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August 29, 1969

Mr. Lessel L. Ramsey  
Deputy Director  
Bureau of Scientific Standards  
and Evaluation  
Food and Drug Administration  
Department of Health, Education,  
and Welfare  
Washington, D. C. 20201

Dear Mr. Ramsey:

As you are aware from our informal conversations since the sending of your letter of May 6, 1969 to the various trade associations which participated actively in the National Conference on Indirect Food Additives, an ad hoc Inter-Industry Committee has been considering the discussion draft you distributed with a view towards consolidating the positions of the major packaging industry interests for presentation. Our objective in this joint effort has been aimed at supplying the Food and Drug Administration with more concise and, thus, more helpful information on this most important subject.

We are now looking forward to the meeting with you and your associates scheduled for September 3, 1969 so that the considered thinking of the Inter-Industry Subcommittee appointed to deal with the subject can be carefully set forth and freely discussed. Preliminary to this session, however, we thought it might be in the best interests of all concerned if we supplied you with this memorandum and the accompanying report entitled "Scientific Basis for Inter-Industry Proposal." Supplying this information in advance may facilitate real progress at the meeting by eliminating the need for coverage of background information about the inter-industry group, as well as discussion of those areas on which a consensus of FDA and industry opinion appears quite apparent.

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Mr. Lessel L. Ramsey  
August 29, 1969  
Page Two

About the "Inter-Industry Committee"

To place matters in proper perspective, we should first point out that the associations which have met to discuss the FDA discussion draft, and, therefore, constitute what we have come to call the Inter-Industry Committee on Indirect Food Additives are as follows:

Can Manufacturers Institute  
American Paper Institute  
American Petroleum Institute  
Adhesives Manufacturers Association  
The Society of the Plastics Industry, Inc.  
National Flexible Packaging Association  
Soap and Detergents Association  
Aluminum Association

The listed associations constitute a good cross section of the packaging industries vitally interested in and affected by the Food Additives Amendment's coverage of incidental food additives. Indeed, representatives of these same groups were the major industry participants in the National Conference on Indirect Food Additives held in February of 1968.

Subsequent to receipt of your May 6 letter, a meeting of the ad hoc Inter-Industry Committee was held in Washington on June 3, 1969, at which time all aspects of the FDA proposal for amendment of Section 121.2500 of the Food Additive Regulations were discussed. At the close of this meeting, a resolution was adopted authorizing the Chairman of the Inter-Industry Committee to appoint a Subcommittee to meet with the officials of the Food and Drug Administration (1) to obtain clarification of parts of the May 6 proposal, and (2) to attempt to bring about certain changes in the proposal deemed desirable by all members of the Committee. It was understood that individual associations would be left free to deal with special limited interests of their members.

The Chairman of the Inter-Industry Group, Mr. Ross Wilcox (American Paper Institute), then appointed the undersigned to serve as chairman of the Subcommittee called for by the Resolution. The other members of the Subcommittee are John P. Frawley, Hercules, Inc.; Llewellyn Burnette, Soap and Detergent Association; Max Goldfrank, Adhesive Manufacturers Association; Oneil M. Banks, American Petroleum Institute; and Einar T. Wulfsberg, American Paper Institute.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Three

This special Subcommittee has now met on two occasions since its appointment. This letter and the attached scientific statement constitute its work product which we respectfully submit for your consideration.

#### Analysis of the Proposal and Its Impact

Firstly, the Inter-Industry Committee expresses its appreciation for the careful consideration which went into the preparation of the draft submitted to us under cover of your May 6 letter. We are equally grateful to FDA for inviting preliminary industry-government consultation on the proposal. One of the major recommendations made by almost all industry representatives at the National Conference on Indirect Food Additives was that an Industry-Government Advisory Committee be established (1) to bring about much needed reforms in the indirect additives regulatory process, and (2) to provide a vehicle for continuing surveillance of problems and possible new approaches to concerns in this area. The action you have taken to invite industry consultation on this FDA "first response to comments received in connection with the February 13-14, 1968 conference on indirect food additives" is a step in improving communications on matters of great mutual interest. We hope that your experience with this approach will lead to an expansion of government-industry cooperation.

