THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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MINUTES

MEETING OF SPI FOOD PACKAGING MATERIALS COMMITTEE

Commodore Hotel
New York City

February 16, 1967
9:30 a.m.

Present:

George W. Ingle, Chairman, Monsanto Company, Hydrocarbons and Polymers Division, Research Dept., Springfield, Mass.
Robert M. Miller, Vice-Chairman, Hercules Inc., Delaware Trust Building, Wilmington, Del. 19899
W. B. Ackart, Union Carbide Corp., River Road, Bound Brook, N. J.
J. A. Blanchette, Foster Grant Co., North Main St., Leominster, Mass.
K. C. Conley, Marbon Chemical, Division Borg-Warner Corp., P. O. Box 68, Washington West Virginia 26181
W. J. Connolly, M & T Chemicals, Inc., 100 Park Ave., New York, N. Y.
J. W. Daum, Glyco Chemicals, Inc., 417 Fifth Avenue, New York, N. Y.
L. J. DeCorte, Sinclair-Koppers Co., Product Development, Frankfort Road, Monaca, Pennsylvania 15061
H. R. Dittmar, Vypak Corp., P. O. Box 55, Rockaway, N. J. 07866
A. W. Downes, Union Carbide Corp., Plastics Division, 270 Park Ave., New York, N.Y.
G. W. Ferner, The Goodyear Tire & Rubber Co., Research Division, 1144 East Market St., Akron, Ohio 44316
R. A. Farrell, Kennedy Car Liner & Bag Co., Prospect & Hodell St., Shelbyville, Indiana 46176
H. J. Frey, E. I. duPont de Nemours & Co., Inc., Plastics Dept., Wilmington, Del.
B. J. Garceau, I.C.I. (Organics), Inc., 55 Canal Street, Providence, R. I. 02901
A. Goldman, Columbian Carbon Co., 20 East 46th Street, New York, N. Y. 10017
R. H. Haas, The Goodyear Tire & Rubber Co., 1144 E. Market St., Akron 16, Ohio
Jerome H. Heckman, Esq., SPI Counsel, Keller & Heckman, 1712 N Street, N. W., Washington, D. C. 20036
K. A. Hochschwender, American Hoechst Corp., 777 Third Avenue, New York, N. Y.
J. A. Houle, Mobil Chemical Co., 150 E. 42nd St., New York, N. Y.
D. H. Hunter, Stauffer Chemical Co., Plastics Div., P. O. Box 320, Delaware City, Delaware 19706
W. A. Knapp, Allied Chemical Corp., General Chemical Division, P. O. Box 405, Morristown, N. J. 07960
A. J. Martin, Plastics Division, Allied Chemical Corp., Box 365, Morristown, N. J.
James R. S. McCartney, Standard Packaging Corp., 200 E. 42nd St., New York, N. Y.
D. D. McCollister, The Dow Chemical Co., Biochemical Research, 1803 Building, Midland, Michigan 48640

