and what they can do for them. No date has been set."

American Paper Institute

James R. S. McCartney delivered a formal report on the activities of the American Paper Institute of interest to the overall SPI Committee with special emphasis in his report on visitations the previous day with officials of the USDA. Mr. McCartney's report follows:

"A meeting of the API's Biological and Chemical Research Committee was held on February 17, 1970. This Committee is the API's counterpart to our SPI Food, Drug and Cosmetic Packaging Materials Committee in that it historically has been concerned with Federal regulations applicable to paper packaging materials. The agenda of the meeting contained several items of mutual interest to the API and SPI. These items have already been covered by Jerry Heckman in his usual thorough manner so there is not much to be added.

- "1. The reorganization of the FDA and what this is going to mean. The API will use all the contacts at its disposal to gain insight into the reorganization of the FDA, who is involved, what they are like and so on. Until things have settled down, little hope is seen for any constructive policy action.
- "2. The status of the GRAS list for food additives. The present review by the National Academy of Science of the GRAS list of food additives is limited to

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direct food additives and not to indirect food additives. Therefore, it does not appear that this review will affect paper food packaging materials.

- "3. The USDA's proposed regulations. The API prepared and filed comments on the proposed USDA regulations in December. Specific proposals were offered for the sections on packaging materials and labeling. As a follow-up to the API's action a meeting was held with Mr. John Sloan on February 25th attended by Zinar Wulfsberg, Paul Cundy and myself.

"It is doubtful that Mr. Sloan had seen the API's proposals and so a copy was left with him. Mr. Sloan was very pleasant and had some interesting things to say:

"(a) The USDA will use the same procedure as in the past in the clearance of packaging materials.

"(b) They are very interested in inks and adhesives and wish to know the specific ones being used.

"(c) They do not accept the barrier theory because they do not know what a 'barrier' is. Any information on this subject would be most welcome.

"(d) The USDA and FDA do not always see eye to eye on things and do not always use the same terminology. The FDA lists under the regulations on components of paper and paperboard items such as anti-foam agents. The USDA thinks of components as films, board, etc., and considers such things as antifoam agents to be 'ingredients.' Thus when they request information on components in food packaging materials they are talking about the film or board as a whole and not all the items going into it.

"(e) The revised version for meat packaging materials will probably appear first in the proposed poultry regulations which should appear in the near future. One therefore, may get a preview of the packaging portion of the proposed meat regulation in the poultry regulations.

James R. S. McCartney"

Can Manufacturers Institute

Charles J. Spiegl, speaking on behalf of the Can Manufacturers Institute, noted that all of the items and problems covered by the previous reports at the day's session were of interest and concern to the Can Manufacturers Institute but that he had nothing to add to the information already provided.

Report of Technical Information Subcommittee

Willard M. Westveer, The Dow Chemical Company, and chairman of the Technical Information Subcommittee, touched on two main items at the day's session, noting first that his Subcommittee, or more properly the Pigments Task Force appointed by the Subcommittee, has been concerned for some four or five years now with developing appropriate methodology for determining whether or not specified colorants migrate from plastic packaging materials. Mr. Westveer reminded everyone about the in-depth studies conducted by the Pigments Task Force, headed by Arnold Finestone, formerly of Foster-Grant Company, Inc. This work involved round-robin testing and an analytical study of extracted materials.

Mr. Westveer reported that, at present, the technical information developed by the colorants task force has been reviewed by several members of the Committee. George W. Ingle, in particular, has been reviewing the data to try to ascertain what further work, if any, needs to be done before it can be assembled in some sort of compilation suitable for study by the overall Committee, and the making of a decision as to what more can be done with it. It is believed that Mr. Ingle will be in a position to make specific recommendations for further evaluation of the data, and perhaps be able to present a documented report for the overall Committee to review at its next meeting on June 10 in Washington, D. C. It was noted by Mr. Westveer, at the time of the next meeting, Mr. Ingle will advise the overall Committee whether, in his opinion, more work such as perhaps further round-robin testing activity will be necessary to carry this study to a successful conclusion.

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Mr. Westveer then noted that, by custom, the chairman of the Technical Information Subcommittee prepares for incorporation in the minutes of each overall Committee meeting a review of recently issued Food Additives Regulations deemed to be of interest. He then provided the Secretary with a document dated February 20, 1970, summarizing recently issued Food Additive Regulations of interest which have appeared in the Federal Register.

(Please note: Attached hereto as Exhibit C is the report prepared by Mr. Westveer dated February 20, 1970.)

