THE SOCIETY OF THE PLASTICS INDUSTRY, INC.
250 PARK AVENUE . NEW YORK, NEW YORK 10017 . 212 MU 7-2678

MINUTES

MEETING OF SPI FOOD PACKAGING MATERIALS COMMITTEE

Commodore Hotel
New York, N. Y.

August 23, 1966
9:30 a.m.

Present:

George W. Ingle, Chairman, Monsanto Company, Hydrocarbons and Polymers Division, Research Dept., Springfield 2, Mass.
George T. Scribe, Vice-Chairman, Union Carbide Corp., 270 Park Avenue, New York, New York
Donald Bartholme, Standard Bag Div., Boise Cascade Corp., Cooper Place, Dunellen, New Jersey
Thomas M. Carty, SPI, 250 Park Avenue, New York, N. Y.
Robert C. Coomey, H. Kohnstamm & Co., 161 Avenue of the Americas, New York, N. Y.
L. J. DeCorte, Sinclair-Koppers Co., Product Development, Frankfort Road, Monaca, Pennsylvania 15061
Harry R. Dittmar, Vypak Corporation, P. O. Box 55, Rockaway, N. J. 07866
Charles S. Doskow, Thatcher Glass Mfg. Co., Inc., 375 Park Avenue, New York, N. Y.
Dr. A. W. Downes, Union Carbide Corp., Plastics Division, 270 Park Avenue, New York, N. Y. 10017
M. J. Dunn, H. Kohnstamm & Co., 161 Avenue of the Americas, New York, N. Y. 10013
Leroy Durkin, Imco Container Co., 430 Park Avenue, New York, N. Y. 10022
R. A. Ferrell, Kennedy Car Liner & Bag Co., Shelbyville, Indiana
Dr. A. B. Finestone, Foster-Grant Company, Inc., 289 N. Main Street, Leominster, Massachusetts 01453
C. T. Fleenor, Marbon Chemical Div., Borg-Warner Corp., P. O. Box 68, Washington, West Virginia
B. J. Garceau, I.C.I. (Organics), Inc., 55 Canal Street, Providence, Rhode Island
C. E. Graham, 2000 P Street, N.W., Suite 700, Washington, D. C.
Jerome H. Heckman, Esq., SPI Counsel, Keller & Heckman, 1712 N Street, N.W., Washington, D. C.
K. A. Hochschwender, American Hoechst Corp., 777 Third Avenue, New York, N. Y. 10017
D. H. Hunter, Stauffer Chemical Co., Plastics Div., P. O. Box 320, Delaware City, Delaware 19706
W. A. Knapp, Allied Chemical Corp., General Chemical Div., P. O. Box 405, Morristown, N. J.
Edmund Lambert, Marbon Chemical, Div. Borg-Warner Corp., Washington, West Virginia
J. R. S. McCartney, Standard Packaging Corp., 200 E. 42nd St., New York, N. Y.

R. M. Miller, Hercules, Inc., Delaware Trust Building, Wilmington, Delaware 19899
J. A. Mitchell, E. I. du Pont de Nemours & Co., Inc., Film Dept., Wilmington 98,Del.
Dr. K. Morgareidge, Food & Drug Research Laboratories, Maurice Ave. at 58th St., Maspeth 78, New York
B. G. Murray, Ferro Corporation, Color Division, 4150 East 56th St., Cleveland, Ohio
Dr. Walter Feist, Celanese Polymer Co., 160 Terminal Ave., Clark, New Jersey
W. A. Patterson, W.R. Grace & Co., Cryovac Division, Duncan, South Carolina 29334
I.F. Peake, E. I. du Pont de Nemours & Co., Inc., Film Dept., Wilmington, Del.
D. W. Pugh, U. S. Industrial Chemicals Co., P. O. Box 208, Tuscola, Illinois
G. A. Richter, Jr., Rohm & Haas, The Rohm & Haas Bldg., Independence Mall West, Philadelphia, Pa. 19105
J. A. Rudy, Owens-Illinois, Plastic Products Div., Toledo, Ohio
L. J. Russikoff, Allied Chemical Corp., P. O. Box 365, Morristown, New Jersey
R. E. Rutherford, Gulf Research & Development Corp., Dwight Bldg., Kansas City, Mo.
S. W. Schaefer, Diamond Alkali Co., Box 191, Painesville, Ohio
E. H. Schaeffer, Shell Chemical Co., 50 West 50th Street, New York, N. Y. 10020
W. W. Sederlund, National Starch & Chemical Corp., 1700 W. Front St., Plainfield, New Jersey 07063
S. Sherman, W. R. Grace & Company, Research Div., Clarksville, Md.
M. E. Smith, Owens-Illinois, Plastic Products Div., Adams & 14th St., Toledo, Ohio
C. J. Spiegl, Continental Can Co., Inc., 7622 South Racine Ave., Chicago, Ill. 60620
F. C. Strochlein, Emery Industries, Inc., 4900 Este Avenue, Cincinnati, Ohio 45232
J. Torter, H. Kohnstamm & Co., Inc., 161 Avenue of the Americas, New York, N. Y.
W. M. Westveer, The Dow Chemical Co., 433 Bldg., Midland, Michigan
D. E. Weisinger, Firestone Plastics Co., Box 699, Pottstown, Pa.
Dr. N. G. White, Shell Chemical Corporation, 50 West 50th Street, New York, N. Y.
Charles L. Condit, Secretary, SPI, 250 Park Avenue, New York, N. Y. 10017

Under the Chairmanship of George W. Ingle, Monsanto Company, a meeting of the SPI Food Packaging Materials Committee was called to order in the Commodore Hotel, New York City at 9:30 a.m.

Mr. Ingle, as the first order of business, referred to a detailed Agenda circulated prior to the day's session and, in so doing, asked for the usual self-introductions.

Minutes Last Meeting Approved

By way of reminder, Mr. Ingle said that the last meeting of the Committee was held on March 3, 1966 in Washington, D.C., and that shortly thereafter all members of the Committee received copies of the Minutes of the meeting. He then inquired as to whether there were any additions or corrections to the Minutes of the March 3 meeting as circulated, and hearing none, declared the Minutes of the last meeting approved as published.

Preliminary Remarks by Chairman Ingle

Before turning to the regular Agenda items, Mr. Ingle reported on two special items to be called to the attention of the overall Committee, as a result of discussions during a pre-meeting session of the Steering Committee.

Firstly, Mr. Ingle noted that the Steering Committee discussed the possibility and desirability of trying to hold a special meeting at least once a year to which appropriate FDA Staff members would be invited and would be asked to participate in some type of informal question-and-answer period designed to bring about a clearer and broader understanding of FDA's thinking at a given time.

It was pointed out by Mr. Heckman that this matter has been discussed in the past with no definite decision made as to whether such sessions should be held. He stated that, in his opinion, such meetings could improve understanding of industry problems and, on the other hand, those of FDA in regulating packaging. Mr. Heckman pointed out that FDA Staffers have expressed an interest in such a program to him from time to time.

In the absence of objections to the Steering Committee's recommendation that efforts be made to arrange such a meeting with officials of FDA, Mr. Ingle announced that the matter will be carried forward so that the next meeting will probably be of this type and will be held in Washington, D. C. with invited guests from FDA. Mr. Ingle noted that it would be highly desirable for such a meeting to be set well in advance so that Committee members can send Mr. Heckman suitable questions and he can put them in order so that the FDA people will have an opportunity to prepare answers prior to the meeting.

Turning to the second "special item", Mr. Ingle reminded that, from time to time, there have been discussions about the scope and objectives of the Committee and the question of whether consideration should be given to changing the stated scope since the Committee has frequently been asked to go beyond strictly food packaging materials problems. This has been the case, for example, in connection with drug applications problems, where the Committee has worked with the Pharmaceutical Manufacturers Association.

Mr. Ingle further noted that, in recent months, the SPI Board of Directors has asked him or the Committee to consider a wide range of matters beyond the original scope of activities, e.g., occupational hygiene matters as they relate to the manufacture of foam and PVC pipe, and more recently the possible problem of waste disposal of plastic containers. Mr. Ingle said that the Board and others undoubtedly have asked the Food Packaging Materials Committee to consider these unrelated problems because the Committee has available a good deal of proven expertise, both technical and legal, in the public health problem area.

