



THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

A G E N D A *

MEETING, SPI FOOD PACKAGING MATERIALS COMMITTEE

Commodore Hotel

Lexington Avenue at 42nd Street
New York, New York 10017

Wednesday, April 17, 1968

Beginning promptly at 9:30 a.m.

- 1: Call meeting to order - George W. Ingle, Chairman
- 2: Self-introductions
- 3: Consider Minutes of last regular meeting (September 20, 1967)
- 4: Report of Nominating Committee - M. C. Stone, Chairman **
- 5: Election of Officers - (N.B. In accordance with Article IV, Section 2 of the Bylaws, the newly elected officers will assume their posts on June 1, 1968 and will serve for a two-year term, i.e., to July 1, 1970)
- 6: Report of Lawyers Advisory Committee - George T. Scribe*
 - (a) Re Bylaws Amendments
 - (b) Legislative Outlook
 - (c) General comments and recommendations
- 7: Report of Committee Chairman - George W. Ingle*
 - (a) Background information re FDA National Conference on Indirect Food Additives
 - (b) Other matters
- 8: Reports on liaison with other organizations
 - (a) Synthetic Organic Chemical Manufacturers Association (SOCMA) - Status report on proposed "Synthetic Organic Colorants in Paper and Paperboard" Food Additive Regulation - W. P. Munro*
 - (b) Pharmaceutical Manufacturers Association - SPI Liaison Group - W. B. Ackart*
 - (c) Manufacturing Chemists' Association (Food Additives Committee) - Taylor W. Hanavan, Esquire*
 - (d) American Paper Institute - James R. S. McCartney*
 - (e) Can Manufacturers Institute - Charles J. Spiegl*
 - (f) SPI Food and Drug Bottling Committee of the Plastic Bottle Division - M. E. Smith*
 - (g) Others
- 9: Report of SPI Counsel - Jerome H. Heckman*
 - (a) The National Conference on Indirect Food Additives and Its Implications
 - (b) Status of FDA proposed "Procedural Regulations"
 - (c) Other Matters
- 10: Lunch - 12:30 P.M.

* Please bring written reports.

** A copy of Mr. Stone's Report, as sent to the Committee Secretary on March 20, 1968, is attached to this Meeting Notice so that all Committee members will be advised of the Nominating Committee's recommendations in accordance with the 10-day notice requirements of Article IV Section 4 of the Committee's Bylaws.

(OVER)

ASI 00000504

- 11: Report of Technical Information Subcommittee - Robert M. Miller, Chairman*
 - (a) Recently promulgated Food Additive Regulations, and related regulatory actions
 - (b) Food and Drug Administration activity re colorants
 - (c) Pigments Task Group Report - Arnold Finestone, Coordinator*
 - (d) Other Matters

- 12: International Developments - Open Discussions
 - (a) British "Food Additives and Contaminants Committee" Inquiry (Please refer to March 6, 1968 letter and enclosures from Jerome H. Heckman to all Committee members)

 - (b) Dutch regulations

 - (c) Others

- 13: New Business

- 14: Plans for Next Meeting

- 15: Adjournment



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MINUTES

MEETING OF SPI FOOD, DRUG, AND COSMETIC
PACKAGING MATERIALS COMMITTEE
(FORMERLY SPI FOOD PACKAGING MATERIALS COMMITTEE)

Commodore Hotel
New York City

April 17, 1968
9:40 a.m.

Present:

- George W. Ingle, Chairman, Monsanto Co., Hydrocarbons & Polymers Div., Research Dept., Springfield, Mass. 01101
- Robert M. Miller, Vice Chairman and Incoming Chairman, Hercules Inc., Delaware Trust Bldg., Wilmington, Del. 19899
- W. B. Ackart, Union Carbide Chemicals & Plastics, One River Rd., Bound Brook, N. J.
- L. G. Adlum, Rexall Chemical Company, P. O. Box 37, Paramus, N. J. 07652
- John A. Carlson, Jr., Vistron Corp. (SOHIO), Midland Bldg., Cleveland, Ohio 44115
- K. C. Conley, Marbon Chemical Div., Borg-Warner Corp., P. O. Box 68, Washington, West Virginia 26181
- L. J. DeCorte, Sinclair-Koppers Co., Product Development, Frankfort Rd., Monaca, Pa.
- Daniel S. Dixler, AIRCO, Air Reduction Co., Inc., Central Research Lab., Murray Hill, N. J. 07901
- George W. Ferner, The Goodyear Tire & Rubber Co., Research Div., 1144 E. Market St., Akron, Ohio 44316
- Robert A. Ferrell, KCL Corp., Prospect & Hodell Sts., Shelbyville, Ind. 46176
- A. B. Finestone, Foster-Grant Co., Inc., 289 North Main St., Leominster, Mass.
- B. J. Barceau, ICI America, Inc., P. O. Box 1274, 151 South St., Stamford, Conn.
- Taylor W. Hanavan, E. I. du Pont de Nemours & Co., Inc., Film Dept., Wilmington, Del.
- Ralph L. Harding, Jr., SPI, 250 Park Ave., New York, N. Y. 10017
- K. A. Hochschwender, American Hoechst Corp., 777 Third Ave., New York, N. Y. 10017
- Thomas J. Hughes, Keller & Heckman, 1712 N St., N. W., Washington, D. C. 20036
- W. A. Knapp, Allied Chemical Corp., General Chemical Div., P. O. Box 405, Morristown, N. J. 07960
- A. F. Kopacki, Stauffer Chemical Co., Eastern Research Center, Dobbs Ferry, N. Y.
- F. S. Landers, Lily Tulip Cup Corp., 500 Commack Rd., Commack, N. Y. 11725
- James R. S. McCartney, Standard Packaging Corp., 200 E. 42nd St., New York, N. Y.
- G. McIntyre, Columbian Carbon Co., P. O. Box 975, Princeton, N. J. 08540
- J. A. Mitchell, E. I. du Pont de Nemours & Co., Inc., Film Dept., 1007 Market St., Wilmington, Del. 19898
- Kenneth Morgareidge, Food & Drug Research Laboratories, Inc., Maurice Ave. at 58 St., Maspeth, N. Y. 11378
- P. Morison, Chemical Sales Dev. & Technical Service, Eastman Chemical Prods., Inc., Kingsport, Tenn. 37662

ASI 00000506

S. Nesmith, USI Chemicals Co., P. O. Box 218, Tuscola, Ill. 61953
A. S. Nyquist, American Cyanamid Co., P. O. Box 425, Wallingford, Conn. 06492
B. N. Olson, Reynolds Metals Co., 10th & Byrd Sts., Richmond, Va. 23219
W. A. Patterson, W. R. Grace & Co., Cryovac Div., Box 464, Duncan, S. C. 29334
I. F. Peake, E. I. du Pont de Nemours & Co., Inc., Film Dept., Wilmington, Del.
R. E. Rutherford, Gulf Research & Development Co., Box 8200, Kansas City, Mo.
G. T. Scriba, Union Carbide Corp., Legal Dept., 270 Park Ave., New York, N. Y.
W. W. Sederlund, National Starch & Chemical Corp., 1700 W. Front St., Plainfield,
New Jersey
A. C. Signore, Monsanto Co., Packaging Div., 101 Granby St., Bloomfield, Conn.
M. E. Smith, Owens-Illinois, Plastic Products Div., Adams & 14th Sts., Toledo, Ohio
C. J. Spiegl, Continental Can Co., Inc., 7622 S. Racine Ave., Chicago, Ill. 60620
M. C. Stone, Eastman Chemical Prods., Inc., Box 431, Kingsport, Tenn. 37662
F. C. Stroehlein, Emery Industries, Inc., 4900 Este Ave., Cincinnati, Ohio 45232
W. M. Westveer, The Dow Chemical Co., 433 Bldg., Midland, Mich. 48640
Charles L. Condit, Secretary, SPI, 250 Park Ave., New York, N. Y. 10017

Under the direction of George W. Ingle, Monsanto Company, a meeting of the SPI Food Packaging Materials Committee (later renamed during the discussions "SPI Food, Drug, and Cosmetic Packaging Materials Committee") convened in New York City at the Commodore Hotel at 9:40 a.m.