In closing his discussion, Mr. Westveer noted that the Steering Committee has made some recommendations to him for improving the regular listing of recently issued regulations. Thus, in the future the reports will indicate the Federal Register citations for each regulation, and will include other clarifications as suggested.

Report of Lawyers Advisory Committee

Chairman Miller called upon Vice Chairman Taylor W. Hanavan, E. I. du Pont de Nemours & Company, Inc., and present chairman of the Lawyers Advisory Committee, to discuss the legislative outlook, recent court decisions which it is felt should be brought to the attention of the Committee, and other matters.

Mr. Hanavan delivered the following report:

"The bulk of this report with respect to pending or possible legislative activity consists primarily of a follow-up on various legislative possibilities reviewed at the last meeting of this committee.

"The 'Child Protection and Toy Safety Act of 1969' noted as pending was passed by Congress, approved by the President on November 6, 1969, and went into effect early in January of 1970. This law amends the Federal Hazardous Substances Act by extending its coverages to toys or other articles intended for use by children which the Secretary by regulation determines present an electrical, mechanical, or thermal hazard.

"This legislation also contained several 'housekeeping' amendments to the Federal Hazardous Substances Act, one of which would seem to impose a new labeling burden for certain products subject to the Act. Section 2(p)(1)(E) was amended to insert the word 'combustible' after the word 'flammable.' As a result, there may be a need of a front panel declaration 'combustible' as a statement of hazard which heretofore could be placed on the

back panel for products falling within the regulatory standard for combustibles.

"You may recall at the last meeting we reviewed certain then pending bills on occupational health and safety requirements. We noted that an anticipated administration bill had not yet been introduced, but it was expected to propose some sort of national occupational safety and health board which would promulgate employee standards of safety and health. The Department of Labor would have a veto power over any proposed standard, but this veto could be overruled by the board in subsequent action by a majority vote of its five members. The administration proposed Senate Bill 2738 (Javits) and House Bill 13373 (Ayers); the House counterpart, has since been introduced in both houses. The Javits bill was referred to the Labor Subcommittee of the Senate Labor and Public Welfare Committee and no hearings have as yet been scheduled. The Ayers Bill was referred to the Select Subcommittee on Labor of the House Education and Labor Committee. Hearings were held and the hearings were inconclusive. The administration bills as proposed not only gave the Secretary of Labor a right to object to proposed safety standards subject to being overruled by a majority vote of the board, but also gave a similar objection right to the Department of Health, Education and Welfare on health questions. As a result of problems raised at the House hearings, a new administration proposal is expected.

"Hearings were held on October 1 and 2 in connection with S-2162 (H.R. 6180), the Safe Packaging Act under which it was proposed to give the Secretary of HEW the authority to set standards for safety closures of packaged products subject to the Federal Hazardous Substances Act. The testimony covered the following:

- "1. No package is absolutely child-proof due to their curiosity and determination. Manufacturers of drugs and household chemicals should not be expected to do a parent job in protecting the child.
- "2. Imposing specific closure requirements would undermine innovation by industry in developing newer and still better containers.
- "3. Legislation seems premature and should be held up until industry and independent researchers can make a thorough investigation of this problem.

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"Senator Moss has made it clear that some sort of legislation will be enacted and compromise legislation is in the mill, though nothing has as yet been introduced.

"The recent decision in Robert L. Ackerly v. Herbert L. Lev, Jr. should be of interest. This was an action brought by Mr. Ackerly to compel FDA under the 'Freedom of Information Act' to disclose records in the possession of the Commissioner which related to the degree or nature of carbon tetrachloride hazards which the FDA Commissioner in a Federal Register notice of February 16, 1968 proposed to bar from interstate commerce as a 'banned hazardous substance' within the purview of the Federal Hazardous Substances Act. The United States Court of Appeals for the District of Columbia was highly critical of FDA's response to Mr. Ackerly's initial request for documents and FDA's conduct thereafter. Ackerly's request was made by a letter dated March 6, 1968. FDA promptly replied with a list of material that had already been published and turned down Mr. Ackerly's request as otherwise too broad. On appeal to FDA's Information Review Officer, three additional memoranda were supplied but access to any other document was denied. These three documents were supplied to Ackerly on April 3, 1968, some two weeks after FDA's Federal Register deadline of March 16 for comments on FDA's proposal to ban carbon tetrachloride. On April 22, at a pre-hearing conference the FDA made available three additional documents.

"The Circuit Court made two pertinent comments with respect to FDA's handling of the situation. 'We are not impressed with the timing in terms of the agency's responsiveness to the Congressional purposes evident in both the Freedom of Information Act and the statutory procedural scheme for rule making by the Agency embodied in the Federal Food, Drug and Cosmetics Act.' The Court also stated 'We confess to a considerable lack of enthusiasm for the caliber of the Commissioner's performance in this seemingly erratic discharge of his responsibilities under the Freedom of Information Act.'

