APPENDIX A

REPORT OF JEROME H. HECKMAN
SPI GENERAL COUNSEL

Prepared for

DECEMBER 15, 1972 MEETING
SPI FOOD, DRUG AND COSMETICS
PACKAGING MATERIALS COMMITTEE

Gentlemen:

Once again it has been quite some time since our last meeting so I have more to report on than I would really like. Nevertheless, as usual, I urge you to interrupt at any time with your questions.

On the more unusual side, you will note that your new Chairman has welcomely and creatively suggested that the reporting from our office be split up so a much more interesting fellow--Dan Dixler--will be telling you about a number of the recent developments affecting your interests. Incidentally, I suppose I should mention here that this sharing of responsibility is somewhat in keeping with the view I have been expressing to many of you for a number of years to the effect that Food and Drug regulatory problems are rarely correctly slotted into "legal" and "scientific." You may even recall my sending you a copy of a paper I gave on this very subject at a Federal Bar Association meeting in New Orleans some years ago, the same being entitled "Why Lawyers and Scientists Must Increas Cooperation and Mutual Understanding in Dealing with Food and Drug Problems."

Our experience continues to be that Dan and I must work ever more closely together on all food and drug matters. This begins to give me a bit of a pseudo-scientist aura from time to time, and I am afraid Dan might feel like some legal training is being forced on him. I should let him speak for himself in this respect because he might even enjoy it. My years at the Bar have convinced me that most people feel like they are born lawyers anyway, and are anxious to practice th profession while the ambition of many of us who do practice is to earn the title of "retired attorney."

In accordance with something of a custom we have established over our years together, a few words about recent changes in the cast of characters at FDA might be in order. Obviously, no one could cover all of the changes because they take place so rapidly. Thus, I will mention just those that would seem to be of special interest to you.

In the Petitions Processing area, a very competent new figure has come upon the scene since last we met, and seems to be taking a close hold on the reins. Dick Ronk was brought in from the field staff and is now Director of the Division of Petitions Processing. I think I will let Dick's competence show for itself since he will be with us at lunch.

To put his function in perspective, however, I should probably tell you that he is reporting directly to Dr. Wodicka and is taking a very deep interest in managing all aspects of petition processing so that it will become more efficient. Lou Buckley is now reporting to Dick, as are all of the scientific and administrative personnel dealing with petitions. Among th new names you might hear are Tom Brown (same name but not our old friend, Thomas W. Brown, who is now in the Commissioner's office) and Jerry McCowin, who have now joined Al Rothschild, Stanley Glassner, Ed Schaeffer, and John Singleton in the Petitions Control Branch. Despite budget cuts, Mr. Ronk has moved these additional people in from other areas of FDA work to try to expedite petition handling.

Dr. Joseph McLaughlin is no longer working directly on indirect additive toxicological problems. Drs. Kokowski and Misra are still on the scene, and we understand that Drs. Malcolm Melman and Theophilus R. Carson will also be helping with toxicological review.

The chemistry group remains essentially the same with Messrs. Holtz and Higginbotham being the primary people involved where indirect additives are concerned.

There has been another slight, but significant, shift in the way petitions are being received and handled. The only way I know to describe the shift is to say that it seems to be about halfway between the old early 1960's procedure of reviewing a petition almost fully before it was even accepted for filing, and the latter-day procedure whereby acceptance for filing has been automatic unless a petition was obviously deficient. As of now, more than a cursory review of incoming petitions is being made before acceptance for filing so that, for example, four of

reporting on this subject to Dan. As far as the aspects of the toxicological guidelines I want to mention are concerned, the point I think I need to make to you is that Mr. Ronk and Dr. Wodicka seem to have come to the conclusion that they must get the toxicologists to agree on a form of toxicological guidelines as a prelude to their promulgating some type of regulations along the lines of the Ramsey proposal.

