SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE

Hotel America
Washington, D. C.

November 7, 1968
9:30 a.m.

Present:

Robert M. Miller, Chairman, Hercules, Inc., 910 Market St., Delaware Trust Bldg., Wilmington, Del. 19899
Taylor W. Hanavan, Vice Chairman, E. I. du Pont de Nemours & Co., Inc., 1007 Market St., Film Dept., Wilmington, Del.
W. B. Ackart, Union Carbide Corporation, Chemicals & Plastics, One River Rd., Bound Brook, N. J. 08805
R. C. Asam, The Goodyear Tire & Rubber Co., Chemical Materials Dept., Dept. 480D, 1485 E. Archwood Ave., Akron, Ohio 44316
Sal M. Cannavo, L. A. Dreyfus Company, P. O. Box 500, South Plainfield, N. J.
K. C. Conley, Marbon Chemical, Development Division, Div. Borg-Warner Corp., P. O. Box 68, Washington, W. Va.
Paul F. Cundy, American Can Co., Research & Development Dept., Box 702, Neenah, Wis.
L. J. DeCorte, Sinclair-Koppers Co., Product Development, Frankfort Rd., Monaca, Pa.
Harry R. Dittmar, Vypak Corp., Div. of Ethyl Corp., 75th and Cleveland, Kansas City, Missouri
Daniel S. Dixler, AIRCO, Air Reduction Co., Inc., Central Research Lab., Murray Hill, N. J. 07971
Andrew G. Engstrom, Glidden-Durkee Div., SCM Corp., 900 Union Commerce Bldg., Cleveland, Ohio 44115
George W. Ferner, The Goodyear Tire & Rubber Co., Research Div., 1144 East Market St., Akron, Ohio 44316
S. Walter Foulkrod, III, Scott Paper Company, International Airport, Philadelphia, Pennsylvania 19113
Lawrence J. Friedman, Hooker Chemical Corp., Ruco Division, New South Rd., Hicksville, N. Y. 11802
Gerhard H. Fuchs, Allied Chemical Corp., P. O. Box 405, Morristown, N. J.
B. J. Garceau, ICI America, Inc., P. O. Box 1274, 151 South St., Stamford, Conn.
Louis A. Guzzetti, Jr., Celanese Corporation, 522 Fifth Ave., New York, N. Y.
R. H. Haas, The Goodyear Tire & Rubber Co., 1144 East Market St., Akron, Ohio
Ralph L. Harding, Jr., SPI, 250 Park Ave., New York, N. Y. 10017
Jerome H. Heckman, Keller and Heckman, 1712 "N" St., N. W., Washington, D. C. 20036
Patrick L. Henry, Allied Chemical Corp., P. O. Box 405, Morristown, N. J. 07960
Karl A. Hochschwender, American Hoechst Corp., P. O. Box 2500, Somerville, N. J.

George W. Ingle, Monsanto Co., 1101 17th St., N. W., Suite 604, Washington, D. C.
John F. Jones, The Standard Oil Co., Midland Bldg., Cleveland, Ohio
William A. Knapp, Allied Chemical Corp., P. O. Box 405, Morristown, N. J. 07960
Donald F. Krank, Armstrong Cork Co., Liberty and Charlotte Sts., Lancaster, Pa.
Frank L. LaMotte, Jr., T. W. Winstead Co., Inc., 10830 Gilroy Rd., Cockeysville, Maryland 21030
F. S. Landers, Lily Tulip Cup Corp., 500 Commack Rd., Commack, N. Y. 11725
Walter Lanferman, Mobil Chemical Co., 150 East 42nd St., New York, N. Y. 10017
W. A. Larkin, M & T Chemicals, Inc., Woodbridge Ave., Rahway, N. J. 07065
James R. S. McCartney, Standard Packaging Corp., 111 Prospect St., Stamford, Conn.
Thomas J. McGrath, SPI, 250 Park Ave., New York, N. Y. 10017
Gordon L. McIntyre, Columbian Carbon Co., P. O. Box 975, Princeton, N. J. 08540
James A. Mitchell, E. I. du Pont de Nemours & Co., Inc., Film Dept., 1007 Market St., Wilmington, Del. 19898
Kenneth Morgareidge, Food and Drug Research Laboratories, Inc., Maurice Ave., Maspeth, N. Y. 11378
Peter Morison, Eastman Chemical Products, Inc., Chemical Sales Dev. & Technical Service, B-230, Kingsport, Tenn. 37662
Wendell P. Munro, American Cyanamid Co., Bound Brook, N. J. 08805
Stanley D. Nesmith, USI Chemicals Co., P. O. Box 218, Tuscola, Ill. 61953
A. S. Nyquist, American Cyanamid Co., P. O. Box 425, South Cherry St., Wallingford, Connecticut 06492
B. Newell Olson, Reynolds Metals Co., 10th and Byrd Sts., Richmond, Va. 23219
I. Frank Peake, E. I. du Pont de Nemours & Co., Inc., Film Dept., 1007 Market St., Wilmington, Del. 19898
Jules Pinsky, Monsanto Co., Packaging Div., P. O. Box 1019, Hartford, Conn. 06101
George A. Richter, Jr., Rohm & Haas Co., The Rohm & Haas Bldg., Independence Mall West, Philadelphia, Pa. 19105
Robert E. Rutherford, Gulf Oil Corporation, P. O. Box 1166, Pittsbrugh, Pa.
A. Merrill Schnitzer, Phillips Petroleum Co., Research & Development Dept., 356 Chemical Laboratories, Bartlesville, Okla.
George T. Scriba, Union Carbide Corp., Legal Dept., 270 Park Ave., New York, N. Y.
A. W. Sheldon, M & T Chemicals, Inc., Woodbridge and Randolph Aves., Rahway, N. J.
Matthew E. Smith,Owens-Illinois, Plastic Products Div., Adams & 14th Sts., Toledo, Ohio 43601
Charles J. Spiegl, Continental Can Co., Inc., 7622 South Racine Ave., Chicago, Ill.
Donald F. Thompson, R & D Division, AviSun Corp., Post Rd., Marcus Hook, Pa. 19061
W. M. Westveer, The Dow Chemical Co., 433 Building, Midland, Mich. 48640
G. F. White, Jr., Reynolds Metals Co., 10th and Byrd Sts., Richmond, Va. 23219
Ambrose G. Whitney, W. R. Grace & Co., Research Div., Clarksville, Md. 21029
Einar T. Wulfsberg, American Paper Institute, 1837 "K" St., N. W., Washington, D. C.
Thomas J. Hughes, Acting Secretary, Keller and Heckman, 1712 "N" St., N. W., Washington, D. C. 20036

Under the direction of Robert M. Miller, Hercules, Inc., a meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee convened in Washington, D. C. at the Hotel America at 9:30 a.m. Referring to a detailed agenda circulated with the Secretary's meeting announcement, Mr. Miller, as a first order of business, asked for the usual self-introductions.

Minutes Last Meeting Approved

By way of reminder, Mr. Miller noted that the last overall meeting of the Committee was held in New York City on April 17, 1968. In the absence of comments as to corrections or additions to the minutes of the last meeting, Chairman Miller declared them approved as developed and circulated by SPI.

Chairman's Remarks

Chairman Miller first expressed the Committee's regrets and condolences at the passing of Joe Blanchette, Foster Grant, who had made great contributions to the Committee through his work on the Pigments Task Group.

Chairman Miller then called on former Committee Chairman, George W. Ingle, Monsanto Company, who presented the following resolution to the Committee bearing on the retirement of George T. Scriba from Union Carbide Corporation:

> WHEREAS, The Food, Drug and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc., has been advised that George T. Scriba, Esquire, of Union Carbide Corporation, is now planning to retire from his present position on January 1, 1969:
>
> AND WHEREAS, the said George T. Scriba has rendered outstanding service to the plastics industry in general, and this Committee in particular, by his having been a founder of the Committee in 1956; by his having served for lengthy periods as a Vice Chairman, Steering Committee member, Chairman of the Lawyers Advisory Sub-committee, and in other capacities as one of the most distinguished Committee members;
>
> AND WHEREAS, this Committee recognizes with deep appreciation the significant contributions Mr. Scriba has made in its work, but also in many areas of the greatest importance to the plastics industry;
>
> AND WHEREAS, this Committee is anxious to express, in a meaningful way, its respect and thanks to Mr. Scriba, and also its hope that he will continue to participate in the Committee's work;
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> NOW THEREFORE BE IT RESOLVED, that the Food, Drug and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, in appreciation for the invaluable contributions made by George T. Scriba over the past twelve years of the Committee's existence, hereby unanimously elects Mr. Scriba to lifetime honorary membership, and extends to him an invitation to attend all Committee meetings, and participate in the Committee's future work to the fullest possible extent;
>
> AND BE IT FURTHER RESOLVED, that the Secretary of this Committee is hereby authorized and instructed to memorialize this Resolution in a permanent form, and present the same, duly executed by the Chairman of this Committee, and the Executive Vice President of the Society, to Mr. Scriba.