"At the last meeting, we reviewed in considerable detail the implications of the U.S. Supreme Court's Difco decision (37 Law Week 4382) which, when coupled with its previous AMP decision, extended the present definition of drugs in Section 201(g) of the Act to include a nylon ligature device and a diagnostic aid known as an antibiotic sensitivity disc. As a result, there was some question at that time concerning the extent to which FDA might attempt to bring within the statutory definition of drug by further litigation or by regulation other

therapeutic devices and diagnostic aids and require pre-market approval as to their safety and efficacy just as with new drugs. The former commissioner of FDA, Dr. Ley, has publicly stated that FDA has neither the funds nor the manpower to follow-up the Difco and AMP decisions in this manner and to my knowledge FDA has not done so. However, we believe there is still another reason for FDA's unwillingness to capitalize on the scope of the Difco and AMP decisions. We understand that the administration is preparing a new device control bill which would require, at least with respect to new devices, FDA prior approval as to safety and efficacy before any marketing of same. Any effort to extend the Difco and AMP decisions into the device field might well prejudice the success of this type of legislation. We believe it would be safe to conclude that FDA will move very slowly in this area at least until there is substantial evidence that Congress will not enact the kind of device legislation that the administration apparently will offer."

International Developments

The Chairman next called upon Thomas J. Hughes, Keller and Heckman, to report on latest developments abroad which have been brought to the Committee's attention. The Chairman reminded everyone that, although SPI cannot assume any direct responsibility to deal with regulatory matters in Europe and elsewhere, it was recognized some time ago that it would be valuable to the Committee to be kept generally aware of what is going on overseas in the food and drug regulatory area.

Thomas J. Hughes then delivered the following report:

"Gentlemen:

"I am glad to have this opportunity to report to you once again on the latest developments with regard to international regulations on food packaging materials, as we have gleaned the same from a wide variety of sources.

"During the course of my report, I would invite those of you who have any additional information with regard to a particular country or countries to interject and contribute to the general discussion. It is largely in this way that we have, over the years, been able to develop a good deal of pertinent information to fill at least some of the gaps in our mutual knowledge of what is happening overseas.

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"UNITED KINGDOM

"As you will note from your respective copies of the agenda for today's meeting, the first topic for my report is a discussion of the effort and objectives of the British Plastics Federation as evidenced by its draft document entitled 'Plastics for Food Contact Applications--A Code of Practice for Safety in Use.' Those of you who were at the last Committee meeting in June will recall our advising that the BPF Code had been submitted to the British Ministry of Agriculture, Fisheries and Food's Food Additives and Contaminants Committee in the hope that the FACC would adopt the same as an acceptable method of 'industry self-regulation.'

"The BPF Code of Practice was made available for purchase last October, and our good friend, Trevor Wells, was kind enough to send us a complimentary copy. The Code is available for purchase from the British Plastics Federation, 47 Piccadilly, London W1V 0DN, England. The price of the Code is 20 pounds in British currency, approximately \$48.00 in American currency.

"Briefly, the Code sets forth the basic principles used in assessing the safety of plastics for food contact applications; recommendations for additives, including 170 trade names and over 90 additional chemical names of additives showing quantities which may be added to plastics for use in contact with food; and guidelines for extraction testing. Additionally, the Code includes a section on polymer specifications, covering these polymers commonly used in the packaging of foodstuffs.

"The latest information we have is that the anticipated Food Additives and Contaminants Committee Report on the 'problem of the "leaching" of packaging chemicals into food' has not, as yet, been officially issued. It is now expected that the FACC Report will be issued in the very near future and it is hoped that it will refrain from recommending the adoption of any detailed legislation on the subject of food packaging by the British Government and will, instead, recommend that packaging industries adhere to 'Codes of Practice' such as the one that has now been published by the British Plastics Federation.

"NETHERLANDS

"Turning next to the current status of the third version of the Dutch 'Draft Packaging and Food Utensils Regulation,' to the best of our knowledge, the period for comment on the main body of the Draft expired last July, and the Draft now has what amounts to 'official' status in the Netherlands.

"I am sure you will be interested to know that the Dutch Ministry of Social Affairs and Public Health has, during the past six months, published several additional 'schedules' to be appended to the subject Draft. The first, and perhaps most significant of these schedules, as far as your Committee is concerned, listed specifications for acceptable plastic materials and antioxidants with a comment deadline date which expired on December 31, 1969. A schedule of 'paper materials' was issued at the same time. The most recent schedule contains specifications and test methods for use in determining the acceptability of colorants and pigments for plastic food contact materials.

