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SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

March 22, 1968

To: Members, SPI Food Packaging Materials Committee

Gentlemen:

We are pleased to send you herewith the minutes of the last meeting of the SPI Food Packaging Materials Committee.

We wish to extend to all of you our apologies for the very unusual delay in the final preparation and transmittal of this set of minutes.

As you are aware, the substantive activities necessary on the Committee's behalf in connection with the preparation of the SPI Comments on the Food and Drug Administration's proposed Procedural Regulations, preparations for the National Conference on Indirect Food Additives, and all of the negotiations and meetings held in connection with these projects, have commanded a great deal of the time and energy of our Counsel's office in the past several months. In any event, we are hopeful that the delay in transmission of the minutes in this instance will be understood in light of all the circumstances.

In connection with the minutes, your special attention is also directed to Pages 15 and 16, which pages set forth the report of the Lawyers Advisory Subcommittee. This report recommended changes in the By-laws, it being duly noted that such changes could not be voted upon until our next meeting because of the notice requirements in the present By-Laws. Please understand that this letter is intended to be your notice that the By-Laws question will be voted upon at the next meeting.

By the way, the next meeting of the Committee will be held at the Commodore Hotel in New York City on Wednesday, April 17, 1968, beginning promptly at 9:30 a.m. A detailed announcement, including an agenda, will be mailed to you later.

Please be assured of our cooperation.

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

Charles L. Condit, Secretary

CLC:ilf
Encl.

SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

MINUTES

MEETING OF SPI FOOD PACKAGING MATERIALS COMMITTEE

Americana Hotel
New York City

September 20,1967
9:30 a.m.

Present:

George W. Ingle, Chairman, Monsanto Co., Hydrocarbons & Polymers Div., Research Dept., Springfield, Mass. 01101
Robert M. Miller, Vice-Chairman, Hercules Inc., Delaware Trust Bldg., Wilmington, Delaware 19899
W. B. Ackart, Union Carbide Chemicals & Plastics, One River Rd., Bound Brook, N.J.
Gordon W. Brewer, Marbon Chemical Corp., Div. Borg-Warner Corp., P. O. Box 68, Washington, W. Virginia 26181
P. E. Campbell, Phillips Petroleum Co., Sales Service Lab., Bartlesville, Oklahoma
John A. Carlson, Jr., Vistron Corp. (SOHIO), Midland Bldg., Cleveland, Ohio 44115
K. C. Conley, Marbon Chemical Div., Borg-Warner Corp., P. O. Box 66, Washington, West Virginia 26181
L. J. DeCorte, Sinclair-Koppers Co., Product Development, Frankfort Rd., Monaca,Pa.
Harry R. Dittmar, Vypak Corp., P. O. Box 55, Rockaway, N. J. 07866
Daniel S. Dixler, AIRCO, Air Reduction Co., Inc., Central Researh Lab., Murray Hill, N. J. 07901
Leroy E. Durkin, Imco Container Co., 430 Park Ave., New York, N. Y. 10022
Warren O. Eastman, General Electric Co., Louisville, Ky.
George W. Ferner, The Goodyear Tire & Rubber Co., Research Div., 1144 E. Market St., Akron, Ohio 44316
Robert A. Ferrell, KCL Corp., Prospect & Hodell Sts., Shelbyville, Indiana 46176
A. B. Finestone, Foster-Grant Co., Inc., 289 North Main St., Leominster, Mass.
Patrick A. Florio, American Hoechst Corp., 777 Third Ave., New York, N. Y.
Karl M. Fox, Research Div., Scott Paper Co., Philadelphia, Pa. 19113
B. J. Garceau, ICI America, Inc., P. O. Box 1274, 151 South St., Stamford, Conn.
Arthur Goldman, Columbian Carbon Co., 20 East 46th St., New York, N. Y. 10017
Taylor W. Hanavan, E.I. duPont de Nemours & Co., Inc., Film Dept., Wilmington, Del.
Jerome H. Heckman, Esq., SPI Counsel, Keller & Heckman, 1712 N St., N. W., Washington, D. C. 20036
K. A. Hochschwender, American Hoechst Corp., 777 Third Ave., New York, N. Y. 10017
Thomas J. Hughes, Keller & Heckman, 1712 N St., N.W., Washington, D. C. 20036
D. H. Hunter, Stauffer Chemical Co., Plastics Div., P. O. Box 320, Delaware City, ~~New Jersey~~ Delaware 19706
B. H. Kirby, American Aniline Products, Inc., 25 MacLean Blvd., Paterson, N. J.
W. A. Knapp, Allied Chemical Corp., General Chemical Div., P.O. Box 405, Morristown, N. J. 07960

F. L. Lyman, Geigy Chemical Corp., Ardsley, New York 10502
J.R.S. McCartney, Standard Packaging Corp., 200 E. 42nd St., New York, N. Y. 10017
T. McGrath, SPI, 250 Park Ave., New York, N. Y. 10017
G. McIntyre, Columbian Carbon Co., P. O. Box 975, Princeton, N.J. 08540
J. A. Mitchell, E.I. duPont de Nemours & Co., Inc., Film Dept., 1007 Market St., Wilmington, Del. 19898
J. F. Mizia, Chemical Materials Dept., General Electric Co., One Plastics Avenue, Pittsfield, Mass. 01201
Kenneth Morgareidge, Food & Drug Research Laboratories, Inc., Maurice Ave. at 58th St., Maspeth, N. Y. 11378
P. Morison, Chemical Sales Dev. & Technical Service, Eastman Chemical Prods., Inc., Kingsport, Tenn. 37662
W. P. Munro, American Cyanamid Co., Bound Brook, N. J. 08805
B. G. Murray, Ferro Corp., Color Division, 4150 E. 56th St., Cleveland, Ohio 44105
S. Nesmith, USI Chemicals Co., P. O. Box 218, Tuscola, Illinois 61953
A. S. Nyquist, American Cyanamid Co., P.O. Box 425, Wallingford, Conn. 06492
J. N. O'Connor, The Dow Chemical Co., Legal Dept., 47 Building, Midland, Michigan
W. A. Patterson, W.R. Grace & Co., Cryovac Division, Box 464, Duncan, S. C. 29334
I. F. Peake, E.I. duPont de Nemours & Co., Inc., Film Department, Wilmington, Del.
D. W. Pugh, U.S. Industrial Chemicals Co., P. O. Box 218, Tuscola, Ill. 61953
G. A. Richter, Jr., Rohm & Haas Company, The Rohm & Haas Bldg., Independence Mall West, Philadelphia, Pa. 19105
B. P. Rouse, Jr., Tennessee Eastman Co., P. O. Box 511, Kingsport, Tenn. 37662
R. E. Rutherford, Gulf Research & Development Co., Box 8200, Kansas City, Mo.
E. H. Schaeffer, Shell Chemical Co., 113 W. 52nd St., New York, N. Y. 10019
G. T. Scriba, Union Carbide Corp., Legal Dept., 270 Park Ave., New York, N. Y.
W. W. Sederlund, National Starch & Chemical Corp., 1700 W. Front St., Plainfield,N.J.
A. C. Signore, Monsanto Co., Packaging Div., 101 Granby St., Bloomfield, Conn.
M. E. Smith, Owens-Illinois, Plastic Products Div., Adams & 14th Sts., Toledo, Ohio
C. J. Spiegl, Continental Can Co., Inc., 7622 S. Racine Ave., Chicago, Ill. 60620
M. C. Stone, Eastman Chemical Prods., Inc., Box 431, Kingsport, Tenn. 37662
F. C. Stroehlein, Emery Industries, Inc., 4900 Este Avenue, Cincinnati, Ohio 45232
D. F. Thompson, R & D Division, AviSun Corp., Post Rd., Marcus Hook, Pa. 19061
M. F. Tietze, Airco Chemical & Plastics Div., Air Reduction Co., Inc., Murray Hill, New Jersey 07971
F. A. Weber, Shell Chemical Co., 113 W. 52nd St., New York, N. Y. 10019
W. M. Westveer, The Dow Chemical Co., 433 Building, Midland, Michigan 48640
G. F. White, Jr., Reynolds Metals, 10th & Byrd Sts., Richmond, Va.
A. G. Whitney, W.R. Grace & Co., Research Div., Clarksville, Md. 21029
D. L. Worthing, Geigy Chemical Corp., Ardsley, N. Y. 10502
Charles L. Condit, Secretary, SPI, 250 Park Ave., New York, N. Y. 10017

Under the direction of George W. Ingle, Monsanto Company, a regular meeting of the SPI Food Packaging Materials Committee convened in the Americana Hotel, New York City, at 9:30 a.m.

