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June 4, 1969

To the Members of the SPI Food, Drug and Cosmetic
Packaging Materials Committee

Gentlemen:

The purpose of this letter will be to give you a brief preliminary report on the meeting of what we are calling for the time being the "Inter-Industry Committee on Indirect Food Additive Regulation." Incidentally, please understand that this is by no means a fixed name since the groups of industry representatives involved are actually getting together rather informally with no real intention to make our group a permanent fixture. Also, in due course, Einar Wulfsberg, representing the American Paper Institute, will be preparing and sending us a set of minutes for yesterday's session so I will not attempt to cover the meeting in detail here. Instead, we shall arrange to send you copies of the minutes when they become available.

At yesterday's meeting, the procedure used was one whereby I gave a brief presentation on some of the points that occurred to me relative to the FDA proposal for revision of Section 121.2500 of the Food Additive Regulations, and then Jack Frawley informally discussed his views on the proposal and its practical worth. A copy of the memorandum I prepared prior to the meeting is enclosed herewith, as is a copy of a draft Jack used in the discussion to point up the ways in which he believes the FDA draft should be revised to make it more valuable as an exempting device, i.e. as a device for eliminating the need for the filing of Food Additive Petitions in cases involving food packaging materials components believed to be of no toxicological significance. This material should give you some idea of the focal points of discussion.

ASI-PR 0000731

After a great deal of rather wide-ranging discussions of the various industries' points of view relating to the FDA proposal, it was unanimously agreed that an effort should be made to have a meeting with the Food and Drug Administration Staff at which all of the industries would be represented jointly, and at which certain salient points of "across-the-board" interest could be raised. The idea developed was that these central points should be handled by a small committee representing all of the industries, with any points relating strictly to special interests of any of the groups being handled in separate meetings that each of them would seek to arrange. More specifically, the meeting culminated in the adoption of the following Motion which should serve to give you a reasonably good idea of what is now planned:

"Upon a motion made by Mr. Heckman, seconded, and unanimously carried, it was resolved that the Chairman of the inter-industry group should appoint a committee of approximately five persons to negotiate, on behalf of the entire group of associations, with the officials of the Food and Drug Administration it deems most appropriate with a view towards (1) obtaining clarification of the so-called Ramsey proposal, and (2) attempting to bring about suitable changes including those set forth as the Frawley (1) and (11) points. This committee shall have the authority to speak on behalf of the following organizations: Can Manufacturers Institute, American Paper Institute, American Petroleum Institute, Adhesives Manufacturers Association, The Society of the Plastics Industry, Inc., National Flexible Products Association, Soap and Detergents Association, and Aluminum Association, and shall have the duty to report back to the inter-industry group on its efforts. The committee shall further take pains in its negotiations with FDA to point out that its task is to negotiate only on points of clarification of language of general interest, and to discuss the basic Frawley points (1) and (11); concepts, it being understood that the individual associations will deal separately with any problems related to the special limited interests of their members, e.g. the Adhesives Manufacturers Association will deal by itself with the question of whether the Section 121.2520 adhesives components list should be deleted or continued." ASI-PR 0000732

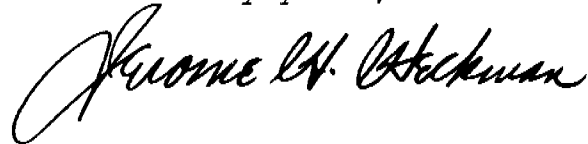
The committee appointed to represent the inter-industry group is as follows:

Chairman: Jerome H. Heckman
Dr. John P. Frawley (Hercules)
Einar T. Wulfsberg (American Paper Institute)
Lewis Burnett (Soap and Detergents Association)
Max Goldfrank (Adhesives Manufacturers Association)
O. M. Banks (American Petroleum Institute)

We have now called a meeting of the committee for Friday, June 13. At that time, an effort will be made to develop plans for a satisfactory meeting with the Food and Drug Administration.

We hope that this letter will serve to bring all of you up to date on what is taking place at the present time. I doubt that I will be making a further report on the situation until our Food, Drug and Cosmetic Packaging Materials Committee meets on June 19 but I would certainly hope to have more to tell you then. If any of you have questions in the meantime, please do not hesitate to let us know.

Cordially yours,



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§ 121.2500 General provisions applicable to Subpart F.

