

Referring to the agenda and commenting on the unusually excellent turnout, Mr. Miller asked that those present introduce themselves in accordance with the custom followed at all Committee sessions.

Minutes of Last Meeting Approved

By way of reminder, Mr. Miller noted that the Minutes of the last meeting held on June 19, 1969, were sent to the full membership. He then asked if there were any corrections or additions to the Minutes, as developed and circulated by the SPI. In the absence of comments, he declared the Minutes approved as mailed.

Remarks of Committee Chairman

At this point, Mr. Miller commented again on the unusually fine turnout at the day's session, noting also that, obviously, there were a number of individuals present for the first time. In view of this he pointed out that, as in the past, the meeting would consist of a single day's session, with the majority of the topics covered on the agenda discussed in the morning. Thereafter, there would be a reception and luncheon and, following then, completion of the topics not yet covered.

In commenting on the format for conducting the business sessions, Mr. Miller indicated that the Steering Committee would be perfectly receptive at any time to receiving suggestions or recommendations for changing the methods of operation of the group, or the format for future meetings.

Report of SPI Counsel

Chairman Miller then called upon Jerome H. Heckman of the Washington law firm of Keller and Heckman, and SPI General Counsel, to give his regular report on regulatory matters of interest to the Committee. Mr. Heckman then gave the following formal presentation:

"Gentlemen:

"We are very glad to have you here in Washington for this first Food, Drug and Cosmetic Packaging Materials Committee meeting of the Seventies. Like all of you, I am sure, we hope the new decade will bring solutions to some of our pressing and depressing national problems. Due to the real sense of urgency and emergency we feel about some of these problems in the environmental control area, I would like to use some of my time today to talk to you about the kind of battles--or challenges--we see shaping up for the plastics industry on what is now commonly called the 'ecological' front. First, however, I will try to take care of my announced assignments.

"As you know, it has been an unusually long time since our last meeting, primarily because we have been waiting for some definitive action by the Food and Drug Administration on what has become known by the shorthand term as 'the Ramsey proposal.' While I am still unable to provide any tangible optimistic intelligence on where the proposal is going at the moment, Mr. Ramsey is due to join us at lunch so perhaps he will be able to let us all in more fully on what we can expect. Before going into more detail about this subject, I thought it would be well for us to cover some of the organizational changes at FDA which should be of interest to you.

"As you are all aware, the Food and Drug Administration has a new Commissioner, Dr. Charles C. Edwards, a surgeon more recently active in the business management field as the head of the health and medical division of Booz, Allen and Hamilton. Even more important perhaps is the fact that a new FDA reorganization with more apparent impact than usual has and is taking place. The significant difference--at least to us--of this reorganization plan is that it is reaching down into all levels of the agency. Previous plans have been characterized, with justification, as nothing more than a game of governmental musical chairs. The players stayed the same, the substructure stayed the same, and only the titles and the Commissioner changed. Not so this time.

"This time the Commissioner and his Associate Commissioners were removed from the agency entirely. A number of other top officials took 'early retirement,' or have been moved to completely different positions, or even different agencies. In addition, FDA has been divided into Bureaus along lines which have proven effective in other governmental agencies.

"Whether all of these changes will provide the sense of direction and increases in efficiency and consistency in application of the law so badly needed at FDA remains to be seen. All we can do is to hope for the best, recognizing that there is virtually no way the situation can worsen.

"Going from the general to the specific, the food additives problems which have always been of prime interest to this group, are now being handled by the new Bureau of Foods, Pesticides and Product Safety. This Bureau is to be headed by Dr. Virgil O. Wodicka, a man with broad industry background. He has been with Hunt-Wesson Foods, Ralston-Purina, and Libby, McNeill and Libby.