The Resolution was unanimously approved by the Committee and both Mr. Ingle and Chairman Miller further expressed the Committee's deep appreciation to Mr. Scriba for his many years of devoted service.

Special Report of SPI Executive Vice President, Ralph L. Harding, Jr., On the New York City Plastic Meat Tray Controversy

Chairman Miller next called upon the Executive Vice President of the Society, Ralph L. Harding, Jr., to report on the latest developments in what has come to be known as the "New York City clear meat trays controversy." Mr. Harding began by noting that the relevant phase of the "controversy", as far as recent SPI activity is concerned, began when word was received on July 26, 1968 that a telegram, reading in part as follows, had been sent to members of the press by the Food, Tray and Board Association (FTBA):

> "On August 1, a new law is scheduled to go into effect in New York City that will require fresh or frozen meat, sold in food stores, to be prepackaged in so-called transparent trays. According to dramatic new evidence based on independent studies conducted for the Food, Tray and Board Association, by a leading University, the new law imposes serious health threats that could affect every family in New York City."

Mr. Harding went on to explain that word of the telegram reached the Society late on Friday afternoon, July 26, and that, at the request of several companies in SPI, the Society moved immediately to set the stage for an SPI press conference to be held the following Tuesday morning, promptly after the press conference called by FTBA to expound on the statements made in its telegram. It was decided that such action on SPI's part was essential even though the Society had played absolutely no part in the legislative, or any other phase of the controversy, as it had previously developed, because the FTBA telegram made it clear that, for the first time, this group had decided to raise or imply the existence of some health threat flowing from the use of plastic meat trays. Obviously, there was little time in which to consult with all SPI members to muster an "industry position" for purposes of countering the FTBA allegations appropriately. The best that could be done, using the membership talent readily available, and the assistance of SPI Counsel, was to make the arrangements for our "counter press conference" and prepare a press release designed to deal appropriately with the health problem claims against both plastic foam and clear trays we anticipated.

Mr. Harding continued to report that, at the FTBA press conference, which was held immediately prior to the SPI meeting with the press, a Dr. Elizabeth Rust of the faculty of the University of Massachusetts, gave a somewhat confused dissertation on a study that she had conducted demonstrating that the use of plastic meat trays results in losses of riboflavin and iron in packaged meat. The evidence against plastics on the riboflavin and iron questions was, as Mr. Harding noted, confusing at best.

As a reaction to Dr. Rust's report, representatives of Monsanto Company promised that there would be independent research into the matter, sponsored by Monsanto. Efforts were also made by Mr. Harding to obtain more detailed information on

Dr. Rust's report and the methodology used to obtain the results allegedly showing that plastic meat trays had a significant deleterious effect on the riboflavin and iron content of packaged meats. Mr. Harding noted that the FTBA flatly refused to release any information on the report other than what had already been given at the FTBA press conference.

Mr. Harding emphasized that SPI had tried to make it very clear at its press conference that it was not trying to promote the use or acceptance of any particular kind of plastic tray, but rather was defending the good name of plastics, in general against the pseudo-health threat charges leveled by the FTBA.

With regard to the ordinance that had been adopted by the City of New York, Mr. Harding emphasized that SPI had, in no way, actively engaged in the sponsoring thereof, and that, in fact, the Society's policies are such that it never has, and never will endorse "restrictive" legislation of this type.

Mr. Harding went on to report that on October 7, 1968, Monsanto Company called a press conference of its own to announce the results of tests it had subsequently conducted on the riboflavin and iron questions. Mr. Harding reported that, according to Monsanto representatives, the results of the test demonstrated that plastic meat trays had no real significant deleterious effect on riboflavin and iron content in meat.

In conclusion, Mr. Harding again pointed out to the Committee that the Society in no way wishes to imply by any of its activities that it favors one segment of the plastics industry over another, nor any one plastic material over another for given applications. The sole purpose of SPI's efforts in the meat tray controversy, as in all other controversies involving applications of plastics materials, was to defend the good name of plastics, in general, from an overall "industry" point of view.

At the conclusion of Mr. Harding's report, Jules Pinsky, Monsanto Chemical Company, noted for the record that Monsanto had not, and would not, promote any legislation, on any level, in favor of the use of clear plastic trays alone for any food packaging applications.

Jerome H. Heckman, SPI Counsel, commented that his office had been contacted by representatives of the United States Department of Agriculture and the Food and Drug Administration for complete information on the New York situation, and that he had supplied both USDA and FDA with substantially the same background information as had just been provided to the Committee by Mr. Harding.

In concluding the discussion on the New York meat tray situation, Chairman Miller noted that the Food, Drug and Cosmetic Packaging Materials Committee had decided several years ago not to take any position on the use of any particular type of plastic for meat and poultry packaging applications, but had decided simply to follow the situation for informational purposes. At all times, however, it had been understood that SPI would be expected to move appropriately if any health problem issues were raised so as to give rise to a need for objective refutation.

PMA Quality Control Section that the National Formulary has agreed to publish a monograph containing methodology for containers for ophthalmic products."*/

Synthetic, Organic Chemical Manufacturers Association (SOCMA)

Mr. W. P. Munro, American Cyanamid Company, gave the following report on the status of the proposed "Synthetic Organic Colorants in Paper and Paperboard" Food Additive Regulation:

"No actions in this area have been taken by the FDA in the past twelve months, i.e., since they received the objections to their Proposed Regulation of August 4, 1967.

"It has been reported very recently that any action awaits an internal policy decision stemming from the subject matter of the Conference on Indirect Food Additives of last February."

Manufacturing Chemists Association (Food, Drug and Cosmetic Chemicals Committee)

Taylor Hanavan, E. I. du Pont de Nemours & Co., Inc., delivered the following report on MCA's efforts with regard to obtaining an exemption from the Good Manufacturing Practices Regulations for Food Additives, and its participation in investigation being conducted by FDA's Advisory Committee Panel on Cancer Testing:

"At the MCA Food, Drug and Cosmetic Chemicals Committee meeting on October 10, it was reported that MCA's request for an exemption from the GMP regulations for food additives was still open and that FDA is preparing a new proposal with thirty days for comments. If food additives are not exempted, the Committee agreed that it would renew MCA's request for such an exemption.**/

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*/N.B. Prior to the publication of these minutes, arrangements are being made by Mr. Ackart to have representatives of the Committee meet with representatives of PMA to discuss the decision to have the methodology applied to ophthalmic products only. It is hoped that an agreement can be reached whereby the methodology will be referenced as applicable to dry powder and tablet form drugs.

**/The new GMP proposal was published in the December 20, 1968 Federal Register The exemption request for plants making food additives was not granted in the proposal on which thirty days were allowed for comment. However, FDA noted that interested persons ". . . who believe circumstances warrant an exception and special regulation for his operation may submit a request for exemption together with a written justification in support of the request addressed to the Commissioner . . .".

- continued -

The Committee's subcommittee on carcinogenicity has been offered an opportunity to appear before a November 12 open meeting of FDA's Advisory Committee Panel on Cancer Testing. In addition, the FDA Advisory Committee on Reproduction Studies is about to forward to FDA recommendations that go beyond MCA's recommendation of not more than a one-generation rat test. The specifics of this recommendation have not been disclosed."

American Paper Institute

Jim McCartney, Standard Packaging Corporation, reported briefly that API was still awaiting the outcome of events that had occurred during and subsequent to the National Conference on Indirect Food Additives.

Can Manufacturers Institute

Charles J. Spiegl, Continental Can Co., reported that no developments of interest to the Committee had occurred within the CMI since this Committee's last meeting.