Referring to a detailed agenda circulated prior to the day's session, Mr. Ingle, as a first order of business, asked for the usual self-introductions.

Minutes Last Meeting Approved

By way of reminder, Chairman Ingle noted that the last full meeting of the Committee was held in New York City on February 16; that shortly thereafter minutes of the business session were circulated. He then asked if there were any additions or

corrections to the minutes of the February meeting. There being none, Mr. Ingle declared the minutes approved as circulated.

Roster of Committee to be Revised

Mr. Ingle pointed out that with the Secretary's last meeting announcement each addressee was asked to return a form on which he was requested to indicate whether he wished to be retained as a permanent member of the group or not. In order to obtain a further indication of those present at the meeting as to who would like to be on the permanent roster, each was asked to designate either in the affirmative or negative when the attendance record was circulated. Further steps to make the Committee mailing list current and reflective of true interest will be undertaken in due course.

Reports on Liaison With Other Organizations

Mr. Ingle then called for the customary liaison reports on activities of other associations of particular interest to the Committee. The same were given as indicated below:

Synthetic Organic Chemical Manufacturers Association (SOCMA)

Mr. W. P. Munro, American Cyanamid Company, delivered the following status report on the pertinent activities of SOCMA:

"In the Federal Register of August 4, 1967, the FDA issued a proposed regulation for safe use of synthetic organic colorants in food packaging paper and paperboard. It embodied wide changes from what was expected, based on Food Additives Petition 367 submitted by the Food Additives Committee of SOCMA.

"The proposed regulation provides that synthetic organic colorants may be safely used in paper or paperboard destined for contact with food under one or more of the situations in subparagraphs 1, 2, 3, and 4 of the text, and all colorants must conform to a subparagraph 5 dealing with adjuvants in the colorants. The first three subparagraphs, simply restated, are: 1) that there is a functional barrier between the colored paper and the food; 2) that the color is already listed as a color additive for food use by an existing regulation (certified food colors), and; 3) that the colored paper or paperboard contacts only dry food.

"The fourth subparagraph contains in it four conditions, and it is believed that all four of these must be met. They are: a) that the colorant is applied prior to the sheet-forming operation (beater dyeing); b) that the paper is not used in contact with food containing over 2% of drainable liquid by weight; c) that it passes an extraction test (already widely known as the sandwich test); and d) that the colorant passes a discoloration test (better referred to as the stability test). These last two tests are essentially as they appeared in Food Additives Petition 367, except that the food simulating solvents are reduced to three- water, 1% citric acid in 20% sucrose solution, and lard oil.

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"The fifth situation, which all colorants must meet, is that the colorant contains only useful adjuvants that a) are already permitted as direct food additives under subpart D of the existing regulations; or b) are already permitted in paper or paperboard under subpart F (indirect food additives).

"The proposed regulation then defines the test methods, the food simulating solvents and the foods that they simulate, and a special procedure for the fluorescent brighteners. The proposed regulation does not mention it, but it is presumed that the cancer clause in the Food and Drug Act dominates, so that no colorant having any record of carcinogenicity is permitted, even if it passes the conditions of the proposed regulation.

"The Food Additives Committee of the SOCMA met shortly after the proposed regulation appeared, the general feeling of its members being that it was acceptable in most respects but seemingly unduly restrictive as to the adjuvants part and unworkable in one detail of the test for stability in lard oil. A formal objection letter was sent to the FDA on August 21. It was proposed there that Subparagraph 5, covering adjuvants, be deleted as unduly restrictive and unnecessary (difficult to enforce also), or, failing that, that it be greatly liberalized since many of the common adjuvants are already authorized for use in contact with food under other situations such as in cellophane.

"Many of the implications of the new proposed regulation are obvious, but some comments would appear to be in order. First of all, note that there is no naming of the colorants that are permissible, or otherwise. This places the responsibility on the dye manufacturer and the user, where it ought to be. A permitted status to those colorants already approved for direct addition to food and in paper or paperboard intended for use in contact with dry food only has been considered common sense policy all the while.

"Subparagraph 1, permitting the colored paper generally where there is a functional barrier between the paper and the food, should provide safety by definition. Exactly what is a functional barrier will probably have to be thrashed out later, but at least the intent there is both to define one permitted use, where there is actually no food additive situation anyhow, and to cover many uses where there is impermeable film between the paper and liquid foods. Paper would not generally be used for containing liquid foods without such a functional barrier.

"Dr. C. B. Shaffer, Central Medical Department of American Cyanamid Co., has separately filed an objection, actually a recommendation that a coating, otherwise permitted for paper, be deemed a functional barrier if the colorant passes the extraction and discoloration tests.

"The API has also filed, asking that colorants, merely for tinting white paper, be permitted without further restriction.

"In Subparagraph 4, the one with four restrictions, there may be some cases where hardship is involved because a color has been customarily applied by a surface sizing or calender staining operation. It is too early to say what this will amount to. The restriction involving not more than 2% drainable liquid in the food was, I believe, a surprise to

"us. I am sure that numerous questions will turn up on this score. The extraction and stability tests are, as stated above, pretty much what the SOCMA Committee had already recommended to the FDA.

"One seeming injustice is that a color may not be used if its stability is less than 90% under the prescribed conditions in all three food simulating solvents. Although I did not say so above, this has also been objected to. If a paper were used solely for non-acid foods, it would seem unfair to deny its use because it had some instability in actual acid solution.

"One could list many comments in the matter of adjuvants. My personal opinion is that no risk to human health is involved from any of the adjuvants used and that most of them, if not all, can be recognized and permitted by the FDA without much struggle. For instance, the sodium salt of a compound may already be permitted and the ammonium salt not. Or the adjuvant may be permitted in the surface of cellophane used for wrapping food, or on cotton textiles for that purpose, but not in paper. One real difficulty about adjuvants is that some of them are purchased and used only by trade name so that the dye manufacturer does not know what they actually consist of and may not even be able to find out. It is difficult to say just how this will shape up.

"Some features about dye adjuvants present very difficult problems which it is hoped the FDA will recognize. For example, suppose colored paper for wrapping oranges comes from Spain. Who knows what adjuvant was in the original colorant, and how would one go about finding out? Also, if the adjuvant has to pass the migration test and is colorless, and the stability test, and no assay exists for the extremely small quantities involved, then what?

"I should be glad to try to answer any questions on this subject. Thank you.

W. P. Munro"

At the close of Mr. Munro's report, there was a great deal of cross-discussion regarding the SOCMA Petition. As far as SPI's direct interest in the matter is concerned, Mr. Jerome H. Heckman, SPI Counsel, pointed out that he had circulated the proposed SOCMA Regulation under cover of his letter of August 11, 1967, and that, based on the limited responses received to this letter and discussions held with various parties, including those most directly involved in the SOCMA situation, the Steering Committee had concluded that no SPI comments should be filed.

Mr. Heckman noted that the basic reason for the decision against any SPI participation in the SOCMA rule-making proceedings were the indications that the Committee had obtained from SOCMA and the paper people to the effect that they were generally satisfied with the regulation and would like to see it finalized, although with some slight modifications, as pointed out by Mr. Munro.

Mr. Heckman further noted that, on the basis of the information given him, he had concluded that the only comments SPI might have filed in conjunction with this matter were comments that would have been in the nature of an opposition to the regulation in principle. Such a position might have been advanced on the grounds, among others, that the proposed regulation will do little more than purport to govern things which are not properly subject to regulation under the Food Additives Amendment. This, for example, would be particularly true with regard to the proposal to regulate colorants in situations where a "functional barrier" exists between the colorant and the food product.