In other words, the administrators want a formal statement as to what may be considered "toxicologically insignificant" in most cases as a basis for their indicating formally when petitions need not be filed because something may properly be considered a "non-additive," i.e. a substance which may not reasonably be expected to become a component of foods. We have recently seen more of an inclination on FDA's part to concur in non-additive status on the basis of the no-migration theory but this has taken place only where there was toxicological background to support a conclusion that even if a given amount of a substance were to migrate to foods--that given amount being the level of sensitivity of the analytical method used in extraction work--there is toxicology to demonstrate that it would present no hazard.

My great hope for 1973--as it has been since May 6, 1969--is that FDA will be able to come up with toxicological guidelines which are only guidelines; that it can make the guideline nature of any such publication clear to its own staff and the public and scientific community; and that this will lead to something tangible as an end-product of all of the effort that has gone on since at least 1966 to better define what is a "non-additive" within the meaning of the statutory provisions that say you need not file a petition if a substance may not reasonably be expected to become a component of foods.

The one thing I do know is that Mr. Ronk feels strongly that something should be done in this area because he believes that FDA should stop promulgating meaningless and unenforceable regulations.

Likewise, by the way, Mr. Ronk feels that the present regulations are so confusing as to require some type of complete revamping and codification. Thus you may well be hearing more from him on this score. It could come in the nature of a plea for help which might present a significant challenge for our Technical Information Subcommittee, or perhaps an entirely n w Subcommittee to work solely with FDA on such a project.

experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use." The very length of the definition is enough to convince one that it could only lead to serious trouble.

During the hearings on the Food Additives Amendment, the Commissioner was asked to supply an exemplary list of GRAS substances and did so. Many of these were really foods but, at the time, it did not bother a zealous FDA too much that it had not even built a clear distinction between food and food additives into the law. This situation pertains to this day.

After the law was adopted, many of you will recall that FDA compiled a long list of substances and proposed that they be considered GRAS. The list was submitted to "experts" on a broadside basis and most of the items included were ultimately printed as the GRAS list now found in Section 121.101. Others were deleted, in some cases on what seemed to be purely subjective bases. As a matter of fact, the statute still allows for purely subjective conclusions about what is or is not GRAS. Another subjective feature relates to the unresolved question of what or who is an expert qualified to evaluate a particular substance's safety.

If I may be allowed to express an opinion, it seems to me that the more direct way for FDA to deal with the GRAS status problem would be to do away with the classification altogether, revamp the Food Additives Amendment entirely, and propose legislation whereby it could selectively move to regulat well-defined categories of substances where hazards might be reasonably anticipated. In other words, my feeling is that FDA should cease requiring preclearance of all food additives and ingredients, should propose regulation of specific and well-defined categories of chemicals that need attention, and then devote its time and expertise to these areas instead of wasting time in requiring clearance where no need for regulatory action is really indicated.

Forgive me for using your time to philosophize in this way. I do so only because it seems to me that understanding the GRAS Rulemaking Proposal, originally instituted on March 25, 1972, can only be understood in this context. It must also be recognized that the rulemaking proposal, prompted in large measure by the cyclamates incident, really amounted to FDA's indirectly conceding the ineptness of its basic regulatory scheme as it relates to the Food Additives Amendment exemptions.

As far as the no-migration situation is concerned--and this is certainly one of the most persistent "pesticides" in the history of any Committee I have ever dealt with--we believe that real progress continues to be made even though it comes in subtle and little-publicized forms. The GRAS rulemaking proposal language indicates that a confrontation with the problem is becoming more of a real possibility, however. By the way, I attribute a willingness to deal with the issue in large measure to Peter Hutt's presence at FDA, and that of Dick Ronk.

In recent months we have had considerable evidence that the Tom Brown letter of August 21, 1970 is quite viable, is becoming more so, and has even been the basis for salutory FDA action in individual cases of considerable importance. Most of the kind of action involved has related to specific company problems and products so I cannot discuss them with you in detail.