"We are advised that an 'official' comment deadline date of December 31, 1969 was also set for the colorants schedule. However, we have recently learned that the Dutch Government is still accepting comments on this subject.

"To summarize the Dutch situation, the Ministry of Social Affairs and Public Health continues to promulgate 'schedules' amending the original 'Draft Packaging and Food Utensils Regulation.' It is our understanding that the Draft and several of the schedules appended thereto are now accorded what amounts to quasi-official status in the Netherlands even though no formal Notice has been given to this effect.

"If anyone else on the Committee has additional information on the Dutch situation, we would appreciate hearing from you.

"CODEX ALIMENTARIUS COMMISSION ACTIVITIES

"From time to time we have reported to you on the status of the Codex Alimentarius Commission activities. We became particularly interested in closely following the Commission's efforts after a recommendation was made, in the latter part of 1966, to the Commission by the Danish government calling for the Commission to give 'high priority. . . to the problem of the migration of chemicals into food.'

"The Commission, which is an arm of the FAO/WHO Codex Food Additive Committee, and which is composed of delegates from the governments participating in the FAO work, has established a number of Committees to deal with various problems as they relate to foods, pesticides, labeling, and standards, etc. For example, the following representative Committees are presently in the process of compiling reports for the Commission:

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(1) the Food Hygiene Committee, (2) the Committee on Pesticide Residues, (3) the Codex Committee on Fats and Oils, and (4) the Committee on Food Labeling, to name a few.

"As far as the direct interest of this Committee is concerned, as we reported at the last Committee meeting, the Commission has given 'low priority' to the problem of incidental additives, (i.e., food packaging materials), and has, as yet, done nothing at all with the recommendations made by the Danish government in 1966.

"Our latest information is that, at the sixth session of the Codex Committee, held in the Netherlands from the 15th through the 22nd of last October, the subject of 'packaging materials' was listed for consideration 'after 1971.'

"OTHER MATTERS OF INTEREST

"(1) EEC--Negotiations continue in the EEC on the subject of food packaging and, now that the Dutch regulations have taken on a more 'official' status, it is anticipated that the EEC will follow suit and, in due course, will adopt 'directives' very similar to those promulgated by the Dutch.

"(2) We have also been advised that the West German Federal Health Office has prepared the first draft of a new 'German Food Law' which will distinguish between 'direct' and 'indirect' food additives. The draft was apparently prepared several months ago, but we have not, as yet, been able to obtain a copy. If anyone on the Committee has more information on the situation in West Germany, we would certainly appreciate hearing from him.

"(3) One final point of interest to the Committee concerns the availability of several volumes of a work entitled 'Fundamental Principles and Objectives of Comparative Food Law.' The volumes, four of which are now available, have been prepared by Professor E. J. Bigwood, of the Universite Libre de Bruxelles, and are an outstanding series on the principles of food law in many countries, including law and policies dealing with the subject of food packaging materials. Copies may be ordered by writing to the American agent appointed to handle the sale of the books in this country. His name and address are as follows:

Mr. Albert J. Phiebig
Box 352, White Plains, New York 10602

"Thank you."

Chairman Miller commented on the desirability of the Committee's members maintaining close liaison with European countries such as the Dutch, English, and so forth. To emphasize the value of this he quoted parts of a communication he received from Dr. J. H. de Wilde dated January 15, 1970, in which Dr. de Wilde said:

"Dear Bob,

"Reverting to the large number of cases in which you have supplied information to the Dutch Food Law Committees, in particular for consideration by the Packaging Subcommittee and by the Preview Committee 'G4', I would like to use the opportunity of starting a new year, to thank you very much for your cooperation. Representing industry on several of these committees it helps tremendously when industry provides the facts and data on which a sensible legislation can be based.

"Most of the Dutch officials know and admit that they do not have the technological experience and knowledge of facts to make the right decisions. When political pressure calls for regulations and industry is given the opportunity to supply basic data, lacking to do so will promote unnecessarily stringent regulations. Avoiding this is in the interest of all of us and it is for this reason that I am very pleased with your cooperation which I hope will continue."

