

SP

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

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FEB 20 1974

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC
PACKAGING MATERIALS COMMITTEE

Shoreham Americana Hotel
Washington, D. C.

January 10, 1974
9:20 a.m.

Present:

Karl A. Hochschwender, Chairman, American Hoechst Corporation, P. O. Box 2500,
Somerville, N. J. 08876
Willard M. Westveer, Vice Chairman, The Dow Chemical Company, 2030 Dow Center,
Midland, Mich. 48640
Watson B. Ackart, Union Carbide Corp., 1 River Rd., Bound Brook, N. J. 08805
Emil P. Albanese, American Cyanamid Co., So. Cherry St., Wallingford, Ct.
J. Brian Armitage, DuPont Plastics Dept., Experimental Station, Wilmington,
Del. 19898
Robert C. Asam, The Goodyear Tire & Rubber Co., 1485 East Archwood Avenue,
Akron, Ohio 44316
W. C. Bachtel, The B. F. Goodrich Co., 500 S. Main St., Akron, Ohio 44318
William S. Barnhart, Pennwalt Corp., 900 First Ave., King of Prussia, Pa. 19406
Roger D. Bejcek, Rubbermaid Industrial Products, Taylorsville Rd., P. O. Box
5338, Statesville, N. C. 28677
Norman D. Bornstein, Cryovac Division, W. R. Grace & Co., P. O. Box 464,
Duncan, S. C. 29334
Herbert B. Carr, Tenneco Chemicals, Organics and Polymers Division, Turner
Place, Piscataway, N. J. 08854
John O. Cole, The Goodyear Tire & Rubber Co., Research Division, 1144 East
Market St., Akron, Ohio 44316
Paul F. Cundy, American Can Co., P. O. Box 702, Neenah, Wisconsin 54911
L. J. DeCorte, ARCO/Polymers, Inc., Frankfort Road, Monaca, Pa. 15061
Louis F. DeMarco, Diamond Shamrock Corp., P. O. Box 348, Painesville, Ohio
44077
Daniel S. Dixler, Keller and Heckman, 1150-17th St., N. W., Wash., D. C. 20036
Grover L. Farrar, Celanese Plastics Co., P. O. Box 828, Greer, S. C. 29651
Robert P. Fischer, Kerr Glass Manufacturing Co., P. O. Box 4000, Lancaster,
Pa. 17604
David H. Fishman, Celanese Plastics, Morris Court, Summit, N. J. 07901
Karl M. Fox, Consultant, 300 Yale Avenue, Swarthmore, Pennsylvania 19081

B. J. Garceau, ICI America, Inc., Concord Pike & New Murphy Rd., Wilmington, Del. 19899
David R. Gaskill, Mobil Chemical Co., P. O. Box 240, Edison, N. J. 08817
Thomas J. Gazal, Celanese Plastics Co., Morris Court, Summit, N. J. 07901
Warren A. Gibson, The Dow Chemical Company, 2030 Dow Center, Midland, Mich. 48640
Robert A. Godfrey, Mobay Chemical Company, Penn-Lincoln Parkway, West, Pittsburgh, Pa. 15205
Max Goldfrank, Stein, Hall & Co., Inc. 12-10 Jackson Ave., Long Island City, N. Y. 11101
Francis W. Greenough, Cryovac Division, W. R. Grace & Company, P. O. Box 464, Duncan, S. C. 29334
Richard Haas, The Goodyear Tire & Rubber Co., 1144 E. Market St., Akron, Ohio 44316
Joseph E. Hadley, Keller and Heckman, 1150-17th St., N. W., Wash., D.C. 20036
G. Frederick Hanna, Borg Warner Chemicals, P. O. Box 68, Washington, W. Va. 26181
Jerome H. Heckman, SPI General Counsel, Keller and Heckman, 1150-17th St., N. W., Wash., D. C. 20036
John E. Jakob, Rubbermaid Industrial Products Corp., P. O. Box 5338, Statesville, N. C. 28677
John F. Jones, The Standard Oil Co., Midland Building, Cleveland, Ohio 44115
Otto S. Kauder, Argus Chemical Corp., 633 Court St., Brooklyn, N. Y. 11231
D. L. Kent, B. F. Goodrich Chemical Co., 6100 Oak Tree Blvd, Independence, Ohio 44131
Charles E. Kimmel, The Dow Chemical Company, 2030 Dow Center, Midland, Mich. 48640
Jack Lawing, Eastman Chemical Products, Inc., Eastman Road, Kingsport, Tenn. 37662
Clyde W. Leaf, BASF Wyandotte Corp., Wyandotte, Mich. 48192
D. D. McCollister, The Dow Chemical Company, P. O. Box 1706, Midland, Mich. 48640
Frank H. McTigue, Hercules, Inc., Polymers Dept., Hercules, Research Center, Wilmington, Del. 19899
Joel Markowitz, Dart Industries, Inc., P. O. Box 37, Paramus, N. J. 07652
Robert M. Miller, Hercules, Inc., Medical Dept., 910 Market St., Wilmington, Del. 19899
Stacey Mobley, E. I. DuPont de Nemours & Co., Inc., Legal Dept., Wilmington, Del. 19898
K. Morgareidge, Food & Drug Research Laboratories, Inc., P. O. Box 107, Waverly, N. Y. 14892
Peter Morison, Eastman Chemical Products, Inc., Kingsport, Tenn. 37662
Bernard G. Murray, Ferro Corp., 4150 E. 56th St., Cleveland, Ohio 44105
Jack B. Murray, Jr., Allied Chemical Corp., P. O. Box 1057R, Morristown, N. J. 07960
M. V. Noble, E. I. DuPont de Nemours & Co., Inc., Film Dept., Wilmington, Del. 19898