In general, the May 6 proposal has met with favorable recognition by industry that the Food and Drug Administration is aware of some of the problems created by past administration of the Food Additives Amendment of 1958, as it relates to incidental food additives. Further, we do feel you have advanced proposals which evidence a willingness to make constructive changes. More specifically, we note that FDA realizes that, as an essential first step, some means must be found for delineating between areas where potential hazards to health may be involved--and therefore warrant the careful attention and the great expenditures of time and expertise required to clear products by the Food Additive Petition route--and those areas where no hazard warrants such expenditures. Actually, we are firmly of the belief that this type of delineation is precisely what the Congress had in mind when, among other limitations, it deliberately restricted coverage of the Food Additives Amendment to any substance "the intended use of which results or may reasonably be

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Four

expected to result, directly or indirectly, in its becoming a component . . . of any food . . ." Therefore, we commend FDA on this new attempt at complying with the implied statutory mandate to clearly distinguish between substances which should be within the purview of the Food Additives Amendment, and those so unlikely to become components of food, or otherwise so toxicologically insignificant, as to demand that they receive only such attention as is necessary to exclude them from unduly complicated regulatory coverage.

With these basic considerations in mind, we heartily endorse in principle those parts of the May 6 proposal which would hereafter make it unnecessary to file Food Additive Petitions concerning components of (1) articles intended for use in contact with Type VIII dry foods (as defined in Table 1 of Section 121.2526(c)), (2) articles intended for repeated use in contact with bulk quantities of food, (3) defoaming agents used in paper and paperboard, and (4) food packaging adhesives complying with the good manufacturing practices requirement of Section 121.2520.<sup>1/</sup> The elimination of the need for filing comprehensive Food Additive Petitions for components used in these applications should be helpful in somewhat reducing the number of petitions and regulations now overburdening the attention of all concerned.

We further endorse, with the important qualifications hereinafter stated in detail, the general

<sup>1/</sup> We are assuming that the FDA intention is to delete substantially all of the components listed in Section 121.2520, and simply permit the use of food packaging adhesives provided they comply with the "good manufacturing practices criterion" in the present regulation. If this is what is intended, we recommend that your proposed new Section 121.2500(d)(5)(vi) be revised to read "as components of food packaging adhesives complying with the good manufacturing practices requirement set forth in Section 121.2520." It should be noted that the industry Subcommittee takes no position on whether the present list of adhesives components should be deleted or not, this subject being left to comment by those in the adhesives industry most immediately interested in this question. Our only purpose is to suggest the possible need for a change in the language to clarify the true intent of the Section 121.2500 provision suggested by FDA.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Five

principle of attempting to establish a level that could be considered a practical "no-reasonable-expectation-of-migration" level as regards packaging materials components. In attempting to establish such a level, the Food and Drug Administration is complying with the Congressional mandate in the Food Additives Amendment which orders, in effect, that petitions not be required for substances unlikely to become components of food.

On the other hand, as regards the proposal to limit what we might characterize as the "no-anticipated-migration-to-food-therefore-no-need-for-a-petition" (the proposed new Section 121.2500 (d, (5) (1)) provision to those components (other than heavy metals, known carcinogens, and substances previously shown to be toxic at 40 ppm or less) to those demonstrated by calculation, extraction studies, or food analysis to result in a transfer to foods of less than 0.05 ppm raises serious questions as to whether this provision will accomplish anything of value.

