SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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FEB 1 1973

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE

Shoreham Hotel
Washington, D. C.

December 15, 1972
9:15 a.m.

Present:

Karl A. Hochschwender, Chairman, American Hoechst Corporation, Route 202-206, North Bridgewater, P. O. Box 2500, Somerville, New Jersey 08876
Willard M. Westveer, Vice Chairman, The Dow Chemical Co., 2040 Building, Midland, Michigan 48640
Watson B. Ackart, Union Carbide Corp, River Road, Bound Brook, New Jersey 08885
J. Brian Armitage, DuPont Plastics Department, Experimental Station, Wilmington, Delaware 19898
Robert C. Asam, The Goodyear Tire & Rubber Co., 144 E. Market Street, Akron, Ohio
W. C. Bachtel, B. F. Goodrich Co., 500 S. Main Street, Department 0013, Bldg. 5-H, Akron, Ohio 44318
C. W. Berndt, Industrial Bio-Test Labs., 1810 N. Frontage Rd., Northbrook, Illinois
Charles E. Blades, Air Products and Chemicals Co., Inc., Possumtown Rd., Box 4, Middlesex, New Jersey 08846
Morris Blumberg, Weston Chemicals, Inc., 103 Spring Valley Road, Montvale, New Jersey
N. D. Bornstein, Cryovac, P. O. Box 464, Duncan, South Carolina 29334
Roger Boyer, Pantasote, 26 Jefferson Street, Passaic, New Jersey 07424
Paul F. Cundy, American Can Company, Box 702, Neenah, Wisconsin 54956
LaVerne J. DeCorte, Sinclair-Koppers Company, Frankfort Road, Monaca, Pennsylvania
Lou DeMarco, Diamond Shamrock, P. O. Box 348, Painesville, Ohio 44077
Daniel S. Dixler, Keller and Heckman, 1150 17th Street, N.W., Washington, D. C.
Ernest M. Dixon, Celanese Corporation, 522 5th Avenue, New York, New York 10036
R. J. Dowling, Uniroyal Chemical, Spencer Street, Naugatuck, Connecticut 06770
Myer Ezrin, DeBell & Richardson, Inc., Water Street, Enfield, Connecticut 06082
Ge rge W. Ferner, The Goodyear Tire & Rubber Company, 1144 E. Market Research Div Akron, Ohio 44316
Robert P. Fischer, Kerr Glass Manufacturing Corp., P. O. Box 4000, Lancaster, Pennsylvania 17604
Thomas R. Fisher, M & T Chemicals, Woodbridge Avenue, Rahway, New Jersey 07065
David H. Fishman, Celanese Plastics, Morris Court, Summit, New Jersey 07901
Gerhard Fuchs, Allied Chemical Corp. Box 1057R, Morristown, New Jersey
B. J. Garceau, ICI America Inc., New Murphy Road & Concord Pike, Wilmington, Rhode Island 19899
David R. Gaskill, Mobil Chemical Co., P. O. Box 240, Edison, New Jersey 08817
R. A. Godfrey, Mobay Chemical Company, Penn-Lincoln Parkway West, Pittsburgh, Pennsylvania 15205

Max Goldfrank, Stein, Hall & Co., Inc. (Celanese) 605 Third Avenue, New York, New York 10016
Paul R. Graham, Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, Missouri
R. H. Haas, The Goodyear Tire & Rubber Co., Akron, Ohio 44316
Joseph E. Hadley, Jr., Keller and Heckman, 1150 17th Street, N.W., Washington, D.C.
G. Frederick Hanna, Borg-Warner Corp., P. O. Box 68, Washington, West Virginia
Jerome H. Heckman, SPI General Counsel, 1150 17th Street, N.W., Washington, D. C.
George W. Ingle, Monsanto Company, 1101 17th Street, N.W., Washington, D. C. 20036
John F. Jones, Vistron Corporation, Midland Building, Cleveland, Ohio
Otto S. Kauder, Argus Chemical Corp., 633 Court St., Brooklyn, New York 11231
Peter P. Klemchuk, CIBA-GEIGY Corp., Ardsley, New York 10502
William A. Knapp, Allied Chemical Corp., P. O. Box 1057R, Morristown, New Jersey
Robert H. Knust, Celanese Plastics Co., Morris Court, Summit, New Jersey 07901
Jack Lawing, Eastman Chemical Products, Inc., Kingsport, Tennessee 37662
Clyde W. Leaf, BASF Wyandotte Corp., Wyandotte, Michigan 48183
G. Fred Macke, General Electric, Plastics Dept., Lexon Lane, Mt. Vernon, Indiana
G. J. Mantell, Air Products & Chemicals, P. O. Box 538, Allentown, Pennsylvania
Joel Markowitz, Dart Industries, Inc., P. O. Box 37, Paramus, New Jersey 07652
Frank H. McTigue, Hercules Inc., Research Center, Wilmington, Delaware 19899
Robert M. Miller, Hercules Inc., 910 Market Street, Wilmington, Delaware 19899
Kenneth Morgareidge, Food & Drug Research Labs., Maurice Ave. to 58th Street, Maspeth, New York 11378
Peter Morison, Eastman Chemical Products Inc., Kingsport, Tennessee 37662
Bernard G. Murray, Ferro Corp., 4150 East 56th St., Cleveland, Ohio 44105
Sheldon Parker, Dart Industries, P. O. Box 37, Paramus, New Jersey 07652
J. K. Peterson, USS Chemicals, 600 Grant Street, Pittsburgh, Pennsylvania 15230
Jules Pinsky, Mearl Corp., 217 N. Highland Avenue, Ossining, New York 10562
Dale A. Pribanic, B. F. Goodrich Chemical Co., 6100 Oak Tree Boulevard, Cleveland, Ohio 44131
Lorence Rapoport, Olin Corp., P. O. Box 200, Pisgah Forest, North Carolina 28768
George A. Richter, Jr., Rohm and Haas, Independence Mall West, Philadelphia, Pennsylvania 19105
Robert E. Rutherford, Gulf Oil Corp., 439 7th Avenue, Pittsburgh, Pennsylvania
A. Marrill Schnitzer, Phillips Petroleum Co., Bartlesville, Oklahoma 74003
Edward F. Schultz, Dow Chemical Co. USA, Plastic Production Department, Bldg. 433, Midland, Michigan 48640
William W. Sederlund, National Starch and Chemical Corp., 1700 West Front Street, Plainfield, New Jersey 07063
Dwight M. Sheets, Shell Chemical Co., One Shell Plaza, P. O. Box 2463, Houston, Texas 77001
William R. Sherman, S. D. Warren, Div. Scott Paper Co., Westbrook, Maine
L. T. Sherwood, Jr., DuPont, Plastics Dept., Chestnut Run, Wilmington, Delaware
Charles J. Spiegl, Continental Can Co., 7622 S. Racine Ave., Chicago, Illinois
E. J. Temple, Monsanto Company, 101 Granby St., Bloomfield, Connecticut 06002
D. C. Thompson, E. I. duPont de Nemours and Co., Experimental Station, Bldg. 353, Wilmington, Delaware
Judith A. Tins, Celanese Corp., 522 Fifth Avenue, New York, New York 10036
P. J. Vanderhorst, DuPont, Film Dept., 1007 Market St., Wilmington, Delaware 19898
George F. White, Jr., Reynolds Metals, 10th & Byrd Streets, Richmond, Virginia
Ambrose G. Whitney, W. R. Grace & Co., Research Div., Clarksville, Maryland 21029
Margaret Wulf, The Dow Chemical Co., P. O. Box 1706, Midland, Michigan 48640

Einar T. Wulfsberg, American Paper Institute, 1619 Massachusetts Avenue, N.W., Washington, D. C. 20036
L. W. Ziemlak, Foster Grant Co., Inc., 289 N. Main, Leominster, Massachusetts
C. L. Condit, Secretary, SPI, 250 Park Avenue, New York, New York 10017

As the newly installed General Chairman of the SPI, Food, Drug and Cosmetic Packaging Materials Committee, Karl Hochschwender, American Hoechst Corporation called to order a regular meeting of the Committee in the Shoreham Hotel, Washington, D. C. at 9:15 a.m.

Referring to a detailed Agenda circulated prior to the day's meeting with the Secretary's meeting announcement, Chairman Hochschwender called for the usual self-introductions which were duly forthcoming.

Minutes of Last Meeting Approved

In the absence of any questions or comments regarding the Minutes of the last meeting, held also at the Shoreham Hotel, Washington, D. C. on March 15, 1972, the Chairman declared the Minutes approved as developed by the Secretary and circulated by mail.

Remarks of Committee Chairman

Chairman Hochschwender spoke informally noting his desire to review some "old points" of reference such as the objectives set forth in the Bylaws of the Committee, and addressing his remarks to the subject of "what this Committee is all about", as he sees it. Dr. Hochschwender cited two major functions of the Committee: (1) To be a type of implementing arm of SPI to develop dialogue with and on federal and state agencies that develop food and drug legislation, it being well recognized that the Committee is in large measure the spokesman f r the plastics industry on this score; and (2) To serve as a source of information and general regulatory guidance to those companies within the plastics industry who have interests in the food, drug and cosmetics packaging materials markets.