Jessie M. Norris, The Dow Chemical Company, 1803 Building, Midland, Mich.
48640
William H. Olson, CRF-SUCS, Consultant to Celanese Plastics, 2347 Paddock
Lane, Reston, Va. 22091
Sheldon Parker, Dart Industries, 115 W. Century Rd., Paramus, N. J. 07652
Jack K. Peterson, USS Chemicals, Plastics Dept., 600 Grant St., Pittsburgh,
Pa. 15230
Dale A. Pribanic, The B. F. Goodrich Chemical Company, 6100 Oak Tree Blvd.,
Cleveland, Ohio 44161
Donald W. Pugh, USI Chemicals Co., P. O. Box 218, Tuscola, Illinois 61953
Julius P. Rakus, Dart Industries, Inc., 115 W. Century Rd., Paramus, N. J.
07652
Francis J. Rattay, Mobay Chemical Company, Penn-Lincoln Parkway West,
Pittsburgh, Pa. 15205
George A. Richter, Jr., Rohm and Haas Company, Independence Mall West,
Philadelphia, Pa. 19105
Robert E. Rutherford, Gulf Oil Corporation, 439-7th Ave., Pittsburgh, Pa.
15237
A. Merrill Schnitzer, Phillips Petroleum Company, 356 Research Building 1,
Bartlesville, Ok. 74004
Kenneth W. Scott, Goodyear Tire & Rubber Company, Research Division, Akron,
Ohio 44316
W. W. Sederlund, National Starch and Chemical Corp., 1700 West Front Street,
Plainfield, N. J. 07063
Dwight M. Sheets, Shell Chemical Co., P. O. Box 2463, Houston, Texas 77024
Matthew E. Smith, Owens-Illinois, P. O. Box 1035, Toledo, Ohio 43602
Carl E. Snyder, The Goodyear Tire and Rubber Company, Research Division,
142 Goodyear Blvd., Akron, Ohio 44316
Charles J. Spiegl, Continental Can Co., 7622 S. Racine Ave., Chicago, Ill.
60620
Edward J. Temple, Monsanto Company, 101 Granby St., Bloomfield, Ct. 06109
George F. White, Jr., Reynolds Metals, 10th & Byrd Sts., Richmond, Va. 23219
Afaf K. Wensky, General Electric Company, Lexan Lane, Highway 69, Mt. Vernon,
Ind. 47620
George L. Wilson, The Firestone Tire & Rubber Co., 1200 Firestone Parkway,
Akron, Ohio 44317
Ronald M. Wilson, Jr., Emery Industries, Inc., 4900 Este Ave., Cincinnati,
Ohio 45232
Einar T. Wulfsberg, American Paper Institute, 1619 Massachusetts Ave., N. W.,
Wash., D. C. 20036
Charles L. Condit, Secretary, The Society of the Plastics Industry, Inc.,
250 Park Avenue, New York, N. Y. 10017

Calling to order a regular meeting of the Food, Drug and Cosmetic Packaging Materials Committee of SPI, Chairman Karl A. Hochschwender, American Hoechst Corporation, first requested the self-introductions which were duly made.

Minutes of Last Meeting Approved

In the absence of comments as to additions or corrections to the Minutes of the last meeting held in Washington, D. C. on May 31, 1973, Chairman Hochschwender declared them approved as written and distributed by the Secretary.

Preliminary Remarks by Chairman

Commenting in a general fashion, Chairman Hochschwender noted that, since the last meeting there had been many developments to be discussed according to the Agenda during the day's session, and that 1974 looks in many respects like it will be more interesting and challenging than 1973. This then prompted Dr. Hochschwender to discuss an amendment which has been made to the SPI Bylaws calling for a permanent Public Affairs Committee to be in operation by June 1, 1974. More pertinently, Chairman Hochschwender referred to a new subcommittee under the overall Public Affairs Committee to be known as the PAC Technical Committee on which he is to represent the FDCPMC as a regular member. Dr. Hochschwender said that, hopefully, the formation of the PAC Technical Committee will open up new channels of communication between the FDCPMC and the overall staff and membership of SPI, as well as the Board of Directors. He noted that he expected to hear momentarily from SPI about the date and place of the first meeting of the PAC Technical Committee, and plans to be present.