In effect, the decision of the Steering Committee was that SPI should not interpose objections of such a general nature using the SOCMA Petition and proposed regulation as a base for such action. Furthermore, since it did not appear that comments advocating extending the coverage of the regulation to plastics substrates would be in order under all of the circumstances, the Steering Committee decided to forego any filing.

There were several questions about the use of pigments in plastics generally as an aftermath of Mr. Munro's report and Mr. Heckman's explanation about why SPI did not file comments in the proceeding. Among other things, this discussion led to a reiteration of the purposes of our own Pigments Task Group work. It is hoped that the work of this Group will place the Committee in a position where it can publish an authoritative SPI manual on suitable extraction methods which, in the opinion of the Committee, would permit a plastics manufacturer to conclude that any pigment which fails to yield measurable extraction according to the sensitivity of the test methods may "not reasonably be expected to become a component of food" and, therefore, need not be cleared under the Food Additives Amendment.

It was noted that a determination of whether this will be possible must await completion of the work of the Pigments Task Group and, it was specially emphasized, that the SPI approach does not envisage asking for any direct Food and Drug Administration approval of any position the Committee takes. In other words, if the Committee is satisfied with the results ultimately achieved by the Pigments Task Group, SPI will take an "industry" position on the matter which individual companies will be free to adopt or reject as they choose.

In this important regard, the SPI approach to the entire problem of colorants for use in plastics differs substantially from the SOCMA approach. SPI's effort aims at reaching an independent conclusion supported by substantial data that packaging colorants meeting certain criteria are not subject to the regulatory provisions of the Federal Food Drug and Cosmetic Act. On the other hand, SOCMA has deemed it in its best interests to obtain formal FDA "approval" for colorants to be used in paper products.

American Paper Institute

Chairman Ingle next called upon James R. S. McCartney, Standard Packaging Corporation, to give a report covering liaison with the American Paper Institute. Mr. McCartney delivered the following report:

> "There has been no interest on the part of the API member companies in filing comments on the FDA's Guidelines for Food Additive Petitions. The paper companies feel that they are not equipped to clear new products for their own use in paper or board for food packaging, and prefer to rely on the large chemical companies who would be able to sell such cleared products throughout the industry.

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"The SOCMA Dye Additives Committee of the API has proposed that the regulation providing for the use of synthetic organic colorants in food packaging paper and paperboard be extended to include the use of tinting colors. Tinting colors are used to maintain a commercially acceptable uniformity of tint or color in white and natural colored paper and paperboard. They do not really 'dye' the paper but just change the color slightly. They are used at very low concentrations. Tinting colors had been included in the original SOCMA Petition and the API is requesting that a new subparagraph relating to their use be included."

In commenting generally on Mr. McCartney's report, it was indicated to all of those present that, while the Committee can perhaps understand the reluctance of companies in the paper industry to comment on some of the areas of concern at the Food and Drug Administration for the reasons Mr. McCartney outlined, our Committee would certainly be grateful if, in any given situation, groups like the American Paper Institute saw fit to support SPI's comments or filings in any proceeding of broad general interest. For example, it was noted that should API see fit to support the SPI comments on the FDA Guidelines, or the comments the Society might prepare in response to the recent Proposed Rule Making governing new "Procedural Regulations," this type of action would be most welcome and could be helpful to lend support for much needed reformation of FDA's policies and procedures. Obviously, any other organization which might care to give such support on the basis of its review of SPI positions should also be encouraged to do so.

Can Manufacturers Institute

Speaking on behalf of the Can Manufacturers Institute, Charles J. Spiegl, Continental Can Co., Inc., delivered the following status report:

"The Food Additives Advisory Committee of the Can Manufacturers Institute studied the 'FDA Guidelines' and concluded that the SPI comments could not be improved upon. Consequently, a letter to this effect was sent to Dr. Goddard and L. L. Ramsey of the FDA. An acknowledgement was received from Mr. Ramsey. There has been no other action of note by the CMI."

SPI Food and Drug Bottling Committee of the Plastic Bottle Division

Matthew E. Smith, Owens-Illinois, delivered the following status report on those activities of the SPI Food and Drug Bottling Committee of the Plastic Bottle Division which are of particular interest to the overall Food Packaging Materials Committee:

"Since our last meeting in February, we have had two general meetings of the Food and Drug Bottling Committee and several interim meetings regarding the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. As a result of these meetings, a formal reply was drafted and sent to the Hearing Clerk of the Department of Health, Education and Welfare in Washington, D.C.,over Bill Cruse's signature, on May 2. Some of the suggestions we asked for were incorporated in the final draft of the regulation.

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"Rather than take time at this meeting to go over the specifics of this Labeling Act, I'll be happy to answer any questions at the end of the meeting."

Pharmaceutical Manufacturers Association

By way of background, Chairman Ingle said that for some years now the SPI Committee has maintained close liaison with the Pharmaceutical Manufacturers Association, principally through Dr. A. W. Downes of Union Carbide Corporation, As pointed out later in the meeting, Dr. Downes has now retired from Union Carbide and will no longer be the liaison representative, but W. B. Ackart of Union Carbide Corporation has accepted the responsibility for continuing the liaison between SPI and PMA which revolves principally around a cooperative testing program.

Dr. Ackart then delivered the following report:

"The cooperative SPI-PMA bottle testing program has been completed, and results were discussed at a Task Group meeting held on July 13, 1967 at the UCC building in New York. Present for the PMA were Messrs. Hilty and Breunig of Eli Lilly, and for the SPI,Messrs. Pinsky and Signore of Monsanto, Smith of Owens-Illinois, and Downes and Ackart of UCC.

"The testing program consisted of an evaluation of bottles made from high density polyethylene, polypropylene, ethylene-butene copolymer, and high density polyethylene pigmented with titanium dioxide. Tests performed included acute systemic toxicity, heavy metals, non-volatile residue, water transmission, light transmission, and eye irritation. Participating laboratories included Hercules, Monsanto, Owens-Illinois, Phillips, UCC, Lilly, Merck, Ciba, Norwich, and Abbott.

"Acute systemic toxicity tests and eye irritation tests showed no evidence of toxicity for any sample in any laboratory.

"Heavy metals tests were negative in all cases, and the method seems adequate. Non-volatile residue tests were in general satisfactory although agreement was not as close as one would hope.

"The light transmission test, as written, is completely inadequate. It is essential to specify use of an integrating sphere to collect all transmitted light, including that which is scattered. Otherwise, data is meaningless.

"The water vapor transmission test, as written, is not satisfactory, A revised procedure was presented by Mr. Signore. UCC volunteered to repeat their test following the Monsanto procedure. This has now been done with results agreeing satisfactorily.

"Dr. Hilty stated that the results of these tests were most helpful in that they showed the areas needing improved methodology. He will prepare a draft of a report on this work which will be circulated before release. Target date for the completed report is the end of August. Dr. Hilty provided copies of a publication entitled 'Survey and Application of Interlaboratory Testing T chniques' by B. N. Nelson."

Following Dr. Ackart's report, he was queried as to whether the final report referred to in his statement will be sent to members of the PMA and the SPI; and, further, what next move is to be undertaken in regard to these tests.

The purpose of this activity, Dr. Ackart indicated, is to develop appropriate methodology which will provide means by which interested parties can determine whether or not a certain product is functional. In answer to the inquiry as to whether there would be additional round-robin testing carried out in this particular program between SPI and PMA, Dr. Ackart said that it would depend a great deal on the details of Dr. Hilty's report yet to be received.

Manufacturing Chemists Association
(Food Additives Committee)

Taylor W. Hanavan, E. I. duPont de Nemours & Co., Inc., delivered the following report as the liaison representative with the MCA Food, Drug, and Cosmetic Chemicals Committee:

> "At the September 12, 1967 meeting of MCA's Food, Drug, and Cosmetic Chemicals Committee, the following matters of interest to this Committee were discussed.
>
> "In connection with FDA's advisory panels on reproduction, carcinogenicity, and potentiation protocols, MCA has requested an opportunity to appear before each of these panels to present MCA's views on each of these problems. In this regard, a subcommittee of toxicologists has been established to prepare MCA's recommendations in each of these areas. Preliminary recommendations have been prepared by the Reproduction and Carcinogenicity Subcommittees. There is still some question as to the scope and objectives of FDA's potentiation panel, so that the MCA Subcommittee on Potentiation has made no recommendation at this time.
>
> "Many members of the Committee felt it desirable that MCA, or its members, file comments with FDA concerning the proposed procedural regulations and, more specifically, in connection with the proposed form of food additive petitions. A subcommitee was appointed to assemble comments of Committee members, and develop a recommendation for Committee consideration in this regard. In addition, because of the scope and complexity of FDA's proposals as to petition form, the Committee resolved that MCA should request an additional sixty days for comment to permit the detailed study in depth that a proposal of this type requires."