The net result of some of this interplay is that the Steering Committee, recognizing the fact that some of the items being referred to it are beyond the presently stated scope of the Committee as outlined in the Bylaws drawn up in 1960, believes consideration should be given now to changing the name of the Committee and revising the Bylaws to cover the range of matters actually being handled. On the other hand, the Steering Committee expressed the view that some less closely related matters which have been brought to the attention of the full Committee or its Chairman, should be referred back to the SPI Board of Directors with the suggestion that perhaps these matters might now properly be handled by another Committee, possibly a new one with a title like "SPI Environmental Health Committee", or something similar.

On Motion by A. W. Downes, Union Carbide Corporation, seconded by Mr. William Knapp of Allied Chemical Corporation, and unanimously passed, the Steering Committee was instructed to review the present Bylaws and develop a set of recommended amendments to be submitted to the full Committee at the earliest possible opportunity. The recommended amendments are to deal with such matters as a possible name change, a redefinition of the scope of the Committee's activities, and any other changes that might appear generally in order to the Steering Committee. It is understood, of course, that no such changes can be finalized without due notice and a proper vote of the full Committee at a duly constituted meeting.

Nominating Committee Report

Returning to the Agenda as prepared, Mr. Ingle noted that since the last meeting he had appointed Fred W. Adams, Continental Can, as Chairman of a Nominating Committee composed of Mr. Adams and Messrs. W. M. Westveer, The Dow Chemical Company, and M. C. Stone, Eastman Chemical Products, Inc. Mr. Adams being absent from the day's meeting, Mr. Ingle called upon W. M. Westveer to announce the suggested slate of officers proposed by the Nominating Committee and previously mailed to the membership. Mr. Westveer presented the following slate:

CHAIRMAN- George W. Ingle, Monsanto Company

VICE CHAIRMAN- Robert M. Miller, Hercules Inc.

Three members to the Steering Committee:

George T. Scriba, Union Carbide Corp.
I. Frank Peake, E.I duPont de Nemours & Co., Inc.
(Film Department)
M. E. Smith, Owens-Illinois, Plastic Products Div.

Thereupon, there being no other nominations for the various offices to be filled, A. W. Downes, Union Carbide Corporation, moved that the nominations be closed, and that the Secretary be empowered to cast a unanimous ballot for the slate as proposed by Mr. Adams' Committee. Arnold B. Finestone, Foster Grant Company, Inc., seconded the motion; the motion was carried unanimously.

It was noted that the incoming officers would serve a two-year term and that the next election would be held in the Spring of 1968.

Reports on Liaison With Other Organizations

Mr. Ingle then called for the usual liaison reports from other organizations conducting work of interest to the overall SPI Committee.

Pharmaceutical Manufacturers Association

A. W. Downes, Union Carbide Corporation, presented the following formal report on "SPI-PMA Liaison":

"As a result of a joint meeting July 8, 1966 of representatives of the SPI Food Bottling Committee, PMA, and SPI Food Packaging Committee, it was decided to reactivate an SPI group to serve as a liaison between SPI and PMA - Plastics Committee.

"The objective of this group is to develop parameters of defining polyethylene resins acceptable for packaging dry drugs (pills, tablets, and powders).

"A meeting of the SPI-PMA liaison group has been scheduled for 9 a.m., September 27th at the Union Carbide Building, 270 Park Avenue, N. Y., N. Y.

"The SPI representatives are as follows:

P. E. Campbell	- Phillips Petroleum Co.
A. W. Downes	- Union Carbide
G. W. Ingle	- Monsanto
R. M. Miller	- Hercules
K. Morgareidge	- Food & Drug Research Lab.
Jules Pinsky	- Monsanto
M. E. Smith	- Owens-Illinois
W. M. Westveer	- Dow"

After Mr. Downes gave his report, Mr. Ingle called on Mr. Heckman who emphasized the necessity for distinguishing carefully between the work and purposes of the Food Packaging Materials Committee PMA Liaison Committee, and the work now being undertaken by a special Ad Hoc Committee composed of representatives from the Food Packaging Materials Committee, and members of the Food Bottling Committee of the Plastics Bottle Division.

It was indicated that everyone should recognize and appreciate the difference in the activities of these two groups, lest there be some unnecessary confusion, since both activities do have some relationship to the packaging of drugs in plastics. and both involve relationships with the Pharmaceutical Manufacturers Association.

Mr. Heckman pointed out that Mr. Downes' Committee was a long-standing one which had worked with the PMA Plastics Committee in developing basic information on parenteral drug applications of plastics, which information is now published in the U.S. Pharmacopeia and the National Formulary.

The work on parenteral drugs has made it apparent that some mutual benefits to both the plastics industry and the pharmaceutical industry might flow from additional work looking towards further publication of technical information relative to the use of plastics in drug applications. As a step in this direction, Mr. Downes has now reconstituted his standing PMA Liaison Committee of the Food Packaging Materials Committee and will work with the PMA Plastics Committee in attempting to develop information as to the requirements of the drug industry where it desires to package so-called dry drugs in polyethylene materials. It was noted, incidentally, that the work will be commenced by concentration on the use of polyethylene for dry drugs simply so that the project will not become unduly complicated at the outset.

Separate and aside from this technical work, to be undertaken as a part of the continuing activity with PMA in this area, the new Ad Hoc Committee, of which Mr. James A. Rudy of Owens-Illinois is the Chairman, has been considering problems presented by the fact that, in supplying so-called "Master File" information to FDA, plastics companies have often specified particular trade-named resins rather than using generic descriptions, such as "polyethylene meeting the specifications in Section 121.2501 of the Food Additive Regulations", etc. What this has led to is that FDA, in approving a new drug application, has at least impliedly frozen the packaging material which a drug manufacturer can use by giving the new drug approval on the basis of the Master File data, specifying a very specific proprietary resin.

It has become apparent for a number of reasons that bottle manufacturers, for example, would like to have more flexibility in this area so that they could substitute different manufacturers' resins, provided the resins all meet the same basic qualifications.

In the course of investigating what might be done about this problem, Mr. Rudy's Ad Hoc Committee had a meeting with the Pharmaceutical Manufacturers Association's representatives. At this meeting, it became apparent that the primary job that must be done is probably educational. It was agreed that both the plastics industry and the pharmaceutical industry should be advised about the possibility of supplying information to FDA which would enable a plastics bottle manufacturer, for example, to use various suppliers of polyethylene instead of being limited to one particular brand which might have been specified in a Master File submission.

The necessity for taking action to provide a bottle manufacturer with more flexibility, as far as raw materials use is concerned, is obviously separate and apart from the technical work that may be done with the PMA Plastics Committee on refining write-ups of the drug industry's requirements, as far as packaging materials are concerned. Thus, the Ad Hoc Committee is presently proceeding on a basis which calls for the preparation of a draft bulletin or manual covering in some detail the way in which the new drug law operates, vis a vis its impact on packaging materials and how plastics industry suppliers of packages for the drug industry might better handle their Master File submissions so that they will not find themselves "frozen" as far as the use of a particular trade-named plastic for a particular drug is concerned.

As of the moment, this work is proceeding with Mr. Heckman drafting a proposed manual or bulletin for the Ad Hoc Committee to review and discuss with the Plastic Bottle Division. After this preliminary draft is prepared and sent to Mr. Rudy, it is likely that it will be discussed informally with the Food and Drug Administration to obtain its reaction and, ultimately, the manual will be published and circulated as widely as possible.

It is hoped that the work of the Ad Hoc Committee will ultimately place the plastics industry in a position where, in submitting Master File information to FDA, the practice will be to specify resins on a generic basis, so that substitutions of one trade-named product for another can be made without any necessity for a drug manufacturer to file supplemental drug applications to advise FDA about an inconsequential switch in a package component.

The natural reluctance of drug manufacturers to file such applications, thereby asking FDA to pass again on an already cleared drug product, is a primary factor which has deprived the plastics industry of the desired flexibility in substituting another supplier's resin or other component for those already specified in Master File information, even where the components are generically the same.

SPI Food Bottling Committee of Plastic Bottle Division

On behalf of the SPI Food Bottling Committee, M. E. Smith, Owens-Illinois, indicated that the two principal areas he planned to discuss at the day's meeting had been quite thoroughly detailed by Messrs. Downes and Heckman. He did note once more that every possible move is being made to arrive at broad parameters for suitable use of materials and that, as an initial step, the joint effort between SPI and PMA has been extended to develop criteria for polyethylene resins acceptable for packaging dry drugs (pills, tablets and powders). Mr. Smith indicated that after polyethylene is considered, the Ad Hoc Committee will then move on to consideration of other materials.