Our Committee has come to the conclusion that virtually no known packaging materials component could be employed usefully that would meet the 0.05 ppm criterion on the basis of calculation alone. The following table will serve to demonstrate the extremely limited applicability of this provision where the calculation method (i.e. assuming 100% extraction of the input to the package) might be used to determine whether or not a component falls within the 0.05 ppm potential transfer to food criterion:

AMOUNT OF ADDITIVE TO GIVE 0.05 PPM ASSUMING 100% MIGRATION

<u>Food</u>	<u>Type Package</u>	<u>Amount of Additive to Give 0.05 ppm</u>
Bread	Polyethylene film 1 mil (cellophane or paper)	14 ppm
Butter or oleo	1/4 lb. stick wrapped in paper	7.2
Ice Cream	1 Gal. Paperboard carton	5.9
Bacon	1/2 lb. (plastic film and paperboard insert)	3.5 (1 side) 1.7 (2 sides)
Milk	1 Pint Paperboard carton	1.6
	1/2 Gal. Plastic bottle	1.5
	1 Gal. Plastic bottle	2.0

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Six

<u>Food</u>	<u>Type Package</u>	<u>Amount of Additive to Give 0.05 ppm</u>
Margarine	1/2 lb. polyethylene tub with lid	1.0
Salad oil	1 quart plastic bottle	0.9
Mayonnaise	12 oz. plastic bottle	0.5

Obviously, virtually nothing could be used as a packaging component under the provision as now written, if the calculation of extraction assuming 100% migration principle had to be employed, since one can hardly conceive of a component that might be used at a level of less than 14 ppm (0.0014%) of the packaging material.

Additionally, the 0.05 ppm criterion will prove virtually useless as a practical matter if one attempts to apply it through a demonstration that less than this amount will extract into the solvents normally employed in preparing data for Food Additive Petitions. It is assumed that this is the type of analytical data the Food and Drug Administration would require to concur in non-additive status under the proposed Section 121.2500(d)(5)(i) exemption clause. There are virtually no known analytical techniques which will give reliable or reproducible results depicting potential migration at levels below .2 ppm where the vast majority of organic chemicals are concerned. Since organic chemicals are the subject of almost all incidental additive questions, it is obvious that one who seeks to employ a given component in a package will seldom be able to demonstrate that less than .05 ppm may be expected to migrate to a food by suitable extraction work. [This assumes, of course, a continuation of the present FDA policy which requires that an assumption of migration be made to the limit of the sensitivity of any analytical method employed, i.e. if the best method available will only demonstrate no extraction to the level of .2 ppm, FDA will insist that this level be assumed to be the extraction of the component in question to foods, and will base its decision on whether or not toxicological data is required for a petition on this assumption.]

Finally, test methods to determine directly the presence of organic compounds in foods are virtually non-existent, and cannot be easily developed or conducted. There may be some special exceptions to this conclusion but they would cover only rare situations.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Seven

In summary then, because of the lack of any practical use for the amounts of a substance one might employ on the calculation theory, and the lack of availability of test methods to demonstrate successfully no extraction below 0.05 ppm in almost all other cases, the present FDA proposal in Section 121.2500(d)(5)(i) would constitute only a fictional exclusion.

It is in light of this analysis, and the implications thereof, that most of the remainder of this memorandum will be directed to the proposed new Section 121.2500(d)(5)(i). In addition, we shall discuss one other point relating to the basics of the proposal that we believe requires some clarification.

Suggested Revision of Proposed Section 121.2500 to Replace the Proposed Paragraph (i) with Two New Paragraphs

When the FDA proposal of May 6 was released for trade association comment, it was recognized immediately that the 0.05 ppm calculation or extraction level used in paragraph (i) of that proposal would prove of no practical disjunctive value as regards a regulatory distinction between "additives" and "non-additives." Furthermore, it was and is the consensus of industry that (1) the level proposed is unnecessarily and unduly restrictive, (2) the report of the National Academy of Sciences categorizing 0.1 ppm of a substance in the total diet (other than a heavy metal, pesticide, or known carcinogen) as toxicologically insignificant supports a higher, more practical base level, and (3) that the adoption of the 0.05 ppm level by FDA will lead other countries in the world, now considering packaging regulation, to use this inordinately severe baseline.

So as to provide additional data to support a recommendation for a change in the said paragraph (i), our Subcommittee has conducted a pilot "market-basket" type study, the results of which are included in the attached report entitled "Scientific Basis for Inter-Industry Proposal." This report also sets forth in detail our reasoning for advocating a change in the proposed Section 121.2500 so that it will include, as paragraphs (i) and (ii), the following replacement sections for the present paragraph (i):

"(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.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Eight

"(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."