Gordon L. McIntyre, Columbian Carbon Co., P. O. Box 975, Princeton, N. J.
W. A. Meeley, Glyco Chemicals, Inc., 417 Fifth Avenue, New York, N. Y.
James A. Mitchell, E. I. duPont de Nemours & Co., Inc., Film Department, Wilmington, Del. 19898
Kenneth Morgareidge, Food and Drug Research Laboratories, Maurice Ave. at Fifty-Eight Street, Maspeth 78, N. Y.
W. P. Munro, American Cyanamid Co., Bound Brook, N. J.
B. G. Murray, Ferro Corp., Color Division, 4150 East 56 St., Cleveland, Ohio
A. S. Nyquist, American Cyanamid Co., P. O. Box 425, Wallingford, Conn. 06492
P. J. Papillo, Geigy Industrial Chemicals, Div. of Geigy Chemical Corp., Ardsley, New York 10502
W. Alexander Patterson, W. R. Grace & Co., Cryovac Div., P. O. Box 464, Duncan, South Carolina 29334
I. Frank Peake, E. I. du Pont de Nemours & Co., Inc., Film Dept., Wilmington, Del.
Jules Pinsky, Monsanto Company, Packaging Division, P. O. Box 1019, Hartford, Conn.
Donald W. Pugh, USI Chemicals Co., P. O. Box 218, Tuscola, Ill. 61953
George A. Richter, Jr., Rohm & Haas Co., Independence Mall West, Philadelphia, Pa.
Robert E. Rutherford, Gulf Research & Development Corp., Dwight Building, Kansas City, Mo.
E. H. Schaeffer, Shell Chemical Co., 50 West 50th St., New York, N. Y. 10020
R. J. Schanno, Glyco Chemicals, Inc., 417 Fifth Ave., New York, N. Y.
A. M. Schnitzer, Phillips Petroleum Co., Bartlesville, Oklahoma
George T. Scriba, Union Carbide Corp., Legal Dept., 270 Park Avenue, New York, N.Y.
W. W. Sederlund, National Starch & Chemical Corp., 1700 West Front St., Plainfield, New Jersey 07063
A. C. Signore, Monsanto Company, Packaging Div., 101 Granby St., Bloomfield, Conn.
Matthew E. Smith, Owens-Illinois, Plastic Products Div., Adams & 14th St., Toledo, Ohio 43606
C. J. Spiegl, Continental Can Co., 7622 S. Racine Ave., Chicago, Ill. 60620
M. C. Stone, Eastman Chemical Products, Inc., Kingsport, Tenn.
W. S. Stoy, Columbian Carbon, P. O. Box 975, Princeton, N. J.
F. C. Stroehlein, Emery Industries, 4900 Este Ave., Cincinnati, Ohio 45232
W. M. Westveer, The Dow Chemical Co., 433 Building, Midland, Michigan
N. G. White, Shell Chemical Co., 50 West 50th St., New York, N. Y. 10020
Ambrose G. Whitney, W. R. Grace & Co., Research Division, Clarksville, Maryland
Charles L. Condit, Secretary, SPI, 250 Park Avenue, New York, N. Y. 10017

Under the direction of George W. Ingle, Monsanto Company, a regular meeting of the SPI Food Packaging Materials Committee convened in the Commodore Hotel, New York City at 9:30 a.m. In welcoming members to the meeting, Mr. Ingle referred to a detailed agenda circulated prior to the day's session by the Secretary and, as the first order of business, asked for the usual self-introductions.

Following the self-introductions, Mr. Ingle noted with regret the sudden passing of R. S. Wechsler, Lily-Tulip Cup Corporation, indicating that indeed Mr. Wechsler's passing was not only a loss to his family but also to the Committee.

Minutes Last Full Meeting Approved

By way of reminder, Mr. Ingle pointed out that the last regular Committee meeting was held on August 23, 1966 in New York City; he noted that the actual last meeting of the Committee was a so-called special meeting, held on December 14, with FDA officials. Mr. Ingle then inquired as to whether there were any additions or corrections to the Minutes of the August 23, 1966 meeting.

Dr. A. W. Downes, Union Carbide Corporation, asked the Secretary to read the following paragraph to constitute an addition to the record kept of the August 23 meeting:

"First paragraph, page 6:

Reference is made to define polyethylene for drug packaging by reference to 121.2501 (Polyolefin Regulation).

(a) The SPI-PMA Liaison Group met subsequent to the meeting of the Food Packaging Materials Committee, and it was the consensus that it would be far better for both the Plastics Industry and the Pharmaceutical Industry to develop generic descriptions and specifications for the basic polymers without any cross reference to Food Additive Regulation status. The group recognizes that in the case of present day resins, the generic descriptions and specifications that are developed for drug packaging purposes may sometimes well turn out to be the same as those in the Food Additives Regulations, but they think that cross referencing would be bad policy. For one reason, a Food Additive Regulation can be amended or modified. Furthermore, it may be possible to prove by PMA methods that a new polymer is acceptable for packaging specific drugs before a Food Additive Regulation is obtained."