(It was noted tangentially at this point that the University of Connecticut is doing some work in this area which would appear to deal with the subject of polyethylene and its applicability to the 100 most used drugs. This is a completely independent study.)

Mr. Smith was then asked by Robert Miller, Hercules Inc., to comment on other items being considered by the SPI Food Bottling Committee which could be of interest to the Food Packaging Materials Committee. Mr. Smith referred to meetings with the Bureau of Weights and Measures, reporting that it has now been definitely ruled that a plastics milk bottle will be dealt with as a package, rather than as a "measured-fill" container, thereby eliminating the problem of meeting the requirement that plastic bottles comply with the fill requirements in Handbook 44.

Continuing in another area, Mr. Smith reported that the National Conference on Interstate Milk Shipments has moved forward in its preparation of recommended instructions for sanitation inspectors. This work was actually commenced a number of years ago and represents a cooperative effort by the U. S. Public Health Service, the Dairy Industry, and Syracuse University Research Corporation, looking towards the development of recommended inspection instructions to be used by local health officials. The instructions have, generally speaking, been finalized and will be published in substantially the present form reasonably soon. It is anticipated that they will be explained and interpreted in a forthcoming special seminar to be conducted by Syracuse University Research Corporation for the benefit of local officials.

In commenting on this matter, Mr. Smith noted that there was some dissatisfaction among the members of the Plastics Bottle Division participating in this work relative to two of the provisions in the present draft of the set of instructions. The provisions in question are Sections 16(a) and (d), the difficulty being primarily one of interpretation. There is some fear that these Sections might be read to indicate that no bottle for dairy use could be molded on a machine which has previously been employed to fabricate articles from materials which are not of the type permitted for use in food contact applications. The only reason this

question has arisen is because Section 16(a) of the instructions does not make it clear that such equipment could be used for the molding of dairy bottles even though it has been used for other, non-food contact containers or articles, provided the equipment is satisfactorily cleaned after use for molding non-food contact items.

A similar type of dissatisfaction exists with regard to Section 16(d) because it implies that a molding plant operator would have to separate completely any equipment used to manufacture plastic milk bottles from other equipment used to manufacture articles not intended to contact foods.

Those on the Food Bottling Committee who are working on this matter intend to recommend slight revisions to Sections 16(a) and (d) and it is hoped that, by this means or by suitable interpretive statements which may be made at the Syracuse University Seminar, a clarification of the true intent of the instructions will be effected so as to resolve these problems.

In commenting generally on the activities of the SPI Food Bottling Committee, J. A. Rudy, Owens-Illinois, stated that every attempt should be made on a continuing basis to make certain that all government agencies recognize SPI as an authority in this whole field and look to it for guidance and information, rather than to other organizations, or entities.

Manufacturing Chemists' Association
(Food Additives Committee)

Mr. Heckman reported that under date of August 16, 1966, he received the following communication from Taylor W. Hanavan, E. I. du Pont de Nemours & Company, Inc., relative to the activities of MCA's Food, Drug, and Cosmetics Committee:

> "The scheduled SPI meeting on August 23 comes during a short vacation period I have planned for some time. As a result, I will not be able to attend. As the liaison representative to MCA's Food, Drug, and Cosmetic Committee, I would like to make the following report. The Food, Drug, and Cosmetics Committee met on April 13, 1966, and no matters of direct interest to the Food Packaging Materials Committee were discussed."

Other Liaison Reports

Mr. Ingle then inquired as to whether there might be any other information of interest about relative activities of other organizations. A. W. Downes, Union Carbide, then noted that he recently received a very general inquiry from the National Flexible Packaging Association, apparently asking for advice about the overall FDA regulatory situation. In the absence of a more detailed statement as to its special interests from NFPA, Mr. Downes indicated he will probably attend its next meeting to try to ascertain in depth just what particular problems are of interest to this group.

Reference was also made during this discussion to the forthcoming American Chemical Society Meeting, to be held in New York City during the week of September 12, and especially to its announced Symposium on plastics and coatings for food contact applications scheduled to take place on September 14. It was pointed out frequently

during the discussions at the days' meeting that several members of the Food Packaging Materials Committee, as well as its Chairman and SPI Counsel, are due to participate on the Symposium Panel.

Before closing the liaison discussions, Wendel F. Munro of American Cyanamid Company commented briefly that "the oldest petition on FDA's Docket, namely SOCMA's Food Additive Petition No. 367 relating to dyes and pigments for use with paper and paperboard, remains pending and in the same general status as reported on at the last meeting of the Food Packaging Materials Committee.

Report of SPI Legal Counsel

George W. Ingle then called on Jerome H. Heckman, Esquire, and SPI Counsel, for his regular discussion of the status of pending SPI Petitions, FDA organizational and procedural changes, and their future implications, and other matters of the type Mr. Heckman is charged to bring to the attention of the Committee.

Jerome H. Heckman then gave the following formal report at today's session. It should be noted that, as is customary, Mr. Heckman's comments were interrupted from time to time for responses to questions and explanatory discussions. For the sake of coherence, the report, in edited form, is set forth in toto first, with brief summaries of the questions or discussions that arose during the report covered thereafter.

> It is good to see all of you again in the course of our continuing mutual Odyssey through the straits of FDA packaging industry regulation. My report this time will necessarily be a little more extemporaneous than I had planned. This is because the most significant development which has taken place since our last session, at least as I see it, is one that came to full blossom only last week. I hope that most of you have received our August 18 letter enclosing copies of the new FDA Guidelines so that you will know what I mean.
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> Incidentally, we have some additional copies in our office for those who might want them, but one of the reasons I circulated the Guidelines as soon as we received the paper, is so that it would not have to be duplicated for the Minutes.
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> For the sake of meeting what I consider to be my normal obligations in giving you these reports, what I would like to do is go over some of the general items of interest first and then comment on the Guidelines, their substance, status, and any possible follow-up action we would like to consider.
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> Olefins Polymer Regulation
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> Firstly, with regard to the Olefins Polymers Regulation, you will recall that the last time we met there was a matter in controversy because we were not satisfied with the Alkene-1-Copolymers definition in the new regulation as it was published.

Since the last meeting, we have been able to obtain publication of a further revised regulation which has been made effective with revisions to meet, at least in essential part, the objections lodged on behalf of SPI, duPont, Phillips and Union Carbide. At the risk of over-generalizing a rather complicated matter, I believe it is fair to say that effective action of this Committee, with the aid of those of its company members directly interested, enabled us to obtain a compromise type amendment of the Alkene-1-Copolymers definition which at least permits the uses of the copolymers of known importance now, as far as I am aware. The new definition probably also covers many potential uses where no more than the usually small percentage of one to eight Carbon Atom Alkene-1-Copolymers would be employed. There is room for broadening that regulation certainly. As a matter of fact, it has been further amended since we got our last amendment to allow another use for non-crystalline polypropylene.

Before passing on to other topics, I would like to remind you that in setting forth the extraction test methods in the new Olefins Polymer Regulation, a simplified procedure was published for polypropylene. A few of our Committee members have expressed the opinion that this same procedure would be satisfactory for all of the olefins and should be made the official procedure for polyethylene and the Alkene-1-Copolymers too. The only reason this was not advocated when consideration was being given to the methods in the new regulation is that it was felt that, in order to tell FDA that these methods could be specified across-the-board, we would have to have at least given everybody in the industry a chance to test their own materials with these methods, and this would have held things up too long at a time when there was a lot of pressure for the new regulation to issue. Thus, it was decided to leave the methodology question for a later day.

Don Pugh of USI, and perhaps others of you, have indicated that you would like to see the methodology provided for in the regulation set forth only the polypropylene method, so it could be used across the board. I might point out that there is really no reason why you cannot use the simpler method anyway if you want to, as long as you are satisfied that it will give you the same assurance of compliance with the regulatory extraction criteria as the one set forth by FDA. FDA has indicated many times that this approach is perfectly proper.

On the other hand, if the Regulation creates a true substantive problem because of the method set forth, further formal action can be considered and I would recommend that the matter be referred to the Technical Information Subcommittee for consideration.

