FFK 4/17/72

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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

MINUTES

MEETING OF SPI FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE

Shoreham Hotel
Washington, D. C.

March 15, 1972
9:20 a.m.

Present:

Robert M. Miller, General Chairman, Hercules, Inc., Delaware Trust Building, Wilmington, Delaware 19899
Watson B. Ackart, Union Carbide Corp., River Road, Bound Brook, New Jersey 08805
William Allen, American Cyanamid Co., Bound Brook, New Jersey 08885
Ronald R. Arnold, M & T Chemicals, Inc., Rahway, New Jersey 07065
Robert C. Asam, The Goodyear Tire & Rubber Co., 1485 E. Archwood Avenue, Akron, Ohio 44316
W. C. Bachtel, B. F. Goodrich Co., 500 S. Main Street, Akron, Ohio 44318
Norman D. Bornstein, Cryovac, P. O. Box 464, Duncan, South Carolina 29334
Roger G. Boyer, Pantasote Corp. of New York City, 26 Jefferson Street, Passaic, New Jersey 07055
Kenneth C. Conley, Marbon Division, Borg-Warner Corp., Washington, West Virginia 26181
Paul F. Cundy, American Can Company, Box 702, Neenah, Wisconsin 54956
Richard A. Dannells, Dart Industries, Inc., P. O. Box 37, Paramus, New Jersey 07450
LaVerne J. DeCorte, Sinclair-Koppers Company, Frankfort Road, Monaca, Pennsylvania 15061
Daniel S. Dixler, Keller and Heckman, 1150 17th Street, N.W., Washington, D.C. 20036
Dr. Ernest M. Dixon, Celanese Corporation, 522 5th Avenue, New York, New York 10036
Thomas J. Dolce, Celanese Plastics Co., Box 828, Greer, South Carolina 29651
George W. Ferner, The Goodyear Tire & Rubber Co., 1144 E. Market, Akron, Ohio 44316
Robert P. Fischer, Kerr Glass Manufacturing Corp., P. O. Box 4000, Lancaster, Pennsylvania 17604
David H. Fishman, Celanese Plastics, Morris Court, Summit, New Jersey 07901
Gerhard H. Fuchs, Allied Chemical Corp., Box 1057R, Morristown, New Jersey
David R. Gaskill, Mobil Chemical Co., P. O. Box 240, Edison, New Jersey 08817
B. J. Garceau, ICI America Inc., 151 South Street, Stamford, Connecticut 06904
Max Goldfrank, Stein, Hall & Co., Inc. (Celanese), 605 Third Avenue, New York, New York 10016
S. F. Goodheart, Levey Div. Cities Service Co., 630 Glendale-Milford Road, Cincinnati, Ohio 45215
Charles H. Goodman, The Dow Chemical Company, 2030 Dow Center, Midland, Michigan 48640

Francis W. Greenough, Cryovac Division, W. R. Grace & Co., P. O. Box 464, Duncan, South Carolina 29334
Taylor Hanavan, E. I. duPont de Nemours, Film Dept., 1007 Market Street, Wilmington, Delaware 19898
G. Frederick Hanna, Marbon Division, Borg-Warner Corp., P. O. Box 68, Washington, West Virginia 26181
Jerome H. Heckman, SPI General Counsel, 1150 17th Street, N.W., Washington, D.C. 200
Michael Hirsch, B. F. Goodrich Chemical, 5100 Oak Tree Blvd. Cleveland, Ohio 44111
Karl A. Hochschwender, American Hoechst Corp., Route 202-206 North, Somerville, New Jersey 08876
John F. Jones, The Standard Oil Co. (Sohio), Midland Bldg., 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
Robert H. Knust, Celanese Plastics Co., Morris Court, Summit, New Jersey 07901
Jack L. Lawing, Eastman Chemical Products, Inc., Kingsport, Tennessee 37662
Clyde W. Leaf, BASF Wyandotte Corp., Biddle Avenue, Wyandotte, Michigan 48183
Jerome H. Ludwig, Synthetic Products Co., 1636 Wayside Road, Cleveland, Ohio 44112
Joel Markowitz, Dart Industries Inc., Chemical Group, W. 115 Century Road, Paramus, New Jersey 07652
Peter Morison, Eastman Chemical Products Inc., Kingsport, Tennessee 37662
Peter M. Nemkov, Keller and Heckman, 1150 17th Street, N.W., Washington, D. C. 20036
Donald W. Pugh, U.S. Industrial Chem. Co., P. O. Box 218, Tuscola, Illinois 61953
Lorence Rapoport, Olin Corp., P. O. Box 200, Pisgah Forest, North Carolina 28768
George A. Richter, Rohm and Haas, Independence Mall West, Philadelphia, Pennsylvania 19105
Robert E. Rutherford, Gulf Oil Corporation, 439 Seventh Ave., Pittsburgh, Pennsylvania 15230
A. Merrill Schnitzer, Phillips Petroleum Co. 356 Research Building 1, Bartlesville, Oklahoma 74004
W. W. Sederlund, National Starch & Chemical Corp., 1700 West Front Street, Plainfield, New Jersey 07063
Dwight M. Sheets, Shell Chemical Company, One Shell Plaza, P. O. Box 2463, Houston, Texas 77001
Matthew E. Smith, Owens-Illinois, 14th & Adams Sts., Toledo, Ohio 43606
Charles J. Spiegl, Continental Can Co., 7622 S. Racine Ave., Chicago, Illinois 60620
Don F. Thompson, Amoco Chemicals, Tech Center, Naperville, Illinois 60540
Judith A. Tins, Celanese Corporation, 522 5th Avenue, New York, New York 10036
Philip J. Vanderhorst, DuPont-Film Department, 1007 Market Street, Wilmington, Delaware 19898
E. J. Vandermark, Northern Petrochemical Co., 2223 Dodge St., Omaha, Nebraska 68102
Willard M. Westveer, The Dow Chemical Co., 2040 Dow Center, Midland, Michigan 48640
George F. White, Jr., Reynolds Metals Co., 10th & Byrd Sts., Richmond, Virginia 2321
Ambrose G. Whitney, W. R. Grace & Co., Research Division, Clarksville, Maryland 2102
Ronald M. Wilson, Jr., Emery Industries, Inc., 4900 Este Ave., Cincinnati, Ohio 4523
L. W. Ziemlak, Foster Grant Co., Inc., 289 N. Main Street, Leominster, Massachusetts
C. L. Condit, Secretary, SPI, 250 Park Avenue, New York, New York 10017

Under the Chairmanship of Robert M. Miller, Hercules, Inc., a regular meeting of the SPI Food, Drug and Cosmetic Packaging Materials Committee convened in the Shoreham Hotel, Washington, D. C. at 9:20 a.m. Mr. Miller commented on the outstanding attendance, noting that there were more present than the Secretary expected.

Further, Mr. Miller mentioned that it had been some time since the Committee conducted a so-called "closed" meeting since at the last few sessions, there have been FDA people on the program, and at times others not part of the Committee. He asked those present to feel free, at any time, to pose questions throughout the day's meeting.

Referring to the detailed Agenda, Mr. Miller then asked for the usual self-introductions.

Minutes of Last Meeting Approved

Indicating that the last meeting of the Committee was held at the Commodore Hotel, New York City, on June 3, 1971, Chairman Miller asked if there were any corrections or additions to the Minutes as developed and circulated by the Secretary. In the absence of comments, he declared the Minutes approved as circulated.

Preliminary Remarks by Mr. Miller

At this point Mr. Miller expressed pleasure that Charlie Stone, Eastman Chemical Products, Inc., and Vice Chairman of the Committee, as well as Chairman of the Lawyers' Advisory committee is reported to be coming along very nicely following a prolonged illness, and more recently, major surgery. Mr. Miller announced that Jack L. Lawing of Eastman Chemical Products, Inc. would represent Mr. Stone at the day's session, and, at the appropriate time, would deliver the report on the activities of the Lawyers' Advisory Subcommittee.

Comments by Chairman Miller on Activities and Scope of the SPI Public Affairs Council and European Developments

Chairman Miller then gave the following report, dealing with the SPI Public Affairs Council and European developments:

Report of Chairman Miller

SPI PUBLIC AFFAIRS COUNCIL

"SPI has formed a new operating division known as the Public Affairs Council. It formerly was designated as the Plastic/Packaging Council and Plastics Council and was initiated as the single focal point of the SPI environment program. It is now a division of SPI and will have representation on the SPI board. A draft of by-laws for the council has been prepared and is ready for adoption. It is composed of management representatives of many member companies and has the following objectives:

a) Convince influential publics about the benefits of plastics.

b) Convince our customers that not only do plastics represent good, modern design and material solutions, but also that plastics do not expose these customers to public relations problems.

c) Respond quickly and accurately to public criticism of plastics.

d) Counteract or repeal anti-plastics legislation.

e) Demonstrate that the plastics industry has a genuine and constructive concern for improving our environment.

"To assist in reaching these objectives, the Council has obtained the services of Hill and Knowlton, one of the leading public relations firms. In addition, the Council has hired its initial legislative representative.

"From its inception in mid-July to the end of 1971, the Council operated on a budget of approximately $391,000. Pledges totalled approximately $340,000 and SPI pledged $50,000 to make up the difference. The Public Affairs Council has a proposed 1972 budget of $975,000. As of the middle of February, pledges have been received in excess of $850,000 from 44 member companies. They hope to obtain pledges of at least $1,000,000. If your company has not joined the Council, please check and see that they know about its activities and can become a member. This is a united plastics industry effort with with we all should be concerned.