"Dr. Wodicka's Deputy Director will be Dr. Albert C. Kolbye, Jr., formerly the CPEHS head of the office of Standards and Compliance. Within the Bureau, your prime contacts will probably

still be with Bill Randolph, Al Holtz, and Drs. Herb Blumenthal and Joe McLaughlin since they will be performing essentially the same functions as heretofore. However, you might want to remember the name of Thomas W. Brown who, with our old friend Les Ramsey as his Assistant Director, will be serving as Director of the office of Compliance within the Bureau. This means that Mr. Brown, formerly District Director of FDA's Detroit office, will be the head of the group within the Bureau that deals with Regulations and Petitions Control, and 'Case Guidance,' i.e. opinion letter writing. In short, Mr. Brown may be the man to see if you have disagreements with such Division of Regulations and Petitions Control people as Bill Randolph and Alan Spiher, and have exhausted your administrative appeal routes through Lou Buckley who will head the Division.

"Aftermath of Cyclamania

"We have, of course, been receiving many questions from the industry about the likely impact of the cyclamates-MSG controversies on packaging materials components, as well as direct additives, in the 'GRAS' or 'prior sanctioned' categories and, hence, heretofore non-food additives under the statutory definition. The situation has cooled somewhat with the departure of Commissioner Ley and FDA's preoccupation with reorganization and the anticipated unveiling of another literary thrust by Nader's Raiders, in this case led by Jim Turner and Robert McLeery (himself an ex-FDAer we're told).

"Sen. Gaylord Nelson has introduced his bill, S.3295, to tighten up the application of the Delaney Clause by eliminating the GRAS list, and the prior sanctions exemption. This, at the same time as Secretary Finch's office has indicated a disposition to provide more flexibility in the application of the clause, and has asked assistance from the chemical industry to suggest corrective language and action. Everyone certainly seems to be running very hard to stay in the same place.

"Again, becoming more specific, we do not see any immediate threat to the established 'GRAS' or 'prior sanctioned' status of plastic packaging materials at this moment, and in the present regulatory context. We do believe FDA will be rechecking food additives of 'a higher priority' to determine whether GRAS status should be revoked or changed. The checking will probably continue to be done by the National Academy of Sciences, already busy at FDA's request in evaluating the use of monosodium glutamate (MSG), salt, and modified starches in baby food.

"In due course, priorities may be established and a system set up so we shall have some better idea of what will be evaluated when. Meanwhile, however, we recommend against undue concern in this connection. Unless there is some dramatic incident of novel impression, the packaging area will remain of low priority concern in FDA's thinking. This, of course, is as it should be on the basis of the track record. Remember, though, that the same 'low priority' hazard rating which leaves FDA relatively unconcerned about packaging materials is what leaves the industry without proper attention for its food additive petitions (required by law--low priority or no low priority), and for its requests for sensible reforms in the overall application of the food additives and other FDA laws.

"FDA Proposal to Modify Section 121.2500

"This brings me quite logically to my next subject where my report must be less optimistic. You will recall, I am sure, that our last meeting was spent in large measure discussing the FDA, or 'Ramsey proposal,' for amending Section 121.2500 of the Food Additives Regulations. If you have read all of your mail, you also know that we moved forward through the so-called Inter-Industry Committee to present the packaging industry's recommendations for revisions in the FDA write-up. The precise changes we suggested, and all of the data supporting them, were sent to you with a full report on our meeting with the FDA staff under cover of our letter of September 4, 1969.

"Thereafter, in November we wrote to let you know of our fears that the FDA reorganization, the cyclamates incident, and the anticipated Nader's Raiders' report were, according to our sources, leaving FDA gun-shy about issuing any proposal to ameliorate present requirements, no matter how reasonable such action might be.

"Unhappily, the dust has not settled enough yet, according to our informants. I am indeed afraid that this is what Mr. Ramsey will confirm at our luncheon session. Of course, you might then wish to inquire of him as to when some action might be forthcoming, at least by way of the promised proposed rule-making, or what exactly is delaying matters now. I am sure he will do his best to try to give you some answers but I have doubt as to whether his answers will satisfy your thirst for knowledge, or our shared desire for some real progress.