Referring to a detailed agenda circulated with the Secretary's meeting announcement, Mr. Ingle, as a first order of business, asked for the customary self-introductions.

Minutes Last Meeting Approved

By way of reminder, Mr. Ingle said that the last overall meeting of the Committee was held in New York City on September 20, 1967. He noted that the Minutes were somewhat delayed in being sent to members of the Committee, explaining that this delay was due to the substantive activities necessary on the Committee's behalf in connection with the FDA's proposed Procedural Regulations, preparation for the National Conference on Indirect Food Additives, etc.

By way of further reminder, Mr. Ingle said that the covering letter to the Minutes gave notice to members of the Committee that there would be recommended changes in the By-Laws voted on at the day's meeting.

In the absence of comments as to corrections or additions to the Minutes of the last meeting held on September 20, 1967, Chairman Ingle declared them approved as developed and circulated by SPI.

Condolences to Jerome Heckman and His Family

Chairman Ingle announced that, representing Jerome H. Heckman, Esquire, Legal Counsel for SPI at the day's session was Thomas Hughes of the office of Keller and Heckman in view of the passing of Mr. Heckman's father, Morris Heckman, within recent days. In this connection, on motion of George T. Scriba, Union Carbide Corporation, duly seconded and carried unanimously, the Secretary was requested to communicate with Jerome Heckman and his family extending condolences on behalf of the Committee.

Election of Officers

Mr. Ingle reported that, subsequent to the last meeting of the Committee, he had appointed a Nominating Committee charged with the task of proposing a slate of officers to guide the activities of the group for a period of two years following the beginning of the Society's fiscal year, i.e., June 1, 1968. Mr. Ingle then called upon M. C. Stone, Eastman Chemical Products Inc., to report on behalf of the Nominating Committee composed, in addition to Mr. Stone, of W. B. Ackart, Union Carbide Corporation, and Leroy Durkin, Imco Containers.

Mr. Stone pointed out that, as indicated in the meeting announcement sent to all members, the following nominees are proposed by the Nominating Committee:

Chairman - Robert M. Miller, Hercules Inc.

Vice Chairman - Taylor W. Hanavan, E. I. du Pont de Nemours & Co., Inc.

Three members to the Steering Committee:

George W. Ingle, Monsanto Company
Matthew E. Smith, Owens-Illinois
William M. Westveer, The Dow Chemical Company

Arnold Finestone, Foster Grant Company moved that the nominations be closed and the Secretary asked to cast a unanimous ballot on behalf of the Committee for the slate of officers as proposed by the Nominating Committee. The motion was seconded and carried unanimously.

In congratulating Mr. Miller and others elected at the day's session, Mr. Ingle said that, indeed, the assignment of guiding the Committee has been a most instructive and enjoyable one. He thanked those on the Committee who have accorded him cooperation in various of the endeavors which have reached fruition during his term of office. Mr. Ingle paid special attention to thanking the Steering Committees with which he has worked pointing out that, in his view, the Steering Committees, during their deliberations, have been unusually effective in searching out and recommending the right answers to the various problems which have arisen over the past several years. Mr. Ingle noted that he looks forward to continuing to work with the Committee.

At this point M. C. Stone, Eastman Chemical Products, Inc., proposed the following two resolutions:

RESOLVED, that this Committee express to George W. Ingle its sincere appreciation and gratitude for his distinguished leadership and service to this body through the years of its growth and for the learning he has brought to its deliberations and its action;

AND BE IT FURTHER RESOLVED, that this Committee express to George T. Scriba and I. Frank Peake its thanks for their dedicated service as members of the Steering Committee, and of various subcommittees of this organization.

Mr. Stone's motion was seconded and carried unanimously.

Report of Lawyers' Advisory Subcommittee

Chairman Ingle called upon George T. Scriba, Union Carbide Corporation, and Chairman of the Lawyers' Advisory Subcommittee for this report.

By-Laws Amendments Approved

Mr. Scriba reminded those present that the notice of the day's meeting announced the fact that the following amendments to the By-Laws of the Committee would be voted on at the day's business session.

"The Subcommittee recommends that the following articles and paragraphs of the Bylaws be amended to read as follows:

ARTICLE I - NAME

"This organization shall be known as the Food, Drug, and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc.

ARTICLE II - OBJECTIVES

"The objectives of the Food, Drug, and Cosmetic Packaging Materials Committee shall be as follows:

- "(a) To constitute a Committee within the Society, in accordance with its Bylaws and Rules, to be informed on the application to plastics of the Federal Food, Drug, and Cosmetic Law, the Federal Meat and Poultry and Seafood Inspection Acts and similar laws, and any regulations adopted under them.
- "(b) To represent and speak for the Society on behalf of the industry before the Federal Food and Drug Administration and the other administrators.
- "(c) To collect such information on food, drug, and cosmetic packaging and allied subjects as may be appropriate or needed for any particular proceeding, hearing, or presentation made by the Society on behalf of the industry.
- "(d) To collect and disseminate among the members of the Society information concerning matters of food, drug, and cosmetic packaging, and allied subjects of interest and, in connection therewith, to publish bulletins, conduct surveys and research projects appropriate to the plastics food, drug, and cosmetic packaging industry's needs and functions.

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Article II-Objectives (cont.)

- "(e) To seek and encourage reasonableness and uniformity in regulatory matters and laws affecting the plastics food, drug and cosmetic packaging industry on an industry-wide basis."

At this point, George T. Scriba moved that the amendments as read by him be adopted by the overall Committee. Robert M. Miller, Hercules Inc., seconded the motion. The motion was carried unanimously.

By way of comment, Mr. Ingle expressed the view that the amendments to the Bylaws represent a major step forward in enlarging the scope of the Committee, and that this change will clear the way for continued Committee handling of a number of problems not strictly limited to the "food packaging materials" area. He thanked Mr. Scriba and members of the Lawyers' Advisory Subcommittee for the time and effort expended in preparing these proposed amendments to the Bylaws.

At this point, Mr. Scriba said that possibly in the future, it may be necessary to consider additional amendments in view of the possibility of new "devices legislation" and the growing interest in foreign regulatory matters with which the Committee is concerned.

Legislative Outlook

In commenting on the legislative outlook, Mr. Scriba first expressed the opinion that there seems to be no real prospect that any of the many bills introduced over the past several years to require pre-marketing approval of "devices" by FDA will be enacted in this Session of Congress. No Committee hearings are scheduled on these measures at this time.

There is some prospect that H.R. 14816, the "Occupational Safety and Health Act," which would give the Department of Labor powers and duties to regulate working conditions, machinery, etc. in manufacturing plants will be enacted this year. Committee hearings have been held.

Tom Hughes, in commenting on H.R. 14816, pointed out that it is a strongly backed Administration Bill, and that it likely will pass the House this session in spite of strong industry objection. If the bill passes the House, it will then go to the Senate and hearings, of course will be held. Mr. Hughes said that Mr. Heckman's office would keep the Committee advised as to the progress this bill is making through both houses. As an incidental matter, it was mentioned during discussion that the Bill proposes broad coverage which would not be limited only to those dealing with government contracts.

By way of passing on general information in this "safety inspection" area, Mr. Ingle revealed he has learned that at least three PVC extrusion plants have been inspected at State level and that it is curious to note that these inspections were prompted due to possible concern over the "corrosive" and "poisonous" effects generated by HCL.

General Comments and Recommendations
by Mr. Scriba

Mr. Scriba then pointed out that FDA had published proposed regulations purporting to set standards for good manufacturing practices, i.e. good housekeeping, in food plants. He noted that the proposal was obviously written for and aimed at true "food plants" with nothing in the language to indicate that FDA was thinking about indirect food additives. Nevertheless, the Manufacturing Chemists' Association has filed comments with FDA which, among other things, urges that these regulations expressly state that they do not apply to direct or indirect food additives plants, as distinguished from "food plants." MCA was successful in having comparable regulations for drug plants so limited several years ago. Whether or not FDA heeds MCA's recommendation, Mr. Scriba noted that it is highly improbable that FDA's inspectors would be told to regard anything specific in these regulations as applicable to plastics.