"Three current 'hot areas' of immediate concern to the SPI Public Affairs Council are the states of Massachusetts, Vermont and New York. Bills pending in Massachusetts concern taxes on non-returnable and no deposit containers and perhaps some actual bans on certain items. Vermont has a bill to be passed momentarily which stipulates a 1 mil/container tax on all separate closed containers (bottles, jars, cans and cartons). We just have been informed that this Vermont bill was not passed but was returned to committee for further consideration. New York has a non-returnable container tax bill before the legislature, as well as one to ban PVC. The SPI PAC is actively engaged in following these actions.

"The Subcommittee on the Environment of the Senate Commerce Committee just concluded hearings (held on March 6, 10 and 13) concerning the environmental aspects (primarily of solid waste disposal) of containers of all types, Ralph Harding. Executive Vice President of SPI, made a statement to the subcommittee regarding the environmental characteristics of plastic containers.

"We do not want to take time to discuss the details of these actions here, but if any of you is interested in them, we suggest you contact Mr. Sam Nuspliger at the SPI office.

INTERNATIONAL DEVELOPMENTS

"The Council of Europe is holding a second symposium on food packaging in Rome on March 23 and 24 as a follow-up on the 1971 symposium in the Netherlands, which I attended as a representative of SPI and reported on at the June 3 meeting. This symposium is being hosted by the Italian government, and, unfortunately, they decided not to invite any delegates from the U. S. Apparently they plan to continue discussion of 'global' migration and the philosophies of policing and regulating food packaging materials. We will have to receive our reports of their deliberations from our European contacts.

"We have received word that the Dutch have come up with a new approach to regulating packaging materials as an attempt to resolve the differences between the French and Italian philosophy and that of the Dutch and Germans so that uniform regulations can be established. We cannot see that this new approach will be of much help to us in our negotiations with FDA, but here is the Dutch proposal as we understand it:

"The old system was like that of West Germany in that positive lists of recommended or approved additives were given for each plastic or packaging material, with limitations on the quantity of many. The limitations resulted from toxicological considerations, self-limiting features or the amounts tested in each instance. This meant an analytical method was required for each additive in each plastic. The Dutch commission analyzed the list, deleting all additives where the limitation was not based on toxicological considerations and where the compounds did not give rise to toxicological problems. This resulted in deletion of 75% of the list. For the remaining 25%, it was decided to replace the maximum concentration in the plastic or other food packaging material with a maximum number of milligrams in food or a food simulating solvent. This number, when converted to ppm's in food, should not exceed the ADI (Acceptable Daily Intake) times 60. An assumption is made that the daily food intake is 1 kg/day. Since 1 kg of food is wrapped in an average of 6 sq. dm. of plastic, and the migration of plastics does not exceed 10-12 mg per sq. dm, this calculates to 60 mg/kg food or 60 ppm. This 60 ppm is an arbitrary number, but it was concluded that if the migration (or extraction) of a specific ingredient does not exceed the ADI times 60, it may be used in any quantity with no limitations or analytical tests required. Since it was established that the maximum migration of

a plastics component was 60 ppm, compounds with an ADI greater than one will meet these criteria.

"The ADI times 60 has been designated as the Packaging ADI (PADI). The ADI used for most of the calculations has been based on the results of 90-day animal feeding studies. If the migration exceeds the PADI, the specific migration of the additive must be determined, and a limitation for that ingredient will be in the regulations. Thus, an analytical method is required for those compounds. The PADI system supposedly incorporates the 'Frawley proposal' to 0.05 ppm, but we have no details on that as yet. Perhaps we will know more after the Rome symposium.

"The Dutch proposal was developed to attempt to resolve the differences noted at the Noordwijk symposium in 1971 between the Dutch and German approach versus that of the French and Italians. The former had positive lists with provisions for petitioning for new additives, while the French and Italians assumed that plastic packaging materials would offer no hazard to public health if the gross migration or extraction is less than 50-60 ppm when using a procedure similar to our end-use extraction test. The French and Italians desired to use this as a means of policing the law. The new Dutch PADI system supposedly combines the two approaches, which may satisfy the Council of Europe.

"The second item concerning international developments is the notice of a forthcoming seminar on the 'Migration of Additives from Plastics and Their Determination in Fat Simulants', sponsored by Unilever in Hamburg, West Germany."*/

Following Mr. Miller's report on European activities, Norman Bornstein, Cryovac Division, W. R. Grace & Company, suggested that in one manner or another it would be quite desirable to assemble a bibliography of foreign papers on extraction studies or methods which have either been delivered, or are to be delivered at some time in the future. Mr. Miller said that this could very well be considered by the Technical Information Subcommittee, and asked that the Subcommittee Chairman report on such matters from time to time to the extent that is possible to assemble such a list.

In closing his report, Mr. Miller noted that the international situation as regards the interests of the Committee's members are becoming more and more important and that, therefore, there is every reason for an adequate liaison to be maintained with the various countries abroad, if, for no other reason, than to try to steer them towards a better regulatory system than ours.

---

*/ Details are contained in the attached announcement, Appendix A.

Nomination and Election of Officers

Chairman Miller reminded those present that, some time ago, he had appointed a Nominating Committee composed of Messrs. Matthew E. Smith, Chairman, Owens-Illinois; and members George W. Ingle, Monsanto Company; and Max Goldfrank, Stein, Hall & Co., Inc; asking that they propose a slate of proposed officers as well as Steering Committee members-at-large for the period beginning June 1, 1972 to June 1, 1974.

He then called upon Matt Smith to give the Nominating Committee report.

Mr. Smith named the following proposed officers: General Chairman Karl A. Hochschwender, American Hoechst Corporation; and Vice Chairman, Willard M. Westveer, The Dow Chemical Company. The appointment of the following members to the Steering Committee, Karl A. Hochschwender, Chairman, American Hoechst Corporation; W. B. Ackart, Union Carbide Corp.; Paul F. Cundy, American Can Company; Taylor W. Hanavan, E. I. duPont de Nemours & Co., Inc.; Robert M. Miller, Hercules, Inc.; George A. Richter, Jr., Rohm & Haas Company; and Willard M. Westveer, The Dow Chemical Company; was also recommended.

Chairman Miller asked if there were further nominations, and in the absence of any, Mr. Smith moved that the nominations be closed and that the Secretary cast a unanimous ballot for the slate as proposed. The motion was seconded and carried unanimously.

At this point, Chairman Miller expressed deep appreciation for the fine co-operation he has had from both the Steering Committee and the SPI office during his tenure of office, and expressed hope that some accomplishments were made during his Chairmanship.

Report of SPI General Counsel

Chairman Miller next introduced Jerome H. Heckman, Keller and Heckman, and General Counsel for SPI, to deliver his regular report on various regulatory activities relating to the interests of the industry.

[Please note: Attached hereto is a reproduction of Mr. Heckman's complete presentation at the day's session, including various attachments in the form of appendices mentioned by him.]

At the outset, Mr. Heckman asked that those present interrupt him at any time should they have questions to pose or, on the other hand, at any point where formal action was requested to be taken at the day's session regarding any one or more of the items he discussed.

In discussing the status of the USDA proposed amendments to meat inspection regulations, Mr. Heckman reminded those present that attached to his report (see attachment to these Minutes) was MPI Notice 69 while available for the

first time at the day's meeting of the Steering Committee was a document labeled MPI Notice 74.

It was requested by Mr. Heckman at the day's session that the Secretary place the MPI 74 Notice in the Minutes. It follows:

"UNITED STATES DEPARTMENT OF AGRICULTURE MPI NOTICE 74
Consumer and Marketing Service
Meat and Poultry Inspection Program
Washington, D. C. 20250

"INFORMATION FOR: All MPI Personnel, Owners, and Operators of Official Establishments, and State Officials

Section 302.3 in the Manual of Meat Inspection Procedures and Section 81.95 of the Poultry Inspector's Handbook

"The above sections are being revised to permit the use of continuing letters of FDA guaranty.

"Please advise those who inquire, that such letters will be permitted whenever letters of FDA guaranty pertain in the instruction to be implemented April 1, 1972.

"An example follows:

'The articles listed herein comprising each shipment or other delivery hereafter made by (name of person or company giving guaranty) to, or on the order of (name and address of person or company to whom the guaranty is given) is hereby guaranteed as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act.'

(Signature of person with responsible position in supplying firm--address)

/s/
Fred J. Fullerton, Director
Field Operations Division"

There was a great deal of discussion at the day's session relating to Mr. Heckman's report on the negative-type publicity which has appeared on the use of phthalate plasticizers ever since the announcement of Dr. Rubin's findings on the PVC blood bags problem. Especially helpful in the course of this discussion was a report given by Peter Morison of Eastman Chemical Products, Inc. relative to a recent meeting of a special MCA Committee called to discuss the phthalates problem. Mr. Morison reported as follows:

Manufacturing Chemists Association Technical Meeting on Phthalates - February 24, 1972

"Thirty-three member companies of MCA most intimately affected convened in Washington, D. C. on February 24, 1972 to discuss the significance of publicity on phthalate plasticizers used in biomedical applications, particularly blood bags and medical tubing.

"It was agreed that some toxicological data on ingestion of phthalates has been published and substantially more information of value is believed to exist in company files. It would be helpful to pool existing unpublished data and appraise its applicability to the current problem.

"It was noted that a test program representing use of plasticized PVC in sensitive applications is under way at Stanford Research Institute and supported by representatives of industry. Results of this program are not expected to be available for some months.

"At the meeting, representatives of eight MCA member companies volunteered to create an Ad Hoc Planning Group on Phthalate Studies for the purpose of developing a program for further consideration which may include a meeting with Drs. Rubin (Johns Hopkins), Autian (University of Tennessee), and Guess (University of Texas), and other researchers in this field.