Other Business

Chairman Miller then asked if there were any new business or other points of interest to be discussed. By way of reminder, he pointed out that the next meeting of the Committee is, according to the Bylaws, the annual meeting and that, in even years, there is to be an election of officers. He then appointed the following Nominating Committee to develop a slate of proposed officers, i.e., a Chairman and Vice Chairman, to serve the Committee for the two years beginning June 1, 1970:

Chairman: Paul F. Cundy, American Can Company
George W. Ferner, The Goodyear Tire and Rubber Company
Robert E. Rutherford, Gulf Oil Corporation

The slate of officers, when prepared and forwarded to the Secretary by the Nominating Committee, will be circulated to the membership at least thirty days prior to the next meeting. The election will then be held at the next meeting as prescribed in the Bylaws.

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Next Meeting

Chairman Miller said that the next meeting of the overall Committee will be held on Wednesday, June 10, at the Mayflower Hotel, Washington, D. C.

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The session then adjourned in order to attend a reception and luncheon with Major General Fred J. Delmore, Coordinator for Industry Relations, FDA; Mr. Lessel L. Ramsey, Assistant Director for Regulations, Office of Compliance, Bureau of Foods, Pesticides and Product Safety, FDA; Mr. Alan T. Spiker, Food and Drug officer, Division of Regulations and Petitions Control, Office of Compliance, Bureau of Foods, Pesticides and Product Safety, FDA; and Mr. Herbert T. Zahrens, Office of Marketed Drugs, Bureau of Drugs, FDA; to be followed, as pointed out in the Secretary's Meeting Announcement, by an informal discussion with the officials.

Immediately following luncheon, Chairman Miller called the group to order once more and introduced the aforementioned Food and Drug Administration staff members.

The session with the FDA officials was, in general, quite informal. Brief reports were heard from Mr. Ramsey who discussed the organizational changes made at the Food and Drug Administration in the wake of the appointment of Commissioner Edwards. For the most part, Mr. Ramsey confirmed and restated the information given the Committee in Mr. Heckman's earlier remarks during the morning's business session. In addition, however, he noted that a complete "Statement of Organization, Functions, and Delegations of Authority" could be found in the February 25, 1970, Federal Register which, of course, would have been received by subscribers to the Register on the day of the meeting.

Mr. Ramsey did discuss the status of the proposal to amend Section 121.2500 of the Food Additive Regulations, but did so rather apologetically, noting that he had no definitive statement to make because FDA is presently attempting to settle down under its new leadership and organization so that nothing tangible could be reported about the prospects for adoption of some form of the proposal. To the further disappointment of many of the Committee members, Mr. Ramsey seemed to indicate that, what with the cyclamates problem having developed, and the frenzy of activity following it, it might be some time before FDA does take action on the proposal. Indeed, at one point, he termed it of "relatively low priority" in the overall scheme of FDA's present concerns.

After Mr. Ramsey's presentation, Chairman Miller then introduced Mr. Alan Spiker who talked to the Committee about his attempts to bring about some solution to the "colorants in packaging materials" regulatory problem.

Mr. Spiker's remarks were taped, as were his responses to various questions from the floor. The verbatim transcription of Mr. Spiker's remarks follows:

"As we have been in the recent past, and in the less recent past, and with relation to the proposal we did get issued in the Federal Register in August of 1967 for paper and paperboard, as I told Jerry and have told some of the others of you, we're working on and trying to issue a similar regulation for colorants for plastics. There are considerable differences in the problems involved as we work on these things, i.e. between paper and paperboard, and the plastics. But I might discuss briefly some of the things that developed on the paper and paperboard to get to the colorants that you are more interested in.

"But there is, and I hope I won't be stealing the march here from the next person--About the SOGMA petition, as you know, we've had this around for some time, and based on that and other things, we did issue the proposal on paper and paperboard. It was our understanding at the beginning of this whole series of events which started in 1961, that when you're talking about paper--I can't trace this down--that anytime you have a liquid in contact with the paper, there was generally a functional barrier of some sort between the paper and the liquid. So this was in the background of the way in which we drafted the proposed regulation which, if any of you have looked at it recently, limits the amount of drainable weight in the food that is in contact with the permissible paper and paperboard. We received then, a comment--couched then as an objection, of course, but simply a comment from our standpoint, because the particular regulation was in proposal stage--and they said 'you've done us wrong here, because you've cut out all of the types of paper cups--this kind of container that we use for liquids.' And it went on to talk a little bit more about this problem. Well, now this was from 1961 to 1966 or '67, we were laboring apparently, under a misapprehension that we didn't have to worry about things like that because it would be taken care of by the tests proposed.