What I think I can say is that, more than ever, you should feel less reluctant to rely on no-migration or, more properly, "no reasonable expectation of a substance's becoming a component of foods" positions where appropriate testing leads you to the scientific conclusion indicated. To be even more specific, we are fervently recommending to our company clients that they forego the filing of Food Additive Petitions in any case where appropriate and diligent testing convinces them that there is no reasonable expectation of migration to foods. Moreover, we are backing our stance on this score by supplying our letters of opinion to our clients as to non-additive status wherever and whenever we are supplied with sound data which Dan Dixler and I can review so that we can independently reach the conclusion that there is no detectable extraction of a substance with a method sensitive to 50 ppb.

You will recognize, of course, that what I am saying is limited to substances which present no special toxicological hazards, e.g. substances other than heavy metals, pesticides, known carcinogens, or those where toxicology is available to show an adverse effect level below 40 ppm. In other words, we are self-actuating the Ramsey Proposal and we think you should do likewise to the greatest extent possible. The difficulty here, as always, is in providing the kind of customer assurance that will be accepted so it would still be better if the Food and Drug Administration would act on the matter more formally.

We have had cases recently where obtaining FDA acquiescence in our opinions of this type was necessary for customer assurance. Our efforts were successful and obtaining the concurrence required less time than the processing of most petitions,

By means of the August 12 rulemaking, FDA did announce its intent to adopt a procedure whereby more prior sanctioned substances could be officially listed in the regulations.

Responsive to this proposal, not yet finalized, we voiced approval of the FDA position and used the occasion to ask that our long prior sanctioned basic resins be among the first officially announced as such. Frankly, we doubt that FDA will list the resins at the same time as it finalizes the organic or procedural rulemaking but we thought we might as well get our oar in early. We may even have some success with respect to our proposal but I cannot give you a prediction in this respect at the moment.

One little point of clarification might be worthwhile here. There has been an exchange of correspondence within the Committee as a result of our decision to seek listing of the SAN resins, as well as those long-published in our SPI prior sanctioned resins manual. So that there will be no misunderstanding about the matter, I would like to make it perfectly clear that there is no difference of opinion as far as I am aware between the one company member of our Committee which filed supplementary comments on the SAN question after our comments were lodged. As I see it, all that Vistron sought to do was to provide better specifications for the SAN resins which are prior sanctioned than we were able to obtain and submit.

Had we had these specifications in time, we would probably have included them in our comments. In any case, I hope this statement will serve to resolve any problem here and reassur our friends at Vistron that we are in basic agreement with their position.

It is, of course, entirely possible that FDA will want tighter definitions on some of the other prior sanctioned resins before it will list them as we have requested. If and when we receive indications to this effect, the Technical Information Subcommittee will undoubtedly be pressed into action to see what can be expeditiously and appropriately done.

Environmental Impact Statements

Among the flood of FDA rulemaking proposals during the past year was one on which we did not comment for your Committ e for the simple reason that it is our opinion that FDA could not be criticized for undertaking a responsibility unequivocally imposed upon it by the Act of Congress known as the National Environmental Policy Act, or NEPA. All that FDA has really done by

Additionally, you should recognize that at least the present tenor of EPA thinking might best be characterized as anti-anything new, rather than one of truly balancing interests where changes in the environment are concerned. In other words, if you come up with a new product that requires some type of government sanction, and if there is any way this might lead to the need for an environmental impact proceeding, you can be almost certain that you will have an up-hill battle with an important government agency--EPA--opposing you.

In short, a new dimension of great significance has been added to your book of "future shocks." My own guess is that the superimposing of this burden has already and will continue to give pause to anyone developing new products if they have not heretofore seen fit to limit innovation because of the substantial roadblocks imposed through longer existing regulations.