After agreement to inclusion of this statement was evidenced, there being no further corrections or additions to the Minutes of the August 23 meeting, Mr. Ingle declared them approved as developed, circulated, and expanded by the above-quoted paragraph.

Review of Special Meeting of December 14, 1966
With Representatives of FDA

Mr. Ingle next redirected the Committee's attention to the meeting held in Washington, D. C. on December 14, 1966, when members were privileged to discuss with Mr. Lessel L. Ramsey, Assistant Director for Regulatory Programs of the FDA's Bureau of Science, and Dr. Joseph McLaughlin of the Bureau of Science's Division of Toxicological Evaluation, a number of questions raised regarding incidental additives regulation. He pointed out that, shortly after this special meeting, Jerome H. Heckman, SPI Counsel, issued a written summary of the question-and-answer session.

Mr. Ingle stated that, without a doubt, it has been agreed that the special meeting with FDA representatives was most interesting and worthwhile; and that everyone who was present is grateful that Messrs. Ramsey and McLaughlin took the time and effort to make the program a success.

Mr. Ingle then indicated that, later on in the meeting, there would be a discussion about possible follow-up actions desirable.

Reports on Liaison With Other Organizations

Mr. Ingle next called for the regular liaison reports on those activities in other associations and groups which relate to the interests of the plastics packaging materials industry.

PMA-SPI Liaison Group

Dr. A. W. Downes, Union Carbide Corporation, delivered the following report on the status of the joint effort between the SPI Committee and the Pharmaceutical Manufacturers Association:

"It was decided to use the ASTM definition of Polyolefin Polymers in connection with the SPI-PMA cooperative effort to develop specifications for packaging dry drugs.

"The final decision as to the definition was referred to Dr. Miller's Technical Information Subcommittee, and is covered in more detail in his report. If the entire Committee is satisfied with the proposed definition, I will forward it to Dr. Hilty.

"Dr. Hilty reported January 24, 1967 that he believed PMA participating laboratories will complete their testing by the Fall of this year, so that an answer may be obtained from FDA shortly thereafter.

"If FDA is satisfied that the tests accurately define the acceptability of the polyolefins for each Manufacturers Product (Dry drugs), we will have made a large stride forward.

"PMA - needs 3 gross of 4 oz. bottles, preferably from three (3) different bottle producers. Preferably, if this seems reasonable to us, there should be 1 gross each made from, (1) polyethylene; (2) ethylene-butene-1; and (3) polypropylene. In addition, they would like to have one gross of 4 oz. bottles using any one of the above mentioned polyolefins pigmented with $TiO_2$ only.

"Furthermore, Dr. Hilty asked if SPI would be willing to cooperate by running the following tests via PMA proposed procedures:

1. Water transmission
2. Light transmission
3. Heavy metal content

"I replied that SPI would be glad to run these tests.

"The important point to keep in mind is that only the particular pharmaceutical company can determine whether their formulation for a particular drug can be satisfactorily packaged in the specific polyolefin.

"At the SPI Food Bottling Committee meeting, the following companies agreed to supply the bottles requested by Dr. Hilty:

1 gross- high density polyethylene 4 oz. bottles - Union Carbide

1 gross- polypropylene 4 oz. bottles - Continental Can

1 gross- ethylene-butene copolymer - Phillips Petroleum

1 gross- high density polyethylene pigmented with $TiO_2$ - Owens-Illinois

"These will be sent to Dr. Hilty for distribution to PMA participating companies. In addition, one (1) gross of each of the above will be sent to Dr. W. B. Ackart, Union Carbide, Bound Brook, New Jersey.

"These will be distributed to the SPI companies participating in obtaining the tests PMA requested SPI to run. The procedure for carrying out these tests will be decided today.