SPI Food and Drug Bottling Committee of The Plastic Bottle Division

Chairman Miller then called on Matt Smith, Owens-Illinois, to report on the latest developments of interest in the Food and Drug Bottling Committee of the SPI Plastic Bottle Division. Mr. Smith reported that the Food and Drug Bottling Committee had supplied the Alcohol and Tobacco Tax Division, of the Internal Revenue Service, with a set of comments bearing on an ATTD proposal (Industry Circular No. 68-21) to provide for the experimental use of PVC bottles, in certain sizes, for the packaging of distilled spirits. (Subsequent to the Committee's meeting, the ATTD issued a second Industry Circular (No. 68-32), which spelled out the procedures to be used by distillers in making application for the use of PVC liquor bottles in the packaging of distilled spirits.)

Mr. Smith also reported that the U. S. Public Health Service apparently intended to begin publishing, on January 1, 1969, its first listing of single service milk container and enclosure plants which have been properly inspected and found to comply with the U. S. Public Health Service Sanitation Standards. The listing will be published quarterly--January, April, July and October--and will cover containers and enclosures for interstate (not intrastate) milk shipments. Inspections would be under the jurisdiction of each State Milk Sanitation Rating Officer. Mr. Smith went on to say that representatives of the Food and Drug Bottling Committee, as well as other interested parties, had objected to such an early listing. However, the U. S. Public Health Service was apparently under a good deal of pressure to promulgate the listing.

Other Matters of Interest

At the conclusion of Mr. Smith's remarks, Chairman Miller asked if there were any other activities that might be of interest to the Committee. Ralph Harding called

the Committee's attention to the fact that a conference will be held in Sweden during April, 1969, on the subject of "The Corrosion Products of Burning Plastics." George Ingle, Monsanto, will represent SPI at this conference in his capacity as the Chairman of SPI's new Committee on Disposal.

Mr. Harding also mentioned the fact that other new Committee's might be established from time to time within the SPI framework under a new organizational plan that had been devised for SPI, and a new set of SPI Bylaws that had been prepared by SPI Counsel.

In response to a question raised by Jules Pinsky, Monsanto Company, concerning the source of news release on self-destructing PVC bottles that had apparently been aired on a Hartford, Connecticut radio station, and elsewhere, Mr. Harding indicated that the release had not been issued from the SPI office in spite of the fact that several news media sources may have given the impression that the release originated with the Society. Mr. Harding emphasized that SPI speaks as "one voice" for the plastics industry and does not engage in promotion for any one segment of the industry as opposed to others.

Luncheon Conference

At this point, Chairman Miller adjourned the meeting for a reception and luncheon conference with Mr. Lessel L. Ramsey, FDA Deputy Director of the Bureau of Scientific Standards and Evaluation.

Mr. Ramsey had been invited to attend the luncheon session in the hope that he would be able to shed some light on the current FDA thinking as to what, if any, changes in the Food Additive regulatory scheme might be proposed as a direct follow-up to the views of industry expressed at the National Conference on Indirect Food Additives.

Mr. Ramsey apologetically advised that he was unable to provide any "hard intelligence" on this subject and could only report that FDA was "taking the matter seriously" and was giving very careful consideration to the proposals, comments, and arguments presented by industry at the National Conference on Indirect Food Additives. When asked if he could give some idea as to when industry might expect a response from FDA in this regard, Mr. Ramsey commented that, due to the change in personnel at the Commissioners level, (i.e., Commissioner Goddard having been replaced by Commissioner Ley), it would be impossible to predict when FDA might be forthcoming with a proposal on substantive changes directly responsive to the positions advanced and suggestions made at the National Conference on Indirect Food Additives.

Mr. Ramsey concluded his remarks by suggesting that Commissioner Ley be questioned on this subject at the December 3 and 4 sessions of the FDA-FDLI Conference to be held in Washington.

(By way of follow-up to Mr. Ramsey's remarks, Mr. Heckman and several other Committee members were in attendance at the referenced FDA-FDLI sessions and it can only be reported that Commissioner Ley was no more definitive in his response to questions on this subject asked at the Conference than was Mr. Ramsey at the Committee luncheon.)

Chairman Miller reconvened the Committee Meeting at 2:30 p.m.

Report of Technical Information Subcommittee

As the first order of business for the afternoon's session, Chairman Miller called on Willard Westveer, Dow Chemical Company, who reported on Food Additive Regulations of interest that had been promulgated since the time of the last Committee Meeting. (Please Note: Attached hereto as Exhibit C is a listing dated November 1, 1968 prepared by Mr. Westveer and entitled "Recently Issued Food Additive Regulations.")

Mr. Westveer discussed several of the Regulations which were of particular interest to the Committee, including an amendment to Section 121.1070 of the Food Additive Regulations which prescribes a method for determining the presence of chickedema in fatty acids.

Arnold Finestone, Foster Grant, co-ordinator of the Committee's Pigments Task Group, was unable to attend the day's session and, in his absence, no report was forthcoming relative to the Pigments Task Group activities.

Report of Lawyers Advisory Subcommittee

Chairman Miller next called on Taylor Hanavan, E. I. du Pont de Nemours & Co., Inc., to give the customary Lawyers Advisory Subcommittee report on legislative and judicial developments of interest to the Committee. Mr. Hanavan prefaced his remarks by paying special tribute to departing Chairman of the Lawyers Advisory Subcommittee, George Scriba. In commenting on Mr. Scriba's qualities as a "distinguished and dedicated lawyer and a true gentleman and pillar of strength" Mr. Hanavan observed that all of the industries with which Mr. Scriba has been involved, and on whose behalf he has labored, have been justly enriched, and that the SPI Food, Drug and Cosmetic Packaging Materials Committee will surely miss Mr. Scriba's vigilant counsel and advice.

Turning to his report, Mr. Hanavan first called attention to an article that had appeared in the October 23, 1968, edition of the Washington Evening Star, wherein FDA Associate Commissioner for Compliance, J. Kenneth Kirk, had been quoted on the possibility that more stringent regulatory controls might be proposed for cosmetics once the new session of congress convenes. Additionally, Mr. Hanavan noted that we might expect to see legislation offered in the next session of Congress bearing on regulatory control over medical and therapeutic devices, including those which involve plastics materials.

Occupational Safety and Health Act

Mr. Hanavan next commented on the status of the Occupational Safety and Health Act which had been introduced in both Houses of Congress during 1967. The proposed legislation, Mr. Hanavan reminded, would have required the Secretary of Labor to appoint various Committees to recommend Occupational Safety and Health Standards and to set up a National Advisory Committee on Occupational Safety and Health to administer the Act. Although both the House and Senate bills have died in their respective Committees, Mr. Hanavan cautioned that the subject matter is by no means dormant.

With further reference to this subject, it was pointed out that, under the Walsh-Healy Act, the Department of Labor had proposed regulations which would require government contractors, or companies having government contracts, to comply with various safety standards. Among those areas which would be standardized would be noise, radiation, gas vapor, fume dust, etc. Mr. Hanavan speculated that perhaps through such regulatory procedures, the Department of Labor would be able to accomplish, without legislation, the ends which were being sought by means of the proposed Occupational Safety and Health Act. Mr. Hanavan noted that many companies and organizations, including the National Safety Counsel, had strongly objected to many of the aspects of the Department of Labor's proposed regulations, and that it was anybody's guess as to what would come of this proposed regulatory effort.

National Commission on Product Safety

The next item in Mr. Hanavan's report concerned the National Commission on Product Safety, which, it was reminded, had been set up to undertake a two year study of th scope and effectiveness of present means of protecting consumers from unsafe household products. The Commission's goals, Mr. Hanavan noted, were (1) the identification of household products that present an unreasonable risk of injury to the consumer, (2) the study of the effectiveness of industry standards and industry self regulation in the field of consumer protection and (3) a thorough review of existing Federal, State and local consumer protection laws, as well as the large body of common law that has developed in nearly all of the separate states in this area. Of particular significance, Mr. Hanavan noted that the Commission is expecte to study closely the degree of legal protection afforded to consumers by product warrantees and guarantees.

Mr. Hanavan went on to report that the Commission had held its initial hearings on October 21, 22, and 23, and that, of interest to the Committee might be the fact that Dr. Milton Helpern, the Chief Medical Examiner for New York City, did, in his testimony before the Commission, cite the efforts of the plastics industry during the "plastics bag crisis" as an excellent example of how some industries cooperate with Federal and State health agencies to remove and minimize health hazards in the home.

Mr. Hanavan also noted that the Federal Trade Commission would be holding hearings, commencing on November 12, concerning factors relevant to national consumer protection education.

AMP Company v. Gardner

Mr. Hanavan then directed himself to a discussion of a recent case that could be of considerable significance to everyone concerned with food and drug regulatory matters.