"The Ad Hoc Committee is composed of representatives of the following companies:

Baxter Laboratories	(Dr. Gesler)
Borden Chemical Co.	(Dr. Cummin)
Eastman Kodak Co.	(Dr. Raleigh)
Enjay Chemical Co.	(Dr. Livingston)
W. R. Grace & Co.	(Mr. Magram)
Monsanto Company	(Mr. Graham)*
Union Carbide Corp.	(To be named)
USS Chemicals	(Dr. Mackay)

*Temporary Chairman

"MCA Will serve only as a vehicle reflecting the position of

its member companies. MCA sponsorship of any program must be approved in advance by its Board of Directors and funded by participating member companies."

Thereafter, Mr. Miller pointed out that the Steering Committee, in a meeting the previous evening, had expressed great concern about the phthalates problem and believes this whole matter should be brought to the special attention of the SPI Board of Directors. In this regard, Bill Westveer, a member of the Steering Committee, first proposed a motion whereby the full Committee would approve approaching the SPI Board of Directors to call a meeting of PVC and plasticizer producers in order to ascertain whether the time has come for a position paper to be prepared on the use of these materials if, for nothing else, than to protect the market where these materials are known to be advantageous and have favorable characteristics.

There was then a great deal of discussion about the matter, one question raised being whether the action proposed by the Steering Committee might result in the preparation of a position paper by SPI which could duplicate or conflict with the present work of MCA in this area. It was noted that at a recent special MCA meeting it was decided that it was premature from a technical point of view to prepare such a paper. In any case, it was reported that the MCA Committee is considering conducting a literature search, and has asked companies represented on the study committee of MCA to make a search of their own files in order to provide more input on the entire matter. The MCA group apparently has also asked various toxicologists to review the works of such researchers as Dr. Rubin and others; determine then, what further information is required; and, finally, recommend what future work should be undertaken, if any.

Mr. Bornstein urged that it would certainly seem more desirable to effect liaison with the MCA Committee, rather than duplicate its activities. Chairman Miller and others agreed that Mr. Bornstein's points were very well taken. He noted that, in the final analysis, the real intent of the motion proposed by the Steering Committee was to make certain the seriousness of the plasticizers matter is brought to the attention of the SPI Board of Directors since it is recognized that the SPI represents a segment of industry, principally fabricators and converters, which are not necessarily represented in MCA activities.

It was further noted that this Committee does believe the matter requires SPI Board of Directors consideration because of its marketing and public relations overtones. The present constitution of the SPI Food, Drug and Cosmetic Packaging Materials Committee would not appear to be of the type which would assure completely appropriate activity on the phthalates matter for this reason. Mr. Heckman noted that perhaps an entirely new Committee should be considered by SPI, and should include marketing people who recognize the problems as they relate to selling the products involved. Furthermore, Mr. Heckman said, call it a position paper or not, what actually is needed is a kind of response

from the Society to answer inquiries which are beginning to be made at various levels, including ones he is receiving from Capitol Hill.

Finally, after much disucssion on the composition of a motion which would direct the whole problem in one form or another to the attention of the SPI Board of Directors, the following motion was carried with one negative vote:

> "The SPI Food, Drug and Cosmetic Packaging Materials Committee orders its Chairman to suggest to the SPI Board of Directors that it consider calling a meeting of PVC and plasticizer producers, as well as users, in order to ascertain what course of action should best be taken to clarify the present phthalate plasticizer situation for the industry, and when necessary, for inquirers on the subject."

Chairman Miller agreed that, for the present at least, there should be liaison between SPI and the MCA Committee on the matter of phthalates, PVC, etc. At this point he asked Norm Bornstein to accept this liaison position and Mr. Bornstein agreed to do so.

At another point in his presentation, Mr. Heckman asked for direction as to whether it is feasible and possible for a small amount of barium compound to be added to plastics generally so that x-rays could more readily detect a swallowed substance.

In dealing with this matter in detail in his report, Mr. Heckman also discussed at the day's meeting the various attachments to his presentation to illustrate that a Dr. William P. Slover, Hartford Radiology Group, Hartford, Connecticut, points out that as a radiologist he is called upon from time to time to find a foreign body which a child has ingested or inhaled, and that he wonders, in the case of plastics, whether it would be possible to impregnate an object with barium, which is readily detected on an x-ray.

Essentially, Mr. Heckman asked for general guidance at the day's session as to how he might answer this inquiry.

Several opinions were offered, such as the fact that a study would have to be made as to how much barium can safely be added to the various molding compounds as they relate to compatibility for one thing, and how such compounding would affect properties such as impact. It was suggested during the discussion that if the designation "barium compound" could be avoided, thus allowing for other materials of this nature to be used, it might be desirable and that care must be taken to assure that the system is not construed as a diagnostic drug.

It was revealed at the day's meeting that the barium compounds have been introduced effectively in polystyrene.

By way of summary, Mr. Heckman said that it would appear that introducing a barium system into plastics does not pose a major problem but, on the other hand, it is not without its problems which would have to be investigated and considered in the context of specific applications. On the other hand, Mr. Heckman noted that this whole matter is also being taken up with the toy manufacturers by FDA in order to resolve any problems which might exist.

During a discussion of the PCB problem, it was noted that in the March 13 edition of Food Chemical News there was an article on the polychlorinated biphenyls.

Speaking on the subject of updated methodology to provide PCB-free "certificates" to customers, Mr. Heckman pointed out that W. B. Papageorge of Monsanto has supplied such a method to many inquirers. The question arose at the day's meeting, however, as to whether Mr. Papageorge has updated his procedure since last summer, or whether it is otherwise adequate for plastics. Dan Dixler, Keller and Heckman, said that his information is recent and that apparently Mr. Papageorge's test method does not include recent updating but, on the other hand, he was not too certain of this.

The question then arose as to whether the Committee should organize a task force to either develop procedures or at least determine whether more specific procedures are actually needed at this time. For instance, it was opined that the paper people, more involved apparently with this problem, may be developing all of the type methodology that is needed, thus making it unnecessary for the SPI Committee to get involved at all. Also brought out was the fact that there is in ASTM a Committee known as F-2 dealing with flexible materials that has considered this matter to some extent. Finally it was decided that Mr. Miller would assign this whole problem to the Technical Information Subcommittee for full investigation and, if necessary, test method development.

At this point, Mr. Norm Bornstein, W. R. Grace & Company, volunteered to work on the project, and Mr. Westveer, Chairman of the Technical Information Subcommittee, asked that others advise him should they care to help on the PCB matter. Watt Ackart also noted that a Union Carbide paper on the subject would appear in the March issue of Modern Packaging Magazine.

At the end of his discussion, Mr. Heckman dealt at some length with devices legislation, and, in this connection, asked the Committee whether it wished to take a position on the FDA sponsored bill on devices, (see Mr. Heckman's attached report) in view of the fact that there may soon be a time when the preparation of testimony is called for either for the legislation, against it, for it in part, against it in part, etc.

On a more specific point, Mr. Heckman said that, as his report indicates, he would like to have the Committee's instructions about the invitation received from the Food and Drug Administration to supply it with information about an SPI Subcommittee which can be called upon to work with the Division of Standards

of the Office of Medical Devices with a view towards development of future device standards, where needed. Mr. Heckman felt that a permanent Subcommittee on "medical devices" is quite in order at this time.

Taylor Hanavan, E. I. duPont de Nemours & Co., Inc. moved that the Chairman appoint and organize a standing Subcommittee on Devices. The motion was seconded and carried unanimously.

Chairman Miller then appointed George Richter, Rohm & Haas Company as Chairman, and the following individuals volunteered to serve on the Subcommittee: Philip J. Vanderhorst, E. I. duPont de Nemours & Co., Inc. (Film Department); Ernest M. Dixon, Celanese Corporation; E. J. Vandermark, Northern Petrochemical Company; Peter Morison, Eastman Chemical Products; Leo Ziemlak, Foster-Grant; and, finally, Daniel S. Dixler, Keller and Heckman, who will serve as Subcommittee Secretary.

Reports on Liaison with Other Organizations

Mr. Miller then called for the regular reports on activities of other organizations relating to the interests of the Committee.

Pharmaceutical Manufacturers Association and U. S. Pharmacopeia--Drug Packaging Materials Subcommittee

W. B. Ackart, Union Carbide Corporation gave the following report:

"The June 3, 1971 report of this Subcommittee included the details of its expanded sphere of interest, name change, and personnel changes which have taken place. We also reported at that time that our report on 'Methodology for Testing Polyolefin Containers for Tablets, Capsules, Oral Powders, and Granules' had been accepted by the Quality Control section of the Pharmaceutical Manufacturers Association who in turn had submitted it to the U. S. Pharmacopeia for publication. Some uncertainty regarding which draft had reached the PMA was satisfactorily resolved through a meeting with the appropriate PMA people.

"Last November, we were contacted by Dr. Jules Pinsky, a charter member of this Subcommittee who is now associated with The Mearl Corporation. Dr. Pinsky told us that the draft of the Methodology had come from Mr. John Ruggiero of the PMA staff to Mr. George Schneller, Chairman of the U. S. Pharmacopeia Advisory Panel on Containers and Packaging who in turn referred it to Jules as chairman of their Task Group on Plastic Containers.

"Dr. Pinsky suggested some modifications in the procedure which were circulated to this Committee and shortly thereafter a

telephone conference call was arranged between Dr. Pinsky and three of us at which agreement was reached regarding the changes. These included (1) the complete removal of the biological test, (2) a narrowing of the density limits from 0.020 g per cc to 0.005 g per cc where one polyolefin resin may be substituted for another in a packaging situation, and (3) a change in the form of the formula for water vapor permeability.