Discussing the number of meetings held, Dr. Hochschwender noted that the attempt has always been to have only so many meetings as are necessary to handle problems relating to the Committee's activities. In this connection, Dr. Hochschwender said that he and the Steering Committee are giving thought to setting meeting dates and announcing them more in advance than has been the case. This should better alert members of the Committee as to when sessions will take place. It was agreed that the next meeting will be held in May of 1973, as hereinafter more specifically indicated.

Referring to the Agenda for the session, Dr. Hochschwender next indicated that he had added two items and that these would be discussed by Dan Dixler of Keller and Heckman. One item relates to action which Japan has taken in preparing lists of additives in plastics packaging, the first such list available being one for PVC; the other item deals with a new kind of solvent which has been developed in Europe, and based upon translations available, Dr. Dixler will discuss this new product.

In concluding his opening remarks, Chairman Hochschwender stated that, unless the Committee determines otherwise, he will ask that everyone abide by the policy which has been traditional since the formation of the Committee whereby only the Chairman, and, under his direction, Counsel and the Secretary may exercise the prerogative to extend meeting invitations to non-members of the Society; the purpose of this policy is to provide the Committee with an atmosphere that promotes freedom of discussion about regulatory problems.

Commendation to Robert M. Miller

At this point, Charles J. Spiegl, Continental Can Company, Inc., moved that the Committee express deep appreciation to outgoing Chairman Robert M. Miller, who served so ably for two terms; and that in this connection, the Secretary write a letter of commendation to Mr. Miller. The motion was seconded and carried unanimously during prolonged applause for Mr. Miller. Chairman Hochschwender commented on the excellent job which Mr. Miller did during his tenure of service, as did Jerome H. Heckman, SPI General Counsel, who said that certainly "Bob deserves all of the plaudits and honors you could possibly bestow on him for his diligent and superb attention to his office."

Mr. Miller in turn thanked the Committee for the appreciation extended to him.

Report of SPI General Counsel

As is traditional, Chairman Hochschwender said, Jerome H. Heckman, Keller and Heckman, and General Counsel of SPI, is asked at each meeting to speak on a variety of subjects which he feels should be brought to the attention of the Committee. On this occasion, Mr. Heckman directed his remarks to recent changes in FDA personnel assignments and attitudes; the "GRAS" list revision and possible impact on packaging materials; the impact of the Freedom of Information Act; shifts in FDA views from time to time on such subjects as the no-migration and prior sanction concepts; the prior sanction rulemaking proposal; the activities of SPI relating to the environment and other pertinent matters.

(Please note: Attached hereto as Appendix A is the report of Jerome H. Heckman prepared for the December 15 meeting).

As is customary, Mr. Heckman, at the beginning of his presentation, said that he would welcome questions from the floor at any time.

One of the major points of discussion during Mr. Heckman's report revolved around a question posed by him as to whether the scientists are inclined to develop methods that are too sophisticated beyond what they need be in establishing a practical basis for detecting the level of extraction from a plastics material or wrap. (See page 9 of Mr. Heckman's report on this matter.) Although this subject caused many comments at the day's meeting, in

balance there seemed to be no disagreement that the scientific and legal angles of this matter should be kept in proper perspective.

Report of Daniel S. Dixler on Technical Matters

Earlier in the meeting Mr. Heckman pointed out that the technical arm of his own staff is embodied in the person of Daniel S. Dixler and that, henceforth, he plans to ask Dr. Dixler to discuss the more technically oriented regulatory subjects on the Agenda while he limits his comments as earlier in the meeting to those more legally oriented.

(Please note: Attached hereto as Appendix B is the detailed technical report given by Dr. Dixler at the day's session dealing with such subjects as the colorants for plastics regulatory proposals; the phthalate esters situation based on a report of a September conference; PCBs; asbestos; FDA Extraction Guidelines; FDA Toxicological Guidelines; the Japanese listing of additives; and, the new fat-simulating solvent mentioned earlier by the Chairman.)

During his report, Dr. Dixler spoke of the suggestion of the Carbon Black Advisory Committee, composed of representatives of leading manufacturers of carbon black, to create a joint task force as part of the Technical Information Subcommittee under the direction of Willard M. Westveer, to conduct appropriate tests on carbon black samples. In particular, as Dr. Dixler sees it, the SPI Task Force would actually be asked to prepare the plastics packaging samples containing carbon black and the extraction tests, on the other hand, would be conducted under the direction of the Carbon Black Advisory Committee.

Dr. Hochschwender asked that interested individuals volunteer to serve on the Task Force on Carbon Black, indicating that he is appointing as Chairman of the Committee, George W. Ingle, Monsanto Company.

Those volunteering at the day's session to serve on Mr. Ingle's Committee were:

Watson B. Ackart, Union Carbide Corporation
Peter Morison, Eastman Chemical Products, Inc.
A. Merrill Schnitzer, Phillips Petroleum Company
G. Frederick Hanna, Marbon Division, Borg-Warner Corporation
David H. Fishman, Celanese Plastics Company
Robert M. Miller, Hercules, Inc.

Mr. Ingle is to check out guidelines with a counterpart from the carbon black industry before embarking upon the preparation of samples.

Principal Luncheon Speaker

Chairman Hochschwender was pleased to introduce as luncheon speaker Richard J. Ronk, Director, Division of Petitions Processing, Food and Drug Administration,

to discuss matters of current interest. (Please note: An edited transcript of Mr. Ronk's remarks is attached hereto as Appendix C. It should be understood that the remarks were made colloquially and somewhat at random. Furthermore, since Mr. Ronk did not review the edited material, quotation of any of his statements for other than internal purposes would not be appropriate.)

Reports on Liaison with Other Organizations

Chairman Hochschwender next called for the customary liaison reports relative to other organizations on matters of interest to the Committee.

Pharmaceutical Manufacturers Association and U.S. Pharmacopia

W. B. Ackart, Union Carbide Corporation and Chairman of the Committee's Drug Packaging Materials Subcommittee, delivered the following report:

"The March 15, 1972 report of this subcommittee stated that our report on Methodology for Testing Polyolefin Containers for Tablets, Capsules, Oral Powders, and Granules had progressed from the Quality Control Section of the PMA, to Mr. John Ruggiero of the PMA headquarters staff, to Dr. Tom Macek of the USP staff to Dr. George Schneller, of the USP Advisory Panel on Containers to Mr. Jules Pinsky of a Task Group on Plastic Containers. This Task Group made some minor recommendations and returned the Methodology with favorable comments to the parent Advisory Panel. It was anticipated that the procedure would be accepted for publication in the near future.

"In mid-September, we inquired of Dr. Macek on the status of the procedure and were informed that it was still under consideration by the USP Advisory Panel on Containers. On December 5, I called Dr. Macek for an up-dating and found he had left the USP. I spoke with a Mr. Tamorria who offered to follow up on its status. Almost simultaneously, Jules Pinsky called me to say that Dr. Schneller was opposed to the Methodology and suggested that a telephone discussion was in order. I called Dr. Schneller of Wyeth Laboratories and found that he had completely misinterpreted the intent of the procedure and was not even aware that the PMA was also interested in the publication of the Methodology. Hopefully, at this point he is convinced of the utility of the procedures and that it is in the interest of his organization as well as ours that the Methodology be published. We will follow-up with both Dr. Schneller and Mr. Tamorria.

"It is of interest that this work was started in January 1967 and our completed report went to the PMA in July 1970."

Following Mr. Ackart's report, both he and Jules Pinsky (Mearl Corporation) expressed the view that any difficulties which had been encountered with the posture of Dr. Schneller toward the methodology for testing polyolefin containers for tablets, capsules, or powders and granules has changed for the better and that in all probability, the desired recognition would eventually be given to the report of Mr. Ackart's Committee.

Manufacturing Chemists' Association

George W. Ingle, Monsanto Company, delivered the following report on the activities of interest to the SPI Committee of MCA's Food, Drug, Cosmetic Chemicals Committee:

"This Committee last met Monday of this week. Substantial activity had taken place during the last Session of Congress, specifically concerned with the preparation and delivery of statements reflecting MCA's positions on these questions.

"1. Opposing Senator Nelson's bills S.76, S.3163 to amend the 1958 Food Additives Amendment including eliminating the GRAS list and expanding coverage of the Delaney Clause;

"2. Opposing FDA's proposal to require Food Additive petitions to include data permitting FDA to write environmental impact statements;

"3. On FDA's proposed "Public Information Policy," we recommended more explicit definitions to bolster 'trade secrets' exemptions; and

"4. On FDA's proposal to regulate prior sanctioned substances, several administrative safeguards were recommended to prevent undue loss of these exemptions.

"In addition, this Committee has sent a representative to the Codex Alimentarius Commission, meeting this year (1972 - Ninth Session) in Rome. A report is available for those interested.

"Further, with representation to the U. S. Pharmacopoeia, this Committee is concerned with the delays in considering the possible merger of USP and the National Formulary, which might lead to FDA's assumption of direction in this field.

"The Committee is also giving greater attention to publicity of the true function and value of food additives, in our food supply, now so frequently questioned by extremists. One popular brochure, 'Your "Breakfast" Chemicals' is being revised for a second printing, and revision of 'Everyday Facts -- Food Additives' has started."

Can Manufacturers Institute

Charles J. Spiegl, Continental Can Company, and liaison with the Can Manufacturers Institute indicated that there were no CMI developments of interest to report on at the day's session.