A. W. Downes"

Following his report, Dr. Downes was queried as to the formulation of the materials in the bottles being supplied for the testing program described in his report. Dr. Downes' answer was that, in general, the bottles being submitted are representative of all of those that are commercially produced with but one exception, namely the bottles pigmented with $TiO_2$.

SPI Food and Drug Bottling Committee of Plastic Bottle Division

Chairman Ingle then called upon M. E. Smith, Owens-Illinois, to present a status report on the activities of the Food and Drug Bottling Committee of the overall SPI Plastic Bottle Division.

Mr. Smith delivered the following status report:

"At our last meeting of the Food and Drug Bottling Committee, we reviewed the work reported on by Dr. Downes to bring all of that Committee up to date on where we stood with the SPI-PMA liaison work.

"I think the only other point of interest to you would be that consideration is being given to a projected information program, a type symposium, that would be held with FDA officials relative to plastics for drug applications. We have 'kicked this around' and find that we do not have all the information necessary so we have now set up a special meeting with Jules Pinsky, as well as Bob Miller, Dr. Downes and myself, and a few others, to try to determine exactly what is desired. Thereafter, we should be able to decide on the direction in which we want to go."

Following his report, Mr. Smith called attention to publicity releases now being widely circulated by the SPI Plastic Bottle Division, and indicated that anyone who would like to be placed on the mailing list to receive these releases illustrating new products, etc., may do so by simply writing to Tom Carty of the SPI Staff.

Manufacturing Chemists Association

The Secretary read the following report prepared and submitted by Taylor Hanavan, E. I. du Pont de Nemours & Company, Inc.:

"Reference meeting of MCA's Food, Drug, and Cosmetic Chemicals Committee:

Act ranging from the prior approval of devices, and of cosmetics, which means cosmetic packaging materials, to enlarging inspection powers. Senators Dirksen and Long have introduced S.924, which would amend the Administrative Procedure Act to provide that when the Food and Drug Administration, or any other administrative agency, issues publicity which discredits or disparages a person under investigation, or a party to an agency proceeding, a Court

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"In 1938, the Congress strengthened the Food, Drug, and Cosmetic Act to require that the safety of drugs be cleared prior to marketing. In 1962, the law was further reinforced to require that the effectiveness of drugs also be cleared prior to marketing.

"The value of these laws is beyond question. Nonetheless, important gaps in the law remain which should be closed now.

1. INSURING THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES

"Under present law, dangerous and worthless devices may be marketed until the Government--sometimes by chance, sometimes by complaint--discovers them and gathers the necessary evidence to establish that they are hazardous or ineffective. This is a laborious process. It requires many months. It is costly.

"In the meantime, the elderly and the seriously ill suffer most. Improper treatment with worthless devices can be the cruelest hoax of all.

"We want to foster continued research and development of lifesaving devices. But we must be sure they have been adequately tested before they are put on the market. We cannot be sure today.

"Congressional testimony has revealed that--

"Defective nails and screws for bone repair have required repeated operations to correct the damage.

"Some artificial eyes have resulted in serious infection.

"Useless heating and vibrating devices have caused the ill to squander their money and delay the pursuit of effective treatment.

"X-ray machines, which would have been properly safeguarded at little cost, emitted excessive doses of radiation.

"I recommend the Medical Device Safety Act of 1967.

"Under this Act, the Food and Drug Administration would be required to preclear certain therapeutic materials--such as artificial organ transplants--used mainly on or in the body. In addition, the FDA will establish standards to assure the safety and performance of certain classes of widely used devices--bone pins, catheters, X-ray equipment, and diathermy machines.

may set aside any action taken by the agency against such person unless he has been given an equal opportunity to publicize his comments at the same time and in the same document in which the agency publicity was issued. This is a further indication of Congress' concern that citizens be treated as citizens, and not as subjects. You will recall that Senate Committee used that language in reporting out amendments to the same Act last year.