"Dr. Pinsky has circulated the revised method to members of his task force and has received no adverse comments. The parent Advisory Panel was also circulated and Dr. Pinsky feels that the Methodology can be cleared for publication this year. When this is accomplished, it is our intent to approach Food and Drug to seek changes in their regulations to permit the interchangeability in dry drug packaging of a polyolefin resin with any other manufacturer's generic counterpart where the basic specifications are the same as determined by the published methodology."

In closing his report, Mr. Ackart said that he had just received some proposed definitions and procedures for a forthcoming edition of the U. S. Pharmacopeia. He said that he would circulate this information to members of his task force.

Manufacturers' Chemists Association

Taylor W. Hanavan, E. I. duPont de Nemours & Co., Inc., reporting on MCA's Food, Drug and Cosmetics Chemical Committee activities, first advised that he considers it one major achievement of the MCA group that George W. Ingle, Monsanto Company, was elected Vice Chairman so that he will soon be the incoming Chairman.

Mr. Hanavan next reported that Dr. Dodgen of National Academy of Sciences, who is working on the FDA GRAS survey and Food Chemicals Codex, has recently been sitting in on discussions with the MCA Committee so that the GRAS survey form now being circulated embodies the MCA suggestions and comments. Continuing, Mr. Hanavan noted that the MCA Committee had provided testimony on the Toxic Substances Control Act of 1971; and has issued 40,000 copies of a new booklet entitled "Food Additives--What they Are and How They are Used." In conclusion, Mr. Hanavan made mention of the recent meeting of the Society of Toxicology and the symposium on mutagenicity studies since this has been the subject of FDA-MCA controversy, just as such work was viewed critically at the Toxicologists' meeting the previous week.

Can Manufacturers' Institute

Charles J. Spiegel, Continental Can Company, Inc. indicated there was nothing new to report in this area.

SPI Market Development Committee of The Plastic Bottle Division

Matthew E. Smith, Owens-Illinois, presented the following report:

> "I wish to point out to some of you that the Food and Drug Bottling Committee of the Plastic Bottle Division is now called the Market Development Committee of the Plastic Bottle Division. This change in name was made to reflect more closely the objectives and plans of our Committee.
>
> "As previously mentioned, members of the Bottle group worked closely with Jerry to help prepare SPI's report to ATFD which they used very favorably in writing their initial Environmental Impact Statement. For obvious reasons, we are following this very closely.
>
> "At our last meeting on February 29 in New York, we discussed the possibility of holding another seminar late in '72 or early in '73. The details are not finalized as yet."

American Paper Institute

Chairman Miller called upon Paul Cundy, American Can Company to report on activities of the American Paper Institute knowing of the concern which the API has presently as regards the PCB problem.

Dr. Cundy reported that API has sponsored research work now being conducted at Hazelton Laboratories to define the scope and significance of the "PCB in paper" problem. The research attempts to answer two questions: an analysis of a broad spectrum of paper, paperboard, and pulp to determine how much PCB may actually be found in such products; and migration tests using paper packaging material with known added quantities of PCB to determine exactly how much PCB could be expected to migrate into foods from paper which contained PCB. In connection with this latter investigation, three different barrier materials are also being evaluated. These are polyethylene, saran coated paper and glassine.

Although the study is not yet completed, Dr. Cundy reported, the 30 day results show that migration even from heavily "spiked" paper is considerably less than was originally believed to be true. When the study is completed, the API hopes that the results will provide firm scientific background to justify limiting the PCB content in food rather than in containers or other packaging materials.

Report of Technical Information Subcommittee

Chairman Miller called upon Willard M. Westveer, The Dow Chemical Company and Chairman of the Technical Information Subcommittee to make his usual report.

In the first place, Mr. Westveer referred to the PCB problem, indicating his Subcommittee would undertake a study of this matter; attempt to determine the relevance and extent of what other groups are doing; gather all of this information; and then make a recommendation on how the Technical Information Subcommittee should proceed. He therefore urged that all present send him any information they have on these matters.

Mr. Westveer then turned the Committee's attention to a listing of recently promulgated food additive regulations, and related regulatory actions. In so doing, he highlighted some of the items in the listing which he felt should be brought to the Committee's attention.

[Please note, attached hereto as an exhibit, dated March 13, 1972, is the regular listing of "Recently Issued Food Additive Regulations"].

Report of Lawyers' Advisory Committee

On behalf of M. C. Stone, Chairman of the Lawyers' Advisory Subcommittee, Jack L. Lawing of that company presented a detailed report. [Please note: This report dated March 15, 1972 is attached as an exhibit]

In concluding his report, Mr. Lawing asked those present to join him in wishing Charlie Stone a quick recovery.

At this point, before the subject of new business was introduced, the matter of the Toxic Substances Act was discussed. William Allen, American Cyanimid Company noted that the Toxic Substances Control Act could be a "Frankenstein monster" although it is generally understood that passage of the legislation in this Session of Congress is unlikely. During the subsequent discussion, it was noted that some customers are asking for impossible guarantees and information about the more than 12,000 substances on the first Government list of toxic substances but this is because of erroneous impressions of Occupational Safety and Health Act responsibilities, not because the Toxic Substances Act has been passed.

New Business

Under the subject New Business, Karl Hochschwender, incoming General Chairman of the Committee, cited two items which he felt would be of interest. One deals with those importing products subject to FDA procedures and regulations. He noted special briefings on this subject are being held in view of the fact that, evidently, FDA is stepping up its inspection program and there is to be more careful screening of certain products under its jurisdiction as they come across the USA borders. Dr. Hochschwender indicated he would be attending one of the briefings to be held on March 16 and would be glad to give a report on the same to the Committee at its next meeting, or perhaps by means of a written report which could be circulated sooner.

Secondly, Dr. Hochschwender said that the U. S. Tariff Commission is investigating on behalf of the Senate Finance Committee non-tariff barriers and that originally the deadline for comments was March 16 but that he has learned that the Tariff Commission has extended this deadline date to April 11. Essentially, the Tariff Commission is looking for information from those who have encountered difficulties in this area so anyone with such information should consider supplying it to the Tariff Commission which will treat it confidentially. The type restrictions referred to by Dr. Hochschwender are those such as unreasonable food additive regulations and similar official policies of foreign governments that hinder the international exchange of goods.

William Allen, American Cynamid Company, again brought up the subject of the Occupational Safety and Health Administration and the Act that it administers indicating that his company is beginning to be deluged with requests for information from customers for labeling information, especially on how much is used of a substance that is "so-called 'toxic'". Mr. Heckman acquainted the Committee with the fact that SPI is strongly involved in this whole matter of OSHA through its Safety and Loss Prevention Committee headed up by a staff man, Jerry Carroll, at the SPI office in New York. Mr. Carroll and his Committee are beginning to issue regular bulletins outlining the impact of OSHA on the plastics industry and most certainly Mr. Carroll or Mr. Shaye (in Mr. Heckman's office) would be receptive to hearing from anyone encountering problems of a nature where some assistance or clarification can be given.

Next Meeting

Mr. Miller announced that the time and site of the next overall meeting of the Committee will be left up to the Steering Committee and the new officers, as is customary.

There being no further business, the meeting was adjourned at 2:45 p.m.

Respectfully submitted,

Charles L. Condit, Secretary

APPENDIX A

SEMINAR

Migration of Additives from Plastics and their Determination in Fat Simulants

Unilever Forschungsgesellschaft mbH, Hamburg, is planning a seminar on

> Methods for the simulation of the migration of additives from plastics packaging material into fatty foodstuffs and for the quantitative determination of the migrated additives

to be held in September 1972.

The meeting will offer the opportunity of exchanging experience for those who are interested in migration. In addition, the discussion on a possible standardisation of the simulation conditions on international level shall be supported by lectures.

Hitherto, the following lectures have been considered:

> On the determination of the total migrate in a synthetic triglyceride fat simulant
>
> Experiments leading to a possible standardisation of the simulation of additive migration from plastics into fat
>
> Methods for the quantitative determination of plastics additives in the fat simulant HB 307 (synthetic triglyceride mixture)

Interested persons are requested to announce lectures until **April 1st, 1972** or to inform Unilever Forschungsgesellschaft mbH of their possible participation.

Hamburg, 13th January, 1972

UNITED STATES DEPARTMENT OF AGRICULTURE
Consumer and Marketing Service
Meat and Poultry Inspection Program
Washington, D.C. 20250

INFORMATION FOR: All MPI Personnel, Owners and Operators of Official Establishments, and State Officials

Implementation of Section 302.3 in the Manual of Meat Inspection and Section 81.95 (b) and (c) in the Poultry Inspectors' Handbook:

The above sections have been rewritten to cover additional nonmeat and nonpoultry products and to require precertification or FDA guarantees.

Because of the delay in issuance of the instruction, many suppliers are unaware of their responsibilities. Therefore, delay implementing the new requirements contained in these sections until April 1, 1972.

Fred J. Fullerton, Director
Field Operations Division

DISTRIBUTION: 02013,02093,ES11-16, ES16-1,S17

December 23, 1971

INFORMATION FOR: Inspectors, Meat and Poultry Inspection Program
Owners and Operators of Official Establishments

Nonmeat Food Ingredient Acceptance into Federally Inspected Plants

After January 1, 1972, all deliveries of nonmeat food ingredients (with the exception of a few crystalline products) must be precertified or accompanied by a Food and Drug Administration guarantee. Inspectors and official establishments shall note the options available for each item. These are listed in Section 302.3 of the Manual of Meat Inspection Procedures, and in Section 81.95 of the Poultry Inspectors' Handbook.

FDA guarantees may be placed on the invoice or on the bill of lading accompanying the shipment. Since product received under guarantee may not be used until the guarantee is received by the plant, it is suggested that the packer request it be placed on the bill of lading. Invoices may not be received for several weeks.