SPI Market Development Committee of the Plastics Bottle Division

On behalf of M. E. Smith, Owens-Illinois, unable to be present at the session, Jerome H. Heckman noted that, for all practical purposes, the Market Development Committee of the Bottle Division is not presently conducting activities which relate directly to the interests of the SPI Committee, although, of course, the Bottle Group is interested in the activities of the Food, Drug and Cosmetics Packaging Materials Committee. Their present work relates to such matters as liquor bottles, testing of mayonnaise containers and, most importantly perhaps, working with the SPI Public Affairs Council to try to bring about a favorable resolution of the PVC liquor bottles matter. PVC is presently permitted for this use on an experimental basis. It is hoped that the authority will be made permanent by July of 1973 but the entire situation is quite complex because it has necessitated the preparation of an Environmental Impact Statement by the Bureau of Alcohol, Tobacco and Firearms of the Treasury Department and has engendered adverse comment by consumer groups, as well as the raising of some difficult questions by the Environmental Protection Agency and others.

American Paper Institute

No formal report was presented. However, with reference to a portion of Dr. Dixler's report (attached hereto as Appendix B, pp. 5-7), for the sake of clarification, Paul Cundy, American Can Company, representing the API's Committee on Biological and Chemical Regulatory Affairs, noted that the PCB problem relating to paper was not occasioned by the presence of PCBs in all paper products, but only in those papers made from recycled carbonless carbon paper. He went on to add that, with the identification of the source, the problem is rapidly disappearing.

Other Subcommittee Reports

Norman D. Bornstein, Cryovac, and Chairman of a Task Force appointed at the last meeting of the Committee to deal with the PCB methodology problem, delivered the following report dealing with two separate matters, ASTM Committee F-2 relating to a Task Group on the analysis of PCB in polymerics, and an MCA Ad Hoc Planning Group on Phthalate Studies:

"I. ASTM Committee F-2 for Flexible Barrier Materials, Task Group on Analysis of PCB in Polymerics

"The Task Group composed of representatives from seven different companies, both producers and consumers, held their first meeting on 30 November. Various aspects of PCB analysis of polymerics were considered; they included the polymerics to be studied, methods for isolating PCB from the polymerics, clean-up procedures, quantitative analytical methodology, methods for calculating the PCB content from gas chromatograms, qualitative analytical methods and the development of a Task Group investigatory program.

"A tentative GC-^{63}Ni EC method has been accepted in conjunction with a method for calculating the results of the chromatograms using an integration procedure.

"Round robin samples of various concentrations of the different Aroclors in n-hexane, as well as pure samples of Aroclors 1242 and 1254, will be prepared and distributed to Task Group members. Interlaboratory agreement will be determined for the tentative standard method as well as those currently employed by the participating laboratories. The variability of the two Aroclors and its affect upon calculations will also be determined. After establishment of satisfactory gas chromatographic and calculation procedures, the Task Group will then concentrate on extraction and clean-up procedures.

"II. MCA Ad Hoc Planning Group on Phthalate Studies

"The primary objective of this group was to recommend an action program relative to the phthalate environmental and toxicological questions which had arisen. The Planning Group has recommended a tentative program and since it is tentative, they have requested that references to this report be of a general rather than a detailed nature.

"A literature search has been accomplished concerning the following subjects: (1) Toxicology, including oral ingestion, metabolic fate, teratology, inhalation, skin absorption, and intravenous injection; (2) Ecological and Environmental Aspects, including natural occurrence, biodegradibility and environmental contamination; (3) Industrial Hygiene and (4) Regulatory Agency Liaison. On the basis of the results of the literature search, the Planning Group has made recommendations for both short range and long range programs which relate primarily to the dissemination of currently available information and the generation of new information."

Report of Medical Devices Standards Subcommittee

George A. Richter, Rohm & Haas Company and Chairman of the Committee's Medical Devices Standards Subcommittee, delivered a detailed report attached hereto as Appendix D.

Report of Technical Information Subcommittee

Chairman Hochschwender next recognized Willard M. Westveer, The Dow Chemical Company, to give his detailed report on recently promulgated Food Additive Regulations, and related regulatory actions. Mr. Westveer reviewed his report highlighting certain subjects he felt to be of special interest to the plastics industry.

(Please note: Attached hereto as Appendix E is Mr. Westveer's report entitled, "Recently Issued Food Additive Regulations" dated December 15, 1972.)

In addition to amendments actually promulgated, Mr. Westveer also mentioned a number of proposals which he felt would be of interest to the Committee. In particular, he noted the proposal concerning limitations on the use of lead in paint intended for household purposes. At this point, Mr. Heckman rose to point out that this proposed Regulation, parts of which were already in effect, did not apply to inks and the like used for plastics and were intended to apply only to paints that were brought into the household for application in the household, and for paints on such items as childrens' toys.

Report of Lawyers Advisory Subcommittee

Chairman Hochschwender called upon Taylor W. Hanavan, E. I. duPont de Nemours and Company, Inc., to deliver a report, in his capacity as Chairman of the Lawyers Advisory Subcommittee, on recent legislation, what he envisions to be governmental attitudes in the future on certain legislative matters, and other subjects.

Following is Mr. Hanavan's report:

> "In 1972 there was extensive legislative activity involving toxic chemical substances, consumer product safety, various forms of consumer protection and medical devices. While only one law, the Consumer Product Safety Act was enacted, it is quite likely that bills in these other areas will be reintroduced in the 1973 Congress with passage of some form of legislation likely.
>
> "Last year various bills providing for regulation of the distribution and use of toxic chemical substances were considered by Congress. The reported justification for this legislation illustrates its significance. The White House's Council on Environmental Quality (CEQ), in studies prior to recommending the Toxic Substances Control Act of 1971, analyzed man's total environmental exposures to the hazards of a toxic substance as a series of exposure inputs during the course of initial production, transportation, use in the production of other products, use in home consumption and waste disposal. CEQ recognized that such laws as the Federal Environmental Pest Control Act; the Occupational Safety and Health Act; and the Food, Drug, and Cosmetic Act each regulate some aspect of the total environmental exposure, but no law provided authority to evaluate the total

exposure of man in his environment to the hazards of a particular compound and regulate same where necessary. CEQ, therefore, proposed through the EPA to Congress legislation giving EPA authority to regulate the distribution and use of all chemical substances where there may be environmental hazards. With respect to new chemical substances, the EPA would promulgate standards for test protocols and the results to be achieved. With respect to any chemical substance, whether new or old, EPA was given authority to promulgate regulations to restrict or prohibit the use or distribution of same to the extent necessary to protect the public health and the environment. It would have been illegal to ship any chemical substance that did not comply with any applicable standard or was in violation of restrictions.

"The Senate passed the so-called Spong bill that would have required a food additive type pre-market approval for all new chemical substances or uses thereof. Industry felt that this was not good legislation. MCA, SOCMA and even EPA and CEQ testified to this effect. The House, on the other hand, passed a much less restrictive bill containing a pre-market screening requirement only for those chemical substances or classes thereof which EPA by regulation would designate as hazardous and for which EPA would establish standards for test protocols. Under this procedure, test data where necessary would be submitted to EPA prior to commercialization and in the absence of a timely objection from the Administrator a new chemical could thereafter be marketed. In conference the House held out for limited pre-market screening and the Senate was equally firm as to pre-market approval. As a result, no legislation was enacted.

"We understand that CEQ plans to have a toxic substances bill reintroduced early in 1973 and that the Senate Commerce Committee has already prepared its own version. We can be certain that there will be a strong legislative push for a toxic substances bill in the next session of Congress

"In the field of consumer protection, there were a variety of consumer oriented bills, the most significant of which, at least in terms of coming the closest to enactment, was a bill which would set up a Consumer Protection Administration with authority to intervene and take part in the decision making of all government agencies when problems of possible consumer interest were involved. This type legislation reflects the great pressure from public segment groups to share in the decision making of administrative bodies. In one version, the Food and Drug Administration was abolished and assigned to this new Consumer Protection Administration. However, later a House committee amendment restored the FDA to its semi-autonomous position in the Department of HEW. While this bill did not pass, legislation of this type can be expected to appear again in the 1973 session of Congress.

"Congress, however, did enact the Consumer Product Safety Act. Under the Act, a consumer product means any article sold for use in or around a household, school, in recreation or otherwise. Excluded from this law, among other items, are articles not customarily sold to consumers, tobacco, tobacco products, economic poisons, foods, drugs, devices and cosmetics. The law establishes a Consumer Product Safety Commission consisting of five commissioners to be appointed by the President. One function of the Commission is to develop product safety information and publish same to the extent possible. The most significant role of the Commission is to develop consumer product safety standards which may be issued in regard to product performance, composition, contents, design, construction, finish or packaging. In addition, this Commission may get into labeling since it may also establish standards for 'marking with warnings or instructions'.

"The Commission has authority to ban hazardous consumer products if the product presents an unreasonable risk of injury and no feasible standard would protect the public. It may also file imminent hazard actions. The Act provides civil and criminal penalties for violation of any of the prohibited Acts.

"There were a series of medical device bills thrown in the hopper. All of them reflected the recommendations of the Cooper Report and all divided up the medical device regulatory control area into three classes of devices. One, those requiring pre-market clearance; two, those which could be marketed in conformance with the standards as established by the Secretary; and three, those which could be marketed without pre-market clearance or conformance with established standards.