At this point, Mr. Ingle, on a completely informal basis, asked for an indication from those present as to how many of their plants have been visited by federal inspectors within the last two years. For varying reasons pointed out at the day's meeting, it appeared that perhaps five, or at the most six plants, have been so inspected. In this regard, it was pointed out that FDA may be building up case histories of refusals in order to lay the groundwork for possible legislation in the future to broaden its inspection rights.

Report of George W. Ingle

Mr. Ingle noted that all members of the Committee received, under date of April 1, 1968 from the offices of Jerome H. Heckman, Esquire, the abstracts of presentations given at the National Conference on Indirect Food Additives held in Washington, D. C., February 13-14, 1968. By way of comment, Mr. Ingle said that most certainly members of the Committee by now are aware of the sterling performance given by Mr. Heckman's office in making known the fact on short notice that the Conference was taking place. He then indicated that although most of those present were at the February meeting in Washington, he would like to point out that the SPI, through Mr. Heckman's office, took the initiative to bring together representatives of other industries in order to provide a measure of cohesion in setting forth industry's position prior to the Conference.

He noted that, as a matter of fact, preliminary meetings held in Washington prior to the Conference were successful in developing a number of important comments from other industries. All in all, with possibly one exception, there was firm agreement by all industry groups that the FDA should establish a government-industry advisory Committee on indirect additives. Mr. Ingle closed his comments on the background of the FDA National Conference by indicating that Mr. Hughes would have a more detailed report on the matter later in the meeting.

Mr. Ingle then dealt with other items which he felt should be brought to the attention of the Committee.

1. Mr. Ingle brought to the attention of the Committee that, within recent weeks, he learned of the availability from Hospital Bureau Incorporated, 201 Park Avenue South,

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New York, New York 10003, of a report entitled "Plastics in Hospitals." (This booklet is available from Hospital Bureau, Inc. at \$5 per copy.)

Mr. Ingle then urged that members of the Committee consider obtaining this book because, as the news release announcing its availability points out, "acceptance of plastic materials by hospitals is growing at a faster pace than the knowledge of their properties, thereby raising questions about their adequacy and utility in some instances, . . ." The news release goes on to say that the report entitled "Plastics in Hospitals" reviews characteristics of many different plastics materials, lists which ones are employed in hospitals, describes tests to indicate safety and effectiveness, discusses problems in use, and details specifications for hospital plastic products now used by governmental agencies. Peculiarly, Mr. Ingle said the news release goes on to say that "no plastics material is 'pure'". Furthermore, the release goes on to say "The Bureau study cautions against trusting vague terms such as 'medical grade' or hospital tested' which, by implication, may convey the impression that a plastics device has been sufficiently tested and is safe in use."

Equally suspect, according to the Bureau, are claims that ingredients in plastics are approved by the Food and Drug Administration. The report emphasizes that such claims are undoubtedly true for plastics approved for packaging materials used for food, but that it does not necessarily follow that such plastics are approved for contact with the human body, or for packaging pharmaceuticals.

2. Another item of information which Mr. Ingle brought to the attention of those present at the day's business session was the fact that there is underway within the United States of America Standards Institute (formerly ASA) activity relating to the interests of the plastics industry, principally the application of plastics to medical usage. Mr. Ingle said that there is in USASI a Committee Z79 relating to such subject as endotracheal tubes, specifications for anesthetic equipment; endotracheal-tube connectors and adaptors, specifications for anesthetic equipment, etc.

Mr. Ingle reported that the Z79 Committee has recently enlarged its scope beyond dealing with the safe use of tubing and is now considering plastics in contact with human tissue. This subcommittee has now been assigned to promulgate a standard, according to the USASI format, incorporating references to plastics in contact with human tissue. Apparently Z79 is studying the possibility of referencing some of the tests contained under the broad heading of containers in the U. S. Pharmacopeia.

At this point, W. B. Ackart, Union Carbide Corporation, mentioned that there still is another subcommittee under Z79 studying the

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sterilization of devices. Apparently there are two opposing schools of thought within the Z79 Committee in that some tend to classify plastics devices as not being reusable, while another group takes the position that there is every reason to expect that at least some of these devices will be sterilized and reused.

Commenting on this whole matter, Mr. Ingle said that the developments covered make it clear that there is an increased penetration of plastics materials in use in hospitals; and that, in all probability, in the future the plastics industry may find there will be greater quality control on components of equipment or devices so used. He further noted that, having been present during some of the Z79 discussion, it is evident to him that there remains a real communications gap between the medical profession and the plastics industry on subjects of mutual concern. It was also pointed out that FDA representatives and representatives of the Public Health Services are watching and weighing the discussions within Z79 so it behooves the plastics industry to close the communications gap as effectively as possible lest it prove most detrimental as regards any standards ultimately adopted.

3. Another item covered by Mr. Ingle during his discussion was that, in the Washington Newsletter of Chemical Week dated April 6, 1968, and elsewhere, it was announced that "a coordinator for scientific affairs has been named by the Food and Drug Administration. He is Daniel Banes, a 50-year-old chemist who has worked for FDA all of his adult life. He becomes Acting Associate FDA Commissioner for Science, a post that was created in a 1966 reorganization of the agency, but until now left unfilled."

4. Of general interest to members of the Committee, Mr. Ingle reminded all present about the availability from SPI (at \$2 per copy) of a special bulletin report entitled "Role of Plastics in Solid Waste." This report was prepared for SPI by Battelle Memorial Institute. Mr. Ingle urged that members of the Committee obtain a copy of the publication.

Reports on Liaison with Other Organizations

In accordance with the traditional practice at each meeting Mr. Ingle next called for reports from those maintaining liaison with other associations and groups engaged in activities similar to those of the Committee.

Synthetic Organic Chemical Manufacturers Association (SOCMA)

Mr. Ingle announced that, unfortunately, W. P. Munro, American Cyanamid Company, was unable to be in attendance at the day's session. He did, however, transmit to the Secretary the following brief report on SOCMA activities:

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"No action or happenings have occurred since the last meeting which should be brought to the attention of the Committee."

In interpreting Mr. Munro's comments, Mr. Ingle said that the report deals with the proposed FDA regulation dealing with organic colorants for paper. The proposal is still in "pending" status.

Pharmaceutical Manufacturers Association;
SPI Liaison Group

W. B. Ackart, Union Carbide Corporation, delivered the following report in connection with the cooperative efforts between SPI-PMA which, at the present time, deal with the bottle testing program:

"Results of the 1967 cooperative SPI-PMA bottle testing program were summarized in this report for September 20, 1967, and appear in the minutes of the last meeting.

"Mr. W. W. Hilty, Chairman of the PMA Plastics Subcommittee, has prepared a detailed report of this study entitled 'Report of the Plastic Subcommittee for Methodology for Testing Plastic Containers for Tablets, Capsules, Oral Powders, Granules and Ophthalmic Products' dated October 9, 1967. This report was circulated to all members of the joint task group for comments and was then submitted to the Quality Control Section of the Pharmaceutical Manufacturers Association at its October 10, 1967 meeting in Washington, D. C. Mr. Hilty's recommendations were that the report and the included methodology be considered a progress report and that members of that Section secure additional data on their own before their spring meeting. The report appeared in the minutes of the October, 1967, PMA meeting and thus was available for consideration by the USP and NF Revision Committees. A copy of the technical report and Mr. Hilty's committee report are attached.

"Mr. Hilty has advised me that the National Formulary has agreed to publish the methodology but the USP is reluctant to accept procedures without specified limits.

"Mr. Hilty and I are in agreement that with publication of the methodology in the NF, the assigned task of the subcommittee will be completed and further activity will be limited to liaison between our respective organizations."

In defining further this particular cooperative effort between SPI and PMA, Mr. Ackart noted that the report now available deals with methodology for testing plastics containers to be used for tablets, capsules, oral powders, granules, and ophthalmic products. Further according to Dr. Hilty, in a report which he issued to the joint SPI-PMA group on October 10, 1967:

"This committee, in collaboration with the Society of the Plastics Industry, has studied various test methods as outlined and discussed in the interim report dated October 9, 1967."