Inspectors are to verify that plants adhere to the noted requirements. If FDA guarantees are used, the inspector shall randomly pick several lots of incoming items, and shall request the plant to show the FDA guarantee for each. Inspectors will ask for verification of this requirement approximately every 2 weeks on 10 to 20 randomly selected lots. The Manual of Meat Inspection Procedures and Poultry Inspectors' Handbook will be revised to reflect this.

Should the plant be unable to produce an FDA guarantee, subsequent lots of all nonmeat food items will be retained until the plant demonstrates compliance. The monitoring program is to be resumed when the inspector is satisfied that the plant is complying with requirements.

Fred J. Fullerton
Director
Field Operations Division

DISTRIBUTION: 02013,02039

December 15, 1971

*-302.1 In order for an official establishment to be eligible to continue to operate under inspection, it must prepare meat or meat products in at least one of the following categories:

A. For Government agencies.

B. For shipment to another official establishment.

C. For shipment in interstate or foreign commerce.

If an official establishment fails to meet this requirement, it shall be reported by the circuit supervisor to the area supervisor for recommended withdrawal of Federal inspection.-*

302.2 The circuit supervisor may permit the slaughter of food animals such as buffalo, reindeer, and elk, provided facilities are adequate and the handling of these animals does not represent a hazard to the meat products normally produced.

Field-dressed game animals may be custom processed by official establishments in the same room where meat products are handled, provided identity of all the products is strictly maintained to prevent commingling of the inspected and uninspected products and no nuisances are created to hinder inspection.

The meat from such animals may not be used as an ingredient in a meat food product because it is not inspected for wholesomeness. Official establishments may prepare custom products consisting of game meat (buffalo, reindeer, elk, deer) combined with pork, beef, or lamb, but only for the owners of the game animals. They are not to be inspected, nor can they be sold.

These custom prepared products must be completely identified and handled separately to preclude intermingling of inspected and uninspected products. An exception is made in the case of buffalo and reindeer slaughtered under the reimbursable program in accordance with Part 340 of the regulations. Such products may bear the marks of Federal inspection and may be used in federally inspected establishments as ingredients of products prepared under inspection.

*-302.3 Acceptance and inspection of certain nonmeat food items entering official establishments.

A. Poultry products and egg products, other than shell eggs, intended for use as ingredients of meat food products are acceptable when identified as having been inspected for wholesomeness by the U.S. Department of Agriculture and when found to be sound and otherwise acceptable when presented as an ingredient. Such products must be received carrying either the marks of wholesomeness or other proper certification by the Department. This would apply not only to products used in the preparation of meat food products, but also to those used in federally inspected establishments to prepare nonmeat food items which would subsequently be used in an inspected meat food product.

*The inspection mark which is permitted to be used shall be contained within the outline of a shield and with the wording and design as set forth below.

Fig. 1

Fig. 2

The plant number may either be printed within the shield as shown or applied elsewhere on the container.

When pressure sensitive labels bearing only the shield are used, the plant number must be printed within the shield.

The acceptability of shell eggs will be determined by the establishment at the time of use and shall be accompanied by an FDA guaranty from the supplier. (See E2 below.) Also, the fact that poultry products have been inspected for wholesomeness when produced does not relieve the meat inspector of the responsibility of reinspecting these products to determine they are acceptable when used in establishments under his supervision.

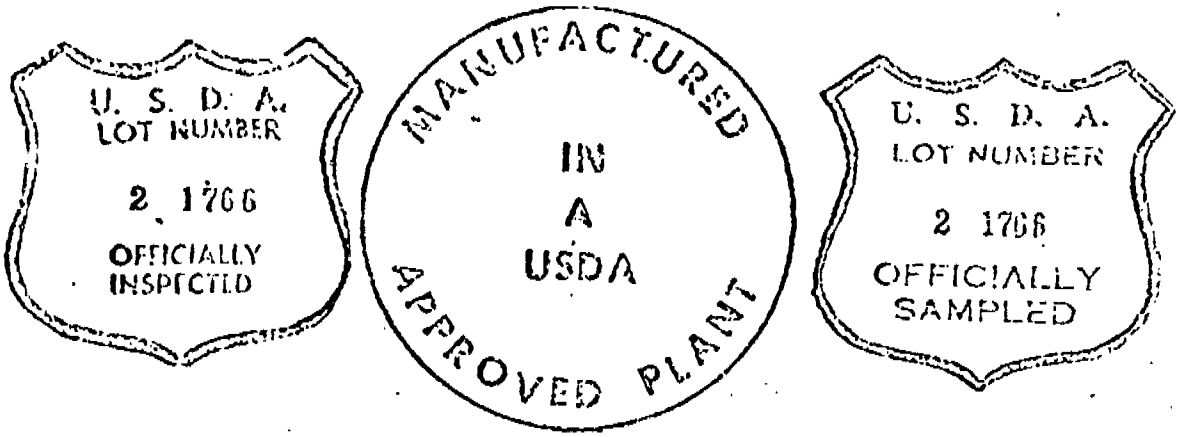
B. Dry milk items intended for meat food products shall be produced in a plant approved by the Department. Dry milk items include dry whole milk and dried whey. Each establishment will be supplied two copies of "Dairy Plants Surveyed and Approved for United States Department of Agriculture Grading Inspection Program." It will be an establishment responsibility to assure compliance with these requirements. The inspector should occasionally check the establishment records to assure proper source of these materials.-*

Compliance is indicated when one of the following requirements is met:

1. The name of the producer of the product is on the package and the producer is on the approved list.

2. A distributor provides a certificate from the Inspection and Grading Branch, Dairy Division, C&MS, identified with the code on each container. Such certificates are issued only when it is known the product originated from an approved plant. After inspection, approximately one week delay in shipment will be required since certificates are issued only after laboratory results are received. Additional certificates for inspected lots would be available from the Dairy Division.

In lieu of the certificate, C&MS inspectors at receiving establishments will recognize any of the following marks of inspection:



Upon request, the Inspection and Grading Branch, Dairy Division, will stamp each container produced at an approved plant. There will be a charge for both certification and marking unless the inspection is performed at an approved plant with a resident dairy inspector. These provisions have been made for distributors who, for marketing reasons, do not wish to identify producing plants to the receiving establishment.

3. The code number on each package is on the approved list. The first two digits will refer to the State and will be followed by digits referring to the approved plant.

*-Product that is purchased in bulk from an approved plant and then packaged in nonapproved plant may not be received into an official establishment without certification as outlined in B2.

C. Sodium caseinate, batters, gravy mixes, flour, breadings, premixes, noodles, macaroni and similar poultry, egg, or dried milk products are not subject to the above requirements. Shipments must be accompanied by an FDA guaranty (See E2 below). The program inspector will sample incoming shipments of these items:

1. When he suspects insect or microbiological contamination; or

2. When directed by the regional director in accordance with provisions of 318.70(1) of the Manual.

D. Each shipment of pizza pie crust or dough, masa, tortillas and similar bakery items used in preparing meat food products in official establishments must be accompanied by an FDA guaranty from the supplier (see E2 below), or be prepared either in an:

1. Official establishment;

2. Approved plant under continuous supervision of any agency of the United States Department of Agriculture; or-*

*-3. Approved manufacturer's plant operating under limited supervision of a program inspector.

To get approval, a manufacturer (Item 3) shall make application to the circuit supervisor in his area.

The circuit supervisor shall:

a. Arrange for initial survey by an inspector in respect to sanitation, good hygienic practices, raw materials, formulation, and facilities.

b. Forward a report of the survey and a recommended action to the regional director.

c. Arrange for routine, unannounced inspections to assure compliance in the manufacturer's establishment after it has been approved.

d. Recommend removal from the approved list when routine inspections indicate serious deficiencies in the manufacturer's operations.

The regional director shall notify the Standards and Services Division to place the establishment on the approved list.

Standards and Services Division shall:

a. Maintain a list of all approved sources of supply which will be included in the Working Reference.

b. Institute revisions reflecting any change in the status of an establishment as reported by the regional director.

The approved plants shall:

a. Maintain their premises and production in accordance with good commercial practices at all times.

b. Allow free access to meat and poultry inspectors.

c. Properly mark all containers bearing approved product including the producer's name and address.

E. Each shipment of spices must originate from a supplier appearing on the list of certified spice suppliers in the Working Reference, or be accompanied by an FDA guaranty (see 2 below).

1. To be certified, spice suppliers must submit their quality control procedures on unground spices (except paprika which is on the ground spice) to the Standards and Services Division for review. These procedures-*

*must include sampling rates, methods of analyses, and acceptable quality levels for various types of foreign material (which must meet FDA standards). Lots failing to meet these levels must be recleaned and retested or so marked as to preclude entering an official establishment as an acceptable lot. All lots of spices from certified plants must bear unique code marks or brand names, and results of analyses on these lots must be available to the Meat and Poultry Inspection Program. Packaging must be sufficient to prevent insect infestation and rodent contamination. The MPI will periodically request samples of unground and ground spices from these cooperating spice suppliers. This is necessary to establish the relationship between fragment counts in these two forms of spices. This will require retention of samples by suppliers from all lots for a period of several months after cleaning and grinding.

2. Alternatively, an FDA guaranty may accompany each shipment. This guaranty is referenced in Section 303(c)(2) or (3) of the Food, Drug, and Cosmetic Act. The definition and suggested forms of such guaranty are contained in Title 21, Chapter 1, Section 1.[illegible] of CFR. One acceptable form is as follows:

> "(name and address of supplier) hereby guarantees the accompanying shipment, as of the date of shipment, to be not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.
>
> (Signature of person with responsible position in the supplying firm)"

These products will be sampled by the program inspector:

a. When, because of shipping or handling conditions, he suspects insect or microbiological contamination.

b. When requested by the regional director under provisions of the random sampling program outlined in 318.70(1) of the Manual. Product received with FDA guarantees shall be sampled more frequently than product from certified suppliers.

c. When requested by the regional director to sample product from certain certified suppliers.