"One bill was unique in that while similar to all the others it did not contain a definition of device. One could argue that the omission of the definition of device was sound in that it left the FDA with administrative discretion to act reasonably in selecting only those device products for control which needed it. On the other hand, the omission of the definition of device also creates a gray area of uncertainty which makes it most difficult for a lawyer to advise his clients. This question appears to be the only remaining unresolved difference of substance. However, we understand that FDA may now be willing to go along with a definition of device in any legislation which, in effect, would limit the term to devices which do not achieve any of their principal or intended purposes by chemical action.

"The Supreme Court decisions in the AMP and DIFCO cases, of course, take a great deal of pressure off FDA in that they have given FDA the broadest possible leeway in determining whether a medical

device should be considered a drug and subject to NDA type pre-market control or merely a device. However, this is an unhappy position for the Agency to be in as it finds itself in the position of having to make hard decisions of the type it would prefer to avoid. Therefore, FDA favors device legislation.

"There would seem to be very little White House pressure for device legislation. However, with most of the major bugs already worked out, it seems likely that device legislation will be enacted in 1973.

"I would like to call to your attention a decision of the California Court of Appeals, the First District, in Putensen v. Clay Adams Incorporated, et al., CCH Product Liability Reports, ¶6,483, 11/20/70, dealing with the use of plastic materials in surgical equipment. In plastic sales there is a temptation to recognize the fact that your product has been used in surgical applications or has a potential for such use. As the Putensen case teaches, this can be risky and may be costly. In this case the defendant manufactured a polyethylene tubing which it sold in 100 foot rolls for a variety of uses. According to the Court, the defendant, in its product literature, stated that the tubing was useful in moving fluids into and from body cavities. A doctor purchased such tubing and after further processing the tubing was used in a heart catheterization. Unfortunately, a kink developed and the patient had to undergo surgery to remove the kinked tube. The Court found that the plaintiff did have actionable claims for breach of express warranty and negligence. A jury might find that it was implied that the tubing was suitable for heart catheterizations. With respect to negligence, the Court ruled that the jury could find the manufacturer knew or should have known that the tubing was being used for heart catheterizations and was negligent in failing to warn that the tubing had a tendency to kink."

Next Meeting

In accordance with the plan announced during Chairman Hochschwender's opening remarks, he, Mr. Condit, and Mr. Heckman discussed arrangements for the next meeting after the day's session was concluded. As a result, this will serve to give those receiving copies of these Minutes advance notice that the next meeting of the Committee will be held in Washington, D. C. on May 31. It is anticipated that an Agenda and formal meeting notice will be sent to all members of the Committee towards the end of April.

Respectfully submitted,

Charles L. Condit, Secretary

ADDENDUM TO REPORT

After the foregoing report was prepared, I had occasion to attend the Annual Food and Drug Administration-Food and Drug Law Institute Meeting. The opening session of the meeting was devoted to a discussion of the philosophy of FDA regulation, the featured speaker being Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare.

Aside from the fact that the session was generally very interesting, and much more informative than usual, it enabled me to pose two questions which Mr. Hutt answered very directly and forthrightly in front of an estimated audience of 400 or 500 attendees.

More specifically, he indicated before the entire group that it is definitely FDA's intention to try to codify and publicize its many "unwritten policies" by use of a technique like the publication of Advisory Opinions. In other words, and at such time as FDA's action priorities allow, the Administration may finally move to publish Advisory Opinions which should be helpful in the education of industry and the public along the lines of suggestions we began making at least as long ago as the time of the National Conference on Indirect Food Additives held in February of 1968.

In response to another question I posed, Mr. Hutt indicated that, although the Food and Drug Administration has not yet seen fit nor found it necessary to afford interested parties the kind of <u>oral argument</u> before the Commissioner on rule making matters that we have recently advocated in our SPI Comments on the GRAS, Prior Sanction, and Colorants Proposals, he feels that this is <u>a procedural device which might well be used at sometime in the future</u> as a helpful and suitable alternative to the type of almost useless evidentiary hearings typified by those conducted in connection with the so-called proposed Special Dietary Foods Regulations.

J. H. H.

Edited Transcript of Richard J. Ronk's Remarks
December 15, 1972 SPI
Food, Drug, and Cosmetic Packaging Materials Committee Meeting

Dr. Karl A. Hochschwender, Chairman:

Ladies and Gentlemen:

One of the things that we are most concerned about doing in this Committee is to maintain a lively dialogue with the regulatory agency that is of greatest concern to us, namely the Food and Drug Administration. There is no better way to have this dialogue than to have it with someone from that agency who is where the action is, and we've got him here. Dick Ronk has been with FDA for ten years. He's spent seven of these out in the field where he was practicing chemistry and enforcement. Before joining the FDA, Mr. Ronk attended Creighton University in Omaha, Nebraska, from which he received his Masters Degree. After his long field experience in FDA, he joined the Bureau of Foods in 1970, in the Guidelines Branch, and in January of 1972 he became the head of (apparently it has a new name again) it's now called the Food and Color Additive Regulations Division. He'll tell you something about this name-the-name game.

I asked Mr. Ronk before we started here whether there was anything else he'd like for me to say about him for which he considers himself famous. You know that some people will say I played football for Columbia, I knew an Assistant Secretary of the Treasury who pulled this on me, other people will say, I have a golf score of so and so, but he answered very cryptically, "mercury in fish." I don't know the details and I don't want to ask him to tell you because I think he has other things he wants to discuss with you today but, if he does make a comment on it, I'm sure it will be interesting.

So without further ado, I'm going to ask Mr. Ronk to speak for as long as he would like but remind him that probably a lot of you are going to have questions for him.

Mr. Ronk:

Thank you for having me this afternoon. I think another thing that the Food and Drug Administration wants to do is to be able to keep in contact and keep communicating with all of the people that are important to us. Certainly consumers are important to us and we are spending a lot of time on consumer education. I think it is also very important for us and the consumers that we keep our channels of communication open with industry.

Food additives is an interesting subject. We could spend hours and hours on any aspect of it. We could talk toxicology with Dr. Frawley; we could spend the afternoon on toxicological testing, the significance of it, the appropriateness of it, and what parameters of safety that we arrive at because of toxicological testing, and whether or not there are elements f risk in the food additive area that should not be borne by society.

Those are questions that I think are important to us. We could spend the afternoon talking about identifying compounds so that we could regulate them more appropriately. These are important things too.

But my principal thrust and my principal job in the agency is to try and provide somewhat of an overview to regulation. I don't necessarily go to the scientist to ask him to tell me whether or not we ought to regulate this material. I go to ask him whether or not he considers it safe. I don't expect his word to be the only word that I would take on that subject. I go to the chemist to ask him is this material identified. And, if it is this material, what things additionally should I look for; what additional things should the toxicologist have available to him to consider to determine the safety of this material.

I go to the Food and Drug officer to have him devise a regulation which will, in the ultimate, protect the public interest so that this safe material that has been identified can be used in a safe manner and in such a way that somebody else can go out into the marketplace and be sure that that regulation is applied.

Now, when we start to talk about packaging areas, I'm not so certain that any of these requirements are necessarily being met at this time. First of all, I don't think that I could give the packaging regulations to an inspector and have him go out into the food industry, go to a fabricating plant and decide whether or not what was taking place there had any meaning vis-a-vis the regulations at all.

The second thing that I don't think that he could do is that I don't think that he could identify the material that was there, nor do I know that the fabricator could either. That's one parameter of safety.

The second thing that happens I think is that I don't think the regulations are regulations. I think that in many cases the regulations do serve a very useful purpose. The public is safer because these regulations exist, but I don't think the regulations are regulations in the sense that other regulations are. I don't think they're as enforceable as they ought to be and I think that we all should do something about that, because if you go to the trouble of filing a Food Additive Petition and assuring the toxicologist that your material can be used in a safe manner, then I think it's incumbent on the Food and Drug Administration to occasionally, at least, go out and find out whether or not this really happens. And so, in order to do that, I think we should have more emphasis on this aspect of packaging regulations.

To go back even a step further, I don't know that the packaging regulations are necessary. The decision was made to regulate packaging. As regards many of the areas of the packaging regulations that you look at, you can see that they are not there because they are food additives. They are regulated on the basis that they are not. Now you may need this particular kind of a regulation to sell materials to your customers. Fine. It may be that the Fo d and Drug Administration will continue to issue these kinds of regulations.

Fine again. But I think we should recognize what these regulations are. And I would submit to you that perhaps the adhesive regulations might be in this category. So if you need things to sell your product, then I think that it is incumbent on the government and others, perhaps, to provide these things to you, but I don't think any of us ought to be fooled nor that our suppliers ought to be fooled on what these things really are. They are lists, not regulations.

The same thing is true about the kinds of correspondence that we have carried on with you in the past and I think that we were less than candid in many instances in not coming right out and saying that "no, I don't think that this is GRAS. I don't think that this is insignificant. I think that it should require a regulation." On the other hand, I think sometimes we asked you to ask us to regulate things that shouldn't have been regulated, on the basis that other people had moved to have them regulated. The packaging regulations to me--and it's taken me a whole year to get even some appreciation for it, much less an understanding--well, you shouldn't have to hire a consultant, althought I'm sure Jerry's [Heckman] business is involved here--but you shouldn't necessarily have to go and hire Jerry so that you can even know whether your material is covered by a set of Federal Regulations. I think that safety should be involved in that; otherwise I wouldn't think it was that important. But safety is involved in that and people should be able to figure out, if they are at least generally familiar with an industry, whether or not their materials are covered by regulations.