Continuing, Chairman Hochschwender reported that within recent weeks he has received a communication from the head of the West German Plastics Society regarding the matter of the PVC prior sanctioned status in the United States. In the communication, concern was expressed over the 0.05 ppm limitation proposed for distilled alcoholic spirits and the possible "fall out" whereby this requirement would be applied to other foods. This whole matter has been brought to the attention of General Counsel, Jerome H. Heckman, and Dr. Hochschwender will write to explain the basis for the 0.05 ppm limitation that was included in the SPI Comments on the Proposed PVC Rulemaking. In addition, the German communication noted that feeding studies were either underway or about to begin soon in cooperation with a group in Holland to establish an oral, no-effect level for vinyl monomer. Dr. Hochschwender's communication will also request that the protocols for this feeding study be sent to him here since it is recognized by all that an appropriate feeding study is probably the only way to resolve the problem of residual monomer in PVC. Chairman Hochschwender opined that it is indeed useful to have this type of international exchange of communications and that whatever more was developed on the German matter would be reported at future meetings of the Committee.

Referring to the last meeting of the Committee when Peter Barton Hutt, Esq., Assistant General Counsel of the Food, Drugs and Product Safety Division of the Food and Drug Administration spoke, it was recalled that during the question-and-answer period Mr. Hutt suggested consideration be given to a recodification, so to speak, of the regulations which deal with indirect additives. As a matter of fact, Mr. Hutt showed interest in receiving input on this matter; and since then, there have been general approaches between SPI Counsel and FDA regarding the subject. Continuing, Chairman Hochschwender said that the Vice Chairman of the Committee, Bill Westveer, The Dow Chemical Company, has been asked by the Steering Committee to review this matter of recodification in order to see what might be done to benefit industry and government. Mr. Westveer is going to look into the situation and will appoint a small ad hoc task force to study the matter with him.

Concluding his preliminary remarks, Chairman Hochschwender stated that before the day was out he would appoint a Nominating Committee to arrive at a proposed slate of officers to serve from June 1, 1974 to June 1, 1976, a two-year period.

Report of SPI General Counsel

Chairman Hochschwender then introduced Jerome H. Heckman, Keller and Heckman, SPI General Counsel, to bring the Committee up to date on a variety of matters and issues relating to the Committee's interests, including the subjects of the Environmental Impact Statements and Environmental Impact Analysis Reports on Plastic Carbonated Beverage and Beer Bottles, the present status of the "GRAS" list, a report on the "prior-sanction status of PVC," and Comments made on FDA proposed rulemaking, and a follow-up report on the enforcement of Subpart F--FDA Pickups and Inspections.

In delivering his report, Mr. Heckman, as he has done in the past, indicated that he would welcome being interrupted at any time with questions from the floor relative to a particular point which he was discussing.

[Please Note: Attached hereto as Exhibit A is the detailed report delivered by Mr. Heckman and further amended by him following the day's session based upon a clarification of some of the matters he brought out as a result of questions posed of him.]

Technical Report by Daniel S. Dixler

As has been customary during the past several meetings of the Committee, the Keller and Heckman report has been divided into two phases, one from a legal point of view, delivered by Mr. Heckman, and the other, from a technical point of view, delivered by Dr. Daniel S. Dixler, although as pointed out during the meeting, there are cross-references frequently between the two reports where some matters interrelate between both technical and legal.

[Please Note: Attached hereto as Exhibit B is Dr. Dixler's detailed report.]

During Dr. Dixler's presentation, the matter of reported difficulties encountered by workers involved in hot-wire cutting of PVC film was raised. In particular, the question was posed as to whether this Committee should become involved with a study of the problem being undertaken at the University of Washington under the partial sponsorship of the Amalgamated Meatcutters Union. There were several who expressed interest in having the Committee discuss this matter and it was suggested that possibly the matter was already under consideration by the SPI Safety and Loss Prevention Committee administered by Jerome Carroll of the SPI staff.

[Please Note: The Secretary investigated this matter following the close of the meeting and discussed it with Mr. Carroll who has already begun building up a file on the subject but indicates to Mr. Condit that some of the principal companies involved in producing the film in question have thus far indicated little interest in getting involved in the so-called problem. Anyone interested in contacting Mr. Carroll is encouraged to do so.]

Report of Lawyers' Advisory Committee

Chairman Hochschwender noted that, unfortunately, Taylor W. Hanavan, Chairman of the Committee's Lawyers' Advisory group was unable to be present to report on legislative matters which have arisen within recent months as Mr. Hanavan usually brings to the attention of the group.