From the legal and procedural point of view, let me note that I really have no doubt but that FDA would be willing to amend the Olefins Polymer Regulation again to simplify the test procedure provision. What I cannot predict, however, in light of past experience, is how many complicated side roads of the regulatory

path we might have to travel, how many new questions might be raised just because a petition is filed, and whether or not we would face presently unforeseeable challenges by the bringing to bear of FDA's usually unpredictable inquisition techniques in dealing with petitions.

While not truly trying to dissuade you entirely from seeking to have an existing and apparently satisfactory regulation revised, I think you must recognize that it is virtually impossible to predict what is going to happen, even where you file a petition that might seem to call for the simplest type of action in the world.

On the regulatory side, it seems to me that you have three alternatives here. One- you can stand on the position that you can use simpler methodology anyway, if you want to, so, unless there is some kind of special problem, why try to have the regulation amended at all?

Two- we could file a petition and take our chances, hoping that this is one that would go through easily, as a few of them do.

Three- we could perhaps just advise FDA, by means of a letter or some other informal filing, that the polypropylene methodology is applicable to the other resins- assuming that the Technical Information Subcommittee so decides -and suggest to FDA that it might want to simplify the regulation on its own motion. If this were done, we would not have filed a petition, and our status would be at least slightly different.

There is one other approach possibility that might be of help. If the Technical Information Subcommittee can decide that there is an adequate relationship between the two methods, I suspect that we could probably obtain a letter from Food and Drug agreeing that either method could be used, so that you could duplicate the letter for your customers if there is a customer relations problem here.

Polystyrene

Turning to perhaps the "second longest pending petition" at FDA, again I simply do not have anything of substance to report on polystyrene. The last time I talked with anybody at FDA on the subject was last Friday, when Mr. Randolph told me that he has not really devoted any time to the matter recently, so he still has to draft a regulation. Of course, the essence of the problem, from a procedural point of view, is that FDA does not believe any practical problem exists because of the delay. The theory is that polystyrene is prior sanctioned; as far as anybody knows, you can sell all of it you want under the "prior sanction" and, therefore, the issuance of a regulation from Mr. Randolph's point of view is not "as important as working on other things."

Dependent on how this Committee feels about the matter, or how the members of the Polystyrene Task Group feel, if we want to elicit their views, I think that we might at this point arrange for some type of a Committee delegation visit to bring more pressure to bear for the issuance of a polystyrene regulation, assuming that the lack of one is creating some type of hardship. The delay may not be inhibiting sales per se, but it would certainly be nice to lay to rest this problem for a couple of reasons. Frankly, it annoys me to have to report the same status every time but, more important, appropriate action might be helpful in some of these European situations where other countries are considering regulations to govern polystyrene. Our government has a chance to provide some leadership here and maybe resolve some very difficult problems that the Europeans are raising. I have used these arguments with Mr. Randolph and with Mr. Ramsey, but so far they have not been overly stirred.

Coatings Petition

The only other SPI petition that is listed on the agenda is the Coatings for Plastics Petition, which we consider inactive although it has not been withdrawn formally. Especially in light of the new Guidelines that have been issued, I would say that our plan, when and if the occasion demands, is to quietly withdraw that petition. Fortunately, it has never been "Noticed for Filing" so this will not present any apparent customer relations problems.

The Guidelines make it clear that if FDA wants to insist on detailed data to support our petition it can do so, and we could not comply on any rational basis.

The most important thing to remember here is that, a good deal of time having passed since our Petition was filed, I believe most of the substances covered in the Petition, that were not conjectural as far as use is concerned, have been covered in one way or another under existing coatings regulations like the ones for the polyolefins, and the one for repeated use articles. There have also been some regulatory amendments in the past few months with regard to some of the other coating materials regulations which Bob Miller is covering in his regular report.

FDA Personnel Changes and New Policies

Now, let me spend a few minutes on the so-called FDA organizational changes which might better be characterized thus far as a game of musical chairs. At the top level, Mr. J. Kenneth Kirk is now officially Associate Commissioner for Compliance so that, in practical fact, he is at the top of the chain of command as far as Food Additive Petitions, among other things, are concerned. He has already moved to Arlington, to the new Crystal Plaza Building, where everyone in the Commissioner's Office will be soon.

Though it may seem like a detail, I might remind you that a few years ago we went to some trouble to try to impress FDA with the idea that it would be very helpful if all the people who deal with Food Additive Petitions were in generally the same area, so that they could confer with each other more readily. Unfortunately, in the past few months there has been some new decentralization so that the Division of Food Additives and Standards people, for example Messrs. Holtz and Munsey who deal with indirect additives, are back in the South Agriculture Building, separated from the Petitions Control Branch and the Division of Toxicological Evaluation.

Aside from these relatively inconsequential changes, there is little more of direct interest to report on the FDA reorganization front, per se.

For those of you who have not yet been thoroughly exposed, you should understand that far from things ever becoming simpler at FDA, they usually become more and more complicated. As you may know, over the years there have been constant complaints that FDA ignores its statutory mandate to act on Food Additive Petitions within the 180 day maximum permitted by its enabling law. This is one of the things that Dr. Goddard has been very disturbed about. He feels that FDA should act within the time allowed by Congress on any matter, and he has so advised the FDA Staff.

There has now been an important change in FDA policy which has taken place in the usual quiet, unannounced way, allegedly because of the pressure Dr. Goddard is bringing to bear for more expeditious FDA action on the filings made with it. The situation is a little complicated, so I ask you to bear with me for a bit of explanation.

To clarify as much as possible what the Staff has done to meet the Goddard requirement for more action, let me try to put the matter in perspective by starting from what has been and moving into what is. Until the early part of this year, a Food Additive Petition would almost never be "Noticed for Filing" within the 30 day period called for by Section 121.51 of the Food Additive Regulations. Instead, the petition was circulated for virtually complete review by the Divisions of Food Additives and Standards, and Toxicological Evaluation, after which extensive inquiries were usually raised. The petition was then "Noticed for Filing" only after almost complete substantive resolution of any problems that came to light in this "pre-acceptance" review process. Even so, FDA seldom took action to promulgate a requested indirect Food Additive Regulation within the 180 day statutory maximum time allowed for such action after a petition is "Noticed."

Since the beginning of this year, FDA has generally speaking established a policy of filing all petitions promptly (i.e., within the time Section 121.51 provides) so long as the petition

is prima facie complete. This is undoubtedly what was originally intended by the procedural time-element safeguards set forth in the law and the regulations.

Unfortunately, however, the new FDA interest in complying with statutory standards and eliminating its huge backlog of petitions-mainly for indirect additives -has brought into play a new twist, perhaps more properly characterized as a "backlash." In its anxiety to eliminate its backlog and industry's complaints about delays, FDA is often advising petitioners, sometimes at what amounts to the eleventh hour, (i.e., just before a 180 day deadline expires) that a Petition Noticed for Filing cannot be acted upon favorably without some extensive new study or studies not previously requested in any way. Simultaneously, it will be stated that unless such data can be made available, the petition will be denied, or a request for "withdrawal without prejudice" may be filed within 30 days. In a number of these cases, the additional data requested might be a 90 day feeding study so that the petitioner really has no choice but to withdraw the petition and suffer any commercial consequences Federal Register publication of the withdrawal might bring about.

These consequences can involve considerable loss of business, or at the very least, a need for some potent re-selling. For example, a customer might be using the petitioner's product on a "no-migration" basis, having been satisfactorily convinced that such use would present no real problem during some interim time while a Food Additive Regulation was being sought to provide more tangible "federal approval" not otherwise obtainable because of the FDA "no-migration" policy. Convincing such a customer that there is still no true safety problem, but only a procedural one when a "Notice of Withdrawal Without Prejudice" appears in the Federal Register relating to the substance he is using will be, at best, difficult and could be impossible.

Under such circumstances, as we see it, the new FDA policies seem overly rigid and impose a very important additional jeopardy for potential petitioners to consider. They may well work to reduce the petition backlog, not only by bringing about many withdrawals without prejudice, but also by discouraging the development of new products or the filing of petitions for any reason. We feel the approaches now in use exalt form over substance and should be re-evaluated, bearing in mind that the statutory and regulatory deadlines were provided to protect industry from arbitrary inordinate delays, not to provide the government with a convenient procedural device to clear its petitions list without substantive determinations. As a minimum, FDA should exert every effort to review a petition promptly after it is Noticed for Filing, and advise promptly as to any and all additional data deemed necessary. In most cases, this would give petitioners time to provide the data before the 180 day-time allowed for action on a petition, and FDA would still have its full time allotment to act in light of the provisions of Section 121.53 of its Regulations.