In commenting further on the information about MCA's decision to request an extension of time in which to file comments on the Food and Drug Administration's newly proposed "Procedural Regulations," Mr. Heckman noted that Mr. Morgan Hoover of the MCA staff had been in touch with him the previous day to effect some liaison on this matter. Mr. Heckman had informed Mr. Hoover that he intended to recommend to the SPI Food Packaging Materials Committee that an extension be requested so he was most pleased to hear that MCA would be moving in this direction.

Mr. Heckman reported that, after their conversation, Mr. Hoover indicated that he would be filing the MCA request for a sixty-day extension immediately. This being the case, Mr. Heckman suggested that an SPI request be filed within the next few days, and that it similarly request a sixty-day extension. (See later discussion for more complete treatment of Procedural Regulations matter and Food Packaging Materials Committee Resolution ordering the filing of a request for a sixty-day extension of the comment deadline date.)

Report of SPI Counsel

Chairman Ingle then called upon Mr. Heckman to give his customary report on matters to be brought to the attention of the group.

(Please Note: Attached hereto as EXHIBIT A is the detailed report delivered by Mr. Heckman at the day's session. As has often been the case in the past, Mr. Heckman did not actually read his prepared report verbatim but, instead, discussed the topics covered in a more general fashion, inviting questions and comments during the course of the presentation.)

Mr. Heckman also provided additional information on subjects which had come to his attention subsequent to the preparation of his report and which he thought might be of interest to the Committee. The topics discussed during Mr. Heckman's report included the following:

Publication of SPI Manual Entitled "Plastics Packaging for Drug Products - The Regulatory Story"

During his discussion, Mr. Heckman announced that publication of the SPI Manual entitled "Plastics Packaging for Drug Products- The Regulatory Story" is underway. The copy is now in "galley" form and has been turned over to the printer with the request that the booklet be printed in quantities of six thousand.

The Secretary was then called upon to discuss the distribution of the booklet. Mr. Condit announced first that all members of the Society, both individual and company, would receive a copy of the publication, as will all members of those committees of the Society especially interested in its contents (e.g., the SPI Food Packaging Materials Committee, and the Plastic Bottle Division). Further distribution of the document will be on a request basis, with the per copy charge yet to be determined.

Mr. Heckman also dealt with the fact that the public relations firm of the SPI Plastic Bottle Division is preparing a "flyer-type" summary sheet which is to summarize the salient features of the document. In all probability, this flyer will accompany each of the Manuals as they are sent out.

FDA "Guidelines for Chemistry and Technology Requirements of Food Additives Petitions" - Status of FDA Consideration of SPI Comments

As is indicated in Mr. Heckman's attached complete report, the Food and Drug Administration Staff is presumably continuing to study the SPI comments on its Guidelines and will, in due course, advise of its reactions, either formally or informally. Mr. Heckman indicated that he would continue to check with the appropriate Staff members at FDA and would keep the Committee advised about any progress in this regard.

New FDA Proposed "Procedural Regulations" -
Relationship to "Guidelines," Food Additive
Petition Policies, Recent Court Decisions, etc.

Here again, Mr. Heckman has given a more detailed report on the FDA proposed "Procedural Regulations" in his prepared statement. (See Exhibit A.) There was some general discussion of the proposal, during the course of which all were reminded that, as Taylor Hanavan reported earlier, MCA will formally request an additional sixty days for comment.

Chairman Ingle then pointed out that, at the previous day's Steering Committee session, a resolution was drafted to be offered for possible approval at the full Committee meeting. He then called upon George T. Scriba, Union Carbide Corporation, who moved the adoption of the following:

> "RESOLVED, that the Society file comments and request a hearing on the Food and Drug Administration's proposed Procedural Regulations, and request an additional 60 days in which to file such comments.
>
> "RESOLVED FURTHER, that the Chairman name a subcommittee to prepare and file such comments.
>
> "RESOLVED FURTHER, that each member of the parent committee send the Secretary his company's comments in writing by October 9th so that they may be considered by the subcommittee."

Robert M. Miller, Hercules Inc., seconded Mr. Scriba's motion and it was carried unanimously.

Chairman Ingle, noting that the motion just carried called for the organization of a new subcommittee to consider comments received by the Secretary on the Procedural Regulations by October 9, announced that the membership of the "Procedural Regulations Subcommittee" would be as follows:

Jerome H. Heckman, Esquire - Keller and Heckman, Coordinator

Taylor W. Hanavan, E.I. duPont de Nemours & Co., Inc.
William A. Knapp, Allied Chemical Corporation
Robert M. Miller, Hercules Inc.
James N. O'Connor, The Dow Chemical Company
George A. Richter, Jr., Rohm & Haas Co.
Charles J. Spiegl, Continental Can Company

In charging the subcommittee, Mr. Ingle noted that this group is to prepare a consolidated presentation on behalf of the overall Committee following receipt of comments by October 9 and, therefore, urged all members to send suggestions and recommendations to the Secretary by the deadline date established.

Impact of "Freedom of Information Act" (P.L. 89-487) -
on Data Submitted in Food Additive Petitions

Again, the discussion by Mr. Heckman on the subject of the "Freedom of Information

Act" [2/] is found in his detailed report which is appended hereto. (See Exhibit A.)

In general, Mr. Heckman's discussion of this matter dealt principally with how the provisions of the regulations applicable to FDA, as promulgated by the Department of Health, Education, and Welfare under the Act, relate to certain portions of the newly proposed FDA "Procedural Regulations." In particular, Mr. Heckman discussed the status of analytical and toxicological data submitted as part of food additive petitions, answering a number of questions in this regard.

Other Matters

Me. Heckman then brought up several miscellaneous matters of interest which he felt should be brought to the attention of the Committee. In addition to those subjects covered in his formal report at the day's meeting (Exhibit A), he pointed out that he had learned informally from FDA officials that the Agency hopes to speed up its paper work because of the greater attention its new "Computer Reports" is focusing on long backlogged petitions.

At this point, George Ingle announced that this year's Food and Drug Administration-Food Law Institute Annual Conference would be held at the Marriott Motor Lodge, Arlington, Virginia on November 27; that anyone interested in attending this meeting is welcome.

Report of Committee Chairman

Chairman Ingle reported that he had recently presented a paper entitled "On Regulating Additives From Food Contact Materials" at the Western Hemisphere Conference on the Importance and Safety of Foods in Mayaguez, Puerto Rico. Mr. Ingle noted that this Conference gave him an excellent opportunity to express his personal philosophies on the whole subject of food additives.

He noted that he had shared the rostrum with speakers from both the Canadian and the U. S. Food and Drug Administrations, and that there had been a most interesting interchange of ideas among those present concerning the subject of incidental additives.

Mr. Ingle said that anyone interested in obtaining a copy of his paper may do so by communicating directly with him.

By way of reminder, Mr. Ingle recalled that at the last meeting action was taken by the Committee in the form of a resolution to urge the establishment of a "government-industry" Advisory Committee on incidental food additive problems. In this regard, he told of a visit that he and Legal Counsel, Jerome Heckman, had made to the FDA offices for the purpose of discussing with Associate Commissioner Kirk the possibility of organizing such an Advisory Committee. Chairman Ingle advised that he and Mr. Heckman had received assurances from Mr. Kirk that the request would be passed along to Dr. Goddard. Associate Commissioner Kirk recommended against submitting any proposal for such a government-industry committee

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2/ The Committee might be interested in an article which appeared in the September, 1967 issue of "FDA Papers" by Joseph M. Mamana of FDA's Office of Policy Management entitled "FDA's Obligations Under the 1966 Public Information Act."

in writing at this time, indicating that it would be best if the idea were first discussed informally in FDA circles with Mr. Kirk taking the responsibility for bringing the matter up. Mr. Kirk indicated that he would let Mr. Heckman know in due course what the reaction might be.