In an impromptu fashion, Jerome H. Heckman delivered a report on several matters including Consumer Product Safety Commission activities, Consumer Protection Agency legislation, the status of legislation on devices, and finally, recent court decisions relevant to the interests of the Committee.

[Please Note: Following the meeting, Mr. Hanavan sent a detailed report to Mr. Heckman. The same was edited and revised on a cooperative basis by Messrs. Hanavan and Heckman and is attached hereto as Exhibit C.]

Reports on Liaison with Other Organizations

Chairman Hochschwender then called upon several individuals to deliver reports on activities within other organizations or associations that relate to the interests of the SPI Committee.

Pharmaceutical Manufacturers' Association and U.S. Pharmacopeia

Watson B. Ackart, Union Carbide Corporation, delivered the following brief report on PMA:

"The May 1973 report of this subcommittee described the loss of interest on the part of the U. S. Pharmacopeia and the National Formulary in the publication of our testing procedures for polyolefin containers intended for dry pharmaceutical products and no further contacts have been made with these organizations. However, there is continued interest on the part of the pharmaceutical manufacturers in generic clearance for polyolefins and we are told that this interest originates within FDA. A copy of our methodology was sent to a packaging development expert at Upjohn for use by an industry committee on which he is working."

Manufacturing
Chemists' Association

Unable to be present at the day's session due to a previous engagement at the National Bureau of Standards, George W. Ingle, Monsanto Company, sent to the Secretary by way of a communication dated December 20, 1973, a report on MCA's FDC Chemicals Committee. This report follows:

"At this Committee's 14 November 1973 meeting, an earlier proposal for reorganizing the Committee was approved. In addition to a Steering Committee, Subcommittees were established under these headings: Consumer Information, Legislative and Regulatory, and Scientific. In addition, if only on a temporary basis, a Subcommittee on the Toxic Substances Control Act was established and is functioning, primarily to help EPA prepare for its administration of the expected TSC Law.

"The purpose of this reorganization is to identify and actively implement those projects in the FDC area which are most important to MCA. Among these is the extent to which MCA members' interest in drug-related questions justifies greater or different activity.

"Each of these subcommittees has met at least once, earlier this week. So far, aside from the TSC Subcommittee, the Consumer Information Subcommittee has been most active. Extensive revisions of two 'best-seller' MCA publications are being prepared, 'Every-day Facts - Food Additives,' and the more detailed 'Food Additives, What They Are/How They Are Used.' In addition,

a number of presentations has been and will be made to various consumer groups concerned with the safety of food additives.

"The Scientific Subcommittee is determining the extent to which this Committee will support the Symposium on Specifications for Food Additives planned to be held by the National Academy of Sciences later this spring. Considerable overseas representation is expected."

Can Manufacturers' Institute

Charles J. Spiegl, Continental Can Company, Inc., said that there was nothing new by way of a report from the Can Manufacturers' Institute.

ASTM Subcommittee
F2.30 Activity on PCB

Norman D. Bornstein, Cryovac Division, W. R. Grace & Company, presented the following summary report as prepared by L. DiBello of Cryovac on the activities of ASTM Subcommittee F2.30, especially as it relates to PCB content in plastics:

"Subcommittee F2.30 of ASTM Committee F2 on Flexible Barrier Materials has met twice for the development of a standard method of analysis and calculation of PCB content in plastics.

"An original set of four unknown PCB samples were sent to each member for analysis of PCB content by their laboratory method and a standard procedure of analysis and calculation as determined by the Subcommittee. A standard sample of Aroclor's 1242 and 1254 were also submitted for comparison vs. their laboratory samples. The initial results of this test showed promise of the reproducibility of the test method and calculation but the Subcommittee felt that the standard PCB samples which were 1242 and 1254 were not representative of PCB analysis on plastics.

"New standards were made of mixtures of 1242 and 1254 with varying amounts of each Aroclor and duplicate samples of each standard were submitted to each member for analysis. These results will be used for a statistical study of the method.

"John Cobler of Dow also agreed at the last meeting to blend a known amount of PCB into various polymers. These samples will be used by the Subcommittee for developing a standard method of extraction after the analytical procedure has been developed."

Cosmetic, Toiletry and
Fragrance Association (CTFA)

A more recent liaison has been brought about between the SPI Committee and CTFA through Jules Pinsky, The Mearl Corporation. Unfortunately, due to inclement weather, Dr. Pinsky was unable, at the last minute, to attend the meeting. Following the session he sent to the Secretary a short communication dated January 7, 1974 which is quoted hereinafter:

"Dr. N. S. Estrin, Executive Secretary, reports that the information furnished by the SPI has been very valuable to the Cosmetic, Toiletry and Fragrance Association. Pertinent details have been passed along to the Scientific Advisory Committee, who are reassured and appreciative.