F. Incoming shipments of other nonmeat food items such as collagen casings, sugar, salt, and similar crystalline chemicals need not be accompanied by an FDA guaranty. The MPI inspector will sample these shipments when he suspects possible insect or microbiological contamination.

G. Dried, frozen, canned, or otherwise processed vegetable or fruit ingredients must be in good condition and be practically free from extraneous or foreign material. The establishment may obtain either a certificate of condition from another Government agency or an FDA guaranty (see E2 above) for each shipment as documentation for this requirement. The necessary facilities, however, should be maintained so that the ingredients may be inspected to detect changes or infestation due to improper handling or storage. -*

*-H. Fresh vegetables and fruits shall be examined for cleanliness and foreign material. Establishments that prepare these products themselves are required to maintain the necessary facilities in a sanitary manner and provide adequate sorting and cleaning.

1. Animal Casings. Finished casings prepared at unofficial establishments may be received into official establishments and used as containers of meat food products provided they present no objectionable condition and are accompanied by an FDA guaranty. (Section E2 above.)-*

302.4 . Each inspector is charged with responsibility to notify his official superior regarding operations affecting inspection in the establishment or parts of the establishment to which he is assigned.

302.5

A. EXTENT OF PROCESSED FOOD INSPECTION SUPERVISION

This part defines the level of inspection coverage required for various processing activities in official establishments. All processing operations require inspection. The Standards and Services Division will determine the degree of coverage a processing activity requires. The establishment will continue to have the responsibility of informing our inspection personnel in advance when and what processing activities will occur as well as the volume and approximate production hours. It will be recognized that inspection supervision can be defined as:

1. Minimal Supervision - coverage calling for unannounced visits to official establishment(s) and/or departments during the designated production activity. One thorough surveillance approximately every 2 weeks should be made for each activity so designated.

2. Limited Supervision - coverage calling for unannounced visits to official establishments and/or departments during the designated production activity. This may also include broad coverage of many establishments by one inspector in large metropolitan areas. Twice a week surveillance should be sufficient to assure compliance for each activity so designated.-*

3. Normal Supervision - coverage called for by operations that may be conducted only when an inspector is on duty. The inspector's assignment may include a department of a large establishment, or one or more establishments.

Minimal and limited supervision will normally be performed by the inspector assigned. Periodically, however, supervisors may wish to perform "odd hour" inspections in addition to minimal and/or limited supervision.

The intensity of inspection for activites requiring minimal or limited supervision would be consistent with the inspectional coverage given similar operations on a normal basic assignment.

Minimal and limited coverage should be designed to assure that the permitted processing operations are being conducted in accordance with all existing regulations, standards, and instructions. No guidelines other than frequency

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

March 6, 1972

Mr. Jerome Heckman
Keller and Heckman
1712 N Street, N. W.
Washington, D. C. 20036

Dear Mr. Heckman:

Per our telephone conversation today, I am sending you, for comment, the letter from the Hartford Radiology Group to Commissioner Barbara B. Dunn, Department of Consumer Protection, State of Connecticut, and her letter to Mac Jensen, Bureau of Product Safety, Food and Drug Administration. Any help you can give us will be greatly appreciated.

Sincerely yours,

Howard I. Weinstein, M.D.
Associate Director for
Medical Review
Bureau of Product Safety

Enclosures

DOERUFF, M. D.
JANZEN, M. D.
ROSS, M. D.
MARSH, M. D.
BAKER, M. D.

HARTFORD RADIOLOGY GROUP
MEDICAL BUILDING, SUITE 301
85 Jefferson Street
Hartford, Connecticut 06106
Telephone 246-5403

ROBERT F. KILEY, M. D.
DONALD R. WIECHE, M. D.
WILLIAM P. SLOVER, M. D.
FRED M. ZITEP, M. D.
WILLIAM A. LYNCH, M. D.

February 22, 1972

Mrs. Barbara Dunn
Consumer Protection
165 Capitol Avenue
Hartford, Connecticut

Dear Mrs. Dunn:

Occasionally I, as a radiologist, am called upon to help find a foreign body which a child, or rarely an adult, has ingested or inhaled. Many times this is a coin or bone which has been swallowed but all too frequently a child has swallowed a toy or piece of a toy. Unfortunately, the toy is usually made of plastic or wood and in this instance the foreign body is not detectable on an X-ray.

It would be helpful to us, and advantageous to the patient, if the plastic could be impregnated with barium which is readily detected on an X-ray. This principle is currently used with the I.U.D. If all plastic toys were so made, then I believe we could be more definitive in our evaluation of the X-rays and this could probably reduce the need for some bronchoscopies or esophagoscopies. If this is possible, the overall risk and cost to the patient can probably be reduced also.

Sincerely,

William P. Slover

William P. Slover, M. D.

WPS/j

State of Connecticut

DEPARTMENT OF CONSUMER PROTECTION
STATE OFFICE BUILDING
HARTFORD, CONNECTICUT 06115

February 24, 1972

Mr. Malcolm Jensen
Dir. Product Safety FDA
5600 Fishers Lane
Rockville, Maryland 20852

Dear Mr. Jensen:

I am enclosing a copy of a letter from a doctor in Hartford. Would you please investigate a suggestion he has made of impregnating plastic with barium so that substances lodged in the body may be detected by X-ray.

We would certainly appreciate any immediate reaction you may have as well as being kept abreast of any studies you might make.

Sincerely,

Barbara B. Dunn
Commissioner

FDA to Propose Tighter Limits on PCBs In Effort to Cut Potential Health Hazard

By JONATHAN SPIVAK
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — The Food and Drug Administration soon will propose significant restrictions on polychlorinated biphenyls, or PCBs, an important industrial chemical deemed to pose potential health dangers.

The agency, worried about PCBs contaminating food and food packaging, intends to establish new limits on the amount of PCBs these products may contain. Moreover, to prevent such contamination, the FDA also will propose banning most industrial uses of the chemical in plants that process or make food, feed or packaging materials.

PCBs are made in the U.S. only by Monsanto Co. They are used widely in electrical equipment as heat transfer agents and in various other industrial applications because of their conducting properties and lack of flammability. However, the chemical persists in the environment after use, and high doses have damaged test animals' livers. Scientists are unsure of its risks to humans at low levels and with long-term exposure, but are eager to minimize any possible hazard.

The new FDA proposal probably will call for limits on PCBs in baby foods and poultry, as well as packaging, and reaffirm existing restrictions in other foods. The ban on food-related factory use would formalize restrictions Monsanto is applying voluntarily, so it probably won't reduce further the company's PCB sales. The restrictions would rule out the chemicals' use in heat exchangers, as a lubricant, in hydraulic fluids and for other purposes except in electrical systems where PCBs can't leak out and contaminate other materials.

Limits on Packaging

One of the chief issues is the restrictions on packaging materials and packaged food. Last fall, PCB levels ranging up to 463 parts per million were found in food packaging made from recycled paper. Much of the contamination was found to result from the chemicals' use in carbonless carbon paper, which then was recycled into packaging materials. This use has been discontinued. But FDA experts say PCB levels ranging up to 10 parts per million have been found in virgin pulp.

The FDA feared the chemical might migrate from the packaging into the food. While the contamination level that [illegible] foods, particularly cereals, [illegible] that in the package, FDA [illegible] they would consider regulatory action.

The new proposals are expected to limit PCBs to five parts per million in any food packaging material, recycled or otherwise. Current regulations for reclaimed fibers and packaging materials don't allow any PCBs. But this standard was set before the problem was known and hasn't been enforced. FDA officials thus were faced with either enforcing the existing total ban or establishing a new limit.

The proposed limit can be met by more careful manufacturing control and by eliminating use of some contaminated paper for recycling, FDA experts insist. The packaging limit would keep possible contamination of contained foods to a fraction of a part per million, they say.

The agency is expected to also propose a limit of 0.1 part per million in infant foods. "Infants take in more food per unit of weight and are also more sensitive," argues one official.

Tougher Poultry Ruling

An existing administrative restriction of five parts per million for poultry will be tightened to make it five parts per million in the fat rather than the whole bird. This change effectively would decrease the permitted levels as much as 10 times, agency experts explain. It would mean that when accidental contamination of turkeys and chickens occurs, such as through PCBs finding their way into feeds, many more birds would be [illegible] destroyed by federal officials.

Existing administrative restrictions of five parts per million in fish and 0.5 parts in eggs would be continued as formal regulations, while a limit of 0.2 parts per million in milk could be toughened.

These proposals still need final review by Charles Edwards, FDA Commissioner, but the agency's course appears clear. The proposed restrictions would be issued initially for a 60-day comment period and then would be republished, probably to take effect immediately.

When contact with PCB contamination is confirmed, [illegible] voluntarily removed its use. The company no longer sells for applications where it can escape into the environment. But the FDA insists Monsanto's PCB sales in the U.S. already have been reduced about as much as they will be.

The regulations primarily would affect makers and users of packaging materials. FDA officials [illegible] the packaging [illegible] the five-parts-per-million [illegible] cient one, and it will provide [illegible] "When people are [illegible] PCB [illegible] it can be kept [illegible] parts [illegible]," argues one [illegible]. The [illegible] that if the [illegible] five parts per million [illegible] companies couldn't meet it. Moreover, [illegible] that the problem of transfer to foods [illegible] becomes apparent.