In covering another phase of the overall effort to bring about a more reasonable general FDA attitude on incidental additives problems, Mr. Ingle mentioned a recent letter that Mr. William T. Cruse, Executive Vice-President of the Society, directed to Dr. James L. Goddard, Commissioner of FDA. Citing past instances of Goddard-plastics industry cooperative work, Mr. Cruse indicated to Dr. Goddard that it might be most worthwhile for both industry and government if the Commissioner could take time during one of his trips to New York to meet with a few representatives of the Society for the purpose of informally discussing some problems of great concern in the food packaging regulatory area. It was felt that an informal session in New York, away from the pressures of Washington, might afford a more convenient and relaxed opportunity to focus the Commissioner's attention on some of the more vexing problems that confront the industry in day-to-day dealings with FDA.

Chairman Ingle reported that Dr. Goddard had now contacted Mr. Cruse to indicate that he would be in New York on October 27 and would be glad to meet with a very small group at that time, it being understood that any such meeting would be wholly informal. In commenting further on this meeting, Mr. Ingle pointed out that the Steering Committee agreed with the thought that the meeting with Dr. Goddard should be extremely small so as to assure the type of informality Dr. Goddard desires and that, therefore, it is contemplated that only Messrs. Condit, Heckman, and Ingle will be present as representatives of the Food Packaging Materials Committee. Mr. Ingle further noted that the group which would attend this session has in mind attempting to pinpoint only one or two areas of special concern in the hope that this might bring about a more favorable reaction and, hopefully, some real interest in our problems on Dr. Goddard's part.

As a result of much discussion at the most recent Steering Committee meeting, it is tentatively planned to focus attention on the so-called "no migration" situation, since it is generally felt that rational reform of FDA's presently unacceptable policies in this area would undoubtedly go a long way towards resolving the greatest number of industry problems. Additionally, Mr. Ingle and Mr. Heckman pointed out that the informal group would probably remind Dr. Goddard about the discussion held with Assistant Commissioner Kirk, and thereby restate our interest in the possibility of a government-industry Advisory Committee established with the objective of bringing about much needed reform in FDA policies and procedures as they relate to indirect food additives generally.

Honorary Membership Extended to Messrs.
A. W. Downes and Frederick W. Adams

Chairman Ingle announced that two members of the Committee who were pioneers in the activities of the group since its inception have now retired, namely, Dr. Frederick W. Adams, and Dr. A. W. Downes. He then referred to the recent meeting of the Steering Committee, at which time a draft resolution was drawn up for consideration at the overall meeting, its aim being the extending of proper recognition to these two former Committee leaders.

Mr. Ingle then moved that the following resolution be adopted:

> WHEREAS, Dr. Frederick W. Adams and Dr. A. W. Downes have in recent months retired from active participation in the affairs of Continental Can Company, Inc., and Union Carbide Corporation, respectively,
>
> AND WHEREAS, their retirement has also occasioned their becoming inactive in the affairs of the Food Packaging Materials Committee of The Society of the Plastics Industry, Inc.,
>
> AND WHEREAS, both Dr. Adams and Dr. Downes have made such significant contributions to the work of the said Committee, to the Society, and, in this way, to the plastics industry as a whole, as to warrant special commendation and recognition,
>
> AND WHEREAS, it is the desire of this Committee to pay due respects, and give proper thanks to these pioneering members of our group, as well as to advise them formally that their further participation in the work of the Committee, to the degree they deem possible, would be welcomed,
>
> NOW, THEREFORE, be it resolved that the Food Packaging Materials Committee of The Society of the Plastics Industry, Inc. hereby extends a sincere and unanimous vote of appreciation to Dr. Frederick W. Adams and Dr. A. W. Downes, and hereby elects them to honorary membership on the Committee so that their presence at any meeting, or participation in any work of the Committee, will be wholeheartedly welcomed at any and all times,
>
> AND BE IT FURTHER RESOLVED that a copy of this Resolution be forwarded by the Secretary of this Committee to Drs. Adams and Downes forthwith so that this expression of appreciation, and their election to honorary membership status, will be made known to them.

Robert M. Miller, Hercules Inc., seconded the Resolution as proposed by Mr. Ingle and the motion was carried unanimously.

Synergism Testing

At this point, Chairman Ingle made passing reference to an article appearing in the June 19th issue of Food Chemical News entitled "HEW Task Force Wants Food Additives Tested for Synergism." Quoting from the article, Mr. Ingle described such tests as an effort to "evaluate the sum total of the toxicological effects of a mixture."

Pointing out that the subject of synergism could open the door to endless consideration of scientific data included in petitions, Chairman Ingle noted that the HEW Task Force's recommendations bear watching, but should not cause undue concern at this point since the scope of the Food Additives Amendment of 1958 does not envisage a requirement for any such data as of the moment.

Report of Lawyers Advisory Subcommittee

Chairman Ingle then called upon George T. Scriba, Esquire, Union Carbide Corporation, Chairman of the Lawyers Advisory Subcommittee.

Proposed Revisions of Committee By-Laws

By way of reminder, Mr. Scriba noted that for some time now he has coordinated an effort to study the possibility of revising the By-Laws of the SPI Food Packaging Materials Committee, principally to study a proposed change in the title of the Committee to reflect more adequately the projects which it undertakes.

Mr. Scriba then presented the following "final report" from the Lawyers Advisory Subcommittee on the proposed revisions of the Committee Bylaws:

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

ARTICLE I - NAME

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

ARTICLE II - OBJECTIVES

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

"(a) To constitute a Committee within the Society, in accordance with its Bylaws and Rules, to be informed on the application to plastics of the Federal Food, Drug, and Cosmetic Law, the Federal Meat and Poultry and Seafood Inspection Acts and similar laws, and any regulations adopted under them.

"(b) To represent and speak for the Society on behalf of the industry before the Federal Food and Drug Administration and the other administrators.

"(c) To collect such information on food, drug, and cosmetic packaging and allied subjects as may be appropriate or needed for any particular proceeding, hearing, or presentation made by the Society on behalf of the industry.

"(d) To collect and disseminate among the members of the Society information concerning matters of food, drug, and cosmetic packaging, and allied subjects of interest and, in connection therewith, to publish bulletins, conduct surveys and research projects appropriate to the plastics food, drug, and cosmetic packaging industry's needs and functions.

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

"We recommend that the name of the Committee be changed, accordingly, throughout the Bylaws.

"We note that Article VII of the Bylaws reads in full as follows:

ARTICLE VII - AMENDMENTS

"Section 1 - These Bylaws may be amended, supplanted, or repealed by a majority vote of the members present at any duly constituted meeting of the Committee, provided the proposed change is fully indicated in the proper notice for the meeting.

"We recommend that these proposed changes in the Bylaws be 'fully indicated' in the notice of the next meeting of the Food Packaging Materials Committee."

Members were reminded that, according to the Committee Bylaws, it would not be possible to vote at the day's session on the proposed revision because the Bylaws provide that any proposed revisions are to be circulated prior to the meeting at which they are to be considered and voted on. For this reason, the matter of changing the name of the Committee, and certain paragraphs in Article II of the Bylaws concerning the Committee's "objectives", will be formally considered at the next meeting of the overall Committee.

Please Note: The previously outlined proposed revisions of the Committee Bylaws are to be considered formal notice that this matter will be taken up at the next meeting.

Report of Technical Information Subcommittee

Chairman Ingle next introduced Robert M. Miller, Hercules Inc., Chairman of the Technical Information Subcommittee.

Mr. Miller reported that the principal project now being undertaken by the Technical Information Subcommittee deals with the activities of the Pigments in Plastics Task Group headed by Arnold Finestone, Foster-Grant Company, Inc.