"Several rumors on the status of the PVC and PVC bottles have been phoned in by frantic members, and Dr. Estrin has told them he has been unable to substantiate any of these rumors."

Report of Medical Devices Standards Subcommittee

Chairman Hochschwender called upon George A. Richter, Rohm and Haas Company, to report on the status of the Subcommittee on Medical Devices Standards (MDSS), prompting Dr. Richter to read the following communication addressed to Mr. Condit dated January 3, 1974:

"In accordance with the plan established at the meeting attended by MDSS members and ASTM representatives on February 21, 1973, an organizational meeting of the new ASTM Section on Medical Plastics (D20.15.23) was held at ASTM headquarters on August 28, 1973. The objective of this meeting was 1) to establish the organizational structure of this new ASTM section on Medical Plastics, 2) to approve the name of the section and 3) to define its scope.

"It was decided that the new group within the ASTM would be organized as a section of D20.15 (Thermoplastic Materials) which is a subcommittee under ASTM Committee D-20 on Plastics. Dr. Leon J. DeMerre of the FDA has accepted chairmanship of this new ASTM section on Medical Plastics. It was also agreed that the scope of the new section would be as follows:

"To develop test methods, specifications, recommended practices, classifications, and definitions for plastic materials (including resins, plasticizers and other adjuvants) for medical applications and to support research and the promotion of general knowledge relating to medical plastics.

"An ad hoc task force was formed to define the problem area and to develop recommendations regarding priorities. The next meeting of Section D20.15.23 on Medical Plastics was scheduled for October 17, 1973 in Boston.

"At the October 17 meeting in Boston the designation of the new section on Medical Plastics was changed by Executive Committee action to D-20.24.03. The principal outcome of this meeting was the selection of two main plastics for establishment of standards, namely, polyethylene and polyvinyl chloride. Standards categories which will be considered are specifications, test methods, classifications, compatability, definitions and applications. Two subsections were formed to develop proposed standards, one for polyethylene and the other for polyvinyl chloride.

"The next meeting of D-20.24.03 was tentatively scheduled for Wednesday, March 6, 1974 in Atlanta, Georgia."

Destiny of Committee

At this point in the business session, Chairman Hochschwender interjected a new item when he charged the Committee, so to speak, to determine its own destiny, a matter which he said he would like to "ventilate" while the Committee was all together. Chairman Hochschwender noted that, in his view, the Committee is owed from time to time a chance to discuss openly any feelings that individuals may have regarding guidelines as to how the Steering Committee and officers should conduct business on behalf of the Committee. For

instance, he asked whether there were any comments as to whether principal speakers should be scheduled at each meeting of the Committee. He also stated that he would welcome any new subject which it is felt would add to the aims and objectives of the Committee or enlarge its scope--all towards varying the program at future meetings of the group. Chairman Hochschwender said, "We want to bring to you what's useful to you!"

Next Meeting

In connection with Dr. Hochschwender's remarks on future programming, the location and possible dates for the next meeting were discussed at this point, although plans for the next meeting were scheduled to be discussed as the last item on the Agenda.

There was some preference voiced for selecting New York City as an appropriate place for some meetings, prompting at this point, Jerry Heckman to suggest Washington, D. C. in either June or July of 1974 for the next meeting. Mr. Heckman felt it would be opportune at the next meeting to have either Richard J. Ronk or someone else from FDA as a speaker which would make Washington, D. C. the preferred location. Not counting out New York City as a possible site for a future meeting, it seemed to be agreed that the next meeting should take place in Washington, D. C. on June 27, 1974. The Secretary has now made the appropriate arrangements again at the Shoreham Americana Hotel.

Report of Technical Information Subcommittee

As is customary, Willard M. Westveer, The Dow Chemical Company, and Vice Chairman of the overall Committee, highlighted a detailed report he has prepared for incorporation in the Minutes on recently-issued Food Additive Regulations.

[Please Note: Attached hereto as Exhibit D is the detailed report which Mr. Westveer asked the Secretary to incorporate in the Minutes.]

Report of Committee on Food Additive Regulation of Furnace Black (COFREB)

Here again, Mr. Condit was called upon by Chairman Hochschwender to read that portion of Mr. Ingle's communication to Mr. Condit dated December 20, 1973, dealing with COFREB, the activities of which Mr. Ingle coordinates on behalf of the overall Committee. Mr. Ingle's report on this matter follows:

"So far this activity has received little but frustrating responses from FDA. The urgency of finding an acceptable replacement for '100% gas' Channel Black has been reduced by (1) FDA's delay in issuing its proposed regulation on Colorants for Plastics; (2) the existence of inventories of this 'gas black';

(3) the availability of 'Indo-Tex EPC,' a 100% gas channel black, imported from Indonesia by the Sid Richardson Carbon and Gasoline Company of Fort Worth; and (4) the apparent use of some oil-enriched gas blacks not permitted for use in food-contact plastics by FDA's proposed order.