Stauffer to Increase Dry-Cleaning Solvent

Welfare Recipients [illegible]

Botany To Clos[e] In New

Clothier [illegible] Shirt [illegible] Plants [illegible]

New Y[ork] [illegible]

APPENDIX C

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE

SPI FOOD PACKAGING MATERIALS COMMITTEE

March 13, 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 121.2514 (b) (Proposed)	F.R. 36(109) Page 10983 6-5-71	E. I. du Pont de Nemours & Co.	Proposal for amendment by revising the item "Silicones (not less than 300 * * *" in subdivision (XXV); By adding to subdivision (XXV) a new item "Silicones (not less than 100 * * * "; By revising subdivision (XXVIII).
Amended 121.2615	F.R.36(109) Page 10947 6-5-71	Hercules, Inc.	Amended to provide for the safe use of hydrogenated a-methylstyrene-vinyl-toluene copolymer resins as a component of polyolefin film intended for food-contact use.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2511	F.R.36(118) Page 11724 6-18-71	Monsanto Co.	Amended to provide for the safe use of 1,3-butylene glycol-adipic acid polyester as a plasticizer in polyvinyl chloride homopolymers used in the manufacture of food-contact articles.
Amended 121.1, 121.3	F.R.36(123) Page 12093 6-25-71	Commissioner of Food and Drugs	Amended by revising paragraph (i) and adding a new paragraph, (k), Definitions and Interpretations to 121.1; Amended by revising 121.3, Eligibility for classification as generally recognized as safe (GRAS).
Notice OSHA 1970	F.R.36(142) Page 13699 7-23-71	Administrator, Health Svcs. and Mental Health Administration.	Notice that the Toxic Substances List, consisting of approximately 12,000 substances, has been compiled and is available for inspection at the National Institut for Occupational Safety and Health . . . copies will be available after July 31 from the Government Printing Office.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2526	F.R.36(145) Page 13919 7-28-71	American Cyanamid Co.	Amended to provide for the safe use of poly((methylimino) (2-hydroxy-trimethylene) hydro-chloride) as a retention aid in the manufacture of paper and paperboard for use in contact with aqueous and fatty foods.
Amended 121.2526	F.R.36(150) Page 14312 8-4-71	Sun Chemical Corp.	Amended to provide for the safe use of Bis (methoxymethyl) tetrakis ((octadecyloxy)-methyl) melamine resins as a water repellent.
Amended 121.2614	F.R.36(155) Page 14729 8-11-71	Vistro Corp.	Amended to revise the specifications and extractives limitations for the nitrile rubber modified acrylonitrile-methyl acrylate copolymers permitted as components of articles intended for food-contact use.
Amended 121.2566	F.R.36(161) Page 16065 8-19-71	Geigy Chemical Corp.	Amended to provide for the safe use of 2-(3'-tert-butyl-2'-hydroxy-5'-methylphenyl)-5-chloro-benzotriazole as an anti-oxidant and/or stabilizer in the manufacture of olefin polymers for food-contact use.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 8.1 and 8.35	F.R.36(166) Page 16902 8-26-71	Toilet Goods Association, et al	Amended by revising 8.1, Definitions and interpretations, color additive, and 8.35 Criteria for evaluating the safety of color additives.
Amended 121.2547	F.R.36(188) Page 19077 9-28-71	Whitmoyer Laboratories, Inc.	Amended to provide for the safe use of sanitizing solutions.
Amended 121.2566	F.R.36(188) Page 19078 9-28-71	Ciba-Geigy Corp.	Amended to revise the limitations, on octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate as to its use in olefin polymers that contact fatty foods.
Statement of Policy	F.R.36(188) Page 19089 9-28-71	Food and Drug Administration	Decision to use a particular GRAS (generally recognized as safe), food additive, or prior sanctioned substance in a food is a voluntary one.
Amended 121.2520	F.R.36(193) Page 19363 10-5-71	The Dow Chemical Company	Amended to provide for the safe use of a chlorinated pyridine mixture as a preservative for food-packaging adhesives.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.1238	F.R.36(205) Page 20430 10-22-71	Scientific Associates, Inc.	Amended to provide for the safe use of certain synthetic fatty alcohols in food, in food-contact articles, and in the synthesis of food additives and other substances for use in food and food contact articles.
Amended 121.2616	F.R.36(205) Page 20431 10-22-71	Scientific Associates, Inc.	Amended by adding to Subpart F the following new section: Synthetic fatty alcohols. Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food. The food additive consists of fatty alcohols meeting the specifications and definition prescribed in 121.1238.
121.101 Study of	F.R. 36(206) Page 20546 10-23-71	Commissioner of Food and Drugs	The Commissioner of Food and Drugs is conducting a comprehensive study of individual substances that have been listed in 121.101

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2566	F.R.36(218) Page 21588 11-11-71	Geigy Industrial Chemicals	Amended to provide for use of octadecyl 3, 5-di-tert-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in polystyrene and/or rubber modified polystyrene.
Amended 121.2520	F.R. 36(231) Page 22827 12-1-71	A. E. Staley Mfg. Co.	Amended to provide for the safe use of starch, reacted with a urea-formaldehyde resin, as a component of food-packaging adhesives.
Amended 121.2526	F.R.36(234) Page 23202 12-7-71	Calgon Corp.	Amended to provide for the safe use of diallyldiethylammonium chloride polymer with acrylamide and diallyldimethylammonium chloride; and partially hydrolyzed diallyldiethylammonium chloride polymer with acrylamide and diallyldimethylammonium chloride, as retention aids in the manufacture of paper and paperboard in contact with aqueous and fatty foods.
Amended 121.2592	F.R.36(236) Page 23291 12-8-71	Union Camp Corp.	Amended to provide for the safe use of glycerol ester of maleic anhydride-modified tall oil rosin, having an acid number of 30 to 40, a drop softening point of 141°C. - 146°C., a color of N or paler, and a saponification number less than 280. (XX) Glycerol

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
			ester of disproportionated tall oil rosin having an acid number of 5 or less, a drop-softening point of 82°-92°C., a color of WG or paler, and a saponification number less than 180.
Amended 8.244	F.R.36(238) Page 23552 12-10-71	Allied Chemical Corporation	Amended to provide that lakes of FD&C Red No. 40 are safe for use in food and drugs, certification is necessary, and Notice published July 9, 1971, specification for the permissible amount of arsenic in the color additive is corrected to read, "not more than 3 parts per million."
Amended 121.2506	F.R.37(11) Page 740 1-18-72	Grain Processing Corp.	Amended to provide for an increase in the maximum amount of ammonium persulfate reactant from 0.3 percent to 0.6 percent when the starch is treated under alkaline conditions.
Amended 121.2526	F.R.37(20) Page 1466 1-29-72	Union Carbide Corp.	Amended to provide for the safe use of ethylene-acrylic acid copolymers as a component of paper and paperboard intended to contact food.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
			coatings for paper and paperboard in contact with bakery products and dry solids only.
Amended 121.2617	F.R.37(28) Page 2959 2-10-72	Mobil Chemical Co.	Amended to provide for the safe use of poly-1-butene resins and butene/ethylene copolymers as articles or components of articles intended for use in contact with food.
Amended 121.2526	F.R. 37(28) Page 2960 2-10-72	Petrolite Corp.	Amended to provide for the safe use of synthetic petroleum wax in or on food and as an article or component of an articl intended for use in contact with food.
Amended 121.2618	F.R.37(28) Page 2960 2-10-72	Petrolite Corp.	Amended to provide that synthetic petroleum wax may be safely used as a component of nonfood articles in contact with food
Amended 121.2566	F.R.37(30) Page 3177 2-12-72	B. F. Goodrich Co.	Amended to provide for an additional safe use of 1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-s-triazine-2,4,6(1H, 3H, 5H)-trione as an antioxidant and/or stabilizer in

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
			polymers used in the manufacture of articles or components of articles that contact fatty foods.
Amended 121.2514	F.R.37(38) Page 3987 2-25-72	E. I. duPont de Nemours & Co., Inc.	Amended in subdivision (XXV) by revising the existing entry on silicones and adding a new entry on silicones, and by revising subdivision (XXVIII).
Amended 121.2566	F.R.37(39) Page 4077 2-26-72	American Hoechst Corp.	Amended to extend the permitted conditions for the safe use of Poly((1,3-dibutyl-distanthianediylidene)-1,3-dithio) as a stabilizer in certain semi-rigid and rigid polyvinyl chloride materials used in the manufacture of food contact articles.
Amended 121.2504	F.R.37(42) Page 4331 3-2-72	American Cyanamid Co.	Amended by reducing to 100 milligrams per square foot the permitted amount of 200 milligrams per square foot of malathion that may be incorporated into paper trays for the safe control of insects during the drying of grapes (raisins) in compliance with 121.1172.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2566 (b)	F.R.37(44) Page 4711 3-4-72	Geigy Chemical Corp.	Amended to provide for the additional safe use of 2(2'-hydroxy-5'-methyl-phenyl) benzotriazole at levels not to exceed 0.25 percent by weight of polystyrene and/or rubber modified polystyrene polymers complying with 121.2510 intended to contact nonalcoholic food.
Amended 121.2514	F.R.37(44) Page 4712 3-4-72	Eastman Chemical Products, Inc.	Amended to provide for the safe use of 2,2-dimethyl-1,3--propanediol as a component of resinous and polymeric coatings for food-contact use.
Amended 121.2602	F.R.37(47) Page 5019 3-9-72	M & T Chemicals, Inc.	Amended to provide for the safe use of the octyltin stabilizers identified in 121.2602(a) (1) and (2) in vinyl chloride-ethylene copolymers complying with 121.2609 that are intended for use in contact with food.

APPENDIX D

March 15, 1972

LAWYERS ADVISORY SUBCOMMITTEE REPORT
J. L. LAWING, ACTING CHAIRMAN
EASTMAN CHEMICAL PRODUCTS, INC.