"Nader" Report

"Reference to the Nader report on FDA was included in your agenda because, frankly, we expected this landmark document to have appeared before now. Apparently, Nader's Raiders must have become afflicted with 'FDAitis.' Their report was announced as due in December, I suppose under a self-imposed FDA style 90 or 180 day rule. If December was the true target date, another 90 days has apparently been requested and granted in the time honored FDA tradition.

"In any case, I have no Nader's Raiders' tome to cover for you. I am sure that FDA would be happy to wait forever in this case but I imagine something will be along from Mr. Turner's group soon. When the word is out, we'll let you know but you will probably read about it in the lay press first since Mr. Nader's people have a way with the Fourth Estate.

"It is already obvious from his statements to the press that Mr. Turner is no admirer of FDA, past or present. He has been quoted as labelling the new reorganization superficial because it will not overcome the agency's characteristic inability to act forcefully, or with sufficient zeal. Like everyone in industry, he has been most critical of FDA's slow-footedness in handling problems. This Nader Report may well make some strange bedfellows-- it should be interesting.

"USDA Regulations

"On the more mundane side, again if the mails have been true, you all know about the comments we filed on the Committee's behalf in response to the Department of Agriculture's Notice of Proposed Rule-making published in the August 14, 1969, Federal Register. In general, we urged the Department to continue its past practices as regards the way in which it has handled approvals for food packaging materials. We took exception to any changed treatment which might serve to confuse the process unnecessarily. We also took this occasion to urge the Department to eliminate the need for supplying information on inks or adhesives unless they are expected to contact foods.

"This entire matter of USDA treatment of inks, adhesives, and colorants generally continues to be vexatious because of the adamant position USDA has taken relative to heavy metals and other known toxic substances regardless of whether they are, in effect, 'barriered' from food contact or not. There is hope that the USDA position may eventually be modified but, at least as of this time,

the Technical Services Division will not approve the use of cadmium pigments, for example, on any realistic basis.

"In the Society's comments, we also recommended strongly that the Department take a more moderate position in requiring the registration of labels bearing the USDA seal. As now proposed, and as indicated in the copies of the Comments sent to all members of the Committee, very burdensome registration requirements would be imposed on meat packaging suppliers. Among other things, multiple registrations and extensive record keeping would be necessary.

"If our recommendations are followed, the proposed regulations would be changed so that an authorization for a particular label would only have to be obtained once and, thereafter, internal records would have to be maintained for three years so that USDA could check such records whenever it wished to make certain that the USDA seal was not being counterfeited or used without authority.

"Finally, our recommendations look towards eliminating the need for the washing of flexible containers prior to filling where such containers are intended to be hermetically sealed.

"No final action has been taken by the Department to finalize its regulations as yet. More pertinently perhaps, on February 2, 1970, we received and relayed to all of you an interesting letter sent to us by John W. Sloane of the Technical Services Division. In this letter, Mr. Sloane advised that the Department does not intend to change its present practices. Furthermore, he has informed us that parts 317.3, 317.4, and 317.15 of the proposed regulations will not be finalized as written, but will be republished as proposals for further comment. Mr. Sloane has indicated that the rewritten version of Section 317.4 'will more specifically maintain the integrity of trade secrets and proprietary information.'

"As we have come to expect over the years, USDA's Technical Services Division continues to operate generally in a way that has always seemed much more practical to us than that of the Food and Drug Administration, at least where packaging materials are concerned. We shall continue to cooperate with the Division and shall keep you posted on developments."

After giving the foregoing statement, Mr. Heckman talked at some length, but informally, with the Committee about the serious problems the entire plastics industry is facing in the broader area of public and official concern about the ecology. He made particular reference to various legislative efforts now under active consideration in the Congress of the United States, and also in the city of Madison, Wisconsin.