Dr. Ackart noted that, in the "final" report resulting from the test program on bottles, the title of the report contains the words "plastic containers" when, in reality, this should be changed to read "polyolefin containers," since the testing program was limited to these particular products. Mr. Ackart will convey this correction to Dr. Hilty, Chairman of the PMA Plastics Subcommittee.

It is Dr. Ackart's understanding that the results of the testing program dealing with methodology for testing polyolefin containers ultimately will be published in the National Formulary and that, in the near future, galleyproof of the document will be available to PMA for review and study. It was mentioned in this connection that, if the work is to be published in the next issue of the National Formulary, it probably will not be available to all interested parties until the next edition which will be printed in 1970.

There then arose a question as to whether there is any possibility at all that SPI may publish this document. Although no decision was reached on this matter, the Secretary did offer to attach the interim final report to the Minutes. (Please Note: Following the meeting, the Secretary suggested to Dr. Ackart that, if PMA approves SPI issuing this report to the Committee for study, it might best be sent to the Committee in a separate communication, rather than by attaching the same to these Minutes. As soon as the PMA position is determined, appropriate action along these lines will be taken.)

In discussing the conclusion of this testing program by the joint SPI-PMA Committee, a question was raised as to whether FDA will acknowledge or challenge the methodology, as contained therein. Obviously, there was no answer to this question at the moment, in the absence of the document being printed and available to either FDA or others for study. Further, it was pointed out that this document is but probably a first step in a long range project aimed at educating both government and industry so as to broaden product acceptance by both.

Dr. Ackart then announced that it is Dr. Hilty's impression that the SPI-PMA joint effort has reached a conclusion. Therefore, Dr. Ackart moved that the SPI Committee discharge SPI-PMA liaison group with thanks, there being no further activity envisioned at this time, and it being assumed that individual companies will now begin using the procedures and technical data generated. Dr. Ackart's motion was seconded and carried unanimously.

Manufacturing Chemists Association

Taylor W. Hanavan, E. I. du Pont de Nemours & Co., Inc., gave the following report:

"The Manufacturing Chemists Association, Food, Drug, and Cosmetic Chemicals Committee at its last meeting on March 26, 1968, did not consider any matters of particular significance to the Food Packaging Materials Committee. However, MCA actions previously recommended by the Committee were reported and may be of interest.

"1. On February 9, 1968, MCA filed comments with HEW requesting that the proposed Good Manufacturing Practice Regulation for food products be revised to exclude food

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chemical plants and the manufacture of food additives, color additives and other chemicals used in food. (Discussed previously during meeting; see above.)

"2. On November 3, 1967, MCA filed a series of comments on FDA's proposed regulation concerning food additive petitions and on February 12, 1968, MCA wrote a letter to FDA's Commissioner Goddard urging the creation of an Industry Government Advisory Committee functioning in accordance with Executive Order Number 11007."

American Paper Institute

James R. S. McCartney, Standard Packaging Corporation, reported on the following activities of the American Paper Institute:

"At the National Conference on Indirect Food Additives, the API supported the formation of a joint Industry-FDA advisory committee on indirect food additives and the adoption of the Frawley proposal in the presentation by Dr. Paul Cundy (American Can Company) and Mr. George Boyd (Counsel for API) respectively.

"Prior to the National Conference, Mr. Edwin A. Locke, Jr., President of the API, representing the seven trade associations (including the SPI) that had been invited to participate at the Conference, had written to Dr. Goddard urging the creation of a joint Industry-Government advisory committee on indirect food additives petitions. It is hoped that the API's support on these items will be helpful towards the eventual streamlining of indirect additives petitions."

Can Manufacturers Institute

Charles J. Speigl, Continental Can Company, Inc., said that there has been no activity by the Can Manufacturers Institute of interest to the Committee since the National Conference held by FDA in February. (Note: The CMI did, of course, participate fully in the National Conference, its position being well enunciated in the Abstracts of the papers presented mentioned earlier in these Minutes.)

SPI Food and Drug Bottling Committee
of Plastic Bottle Division

Matt Smith, Owens-Illinois reported that since the September 20, 1967 meeting of the SPI Committee, the Food and Drug Bottling Committee of the Plastic Bottle Division has held three meetings. According to Mr. Smith, there was nothing discussed at these meetings of special interest to the Food, Drug and Cosmetic Packaging Materials Committee, other than with regard to items otherwise discussed, or to be discussed at the day's session.

Report of SPI Counsel

At this point, Mr. Ingle called upon Thomas Hughes, Keller and Heckman, to report on behalf of Jerome H. Heckman on those matters which Mr. Heckman normally covers for the Committee, principally FDA activities and other matters of interest.

Mr. Hughes then gave the following presentation:

Firstly, let me convey to you Mr. Heckman's regrets about his unexpected inability to attend today's meeting. Under the circumstances, I am sure you all understand the reason for his absence, and will join with your Chairman and Steering Committee in expressing our sincere sympathies to Mr. Heckman on the passing of his father.

As you are all well aware, at this point in your Committee meetings, Mr. Heckman conducts a rather "free wheeling" and informative discussion on matters of particular interest to the Committee from the "Washington Scene." I have been fortunate enough to have been able to work closely with Mr. Heckman on many of the matters on which he had intended to report at this meeting so, even though the information that I will be passing along to you may not be "first hand" from Mr. Heckman, it will at least, hopefully, be the "next best" thing. As is Mr. Heckman's practice when delivering his report, I hope you will not hesitate to interrupt me at any time if you have questions or comments on any part of my subject matter.

NATIONAL CONFERENCE ON INDIRECT FOOD ADDITIVES
AND ITS IMPLICATIONS

The first subject on which Mr. Heckman had intended to report is the impact of and recent developments following the National Conference on Indirect Food Additives held in Washington on February 13 and 14.

Our latest bit of "intelligence" comes by way of a fairly reliable rumor, and is that Dr. Goddard has lent a "favorable ear" to the recommendations made at the recent National Conference that a joint government-industry advisory committee be established to deal with the problems of regulating indirect food additives. As you all know, shortly after the Conference terminated, Dr. Goddard made public his intention to consult with interested parties on an "industry-by-industry basis" and, as you are also probably well aware, all of the industries involved voiced strong objections to such isolating treatment.

Rumor now has it that there is something in the nature of a Staff Memorandum being prepared at FDA which, among other things, might recommend to the agency administrators that FDA adopt .05 ppm (50 ppb) as a "no migration" or "of no toxicological significance" level, the thought being that no food additive petitions would hereafter need to be filed to use substances extractable only in

an amount below this level. This, of course, is a direct result of the much discussed "Frawley concept" proposed by Dr. Jack Frawley of Hercules. I assume, but have no information to verify my assumption, that such a "no migration" level would not apply to substances which are heavy metals, pesticides, or known carcinogens, as was advocated by Dr. Frawley.

We have also heard it rumored that the Staff might further recommend that insignificant components of reusable food containers be exempt from the necessity for coverage in Food Additive Regulations. Precisely what is meant by "insignificant components" is not clear at this point so we will just have to wait and see what, if anything, comes from a recommendation along these lines.

It is our understanding that FDA is now moving to firm up some type of policy embodying these concepts, after which it will hold industry-by-industry or some sort of series of meetings to discuss its proposals. It may also have separate sessions to consider with appropriate industries modifications, or even abolition of some of the regulations for specific groups of "indirect food additives", e.g. adhesives. In due course, we understand that an overall joint industry-government advisory committee will be established to deal with the matter of indirect food additive regulations on a continuing basis.

We shall, of course, continue in our efforts to develop information on the aftermath of the National Conference.

STATUS OF FDA PROPOSED "PROCEDURAL REGULATIONS"

You will recall that, at our last meeting in September, the subject of the FDA proposed procedural regulations was discussed at some length. Shortly after that meeting, the Society formally requested an extension in the time allotted for commenting on the proposals and, on November 6, 1967, submitted an extensive 69 page filing voicing the Society's objections to the overall FDA indirect food additive regulatory scheme.