Mr. Miller then made reference to the customary listing of recently issued Food Additive Regulations which he prepares for attachment to the minutes of the meeting. He noted that these listings include not only new regulations but also amended regulations, proposed regulations, withdrawals of petitions, and Notices of Filing deemed of interest to the SPI Food Packaging Materials Committee.

Please Note: Attached hereto as EXHIBIT B is a listing dated September 15, 1967 prepared by Mr. Miller and entitled "Recently Issued Food Additive Regulations."

At this point, Mr. Miller discussed certain of the recently issued Food Additive Regulations which were of particular interest to the Committee. (See Exhibit B attached.)

Pigments in Plastics - Pigments Task Group Report

Mr. Miller then introduced Arnold B. Finestone, Foster-Grant Company, Inc., the Chairman of the Pigments Task Group Subcommittee dealing with the pigments in plastics project.

By way of reminder, Dr. Finestone said that the principal activity of his Pigments Task Group has been a research study using atomic absorption spectrophotometry as an analytical technique for determining trace quantities of inorganic pigments.

As pointed out by Dr. Finestone at the last meeting, fourteen companies participated in the preparation of pigmented specimens from seven polymers. Several pigments, namely chromium oxide, mercadium red, medium cadmium red, and sun yellow C, were used at two levels. The specimens were then extracted, concentrated, and assayed by Jarrell-Ash. Dr. Finestone then announced that a session of the Pigments Task Group was held on the previous day and, in this connection, gave the following report:

> "Since the February meeting of the Food Packaging Materials Committee, the extraction work was completed and the raw analytical data obtained from the atomic absorption work carried out by Jarrell-Ash. This data, in its initial form, was submitted to the Pigments Task Force for review and was the basis of a meeting held by this Task Force on September 19, 1967. The data, at this point, left several questions to be resolved, but in general showed good correlation between the various laboratories. In order to resolve the sensitivity of the test procedures for the various materials involved, and to determine what further work is required to arrive at our originally defined goal, a Subcommittee to the Pigments Task Force has been established and consists of Harshaw Chemical Company, Monsanto, and Foster Grant Co., Inc.
>
> "At the present time, our initial results indicate that cadmium can be measured at the current level of concentration of the extracted solutions at the 10 ppb. The other metals, copper, chromium, nickel, and mercury, may require further concentration in order to reduce the noise level of the equipment used to analyze these metals.
>
> "As we all know, the task carried out to date was quite extensive and required considerable effort on the part of the Pigments Task Force. I would, therefore, like to express my own personal thanks for the speed and thoroughness which was exhibited by the participating members in this effort."

In the discussion that followed, Dr. Finestone reiterated the fact that the principal aim of this activity is to arrive at a methodology which will enable any company interested in using the method to determine for itself that there is no measurable pigment extraction in a given application according to the sensitivity of the method.

In further discussing the raw data now available to the Pigments Task Group, Dr. Finestone revealed that the accuracy of the .01 ppm (i.e., 10 ppb) range was estimated by Jarrell-Ash to be between plus or minus 2-10% depending on the element analyzed. These figures are based upon calibration curves prepared from known standards.

At the conclusion of Dr. Finestone's remarks, it was again noted that the ultimate objective of this activity is to develop an SPI manual which will contain a recommendation for test methodology that will, in SPI's view, allow individual companies to determine whether or not there is measurable extraction of a colorant in a given plastics use according to the sensitivity of the method. (See Mr. Heckman's remarks above, following Mr. Munro's report on the SOCMA Petition.)

In some of the discussions which arose after Dr. Finestone's report it was pointed out, among other things, that the Food and Drug Administration has confirmed the fact that so-called FD & C or D & C colors may be used in food packaging applications, so long as such use does not result in a given color being present in a food at a level higher than the tolerance established by FDA, and so long as the pigment does not color the food in a way that would be visible to the naked eye.

In response to another question, Mr. Heckman pointed out once more that, while it has generally been true that FDA has raised no questions about the use of FD & C colors or D & C colors in drug packaging, it cannot be said categorically that such colors may be used in any drug package. As is the general case with the drug packaging situation, FDA, in approving a new drug on the basis of a New Drug Application, passes on all phases of the matter and in so doing decides whether any component or an entire package is suitable for the specific intended use or not.

International Developments

Mr. Ingle noted that the Committee, at the end of each of its business sessions, conducts a general discussion and exchange of information on international developments. He then asked whether there were any comments at the day's meeting on such international developments which would be of interest to the members.

Jerome H. Heckman reported that Spain has adopted, but to the best of his knowledge not yet published, a new Food Code (August 18, 1967) which will cover a wide variety of matters including the general subject of food packaging materials.

Taylor Hanavan, E.I. duPont de Nemours & Co., Inc., pointed out that the Committee should be alerted to the fact that there is every possibility that the Codex Alimentarius Commission could come to some sort of international approval list which would have great impact on food packaging, especially for companies with export business. (See Mr. Heckman's report delivered at the February 16th meeting of the Committee under that section entitled "The Codex Alimentarius Commission and its New Interest in an Initiative on Indirect Additives.")

Robert M. Miller indicated that the British are still considering what, if anything more, they are to do about indirect food additives. He added that Jack Frawley of his company will be in attendance at a meeting to be held in England soon on this subject. It is anticipated that the "Frawley" approach to the indirect additive question generally, will be given careful consideration by the British authorities. Members will recall that copies of Dr. Frawley's paper advancing his theory that most indirect additives should be considered "generally recognized as safe" if they are used at specified low levels, have been previously circulated to the Committee.

Mr. Miller pointed out that we might very well watch developments in England on this score with great interest since, obviously, if the "Frawley" approach were to be adopted in the United Kingdom in some form or another, this could have a salutory influence on other countries, including perhaps even the United States.

The membership was reminded about the proposed Dutch regulations to govern incidental additives, and a question was raised as to whether any of those present knew of any comments having been filed in response to the Dutch request for recommendations. (As pointed out at the last meeting, the Dutch are holding the matter open for comment until December 23 of 1967.) It was indicated by several of those present that comments had been filed with the Dutch government, presumably through their Dutch subsidiary companies, so that appropriate views on the proposals are being made known.

Other Business

There was no further business offered for discussion at the day's meeting, except that Mr. Heckman asked for and obtained agreement from the members of the new FDA Procedural Regulations Subcommittee that their first meeting be held on Tuesday, October 17, 1967, in Mr. Heckman's office in Washington, D. C.

Next Meeting

Mr. Ingle announced that, as usual, the dates and site for the next meeting of the full Committee will be left up to the Steering Committee, depending on developments in the regulatory and technical areas. He did point out that the Steering Committee may have a better idea as to when the next meeting should be held after the anticipated informal luncheon with Dr. Goddard on October 27.

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

Respectfully submitted,

Charles L. Condit
Secretary

CLC:ilf
Encls.

EXHIBIT B

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE
SPI FOOD PACKAGING MATERIALS COMMITTEE

September 15, 1967

Recently Issued Food Additive Regulations

The following final new food additive regulations, amended regulations, proposed regulations, withdrawals of petitions, and notices of filing, deemed of interest to the SPI Food Packaging Materials Committee, have been published in the Federal Register since our February 16, 1967 meeting:

SECTION	TYPE	DATE	SUBJECT
---	Filing	2/16/67	Provide for 2,2'-methylenebis (4-methyl-6-nonylphenol) and 2,6-bis(2-hydroxy-3-nonyl-5-methylbenzyl)p-cresol as antioxidants and/or stabilizers in acrylonitrile-butadiene-styrene resins
121.2520	Filing	2/16/67	Amend to provide for use of polyester adipic acid, phthalic acid and propylene glycol
121.2553	Amendment	2/16/67	Provide for use of isopropyl oleate as an adjuvant in mineral oil lubricants used with incidental food contact. Originally proposed to provide for similar use of polyisobutylene, but this proposed use withdrawn
121.2507	Amendment	2/16/67	Provide for the use of additional optional substances; originally proposed to provide for dibehnyl ketone, di(2-ethyl-butyl) phthalate, dihydroabietyl phthalate and glyoxal, but this proposed use was withdrawn
121.2507	Amendment	2/16/67	Amend to provide for the use of polybutadiene resin in food packaging cellophane with certain limitations
121.2522	Withdrawal	3/2/67	Polyurethane resin as a coating on articles intended for repeated use in contact with non-alcoholic foods