I think that in many measures it is a mistake for us to write open-ended */ regulations. I think language like "anything in subpart F" is meaningless. What does that mean? Is that what was really intended? At this point in time it's very difficult to find out what was really intended, but I think we need to rebuild this whole section of the regulations along lines, not necessarily that are meaningful to consumers. Consumers don't use these regulations. Your suppliers use these regulations. You use these regulations. We use these regulations. So they ought to be organized in a way that's useful for us.

We shouldn't have to go to Ray Gallant [of Food Chemical News] and say here's three hundred dollars or four hundred dollars, send me your system so I can look substances up in your Guide system and find out what's regulated. The tragedy is that that's what the Food and Drug Administration does too, we look them up in the FCN system. And probably that's the way we should do it as matters stand.

When you stop and think about the kind of money that you would have to spend as we've been doing, how much money would you have to spend for a computer program that's going to organize this for you, it's cheaper to go to Ray and buy forty of these Guides than to do it yourself. But that's not necessarily the way things ought to be. Things should be organized, so we will be trying to remedy some of these things.

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*/ Editor's note: Here Mr. Ronk was undoubtedly referring to language f the type used in Section 121.2514 which allows us f any substance regulated in Subpart F if it meets the other 121.2514 requirements.

It's rather like a fellow starting to build the Washington Cathedral and I see that as a resident of Washington they're continuing building on this thing. It would be like we started to build it and we had no plan, we didn't know where we were going so we built a little chapel over here and because this chapel sits here, now we have to build this one here and unless you know these things, as Mr. Buckley [of the FDA Staff] and the people that you deal with know, you just don't know where all the little chapels are after a while, and you don't know how you got this peak or this particular wing of the building.

So, we will be working in that area to resolve some of the problems along these lines. These are all difficult tasks. You say when is it going to happen? Well, it's not going to happen tomorrow, that's for sure, because we're not going to be able to spend the kind of resources necessary. I think the first thing that we're going to do is to try and use some of the techniques that are successful in business and I think we're going to try and work these things out. I think we're going to try and decide what the critical path is and then once we decide how these events ought to take place, then I think we can decide who should participate and who should handle each one of these events. I think we may get back to you at that point to show you what our plan is for looking at these materials. Now, this will happen fairly soon because as you know, we're reviewing the GRAS list. The President of the United States told us that we should review the generally recognized as safe list. And then we would review, also, all regulated additive materials.

Now, we're entering into a contract with the Flavor and Extract Manufacturers Association to handle their part of the action. Flavors! They know more about flavors than anyone. So we're entering into a contract with their association to write flavor monographs for us to evaluate. There'll be a considerable savings for the government in this approach. The savings is that there's much material that they have in their files that is not available to us, and they will extract this material, free of charge, from their files as the contribution of the individual firms in the Association. Now this is something that they had to do and they knew that they had to do this because, as you know, they have their own GRAS list.

Now, we don't argue with that particular concept but there was a time at Food and Drug, as Dr. Frawley can probably tell you, that that concept was not necessarily accepted, i.e. that other people can determine the GRAS material status of a thing other than Food and Drug.

So we are changing. I hope we're changing for the better. I hope that we're going to come up with not only answers to problems, but reasonable answers to problems. And this is extremely important in this climate. We'll leave this meeting and one of the reasons why I had to ask to speak a little earlier if possible is to go back and talk to the consumer groups. We have a meeting once a month with the consumers. I don't know whether these are real consumers or whether they're consumers consumers. They probably are consumers' consumers. It's pretty hard to go and talk to the man on the street. You talk to your wife and I think maybe she comes cl se to the man on the stre t.

It's possible, but for the government to run its business as it did in the past on the basis of what my wife thinks about a product--well, I think that there was a fellow that said that with cyclamates; I think that he said that his wife used them so they must be safe and I think that he was rather high up in the Administration, too.

But, we want to know what consumers think. Consumers are looking at food additives. Consumers are looking at parameters of things and I think we're going to have to be able to tell consumers we know that packaging is safe. How do we know? We know that the packaging is safe because these materials are either GRAS materials or they're regulated. We know that these regulations are used by the industry. We know that these regulations are enforceable and that's how we know the packaging is safe.

Now I think before we spend a tremendous treasure on this particular problem, we ought to look back right at the basic assumptions as we are now. Should we regulate packaging? What is the hazard involved to the consumer? Is there any hazard involved to the consumer? Do these things get into foods? And I think some of the information that you presented at a previous meeting, where you had an FDA and industry meeting on some of the numbers that had been developed about the parameters of actual migration to food products is important. Because when you talk about the kinds of chemicals that are in your materials as opposed to the kinds of things that are direct additives, you are talking about a term that Dr. Gerard, who is on the FEMA GRAS panel, calls Xeno Chemicals.

I think that is an interesting term. I heard it for the first time the other day. He made the point that a Xeno Chemical is one that is not formed in the human system. Many of the things that you eat are biologically part of your own system. Squalene comes out of your ears, for instance. When you start to talk about materials that have metabolic pathways that are known, you're talking about something that has possibilities of regulation. But most--if you look down your packaging lists--you're talking about Xeno Chemicals - the stranger. These are foreign to the human system. So you have to be sure that these materials are not in any way a significant parameter of food consumption. I don't think that they are. I wish I could say that I was absolutely certain and I think that over the next two years, two and a half years--by the time that's over, I think we will be able to say that we are as certain as you can be that this is not so. Then I think we ought to base regulation on facts, rather than on just assumptions.

I'd be willing to answer any questions that you have about any facet of food additive regulations but I would like to invite you to come in to talk with us--don't come too often--but come as often as you need to and we will try and be reasonable about these things.

I think one of the things that is very difficult for the government to do, and I say this very sincerely--it's very difficult not to be arbitrary. It's very easy to be arbitrary. But it's very difficult also to say no. And there are times when we're going to have to say no and the no is going to hav to be final. Now, you're just going to have to be objective enough about

your own business to realize when we are being arbitrary and when we're not. We are going to try to be as objective as we can about our problems and we hope that you will be as objective as you can about your problems. Thank you.

Mr. Heckman:

Dick, could you comment on--to the extent possible--on the future of something like the Ramsey proposal and also on the comments you've made on other occasions with respect to the matter of levels of sensitivity of testing and that sort of thing. I think you know what I mean or else I'd be more specific.

Mr. Ronk:

Well, the Ramsey proposal, I think was a very good adaptation of the Frawley proposal and I think that basically the way that I read our toxicological community in the agency they couldn't quite accept Jack's proposal. They didn't accept it because I think that they thought that there were areas where we should look. They looked to materials such as natural toxins and other things that could be significant at these levels so that, since although these things may have been irrelevant, really, as far as this proposal is concerned, they couldn't fantasize all possible worlds where this might work. And you know it's very difficult to take something that's very specific like a proposal and then to translate it into all possible situations and leave yourself the flexibility to be able to act in those situations where you need to.

That's the problem with any kind of a guideline. Whether we write a chemical guideline or we write a toxicological guideline you're writing away flexibility. And so you have to have the ability to write into that document the necessary leeway that you need to be reasonable in all situations.

We are still looking at the Ramsey proposal. We've resurrected it, we pick it up, we put it back, pick it up and put it back again. And the key to the Ramsey proposal and the Frawley proposal is some definition of toxicological insignificance. Now we will not be able to use that word "insignificance." That word is anathema in the realities of 1972 America. We can use some other word for that, it will mean the same thing but we can't use that word. That word is not a good word.

So, we have written a set of guidelines and I have looked them over carefully and I have watched our toxicologists to see whether or not they follow these guidelines. I don't tell them to follow these guidelines but they said these guidelines fit almost all situations so, I watch to see whether or not they follow these guidelines. And they don't, so that's the first question you have about the guidelines. In some questions, they are more lenient than the guidelines and in some questions they're tougher than the guidelines. So you go look at the guidelines again and say what is it in the guidelines that's wrong.

So you go to Dr. Blumenthal and Dr. Freidman and you ask them "what is it about this guideline that is not appropriate," and they say well it just doesn't quite meet the mark, there are some other things we need to do. So we're working on those other things we need to. If the guidelines could issue it would give you a number which you wouldn't like because it would be a lot lower than you would want but it would be a number that would relate to migration. Now, I think that that's somewhat alluded to in the GRAS affirmation document.

Now there are a lot of things that you can read into that document and I'm sure that there's a lot of things that, if I were sitting in your shoes, I would read into that document, but I don't know that they're true or not. I say that very honestly. I don't know whether they're true or not. I could read into that document that since the National Academy of Science defined toxicological insignificance in a document it put out about 1970, that that's toxicological insignificance as far as an expert who is qualified to say GRAS. That in his judgment these materials would be GRAS. Now, if then you go ahead and say okay, I've run my extraction test and extractable materials don't come out at levels higher than that particular level which the National Academy of Science reports, then, in fact, it is GRAS.

But, you probably noticed that there were a number of caveats in the GRAS affirmation document itself that kind of warned you against doing that. Nevertheless I don't know that that wouldn't be a reasonable assumption. So, it would have some advantages, it might have some disadvantages. The disadvantage you would have is that none of your catalysts, none of your processes, nothing would be trade secret. Nothing would be trade secret. It would be part of that GRAS application petition. It would go on file with the Hearing Clerk the day that we filed it. Anybody that went out to Parklawn could look at the whole thing. But you would have the advantage that you could market that material while the safety was decided. Now, I don't know what your superiors would think about that. I don't know, I really don't know what we would think about that.