Those of you who were in attendance at the National Conference in February will remember that, in Dr. Goddard's opening remarks, he promised that the proposed regulations would be finalized within 30 days from the date of the Conference (i.e. by March 14). As a result of the controversy that ensued at the National Conference, the 30 day figure was changed to 90 days in the official printed transcript of the proceedings of the Conference. This would mean that, if FDA was serious about finalizing the regulations, something in this regard would be forthcoming by the middle of May. However, and again by way of what we consider to be fairly reliable rumor, we understand that FDA will do nothing in the way of finalizing these regulations until some firm decisions have been reached as a result of the recommendations made during the National Conference.

Although there is no way to be absolutely certain that FDA will not finalize these regulations during the next month, I believe it is fairly safe to assume that FDA will direct itself more fully to the substantive objections and criticisms raised at the National Conference before it decides to promulgate regulations which would probably result in additional controversy.

In connection with all of this activity revolving around the National Conference and the proposed procedural regulations, Mr. Heckman has asked that I again mention an idea he espoused in general terms in his presentation at the National Conference. Those of you who were there will recall his suggestion that FDA might eliminate many of the problems involved in the processing of indirect food additives petitions if it would publish sample forms of petitions to better instruct companies in the method of drafting effective and coherent food additive petitions. In this connection, Mr. Heckman has given additional, but still only general and preliminary thought to the subject and wanted me to suggest the possibility that, at an appropriate future date, our Committee might want to set up a special task force for the purpose of drafting an SPI Manual which would, perhaps, include samples of various forms of petitions strictly for guidance purposes.

Actually, I am not able to give you too much detail on this particular item since it is Mr. Heckman's "brain child" and we have not had an opportunity to discuss it a great deal prior to today's meeting. However, I did want to pass the idea along to you so that some thought can be given to the proposal thereby placing the Committee in a better position to further discuss this matter at an appropriate future date.

OTHER MATTERS

A. Recently Passed Meat Inspection Act.

As you certainly know, Congress recently passed the new Wholesome Meat Act to amend the Federal Meat Inspection Act. Without going into great detail as to the substance of the Act, I thought I would simply point out the fact that it has been passed and also note, among other things that it provides that if, after a certain period of time, the appropriate state agencies have not established adequate meat inspection procedures, the United States Department of Agriculture will be empowered to move in and inspect intrastate as well as interstate meat and meat processing plants.

I might also point out that one of the provisions of the new bill defines various terms, such as "adulterated," and then coordinates these definitions with the appropriate provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

Thus, under the new Act, a meat substance will be deemed to be adulterated "if it bears or contains any food additive which is

unsafe within the meaning of Section 409 of the Federal Food, Drug, and Cosmetic Act." At first blush, this provision might frighten many of you who will conclude that USDA will now be interpreting these definitions in much the same fashion as does FDA. However, we have every reason to believe that USDA will continue to implement its "enlightened" approach to packaging materials and will interpret Section 409 of the Food, Drug, and Cosmetic Act as it was intended to be applied by Congress. In other words, we believe that USDA will continue, as in the past, to exercise sound judgment and allow materials to be used in meat packaging applications which "may not reasonably be expected to become components of foods" (i.e. a "no migration" approach), in addition to materials which may be the subject of FDA regulations under Section 409 of the Food, Drug, and Cosmetic Act.

B. New York City "Peek-A-Boo" Bill.

While on the subject of meats and meat inspections, I thought I would also note that New York City's Mayor Lindsay signed a bill on January 26, 1968, which will require that pre-packaged meats in the City of New York be visible from "all sides". The ordinance is to become effective on July 26, 1968, and will undoubtedly have a profound effect on the sale of plastic meat trays in the City of New York and other cities which may ultimately follow the New York City precedent.

C. The last item I thought I would mention to you concerns the Codex Alimentarius Commission and its bearing on the establishment of international requirements for suitable food packaging materials. Actually, Bill Westveer of Dow Chemical was kind enough to inform us that, at the recent joint FAO/WHO Food Standards Meeting of the Codex Alimentarius Commission, a decision was reached whereby the Commission will begin to consider food packaging materials approximately five years from now (i.e. 1973 or thereabouts).

As you know from previous discussions on this subject by Mr. Heckman, it is thought that ultimately the Codex Alimentarius Commission will be in the position of promulgating internationally recognized and accepted standards for the use of food packaging materials.

I mention this to you on the possibility that the Committee may want to begin reconsideration of the entire question of the posture of this Committee in connection with international problems. At the present time, of course, the established policy is that the Committee shall do nothing more than exchange information on international developments leaving it to individual member companies to take action as they deem best. If it is deemed that this policy should be reconsidered with a view towards the adoption of something more "activist" in nature, perhaps you will want to discuss this further at this afternoon's session in connection with the open discussion on international developments.

* * * * *

This concludes my report on the matters of greatest priority that I know Mr. Heckman wanted to comment on. I assure you that you will be hearing more from Mr. Heckman, particularly on the subjects of the National Conference and the proposed procedural regulations in the coming months.

Thank you.

During discussion of Mr. Hughes' report, members of the Committee were reminded that, some time ago, the Steering Committee was empowered to deal on an ad hoc basis with FDA, if called upon, in connection with the possible organization of a government-industry advisory committee or other relevant matters. Mr. Scriba pointed out that every effort should be made to continue the dialogue already established with the other associations that have expressed an interest in the "government-industry advisory committee" idea.

It was also brought out during this general discussion on Mr. Hughes' report that Mr. Heckman is giving some thought to the possibility that the Committee, at an appropriate future date, may want to set up a special task force for the purpose of petitions in order to assist the plastics industry in the effective preparation of Food Additive Petitions. This matter was discussed at some length during the day's session, but it was decided that it would be best to delay any decision on the matter until Mr. Heckman has had an opportunity to personally explain and further elaborate on the idea at a future Committee meeting.

Several times during this discussion, it was pointed out that this whole matter of the possibility of writing a manual presenting sample forms of petitions is quite embryonic at the present moment and that Mr. Heckman simply is thinking over the whole matter with no firm ideas, at this point, as to "how" or "when" such a manual should be published. In commenting on this subject several members indicated their belief that such a manual would be a great service to all of SPI's members. It was further obvious that the Committee would not be able to rush into such a project in view of the fact that it would be "long range" in its preparation.

Finally, George T. Scriba, Union Carbide Corporation, moved that the Steering Committee of the overall Committee be empowered to go ahead with this project of establishing a task force to prepare a manual of sample petitions for indirect food additives if, between now and the next meeting of the overall Committee, it seems desirable to do so. This motion was seconded and carried with three voting in the negative.

In commenting on the negative votes, Mr. Ingle noted that under no circumstances would the Steering Committee undertake to issue a formal publication through SPI without giving the overall Committee ample time to review and comment on the salient features of the document.

During a discussion, the question was raised as to the status of activity of the Food Protection Committee set up by the National Academy of Sciences which

originally set out to define "zero migration" or "toxicological insignificance." It was revealed that two meetings have been held but that no final report is envisioned in the near future.

At this point, W. W. Sederlund, National Starch and Chemical Corporation, commented that he thought it might be of interest to the overall Committee to know that his company, and he assumed other companies, had received during recent weeks a form letter from the U. S. Department of Agriculture, under Mr. O. L. Bennett's signature, requesting a listing of all those products for which the particular company involved has already received USDA letters of approval. The reason for this request is that the recently passed Wholesome Meat Act, and the companion Wholesome Poultry Bill, will involve a larger segment of the meat packaging industry than before vis a vis the Federal Meat Inspection program. This being the case, it is anticipated that an increasing number of meat packers will be requesting USDA acceptance of packaging materials, many of which will be duplications of previous such requests. It is therefore hoped that the listings being requested by USDA will help to avoid unnecessary repetition of approvals already granted by USDA.

Report of Technical Information Subcommittee

Chairman Ingle then asked Robert M. Miller, Hercules Inc., to report on the activities of the Technical Information Subcommittee.