"There is no indication that either Bill will move. In fact, as to Mrs. Sullivan's Bill, it had previously been authoritatively reported that the Department of Health, Education, and Welfare had rejected the Food and Drug Administration's request to seek wider food factory inspection powers.

"I have no general comments or recommendations."

At the end of his report, Mr. Scriba made reference to a communication received by The Society from acting Secretary of Commerce, A. B. Trowbridge, inviting SPI to attend a Tuesday, February 28 meeting in Washington, D. C., regarding the Fair Packaging and Labeling Act of 1966 which, as the communication points out, assigns certain responsibilities to the Secretary of Commerce. Mr. Scriba announced that The Society will be represented at this February 28 meeting.

(Please Note: Thomas Hughes of Mr. Heckman's office represented The Society at this February 28 meeting.)

Report of Technical Information Subcommittee

Chairman Ingle next called upon Robert M. Miller, Chairman of the Technical Information Subcommittee to deliver a status report.

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"In every case, the rights of the parties will be protected by fair hearings.

"This new law will not apply to simple and ordinary patient care items which have withstood the test of time and are generally recognized as safe and reliable. It will not apply to an item specially ordered or designed by a surgeon or physician. Nor will it inhibit the research and development essential to the advancement of the medical arts. It will, however, protect physician and patient alike from devices which are dangerous and unreliable."

As of this writing, the actual legislation had not been submitted to the Congress. Copies will be appropriately distributed, as soon as they become available.

Following herewith is Mr. Miller's report of the Technical Information Subcommittee, as delivered at the day's session:

"The Technical Information Subcommittee of the SPI Food Packaging Materials Committee convened after the SPI-FDA Question-and-Answer Panel on December 14 to consider three major items:

1. A polyolefin definition for PMA
2. A progress report on the pigments in plastic study
3. Analytical procedures for polyolefins in 121.2501

"1. Polyolefin Definition for PMA

"Dr. Downes' PMA Liaison Committee has been requested by the Pharmaceutical Manufacturers' Association to furnish a definition and identity test for the polyolefins under consideration for use in containers for packaging tablets, capsules, oral powders, and granules. A test regimen has been developed, and a cooperative test program will be conducted by the PMA and SPI. It was decided to have the Food Packaging Materials Committee Technical Information Subcommittee review the proposed definition to make certain the proper materials were covered and to make the final decision on what should be submitted to PMA.

"It was pointed out that the PMA does not wish to use the definition for olefin polymers in Section 121.2501 of the Food Additive Regulations, or a reference to it; they do not want to be tied to this definition. They desire a simpler description, and also require some type of identity test.

"The Liaison Committee had considered several possible definitions, and proposed the following for consideration:

A) Polyolefins are materials prepared by the polymerization of olefinic monomers limited to ethylene, propylene, and ethylene-alkene-1 copolymers, and identified by their characteristic infrared spectra.

B) Polyolefins are polymers prepared by the polymerization of an olefin or olefins as essentially the sole monomer or monomers and identified by their characteristic infrared spectra.

"The second definition is the one proposed by ASTM Committee D-20, with the addition of the identity test. A discussion of these suggested definitions followed, with emphasis on the objective of the definition and whether adjuvants should be included in it. It was decided that the present purpose was to furnish PMA a simple definition for their program and test regimen and not an 'FDA drug container material' definition, and that it should refer only to the base resin and not the adjuvants. A modification can be made at a later date, if necessary.

"After consideration of these definitions, the Technical Information Subcommittee voted to adopt the ASTM definition [B], above, with addition of the infrared identity test. Dr. Downes will inform the PMA Committee of our recommendation, and he believes it will be adopted by them.

"2. Progress on the Pigments in Plastics Study

"Dr. Finestone, Chairman of the Pigment Task Group, was unable to be present because of the snowstorm, but he forwarded the following status report:

1. ABS - Plaques molded by Monsanto and shipped to Foster Grant.

   Extractions:

   Foster Grant in progress. Will be complete about the end of December.