In light of the policy being followed now, there is still a new reason to consider the pros and cons of filing a petition very carefully. I know this is somewhat contrary to what FDA would like to see because they constantly urge the filing of petitions, but they also continually impose new roadblocks. If you have to worry about being compelled to "withdraw without prejudice" at some point, I would think that you might think a long time before you file a petition and perhaps --I throw this out for whatever it is worth-- perhaps you might want to have some type of commitment in writing, or group of commitments in writing, from FDA to the effect that data that you have prepared is adequate to support the issuance of a regulation before you even file a petition.

One possibility that you might consider is, prior to filing a petition submitting all of the data that you would normally file in a petition under cover of a letter, asking only for FDA's reaction on the data, i.e., "Is it adequate to support the issuance of a regulation?" You might have to wait a while for an answer, but probably no longer than on regular petitions. You should, of course, try to phrase such letters carefully so as to elicit as direct and dispositive an answer as possible, and then file the petition afterwards. I mention this possibility for whatever it might be worth and without any guarantees that this ploy to avoid the new jeopardy will work or will not be "counterintelligenced."

Recent Cases of Special Interest

While I have not done this previously, I would like to mention two court cases, at least for those of you who are lawyers; and maybe for those of you who have the kind of problem they involve in your company once in a while. The first case is reported as Joseph F. Lewis v. Martha Baker db/s Baker's Pharmacy and Richardson Merrell, Inc., decided by the Supreme Court of the State of Oregon on April 20, 1966. The reason I think this case may be of interest to you is because the Court held in effect that, if there is an existing FDA approval for a substance (in this case for a Drug), this constitutes a factual finding that the substance is reasonably safe for its intended use and that, therefore, a cause of action on the strict liability theory (i.e., without proof of negligence) in selling it to somebody does not lie, even though the substance may have caused some kind of serious illness. For more complete information you may want to read this case which is reported beginning with Paragraph 5546 of the CCH Products Liability Reports. My main reason in mentioning the Lewis case is because it provides some assurance that, if you have Food Additive Regulation coverage or an FDA letter on a product, an added legal defense to liability for such things as allergic reactions exists.

The other case I want to mention is one decided June 7, but published only about a week or so ago. This is the case of Power Ski of Florida v. Allied Chemical Corporation. It does not deal with a matter on all fours with any immediate issue, but it may be helpful in connection with a kind of question we receive from some of you all the time, i.e., the matter of the liability of components suppliers. The question boils down to the matter of what liability exists when you supply a component, someone else makes something with it, or changes it, and the final product is alleged to cause an injury because of the component. In the Power Ski case, the Court says, in sending the case back for further trial, that the question of whether or not the supplier of a component should have known what it was going to be used for, and therefore had some responsibility even though it only supplied a component, is a valid question to be taken up in a trial. This case is reported in Paragraph 5579 of CCH's Products Liability Reporter.

The FDA Guidelines

Turning to the "Guidelines" that FDA has now made available to us, let me first note here that we did get some special treatment by Mr. Ramsey in making these available to us. They are going to be published as is. This is not a matter on which we have a right to comment before publication, according to FDA. Distribution will be made by means of sending copies to everybody on the Food Additives Regulations mailing list and those of you who get the amendments to the Food Additive Regulations will get the document again that way.

I have some problems with the Guidelines --with the substance of the Guidelines-- and with some of the little questions they raise. I know from some of the members of the Steering Committee that you have already come up with some questions.

As far as the status of these Guidelines go, at least in my opinion, I think that you have to assume that the FDA Staff will now use these as a check-off list to some extent on any petition filed. I suggestthis is to be expected even though it is contended by FDA that the material constitutes only a set of Guidelines so that there is no real force of law behind them. I think you have to assume, as a practical matter they are going to be looked at by every member of the staff every time they look at a petition, and I think they mean what they say where it is indicated that, if you are not supplying some of the information requested, you had better explain why.

While we have various problems from the legal point of view, for example with the matter of requiring data on intended technical effect, perhaps the first question to be considered is what, if anything, we should do to make our ideas about the Guidelines known. What I

suggested to the Steering Committee yesterday is that we talk about the Guidelines at this meeting as much as you would like, and then consider whether or not we should let FDA know that we would like to make some comments about the Guidelines. There are any number of approaches you could use. For example, I think these Guidelines would form a good topic for some of the question-and-answer sessions that we might have with the FDA Staff at the forthcoming meeting.

The more tangible proposal that I advanced as a possibility yesterday, and that I pass on here for your consideration, is whether we might be well advised to acknowledge receipt of copies of the document from Mr. Ramsey, letting him know that our Committee has been supplied with copies and that the members of the Committee may have some helpful comments to make in due course. In this way, we can inform him that we are thinking in terms of sending him some information, even though perhaps it may be several months before you send in your comments and suggestions, and we have an opportunity to composite them and put a letter together, if that's what you want to do. I think the floor should be open for questions and discussion on this point now, as I have hereby concluded my regular report.

Thank you.

Questions, Comments, Actions Arising From Counsel's Report

After Mr. Heckman's general discussion about the matter of amending the polyolefins test methods specified for polyethylene and Alkane-1-Copolymers, and after some general observations by Mr. Pugh of U. S. Industrial Chemicals about the entire situation, it was decided to refer this matter to the Technical Information Sub-committee so that it may: (1) Collect such data as may be available to show correlations between the so-called polypropylene method and the methods now specified for polyethylene and Ethylene-Alkane-1-Copolymers, and; (2) To make general recommendations to the full Committee in this area.

It was the consensus of all those present that the Society should be most reluctant to file any petition with the Food and Drug Administration to seek formal amendment of the present Olefins Polymer Regulation, although it should perhaps make available the data and/or any conclusions therefrom that the Technical Information Sub-committee is able to assemble. After this is done, further consideration will be given to the best possible use to make of this data, in line with Mr. Heckman's general recommendations.

In reference to Mr. Heckman's announcement that the polystyrene petitions are still "in limbo", he had posed a question as to whether in reality the lack of a regulation on polystyrene is hampering the sales of material. It seemed to be the general consensus that it could not be stated, as a matter of fact, that the delay in the issuance of a regulation is presenting any practical problem and, therefore, no instructions were given as to additional formal approaches to FDA. Mr. Heckman will, of course, continue to check with the appropriate FDA Staff Officials and use reasonable efforts to see that the regulation is issued as promptly as possible.

After considerable discussion of the Guidelines problem, the general legal status of the Guidelines, and related matters, it was agreed by the Committee that the following steps should be taken:

1. Mr. Heckman was instructed to write a short letter to Mr. Ramsey, as promptly as possible, to acknowledge receipt of the preliminary copies of the Guidelines and thank him for the consideration given in providing this material so that it could be made available to the SPI Committee at its August 23 meeting. In this same letter, Mr. Heckman is to indicate to Mr. Ramsey that the members of the Committee are interested in supplying the Food and Drug Administration with their general comments on the material set forth, and will be doing so in the near future.

2. All members of the Committee, who desire to do so, are to submit to Mr. Heckman, in writing, any comments, criticisms, or suggestions they might have in connection with the Guidelines. So as to provide an orderly procedure, a deadline date of September 30 was set for the submission of such comments to Mr. Heckman.

3. After September 30, Mr. Heckman will attempt to sort out the comments received, and composite them in a draft letter or set of comments, so that the same can be recirculated to the entire Committee. In this way, the views of the Committee will be elicited first and, thereafter, a letter or similar filing will be submitted to Mr. Ramsey relative to the Guidelines. It is hoped that this will lead to some valuable clarifications, or perhaps even changes in the FDA publication. Another possibility is that this work will provide the basis for some interesting questions and answers at the next meeting of the Food Packaging Materials Committee, at which FDA officials are expected to be present.

Report of Lawyers' Advisory Subcommittee

Chairman Ingle called upon George T. Scriba, Union Carbide Corporation and Chairman of the Committee's Lawyers' Advisory Subcommittee.

Mr. Scribe, referring to the legislative outlook, indicated that there is essentially no imminent activity relating directly to food packaging. He did direct attention to several items he felt should be brought to the attention of the overall Committee, if for nothing else, as a means of keeping the group informed of matters of general interest.