"Regardless, to provide for greater future flexibility of supply, COFREB met with a large group of FDA staffers on 16 August 1973 to discuss a proposed protocol described in a 9 July 1973 letter to FDA. While FDA emphasized the difficulties and necessary conditions in our proposed proof of no migration of carcinogenic PNAH's (polynuclear aromatic hydrocarbons) by a method validated to 2 PPB, at FDA's insistence, there was no FDA denial of the feasibility of the project. Reference was made to the necessity of obtaining higher administrative concurrence because of the implications of the Delaney Clause.

"On 1 November 1973, FDA's Mr. John Singleton (no longer in the Division of Food and Color Additives) replied in writing. Aside from demanding proof of lot-to-lot reproducibility of the type and level of PNAH's present on each carbon black, Mr. Singleton dismissed our 'no migration' concept 'because the Delaney Clause prohibits the addition of known carcinogenic substances to food directly or indirectly, etc.'

"For several reasons, we consider Mr. Singleton's letter non-responsive to the questions involved. We are now asking the members of COFREB to comment on a simpler proposal. This is based on a Wesson Oil extraction of the most likely (finest particle size, lowest PNAH content) furnace black pigments, for which data on benzene-extracted PNAH-contents are available. It is probable that one or two pigments will show no detectable PNAH's of any kind by a PPB-sensitive method. If this limited work proves affirmative, after review with FDA, the necessity of extracting black-pigmented plastics may be voided.

"In any event, we must convince FDA that we are not asking for an infraction of the Delaney Clause, if our data will soundly justify specifying pigments which, when incorporated in plastics, will provide 'no migration' by FDA's most conservative analytical method."

Following a reading of Mr. Ingle's report, there was some discussion as to whether all of the companies interested in the subject of carbon black are either serving on or taking an interest in the activities of Mr. Ingle's subcommittee. For instance, it was suggested that there could be at least fifteen companies who should have an interest in the activity. Mr. Robert M. Miller, Hercules, Inc. said that there was some question as to the degree of interest held by those participating or commenting on the affairs of the Committee. Mr. Miller referred to the results of the discussions held with FDA under Mr. Ingle's direction, commenting that there is some frustration as to what direction the Committee should take. For example, there is now some discussion underway as to whether those interested in the subject should be asked to contribute financial support for analytical work, but, in Mr. Miller's opinion, it is not too clear whether this analytical work would result in information which would definitively lead FDA to issue a regulation permitting the use of furnace black as a colorant for plastics. Mr. Miller said that there is every indication that FDA will insist on feeding studies in order to prove that carbon black is not carcinogenic.

It was quite obvious to Chairman Hochschwender and others that Mr. Ingle and his committee need to pursue this matter further, it being noted that, in this connection, there is really no firm recommendation as yet from Mr. Ingle's group. Therefore, Dr. Hochschwender expressed the hope that by the next meeting of the full Committee Mr. Ingle will have developed on behalf of his task force an overall recommendation for some action by the Committee. Further, Chairman Hochschwender urged those others who are not participating on Mr. Ingle's task force to communicate directly with him should they wish to comment or participate in the committee's work so that Mr. Ingle can have maximum input in arriving at a recommendation for the next meeting.

New Business

As an item of new business, Dr. Dixler reported that Mr. Francis Greenough, W. R. Grace & Company, had requested we bring to the attention of this Committee that the U. S. Department of Agriculture, through its Animal and Plant Health Inspection Service (APHIS), had proposed new poultry labeling regulations that might adversely affect the plastics packaging industry. The initial regulation was proposed in the Federal Register for September 21, 1973 and proposed a new Section 381.142 which would ostensibly limit packaging materials for poultry to materials which comply with Section 409 of the Federal Food, Drug and Cosmetic Act. However, the proposed regulation went on to limit materials used in packaging to those listed in Subparts B, E and F of the Food Additive Regulations set forth in Section 121 of Title 21 of the Code of Federal Regulations. Although this regulation appeared innocent, it could have the effect of banning from packaging materials the use of any items that are GRAS but not listed in Section 121.101, prior sanctioned materials not listed in Subpart E, and materials which do not migrate and which are therefore not covered by Food Additive Regulations. These latter three classes of materials, however, are permitted by the Food, Drug and Cosmetic Act.

Mr. Greenough indicated he had written Comments on behalf of his company but requested the Society likewise file Comments on behalf of the entire industry. It was decided that the Society's General Counsel should develop and submit appropriate Comments in this matter.