The PVC liquor bottle case could be a landmark situation in this respect. We are working hard to bring about a favorable result which will allow the use of PVC liquor bottles on a permanent basis with the approval of the Bureau of Alcohol, Tobacco and Firearms of the Department of the Treasury. Frankly, we are confident that the facts are on our side but the public relations problem is a difficult one so no promises can be made at this time. The matter should be resolved by June of 1973, the controversy having started in about October of 1971. Since this question is really being handled as an SPI Public Affairs Council and Plastics Bottle Division problem, I will not try to give you the details here although I would be glad to answer your questions on the subject now, or perhaps informally later today. Suffice it to say that the lessons we have learned in the PVC liquor bottle case have been sufficiently bitter to warrant our warning you that the NEPA problem cannot be ignored in your product planning if any type of governmental approval might be involved.

Freedom of Information Act and
FDA Public Information Rulemaking

On May 5, 1972, FDA issued a Notice of Proposed Rulemaking which outlined the Agency's intended policy changes with regard to public disclosure of information, thereby implementing Public Law 89-487, better known as the Freedom of Information Act of 1967. Basically, the reason behind the FDA decision to offer the proposal was that considerable pressure had been brought to bear upon it recently by consumer groups and the news media to release heretofore confidential documents in its files, and generally to liberalize its disclosure policies.

summary of each type of comment submitted and will reflect whether the final order accepts, rejects, or modifies it, and also provide an explanation for the decision.

A major concern of industry in connection with this proposal is, of course, the "trade secret" area, although it specifically states that they will not be subject to public disclosure. A "trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business and which gives him an opportunity to obtain an advan- over competitors who do not know or use it."

It is the strong conviction of industry that an overall definition of a trade secret cannot be made since the use of certain data, not the data per se, determines whether it can be classified as a "trade secret," and it is the manufacturer alone who is capable of making that determination.

Disregarding the rather tremendous burden that will be placed on industry and the government in searching files for inquirers, and this could well require the full time of almost every staff member from some of the inquiries we have already seen, the major controversy will probably rage around the question of what is and what is not a legitimate trade secret in a given situation. We suspect that the courts may eventually have to evolve more specific guidelines in this respect. It is one area where we would imagine that affected interests will be less reluctant to resort to the courts than they have been with respect to other areas of FDA activity. A lot will probably depend on what inquirers have to be confronted since fear of publicity is what so often precludes valid suits to contest FDA action.

This is one area where you will have to do a good bit of "playing it by ear," just as the FDA staff is now doing. I can tell you that those on the staff who are being charged with answering "FOI" inquiries feel as if they are caught somewhere between Scylla and Charybdis in that they must try to release information to the greatest extent possible under the Freedom of Information Act but can be prosecuted for revealing confidential information improperly under Section 301(j) of the Food, Drug and Cosmetic Act. Section 301(j)can lead to imprisonment for not more than one year and/or a fine of $1000 for each violation so people like Ruth Cockerham, who is handling may of the "FOI" requests, are anything but comfortable about their responsibiliti s.

From your point of view, we would recommend, as we hav previously done in correspondence, that you carefully label almost everything you fil which might reasonably be considered a trad

APPENDIX B

REPORT OF DANIEL S. DIXLER
KELLER AND HECKMAN

Prepared for

DECEMBER 15, 1972 MEETING
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Gentlemen:

Mr. Heckman's introductory remarks promised that the following report would be "interesting." I am sure it will be because the subject matter has, I am sure for all of us, a strong inherent interest and I hope that I will not blunt it in the course of my presentation. Although I plan to stay relatively close to the prepared report which will appear in the minutes of this meeting, I do want you to feel free to interrupt at any time with questions or requests for further clarification of any points. As far as questions are concerned, I do not know that I can answer them but we certainly have enough knowledgeable people here to turn to for assistance in that regard.

A second point Mr. Heckman made had to do with my becoming a bit of a lawyer. Actually since I am not a member of the Bar and I am with a law firm I often find it necessary when meeting new people to explain my position to them. With that out of the way, I hope they will accept any legal opinions that I may offer with as much weight as they assign to the legal opinions they receive from their barbers, taxi drivers, bartenders, and even chemists. It is really not quite that bad, because I do have exposure to an excellent teacher; but--you have been warned.