As far as what the order says, that's what it says. I don't know whether or not, and I think maybe Dr. Frawley might comment later to you on it, whether or not he thinks that the proposal that the National Academy came out with really did define the toxicological insignificance in every situation. I don't know whether it did or not. Probably this does require more, as the GRAS affirmation document says.

Go a step further, I don't know, how in the world do you list it? How in the world would you list--let's say you came in and you had a gasket sealing compound and you're going to have this in five-gallon pails or something and the dilution factor is a part of the safety and so it goes as long as it's going to be used in this manner it's going to be safe. How are we going to list that? What are we going to say? We are going to say this is the compound, the name, and these are its limitations, it's limited to five-gallon pails or whatever, and what else would you say about it? The format of this particular regulation kind of defies me; I can't quite see how we'd organize it.

We didn't write that portion of the document. I'm fairly certain I know who did and he is a fellow that reminds you a little bit about like Henry Kissinger. He's a brilliant fellow, his mind goes everywhere, but I don't think he has enough peers to knock his ideas off. You know, so that people like myself that are not quite that brilliant, we don't think in terms of upper echelon terms, we're kind of at a loss at how you implement these ideas. It's kind of like being at a loss about how to bring about the peace in Viet Nam and so on. So these are kinds of problems that we have and we're trying to approach these things.

As far as "no migration" is concerned, it's really an extra category of food additives. There's prior sanction, there's GRAS, there's regulated materials, but there are also things that are not food additives so that if the material does not get into the food and there isn't reasonable expectation for it to get in there, you run the migration studies and find out it didn't, well that's not a food additive. It's just not a food additive. We can write you a letter that says that it's not a food additive.

Now, as far as the methodology is concerned, we have been arbitrary in the past. No question about that. In some cases we've asked people to make a technological breakthrough before we would regulate a material. DES might be a good example. When do you stop developing sensitivity? If Leo Freidman comes to me and says "well, Delaney Clause aside, I don't know about the Delaney Clause, that's a social issue, let's set it off over here. I don't know about it. I'm only talking about it as a scientist now. In my view, 10 parts per trillion of DES in food would be safe." Should the Food and Drug Administration then go and develop a method that's sensitive to one part per trillion? There are people who would do that and live with that. These are the kinds of problems that you have when you start talking about scientific issues and social issues in the same context and that's the context we're in.

The Delaney Clause is the law and when we do find a carcinogen in a substance we will take it off the market. That's it. That's what the Congress has decided; that's what the law is now.

So that is what you should consider when you're working with materials that are going to present you with those kinds of problems. But I don't think we should demand from you, and I don't think that we will demand from you, sensitivities far greater than is necessary to determine the safety in use of this material. I don't think we have to go on and on and on. If one part per billion is safe, you don't need one part per trillion sensitivity. If one part per million is fine, it's interesting that there are methods that will go to one part per billion, but they're not necessarily necessary. So I think that, if I were developing materials, I would find out what my material is. I'd know what my material is. I'd know what the parameters of migration are. Maybe before I decide to set up a system to define the parameters of migration, maybe I would go to a toxicologist and ask him how low do I need to go? What number am I interested in? Am I really interested in a parts per trillion or is a part per million good enough? Then I don't think

that if a part per million will establish the safety of this particular thing, I don't think that there is very much information gathered by knowing necessarily that a method sensitive to a part per trillion has been used on this particular procedure. Each individual case has to be looked at but that's the situation.

I think the way the petitions come in also is important, and we're doing some things-we're going to be real tough on your petitions when they come in. There's no question about it. You see, you can't have that both ways either. You can't come and see Dr. Wodicka and go to see the Commissioner and say that you know that Ronk and Rothschild, they're really sitting on that stuff down there and they're not turning it out and we've had 15 umpteen amendments in this particular petition and the clock has only been running on it for 120 days of the two years it's been in there. And so when we finally get the last information and then the regulation is not forthcoming within a week or two and you go to see the Commissioner and say you know they're holding it up--well that's all right, I don't care. But one of the things that we will do is, if we file it, it's going to have a 90% chance of flying through the agency in that 180 days. If we do file it. But we aren't going to file anything that in our minds we know is not going to make it on the basis that you may give us the added data we need or you may not.

Now, the other thing--guidelines are wonderful and I think that in your meeting you had several years ago--we will get chemical guidelines out but I don't think that's going to solve anybody's problem because in my own heart, I know that Jack Frawley knows how to file a petition. I know that he knows what ought to be in there. I know that Jerry knows what should be in a petition and I think I know that most of you know, who have been in this business very long, what ought to be in a petition--what's needed and what's not. I also know that one of the real problems that you have in deciding whether or not it's worthwhile to regulate something is what Food and Drug is going to require. And I think you're very foolish if you don't come in and find out what that's going to be before you start a two-year feeding study. And I don't think anybody's going to either, whether we have a toxicological guideline or not, so the guidelines will help but they won't solve this problem because I think the problem of filing a food additive petition and the probl m of regulating materials is somewhat of a negotiation process. We're going to decide on what's feasible. We're not going to go and put goldplating all over it. I don't expect you to do that but I do expect the petitions that you file will be your best effort and I think that they could be that.

[There were more questions and answers with Messrs. Ronk and Rothschild but most of them were not readily transcribable. The foregoing certainly sets forth the essence of Mr. Ronk's "message" to the Committee.]

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APPENDIX D

ROHM AND HAAS COMPANY

December 15, 1972.

Mr. Charles L. Condit,
The Society of the Plastics Industry, Inc.
250 Park Avenue
New York, New York 10017

Dear Charlie:

Below is the report of Medical Devices Standards Subcommiteee (MDSS) for the period March 15 to December 15, 1972.

MDSS was formed at the meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee on March 15, 1972 with the initial purpose of formulating recommendations with regard to the development of standards for plastic medical devices. The effort of MDSS to date has been directed towards 1) a sharper definition of its objective, 2) exploration of the activities of other groups and committees with similar objectives and 3) a decision as to th appropriate modus operandi of MDSS.

The concensus of the Subcommittee is that we should be concerned with the development of standards for plastic materials used in medical devices and not standards for devices per se. It is recognized that the nature and intended use of the device must be considered in developing appropriate standards for plastic materials and that the standards for a given polymer to be used in one device may differ from those of the same polymer to be used in another devic .

We have consulted several related organizations regarding their activities, including the Association for the Advancement of Medical Instrumentation (AAMI), the American National Standards Institute (ANSI), Dow Corning Center for Aid to Medical Research, Pharmaceutical Manufacturers Association/SPI Food, Drug, and Cosmetic Packaging Materials Committee (PMA/SPI FDCPMC), and the American Society for Testing and Materials (ASTM).

Although an AAMI/FDA National Conference on Medical Devices Standards on May 20-21, 1972 was "closed" by the time we made contact, a description of the proceedings was published in the July-August issue of the Journal of the Association for the Advancement of Medical Instrumentation (copy in MDSS file).

Dr. Ackert of PMA/SPI FDCPMC gave us several suggestions and forwarded a copy of "Methodology for Testing Polyolefin Containers for Tablets, Capsules, Oral Powders, and Granules" which he understands will appear in the next supplement to the U.S. Pharmacopoeia.

Mr. Bagner of ANSI forwarded the minutes of the first meeting (held in March) of the International Organization for Standardization Committee ISO/TC 150 which is responsible for Implants for Surgery.

We have had productive contact with ASTM. Dr. Dixler consulted Mr. William F. Carroll of the ASTM committee which is developing a standard for thermoplastic PVC disposable medical examination gloves. Mr. Carroll indicated that he would be in touch with us when his group is ready to consider standards for the plastic material used in the gloves.

In reply to our inquiry, Dr. Horace Grover described the activities of his ASTM committee (ASTM/F-4) which is developing standards for surgical implants. This committee has been entrusted with technical coordination of U.S.A. activities in connection with the International Standards Organization Committee ISO/TC 150 on Surgical Implants.

On November 20, 1972 Dr. Ernest Dixon and I met with Mr. William F. Hulse, Group Manager, Standards Development Division, ASTM to explor the possibility of a cooperative effort between MDSS and ASTM in the development of standards for plastic materials in medical devices. Mr. Hulse described the general modus operandi of ASTM and listed several ASTM committees which are currently developing standards for medical devices or in related areas as follows:

1. ASTM/F-4 is working on the development of consensus standards for surgical implants. The scope of this committee is "The development of definitions of terms and nomenclatures, methods of testing, specifications for surgical implants and materials for surgical implants (including basic and composite materials), and their application. The committee will encourage research in this field and will promote liaison with other ASTM committees and outside organizations with mutua interest."

Several standards have already been established and published including those listed below:

F 55-66 Spec. for Stainless Steel Bars and Wire for Surgical Implants

F 56-66 Spec. for Stainless Steel Sheet and Strip foı Surgical Implants

F 67-66 Spec. for Titanium for Surgical Implants

F 75-67 Spec. for Cast Cobalt Chromium Molybdenum Alloy for Surgical Implants

F 86-68 Rec. Practice for Surface Requirements on Metallic Surgical Implants

F 90-68 Spec. for Wrought Cobalt-Chromium Alloy for Surgical Implants

F 114-69 Standard Specification for Bone Screw Threads

F 115-69 Standard Specifications for Bone Screw Heads

F 116-69 Standard Specification for Medical Screwdriver Bits

F 117-69 Standard Method of Test for Driving Torque of Medical Bone Screws

2. ASTM/D-10 is developing consensus standards for packages of all types used in the handling, storage, and distribution of goods. Mr. Hulse indicated that a subcommittee of ASTM/D-10 is developing standards for packages for the storage of blood.