The case was AMP Company v. Gardner and involved two types of plastic devices used in surgery. The company involved, Mr. Hanavan reported, had apparently submitted a request to the Food and Drug Administration for an FDA opinion as to whether the plastic articles in question might be properly classified as "new drugs", or "devices" under the Federal Food, Drug and Cosmetic Act, as amended. FDA ruled tha

the products were properly classified as drugs and that as the products were not generally recognized as safe and effective, they were also new drugs for which New Drug Applications would be required.

Mr. Hanavan noted collaterally here that the Food, Drug and Cosmetic Act, as amended, defines devices and drugs essentially the same way, the only difference being that a "device" is an instrument, apparatus or contrivance and a "drug" is an article. However, both statutory definitions cover use "in the diagnosis, cure, mitigation, treatment or prevention of disease," or a use that affects "the structure or any function of the body of man or other animal." Mr. Hanavan pointed out this gives a great deal of flexibility to FDA, subject only to the limitation that the definition of drugs expressly exempts devices. It can be assumed, however, Mr. Hanavan added that in light of the AMP case, this limitation will be given a very narrow construction.

In the AMP Company case, the Court of Appeals in affirming the District Court in effect ruled that the Food and Drug Administration had properly classified AMP's products as "new drugs". The Supreme Court denied certiorari on October 14, 1968. Mr. Hanavan read the following quote from the District Court opinion in the case:

> "The remedial nature of the Food, Drug and Cosmetic Act warrants a liberal construction for the protection of the public health and thus, defines that the plaintiff's product is a drug. The public will be better protected by classifying plaintiff's product as a drug rather than device, so that proper testing controlled by the government, can be pursued. It would seem that where an item is capable of coming within two definitions, the definition affording the public the greatest protection should be accepted."

As far as the plastics industry is concerned, Mr. Hanavan pointed out that the definition of drugs includes "articles intended for use as components of any (drug)" and that this Court decision may be important in terms of imposing a duty on plastics materials suppliers to know that their materials are being used for or as components of drugs or new drugs. Because certain materials may not be appropriate for such drug use, for reasons known perhaps only to the materials manufacturer or supplier, the questions of civil product liability make it encumbent upon the manufacturer and/or supplier to be extremely careful in making an effort to determine the end use for its product. If nothing else, the AMP Company decision emphasizes the need for the plastics industry to proceed with caution in this area.

In conclusion, Mr. Hanavan noted as further evidence of the possible implications of the AMP case that Mr. William Goodrich, Assistant General Counsel for the Department of Health, Education and Welfare, assigned to FDA, has been quoted in a local Washington newspaper as stating that, in his opinion, the AMP Company decision now gives FDA the means by which to regulate, before sale, intra-uterine birth control devices. Again, Mr. Hanavan expressed the opinion that the AMP Company case, especially as viewed by Mr. Goodrich, gives rise to a stronger than ever need for the plastics industry to take a good hard look at where it is going, and what it is doing in the medical and therapeutic devices area.

In commenting on Mr. Hanavan's report, Dr. Morgareidge, Food and Drug Research Laboratories, Inc., called the Committee's attention to the fact that there is in existence an ASTM Standard for medical devices; namely, ASTM F4.

George Ingle, Monsanto Company, also noted that USA Standard Institute Committee Z79 was working on the drafting of a standard for PVC and other plastics for tissue contact applications. Mr. Ingle went on to state his personal conviction that plastic manufacturers who plan to enter the field of supplying PVC and other plastic materials for tissue contact are going to have to do a great deal more than is presently being done with their quality control procedures, because, for example the evidence to date is that there is extreme variability in the tissue contact toxicity of anyone of the "garden type variety" of PVC ingredients which are customarily used. As an example, Mr. Ingle pointed out that there are many commercial grades of epoxidized soybean oil, and preliminary data that has come to the attention of the USASI Z79 Committee indicates that there is considerable variation in the response of various grades of epoxidized soybean oil from one grade to another, and from one batch of one grade to another batch of the same grade, insofar as tissue contact toxicity is concerned. Mr. Ingle concluded by stating that the proposed USASI Standard was anticipated to be distributed within the next several months and that there would, undoubtedly, be ample occasion for comment on the proposed Standard.

Report on International Developments

Chairman Miller next called upon Mr. Hughes, of the law firm of Keller and Heckman, to deliver a report on the latest international developments of interest to the Committee (Please Note: Attached hereto as Exhibit D is a copy of Mr.Hughes' prepared remarks.) In giving his report, Mr. Hughes invited open discussion and comment from the Committee members.

During Mr. Hughes' report on the developments in the United Kingdom and the current status of the British Food Additives and Contaminants Committee proposal for the establishment of a food packaging regulatory scheme in the UK, Newell Olson, Reynolds Metals Company, moved that the ad hoc Subcommittee, established during th April 17, 1968 Committee Meeting to deal with the British situation, be formally dissolved as there apparently was no further need for the Subcommittee to deliberat the British situation. Accordingly, the ad hoc Subcommittee was dissolved by Chair man Miller.

With further reference to the British situation, Mr. Hughes, also pointed out, during his discussion, that the British Plastics Federation had recently published a new list of polymer specifications, which, as is customary in the UK, had been submitted to the British Industrial Biological Research Association (BIBRA).

New Business

There was no further business offered for discussion at the day's meeting.

Next Meeting

Mr. Miller announced that, as usual, the dates and site for the next meeting of the full Committee will be left up to the Steering Committee.

The day's session was adjourned at 3:30 p.m.

Respectfully submitted,

Thomas J. Hughes
Acting Secretary

TJH:vw
Encs.

Exhibit A

Report of
Jerome H. Heckman, SPI Counsel
Prepared for SPI Food, Drug and
Cosmetics Packaging Materials Committee
Meeting
Washington, D. C.
November 7, 1968

Gentlemen:

It is good to see so many of you again. Please let me start by thanking all of you who were so understanding about my being unable to attend your last meeting in April. My family was very grateful for the many expressions of sympathy received regarding my father's passing. It was a trying time so your understanding was deeply appreciated.

I would also like to publicly thank my very capable associate, Tom Hughes, for filling in on my behalf on extremely short notice. From what I have heard since April, Tom did a great job. As a result, of course, he will now have to pay the usual price for his success. Thus, you will have noted that he is listed on the Agenda to give you a report a little later on today on some of the overseas developments which have come to our attention recently.

In accordance with our custom, I will try to "hit some of the high spots" here on a variety of matters. In many instances, I have attempted to abbreviate my own discussion of some of the topics since, even with some abbreviation, I am afraid I must preempt a rather substantial amount of your time at this meeting. What I will try to do today, as best I can, is to report on what I consider my major topics, alluding only briefly to those which I believe others will be covering in greater depth. Again, in accordance with our custom, I hope you will feel entirely free to interrupt at any time for such questions, discussion, or even actions, you deem appropriate.

National Conference on Indirect Food Additives

In Tom's report at the last meeting, he, and I am sure some of the others who were present at, or participated in, the National Conference on Indirect Food Additives briefed you on how the Conference came to be, and how we organized industry participation in it. Since I was not present in April, I might merely add here that we believe the Conference was a most worthwhile undertaking, if for no other reason than because of the record it provided relative

to industry's problems with the present regulatory scheme relating to incidental food additives.

As of this moment, we cannot say that the Conference has brought about patently obvious tangible results. It may well be that our FDA guests at today's luncheon will change this status by giving us a more "official" insight into what steps the Food and Drug Administration is planning as an aftermath of the February sessions. In the meantime, however, I should at least remind all of you--including especially those who were not at the Conference--that the proceedings were fully transcribed. This, in and of itself, constitutes a real contribution as we see it.

I might also mention that we still have a fairly substantial supply of the complete transcripts of the Conference in our office so any of you who might like to have the background information which the transcript provides are invited to let us know. We can arrange to send you a copy but the transcript is some 309 pages long so I am sure you will forgive us if, in mailing the material, we make use of the lower class mailing rates, and ask you to anticipate the slight delay this might occasion.

Aside from whatever benefits in the way of background information the transcript provides to interested parties in both this country and overseas--and we have had occasion to send copies to contacts overseas who have found the transcript quite useful--we believe that some psychological benefits of regulatory significance have already accrued as a result of the Conference, and that other, more recognizable benefits, will be forthcoming.