"My purpose in mentioning this is simply to illustrate the fact that we do have some problems with communications and we have some problems in the same way, I believe, with the plastic area because we are not getting the requests /petitions/ that we had hoped we would have for the various colorants that you might be wanting to use. For about eight or nine colorants that were on the last extension list--and I'm sure

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there are more colorants being used than are on that list-- we did have some petitions in for a few colors in plastic materials, and we had published the Notice of Filing of these. Then at long last we learned that the hope for the modification of the sandwich test for testing colored plastics probably would not work, so we had to advise the petitioners of this, and we suggested another analytical method that they might try out and use. This is now two years ago at least, and we have not as yet received anything from them, including the requested samples of colored plastics which we had requested from these three or four firms, so that we could try out the analytical method we were proposing.

"What I am trying to do at the present time is to develop a regulation which will be entitled 'Colorants and Plastics' and I will intend to pick up all the colorants that are listed in the various regulations and bring them out into a single regulation, not making any particular changes in the thing. I will explain this in a moment or two. I would bring this into a single, particular regulation to which we can all refer when we are concerned primarily with colorants. In other words, I have colorant X. I want to know what, under the Federal Food, Drug and Cosmetic Act, can I put this in. Hopefully, then, this will point out to many of you that we really do not have data on very many colorants that are suitable for plastics. And hopefully, this will show you that we need petitions from you in which you will advise us of your colorants that need to be recognized by regulation.

"Now, the idea sounds simple to do this, but when you try to work it out practically with people, it's somewhat more of a problem. Some of the colorants are simple substances, and the suggestion was made that we should, instead of simply listing the specific plastic substrates for which these colorants were approved--we should say that you can use these simple colorants in all plastics. But then, after proceeding in this fashion, we then find out that others have some concern in a few instances about some of the substances, and their possible toxicity and different extraction rates about which we have, really, no hard data. If you put them into one substrate that we've already looked at, into another substrate, and so on--and so at the moment I have a 'no' on that procedure that we had up to that point. So I have to come back and start over again to try to come out with this type of regulation. But my purpose, again, in mentioning this is that we need more communication as to the colorants which are being used in the various plastics materials, and which may be reasonably expected to migrate and hence, by definition at the present time, are food additives."

In response to various questions posed, Mr. Spinner had the following additional comments.

"QUESTION: Who is going to handle direct additives and indirect additives and who will inherit this color thing, since you have been moved up?

ANSWER: This is one of the problems--I'm going to be stuck doing that, along with everything else. So--and the rest of them, our personnel, has not changed. So they would be essentially the same people as you've talked to before--as of the present time.

QUESTION: In connection with the use of colorants in plastics, do you have any change--do you have any guidelines to offer us in connection with extraction methods we can rely on, telling us that we do or don't have a migration problem? For example, if you don't see the color getting into the food, is it therefore not an additive?

ANSWER: This is the basic problem that became evident when we analyzed some of the data that showed up in the substances, or in the tests for the use of visual checking. The 'sandwich test' or the modification of the 'sandwich test,' where you would take a piece of colored plastic and squeeze it between some absorbant material with a solvent there, and then look at the paper. There is some very good work done by one of the petitioners on a, I think it was a cadmium sulphide containing color, and it passed the sandwich test. But they made the mistake or--I won't say that, they did a good job on it--they took the colorless material that came through and ran it for cadmium, and found that I think it was up to 2,000 ppb. of cadmium came through. It became quite evident--on the basis of things like this, and other things--that we might be concerned about that which was coming through that we would not detect by the visual tests. So what we suggested then--and gave them the proposed analytical method--and we'll be glad to furnish this to anybody that wants it--was to cut up strips of it and extract it, and eventually test it in some kind of extraction cell, and then test the material that came out for the total extractives, and then run some kind of confirmatory test--and this was, of course, what we could not

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provide for them. But we suggested they run some kind of confirmatory test to see what was the actual make-up of the material that came through. Assuming that there would be a suitable spectrophotometric or even a spot test, as was used in the case of the cadmium to determine some key part of it, whether or not it actually extracts through. I think this would be a suitable one for any plastic product. And if you can give us an idea of the sensitivity of the method used, of course, that would be sort of essential.

QUESTION: Taking a number at random, suppose we don't see any concentration at 50 ppb, and it has no--like suppose it is an organic material that has no adverse known toxicity. Is this a food additive?

ANSWER: You're not going to get me--I will tell you this--in my opinion it is a food additive. This is my opinion. The reason I say that is, and Jerry here and I have these arguments all the time, that this--the way in which Congress worded the law, 'may reasonably be expected to become' is the point at which you determine whether it is a food additive or not, not after you have run an experiment. Because you ran the experiment because you had some reasonable expectation that it might migrate.

HECKMAN: [To the audience] I'm glad you heard it directly!