Thus, he dimcussed briefly the new Rule No. 66 passed in Los Angeles, California, which relates to air pollution and more pertinently prescribes rather severe limits for the emission of solvents by users. Mr. Scriba indicated that details on Rule 66 may be obtained by communicating with the National Paint, Varnish and Lacquer Association.

Next, Mr. Scriba indicated consideration is being given to supplementing the Federal Hazardous Substances Labeling Act by amending it to give FDA new authority over unpackaged "hazardous articles"; toys, etc., when a finding of potential risk is made. S.3298 and Title II of H.R. 13886 are the Senate and House Bills respectively under consideration which would provide the additional regulatory power in this area. */

Mr. Scriba also directed the Committee's attention to the so-called "Child Safety Act" legislation proposed by means of Title I of H.R. 13886 and S.3196. The portion of this legislation of most direct interest to the plastics industry would appear to be a proposal to amend the Federal Food, Drug, and Cosmetics Act to require safety closures on bottles used for household drugs, particularly aspirin. Mr. Heckman supplemented Mr. Scriba's report in this regard by informing the Committee that Dr. Allan B. Coleman, Chairman of an American Pediatrics Association Child Safety Committee, has been in touch with him to suggest that the plastics industry might want to participate in a program to develop standards for such safety closures, since it has become apparent at the hearings on H.R. 13866 held thus far that such standards will be needed, especially if action is taken on the legislative proposal.

It was suggested at this point, that the matter of developing Commercial Standards is always more properly within the realm of activity of the various product divisions within the Society. In this instance, the appropriate product division is the plastic bottle group since it has been developing closure standards in other areas. Thus, M. E. Smith of Owens-Illinois was asked to take this matter up with the Plastic Bottle Division, perhaps through its Food Bottling Committee, or whatever other subgroup is appropriate. Mr. Smith agreed to undertake this assignment with Mr. Heckman, promising that he would supply copies of all background information on the subject made available to him by Dr. Coleman.

Finally, Mr. Scriba called the Committee's attention to the proposed amendments to the Administrative Procedures Act (APA) contained in S.1336, now before the House of Representatives Judiciary Committee, having been passed by the Senate in June. Mr. Scriba pointed out that this bill looks towards strengthening the APA, so as to bring about further assurance that those who must deal with federal agencies will be afforded effective procedural "due process."

Mr. Scriba noted that, as the Senate Report on this legislation states, the continual aim of Congress is to try to provide as much assurance as possible that those who deal with the agencies "will be treated as citizens, and not as subjects." Mr. Scriba pointed out that, while it might appear that this matter is of interest only to lawyers, he believes everyone should at least be aware that procedural rights are very important and should not be foregone lightly in dealing with the Food and Drug Administration which, after all, has no exemption from complying with the requirements of the Administrative Procedures Act in its rule-making and other activity.

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*/ Post meeting note: On September 1, 1966 the Senate passed S.3298 with amendments. This Bill will bring unpackaged, as well as packaged, "hazardous articles", and household articles treated with pesticides, under the Act. It will also give FDA power to ban hazardous toys and other children's articles from Interstate Commerce.

Report of Technical Information Subcommittee

Chairman Ingle called upon Robert M. Miller, Hercules, Inc., and Chairman of the Technical Information Subcommittee.

Mr. Miller supplied a written report including his regular listing of recently issued Food Additives Regulations. He then commented briefly on some of the petitions filed since the last meeting, those which have recently been withdrawn, and other highlights of his report. (Please Note: Attached hereto as EXHIBIT A is the report by Mr. Miller on behalf of the Technical Information Subcommittee.)

Pigments Task Group

One of the most active phases of activity of the Technical Information Subcommittee, Mr. Miller said, relates to the work of the special Pigments Task Group under the direction of Arnold B. Finestone of Foster Grant Company, Inc. Mr. Miller then called upon Dr. Finestone to give a report on this activity.

Dr. Finestone noted that, earlier this year, a communication was sent to all members of the full Committee regarding the membership's interest in participating in a "round-robin" testing program using the atomic absorption evaluation method to determine heavy metals extraction potential from plastics. When the first communication did not produce much of a response, a second letter was sent to everyone by the Secretary under date of May 20, 1966. Now, at least sixteen companies have signified preliminary intention to participate in the atomic absorption evaluation program.

Dr. Finestone then read the following parts of a communication of August 8, 1966, covering the details of how the proposed round-robin testing program would be handled.

"Subject: Pigments Task Group Proposal for Atomic Absorption Evaluation" Program

"The results of the letter 5/20/66 and attached questionnaire from the Pigments Task Group Chairman to the SPI Food Packaging Materials Committee members concerning participation in a program to define the applicability of atomic absorption techniques have been tabulated. The statistics derived from the survey are as follows:

'Sixteen companies have signified preliminary intention to participate, and this extremely generous response will allow us to carry out the request of the Food Packaging Materials Committee.

'Five metals are of primary interest (Cd, Hg, Ni, Cu, Cr).

'Seven polymer types are of primary interest (polystyrene, impact, ABS, Nylon, polyethylene, polypropylene and PVC).

'At least two concentrations of each pigment (0.25 and 1%) should be checked.

'Six extraction conditions are required.'

"Considering the above factors, a practical program has been formulated to minimize the work load per participating company while attempting to maximize consistency.

'1. One company could supply all five pigments necessary; 150 grams of each of five types should be sufficient for the entire program.

'2. All samples of a polymer type would be made by one company. Therefore, seven companies would prepare specimens from one polymer type at two concentrations and from five pigments. Details of suggested specimen preparation are attached to maximize uniformity.

'3. To keep the extraction work at a minimum, each company would extract only one polymer type. This would allow each of the seven polymer types to be extracted by two companies.

Total extractions per company:

1 material x 5 pigments x 2 concentrations

+ 1 blank = 11 samples x 6 solvents = 66 extraction samples.

Details of modified extraction procedure are attached.

'4. Total work for Atomic Absorption:

66 samples x 14 companies = 924 analyses.

'5. Cost: Jarrell Ash has quoted a 75 cents cost per analysis, which totals $70 per participating company. Allowing for contingencies, the analytical cost per company should not exceed $125.

'6. A suggested participation flow scheme and time table is attached.'

"The above program will not answer every question; however, it does incorporate the suggestions made by those responding to the Pigments Task Group's survey. In addition, it is workable and practical while covering the desired polymer, metal and solvent combinations. A complete round-robin has been suggested as an alternate, with each company extracting each polymer type. The number of extractions involved, however, makes this approach impractical.

"Allowing the members receiving this proposal time for approval, a reply would be in order by August 22. Assuming all affirmative replies, the program, as outlined in the flow-scheme, could start August 29."

Dr. Finestone pointed out that the present intention is to have each company extract only one polymer type, with one laboratory handling the analysis by atomic absorption. By doing this, the cost to each company, as Dr. Finestone's report points out, will be kept at a minimum, the cost probably being around $70 and not exceeding $125 per company.

In referring again to his report as presented at the day's meeting, Dr. Finestone said that it may now be necessary for him to revise the protocol for the proposed round-robin program in light of the "Guidelines" which Mr. Heckman was able to obtain from FDA just prior to the day's meeting. Thus, there may be a slight additional delay in commencing the program.

In response to a question about overall timing for completion of the Pigment: Task Group assignment, Dr. Finestone said that, hopefully, by the middle of October, the actual evaluation will have been completed, and then it will be up to his Group to begin interpreting the data. Mr. Ingle said that he would hope that possibly Dr. Finestone would have a completely definitive report on progress at the next meeting of the Committee.

In response to questions from new attendees at the day's session, Dr. Finestone reminded that, as originally conceived and as still intended, the aim of the overall Committee in this area is to prepare a manual or detailed bulletin dealing with the proper evaluation of the use of pigments in plastics.

International Developments

Mr. Ingle noted that the Agendas for the past several meetings have provided for open discussion of international developments, the objective being to give the members of the Committee an opportunity to exchange information on the status of packaging materials regulations as they exist or are being promulgated in European countries and elsewhere in the world.

Referring to the Dutch Food Packaging Legislation, which was discussed at earlier meetings of the overall Committee, Robert Miller stated that under date of July 7 he had communicated with Jerome H. Heckman, Esq., regarding an up-to-date report which a Hercules representative in the Hague has provided on the projected Dutch Food Packaging Legislation. He then read and commented generally on the following portions of his earlier letter, dealing with the packaging decree in the Netherlands:

"The meeting was told that the Minister has received so much criticism on the present draft that another draft will be prepared, with publication expected in the fourth quarter of this year.