For example, he noted that, as framed, an Ordinance under very active consideration in the city of Madison, Wisconsin, would ban all non-disposable containers after 1976, and would impose a requirement for the collection of a \$1 deposit on all returnable containers. This proposed Ordinance in Madison, a copy of which is attached hereto as Exhibit A, was introduced by Alderman Ashman and was the subject of lengthy written Objections filed on behalf of the Society. Other groups also opposed the Ordinance quite vigorously. Nevertheless, and to everyone's considerable surprise, the Ordinance came up in the City Council and was the subject of an eleven-to-eleven tie vote. Further efforts are underway to attempt to dissuade the City Council from adopting such restrictive and wholly unreasonable, even unreasoning, legislation; however, these efforts will be quite expensive and will demand very delicate handling to a degree not anticipated when the Ordinance first came to the attention of the packaging and other industries.

On the Congressional front, Congressman Scheuer, with co-sponsorship by twelve other members of Congress have introduced a measure, H. R. 15959, which would impose a rather heavy tax schedule on all other disposable containers. Indeed, Mr. Heckman noted that plastic containers would be singled out for the highest of all the taxes in the proposed Scheuer schedule so that plastic bottles would be taxed at the rate of 25¢ each, regardless of the size or the product packaged.

Although no language to ban any type of bottles seems to have been included in the legislative proposal, in a Press Release made public by the Congressman's office on the day H.R. 15959 was introduced, it was stated that the Bill would bar "the use of potentially dangerous plastic containers" altogether. (See Exhibit B for copy of Release.)

There was a great deal of cross-discussion about the entire environmental or ecological concern situation, with Mr. Heckman emphasizing his strong feeling that the industry should be aware of the attacks it is now facing, and should be developing very constructive and positive approaches to try to deal with the problems presented. He pointed out that efforts are already underway, to be explained further by Mr. Ingle, on the technical front, and that these efforts should provide some sound answers from a technical point of view. On the other hand, he noted that the industry might not be able to wait for these answers, and especially for the public to be educated about the solutions they might suggest. In Mr. Heckman's opinion, the industry needs a legislative or regulatory "survival plan" of some type while the technical data is being acquired, and this would seem to demand some most effective public relations work to help counter-educate the public on what the real hazards are, and on the necessity for looking at the problem with true perspective, rather than rushing into legislative bans on useful products.

Report on Matters of Interest Regarding SPI Waste Disposal Committee

Chairman Miller then called upon George W. Ingle, Monsanto Company, Washington offices, to discuss the activities of the relatively recently formed SPI Plastics Waste Management Committee.

"At last week's SPI Board meeting (February 20, 1970), the Plastics Waste Management Committee project 'Incineratability of Plastics' was approved. This study, to be conducted at New York University's School of Chemical Engineering, under the direction of Drs. Elmer Kaiser and Arrego Corroti, will cost \$90,000 and require one year for completion. Ancillary costs, including public relations contingencies, and SPI's contribution to 'Keep America Beautiful,' will raise SPI's total investment on the solid waste disposal problem to at least \$125,000 through June of 1971.

"Supporting activities of the Plastics Waste Management Committee include collection of data for compositions of major plastics occurring in solid waste.

"The next meeting of the Plastics Waste Management Committee will take place on Thursday, March 26, at the Mayflower Hotel, here in Washington. Representatives of the Department of the Interior's Bureau of Mines will describe their pilot-scale process for separating and reclaiming non-combustibles in incinerator-output.

"This week I will be giving a paper entitled Options in Plastics Waste Management at the combined meeting of SPI's Foam Cup and Rigid Container Divisions.

Respectfully submitted,
George W. Ingle"

Following Mr. Ingle's report, Chairman Miller commented on the fact that the Society prepared one of the first pieces of information on solid waste based upon a literature search which it sponsored at Batelle Memorial Institute. As a result of this research the Society has available to interested Committee members a booklet entitled "Report on the Role of Plastics in Solid Waste."