On the psychological side, and you will appreciate that this is by no means easy to explain or understand, we have the strong feeling that the FDA Staff has taken some of the points made at the National Conference on Indirect Food Additives into account in its day-to-day handling of Food Additive Petitions. As a result, we believe that the staff is asking for at least slightly less in the way of data in connection with some petitions than might otherwise have been the case. Likewise, we believe there is a growing understanding at staff level of the need for delimiting those areas where petitions will have to be filed in the future. In other words, while it cannot be said that the so-called "Frawley concept" has been or will be wholeheartedly embraced by the regulatory agency, it does appear that some of the FDA thinking is proceeding down more moderate lines with the necessity for such a shift having been indicated by the forceful way in which the Frawley approach has been presented and supported.

Hopefully, Mr. Ramsey will be giving us some clearer indications in this connection later today. He may even be in a position to let us know more firmly whether the FDA staff proposal for significant changes in the Food Additive Regulations which

would limit the necessity for filing petitions is making real progress at the top levels in the agency.

All of the information we have received up to now, and much of this has already been called to your attention in our correspondence and by the trade press, indicates that the FDA staff believes the necessity for filing petitions on indirect food additives could be reduced by the adoption of added provisions to the so-called "good manufacturing practices" regulation set forth as Section 121.2500 of the present Food Additive Regulations.

At the risk of being repetitious, but so that those of you who may not be aware of the movement, will have a clear idea of what we understand the staff is proposing to do, let me point out here that if the staff recommendations are adopted, Section 121.2500 will be amended to, in effect, classify the following items as "non-additives," which may be used without petition type clearance, as a matter of good manufacturing practice. The language we have seen to accomplish this change would result in the addition of the following new Section (d)(5) to Section 121.2500:

"§121.2500 General provisions applicable to Subpart F.

* * *

"(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

* * * *

"(5) Substances (except heavy metals, as defined in Food Chemicals Codex, and compounds of such heavy metals; 'economic poisons', as defined in §2a of the Federal Insecticide, Rodenticide, and Fungicide Act; and substances prohibited under §409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act) as provided under subsection (i), (ii), (iii), (iv) or (v) of this subparagraph:

"(i) As components of food-contact articles provided any substance so used contributes no more than 0.05 ppm of additives to the contacted food.

"(ii) As components of articles intended for use in contact with dry food of type VIII described in table 1 of §121.2526(c) provided the finished food-contact surface contains no free oils not otherwise permitted for such use.

"(iii) As components of articles intended for repeated use in contact with bulk quantities of food provided the finished food-contact article is thoroughly cleansed prior to first use in contact with food.

"(iv) As components of defoaming agents employed prior to or during the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food.

"(v) As components of food-packaging adhesives complying with §121.2520."

According to the best advice we have, if and when FDA's "topside" approves such a change in the regulations, it will not be published immediately but, instead will be discussed informally with representatives of the industries who participated in the National Conference on Indirect Food Additives. Presumably, at least, this would give all of those interested an opportunity to suggest changes in the proposal even before it is published and time is allowed for official "Comment," as is required by the Administrative Procedures Act.

If the matter does develop in this way procedurally, we may well want to meet again with representatives of other industries, as we did prior to the National Conference on Indirect Food Additives, so that industry positions can be as coherent, and therefore as effective, as possible.

Among other things, and again assuming that the proposals we have seen are eventually advanced to us in an official or semi-official way by FDA, I, for one, would like to see a degree of clarification of at least one of the major proposals we know about now. The one I have in mind is the one that would eliminate the need for Food Additive Petitions on "components of food contact articles provided any substance so used contributes no more than 0.05 ppm of additives to the contacted food."

In our view, this provision would need considerable clarification to make it of any real value since, what we would hope, is that it is intended to eliminate the need for petitions on substances where "no more than 0.05 ppm of additives" are detected in food simulating solvents under realistically established tests. If the presently contemplated language were revised to make this intent clear, we believe a forward step of consequence would have been taken. On the other hand, if the language is left as it is, and thus remains open to the interpretation that petitions may be avoided only where an in-food test--usually wholly impractical--shows that no more than 0.05 ppm finds its way into the food, or if it is interpreted so that it will cover only substances which would lead to no more than an 0.05 ppm addition to food if all of the substance migrated from the package, the provision will be virtually useless.

Without going into greater detail, let it suffice to say that we believe the language we have seen is inadequate at the moment, so we must hope that FDA will provide an opportunity for clarification at the earliest possible opportunity. Other aspects of the proposal could likewise point the way towards a necessity for meeting with our sister packaging groups, and working diligently to make reforms as useful as possible, all towards the end of continued protection of the public but with less of an unnecessary burden on industry.

With the various procedural possibilities in mind, one of our first recommendations to you today is that you empower your Steering Committee to act on your behalf in any negotiations which may become necessary, or appear desirable, as far as meeting with other industry groups, or the FDA Staff is concerned. We believe that your best interests will be served if you provide such authority here so that the Steering Committee can act promptly and effectively on your behalf as circumstances dictate.

Before leaving the subject of the National Conference on Indirect Food Additives to report more specifically on the still pending proposed revision of the FDA Food Additive Procedural Regulations, I would like to call your attention to a collateral development which, it seems to us, has a sort of overlapping bearing on both of these matters.

In the October 28 issue of Food Chemical News, a story appeared announcing that the Food and Drug Administration is establishing a "compliance policy guidance system" which will enable the agency to make public more of its current regulatory policies. According to the FCN article, the new system is being established in FDA's Division of Case Guidance and "will update and identify current FDA regulatory policies." The article indicates that the system "will include procedures for making public advisory opinions, trade correspondence, and other formal and informal regulatory policies."

If this system does indeed come to be, we believe that this will constitute a response, albeit an oblique one, to the recommendation we made to the Food and Drug Administration in both our SPI Comments on the Procedural Regulations and, again, in our presentation at the National Conference on Indirect Food Additives. If you will recall, in both of these presentations, we urged the agency to do something about the communications gap that exists because those other than parties dealing on a day-to-day basis with FDA have no way of knowing about the shifting sands of regulatory policy which are brought to bear in the handling of Food Additive Petitions, as well as in the handling of very important requests for advisory opinions about product status. In our Comments we went into considerable

detail on this point and urged the agency to adopt a system similar to that used by the Federal Trade Commission for publishing Advisory Opinions without revealing the names of inquirers, or the details relative to any particular product.

We have the very definite impression that the procedure FDA is apparently planning to install as a new "compliance policy guidance system" will, in actuality, be along the lines that we suggested.* If this is so, we can be grateful for a modicum of progress in the slow process of bringing about meaningful regulatory reform.

Status of FDA Proposed "Procedural Regulations"

To place this part of my report in perspective, let me remind you that comments on the FDA proposal for a complete revision of its Procedural Regulations were submitted in a 69 page document we filed on your behalf on November 6, 1967. Among other things, we strongly urged that FDA do nothing in the way of adopting new Procedural Regulations until such time as some of the more basic problems relating to incidental additive regulations had been thoroughly aired, and agonizingly reappraised. It was in this set of Comments that we first advanced the idea of establishment of an Industry-Government Advisory Committee to do the job of working over the regulatory scheme in a truly comprehensive way.

This recommendation for the establishment of an Industry-Government Advisory Committee was carried forward even more forcefully in the National Conference on Indirect Food Additives. Indeed, in summarizing the Conference, most of the FDA spokesmen noted that the one point that they had heard supported most unanimously by all of the industries represented was the request

*/ Subsequent to the giving of this report, and during the question and answer session held with Mr. L. L. Ramsey of the Food and Drug Administration at the meeting, it was learned that the so-called "compliance policy guidance system" will not really be along the lines of the Advisory Opinion procedure previously recommended by SPI in its November 6, 1967 comments on the proposed Procedural Regulations. Instead, Mr. Ramsey advised that this new system will be reflected by publication of some sort of manual to recap the enforcement policies communicated confidentially to the field staff of FDA during the past ten or fifteen years. He further advised that the only thing really "new" about the matter is that the policies will now be made public information for the first time. He further indicated that the last estimate he had heard of a possible publication date leads to a conclusion that the availability of the material in question is at least three years away.

for establishment of an Industry-Government Advisory Committee to reevaluate and deal with all aspects of the incidental additives regulatory problem.

Strangely enough, we have not heard a great deal from FDA about the Industry-Government Advisory Committee proposal in recent months although we have been hearing much about the FDA Staff plan to revise the "good manufacturing practices regulation" to eliminate the need for petitions in a number of areas. Whether this means that FDA is of the opinion that the Industry-Government Advisory Committee suggestion can be sidestepped by the finalization of some proposal to eliminate the need for the filing of petitions in specific areas is not clear yet.