Mr. Heckman pointed out that time (final Comments were due to be filed by January 25, 1974) would not permit the usual circulation of a draft for consideration by the membership of the Committee. It was agreed that the Comments would be filed without previous submission to the membership of the Committee, but of course, copies of the Comments would be circulated.

Nominating Committee Appointed

Chairman Hochschwender reminded those present that earlier in the meeting he indicated he would be appointing a Nominating Committee to recommend a proposed slate of officers for presentation and election at the next meeting of the Committee. The new officers, when elected, will serve from June 1, 1974 to June 1, 1976. Chairman Hochschwender then named the following to the Nominating Committee:

Peter Morison, Chairman	Eastman Chemical Products, Inc.
Charles J. Spiegl	Continental Can Company, Inc.
Matthew E. Smith	Owens-Illinois, Inc.

[Please Note: The Secretary, in reviewing the Bylaws of the Committee notes that "the slate of nomination shall be mailed by the Secretary to all members at least ten (10) days prior to the meeting where the election is to take place," i.e., the next meeting. With this in mind, the Secretary, as he circulates these Minutes, would like to remind Mr. Morison to have the proposed slate of officers in the Secretary's hands in time to incorporate in the meeting notice for the Washington business session to be held on June 27.]

There being no further business, Chairman Hochschwender declared the session adjourned at 3:15 p.m.

Respectfully submitted,

Charles L. Condit
Secretary

EXHIBIT D

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE

SPI FOOD PACKAGING MATERIALS COMMITTEE

January 10, 1974

Recently Issued Food Additive Regulations

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

<u>TYPE & SECTION</u>	<u>REFERENCE</u>	<u>PETITIONER</u>	<u>SUBJECT</u>
Amended 121.1030	F.R. 38(99) Page 13556 5-23-73	Atlas Chemical Company	Amended to provide for the safe use of polysorbate 60 as an emulsifier in chocolate flavored syrups where- by the maximum amount of the additive does not ex- ceed 0.05 percent on a dry weight basis.
Amended 121.2524	F.R. 38(99) Page 13557 5-23-73	E. I. du Pont de Nemours and Co.	Amended to extend the pre- sent limited use of poly- ethylene terephthalate, a form of polyethylene phthalate, in the manufac- ture of film to use in other articles intended to contact food.

<u>TYPE & SECTION</u>	<u>REFERENCE</u>	<u>PETITIONER</u>	<u>SUBJECT</u>
Amended 121.2526	F.R. 38(107) Page 14751 6-5-73	American Cyanamid Company	Amended to provide for the safe use of acrylonitrile polymer with styrene, reaction product with ethylenediamine, acetate as a sizing material in paper and paperboard intended for use in contact with food.
Amended 121.2547	F.R. 38(107) Page 14751 6-5-73	Economics Laboratory Inc.	Amended to provide for the safe use of an aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, and polyoxyethylene-polyoxypropylene block polymers for sanitizing food-processing equipment and utensils that contract food.
Amended 121.2566	F. R. 38(112) Page 15443 6-12-73	Gulf Oil Corp.	Amended to: (1) Change the basis of the limitation on the amount of 2,6-di-tert-butyl-4-ethylphenol which may be used in ethylene polymers and copolymers, and (2) permit increased levels of the food additive in intermediate thicknesses of the polymers and copolymers between 0.0025 and 0.025 inch.
Amended 121.2566	F.R. 38(117) Page 15953 6-19-73	Argus Chemical Corp.	Amended to provide for the safe use of 4,4'-isopropylidenediphenol alkyl (C ₁₂ -C ₁₅) phosphites as stabilizers in the manufacture of rigid vinyl chloride plastics intended for use in contact with food, except milk, under conditions where hot filled or pasteurized below 150°F and/or under storage conditions.

<u>TYPE & SECTION</u>	<u>REFERENCE</u>	<u>PETITIONER</u>	<u>SUBJECT</u>
Pro- cedures 122.10	F.R. 38(129) Page 18101 7-6-73	Commis- sioner	Temporary tolerances for polychlorinated biphenyls (PCB's). Temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established as follows: (1) 2.5 parts per million in milk (fat basis). (2) 2.5 parts per million in manufactured dairy products (fat basis). (3) 5 parts per million in poultry (fat basis). (4) 0.5 parts per million in eggs. (5) 0.2 parts per million in finished animal feed for food-producing animals. (6) 2 parts per million in animal feed components of animal origin. (7) 5 parts per million in fish and shellfish. (8) 0.2 parts per million in infant and junior foods. (9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