   Marbon just receiving plaques. Will start about December 15. Finish about January 15, 1967.

2. Polystyrene - (Completed) Plaques molded by Dow and shipped about October 20, 1966.

   Extractions:

   Dow completed and shipped to Foster Grant and Received.

   Cosden Oil completed, shipped to Foster Grant and received.

3. Impact Polystyrene - Completed. Plaques molded by Foster Grant and shipped October 18, 1966.

   Extractions:

   Foster Grant completed.

   Union Carbide completed. Shipped to Foster Grant, not received.

4. PVC - Plaques molded by Owens-Illinois shipped November 14, 1966.

   Extractions:

   Owens-Illinois will be completed about December 23, 1966.

   Hercules will be completed about December 23, 1966.

5. Polyethylene - Plaques molded by du Pont shipped November 17, 1966.

Extractions:

du Pont probably finish early January.

Phillips probably finish early January.

6. Polypropylene - Plaques molded by Tennessee-Eastman Shipped November 7, 1966.

Extractions:

Tennessee-Eastman finished by December 16, 1966.

Harshaw finished by first of year.

7. Nylon 6 - Plaques molded by Gulf shipped December 2, 1966.

Extractions:

Gulf just starting, probably finish about January 15, 1967.

Emery - SPI contact out until December 12.

"3. Analytical Procedures for Polyolefins in 121.2501

"As indicated in the minutes of the August 23, 1966, Food Packaging Materials Committee meeting, the methodology question on the differences in procedures for determining the soluble and extractable fractions of polypropylene and the other olefin polymers was referred to the Technical Information Subcommittee. This question, particularly with regard to the hexane extractable fraction, had been posed previously by Don Pugh of USI, with the idea that perhaps a uniform procedure for all the olefin polymers could be established. In the current regulation, different sample size, solvent volume, solvent grade, and filtration temperature are specified. Since the method for polypropylene is simpler, it was suggested that it, or a comparably simple procedure, be used.

"Since it had been pointed out that one could use any procedure he chose for his own control purposes, as long as the results were comparable to the regulation method, it was decided to review our experience with different procedures. It also was the consensus of the Technical Information Subcommittee that SPI only would examine industry experience with various methods and not at this time make any contact with FDA, with a view toward amending the regulation. Some of the member companies have contributed their own hexane extractable methods and comparative data for information. These are included in the attached report.

"The Technical Information Subcommittee recommends that SPI do nothing at this time to revise the hexane extractable or xylene soluble procedures specified in Section 121.2501, and that each company continue to use whatever method they so choose. The Technical Information Subcommittee report is for information only.

Respectfully submitted,

Robert M. Miller, Chairman
Technical Information Subcommittee
Food Packaging Materials
Committee"

By tradition, Mr. Miller has been preparing for each full meeting of the Committee a report on recently issued Food Additive Regulations. Mr. Miller thus noted that the Minutes would include a detailed summary of 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. (Please Note: Attached herewith, as EXHIBIT C, is Mr. Miller's report on this survey of Food Additive Regulations.)

As an added report at the day's session, Mr. Miller made reference to the "Analytical Procedures for Olefin Polymers in Section 121.2501 with regard to the determination of hexane extractables in polyethylene film." (Please Note: For informational purposes, this document in reference to analytical procedures is attached hereto as EXHIBIT D.)

During his report, Mr. Miller made "highlighting type" references to certain of the recently issued regulations or orders covered in his report, and there was some helpful cross discussion of a general nature on those of the recent FDA or Petitioner actions of broader interest. For summary purposes here, it need only be noted that everyone present felt Mr. Miller's coverage even more interesting and valuable than usual, so those who were not present are urged to give the attached EXHIBIT C their special attention.