* * * * *

(d) ***

(5) Substances (except heavy metals, as identified under Heavy Metals Test in Food Chemicals Codex, and compounds of such heavy metals; substances prohibited under §409 (c)(3)(A) of the Federal Food, Drug, and Cosmetic Act; and any other substances that have been demonstrated to produce toxic reactions when present at levels of 40 parts per million or less in the diet of man or animals) used as provided under subsection (i), (ii), (iii), (iv), (v) or (vi) of this subparagraph:

(i) As components of food-contact articles, provided any substance is present in the container or coating or other food contact surface at a level of 0.2% by weight or less.

(ii) As components of food-contact articles, provided any substance so used contributes no more than 0.5 parts per million of additive to the contacted food as determined by analysis of the food, or by appropriate extraction studies, or by calculation assuming 100 percent migration.

(iii) As components of articles intended for use in contact with dry food of type VIII described in table 1 of §121.2526(c), provided the finished food-contact surface contains no free oils not otherwise permitted for such use.

(iv) As components of articles intended for repeated use in contact with bulk quantities of food, provided the finished food-contact article is thoroughly cleansed prior to first use in contact with food.

(v) As components of defoaming agents employed prior to or during the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food.

(vi) As components of food-packaging adhesives complying with §121.2520.

paper...

Remarks of Jerome H. Heckman,
General Counsel, The Society
of the Plastics Industry, Inc
Prepared for
Meeting of Inter-Industry Committee
on Incidental Food Additive Regulations

June 3, 1969

Gentlemen:

My understanding of the framework for this meeting is that it reflects a desire on the part of all of us, representing our respective industries, to compare notes so that as much in the way of intelligent viewpoint as is possible can ultimately be conveyed to the Food and Drug Administration in the "industry-by-industry" sessions called for in Mr. Ramsey's letter of May 6. Thus, I hope I am correct in thinking that what Einar Wulfsberg really had in mind for me was the noting of some points for possible mutual discussion, rather than the providing of any definitive dissertation on the legal implications of the FDA proposal in the restrictive sense.

Actually, I think that about all I really could say in a narrow legalistic vein is that we can see nothing objectionable or illegal about the Food and Drug Administration's concept of using the so-called "Good Manufacturing Practices Regulation" Section 121.2500) as a vehicle for attempting to delimit the areas where Food Additive Petitions will have to be filed in the future. Frankly, the only criticism I have of FDA's concept here is that it simply does not go far enough, although it would appear to be a perfectly legal step in the right direction. Since we do feel strongly that the proposal does not do enough--or perhaps I should say, say enough--to solve some basic practical problems which we believe susceptible of immediate solution, I would certainly hope that all of us, in every conversation we have with the Food and Drug Administration Staff about the proposal, will use the opportunity to emphasize our understanding from Mr. Ramsey's letter that the move contemplated is truly nothing more than "a first response to comments received in connection with the

February 13-14, 1968 Conference on Indirect Food Additives." My thinking is that we should not only emphasize the "first response" understanding, but should use the informal conferences to try to get some idea of what FDA may be considering in the way of further responses. As I see it, we should let it be known that we would not be very well pleased if the matter of further reform in the incidental additive regulatory sphere was left in abeyance, or conveniently ignored, for a long time after the instant proposal is formally considered, and perhaps adopted. Indeed, perhaps the previous insistence on a continuing Government-Industry Advisory Committee to work towards bringing about additional significant changes should be restated by all of us.

Aside from this basic comment and recommendation, I would like to use this opportunity to make a few personal observations about the FDA proposal per se, my hope being that this will help set the stage for some free-wheeling discussion after Dr. Frawley deals more fully with the scientific implications of what the Food and Drug Administration is proposing to do.