"This new draft will permit a total contamination of food by the packaging material of 100 ppm. This is a victory for industry, since the government representatives wanted to allow only 10 ppm. Analysis methods to determine the amount of contamination will not be given in the draft decree, another victory for industry. However, analytical methods to determine the content of packaging

materials in the food will have to be developed. Since the decree will specify contamination in the food, strictly speaking it no longer will be sufficient to use food simulating solvents, but the consensus is that the food law inspectors will accept simulating solvents if the total contamination is less than the 100 ppm. If more than 100 ppm is extracted by the solvents, an analytical procedure for the food will have to be supplied if the material is to be used (assuming this would result in less than 100 ppm). The government is interested in a comparison of extraction using food simulating solvents with actual migration to food and asked for any available data (FDA Rutgers Study).

"The current draft decree states that certain chemicals could not be used. The new draft probably will say 'may not be present'. In the new draft there will be an article to the effect that chemicals may be approved by 'Ministerial Decree', permitting additions to the list without changing the law, which would take much time."

A. W. Downes, Union Carbide Corporation, made mention of some general impressions which representatives of his company have received upon visiting Europe recently. For instance, Mr. Downes said that one feeling the Union Carbide people stressed is that the foreign regulatory agencies seem fully aware of FDA Food Additive Regulations, but are still desirous of actually seeing any data used in obtaining FDA approvals before they will approve food packaging materials components. Mr. Downes reminded that European agencies may sometimes agree that an ingredient is safe in food, but still do not "want it in the food", so extraction information is always relevant to them. Also, he mentioned information he has received confirming that different agencies within a country often vie with each other for a dominant position in any regulatory situation.

Dr. Finestone, Foster Grant Company, commented on his participation in Committees in the Netherlands and elsewhere, most pertinently the BIT (Bureau Internationale Terminal) which is composed of representatives from industry in the six Common Market countries. Dr. Finestone noted that there is a continuing difference of opinion among representatives of the six countries participating in BIT, ranging all the way from a liberal point of view regarding materials coverage by implication, to a much more restrictive point of view, demanding positive listing of any "input" substance used in making a packaging material. Negotiations are always in progress to resolve major differences of opinion and the whole situation is further confused by the problem of deciding among these countries as to whose concept of appropriate extraction tests, among other things, is to be accepted.

Mr. Ingle noted that the subject of international developments will be included on future agendas to allow for similar exchanges of information.

Next Meeting

Mr. Ingle stated his understanding that the next meeting is to be held in Washington, D. C., assuming arrangements can be made for the Committee to meet with representatives of FDA as previously discussed. It was agreed that the Steering Committee will try to choose a day at the end of November, or during the first week in December for these next sessions.

There being no further business, the meeting was adjourned at 2:50 p.m.

Respectfully submitted,
Charles L. Condit, Secretary

CLC:idh
Encl.

EXHIBIT A

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE OF SPI FOOD PACKAGING MATERIALS COMMITTEE

August 23, 1966

The Technical Information Subcommittee has not met formally since the March 3, 1966 full Committee meeting. The only major current project under consideration is the colorant in plastics problem regarding FDA status, and this is being handled by our Pigments Task Group under the Chairmanship of Dr. Arnold Finestone. He will report on this group's activities later.

One of the assignments of the Chairman of the Technical Information Subcommittee is to serve as liaison with the 3-A Standards Committee and the Dairy and Food Industries Supply Association. Since our last meeting, I would like to report that the proposed addition of Nylon 6 to the 3-A Sanitary Standards for Plastics was adopted at the recent 3-A meeting in Oklahoma City. Official copies have been sent to the required signers for validation. In addition, a new amendment to the 3-A Sanitary Standards for Plastics has been proposed to include ABS as a new generic class of plastics with appropriate performance specifications. This proposal must go through the usual approvals and, if approved, will be added to the standards at the next annual meeting.

The following final new food additive regulations, amended regulations, proposed regulations, withdrawals of petitions, and notices of filing, deemed of interest to the SPI Food Packaging Materials Committee, have been published in the Federal Register since our March 3, 1966 meeting:

SECTION	TYPE	DATE	SUBJECT
--	Filing	3/4/66	Partially oxidized polyethylene as protective coating or component of coating for fresh fruits and vegetables
121.2531, 121.2589	Amendment	3/4/66	Provide for uses of another mineral oil
121.2541	Amendment	3/9/66	Provide for emulsifiers in PVC and/or vinyl chloride--vinyl acetate copolymers for food contact
121.2574	Withdrawal	3/9/66	Add monochlorobenzene to polycarbonate resins
--	Filing	3/10/66	Provide for use of polyvinyl alcohol as tableting adjuvant in vitamin concentrates and multivitamin concentrates

Exhibit A

SECTION	TYPE	DATE	SUBJECT
121.2511	Filing	3/10/66	Provide for additional emulsifiers and/or surface active agents (alkyl phenoxypolyethoxyethanol)
121.2536	Filing	3/15/66	Provide for use of polymers produced from ethyl acrylate, styrene, acrylonitrile, acrylic acid, and N-methylolacrylamide as components of resin-bonded milk filters
--	Filing	3/15/66	Chlorinated polyethylene
121.2514	Filing	3/15/66	Add ethylene-isobutyl acrylate copolymers
--	Filing	3/15/66	Monton wax derivatives as lubricants for PVC
121.2569	Filing	3/15/66	Add polyterpene resins
121.2569	Filing	3/15/66	Add dicyclohexyl phthalate as plasticizer
121.2541	Filing	3/15/66	Add sodium or ammonium nonylphenoxypolyethoxy (4 moles) sulfate as emulsifier
--	Filing	3/15/66	Use of poly/2-(diethylamino)ethyl methacrylate/ phosphate as suspending agent in vinyl chloride copolymer resins and hydrogen-n-butyl-(3,6-endomethylene-1,2,3,6-tetra-hydro-cisphthalate) as monomer in vinyl chloride copolymer resins
121.2569	Filing	3/17/66	Glycidyl acrylate and glycidyl methacrylate as comonomers in vinylidene chloride copolymers
121.2566	Amendment	3/22/66	Add substance as antioxidant for polyamide resins
--	Withdrawal	3/22/66	Triethylene glycol in ink for printing food contact materials
--	Filing	3/22/66	Coated polycarbonate film

Exhibit A

SECTION	TYPE	DATE	SUBJECT
--	--	4/13/66	NRC Pesticide Residues Committee--Statement for Implementation of Report on No Residue and Zero Tolerance
--	Notice	4/23/66	Notice of opportunity for hearing--proposal to refuse to approve NDA with prejudice--Dextran Injection 6% in plastic containers
121.2597	Filing	5/3/66	Provide for increased levels of acrylic modifiers in semirigid and rigid PVC plastics
121.2503	Filing	5/3/66	Provide for terpene resins in polymeric films
121.2501	Amendment	5/7/66	Olefin polymers--define copolymers
121.2507, 121.2514, 121.2569	Filing	5/7/66	Provide for use of 4,4-bis(4-hydroxyphenyl) pentanoic acid-modified polyamide resins in coatings
121.2501	Amendment	5/17/66	Additional uses of noncrystalline polypropylene
121.2541	Amendment	5/18/66	Add sodium n-alkylbenzenesulfonate as emulsifier
--	Notice	5/28/66	Order refusing approval of supplemental NDA for Dextran Injection 6% packaged in plastic containers
121.2599	New Reg.	6/7/66	Vinylidene chloride copolymer coatings for nylon film
121.2570	Amendment	6/7/66	Extraction tests unnecessary for ethylene-vinyl acetate copolymers in adhesives
121.2526	Withdrawal	6/25/66	Use of alicyclic petroleum hydrocarbon resins
--	Withdrawal	6/25/66	Vinyl chloride-cetyl vinyl ether copolymers
121.2541	Amendment	6/25/66	Add substances as emulsifiers