Turning now to the subject matter assigned by your agenda, the first item concerns the Food and Drug Administration's proposal to issue a regulation for colorants for plastics.

Colorants for Plastics Regulatory Proposals

To put this proposed regulation into perspective, a brief review of the history may be helpful. After the Food Additives Amendment went into effect the status of most colorants b came somewhat anomalous. As was true of other

additives, a number of commercially used colorants were placed on an extension list. This meant that the Commissioner did not believe that their continued use constituted a health hazard, but additional extraction work and possibly toxicology would be required in order to permit these colorants to be regulated. In addition, F, D and C colors and their lakes were permitted to be used. Finally, as a basic premise of the Food Additives Amendment, those colorants which were not reasonably expected to become components of food were not food additives and accordingly were outside the regulatory scope of the law and could be used in packaging without any FDA action. In a practical and realistic sense this last category probably embraced most of the commercially used colorants because, if they did migrate in any reasonable or significant quantity, they would color the food; and regardless of the regulatory status of the colorant per se this would render the food adulterated.

Subject to certain limitations the extension lists including colorants were renewed, under a Congressional authorization, until 1965. By this time Congress had decided that enough interim time had been granted, and all materials including the colorants which had remained on the extension list since the enactment of the amendment had to be either regulated or dropped.

Petitions had been filed for some of the colorants generally not because they really migrated, but only because the manufacturers felt that a regulation would permit marketing without any possible "cloud" on the colorants' regulatory status. The Food and Drug Administration was not, at that time, prepared either to act on these petitions or to conclude that any of the pigments were really non-migratory. Instead, the Food and Drug Administration took a rather unusual and perhaps quasi-legal position. [It informed interested parties that although the extension list had expired it did not propose to take any action against the use of colorants which were on the list without further notice so long as the colorants were used in accordance with any of the listed limitations.]

A few pigments were permitted in a number of scattered Regulations. Regulation §121.2514 listed a relatively large number of colorants; other Regulations, only one or a few. Ultramarine Blue had its own regulation.

A recent informal follow-up with FDA'ers indicates that the Comments may be heeded with regard to limitations on the plastics with which chromium oxide green, phthalocyanine green, and quinacridone red may be used. We received "no comment" on the "no-migration" reaffirmation statement which we urged.

The carbon black problem deserves some separate comment. The only regulated black, channel black, will no longer be commercially available. The Carbon Black Advisory Committee, an industry group, has been testing a number of furnace blacks with a view to finding a suitable substitute for the regulated channel black. The Food and Drug Administration had recommended that a number of furnace blacks be screened to find those low in PNA content, and that these be used in a variety of plastics to provide test samples. These test samples were to be extracted and the extracts analyzed for possible extracted PNA in the low parts per billion range.

The Carbon Black Advisory Committee has requested that the SPI work cooperatively with it to furnish some standard materials compounded with furnace blacks which the Advisory Committee would recommend.

Phthalate Esters Situation

Many of you will recall that Dr. Rubin of Johns Hopkins University presented a most interesting talk at one of our meetings on the extraction of phthalate plasticizers from PVC blood bags and similar devices. Subsequent work by his and other groups appeared to indicate that phthalate esters, and most particularly dioctyl phthalate, was rather widely distributed through the environment. In light of the recent findings that long-lasting chemicals such as chlorinated insecticides, polychlorinated biphenyls and dimethyl mercury appear to be very widely distributed through the environment, fears began to develop as to how widely distributed the phthalates were, and whether they constitute an environmental problem.

In order to bring together the best current information on the subject, the National Institute of Environmental Health Sciences held a symposium early in September. The full proceedings are expected to be published in January but we believe it is fair to say that the general opinion of the participants could be summarized as:

the wide use of PCB as a heat exchange medium and its leakage into animal feed precipitated a crisis that resulted in the contamination and seizure of animal feed, and in some cases animals which were fed either contaminated feed or feed which was believed to be contaminated. Furthermore, the use of PCB in the preparation of carbonless carbon paper and the subsequent recycling of such paper to form paper and paperboard that was used to package food led to the presence of PCB's in paper packaging materials and to the detection of PCB in a variety of food which had been packaged in paper and paperboard.