Recently Promulgated Food Additive Regulations, and Related Regulatory Actions

Mr. Miller said that, as he has done at several of the past meetings of the overall Committee, he had again prepared a listing of new Food Additive Regulations, amended regulations, proposed regulations, withdrawals of petitions, and notices of filing deemed of interest to the Committee which have been published in the Federal Register. He then gave the Secretary the listing prepared especially for attachment to the Minutes of the day's session.

(Please Note: Attached hereto as Exhibit A is the listing as compiled by Mr. Miller.)

Rather than read all of the items contained in the listing (See Exhibit A) at the day's session, Mr. Miller simply highlighted the categories of subjects in the listing including items on colorants, categories of antioxidants and stabilizers, several items on polymers and copolymers, several withdrawals, several petitions and regulations on coatings, and, under a special category, such items as the proposal dealing with "promulgation of federal regulations to establish criteria for current good manufacturing practices (sanitation in the manufacture, processing packing and holding of human food, etc.)"

Mr. Miller concluded his report by indicating that upon reviewing the listing he compiled for the day's meeting it is obvious that there is little activity at the present moment relating to colorant petitions.

Pigments Task Group Report

Mr. Miller then introduced Arnold Finestone who has acted as coordinator of a special task group on pigments for some months now.

The Secretary is noting herewith that under the direction of Dr. Finestone the principal activity of the Pigments Task Group has been one of conducting a research study using atomic absorption spectrophotometry as an analytical technique for determining trace quantities of inorganic pigments. In this regard some fourteen companies have participated in providing pigmented specimens for seven polymers. Several pigments, namely chromium oxide, mercadium red, medium cadmium red, and sun yellow C were used at two levels. The specimens were then extracted, concentrated and assayed by Jarrell-Ash. Dr. Finestone then introduced the final report resulting from the research with the atomic absorption spectrophotometer arrangements:

"The extraction of the polymers, analysis of the extracts and tabulation of the Atomic Absorption data from the Pigments Task Force study of this analytical method were completed last year.

"A preliminary report was made to the Food Packaging Materials Committee last September.

"Further information has since been collected on sample preparation from participating companies in questionnaire form.

"The full data and questionnaire results were examined by a Task Force Subcommittee and a final report prepared.

"The basic conclusions are as follows:

"1. Most of the pigment/polymer combinations evaluated indicated no significant migration of pigment (to the limit of detection, which in most areas is 30 to 50 ppb.) Exceptions were (a) Monarch Blue G and Medium Cadmium Red in impact polystyrene when extracted with 3% acetic acid and (b) Medium Cadmium Red and Sun Yellow C in nylon when extracted with most of the solvents used.

"2. The analytical procedure used by the Task Force was found to be generally satisfactory, but a few modifications must be made. The major change would be to obtain lower detection limits of the various metals. It is suggested that this be accomplished by either concentrating the solutions further or by evaporating the samples to dryness and taking them up in an appropriate solvent. Additional minor analytical changes are summarized in Appendix I.

"3. A meeting of the Pigments Task Force will be held to determine future technical activity. However, it is recommended that Atomic Absorption analysis be accepted as an analytical test for measuring trace pigment cations in food simulating extracts. Analytical work up procedures will be required as indicated in Part 2 to reach the suggested 10 ppb sensitivity.

APPENDIX I

COMMENTS CONCERNING EXTRACTION
PROCEDURE AND CONCENTRATION TECHNIQUES

"The extraction and concentration procedure submitted to the Food and Packaging Committee by Dr. A. B. Finestone on August 8, 1966, was generally followed by the Pigments Task Group participants. The major deviation was in using extraction media from sources other than those recommended. This undoubtedly led to some of the variations noted in the data.

"While the overall procedure appears to be satisfactory, the following comments should be considered in any future work:

- "1. Cation concentrations in the extraction media should be low enough not to interfere with the analysis of the extracts.
- "2. Plaques should be separated during the extraction period to expose all surfaces.
- "3. After extraction and before concentration, samples should be filtered through coarse filter paper to remove any solid material.
- "4. Acidification of solutions before concentration to retard bacteria growth should be explored.
- "5. A clean atmosphere should be maintained during the evaporation. It has been suggested that freeze drying techniques might be useful.
- "6. For metals with low sensitivity, further concentration would be useful. It may be preferable to take all samples to dryness and take them up in appropriate solvent (acid) to a volume commensurate with sensitivity of the particular metal to be analyzed.
- "7. Blanks should be prepared both from extraction media and from unpigmented specimens. These should be prepared at the same time as samples."

In concluding his report Dr. Finestone said that there is a determination to be made as to what, if any, tasks his pigment group is to undertake in the future. He then expressed thanks to those members in industry and representatives of his committee for the fine cooperation they extended in this research program. In summary, Dr. Finestone said that the data obtained will illustrate to industry that a sophisticated analytical procedure is available and furthermore, as he points out in his report, he is satisfied that the atomic absorption spectrophotometry analytical technique can be further developed to the point where 10 ppb can be determined. Dr. Finestone pointed out however, that this may be neither necessary nor desirable,

in view of the fact that FDA may reach a decision as to a "no-migration" determination at a significantly higher level (i.e. 50 ppb, which would make the necessity for determining down to 10 ppb unnecessary).

Originally, Dr. Finestone said, it was suggested that an SPI Manual would be published based on the results of this research program undertaken by the Pigments Task Force. At this time, however, he expressed his view that the Steering Committee should study the question of how much of the technical data, if any, should be released in published form. Here again this whole matter depends much on FDA's ultimate determination with respect to "no-migration."

Finally, Dr. Finestone moved that the report be accepted as final in that the technical data illustrates that the atomic absorption technique is satisfactory in detecting 30-50 ppb; that publication of the data be withheld until further consideration is given to it by the Pigments Task Force and the Steering Committee. Dr. Finestone's motion was seconded and carried unanimously.

In concluding this discussion, Chairman Ingle thanked Dr. Finestone and members of the Pigments Task Force for the monumental task which they undertook on behalf of the overall Committee.

International Developments

As has been tradition for the past several meetings, Mr. Ingle then turned the Committee's attention to an open discussion of international developments.

Activity British "Food Additives and Contaminants Committee"

By way of reminder, Mr. Ingle said that under date of March 6, 1968, Jerome H. Heckman, Esquire, sent a communication to all members of the Committee to which was attached a communication from Robert M. Miller dated March 4 and attached to that, a letter to interested parties from the British Food Additives and Contaminants Committee dealing with the subject of the leaching of substances from packaging materials to food. Mr. Ingle noted that the British Plastics Federation, which circulated this document, had asked that all comments be submitted to the Federation by a deadline date of May 10, 1968.

W. W. Sederlund, National Starch & Chemical Corporation, said that from a "paper industry" point of view the British proposal has been found not particularly practical as regards extraction tests and that comments have been submitted to the United Kingdom through his company's European affiliates. Others volunteered comments to the effect that their individual companies had also directed recommendations on the British document to their respective European affiliates.

Robert M. Miller, Hercules Inc., noted that a careful review of the English document will reveal that there is apparent indecision as to the best regulatory approach to be followed. At this point, it is not entirely clear whether the English approach will be one of including a "permissive list" of materials or, on the other hand, a "prohibitive list" of materials. In reality, Mr. Miller said the British document poses more questions than it actually answers. All in all, it was apparent during

the discussion of the UK proposal that the British would like to come up with a procedure somewhat different than the indirect food additive regulatory approach in the United States.

At this point, Mr. Ingle queried the Committee as to whether it might be desirable to form an ad hoc subcommittee to discuss the question of whether it might be more desirable to draft a joint set of comments on the British proposal and submit such comments to the British Plastics Federation so that the BPF could, in turn, make them known to the Food Additives and Contaminants Committee, or to leave the matter of commenting on the proposal to the individual companies concerned with them.

It was pointed out to the Committee that the present established policy is that the Committee shall do nothing more than exchange information on international developments of interest, leaving it to the individual member companies to take action as they deem best. It was also noted that perhaps representatives of the companies most interested in the British proposal might want to form an ad hoc subcommittee to discuss this matter further and to decide whether or not it might be desirable to draft a joint set of comments on the proposal in question.