(Please note: The Secretary will be pleased to send a copy of this booklet to those interested in obtaining it.)

In closing his discussion, Mr. Ingle noted that there will be a meeting on waste management developments on Thursday, March 26, at the Mayflower Hotel, Washington, D. C. This meeting is being sponsored by the SPI Plastics Waste Management Committee and will deal principally with a discussion of the

various problems faced by the industry and the efforts already undertaken to develop technical information on proper incineration and related questions. In concluding his remarks, Mr. Ingle endorsed some of the statements made by Mr. Heckman, noting especially that everyone in industry should be making a special effort to constantly remind the public that it need not do without the products it has come to depend upon for packaging convenience and safety but should, instead, concentrate on learning about and utilizing the technology already available to deal in a sensible way with solid waste management problems.

Report of Food Additives Petition Manual Subcommittee

(Please note: The Secretary is noting herewith for the benefit of new Committee members that this Subcommittee has been charged to develop a proposed Food Additives Petition Manual which, it is hoped, will ultimately explain the various regulatory considerations one must take into account in preparing to file a formal petition, and accumulating appropriate data for such a filing with the Food and Drug Administration. It was thought, when the Subcommittee was organized, that such a manual would be most helpful for technical, administrative, and legal corporate personnel in the drafting of food additives petitions relating to incidental additives.)

Mr. Hochschwender delivered the following formal report for the Subcommittee at the Washington business session:

"Gentlemen:

"Progress on the compilation of a Food Additives Petition Manual has been somewhat slower than originally anticipated due to a number of unforeseen circumstances. Perhaps the most significant of these has been the uncertainty at the Food and Drug Administration as to when and how the proposed amendment to Section 121.2500 of the Food Additives Regulations will be finalized.

"In any event, I would like to thank the members of the Subcommittee who have completed their assignments and given us the benefit of their very helpful recommendations. I have been working closely with SPI Counsel on this project and am pleased to report that a preliminary rough draft of the Manual has now been completed.

"Counsel and I will be working on further refining the draft during the next few weeks and will endeavor to have a presentable 'first draft' available for circulation to the Subcommittee in the very near future. After the Subcommittee has been given a

reasonable period to review the draft, I will suggest a time and place for a meeting of the Subcommittee to discuss the draft further. Thereafter, we will make every effort to prepare a final draft for review by the full Committee as soon as is practicable. It should be kept in mind, however, that completion of the Manual will necessarily be delayed until the proposed amendments to Section 121.2500 are finalized.

"Thank you."

Reports on Liaison with Other Organizations

Chairman Miller noted that, as is customary, the agenda called for a number of liaison reports from organizations doing similar work to the SPI Committee, or involved in activities relating to the interests of the SPI group.

With these preliminary remarks he then called for the formal reports as indicated on the agenda.

Synthetic Organic Chemical Manufacturers Association (SOCMA)

Referring to the SOCMA item on the agenda, Mr. Miller said that it was hoped that there would be delivered a status report on the proposed "Synthetic Organic Colorants in Paper and Paperboard" proposed food additive regulation, but that at recent meetings there has been little progress reported with everyone awaiting action by FDA.

He then noted that W. P. Munro, American Cyanamid Company, who has been the liaison representative between SOCMA and SPI for a number of years now has retired from his company. He then commented on the excellent manner in which Mr. Munro has acted in this capacity over the years and requested, on behalf of the SPI Committee, that the Secretary communicate with Mr. Munro and wish him the very best of luck in his retirement, thanking him for the diligence he has shown in keeping the SPI Committee posted on the SOCMA effort.

There was nothing further to report on the SOCMA matter since action on the aforementioned proposed regulation remains in pending status. This item will be carried, however, on future agendas.

Pharmaceutical Manufacturers Association - SPI Liaison Group

Chairman Miller called upon Wat Ackart, Union Carbide Corporation, and chairman of the liaison group between SPI and the Pharmaceutical Manufacturers