Pigments in Plastics - Pigments Task Group Report

Mr. Miller then introduced Mr. Joseph Blanchette, Foster Grant Company, advising that Mr. Blanchette would give a more up-to-date report on the activities of the Pigments Task Group in the absence of the Task Group Chairman, Dr. Arnold Finestone. (Dr. Finestone was unable to be present at the day's meeting due to an extended business trip in Europe.) Mr. Blanchette then read the following report prepared by Dr. Finestone dealing with the present program for the evaluation of atomic absorption photometry as an analytical technique for determining trace quantities of inorganic pigments in plastics materials:

"The program for the evaluation of Atomic Absorption Spectrophotometry as an analytical technique for determining trace quantities of inorganic pigments, has been described in the Pigments Task Group proposal of August 8, 1966 submitted by A. B. Finestone. The present report is a summary of the status of the program.

"Fourteen companies are participating in the preparation of pigmented specimens from seven polymers. Five pigments, Monarch Blue G, Chromium Oxide, Mercadium red, medium Cadmium red, and Sun Yellow C, were used at two levels, 0.25 and 1.0%. The specimens are being extracted and concentrated, and will be assayed by Jarrell Ash. Since the cost of the analytical work is minimized by the submission of all samples at one time, the Chairman of the Task Group has been collating the samples until all are completed.

"The status of the sample preparation work, as of February 10, 1967, was as follows:

| Participating Company | Polymer | Specimen Preparation | Extraction and Evaporation |
|---|---|---|---|
| Monsanto | ABS | Completed | |
| Foster Grant | ABS | | Completed |
| Marbon | ABS | | Estimated completion date 2/16/67 |
| Dow | Polystyrene | Completed | Completed |
| Cosden Oil | Polystyrene | | Completed |
| Foster Grant | Impact | Completed | Completed |
| Union Carbide | Impact | | Completed |
| Owens-Illinois | PVC | Completed | Completed |
| Hercules | PVC | | Completed |
| Du Pont | Polyethylene | Completed | Completed |
| Phillips | Polyethylene | | Completed |
| Tennessee-Eastman | Polypropylene | Completed | Completed |
| Harshaw | Polypropylene | | Estimated completion date 2/17/67 |
| Gulf | Nylon 6 | Completed | Estimated completion date 3/10/67 |
| Emery | Nylon 6 | | Estimated completion date 3/1/67 |

Respectfully submitted,

A. B. Finestone
Chairman, Pigments Task Group"

* * *

In closing his report, Mr. Blanchette said that indeed he would be remiss if he did not commend those companies now participating in the atomic absorption work, since he feels that the cooperation has been remarkable. He further expressed hope that all data would be available for Dr. Finestone's analysis by the end of March of this year.

Following Mr. Blanchette's report on the activities of the Pigments Task Group, which was accepted with approval and without further comments, M. C. Stone, Eastman Chemical Products, discussed matters of interest relating to FAP No. 4B1473.

Mr. Stone's report, as delivered at the day's session, follows:

"Eastman Chemical Products FAP 4B1473 (now 4R), noted for filing in Federal Register for March 1, 1966, covers five classes of pigments for use in polyolefins.

"As first submitted to FDA, the Petition covered two additional classes of pigments- cadmiums and benzidine yellows.

"The cadmiums were withdrawn after ECPI discovered that colorless cadmium salts were dissolved from a number of these pigments on exposure to 3% acetic acid and 50% aqueous ethanol, for various periods and at various temperatures. This was reported to SPI Committee in October, 1965.

"In January, 1966, in conference with FDA about the Petition, Dr. Kokoski of FDA made the point that the benzidine yellows must be demonstrated to be free of unreacted benzidine, a carcinogen.

"We obtained a colorimetric procedure from a pigment supplier for testing for the unreacted benzidine or dichloro benzidine, as it turned out. Dichloro benzidine is also a carcinogen. The results were ambiguous, so we withdrew the benzidine yellows from our Petition until we could be sure.