The following members volunteered to serve on such an ad hoc subcommittee for this purpose:

W. B. Ackart, Union Carbide Corporation
W. A. Patterson, W. R. Grace & Co.
B. J. Garceau, ICI America Inc.
B. Newell Olson, Reynolds Metals Company (later appointed
coordinator of the ad hoc group)
Robert E. Rutherford, Gulf Oil Corporation
Kenneth C. Conley, Marbon Chemical Div. Borg-Warner

In organizing the above Ad Hoc Subcommittee under the direction of Mr. Olson, Chairman Ingle charged the group to convene either following the day's session or at some other time and to make its recommendations known to the Steering Committee of the full Committee at the earliest possible date since the deadline date for the filing of comments on the proposal was set at May 10, 1968.

Dutch Regulations

In discussing the Dutch Regulations, Mr. Ingle said that the proposal was circulated to all members of the Committee some months ago.

Dr. Finestone spoke at length on the salient features of the Dutch proposal since he has followed the matter quite carefully during his various visits to the Netherlands. All in all, Dr. Finestone points out that there is considerable "in-fighting" between various countries in Europe as to what posture food additive regulations shall take. For instance, he noted that several countries have taken different approaches on the matter including Italy, England, the Netherlands, France, Germany and the BITMP representing the six common market countries. At this point, Dr. Finestone said it is difficult to get any country or any groups within the countries to commit themselves on the posture which they are presently taking in regard to the regulation of food packaging materials.

As a point of information, Mr. Ingle said that a firm known as International Technical Surveys Inc. has notified several companies in the United States that they are willing to compile a summary of all food additive regulations throughout the world for a fee. However, Mr. Ingle noted that the survey seemed to be more in the nature of a listing of available literature on the subject than a compilation of substantive information.

Next Meeting

Mr. Ingle said that the date of the next meeting rests in the hands of incoming Chairman Robert M. Miller, Hercules Inc., with the help of the Steering Committee. Mr. Ingle assumed that, as in the past, the decision as to when the next meeting takes place will depend a great deal upon developments in FDA and particularly the decision as to whether a government-industry advisory committee or committees are to be organized.

The day's session was adjourned at 2:00 p.m.

Respectfully submitted,

Charles L. Condit
Secretary

CLC:vw
Enc.

EXHIBIT A

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE
SPI FOOD PACKAGING MATERIALS COMMITTEE

April 15, 1968

Recently Issued Food Additive Regulations

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 last meeting:

<u>SECTION</u>	<u>TYPE</u>	<u>DATE</u>	<u>SUBJECT</u>
121.2514	Filing	9/23/67	Provide for use of 2,2-dimethyl-1,3-propanediol and 2,2,4-trimethyl-1,3-pentanediol in production of polyester resins
121.2566	Filing	9/23/67	Provide for use of butylthiostannonic acid as a stabilizer in polyvinyl chloride articles
121.2569	Withdrawal	9/26/67	Provide for the use of glycidyl acrylate and glycidyl methacrylate as comonomers in vinylidene chloride copolymers used in coatings for polyolefin food-contact films
---	Filing	9/28/67	Provide for the use of dimyristyl thiodipropionate as an antioxidant in plastics
---	Filing	9/30/67	Provide for the use of carbon black as a colorant in polyethylene and ethylene alkene-1 copolymers for food-contact use
121.	Filing	10/10/67	To provide for the use of tetraethylene glycol di(2-ethylhexoate) and polyethylene glycol (400) monolaurate as a finish on twine fabricated from nylon complying with 121.2502
121.2597	Amendment	10/10/67	Provide for the use of polyvinyl chloride modifiers produced by combining butadiene-styrene copolymers with acrylic polymers during polymerization of the acrylic polymers
121.2574	Amendment	10/17/67	Provide for the use of monochlorobenzene as a solvent in the production of polycarbonate resins

SECTION	TYPE	DATE	SUBJECT
121.2599	Filing	11/1/67	Amend to delete from paragraph (b) the limitation "Finished vinylidene chloride copolymer coatings containing polymer units derived from methyl acrylate and/or methacrylic acid are limited to use in contact with nonalcoholic foods having a pH above 5.0"
121.2601	New Reg.	11/1/67	Amend to provide for the use of partial phosphoric acid esters of polyester resins as food-contact coatings on aluminum when used in accordance with certain limitations
121.2569	Amendment	11/1/67	Provide for the use of 4,4'-Isopropylidenedi-phenolepichlorohydrin average molecular weight 900 and Polyethylenimine with a limitation for the latter to be used only as a primer subcoat to anchor epoxy surface coatings to the base sheet
121.2541	Amendment	11/1/67	Provide for the use of (para-Nonyl-phenyl)-omega-hydroxypoly(oxyethylene) sulfate, ammonium or sodium salt with certain limitations
121.2520	Amendment	11/1/67	Provide for the use of dimethyl-alpha-methylstyrene, in polymers used in food-packaging adhesives
121.2522	Amendment	11/2/67	Provide for the use of 1,3-Butyleneglycol and Pentaerythritol-linseed oil alcoholysis product as reactants in the preparation of polyurethane resins for use in contact with dry, bulk food
121.2520	Amendment	11/2/67	Revise nomenclature and description of Polyoxyethylene (6-7 moles) nonyl-phenoxyphos. for consistency with current nomenclature and to provide for increased poly(oxyethylene) content of these substances that may be used in the formulation of food-packaging adhesives
121.2507	Filing	11/10/67	Provide for the use of N-acyl sarcosines that have lauroyl or stearyl acyl group as release agents in coatings for cellophane

SECTION	TYPE	DATE	SUBJECT
---	Withdrawal	10/19/67	Provide for the use of tetrahydrophthalic anhydride as a curing agent for epoxy resins used as articles or components of articles for <u>repeated</u> food-contact use
121.2541	Amendment	10/19/67	Provide for the use of poly(oxypropylene) block polymer with poly(oxyethylene) as a surface-active agent in polyolefin films or coatings
121.2507	Filing	10/25/67	Provide for the use of diisobutyl phthalate and 2,2,4-trimethyl-1,3-pentanedid diisobutyrate as optional components of cellophane
121.2566	Filing	10/25/67	Provide for the use of poly(1,4-cyclohexylene-dimethylene-3,3'-thiodipropionate), partially terminated with stearyl alcohol, as a stabilizer in polypropylene
121.2566	Filing	10/25/67	Provide for the use of 2-phenyl-indole as a stabilizer in polymers
121.2566	Filing	10/25/67	Provide for the use of 2,6-bis(1-methylheptadecyl)-para-cresol as an antioxidant and/or stabilizer in olefin polymers
121.2526	Withdrawal	10/28/67	Amendment providing for the use of styrene-butadiene-acrylonitrile-methacrylic acid copolymers containing not more than 20 weight percent of total polymer units derived from methacrylic acid, as components of the food-contact surface of paper and paperboard
121.2600	New Reg.	10/28/67	Provide for the use of vinylidene chloride copolymer food-contact coatings for polycarbonate film complying with 121.2574
121.2569	Amendment	10/28/67	Provide for the use of (Polyvinyl alcohol at levels not to exceed 6% of the total coating weight) in the formulation of resinous and polymeric coatings for polyolefin films
121.2566	Amendment	10/28/67	Provide for the use of calcium myristate and zinc palmitate as antioxidants and/or stabilizers
121.2526	Amendment	10/28/67	Provide for the use of Tetrasodium N-(1,2-dicarboxyethyl)-N-octadecylsulfosuccinamate used only as an emulsifier in resin latex coatings and limited to use at a level not to exceed 0.05% by weight of the coating solids