If these provisions are substituted for those proposed in the May 6 document sent to us by FDA, two very important objectives--of great practical importance to the FDA Staff, as well as industry--will have been advanced. Firstly, the use of the 0.2% input level limitation suggested will provide a truly workable criterion which can be employed by companies that convert components into final packaging materials. If these companies can deal with a clear-cut input limitation such as that envisaged by the new paragraph (i) suggested by our Subcommittee, their problems will be importantly minimized, and regulation will be much closer to the desirable status of being self-enforcing.

Secondly, if our recommendation for an increase in the permitted level of extraction from 0.05 ppm to .5 ppm is accepted--and we respectfully submit that the attached scientific statement fully justifies the conclusion that this change will not in any way prejudice public health or safety--another workable level of real meaning will have been established. At the 0.5 ppm level recommended, it will be possible for industry to determine potential migration to foods, sometimes by calculation, but more often by existing analytical methods, which will clearly delineate whether a component is or is not a food additive.

It should be understood by the Food and Drug Administration that what it does here will have far reaching impact on exports, as well as domestic trade. It is no secret that most European and many other foreign countries have already, or are planning to follow this country's lead in establishing regulations for food packaging materials. Proposals of great significance are now being considered in the United Kingdom and the Netherlands, as well as elsewhere. The proposed Dutch regulations may well form the basis for new packaging materials restrictions throughout the European Economic Community.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Nine

Indications of the great weight given U. S. policies by foreign regulatory agencies and experts now working towards revised regulatory plans for packaging materials have been received with increasing intensity in recent months. Our Subcommittee has been in contact with influential European leaders recently and we have been informed, almost without exception, by correspondents in London, The Hague, Brussels, Frankfurt, and elsewhere that those in Europe interested in these problems are aware of the new FDA proposal, and are anxiously awaiting indications of what action will be taken. It is quite clear that they view our Food and Drug Administration as the best equipped in the world to make decisions which can be followed, or at least referenced, with considerable confidence.

In light of these additional facts, we respectfully urge you to give careful consideration to the adoption of our Subcommittee's counter-proposal regarding Section 121.2500 (d) (5) (i) because of the tremendous impact your decision in this area will have on international trade, and also because we believe that the proposal recommended to you here is a practical one which can be adopted with assurance that the public health will be fully protected.

Additional Question for Discussion and Resolution

In addition to the points raised above, our Subcommittee's consideration of the May 6 proposal has led us to set forth the following question for consideration at our September 3 meeting:

Are we correct in assuming that, if the instant proposal is adopted, any component used in making repeated use articles, defoaming agents, packages for Type VIII dry foods, or adhesives, and meeting the qualifying criteria set forth in proposed Section 121.2500 (d) (5) (ii) through (v), may be so used so long as it is not a heavy metal, a known carcinogen, and has not previously been shown to be toxic to man or animals at levels of less than 40 ppm? There is some confusion on this point because of the language in the proposal which could be read to require advance toxicological work to show a substance is non-toxic at the 40 ppm level.

Mr. Lessel L. Ramsey  
August 29, 1969  
Page Ten

Our belief is that the entire thrust of the proposal is aimed at eliminating the need for such studies for minor packaging materials components. Thus, we would appreciate clarification of this point and would suggest that this be provided by an explanatory statement when the proposal is issued as a Notice of Proposed Rule Making, or by a letter advising us concerning the proper interpretation.

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We hope that this letter will serve to provide you with information that will aid in making our conference on September 3 as productive as possible. By way of summary, and also perhaps to provide something in the nature of an informal agenda for the meeting, we would recommend that the following topics alluded to in this letter be discussed at our session:

1. Our Subcommittee's recommended paragraphs (i) and (ii) vis a vis paragraph (i) in the present proposal.
2. The need for clarification of the intent of the 40 ppm toxicological level phrase in the present proposal.

Our Subcommittee again thanks you for this opportunity to work with the Food and Drug Administration in attempting to bring about sound improvements in the regulation of incidental food additives.

Cordially yours,

*Norman W. Heckman*