Gentlemen:

As some of you are aware, the Chairman of your Lawyers Advisory Subcommittee, Charlie Stone, underwent surgery in January and is not able to present this report in person. I am sure all of you join me in the hope for Charlie's speedy recovery.

We continue to watch legislative developments regarding the so-called Toxic Substances Control Act (S. 1478 and H.R. 5276). As last reported, the regulatory scheme envisioned by the proposed bills would permit the Administrator of the Environmental Protection Agency (EPA) to initiate standards for test protocols and criteria for various classes of chemical substances consistent with the objective of protecting health and the environment. Additionally, the Administrator of the EPA may publish regulations for any chemical substance produced in commercial quantities. In this connection, the Administrator would be empowered to restrict or prohibit the use or distribution of any chemical substance to the extent necessary to protect health and the environment. These regulations would have to be referred in advance of their publication to select committees of a proposed Toxic Substances Board.

H.R. 5276 is still pending in the House of Representatives and no action has been taken nor is any presently scheduled. The legislative counterpart of H.R. 5276 in the Senate, S. 1478, has received more active legislative consideration. The Environment Subcommittee of the Senate's Commerce Committee reviewed the bill during closed sessions held in February. On March 6, the Senate version of the Toxic Substances Control Act was reported out to the full Commerce Committee with amendments. The revised Senate bill will not be published for two to three more weeks.

Turning next to Senator Muskie's bill (S. 573) which would amend the Clean Air Act and the Federal Water Pollution Control Act, there has been no definitive action with regard to this proposal. In effect, the bill would

require the Administrator of the Environmental Protection Agency to designate substances or combinations of substances in manufactured products which would adversely affect the public health or contribute to the violation of any air and water standards. More than a year has passed since the Senate Public Works Committee requested reports relative to this bill from a number of Federal agencies, including the Environmental Protection Agency and the Council on Environmental Quality. Reportedly, certain of the agencies contacted to submit reports have not responded to the Public Works Committee's request and we question whether S. 573 will warrant serious consideration during the current session of Congress.

The matter of distinguishing between drugs and devices continues to be a subject of tremendous interest to many members of the Food, Drug and Cosmetic Packaging Materials Committee. On December 14, 1971, Representative Staggers introduced an Administration Sponsored Bill (H.R. 12316) which looks toward the ultimate adoption of a new regulatory approach to be applied to devices. This recent bill contrasts the legislation noted in the previous report of the Lawyers Advisory Subcommittee. In essence, the earlier device legislation (H.R. 1545) would have established three categories of device classification including (1) those devices generally recognized by qualified experts as safe, reliable and effective for their intended purposes, which would be exempt from requirements for standards and pre-marketing clearance; (2) those devices for which the scientific experts require reasonable standards based upon composition, design, property or performance and which must be accompanied by adequate instructions for usage and warnings of limitations; and (3) devices requiring pre-marketing clearance because they are not generally recognized by the scientific experts as safe, reliable and effective, or have not become established in wide use by the medical profession as being safe, reliable and effective.

The latest proposal, to be known as the Medical Device Safety Act, seems to many to envisage a more realistic approach. Among other things, the Administration Sponsored Bill does not propose exemptions from coverage by using poor legislative techniques such as exempting items designated "generally recognized as safe" from a broad pre-clearance requirement. Furthermore, it avoids attempting to define the term "device" so that the law will require strict, drug-type pre-clearance for everything.

Instead, the legislation would actually exempt all devices from any type of pre-clearance requirement unless and until findings were made with respect to specific items that either a standard should be developed, or complete ad hoc pre-clearance should be ordered because the device is of the type that might be characterized as "life-threatening" or likely to present an "unreasonable hazard".

In effect, this type of legislation parallels the most recent format embodied in various amendments to the Federal Hazardous Substances Act and seems more sensible in approach than was the Food Additives Amendment of 1958 which has been distorted to require pre-clearance of almost all packaging materials despite their conceded insignificance as public health problems. Moreover, there is a requirement for the registration of device manufacturers which some believe should be narrowed so that legislation would only be required of those manufacturing devices which have been deemed to demand either the standards-making or strict pre-clearance procedures.

On the Food Additives Regulatory front, Senator Gaylord Nelson introduced legislation on February 14, 1972, (S. 3163) to be known as the Food Protection Act of 1972, which would prohibit the use of additives unless they are adequately proven to be safe, effective and to have a demonstrable benefit. The bill would broaden the authority of FDA over the regulation of food additives in the areas of testing, factory inspection and registration of producers. Third party testing procedures of all additives would be mandatory in lieu of requiring FDA to rely upon the tests of the producer. Additionally, the Federal government would be required to set nutritional standards for food with the alleged goal of eliminating the use of unsafe, untested and unnecessary chemicals in the food supply. The progress of this legislation should be watched very closely so that any significant developments will be made known to the Committee.

Two recent court cases involving FDA, which we believe will be of interest, have been decided by the U. S. Court of Appeals for the District of Columbia Circuit since your last meeting. The first concerns the seizure by FDA of an automatic dishwashing detergent packaged in a container closely resembling a milk carton. The Court of Appeals upheld the District Court's finding that the Food and Drug Administration was entitled to seize all existing stocks of

the new product under a previously unused clause of the Hazardous Substances Act which permits FDA seizure of potentially dangerous substances in food-type containers. This case would seem to add a whole new dimension to some of the problems being encountered in the packaging field. The ruling will undoubtedly give rise to some confusion in the future as to exactly where the line can be drawn in determining whether a package is so similar to another that it cannot be marketed.

The second case, (Unimed, Inc., Petitioner v. Elliott Richardson, Secretary of Health, Education and Welfare, et al., Respondent), decided on February 2, 1972, by the Court of Appeals points up the virtualimpregnability of a FDA administrative judgment. Though conflicting expert testimony may be presented, the agency entrusted with the regulatory responsibility will be upheld in its judgment barring an irrational or arbitrary view of the evidence submitted. The case centered around a drug manufacturer trying to satisfy the regulatory requirement that substantial evidence is needed to establish a claim as to the efficacy of a drug. At every level of the proceedings, there was never any suggestion that the drug was dangerous to health. The drug manufacturer had submitted five studies designed to show the effectiveness of the drug; nevertheless, the Court held that FDA had offered enough evidence to support its view that the manufacturer's studies did not warrant a favorable conclusion as to the drug's effectiveness.

Lastly, with the enactment of the Occupational Safety and Health Act of 1970 (OSHA), SPI attention was focused on the broad regulatory impact of the new law. Immediate interest was expressed by the membership in rules proposed in accordance with the Act for inspection procedures including authority for Compliance Officers to photograph establishments covered by the Act.

In response, Comments were filed on behalf of SPI objecting to the taking of photographs. Specifically, the Society indicated in its statement to the Assistant Secretary of Labor for Occupational Safety and Health that "cloaking a Compliance Officer with authority to take photographs runs counter to the well established and sound plastics industry practice aimed at preserving trade secrets by prohibiting any photographs of manufacturing or research and development areas within a company's plant."

Final promulgation of the inspection regulations (29 C.F.R. Part 1903.7(b)) placed limitations so as to require a degree of justification for the taking of photographs. The taking of photographs involving trade secrets is fully protected and in keeping with the urging of SPI. Furthermore, an employer may identify an inspection area as one which contains or might reveal a trade secret. Unless the Compliance Officer has a clear reason to contradict an employer's allegation that a trade secret is involved, information obtained in such areas, including all negatives and prints of photographs, and environmental samples shall be labeled "Confidential-Trade Secret" and shall not be disclosed.

Additionally, the inspection rules insure that Compliance Officers must take reasonable precautions so that action with flash, spark-producing, or other equipment would not be hazardous from the point of view of safety considerations or as the photography may relate to interference with light sensitive products commonly used by the plastics industry. This revision of the regulation was also fully consistent with the Comments filed on behalf of SPI.

Thank you,

MCA Liaison Report

In connection with the proposed National Academy of Sciences-National Research Council (NAS-NRC) review of the so-called GRAS list, the Food, Drug, and Cosmetic Chemicals Committee invited Durwood Dodgen, Executive Director of the NAS GRAS Review Committee, to review the proposed study and, more particularly, the results of the pilot program conducted by NAS. The comments of the Committee members were most pertinent, and the final questionnaire submitted to industry included many of them.

The Committee continued to cooperate with the FAO-WHO Joint Expert Committee on Food Additives in carrying out through Morgan Hoover, Secretary of our Committee, the coordination of development of toxicity data for products proposed for evaluation by the Joint Expert Committee and for consideration by the Codex Alimentarius Commission. Mr. Hoover served as one of industry's advisors to the U. S. Delegation at the Eighth Session of the Codex Alimentarius Convention in Geneva, Switzerland, July 1 to July 9, 1971.

We prepared and filed detailed comments with the U. S. Department of Agriculture in connection with proposed major revisions to its current approach to the approval of food additives for use in federally inspected meat and poultry plants.

MCA also filed with the Hearing Clerk comments on an HEW proposal concerning "Label Declarations on Standarized and Non-standardized Foods." In this regard, we supported GMA in the position that functional and general names for ingredients as opposed to specific chemical names should be permitted.

The Chairman of the Committee has also served as a member of MCA's Ad Hoc Committee on Chemical Regulation, formed specifically to review, study and develop a chemical industry position with respect to the proposed Toxic Substances Control Act of 1971 (H.R. 4152) and related bills.

Some 40,000 copies of the revised booklet "Food Additives: What They Are, How They Are Used" have been distributed to home economists, educators, government officials, members of the press, and key individuals in member companies. The Food, Drug, and Cosmetic Chemicals Committee, as one of its major projects, recently updated this MCA booklet which was originally published about ten years ago.