In our view, the Industry-Government Advisory Committee concept should continue to be pressed as a matter of policy. Further, we are of the opinion that FDA should perhaps again be urged to forego the publication of any final revision of the procedural Regulations until such time as an Industry-Government Advisory Committee has been formed, and has made an effort to come up with more realistic changes.

As far as we are aware at the moment, consideration of the Procedural Regulations is in a state of limbo, the likelihood being that no moves will be made on this score until more definite National Conference "aftermath action" is taken. Nevertheless, we believe it might be in order for this Committee of SPI to consider reemphasizing our interest in having FDA appoint an Industry-Government Advisory Committee, and delay publication of any new Procedural Regulations, unless and until such an Advisory Committee has studied the situation, and has given the agency the benefits of its thinking on how Procedural Regulations should be written to facilitate industry, as well as FDA, action required under the Food Additives Amendment. It seems to us that a suitable Resolution in this connection might well be considered with a view towards forwarding the same to the Food and Drug Administration at such time as this might appear tactically desirable.

Consideration of SPI Petitions Manual

While on this subject of the Procedural Regulations, and to take up a point which I believe was discussed, but more or less left in abeyance at your last meeting, I would like to raise with you now a possibility for constructive Committee work which I believe would prove helpful to the Food and Drug Administration, as well as to plastics and other packaging interests. I might note here that I have discussed my embryonic idea in this connection with members of your Steering Committee, and indeed in an informal way with our friends on the FDA Staff, on a number of occasions during the past year. Everyone seems to

feel that the idea has merit although it is also recognized that the task it would involve would be a formidable one, demanding a substantial expenditure of time and effort, as well as government-industry cooperation.

In a way at least, I first raised this idea in a semi-official way in my own paper at the National Conference on Indirect Food Additives when I asked the following question:

> "On this matter of what petitions should contain, would it not be better for FDA to avoid the adoption of unduly restrictive procedural regulations such as those recently proposed and, instead, work closely with industry (perhaps through its trade association spokesmen of the type here represented) to develop more informative educational materials such as manuals depicting in 'dummy form' how various types of petitions should be structured?"

Since that time I have found that many FDA Staff members do feel that it would be very constructive if publications could be developed by a trade association such as SPI to depict concretely what a good petition should look like to facilitate consideration by the administrative agency, and, therefore, to facilitate and expedite satisfactory regulatory action. My feeling is that this is an activity which should be undertaken, perhaps as a cooperative effort by members of the Technical Information Subcommittee, and the Lawyers' Advisory Subcommittee, since the problems involved would undoubtedly bring into play both the scientific and legal disciplines.

For your consideration, I would therefore recommend that your Chairman be empowered to appoint a special committee to develop a "Food Additives Petition Manual" which could eventually be published as an SPI document and would, hopefully, set forth sample Food Additive Petitions, using as prototypes fictitious or real components, as you deem best. Recognizing the fact that, in actual petition situations, different types of substances must be treated differently as a matter of common sense, it would seem to us that such a Manual, to be as worthwhile as possible, would need to include sample petitions relating to (1) a substance which is only an adjuvant used with other packaging materials, (2) a total formulation case, and (3) a basic polymer case.

There may be other areas which would need to be covered, and certainly much thought would have to be given to the development of a practical, as well as a suitable format for such a publication. Among other things, any committee appointed to work on this project would need to decide whether extensive example data on actual migration and/or toxicological studies would need to be included, or whether it would suffice if this type of material was simply blocked out in brief form, but with sufficient particularity to provide a real guide for prospective petitioners.

It seems to me that, if nothing else is accomplished, any manual of this type which we undertake to prepare, and ultimately publish, should stress a syllogistic approach to the preparation and filing of Food Additive Petitions. While it may not be possible to prepare a Manual which will answer every question that might come up in the course of a petition problem, the examples of such petitions set forth should at least make it clear that a petition is, after all, a document which should be fully self-contained, and in the purest possible sense logically dispositive of all questions that can be reasonably anticipated.

My point here is difficult to make understood in the abstract. What I am trying to convey is the idea that, in our opinion, a sound Manual should make it apparent that a good petition must meet the following requirements, as we see it:

1. The petition should first set forth sufficient background about the petitioner and its interest in the incidental food additive to set the stage for the more detailed logical and technical exposition in the Petition. Very often, a complete explanation of how the substance was "discovered" for the particular use contemplated will cast a great deal of helpful light on the overall situation, and will obviate the need for extensive explanations about such subjects as the usefulness of the product.

2. The petition should state in narrative form how the petitioner analyzed his regulatory problem, and set about undertaking whatever test work he deemed necessary to provide the Food and Drug Administration with a sound and complete basis for promulgating a regulation. On occasion, this type of explanation, provided a sound and thorough rationale is given, can help demonstrate why it might be unnecessary to perform certain extraction or other analytical work which might be required in other circumstances. Furthermore, this type of explanation can, on occasion, set forth a reasonable basis for satisfactory arguments that additional toxicological studies are not needed. In this discussion, incidentally, such subjects as an estimate of how much of the diet might be packaged in materials containing the substance of the petition can be set forth to provide FDA with a rational basis for concurrence in the petitioner's point of view about the amount of technical data required to give adequate assurances of safety.

3. Obviously, the petition will always need to discuss the ultimate conclusions reached in connection with the technical work done to support safety of the additive. As I have on occasion indicated to the laboratory people with whom we have worked on Food Additive Petitions, we recommend that their work, and their reports, be prepared in the same way that they would prepare documentation if they were readying themselves to be expert witnesses in a lawsuit, or administrative hearing. We always seem to have some difficulty in making our intent in this connection clear.

The idea, as we see it, is that the people who prepare either analytical or toxicological data to be used as appendices for petitions--and we normally like to supply the complete technical data as appendices, referring only to the conclusions to be drawn from the technical reports in the body of a petition--should recognize that they are, in effect, preparing expert testimony which the Food and Drug Administration will be relying upon in its analysis of the total petition.

For those of you who may not have had much occasion to prepare expert testimony, let us point out here that, to be effective, such testimony must always be fully explanatory in and of itself. Nothing should be left to the imagination on the assumption that the data will be reviewed by another expert who "will know what you mean." In other words, we believe that an analytical report should state in clear, complete, and narrative form why certain tests were selected for the work, how one could be assured that these tests were valid for the intended analytical purpose, and how the tests were actually conducted. The report should also, obviously, include the data obtained but the expert, because he is an expert, should not leave the matter there.

As an absolute essential--as the "punch line" for the technical report, if you will--it should state the expert's conclusions based on the data he has compiled. It should also include any relevant observations that can be made on the basis of the scientist's general expertise in the field. An expert witness who simply performs technical studies and cannot explain what the studies demonstrate in support of a petition, or set forth how his expertise permits further relevant conclusions, is virtually useless. The same is true of an

analytical report which assumes that those who review the data will understand why it was accumulated in the way it was, and what it is intended to demonstrate. The by-word should be "assume nothing" and "explain everything."

4. The body of the petition should be used to rationalize all of its parts, including any appendices. In every case one of those appendices should be a proposed regulation in precisely the form in which the petitioner believes the Food and Drug Administration should promulgate a response to his filing.

I realize that many of you have probably filed petitions which meet the essentials of this listing. On the other hand, I know from my own experience, and from what various FDA Staff members have told us that this is by no means universally true. Indeed, dissatisfaction with so many of the petitions filed thus far is what led to the proposal for revised Procedural Regulations. We happen to think that this is the wrong way to solve the problem, and that a better way would be to prepare sample petitions as an educational tool to improve the situation. It is for this reason that we recommend the approach I have been discussing.

As a final word on this subject, I might point out here that we have discussed this idea with many members of the FDA Staff, and have reason to believe that we could count on the agency's cooperation if we set about preparing a manual of the type suggested. This type of cooperation would certainly include FDA's help in reviewing our drafts, and making suggestions as might be indicated. It might even include some type of FDA letter or other note of approval which might be included in the manual although this is not entirely necessary, nor can we say that there is any advance commitment in this connection.

Regulatory Developments Regarding Plastics for Drug Use

As I hope all of you are aware by now, the SPI Manual entitled "Plastics Packaging for Drug Products--the Regulatory Story" has been available for quite some time and has, we believe, been widely disseminated. Even so, we find ourselves continually explaining how regulation of packaging materials for drugs and cosmetics differs substantially from the regulatory approach employed in the case of food packaging materials. We still hear the plaguing question: "Is this product FDA approved for drug packaging?" from a great many drug people, as well as from packaging suppliers. The availability of the drug manual does help to answer some of these questions.