SECTION	TYPE	DATE	SUBJECT
---	Filing	3/2/67	To provide for the use of di(n-octyl) tin S,S'-bis-(isoctylmercaptoacetate) and di (n-octyl)tin bis-maleate as stabilizers used alone or in combination at levels not exceeding a total of 3 pph of the several vinyl polymers that are intended for use as articles or components of articles that contact food.
121.2526	Amendment	3/2/67	Provide for the use of n-alkylsulfonate as an emulsifier for vinylidene chloride copolymer coatings for paper and paperboard intended for use in contact with aqueous and fatty foods
---	Statement of Policy on Labeling	3/2/67	Aspirin--includes recommendation concerning safety closures
121.2511 and 121.2526	Filing	3/4/67	Amend plasticizers in polymeric substances by substituting a 17% maximum limit of addition of butyl benzyl phthalate. Also proposed to add to paragraph (a) (5) and remove from (b) (2) of 121.2526
121.2507	Withdrawal	3/14/67	Stearamido-ethyl stearate as a component of vinylidene chloride coatings on cellophane
121.2514	Withdrawal	3/15/67	Allyl alcohol in the production of resinous and polymeric coatings
121.2541, 121.2506, 121.2507, 121.2525, 121.2531, and 121.2557	Amendment	3/15/67	Provide for the use of sorbitan monolaurate as an emulsifier and/or surface-active agent in the manufacture of articles intended for use in contact with food. Also delete references to sorbitan monolaurate from 121.2506, 121.2507, 121.2525, 121.2531 and 121.2557
---	Proposal	3/17/67	FDA proposed regulations on required label statements for foods under FPIA.
121.1142	Amendment	3/22/67	Add to Subpart D: Oxidized polyethylene as a component of food with certain restrictions
---	Withdrawal	3/25/67	Provide for the use of N-alkyl (C_{14}-C_{18})-1,3-propanediamine-N,N',N'-triacetic acid as an antioxidant and/or stabilizer in certain polymers for food-contact use

SECTION	TYPE	DATE	SUBJECT
---	Withdrawal	3/25/67	Provide for the use of 2,2'-di-tert-butyl-4,4'-isopropylidene-diphenol bis (p-nonyl phenyl) phosphite as an antioxidant and/or stabilizer in certain polymers for food-contact use
191.	Proposal	4/5/67	Amendments to the hazardous substances regulations to prescribe requirements, exemptions and procedures reflecting the "banned hazardous substances" and other provisions of the Federal Hazardous Substances Act
121.2532	New Regulation	4/5/67	Provide for the use of chlorinated polyethylene as articles or components of articles for food-contact use within certain limitations.
121.2548	Withdrawal	4/7/67	Provide for the use of polyvinyl butyral as a component of zinc-silicon dioxide matrix coatings for food-contact use
121.2514 and 121.2564	Amendment and New Regulation	4/7/67	Delete from paragraph (b) (3) (xviii) "Ethylene-acrylic acid copolymer containing ***." Also add to 121.2564 ethylene-acrylic acid copolymers for use as components of articles intended for use in contact with food with certain limitations
121.2520, 121.2526, 121.2562, and 121.2571	Amendment	4/7/67	Delete 1,2-dihydro-2,2,4-trimethylquinoline, polymerized as a component of certain food-contact articles from paragraphs (c) (5) of 121.2520, (a) (5) of 121.2526, (c) (4) (iii) of 121.2562, and (b) (2) of 121.2571.
121.2517, 121.2507, 121.2526, 121.2571, and 121.2577	Amendment	4/11/67	Provide for additional uses of oxidized polyethylene as a component of food-contact articles with separate regulations (121.2517) Other regulations have been revised to provide for specific uses
121.2526	Filing	4/13/67	Provide for the use of styrene-butadiene-acrylonitrile-methacrylic acid copolymers as components of the food-contact surface of paper and paperboard with certain limitations

SECTION	TYPE	DATE	SUBJECT
---	Filing	4/19/67	Provide for use of tetra-hydrophthalic anhydride as a curing agent for epoxy resins used as articles or components of articles for repeated food-contact use
121.2550	Withdrawal	4/19/67	Polyoxyethylated (20 moles) oleyl alcohol in manufacture of closure-sealing gaskets for food containerswhen used at levels not to exceed 1% by weight of the gasket composition
121.2514	Amendment	4/19/67	Provide for use of ethyl acrylate-styrene-methacrylic acid copolymers and ethyl acrylate-methyl methacrylate-styrene-methacrylic acid copolymers as modifiers for epoxy resins
121.2520	Amendment	4/20/67	Provide for use of additional optional substances in the formulation of food-packaging adhesives
121.2522	Amendment	4/20/67	Provide for use of 2,2-dimethyl-1,3-propanediol and polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2-4 moles of propylene oxide) as reactants in preparation of polyurethane resins that contact dry bulk food
121.2511	Amendment	4/20/67	Provide for use of 2,2,4-trimethyl-1,3-pentanediol diisobutyrate as a plasticizer in cellulosic plastics
121.2574	Filing	4/25/67	Provide for use of monochlorobenzene as a solvent in production of polycarbonate resins for food-contact use
121.2566	Filing	4/25/67	Provide for use of calcium myristate and zinc palmitate as antioxidants and/or stabilizers for polymers
---	Filing	4/25/67	Provide for cyanoguanidine-formaldehyde resins as a drainage aid in manufacture of paper and paperboard used for packaging dry, aqueous and fatty foods
---	Filing	4/25/67	Provide for use of N,N-bis(2-hydroxyethyl) n-alkyl (C_{14}-C_{13}) amine as an antistatic agent in vinylidene chloride copolymer coatings

SECTION	TYPE	DATE	SUBJECT
---	Filing	4/25/67	Provide for use of dodecanolethylene oxide (9.5 moles) condensate as an antistatic agent in polyolefin films for food-contact use
121.2576	Withdrawal	4/25/67	Amendment to provide for use of 1,4,5, 6,7-7-hexachlorobicyclo-(2.2.1)-5-heptane-2,3 dicarboxylic acid (as a reactant) and 2-methyl hydroquinone (as an inhibitor) in production of cross-linked polyester resins for repeated food-contact use
121.2574	Filing	4/25/67	Provide for vinylidene chloride copolymer food-contact coatings on substrates of polycarbonate resins that comply with 121.2574
---	Filing	4/28/67	Provide for use of certain synthetic alcohols for use in food and food-contact surfaces
121.2542	Withdrawal	4/28/67	Amendment to provide for use of tri-ethylenetetramine to replace all or part of the diethylenetriamine used in formulating polyamide-epichloro-hydrin resins
121.2527	Withdrawal	4/28/67	Amendment to provide for certain sub-stances as antistatic and/or antifogging agents in polyolefin, polyvinyl chloride and polystyrene food-contact articles
121.2566	Amendment	4/28/67	Delete specific restriction on the use of tris(2-methyl-4-hydroxy-5-tert-butyl-phenyl) butane as an antioxidant and/or stabilizer at levels not to exceed 0.1% by weight of olefin and/or vinyl chloride polymers
121.2521	Amendment	4/28/67	Provide for use fo vinyl chloride-propy-lene copolymers as components of articles intended for use in contact will all types of foods including foods containing free fat or oil or more than 8% alcohol
121.2514	Amendment	4/28/67	Provide for use of dibutyl phthalate, 4,4'-methylenedianiline, salicylic acid, and styrene oxide as components of epoxy resins