"Now we find that many benzidine yellows contain as high as 30 ppm of unreacted dichloro benzidine. The colorimetric procedure is sensitive to less than 1 ppm in the pigment itself."

International Developments

Mr. Ingle noted that it has become customary to have a brief general discussion on international developments at the end of each regular meeting, so that industry can be made aware of some of the regulatory developments abroad. As an incidental matter, before opening the floor, Mr. Ingle stated that hopefully Dr. Arnold Finestone, when he returns from his trip abroad, will possibly have something to report at the next meeting on the regulatory situation in Europe.

Mr. Miller was then recognized, and discussed a recent visit by Dr. Jack Frawley, of his company, to England, where he was queried by knowledgeable technicians and government officials on the theories advanced in his ACS paper on the subject of incidental food additives and toxicology. (Copies of Dr. Frawley's paper were sent to the entire SPI Committee following the close of the ACS session in New York City last September.)

Mr. Miller noted that what Dr. Frawley actually delivered to the British was a revised and extended version of the paper he gave at the ACS sessions. The most significant difference, he noted, was that Dr. Frawley had now had an opportunity to review an additional 77 toxicology reports on chronic feeding studies which only served to bolster the conclusions he had reached earlier on the basis of 143 such reports investigated by him.

Mr. Ingle then announced that on April 25 through 28 a meeting would be held in Puerto Rico, at which he is to give a paper. Mr. Ingle understands that the three-day meeting there covers a broad variety of topics dealing with food technology, the indirect additive situation, and other related subjects.

Mr. Heckman had alluded earlier to the fact that developments were being awaited with regard to an anticipated new Dutch proposal for Food Additive Regulations in that country. At this point in the meeting, Dr. Donald McCollister of The Dow Chemical Company, reported that the new Dutch proposal has apparently been released. Dr. McCollister indicated that he had a copy of the proposal in Dutch, and was having it translated immediately. He promised to send a translated version to Mr. Heckman as promptly as possible. Mr. Heckman, in turn, indicated that he would send copies to all members of the Food Packaging Materials Committee in light of the past interest in the proposed Dutch regulations, it being recognized that they could well set a pattern for most of the rest of Europe.

In response to a question from the floor as to whether or not it might be advisable for the SPI Food Packaging Materials Committee to prepare formal comments for filing with the Dutch Government as a means of providing our suggestions on any changes we might think desirable in the Dutch regulations, Dr. A. W. Downes reminded all present that this possibility had been discussed previously. The conclusion reached at that time, and still applicable, was that the Dutch probably would not be too receptive or responsive to comments from those in foreign countries, but would be much more receptive to comments from Dutch companies, including affiliates of American companies, which are Dutch-based. Dr. Downes recommended, as has been previously recommended, that the matter of advising the Dutch Government about changes in its new proposal be handled by funneling the necessary information to appropriate Dutch subsidiaries and relying on them to make our views known.

New Business

A. J. Martin of Allied Chemical Corporation, inquired as to whether, at some time in the future, it would be desirable for the Committee to initiate an investigation or critical review relative to the limitations of the various methods now used under regulatory mandates for analyzing extraction. Mr. Ingle replied that, as soon as Dr. Finestone completes his present evaluation with the atomic absorption spectrophotometry, an appropriate group under Mr. Miller's Technical Information Subcommittee could possibly consider this matter.

Next Meeting

Mr. Ingle pointed out that customarily no specific date is set for subsequent meetings of the overall Committee, selection of dates being left to the Steering Committee, depending upon the volume of matters to be brought to the attention of industry and also whether an emergency type situation comes to bear. He therefore asked that, as usual, the Steering Committee be given the prerogative to determine the date and site for the next meeting. There was no objection to this procedure.

Adjournment

The day's session was adjourned at 12:35 p.m.

Respectfully submitted,

Charles L. Condit
Secretary

CLC:idh
Encls.