3. ASTM/D-20 on plastics is interested in "the development of test methods, specifications, recommended practices, nomenclature, definitions, and the stimulation of research relating to plastics, their raw materials, components, and compounding ingredients, and to finished products made from plastics such as sheets, rods, tubes, pipes, cellular materials, and molded or fabricated articles". I do not believe that any of the subcommittees of ASTM/D-20 is directed towards standards for plastics in medical devices.

Mr. Hulse mentioned the subcommittee working on standards for PVC disposable gloves for medical examination, but I do not recall the committee under which this group operates. He mentioned that task forces are often formed to work on standards for individual products. He also made note of ASTM/D-702 which has responsibility for standards for cast methacrylate plastic sheets, rods and other shapes including sterilization of such articles. ASTM/D-1239 is concerned with the r sistance of films to extraction.

Mr. Hulse pointed out that the Association of Official Analytical Chemists (AOAC) is active in the development of standard analytical t st methods. It is interesting that Mr. L. L. Ramsey is president of AOAC. Mr. Hulse feels that, before MDSS becomes further involved with the development of standards for plastics in medical devices,

we should explore how we and AOAC would fit into the general scheme. Dr. Dixler has agreed to determine whether the scope of past AOAC activity overlaps our area of interest.

Mr. Hulse emphasized that ASTM is a "management system for the development of standards". He recommended that we consider placing on or more SPI member(s) on each of the pertinent ASTM committees so that we could supply our input to the development of standards for plastic materials in various medical devices. He feels that our purposes could be served within the framework of existing committees but that if needed, other committees could be formed. He suggested that we meet on a more formal basis with ASTM so that immediate objectives can be established and questions of procedure resolved. He also suggested that Mr. Cangelosi of the FDA be invited to attend such a meeting.

Oth r options (in addition to Mr. Hulse's suggestion) are 1) to develop cooperation with ASTM wherever possible through current r presentatives from companies represented by MDSS membership and 2) to encourage appropriate ASTM committees to seek MDSS advice when, in the development of standards for a particular medical device, ther is need to consider standards for plastic materials of construction. I plan to seek the guidance of the Steering Committee and MDSS memb rship regarding this procedural question.

Sincerely yours,

George A. Richter, Jr.

GAR/je

cc: Members of MDSS of the SPI FDCPMC
Mr. Lou DeMarco, Diamond Shamrock Chemical Co.
Dr. Daniel S. Dixler, Keller and Heckman
Dr. Ernest M. Dixon, Celanese Corporation
Mr. Peter Morison, Eastman Chemical Products Co.
Mr. Philip J. Vanderhorst, E. I. du Pont de Nemours and Co.
Mr. Edward J. Vandermark, Northern Petrochemical Co.
Dr. Leo W. Ziemlak, Foster-Grant Co., Inc.

Jerome H. Heckman, Esq., Keller and Heckman
Dr. K. A. Hochschwender, American Hoechst Corp.

APPENDIX E

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE

SPI FOOD PACKAGING MATERIALS COMMITTEE

DECEMBER 15, 1972

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:

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2566	F.R. 37(55) Page 5749 3-21-72	Geigy Industrial Chemicals	Amended to provide for the safe use of tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyhydro-cinnamate)] methane as an antioxidant and/or stabilizer in certain polymers authorized for use in the manufacture of articles or component of articles intended for food contact use.
Amended 121.2514	F.R. 37(58) Page 6052 3-24-72	Procter & Gamble Co.	Amended to provide for the safe use of (alkoxy C_{10}-C_{16}) -2,3-epoxypro-pane, in coatings that are intended for contact with dry bulk foods at room temperature.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2531	F.R. 37(58) Page 6053 3-24-72	Emery Industries	Amended to provide for the safe use of di(2-ethylhexyl) azelate as a surface lubricant or component of surface lubricants employed in the manufacture of metallic articles that contact food.
Amended 121.2509	F.R. 37(60) Page 6290 3-28-72	Goodyear Tire & Rubber Co.	Amended to provide for the safe use of N,N'-dioleoylethylenediamine as a release agent in polyvinyl chloride films for food-contact use.
Amended 121.2520	F.R. 37(62) Page 6469 3-30-72	B. F. Goodrich Co.	Amended to provide for the safe use of 1,3,5 tris (3,5-di-tert-butyl-4-hydroxybenzyl)-s-triazine-2,4,6(1H,3H,5H)-trione as a component of food packaging adhesives.
Amended 121.2524	F.R. 37(62) Page 6469 3-30-72	Minnesota Mining & Manufacturing Co.	Amended to provide for the safe use of ethylene terephthalate-isophthalate copolymers as the base sheet in the production of food-contact polyethylene phthalate films.
Amended 121.2526	F.R. 37(62) Page 6470 3-30-72	Milchem, Inc.	Amended sodium polyacrylate as a component of paper and paperboard intended for use in contact with food.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2526	F.R. 37(67) Page 6925 4-6-72	Monsanto Co.	Amended to provide for the safe use of poly-amine-epichlorohydrin resin as a wet strength agent and/or retention aid in the manufacture of paper and paperboard for food-contact use.
Amended 121.2526	F.R. 37(83) Page 8525 4-28-72	National Starch & Chemical Corp.	Amended to provide for the safe use of a mixture of (2-alkenyl) succinic anhydrides, as a sizing agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with aqueous and fatty foods.
Amended 121.2505	F.R. 37(87) Page 9023 5-4-72	Syracuse University Research Corp. on behalf of Betz Laboratories, Inc.	Amended to provide for the safe use of β-Bromo-β-nitrostyrene as a slimicide used in the manufacture of paper and paperboard intended for food-contact use.
Amended 121.2526	F.R. 37(90) Page 9316 5-9-72	Sun Chemical Corp.	Amended to provide for the safe use of bis (methoxymethyl) tetrakis (octadecyloxy) methyl) melamine resins as a water repellent employed in the manufacture of paper and paperboard intended for use in contact with fatty foods.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2571	F.R. 37(90) Page 9317 5-9-72	Nopco Chemical Division, Diamond Shamrock Chemical Co.	Amended to provide for the safe use of a modified polyacrylamide condensation product as a dry strength and pigment retention aid agent in paper and paperboard intended for use in contact with dry food.
Amended 121.2526	F.R. 37(96) Page 9762 5-17-72	Minnesota Mining & Manufacturing Co.	Amended to provide for the use of higher levels of ammonium bis (N-ethyl-2-perfluoroalkylsulfonamido ethyl) phosphates in heavyweight paper and paperboard, and to provide for additional uses of treated paper and paperboard in contact with aqueous and fatty foods.
Amended 121.2514	F.R. 37(109) Page 11241 6-6-72	PPG Industries	Amended to provide for the safe use of copolymers consisting of butyl acrylate, styrene, methacrylic acid, and hydroxypropyl methacrylate as a component of resinous and polymeric food-contact coatings.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2620	F.R. 37(119) Page 12143 6-20-72	Imperial Chemical Industries, Ltd.	Amended: (1) to provide for the safe use of hydrogenated castor oil as a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles intended for food-contact use, and (2) to provide a cross-reference for uses of this additive that are permitted elsewhere in Subpart F.
Amended 121.2520	F.R. 37(122) Page 12383 6-23-72	Procter & Gamble Co.	Amended to provide for the safe use of a,a',a" -1,2,3-Propanetriyltris [omega-(2,3-epoxypropoxy) poly (oxypropylene) (24 moles)]
Amended 121.2526	F.R. 37(122) Page 12383 6-23-72	Monsanto Co.	Amended to provide for the safe use of a polyamine resin as a retention aid and/or flocculent in the manufacture of paper and paperboard intended for use in contact with aqueous and fatty foods.
Amended 121.2526	F.R. 37(124) Page 12633 6-27-72	E. I. du Pont de Nemours & Co., Inc.	Amended to expand the permitted conditions of food-contact use for paper and paperboard containing diethanolamine salts of mono- and bis(1H,1H,2H,2H-perfluoroalkyl) phosphates