QUESTION: We are one of the companies that received your suggestions for testing but we have not submitted more data because we have been awaiting some action on the 'Ramsey proposal' since this could have an important bearing on everything. But if its bogged down, I suppose we should consider doing something more on this--

ANSWER: That's what we finally came to the conclusion, because the proposal seems to be, no telling when there will be some action."

Finally, Major General Fred J. Delmore spoke to the group emphasizing his personal interest in seeing the lines of communications between industry and the government expanded and strengthened. The thrust of General Delmore's remarks were devoted to the subject of "government-industry" cooperation and those present were urged to "speak out" on matters of concern to the plastics

food packaging industry. "Unless FDA hears from industry on matters of concern," commented General Delmore, "the Food and Drug Administration can only surmise what the problems of industry are and what the most desirable and effective solutions to the problems might be."

In closing, General Delmore praised SPI and the Committee for its continuing efforts to bring constructive reform to some of the problems surrounding the regulation of food packaging materials.

Chairman Miller thanked the FDA representatives, on behalf of the Committee and expressed the hope that there would be many more opportunities in the future for such informal dialogue between the Food and Drug Administration and members of the plastics food packaging industry.

There being no further business to come before the meeting, the same was adjourned at 3:15 p.m.

Respectfully submitted,

Charles L. Condit
Secretary

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to create Section 23.44 of the Madison General Ordinances entitled "Sales of Substances in Containers".

Public Hearing

Feb 10, 1970

@ 7:30 PM

AN ORDINANCE

Referred to	-----	Exhibit A
Reported Back	-----	
Adopted	-----	Placed On File
Rules Suspended	-----	
Re-ferred to	-----	
Public Hearing	-----	

Ordinance No. -----

File Number -----

y Alderman Ashman

PREAMBLE

WHEREAS, problems of litter and waste disposal are becoming a major problem in and around Dane County and in the City of Madison, as well as throughout the United States; and

WHEREAS, some of the largest contributors to these problems are the aluminum can, the throw away bottle and the plastic containers; and

WHEREAS, it is in the interest of the City of Madison to eliminate this sort of waste;

NOW THEREFORE:

The Common Council of the City of Madison do ordain as follows:

Section 23.44 of the Madison General Ordinances entitled "Sales of Substances in Containers" is created to read as follows:

"23.44 SALES OF SUBSTANCES IN CONTAINERS.

(1) After July 1, 1975, it shall be unlawful for any person firm or corporation to sell, dispense or give away any substance within the City of Madison in any container of metal, glass, plastic or other non-degradable material, except in a returnable, reusable container for which a deposit of not less than One Dollar shall be charged.

(2) No material shall be accepted at any landfill site operated by the City of Madison from any source whatsoever which contains containers of metal, glass, plastic or other non-degradable material.

(3) From July 1, 1975, to July 1, 1976, this section shall apply only to containers containing soda water beverages and fermented malt beverages. Beginning July 1, 1976 and thereafter this section shall apply to all containers described in Subsection (1).

(4) Penalty. Any person who violates any provision of this section shall be subject to a forfeiture of not more than \$500.00

6-72-67

Drafted by Ted Fischer. Assistant City Attorney

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Exhibit B

NEWS From

Representative JAMES H. SCHEUER

FOR RELEASE
TUESDAY P.M.'s - FEBRUARY 17, 1970

Congressman James H. Scheuer (D-Bronx) today introduced a solid-waste, environmental quality bill designed to reduce the "glass pollution" which gluts our cities' parks, recreation areas, empty lots, streets, garbage trucks and disposal plants. In addition, the bill would prevent the hazard arising from billions of bottles composed of poly-vinyl-chloride, a plastic substance which is virtually non-disposable and which emits poisonous gasses when incinerated.

Co-sponsoring the bill are: J. Herbert Burke (Fla.), Daniel E. Button (N.Y.), Shirley Chisholm (N.Y.), Seymour Halpern (N.Y.), Henry Helstoski (N.J.), Abner J. Mikva (Ill.), Richard L. Ottinger (N.Y.), Bertram L. Podell (N.Y.), Adam C. Powell (N.Y.), Henry S. Reuss (Wis.), Robert O. Tieruan (R.I.), and Jerome R. Waldie (Calif.).

The concept of the Bottle Bill is simple. It ends no-deposit, no-return, throw-away bottles by requiring a money deposit on all soda, beer, wine, and liquor glass containers, as follows:

- 2¢ on a container of 13 ounces or less;
- 5¢ on a container of more than 13 ounces;
- 10¢ on a container or one quart or less filled with wine or distilled spirits;
- 25¢ on a container of more than one quart which is filled with wine or distilled spirits.

Any bottler who produces a no-deposit bottle would be taxed an amount equal to the minimum deposit for that type bottle.