SECTION	TYPE	DATE	SUBJECT
121.2526	Filing	5/4/67	Provide for the use of glyoxal as an insolubilizing agent
121.2566	Amendment	5/12/67	Provide for use of tetrakis[methylene-(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane as an antioxidant and/or stabilizer in olefin polymers
121.2507	Filing	5/13/67	Amend to provide for the use of 2-stearamido-ethyl stearate as additional component of cellophane
121.2501	Filing	5/13/67	Amend to provide for use of poly (4-methyl-pentene-1)
121.2553	Filing	5/13/67	Amend to provide for use of polyisobutylene (viscosity average molecular weight 35,000-140,000 (Flory)) as a thickening agent in mineral oil lubricants
121.2514	Filing	5/13/67	Amend to provide for use of di(n-octyl) tin S,S'-bis (isooctylmercaptoacetate) as a curing catalyst for methyl-phenyl-polysiloxane used in resinous and polymeric coatings
121.2569	Amendment	5/16/67	Provide for the use of a-methyl-styrene-vinyltoluene copolymer resins as components of food-contact coatings for polyolefin films
121.2510	New Regulation	5/16/67	Provide for use of polystyrene and rubber-modified polystyrene
121.2514	Amendment	5/16/67	Provide for use of ethylene-isobutyl acrylate copolymers
121.2526	Filing	5/18/67	Amend (b) (2) to provide for use of liquid methylhydrogenpolysiloxane
121.2574	Amendment	5/27/67	Provide for manufacture of polycarbonate resins for food-contact use by alternate method set in paragraph (a) (2)
121.2543	Filing	5/30/67	Amend to provide for use of kraft paper in the packaging of flour to be irradiated with gamma radiation from cobalt 60 or cesium 137 for insect control in pre-packaged flour

SECTION	TYPE	DATE	SUBJECT
121.2589	Withdrawal	6/2/67	Provide for the use of homopolymers and copolymers derived from one or more of the methacrylic esters of 1-dodecanol, 1-tetradecanol, 1-hexadecanol, and/or octadecanol as adjuvants added to mineral oil subject to the provisions of paragraphs (b) and (c)
121.1148	Filing	6/2/67	Provide for use of sulfonated tetra-polymer of styrene, divinylbenzene, acrylonitrile and methyl acrylate in the purification of foods including potable water
121.2520	Amendment	6/2/67	Provide for the use of an additional optional substance--polyester of adipic acid, phthalic acid, and propylene glycol, terminated with butyl alcohol--in the formulation of adhesives
121.1148	Amendment	6/2/67	Provide for the use of an ion-exchange resin system specified for removing undesirable anions and cations from potable water
121.2502	Filing	6/6/67	Amend regulation to change the maximum extractable fraction in selected solvents for nylon 11 resins listed in that section
121.2526	Filing	6/6/67	Provide for petroleum alicyclic hydro-carbon resins as modifiers in wax-polymer blend coatings for corrugated paperboard containers under specified conditions
121.2543	Amendment	6/10/67	Provide for use of additional substances as packaging materials that may be subjected to radiation in the radiation preservation of prepackaged foods
121.2520 and 121.2582	Amendment	6/10/67	Provide for use of ethylene-methacrylic acid-vinyl acetate copolymers and/or their ammonium, calcium, magnesium, sodium and/or zinc-partial salts as articles or components of articles intended for use in contact with food
121.2522	Filing	6/14/67	Amend to provide for use of 1,3-butylene glycol and the alcholysis product of pentaerythritol and linseed oil as optional components of polyurethane resins

SECTION	TYPE	DATE	SUBJECT
121.2520	Amendment	6/14/67	Provide for use of additional optional substances
121.2508 and 121.1208	New Regulations	6/16/67	Provide for the use of 4-Hydroxy-methyl-2,6-di-tert-butylphenol as a direct additive to food and for its use as antioxidant in food contact circles
121.2562	Filing	6/20/67	Provide for the use of trisnonyl phenyl phosphite formaldehyde condensation product as an antioxidant in rubber articles
121.2585	Withdrawal	6/21/67	Amendment to provide for use of glycydil esters of dimerized and trimerized fatty acids derived from linoleic acid as optional components of thermosetting epoxy resins used in beverages containing a limited amount of alcohol
121.2550	Filing	6/21/67	Provide for use of oleyloxypolyoxyethylene glycol (20 moles)
121.2527	Amendment	6/21/67	Provide for additional use of N-acyl sarcosines as antistatic and/or anti-fogging agents in ethylene-vinyl acetate copolymer film. Also delete existing thickness limitation for film used for dry food packaging. Also delete polysorbate 80 from this section.
121.2520 and 121.2522	Amendment	6/21/67	Provide for use of polyethylene adipate modified with ethanolamine as an optional substance in polyurethane resins for use in adhesives and for use as the surface of articles that contact dry, bulk food. Add polyethyleneadipate modified with ethanolamine to Regulation 121.2522
121.2520	Amendment	6/28/67	Provide for use of azelaic acid as a comonomer in polyester resin
---	HEW Regulation	6/30/67	Describes the availability to the public of records of the Department of Health, Education, and Welfare, pursuant to Public Law 90-23, the Public Information Act
---	Consumer and Marketing Regulation	7/4/67	Describes the rules established for implementing 5 U.S.C. 552 (a) (2) and 552 (a) (3). These rules are incorporated in a new subpart--Public Information

SECTION	TYPE	DATE	SUBJECT
---	HEW Statement	7/7/67	Describes organization, functions and delegations of authority for Department of Health, Education, and Welfare
121.2511 and 121.2526	Withdrawal	7/13/67	Amendment regarding the use of butyl benzyl phthalate as a component of food-contact articles
121.2566	Filing	7/15/67	Provide for the use of octadecyl 3,5-di-tert-butyl-4-hydroxy-hydrocinnamate as an antioxidant and/or stabilizer with certain limitations
121.2543	Amendment	7/19/67	Provide for the use of kraft paper as a container incidentally subjected to radiation during the irradiation of flour and to effect editorial clarifications
---	Miscellaneous Amendments	7/21/67	Regulations for the enforcement of the Federal FD & C Act and the FPLA. Miscellaneous amendments
121.2520	Filing	7/21/67	Provide for the use of (1) copolymers of a-methylstyrene and dimethyl-a-methyl-styrene; (2) copolymers of a-methyl-styrene, styrene and dimethyl-a-methyl styrene; and (3) polymer of dimethyl-a-methylstyrene as components of adhesives
121.2597	Filing	7/27/67	Provide for the use of polyvinylchloride modifiers produced by combining styrene butadiene copolymers with acrylic poly polymers either during or after polymerization of acrylic polymers for use in finished plastic food-contact articles with a specified limitation
121.2589	Filing	7/29/67	Provide for the use of an additional grade of mineral oil in lubricants with incidental contact as provided under 121.2553
---	Withdrawal	8/4/67	Provide for the use in food and food-contact surfaces of synthetic alcohols manufactured by utilizing aluminum, ethylene, hydrogen and air as raw materials in a specified series of chemical reactions

SECTION	TYPE	DATE	SUBJECT
121.	Proposal	8/4/67	Provide for the use under certain conditions of synthetic organic colorants in food packaging paper and paperboard
191.9		8/4/67	Description of banned hazardous substances
191.	Amendment	8/4/67	Description of prescribed requirements, exemptions, and procedures reflecting the "banned hazardous substances" and other provisions of the Federal Hazardous Substances Act as amended by the Child Protection Act of 1966
121.2514	Filing	8/8/67	Provide for the use of vinyl acetate-dibutyl maleate copolymers, optionally containing acrylic acid or glycidyl methacrylate, as components of coatings applied to metal foil for use in contact with dry food
121.	Proposal	8/8/67	Proposes that procedural food additive regulations be revised to obtain improvements in the quality and organization of food additive petitions submitted and to expedite their scientific review by the Food and Drug Administration
121.2514, 121.2526, 121.2571, and 121.2520	Amendment	8/10/67	Provide for the use of mono-n-butyl ester of 5-norborene-2,3-dicarboxylic acid and poly[2-(diethylamino)ethyl methacrylate] phosphate as components of food-contact articles
121.2526	Filing	8/17/67	Provide for the use of tetrasodium N-(1,2-dicarboxyethyl)-N-octadecylsulfosuccinamate as an emulsifier in resin latex food-contact coatings for paper and paperboard with a specified limitation
121.2531	Filing	8/17/67	Provide for the use of stearyl stearate as a component of lubricants used in the manufacture of metallic articles
121.2502	Amendment	9/2/67	Provide for increased levels of extractable fractions for Nylon 11 resins used in food-contact articles