Although the use of PCB has since been restricted to "closed systems" which should eliminate the significant risk that any more PCB will contaminate food or become dispersed thrugh the environment, the Food and Drug Administration published a proposal to limit the amount of PCB in food packaging materials as well as foods. The rationale for this proposal was the finding of contaminated paper packaging but the FDA proposal put limitations on not only paper and paperboard but on plastic packaging materials as well.

Such a proposal would require the development of quality control procedures that do not now exist to permit a manufacturer to test his plastic materials rapidly and accurately. Furthermore, to the best of our knowledge, no migration of PCB from plastic to foods has ever been demonstrated.

On the basis of our most recent informal contacts with the FDA staffers who are still working on the PCB proposal, it is to be anticipated that the Food and Drug Administration will probably finalize a version of its proposal in the near future. Indeed, we understand that the final Environmental Impact Statement may be published next week. We have been given reason to believe that the comments filed in the proceeding will be heeded, at least to the extent that so many of them pointed out that the real problem which gave rise to the issue revolved around paper packaging materials. While we certainly have no assurance in this regard, our understanding is that FDA is planning to limit the application of the new rules to paper products. Our informants indicated that the FDA will continue to keep an eye on plastic packaging materials, and if problems are discovered, plastics will be covered by the rules. It is now expected that the FDA will point out that the basic intent is definitely to limit PCB contamination of

Subsequent to that meeting I met with Mr. Holtz and others of the FDA Science and Technology staff, including Mr. Higgenbotham and Mr. Howard offering suggestions and recommendations for the guideline revision that reflected the experience of the Society of the Plastics Industry members. We were subsequently advised that a working draft of the proposed guidelines has been completed and is now awaiting some "rewording."

Toxicological Guidelines

Promised for even longer than the extraction guidelines have been toxicological guidelines for food additives. Periodically an announcement appears in Food Chemical News--and Lou Rothshild, the editor, is generally quite reliable in this respect--stating that some FDA'er has announced that the toxicological guidelines will be issued in a "few weeks," "soon," "shortly"--but somehow this has not yet happened. We believe that there is not too much trouble with respect to the actual testing procedures but there is a good deal of internal soul-searching about fixing the levels of additive in the diet at which various types of testing should be recommended.

Recently, in connection with the GRAS Affirmation Regulation, the Food and Drug Administration has acknowledged that indirect additives which migrate at low levels might properly be the subject of GRAS affirmation petitions. We believe that part of the delay in issuing the toxicological guidelines concerns the problem of dealing with insignificant quantities of indirect additives without embracing the NAS-NRC concept of "toxicological insignificance" which FDA has stated to be unacceptable. The last word we have heard is that the toxicological guidelines will be issued, "soon."

Fat-Simulant

As you well know, measuring migration of indirect additives to fatty foods is a continuing problem. The use of volatile solvents to simulate natural fats gives problems because the solvents are often much more "active" than natural fats--but variably so. Thus, extraction by heptane often exaggerates natural fats by a factor that ranges as high as 100, but the factor varies significantly from one plastic matrix to another, and from one additive to another.

will be accepted in Japan. A comprehensive list of applicable FDA regulations was included in the Japanese; and from these regulations, permitted substances were selected.

An important omission resulted from this approach; no unpublished GRAS, prior sanctioned, or non-migratory substances were listed. This means that American companies interested in exporting to Japan PVC products for food contact uses may find that their products, though acceptable in the United States, may include components which are not on the Japanese list. At any rate, and in accordance with our long established policy regarding foreign regulatory matters, we are merely calling to your attention such items as have been called to our attention, invite such information as you may wish to forward to us; but leave to individual companies the assessment of their interests and involvements.