As my first observation, and without meaning to transgress into the scientific area, I would like to note here that I, for one, continue to wonder why the Food and Drug Administration cannot solve some of its problems, and many of ours, by moving back to what I will call the pre-Food Additives Amendment Lehman doctrine as regards what constitutes insignificant extraction from packaging materials. It seems to me that nothing has really happened since 1958 to warrant a change from the criteria used then to pass on the safety of food packaging materials components. The only thing that has changed is that analytical techniques have become more sophisticated so that extraction into food simulating solvents, admittedly designed to exaggerate grossly the potential migration of packaging materials components into foods, has become sophisticated to the point where clearly de minimis quantities of potential extractants now show up in the analytical process. While this increased sensitivity of analytical techniques can be important as regards regulation of direct additives and pesticides residues, and may be generally interesting from the viewpoint of the scientific aesthete vis a vis packaging materials, no practical experience indicates that the "approvals," now called "prior sanctions," issued freely before 1958 on the basis of data showing less than 1 ppm extraction have ever created any health hazard. As we attempted to put this point and the problem that has arisen in the comments filed

on behalf of The Society of the Plastics Industry in response to the Food and Drug Administration's August 8, 1967 Notice of Proposed Rule Making looking towards amendment of the Procedural Regulations:

"Extraction studies revealing no detectible extraction in accepted simulating solvents at a level higher than 1 ppm were deemed satisfactory in all but a few special cases to sustain non-additive status before 1960. Despite the fact that there is no known instance of any material 'cleared' under this criteria having given rise to any public health problem (or even a remote implication of one), in preparing to file a petition for a 'virtual' non-migrant at the current time, data must be supplied using extraction methods sensitive to a level of 0.01 ppm. Furthermore, toxicological information requiring at least ninety-day, two species studies are considered minimal and are demanded in many situations where extraction is detectible at any level above 0.01 ppm.

"Advances in analytical techniques need not and should not be unreasonably used as a basis for constantly changing regulatory criteria in an area where all available expertise, and all experience, indicates that it is simply wasteful of scarce scientific and administrative talent to insist on very costly, time consuming studies for no purpose rationally related to the public health."

With this background in mind, and despite the fact that we recognize FDA's problem in attempting to convert the National Academy of Sciences-National Research Council finding that .1 ppm of any substance (other than heavy metals, pesticides, and known carcinogens) in the diet is toxicologically insignificant to an amount which may be deemed toxicologically insignificant in a specific package or packaging material, we cannot understand why the old less-than-1-ppm rule of thumb employed by Dr. Lehman in rendering his opinions cannot be pressed back into service. In other words, it seems to this layman that successful experience should be relied upon by FDA to use 1 ppm as a dividing line between food additives and non-food additives since this was done without any adverse consequences up until

the adoption of the Food Additives Amendment, and even after the adoption, until FDA stopped issuing its "non-additive" status letters in 1960.

I simply cannot understand from the simplistic point of view of pure logic (as contrasted to scientific mysticism) why the "expert body" that is FDA now finds it impossible to make the same reasonable judgments previously made that 1 ppm is a safe level at which to draw the line when it has the benefit of the earlier wholly positive experience using this criterion, and now has the added scientific safety factor provided by the NAS-NRC report. I leave it to you to discuss the possibility of taking this position in your conferences with the Food and Drug Administration Staff in the meetings anticipated. It simply seems to me that this is not an unreasonable position to take provided FDA's thinking can be reoriented away from abusing the advances in analytical techniques which have come to bear.

Again, from the layman's point of view, it seems to me that while the new techniques may show potential extraction into solvents at extremely low levels which could not be detected prior to 1958, where packaging materials are concerned these techniques do not give practical cause for raising the threshold level as to what constitutes a reasonable expectation of a packaging materials component becoming a validly recognizable component of foods. My feeling is that FDA should agree that the simulated solvents approach is itself a sufficient exaggeration so that it may be concluded in all but the most unusual cases that anything which will not migrate into a solvent (at the high temperatures and other exaggerated conditions used in testing "to equilibrium") at a level higher than 1 ppm: may not reasonably be expected to become a component of food and, therefore, should not be considered a food additive. I admit that the point I am making perhaps has some loopholes from a scientific purist's point of view, but I think it is time that scientific purism was put in its proper place.

One other point seems to me to deserve mention and discussion in connection with the FDA proposal which, I suspect will be commanding most of your attention, i.e. the proposal to exclude the need for Food Additive Petitions where potential migration can be calculated or demonstrated to be less than 0.05 ppm. Assuming that this criterion cannot be changed to a truly useful level such as has been suggested in Dr. Frawley's writings, the FDA proposal will only be helpful in those

few cases where potential migration can be calculated to be lower than 0.05 ppm due to the amount used in the packaging material vis a vis the volume of substance to be packaged, or perhaps where the amount used in the package is so minute as to make one wonder whether there is any purpose in its use in any case.