Aside from the educational effort that this Manual is intended to further, there has been progress in the work with the Pharmaceutical Manufacturers Association but I will leave a discussion of this subject to Wat Ackart who will be talking with you later.

The main development or item I would like to call to your attention relates to a Notice published by the Food and Drug Administration in the July 11 Federal Register at Pages 9954 through 9955. This Notice amended various sections of the New Drug Procedural Regulations dealing with so-called "Supplemental Applications" so as to eliminate the need for filing such Supplemental New Drug Applications under certain conditions. As a result of this Notice, it is no longer necessary for drug companies to file Supplemental New Drug Applications in cases where, among other things, they are planning "a different container size for solid oral dosage forms where container and closure are of the same materials as those provided for in the approved application." Other situations involving relatively minor changes in drug production were relieved of the requirement for the filing of Supplemental New Drug Applications.

Perhaps of even greater significance is the fact that, in issuing this Notice, FDA stated that "the Food and Drug Administration will consider any categories suggested by interested persons of changes that may be appropriate for inclusion in Section 130.9(a)(5) as not requiring prior approval of a Supplemental Application for implementation." The reason this could become significant is because it seems to us that, for the first time, the agency has provided an avenue whereby we might be able to eliminate the drug manufacturers' need for filing supplemental applications on other changes in his packaging program, assuming, of course, that we can identify areas where such changes should not present a cause of concern to FDA, and, therefore, might be listed as exempt from the Supplemental New Drug Application requirement.

Whether or not, for example, FDA might be willing to take the position that Supplemental New Drug Applications need not be filed for a change in the packaging of all dry drugs from currently used materials to olefin polymer bottles is a question we think might be explored. Depending on your wishes in this connection, it may well be that we could consider setting up a conference with the appropriate FDA Staff people to discuss this area and determine further what the possibilities are.

I am sure that I need not point out that, if it were possible to exempt such an area as the one I have used as an exemple from the necessity for the filing of Supplemental New Drug Applications, some interesting new markets might be opened up, or at least made less difficult to enter. For this reason, we recommend that the Committee consider instructing the

Pharmaceutical Manufacturers Association-SPI Liaison group, or some other ad hoc committee, to take this possibility up with the Pharmaceutical Manufacturers if you think necessary, and then be empowered to explore the situation with the Food and Drug Administration Staff. We would, of course, be very happy to help with this project.

Publications of Interest

During the past several months there have been, as always, a number of articles and publications which many of you would find of interest. We do not compile bibliographies of such items for these meetings but I do try to mention any which seem to us to be of particular significance.

In this vein, I would like to call your attention to the availability of the first volume in a planned series being published by the Institute of European Studies of the Food Law Research Center of Brussels University. This first volume is entitled "Fundamental Principles and Objectives of a Comparative Food Law". The publication seems to us to be of unusual value because of the survey type treatment, and commentary, it provides on the basic concepts of food and food additive regulation throughout the world.

As far as we know, the best way to obtain the book is through a Mr. Albert J. Phiebig, Post Office Box 352, White Plains, New York, 10602. Mr. Phiebig, I believe, serves as the American agent handling this publication, and perhaps others. The price tag on this first volume, by the way, is $6.

In this same area, and for those who may not have seen it, you may want to look at the September issue of Modern Packaging which contains articles by Alan Spiher and Jack Frawley under the heading "Ten Years of Food Law--Has it Been Worth the Effort?" Jack's paper while, as usual, excellent, constitutes only an abbreviated restatement of what I believe we can call the industry point of view on the Food Additives Amendment. Mr. Spiher's statement, as you might expect in light of Mr. Spiher's background at FDA, is a general apologia for regulation of food additives. I doubt that it will contribute a great deal to your knowledge but you might want to look the article over.

One other article that I have noted lately appeared in the October 10, 1968 issue of the Food and Drug Packager. This article was entitled "PVC for Foods--Some Points to Ponder" and was written by Mr. William A. Larkin, Market Manager for Plastic Product Activities at M & T Chemicals Inc. To a degree at least, Mr. Larkin has attempted to provide some of the background on the only tin stabilizer regulation thus far promulgated by the Food and Drug Administration.

This article does point up the one major problem that exists as a result of the regulatory approach used in the tin stabilizer regulation. That approach, as all of you undoubtedly know, involves the necessity for applying a so-called "in-food" test. The use of such a test imposes a burden on the food processor who is the only one that can apply it, and this undoubtedly explains why we have not yet seen a great influx of tin stabilized PVC bottles in the food packaging area.

* * *

There have, of course, been other developments of interest during the several months that have elapsed since our last meeting. Information about some of them will be conveyed to you by subsequent reports today. Due to the length of my report, let me conclude by simply noting that there is a possibility that, by the time of our next meeting, the latest Department of Health, Education, and Welfare reorganization plan may have been put into effect. I will not dwell on this subject other than to say that, as far as we can determine, while FDA may then be operating under the aegis of the new Consumer Protection and Environmental Health Service, and while there may or may not be a change in the Office of the Commissioner, it appears to us that the reorganization will not directly affect any of your activities or interests. To put it simply, all that we are seeing or anticipate are some additional title changes, office shifts, and more "musical chairs" playing, but no real revisions of substance for those interested in incidental food additives.

I thank you sincerely for your patience.

II

CONTAINERS AND ACCESSORIES IN PLASTICS OR ELASTOMER

Plastics, owing to their particular qualities, may be employed for the manufacturing of containers, equipments or accessories to be used by chemists or in medicine.

They are formed with high polymers to which a certain number of adjuvants are incorporated such as : softeners, stabilizers, cases, antioxidants, pigments, dyestuffes, lubricants, emulsifiers ... These adjuvants (1) are utilized as far as the plastic material containing them is in conformity with the tests eventually prescribed, excluding metallic derivatives which are likely to give with the plastic material some soluble and toxic components (particularly the soluble components of barium and cadmium).

They are inactive on the drugs with which they are into contact, that is to say that this contact, short or prolonged, should provoke no qualitative or quantitative modification or alteration of the drugs. Certain catagories of containers, equipments or accessories must answer to particular tests. For these categories, the chemical nature of the plastics' components (adjuvants included) should be known by the manufacturer who employes them.

(1) The legislation concerning "coatings, varnishes and plastics in contact with food", established by the Ministry of Agriculture includes a list of authorized substances ; the use of these substances is recommended.

For the injectable preparations (drugs), the choice of the plastic material depends on toxicity tests related to the nature and the use of the preparation ; these tests should be made with the injectable preparation after it has remained in the container for a minimum period of three months and if necessary at various temperatures.

The containers, equipments and accessories to be used by chemists or in medicine cannot be re-utilized. In case of injectable preparations, they may be used for aqueous preparations only.

II

RÉCIPIENTS ET ACCESSOIRES EN MATIÈRE PLASTIQUE OU ÉLASTOMÈRE

Les matières plastiques, en raison de leurs qualités propres, peuvent être utilisées pour la fabrication de récipients, d'appareils ou d'accessoires destinés à des usages pharmaceutiques ou médicaux.

Elles sont constituées par des hauts polymères auxquels sont généralement incorporés un certain nombre d'adjuvants : plastifiants, stabilisants, charges, antioxydants, pigments, colorants, lubrifiants, émulsifiants... Ces adjuvants (1) sont utilisables dans la mesure où la matière plastique qui les contient reste conforme aux essais éventuellement prescrits, à l'exclusion des dérivés métalliques susceptibles de donner avec la matière plastique considérée des composés solubles toxiques (notamment les composés solubles du baryum et du cadmium).

Elles sont inactives sur les préparations avec lesquelles elles sont en contact, c'est-à-dire que ce contact, qu'il soit court ou prolongé, n'entraîne aucune modification ou altération qualitative ou quantitative de ces préparations. Certaines catégories de récipients, appareils ou accessoires, doivent répondre à des essais particuliers. Pour ces catégories, la nature chimique des composants de la matière plastique (adjuvants compris) doit être connue du fabricant utilisateur.

Pour les préparations injectables, le choix de la matière plastique est subordonné à des essais de toxicité en rapport avec la nature et l'emploi de la préparation, effectués une fois pour toutes avec la préparation à injecter, après trois mois au moins de conservation, le cas échéant à des températures variées.