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Proposal	Section 6 7-12-72	Commissioner of Food & Drugs	Proposes to establish procedures for preparation of environmental impact statements. Lists outline for report.
Amended 121.2514	F.R. 37(152) Page 15859 8-5-72	Mohawk Industries Inc.	Amended to provide for the safe use of cyclohexanone-formaldehyde resins as components of articles intended for use in contact with food.
Amended 121.2520	F.R. 37(153) Page 15916 8-8-72	Moore & Munger Inc.	Amended to provide for the safe use of synthetic paraffin waxes, differing from those prescribed under 121.2575 Parafin, synthetic (21 CFR 121.2575), as components of food-packaging adhesives.
Amended 121.2575	F.R. 37(153) Page 15916 8-8-72	Moore & Munger Inc.	Amended in 121.2575 by adding a new paragrph (c) to read as follows 121.2575 Paraffin, synthetic.
Amended 121.2520	F.R. 37(153) Page 15916 8-8-72	General Mills Chemicals, Inc.	Amended to provide for the safe use of polyamides derived from dimer diamine as components of adhesives for bonding seams of food-packaging material.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2520	F.R. 37(154) Page 15992 8-9-72	Witco Chemical Corp.	Amended to provide for the use of 4-[2-[2-(2-alkoxy (C_{12}-C_{15}) ethoxy) ethoxy] ethyl] disodium sulfosuccinate as a component of paper and paperboard in contact with dry food and food packaging adhesives.
Amended 121.2571	F.R. 37(154) Page 15992 8-9-72	Witco Chemical Corp.	Section 121.2571(b)(2) is amended by alphabetically adding to the list of substances a new item as follows 4-[2-[2-(2-alkoxy (C_{12}-C_{15}) ethoxy) ethoxy] ethyl disodium sulfosuccinate.
Amended 121.2526	F.R. 37(154) Page 15992 8-9-72	Buckman Labs, Inc.	Amended to provide for the safe use of N,N,N',N'-tetramethylethylenediamine polymer with bis (2-chloroethyl) ether, first reacted with poly(acrylic acid) as a drainage aid, flocculent, or retention aid in the manufacture of paper and paperboard in contact with aqueous and fatty foods.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2597	F.R. 37(155) Page 16075 8-10-72	Rohm & Haas Co.	Amended to provide for the safe use of not more than 30 weight-percent of polymer units derived from copolymers of methyl methacrylate, α-methyl-styrene and acrylonitrile as modifiers in semirigid and rigid vinyl chloride plastic food-contact articles.
Proposal 121.2006	F.R. 37(155) Page 16078 8-10-72	Commis-sioner of Food & Drugs	Declaring paint and other similar surface-coating materials for use in or around the household to be a banned hazardous substance if shipped in interstate commerce after December 13, 1972, containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or the dried film. Separate provisions of that order also banned shipment in interstate commerce after December 31, 1973, of paint and other similar surface-coating materials for use in or around the household that contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or the dried film.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Order 191.9(a)(6)	F.R. 37(155) Page 16079 8-10-72	Commissioner of Food & Drugs	The Commissioner concludes that those portions of 191.9(a)(6) pertaining to the 0.5 percent lead level should be confirmed as effective. Those portions pertaining to the 0.06 percent lead level will be the subject of a separate document to be published at a later date.
Amended 121.2514	F.R. 37(156) Page 16175 8-11-72	W. R. Grace & Co.	Amended to provide for the safe use of urea as a component of resinous and polymeric coatings for food-contact use as a side seam cements.
Amended 121.2526	F.R. 37(156) Page 16175 8-11-72	Lubrizol Corp.	Amended to provide for the safe use of the reaction product of N-(1,1-dimethyl-3-oxobutyl) acrylamide and formaldehyde as a component of polyvinyl acetate latex coatings for paper and paperboard intended for use in contact with food.
Amended 121.2526	F.R. 37(156) Page 16176 8-11-72	Buckman Laboratories, Inc.	Amended to provide for the safe use of 2-Bromo-4'-hydroxy-acetophenone as a preservative in paper coating formulations, binders, pigment slurries and sizing solutions at a level not to exceed 0.006 percent by weight of the coating, solution, slurry or emulsion.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2566	F.R. 37(157) Page 16389 8-12-72	Gulf Oil Corp.	Amended to provide for the safe use of 2,6-di-tert-butyl-4-ethylphenol as an antioxidant and/or stabilizer in ethylene polymers and copolymers intended to contact non-alcoholic foods.
Proposal 121.2006	F.R. 37(157) Page 16407 8-12-72	Commissioner of Food & Drugs	(a) Talc is a naturally occuring hydrous magnesium silicate for which no food grade specifications exist. Talc is subject to a prior sanction for use in coating polished rice. (b) Talc containing asbestos-form particles may be injurious to health. Accordingly, any food or food packaging material containing talc that is not free of asbestos-form particles shall be deemed to be adulterated in violation of section 402 (a)(1) of the Act.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Notice	F.R. 37(168) Page 17470 8-29-72	FDA	Notice is hereby given that FD Form 2512, "Cosmetic Product Ingredient Statement", FD Form 2513, "Cosmetic Raw Material Composition Statement", FD Form 2514, "Notice of Discontinuance of Commercial Distribution of Cosmetic Product or Cosmetic Raw Material", and a pamphlet of detailed instructions for use in completing the forms are now available for distribution. Those desiring FD Forms 2512, 2513, and 2514, and the pamphlet of instructions may submit requests to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. 20204, or to any Food and Drug Administration district office.
Amended 121.2619	F.R. 37(175) Page 18195 9-8-72	E. I. du Pont de Nemours Co., Inc.	Amended to provide for the safe use of ethylene-vinyl acetate-vinyl alcohol copolymers as articles or components of articles intended for use in contact with food.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2526	F.R. 37(178) Page 18528 9-13-72	Velsicol Chemical Corp.	Amended to provide for the safe use of styrene-isobutylene copolymers as components of paper and paperboard in contact with aqueous and fatty foods.
Amended 121.2527	F.R. 37(178) Page 18529 9-13-72	M & T Chemicals, Inc.	Amended to provide for the safe use of glycerol ester mixtures of ricinoleic acid as an antifogging agent for permitted plasticized vinyl chloride homo- and/or copolymers in food-contact articles.
Amended 121.2520	F.R. 37(179) Page 18615 9-14-72	GAF Corp.	Amended to provide for the safe use of a-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) sulfate, ammonium salt as a component of food-packaging adhesives and of paper and paperboard in contact with dry food
Amended 121.2571	F.R. 37(179) Page 18615 9-14-72	GAF Corp.	Amended to provide for the safe use of a-(p-nonylphenyl)-omega-hydroxypoly (oxyethylene) sulfate, ammonium salt as a component of food-packaging adhesives and of paper and paperboard in contact with dry food.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2541	F.R. 37(185) Page 19820 9-22-72	Atlas Chemical Industries, Inc.	Amended to provide for the safe use of sorbitan monopalmitate, sorbitan trioleate, and sorbitan tristearate as emulsifiers and/or surface active agents in the manufacture of food-contact articles.
Amended 121.2526	F.R. 37(190) Page 20324 9-29-72	Nalco Chemical Co.	Amended to provide for the safe use of phosphoric acid esters and polyesters (and their sodium salts) of triethanolamine in the manufacture of paper and paperboard in contact with aqueous and fatty foods.
Amended 121.2526	F.R. 37(195) Page 21151 10-6-72	American Cyanamid Co.	Amended to provide for the safe use of isophthalic acid as a reactant with diethylenetriamine in the manufacture of polyamide-epichlorohydrin water soluble thermosetting resins intended for use as components of paper and paperboard in contact with aqueous and fatty foods.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2511	F.R. 37(201) Page 21905 10-17-72	Esso Research & Engineering Co.	Amended to provide for the safe use of diisononyl adipate as a plasticizer in vinyl chloride homo- and/or copolymer films for food contact use.
Amended 121.1241	F.R. 37(202) Page 21991 10-18-72	Environmental Protection Agency	A tolerance of 1 part per million is established in potable water for residues of copper resulting from the use of the algicides or herbicides copper sulfate and basic copper carbonate (malachite) to control aquatic plants in reservoirs, lakes, ponds, irrigation ditches, and other potential sources of potable water.
Amended 121.2621	F.R. 37(203) Page 22374 10-19-72	Phillips Petroleum Co.	Amended to provide for the safe use of polyphenylene sulfide resins (poly(1,4-phenylene sulfide)resins) as coatings or components of coatings of articles intended to contact food.
Petition	F.R. 37(212) Page 23344 11-2-72	Cosmetic, Toiletry & Fragrance, Association	Petition proposing the issuance of regulations to establish a procedure for the voluntary filing of cosmetic product experience to the extent that such experience involves any allergic reaction or other bodily injury caused by exposure to a cosmetic product.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2520	F.R. 37(214) Page 23538 11-14-72	E. I. du Pont de Nemours & Co.	Amended to provide for use of fumaratochromium (III) nitrate as a component of food packaging adhesives
Amended 121.2535	F.R. 37(214) Page 23538 11-4-72	Celanese Fibers Marketing Co.	Amended to provide for the safe use of polyethylene terephthalate fibers and of 4-ethyl-4-hexadecyl morpholinium ethyl sulfate as a lubricant in the manufacture of polyethylene terephthalate textile and textile fibers used as articles or components of articles intended for use in contact with food.
Amended 121.1246	F.R. 37(226) Page 24816 11-22-72	Stauffer Chemical Co.	Amended to provide for the safe use of molecular sieve resins consisting of purified dextrans cross-linked with epichlorohydrin in the final purification of partially delactosed whey.
Amended 121.2562	F.R. 37(230) Page 25229 11-29-72	B. F. Goodrich Co.	Amended to provide for the safe use of polyurethane resins as elastomers in the formulation of rubber articles intended for repeated food-contact use.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.1244	F.R. 37(231) Page 11-30-72	Eastman Chemical Products Inc.	Amended to provide for the safe use of tertiary butylhydroquinone (TBHQ) in food as an antioxidant alone or in combination with BHA and/or BHT, whereby the total antioxidant content of the food does not exceed 0.02 percent of its oil or fat content, including its essential (volatile) oil content.