<u>TYPE & SECTION</u>	<u>REFERENCE</u>	<u>PETITIONER</u>	<u>SUBJECT</u>
Amended 121.2520	F.R. 38(130) Page 18245 7-9-73	Ciba-Geigy Corp.	Amended to provide for safe use of thiodiethylenebis (3,5 - di - tert - butyl - 4 - hydroxyhydrocinnamate) as an adjuvant for polymers used in adhesives for food-packaging materials.
Amended 121.2571	F.R. 38(130) Page 18246 7-9-73	E. F. Houghton & Co.	Amended to provide for the safe use of polyamide polyamine-epichlorohydrin water-soluble thermosetting resins, as components of paper and paperboard for food contact use.
Amended 121.2520	F.R. 38(131) Page 18367 7-10-73	Alcolac, Inc.	Amended to provide for the safe use of polyethylene glycol mono (hydrogen sulfate) dodecyl ether, ammonium salt, as a component of adhesives intended for use in food-contact articles.
Amended 121.2566	F.R. 38(136) Page 19025 7-17-73	Weston Chemical, Inc.	Amended to provide for the safe use of distearyl pentaerythritol diphosphite as an antioxidant and/or stabilizer in the manufacture of polyolefin plastics intended for food contact use.
Amended 121.2520	F.R. 38(156) Page 21920 8-14-73	Union Carbide Corp.	Amended to provide for safe use of poly(oxycaproyl) diols and triols as components of food-packaging adhesives.

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Amended 121.2526	F.R. 38(156) Page 21921 8-14-73	Nalco Chemical Company	Amended to provide for the safe use of polyacrolein-sodium bisulfite adduct for modifying starches and starch gums used in the manufacture of paper and paperboard for use in contact with food.
Amended 121.2531	F.R. 38(165) Page 22889 8-27-73	Shell Chemical Company	Amended to provide for the safe use of an additional synthetic primary alcohol mixture of straight- and branched-chain alcohols for use as a component of surface lubricants used in the manufacture of metallic articles.
Amended 121.2536	F.R. 38(165) Page 22889 8-27-73	Celanese Fibers Marketing Company	Amended to provide for the safe use of polyethylene terephthalate fibers in the manufacture of resin-bonded filters.
Amended 121.2536	F.R. 38(165) Page 22890 8-27-73	American Cyanamid Company	Amended to provide for the safe use of melamine-formaldehyde chemically modified with methyl alcohol as a component of resin-bonded filters in food-contact use.
Amended 121.2553	F.R. 38(165) Page 22890 8-27-73	Standard Oil Company of California	Amended to provide for the safe use of magnesium ricinoleate, sodium metaborate, and polyurea (produced by reacting tolylene diisocyanate and amines) as components of lubricants with incidental food contact.

<u>TYPE & SECTION</u>	<u>REFERENCE</u>	<u>PETITIONER</u>	<u>SUBJECT</u>
	F.R. 38(198) Page 28624 10-15-73	Commis- sioner	The Commissioner of Food and Drugs has initialed a recodification program for Chapter I of Title 21 of the Code of Federal Regulations. This is the first document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.
Amended 121.2526	F.R. 38(205) Page 29465 10-25-73	Wells Labora- tories, Inc.	Amended to provide for the safe use of dimethyl glutarate, in the preparation of polyamide-epichlorohydrin water-soluble thermosetting resins intended for use in the manufacture of uncoated paper and paperboard in contact with aqueous and fatty foods.
Amended 121.2547	F.R. 38(205) Page 29465 10-25-73	Lithium Corp. of America	Amended to provide for the safe use of an aqueous solution containing lithium hypochlorite for sanitizing food-processing equipment and utensils that contact food.
Amended 121.2547	F.R. 38(205) Page 29466 10-25-73	West Chemical Products	Amended to provide for the use of isopropyl alcohol as an optional adjuvant, rather than as a required ingredient, for sanitizing food-processing equipment and utensils that contact food.
Amended 121.2511	F.R. 38(206) Page 29577 10-26-73	Esso Research and Engineering Company	Amended to provide for the additional safe use of diisononyl adipate as a plasticizer in vinyl chloride homo-and/or copolymer films for food contact use.

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Amended 121.2526	F.R. 38(211) Page 30257 11-2-73	Monsanto Company	Amended to provide for the safe use of (1) a polyamine-epichlorohydrin resin prepared by reacting hexamethylenediamine with 1,2-dichloroethane to form a prepolymer and further reacting the prepolymer with epichlorohydrin resin prepared by reacting the resin formed in (1) above with nitrilotris (methylenephosphonic acid), pentasodium salt. These resins are to be used as components of paper and paperboard in contact with food.
Amended 121.2514	F.R. 38(211) Page 30257 11-2-73	PPG Industries Inc.	Amended by deleting the restrictions. Butyl acrylate-styrene-methacrylic acid-hydroxyethyl methacrylate copolymers containing no more than 20 weight percent of total polymer units derived from methacrylic acid and containing no more than 7 weight percent of total polymer units derived from hydroxyethyl methacrylate; for use only in coatings that are applied by electrodeposition to metal substrates.