SECTION	TYPE	DATE	SUBJECT
121.2514	Withdrawal	11/10/67	Providing for the use of di(n-octyl)tin S,S'-bis (isooctylmercaptoacetate) as a curing catalyst for methyl phenylpolysiloxane used in resinous and polymeric coatings
121.2520	Filing	11/15/67	Provide for the use of dipentaerythritol pentastearate as a component of adhesives
121.2511	Filing	11/15/67	Provide for the use of 2,2,4-trimethylpentane-1,3-diisobutyrate as a plasticizer in cellulosic food-contact articles
121.2526	Filing	11/15/67	Provide for the use of 2-hydroxy-4-n-octoxybenzo phenone as an adjuvant in petroleum wax used as a component of paper and paperboard for use in contact with aqueous and fatty foods.
---	Withdrawal	12/2/67	Provide for the use of cyanoguanidene-formaldehyde resins as drainage aid in the manufacture of paper and paperboard used for packaging dry, aqueous and fatty foods
121.2526	Amendment	12/2/67	Provide for the use of glyoxal with certain limitations as a component of the food-contact surface of paper and paperboard intended for use in contact with aqueous and fatty foods
121.2526	Amendment	12/2/67	Revision of Petroleum alicyclic hydrocarbon resins to meet certain specifications to permit background interference correction
121.2520, 121.2550 & 121.2571	Miscellaneous Amendments	12/2/67	Provide for the use of alpha-cis-9-Octadecenyl- <u>omega</u> -hydroxypoly(oxyethylene) in the formulation of closure-sealing gaskets for food containers for 121.2550 and revised in 121.2520 and 121.2571 for consistency
121.2541, 121.2520, 121.2536, 121.2550, 121.2547, 121.2519 & 121.2571	Amendment	12/12/67	Provide for the additional use of alpha,Di-sec-butylphenyl- <u>omega</u> -hydroxy-poly-(oxyethylene, alpha-(para-Dodecylphenyl)- <u>omega</u> -hydroxy-poly(oxyethylene) alpha-(para-Nonylphenyl)- <u>omega</u> -hydroxypoly(oxyethylene); and alpha-para-(1,1,3,3-Tetramethylbutyl) phenyl- <u>omega</u> -hydroxypoly(oxyethylene) under 121.2541 as emulsifiers and/or surface-active agents. Delete Polyoxyethylene (molecular weight 1900) di-sec-butylphenylate from 121.2520. Delete Polyoxyethylene (9-10 moles)ether of octyl-or nonylphenol from 121.2536. Delete Polyoxyethylated (8-10 mols) octylphenol from 121.2550. Revise 121.2547 (b) 121.2520, 121.2519 and 121.2571 for consistency with 121.2541

SECTION	TYPE	DATE	SUBJECT
121.2566	Amendment	12/13/67	Provide for the use of octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in olefin polymers
121.2531	Amendment	12/13/67	Provide for the use of stearyl stearate in surface lubricants used in the manufacture of metallic food-contact articles under conditions such that the total residual lubricant does not exceed 0.2 milligrams per square inch of food-contact surface
121.2526	Withdrawal	12/13/67	Provide for the use of methyl-hydrogenpoly-siloxane with certain specifications as a release agent used for packaging frozen and concentrated fruit and vegetable juices
128.--	Proposal	12/15/67	Promulgation of certain regulations to establish criteria for current good manufacturing practice (sanitation) in the manufacture, processing, packing or holding of human foods
121.2514	Amendment	12/19/67	Provide for the use of vinyl acetate-dibutyl maleate copolymers produced when vinyl acetate and dibutyl maleate are copolymerized with or without one of the monomers
121.2505	Amendment	12/21/67	Provide for the use of chloromethyl butane-thiolsulfonate and methylenebisbutanethiol-sulfonate as slimicides in the manufacture of paper and paperboard
121.2505	Amendment	12/21/67	Provide for the use of chlorinated levulinic acids as slimicides in the manufacture of paper and paperboard
---	Withdrawal	1/9/68	Provide for the use of aluminum oxide, chromium oxide, cobalt oxide, magnesium oxide and zinc oxide as colorants for polymeric films that contact food
---	Withdrawal	1/9/68	Proposal issuing a regulation to provide for the use of chromium oxide green as a colorant in food containers
121.2562	Amendment	1/9/68	Provide for the use of ethylene-propylene-1,4-hexadiene copolymers, vinylidene fluoride-hexafluoropropylene copolymers and vinylidene fluoride-hexafluoropropylene tetrafluoroethylene as additional optional substances in the formulation of rubber articles

SECTION	TYPE	DATE	SUBJECT
121.2566	Filing	1/26/68	Provide for the use of 2,2'-di-tert-butyl-4,4'-isopropylidene-diphenol bis (para-nonylphenyl) phosphite and N-alkyl (C ₁₄₋₁₆)-1,3-propanediamine-N,N,N'-triacetic acid as antioxidants and/or stabilizers in polymers
121.2576	Filing	1/26/68	Provide for the use of vinyl-cyclohexene dioxide as an optional component in cross-linked polyester resins
---	Filing	2/3/68	Provide for the use of vinyl chloride-vinyl cetyether copolymers in articles that contact food
121.2589 121.2553	Withdrawal	2/6/68	Provide for the use of an additional grade of mineral oil in lubricants with incidental food contact as provided under 121.2553
121.2566	Filing	2/10/68	Delete for "Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate" under "Limitations" the sentence "the average thickness of such olefin polymer film shall not exceed 0.0015 inch"
---	FPLA Regs.	2/14/68	Fair Packaging and Labeling Act amended to exempt certain milk products packaged in plastic containers
121.2536	Amendment	2/27/68	Provide for the use of melamine-formaldehyde chemically modified with urea for use in fabricating resin-bonded filters
121.2520	Amendment	2/27/68	Provide for the use of di-pentaerythritol pentastearate in the formulation of adhesives
121.2562	Amendment	3/2/68	Provide for the use of Tri (nonylphenyl) phosphite-formaldehyde resins as an optional substance under Antioxidants and antiozonants in the formulation of rubber articles
---	Withdrawal	3/6/68	Provide for the use of Pigment blue 15, pigment green 7, pigment green 17, pigment violet 19 and pigment white 21 as components of polyolefin food-contact articles
121.2535	Amendment	3/8/68	Provide for the use of mineral oil in the processing of jute fiber employed in the production of textile bags that contact food

SECTION	TYPE	DATE	SUBJECT
121.2522	Filing	3/15/68	Provide for the use of polyurethane resins as a component of single use, disposable nursing-bottle nipples that contact liquid food
121.2566	Amendment	3/15/68	Provide for the use of 2,2'-Methylenebis(4-methyl-6-nonyl-phenol) and 2,6-bis(2-hydroxy-3-nonyl-5-methyl-benzyl)-para-cresol mixtures (varying proportions) as an antioxidant and/or stabilizer in acrylonitrile-butadiene-styrene copolymers used in contact with non-alcoholic foods
121.2507	Amendment	3/15/68	Provide for the use of N-acyl sarconsines with certain limitations in the manufacture of cellophane
121.2592	Filing	3/19/68	Propose to change the specifications regarding dehydroabiatic acid content for disproportionated rosin
121.2543	Amendment	3/19/68	Provide for the use of additional substances as packaging materials that may be subjected to radiation in the radiation preservation of prepackaged foods
121.2522	Filing	3/26/68	Provide for the use of hexamethylene diisocyanate maleic anhydride and phthalic anhydride as reactants in the preparation of polyurethane resins for use in contact with dry, bulk food
---	Filing	3/29/68	Provide for the use of vinyl-chloride-ethylene copolymers as components of articles intended for food-contact use
121.2520 and 121.2571	Filing	3/29/68	Provide for the use of alpha-(para-1,1,3,3-Tetramethylbutylphenyl)-omega-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium and ammonium salts having a poly(oxyethylene) content average 6-9 or 40 moles
121.2566	Filing	3/29/68	Provide for the use of 2-(2'-hydroxy-5'-methylphenyl) benzotriazole as a stabilizer in rigid polyvinyl chloride
121.2586	Amendment	4/2/68	Provide for the use of optional substances as processing aids in the production of petroleum wax intended for use as a component of the food-contact surface of paper and paperboard

<u>SECTION</u>	<u>TYPE</u>	<u>DATE</u>	<u>SUBJECT</u>
---	Amendment	4/3/68	Removal of restriction on the use of octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate as an antioxidant in olefin polymer film limiting such film to an average maximum thickness of 0.0015 inch