Congressman Scheuer said, "The time for talk about the environment has ended. We need action now. Glass litterers the streets of my district in the heart of New York City--it litters our parks, play areas, vacant lots, and roadsides.

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"The garbage problems in my district are tremendous--they help create a slum atmosphere and threaten the health of our citizens.

"Hundreds of millions of dollars are spent by cities every year collecting and disposing of glass bottle fragments. This bill can make a major contribution to lowering that cost and improving the efficiency of our municipal garbage collection systems.

"The provisions barring the use of potentially dangerous plastic containers will prevent a new and even more dangerous threat to the environment."

All containers made of plastic shall be taxed 25¢ per item unless they are certified as "disposable" (i.e. biodegradable) by both the Secretary of Health, Education and Welfare, and the Secretary of the Interior.

To assist retailers in bearing costs, a small tax credit will be provided for handling empty bottles.

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REPORT OF TECHNICAL INFORMATION SUBCOMMITTEES
SFI FOOD, DRUG AND COSMETIC PACKAGING
MATERIALS COMMITTEE

February 20, 1970

Recently Issued Food Additive Regulations

The following final new food additive regulations and amended regulations deemed of interest to the SFI Food, Drug and Cosmetic Packaging Materials Committee have been published in the Federal Register since our last meeting:

<u>SECTION</u>	<u>TYPE</u>	<u>DATE</u>	<u>SUBJECT</u>
8.206	Amended	7/12/69	FD&C Blue Number 1. "Lakes only."
8.501	Amended	7/12/69	FD&C Red Number 3. FD&C Yellow Number 5. "Lakes only."
121.2547	Amended	7/12/69	Provide for safe use of an aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecylbenzenesulfonic acid, together with components generally recognized as safe. Sanitizing solution on food-processing equipment and utensils and other food-contact articles, except milk containers or equipment.
121.2557	Amended	7/18/69	Provide for the safe use of the sodium salt of polyacrylic acid in defoaming agents used in processing food and in food-contact coatings.

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SECTION	TYPE	DATE	SUBJECT
121.2522	Amended	7/18/69	Provide for the safe use of a-Hydro-omega-hydroxypoly (oxytetramethylene) and Poly (oxycarbonylpentamethylene) as reactants in the preparation of polyurethane resins for use in contact with dry bulk food.
121.2559	Amended	7/18/69	(1) Provide for use of resins produced by the condensation of allyl ether of mono-, di-, or trimethyl-ol phenol and capryl alcohol as optional adjuvants. (2) Should be expanded to provide for use of its subject resins in contact with food at temperatures not to exceed 160°F. Xylene-formaldehyde resins condensed with 4, 4'-isopropylidene-diphenol-epichlorohydrin epoxy resin.
121.2566	Amended	7/18/69	An antioxidant and/or stabilizer in polymers used in the manufacture of articles for food contact use. 2, 6 Bis(1-methylheptadecyl)-p-cresol, Poly(1, 4- cyclohexylenedimethylene - 3, 3'-thiodipropionate) partially terminated with stearyl alcohol.
121.2566	Amended	8/8/69	Provide for use of the hydrogenated 4, 4'- isopropylidenediphenol-phosphite ester resins as antioxidants and/or stabilizers in rigid polyvinyl chloride bottles intended for contact with foods of types VIII and IX as described in table 1 of §21.2526(c).

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<u>SECTION</u>	<u>TYPE</u>	<u>DATE</u>	<u>SUBJECT</u>
121.2501	Amended	8/14/69	Clarify the temperature conditions to be used for determining compliance with the Mooney viscosity specifications. Olefin polymers.
121.2520	Amended	8/15/69	Provide for the safe use of epsilon-Caprolactam-(ethylene-ethyl acrylate) graft polymer as a component of food-packaging adhesives. ←
121.2526	Amended	8/15/69	Provide for the safe use of Sodium carboxymethyl guar gum in the formulation of paper and paperboard for use in contact with aqueous and fatty foods.
121.2514	Amended	8/15/69	Provide for sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.
121.2611	Amended	9/9/69	Provide for the safe use of styrene-methyl methacrylate copolymers as components of plastic articles intended for food-contact use.
121.2526	Amended	9/16/69	Provide for the safe use of modified guar gums as components of paper and paperboard for food-contact use.
121.2531	Amended	9/17/69	Provide for the safe use of partial methyl esters of dimers and trimers of C ₁₈ unsaturated fatty acids in surface lubricants used in the manufacture of metallic food-contact article under conditions such that the total residual lubricant does not exceed 0.015 milligram per square inch of food-contact surface.

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