At the very best, and even assuming that there might be test methods to detect 0.05 ppm equivalent levels as regards some substances, attempting to prove the absence of potential migration at levels of 0.05 ppm will be virtually impossible where extraction studies are to be relied upon to establish the hypothesis unless a standard surface-to-volume ratio for the testing can be agreed upon, and finitely expressed by FDA.

The ratios which have been used in the past have varied from 2-1 (volume to surface) up to 100-1 or more, depending on the intended use of the packaging material to be expressed in a regulation. It seems to us that a standard ratio of 10-1 (the ratio used in developing the so-called can enamels regulation, Section 121.2514) might be a good starting point for standardizing in this respect. In any case, it would appear that trying to settle definitely on some standard ratio would be a worthwhile effort. If this is done now, even if the 0.05 ppm regulatory criteria must be accepted for a time, perhaps the ratio will prove a valuable baseline for that day in the future when the 0.05 ppm level is raised on the basis of experience to something more realistic like 1 ppm.

Aside from these observations on the part of the FDA proposal that is apt to provoke the most comment, I would like to direct your attention to the necessity for impressing the Food and Drug Administration with the practical problems encountered because of the regulatory scheme employed. These are the day-to-day problems that really come to bear in the most frustrating and difficult ways because they relate to inhibitions on sales of products which should, in fact, present no problem.

The truth of the matter is that, because of the general, though very vague recognition of purchasing agents and others that FDA does somehow regulate packaging materials for foods and drugs, your company personnel must constantly be faced with the necessity for attempting to provide some tangible evidence that a given product is "FDA approved." Due to the fact that purchasing agents

and others not dealing with FDA on a day-to-day basis cannot know the intricacies of FDA's regulatory approaches and policies, it continues to be most difficult, and sometimes impossible, to sell a product unless an FDA letter, or very specific regulation can be cited and explained to be applicable. The problem is compounded by the fact that, as Bill Randolph of FDA has recently pointed out in a paper he gave in Nicaragua, "FDA has 'no authority' to give 'approval' of individual proprietary products." The difficulty here is that what Mr. Randolph said may be a fact, but it does not satisfy customers, nor does it leave salesmen with any way to give the kind of assurances of product safety that customers demand.

I believe that, as an absolute minimum, we must elicit from FDA some type of promise, preferably in the form of a written policy statement, regarding when it will confirm the satisfactory status of proprietary products under its regulations, including the revised Section 121.2500. What those of us who deal with day-to-day Food and Drug Administration regulatory problems, and, incidentally, inquiries from foreign customers, must have at some point is a well constructed procedural schematic whereby, in appropriate cases, and when absolutely essential, we can readily and expeditiously obtain from the Food and Drug Administration Staff a simple letter of concurrence in appropriate product status under the Food Additives Amendment of 1958. Thus, for example, we should be able to obtain unequivocal letters concurring in non-food additive status due to the absence of a reasonable expectation of a product's becoming a component of food where the specific facts set forth in a letter of inquiry call for such a conclusion. Letters of this type should no longer be withheld as they have been since the Food and Drug Administration's peculiar policy decision on so-called "no migration" situations in 1960 and 1961.

If I have any "message" worth conveying today at all, I think it is that we will have accomplished virtually nothing if we are unable to move the Food and Drug Administration in the direction of cooperating with industry to resolve questions as to whether something is or is not an uncleared food additive within the meaning of the law. There is no reason for the Food and Drug Administration to avoid this question by peculiar semantical exercises when the result of this avoidance is customer apprehension and unwillingness to use products which may be safely employed because they are not expected to become components of food, or for any other valid reason.

The same type of letters that are given in cases involving prior sanctioned or generally recognized as safe substances (also exempt from the Food Additives Amendment of 1958) should once again be given in the practical "no expectation of migration cases." In short, FDA must somehow be convinced to meet its obligations forthrightly so that it, like the Department of Agriculture's Consumer and Marketing Service (and like Dr. Lehman before 1960) will make practical judgments, and give accurate and direct, instead of artful, answers to industry's status inquiries.

I hope we can discuss all of these matters fully today, and that I may have contributed something in the way of starting the dialogue.

Thank you.