Les récipients, appareils et accessoires destinés à des usages pharmaceutiques ou médicaux ne peuvent pas être réutilisés. Dans le cas de préparations injectables, ils ne peuvent être employés que pour des préparations aqueuses.

(1) La législation sur les « enduits, vernis et matières plastiques en contact avec les matières alimentaires », établie par le Ministère de l'Agriculture, comporte une liste de substances autorisées, dont l'usage est recommandé.

EXHIBIT C

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE
SPI FOOD PACKAGING MATERIALS COMMITTEE

November 1, 1968

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:

SECTION	TYPE	DATE	SUBJECT
121.101	Deleting	4/11/68	Substances that are generally recognized as safe by deleting the item "Nordihydroguaiaretic acid."
121.2536	Amended	4/12/68	To provide for the safe use of a-(p-Nonylphenyl)-omega-hydroxpoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters in the production of resin-bonded filters to be used for filtering food.
121.2527	Amended	4/17/68	Provide for the use of N,N-bis(2-hydroxyethyl)alkylamine in vinyliden chloride copolymer coatings as an Antistatic and/or antifogging agents in food-packaging materials.
121.2526 (b)(2)	Amended	4/20/68	Provide for the use of Disodium N-octadecylsulfosuccinamate in the formulation of paper and paperboard used in contact with aqueous and fatty foods.
121.2585	Amended	4/20/68	Provide for the use of tetrahydrophthalic anhydride as a curing agent in the production of 4,4'-isopropylidenediphenol-epichlorohydrin thermosetting epoxy resins intended for repeated food contact use.

ECTION	TYPE	DATE	SUBJECT
21.2603	New Reg.	4/20/68	Provide for use of poly(2, 6-dimethyl-1, 4-phenylene) oxide resins as components of articles intended for food-contact purposes.
21.2604	New Reg.	4/20/68	Provide for use of methyl glucoside-coconut oil ester as a processing aid in the manufacture of starch intended for use as a component of articles that contact food.
21.2506	Amended	4/26/68	Provide for the use of industrial starch modified by treatment with not more than 6 percent of phosphoric acid and 20 percent urea, as internal sizing for paper and paperboard intended for food packaging.
21.2501	Amended	5/7/68	To provide for use of poly(methylpentene) and olefin basic copolymers mfg. by copolymerization of 4-methylpentene-1 and other 1-alkenes as articles or components of articles intended for food-contact use.
21.2585	Amended	5/14/68	Provide for use of a mixture of di-and tri-glycidyl esters as optional components of thermosetting epoxy resins intended for repeated use in contact with alcoholic beverages containing not more than 8 percent of alcohol.
21.2547	Amended	5/24/68	Provide for the use of an additional sanitizing solution, as set forth below on food-processing equipment and utensils that contact food and on beverage containers except those used for milk.

SECTION	TYPE	DATE	SUBJECT
121.2592	Amended	5/24/68	Provide for the use of certain disproportionate rosins having a minimum dehydroabietic acid content of 35% as components of articles that contact food
121.2520	Amended	5/28/68	Remove the upper molecular weight specification for polyoxypropylene-polyoxethylene condensate used in the formulation of food-packaging adhesives
121.2562	Amended	6/5/68	Provide for the use of Diethyl xanthogen disulfide and Tridecyl mercaptan in the formulation of rubber articles intended for repeated food-contact use.
121.1070	Amended	6/19/68	Provide for use of a modified electron capture method (specified below) as an alternative to the gas chromatographic-electron capture method presently prescribed for determining the presence of chick-edema factor in fatty acids.
121.2526	Amended	6/19/68	Provide for the safe use of Polyamide-epichlorohydrin modified resin in the formulation of paper and paperboard used in contact with aqueous and fatty foods.
121.2566	Amended	6/20/68	Remove the restriction on the use of octadecyl 3.5-di-tert-butyl-4-hydroxyhydrocinnamate as an antioxidant in olefin polymers that limits use of the additive to film.

SECTION	TYPE	DATE	SUBJECT
121.2505	New Reg.	6/20/68	Provide for the safe use of polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids as lubricants in the fabrication of polyvinyl chloride articles intended for use in contact with food.
121.2541	Amended	6/25/68	Provide for additional use of Polysorbat 40, Polysorbate 85, Sorbitan monooleate as emulsifiers and/or surface-active agents in the manufacture of articles intended for use in contact with food.
121.2520	Amended	7/6/68	Provide for the use of an additional monomer, vinyl alcohol (from alcoholysis or hydrolysis of vinyl acetate units) in polymers used in the formulation of food-packaging adhesives and(2) that, to avoid duplication, polyvinyl alcohol as a separate item should be removed from the list of components of adhesive
121.2522	Amended	7/11/68	Provide for the safe use of Hexamethylene diisocyanate, Maleic anhydride, Phthalic anhydride as reactants in the preparation of polyurethane resins for use in contact with dry bulk food.
121.2606	New Reg.	7/27/68	Provide for use of tetraethylene glycol di-(2-ethylhexoate) and polyethylene glycol (400) monolaurate as finishes on nylon twine used for tying meat.

SECTION	TYPE	DATE	SUBJECT
121.2607	New Reg.	7/27/68	Provide for use of tetraethylene glyc di-(2-ethylhexoate) and polyethylene glycol (400) monolaurate as finishes on nylon twine used for tying meat.
121.2566	Amended	8/9/68	Provide for use of 2, 2'- Methylenebi (4-methyl-6-tert- butylphenol) as an antioxidant and/or stabilizer in polymers used in the manufacture of articles intended for food-contact us
121.2571	Amended	8/31/68	Provide for use of a-(p-(1, 1, 3, 3 - Tertramethyl-butyl) phenyl) - omega hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydro phosphate esters as a component of paper and paperboard in contact with food and as a component of food-packaging adhesives.
121.2501	Amended	8/31/68	Provide for the additional safe use of (1) olefin copolymers of ethylene and propylene and (2) olefin copolymers c ethylene and propylene containing as modifiers one or more of the monome 5-methylene-2-norbornene and 5-ethy dine-2-norbornene, when intended for food contact use.
121.2550	Amended	8/31/68	Provide for the additional safe use of (1) olefin copolymers of ethylene and propylene and(2) olefin copolymers of ethylene and propylene containing as modifiers one or more of the monom 5-methylene-2-norbornene and 5-ethy lidine-2-norbornene, when intended f food contact use.

SECTION	TYPE	DATE	SUBJECT
121.2527	Amended	9/4/68	Provide for the safe use of a-n- Dodecanol-omega-hydroxypoly (oxyethylene) as an antistatic agent in polyethylene film used in contact with food
121.2531	Amended	9/4/68	Provide for the safe use of sodium nitrite as an optional component of surface lubricants used in the manufacture of metallic food-contact articles.
121.2526	Amended	9/27/68	Provide for use of Ammonium bis(N-ethyl-2-perfluoroalkyl-sulfonamido ethyl) phosphates, in the manufacture of paper and paperboard used in contact with aqueous and fatty foods.
121.2514	Amended	10/10/68	Provide for the safe use of sodium pentachlorophenate as a preservative in the manufacture of sealing compounds.
8.515	Color additive	10/15/68	Require on certificates and labeling on expiration date beyond which batches of FD&C Violet No. 1 - Aluminum Lake should no longer be used.
121.2513	Amended	10/15/68	Regarding specifications for and additional uses in food and food-contact articles fo polyethylene glycol (mean molecular weight 200- 9,500)
121.2514 121.2569 121.2507	Amended	10/23/68	Provide for the safe use of certain polyamide resins derived from dimerized vegetable oil acids, ethylene-diamine, and 4, 4-bis-(4-hydroxyphenyl) pentanoic acid in food-contact coatings on cellophane and polyolefin films and as components of food-contact resinous and polymeric coatings.

EXHIBIT D

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

Gentlemen:

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

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

UNITED KINGDOM

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NETHERLANDS

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

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

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

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

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

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

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

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

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

BELGIUM

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

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

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

In general, the draft Decree seeks to prohibit the use of food packaging materials or components, which are likely to become components of food, if such material or components (a) will contaminate the food with noxious substances in such quantity that the food becomes harmful or dangerous to health; or (b) will impart inoffensive substances to foods, but in undesirable quantities under the normal conditions of use; or (c) will change the organoleptic characteristics of the food when in contact with food stuffs under normal conditions of use.

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

ITALY

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

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

EEC

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

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

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

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

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

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

* * *

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

Thank you