Exhibit A

SECTION	TYPE	DATE	SUBJECT
121.2569	Withdrawal	6/30/66	Dicyclohexyl phthalate as plasticizer
121.2526	Amendment	7/2/66	Add item as emulsifier for vinylidene chloride copolymer coatings
121.2514	Amendment	7/2/66	Add certain acrylic copolymers as modifiers for epoxy resins
121.2541	Amendment	7/9/66	Add item as polymerization emulsifier for PVC and/or vinyl chloride-vinyl acetate copolymers
121.2592	Withdrawal	7/12/66	Esters of gum rosin
--	Filing	7/23/66	Use of 2,5-di(5-tert-butyl-benzoxazolyl-2')thiophene as optical brightener in certain polymeric compounds
121.2513, 121.2527	Revocation Amendment	7/27/66	Revoke 121.2513, antifogging agent; amend 121.2527 to provide for antistatic and/or antifogging agents, and add new substances
121.2590	Amendment	7/28/66	Provisions not applicable for use in adhesives
121.2566	Amendment	8/2/66	Add 2-hydroxy-4-n-octoxybenzophenone as stabilizer in polyethylene and polypropylene plastics
121.2514	Amendment	8/6/66	Add substances for can end cements
121.2527	Filing	8/9/66	Provide for use of amine in molded or extruded polyethylene food containers
121.2550	Amendment	8/12/66	Add certain items, revise listing of substances for closures with sealing gaskets
--	Filing	8/19/66	Use of certain resins as food contact coatings
121.2514	Filing	8/19/66	Add allyl alcohol to styrene copolymers

Exhibit A

SECTION	TYPE	DATE	SUBJECT
--	Filing (2 petitions)	8/20/66	Certain vinylidene chloride copolymers as coatings for nylon film
--	Filing	8/20/66	Certain epoxy resins and certain polyethyleneimine resins as components of coatings on polypropylene film
--	Filing	8/20/66	Certain ethylene-propylene polymers optionally containing a nonconjugated bicyclodiene
--	Filing	8/20/66	Dimyristyl thiodipropionate as antioxidant in plastics
--	Filing	8/24/66	N-alkyl (C_{14}-C_{18})-1,3-propanediamine-N,N',N'-triacetic acid as antioxidant in certain polymers

It will be noted from the above listing that there have been numerous notices of filing and amendments to existing regulations since our last report. The many filing notices suggest that FDA is receiving numerous petitions and are following the procedure in the Food Additive Regulations of filing them before making a complete review. In addition, the above listing contains several more notices of withdrawal of petitions than usual, again reflecting FDA's new policy. Several of these listed items already have been discussed, but I would like to point out some of the others of interest:

Several notices of filing have been published pertaining to coatings for plastics; among them are a Morton Chemical Petition for vinylidene chloride copolymers coatings for nylon film and an FMC Petition to provide for the use of coated polycarbonate film for food packaging.

Already mentioned are the amendments to 121.2501, one defining the copolymers, and the other providing additional uses of noncrystalline polypropylene.

Two items of interest were FDA notices concerning the refusal to approve New Drug Applications by Pharmachem Corporation for Dextran Injection 6%, packaged in plastic containers. The first was a notice of opportunity for a hearing and a proposal to refuse to approve the New Drug Application, while the second was the order refusing approval. The casual reader of these notices might get the impression that the plastic containers were at fault, whereas the refusal actually was based on inadequate tests of the packaged drug to demonstrate its safety and stability.

An amendment to 121.2570, ethylene-vinyl acetate copolymers was published, stating that the extraction tests in 121.2570 are not applicable to those ethylene-vinyl acetate copolymers used in food packaging adhesives. The point of interest is that the amendment states the test is unnecessary because permitted use in adhesives under the conditions prescribed by 121.2520 is not expected to result in significant amounts becoming components of food. This is one of the first times that FDA has published such a statement.

A petition has been filed by Rohm-Haas to amend 121.2597 to provide for increased levels of acrylic modifiers in semi-rigid and rigid PVC plastics.

A petition by Kureha Chemical Industry Limited for the use of vinyl chloride-cetyl vinyl ether copolymers in food contact articles has been withdrawn.

Section 121.2513, Antifogging Agents, was revoked and 121.2527 was amended to provide for antistatic and/or antifogging agents, and new compounds were added. There also were other petitions noted for antioxidants and stabilizers.

Another notice of potential interest not mentioned at the meeting was published in the Federal Register of June 21, 1966, Page 8594. This concerned a Notice of Proposed Rule Making for Biological Products published by the Public Health Service, where they refer to the requirements for containers and closures. These requirements seem quite similar to those for drug containers, but I thought the Committee should be aware of them. That part of the notice relating to them is quoted below:

"§73.36 Physical establishment, equipment, animals and care.

* * * * *

(b) Containers and Closures. All final containers and closures shall be made of material that will not hasten the deterioration of the product or otherwise render it less suitable for the intended use. All final containers and closures shall be clean and free of surface solids, leachable contaminants and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use. After filling, sealing shall be performed in a manner that will maintain the integrity of the product during the dating period. In addition, final containers and closures for products intended for use by injection shall be sterile and free from pyrogens. Except as otherwise provided in the regulations of this part, final containers for products intended for use by injection shall be colorless and sufficiently transparent to permit visual examination of the contents under normal light. As soon as possible after filling, final containers shall be labeled as prescribed in §73.50 et seq., except that final containers may be stored without such prescribed labeling, provided they are stored in a sealed receptable labeled both inside and outside with at least the proper name of the product, the filling lot number, and date of filling."

Respectfully submitted,
Robert M. Miller.

Minutes of Meeting

SPI - PMA Liaison Group

September 15, 1966 - 9 a.m.

270 Park Avenue, New York

The following were in attendance:

SPI

P. E. Campbell - Phillips Petroleum - Bartlesville, Oklahoma
A. W. Downes - Union Carbide Plastics Division - 270 Park Avenue, New York, N.Y.
Robert M. Miller - Hercules, Inc., Wilmington, Delaware
Kenneth Morgareidge - Food & Drug Research - Maspeth, N. Y.
A. C. Signore - Monsanto Packaging Division - 101 Granby Street, Bloomfield, Conn.
M. E. Smith - Owens Illinois - 14th & Adams Streets, Toledo, Ohio
W. M. Westveer - Dow Chemical - Midland, Michigan

PMA

Fred Backer - Merck Sharp & Dohme, West Point, Pa.
Harold H. Bryant - Huntingdon Res. Center (B-D), Baltimore, Md.
W. W. Hilty - Eli Lilly & Company - Indianapolis, Indiana
E. O. Krueger - Abbott Laboratories - North Chicago, Illinois
Richard W. Pecina - Abbott Laboratories - North Chicago, Illinois

The purpose of this meeting was to develop test procedures which would be satisfactory for prescribing Polyolefin Polymers acceptable for packaging dry drugs (pills, tablets, etc.).

The outline submitted by Mr. Krueger was reviewed to determine whether there was a need for any additional tests not included in Mr. Krueger's outline.

The question of oxygen permeability was discussed and the consensus was that if a drug was sensitive to oxygen, it would never be packaged in plastics so that a test for oxygen transmission was unnecessary.

Dr. Wayne Hilty of Eli Lilly & Company then discussed in detail the procedures which were recommended for the following tests deemed necessary both to satisfy the Drug Industry as well as FDA.

Several suggestions were made for clarifying and improving the recommended procedures, and Dr. Hilty is to rewrite the test procedures and submit them to the group. It was estimated that it would probably be after the first of the year before test work could be started to develop limitations for the following tests:

I. Acute Systemic Toxicity
II. Heavy Metals
III. Non-volatile Residue
IV. Water Transmission
V. Light Transmission

Also although not originally planned for consideration was the packaging of ophthalmic drug products which would require an eye irritation test in addition to the five cited above.

The PMA group pointed out that some definition of identity of the Polyolefin would be required.

It was agreed that the SPI representatives would each draft a suitable statement for the Polyolefins and send them to A. W. Downes, 370 Park Avenue, New York, N. Y. by October 15th. These will be edited and resubmitted for review by the Technical subcommittee.

No plans for another meeting appeared to be justified with the PMA group pending the development of test data based on the procedures recommended.

After receiving the drafts of the proposed identity statement for polyolefins a meeting may be required of the SPI Liaison Group with the Technical subcommittee of the Food Packaging Committee to agree on the proposed identity statement for Polyolefins.

The meeting adjourned at 11:50 a. m.

A. W. Downes

A. W. Downes
Chairman SPI-Liaison Group

AWD:MK

copies to: Attendees
Mr. C. L. Condit, SPI, 250 Park Ave., New York
Mr, J. Heckman, Keller & Heckman, 1712 N Street N. W., Washington, D. C.