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June 16, 1969

Mr. Robert M. Miller
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Dear Bob:

Following up on our recent letter concerning the meeting of the inter-industry group to deal with the Food and Drug Administration on its new Section 121.2500 proposal, I am herewith enclosing reproductions of the Minutes of the meeting, as promised. The Minutes were prepared by Einar Wulfsberg and I believe you and the other members of our Committee will find them fully self-explanatory.

As you are aware, the Committee appointed by the inter-industry group to conduct the actual negotiations with Food and Drug met in my office on Friday. I am planning to report on its deliberations and all other phases of this interesting matter during our full Food, Drug and Cosmetic Packaging Material Committee sessions this week.

Cordially yours,

Jerome H. Heckman

encl

cc SPI Food, Drug and Cosmetic Packaging
Materials Committee

MINUTES OF THE MEETING OF THE INTER-INDUSTRY COMMITTEE ON INDIRECT ADDITIVES

JUNE 3, 1969

THE MAYFLOWER HOTEL, WASHINGTON, D. C.

The meeting was called at the invitation of the American Paper Institute as the principal for the several trade associations joining in the letter of February 9, 1968 to the Commissioner of Food and Drugs proposing an Industry Government Advisory Committee on Indirect Additives. The need for a meeting was prompted by the receipt by each of the organizations of an FDA letter of May 6, 196 (L. L. Ramsey, Assistant Director of Regulatory Programs, Bureau of Science) with a proposal for certain simplifications of the food additive regulations. Mr. Ramsey requested a discussion of the proposal with FDA on an industry-by-industry basis. The objectives of this meeting were to insure a common understanding of the proposal and determine the degree of consensus as to response which could be made to FDA. A roster of participants is attached.

1. Mr. Ross Wilcox, Chairman, reviewed the history of the efforts to achieve some simplification of the regulations on indirect food additives, beginning with the national conference in February 1968. He welcomed the participation of representatives from associations joining the original group for this meeting.

2. Mr. J. Heckman presented a counsel's view of the FDA proposal. He agreed with the use of Sec. 121.2500 as a vehicle for the proposed changes. He expressed the view that the FDA proposal had merit as a first reponse. He urged emphasis by all that the proposal be so regarded in discussions with FDA. The current dilema requiring costly and time consuming studies is the product of increased sensitivity of analytical methods and the use of exaggerated solvents which combine to reveal minute amounts of substances which under real conditions have no relevance nor toxicological significance. Very desirable would be a return by FDA to the former practice of regarding extractived from packaging at 1 pmm level as insignificant as was done prior to the Food Additives Amendment. At no time then or since, has there been any untoward experience in packaged food.

As to the FDA proposal to exclude from the need for petition, substances calculated or demonstrated to migrate at less than than 0.05 ppm there is the problem that this figure does not correlate with extraction studies without relating to an expressed surface-volume ratio. With some standard ration it would appear that the 0.05 ppm level could serve an interim purpose as a baseline pending a more realistic critieron.

Mr. Heckman urged that FDA be persuaded to return to the practice of providing letters of concurrence as to "not food additive" status of products where it is clearly demonstrated that there is no reasonable expectation of its becoming a component of food. Refusal of FDA to so recognize proprietary products since the era,,1960-61 has greatly inconvenienced sales to parties unfamiliar with FDA's regulatory approach.

3. Dr. Jack Frawley discussed the FDA proposal with reference to its technical aspects. He remarked that he is not in complete agreement with Mr. Heckman on the need for FDA letters relating to company products citing the fact that the number of affected items sold by his firm made such approach impractical.

In attempting to exclude substances from the need for petition action, FDA has certain options: (1) by level of use such as 0.2% in the package per Frawley proposal, (2) by excluding specific uses such as in adhesives, dry food containers, etc.

To exempt on the basis of amount of use the options further include: (a) in the package as above, (b) in the food packaged, cf. the 0.05 ppm limit proposed by FDA and (3) in the total diet cf. the 0.1 ppm level of toxicological insignificance of the National Research Council. Despite the lack of any scientific correlation between actual food or the diet and packaging constituents, FDA clings to criteria relating to packaging materials.

Any attempt to compare the current FDA proposal with the Frawley proposal to the Hearing Clerk, October 23, 1967, leads to problems of interpretation of the language in subparagraph (5i) of the text. As a counter proposal Dr. Frawley suggested including the limit of 0.2% for components of food contact articles and a maximum of 0.5 parts per million extraction to food as demonstrated by appropriate tests or as calculated assuming 100% migration.

Of particular significance in the FDA proposal is the fact that a level of toxicological insignificance is recognized.

General Discussion

4. The question was raised whether FDA could go direct from the current proposal to a final order. The opinion was negative.

5. The belief was expressed that FDA could be persuaded to meet the interested industries in a joint conference if deemed desirable. The difficulty recognized was the size of such a group.

6. On an industry by industry basis there is a need for some coordination of response.

7. The matter of continuing the request for an Industry-Government Advisory Committee for further dialogue on indirect additives was supported without dissent.

8. As attorneys, Higgs, Hanavan and Heckman questioned the clarity of the FDA proposal, for example, no basis is given for the studies needed to demonstrate toxicity at 40 ppm.

9. The urgency of effective simplification of U. S. Food Additive Regulations was urged by Mr. Heckman in view of the trend amoung foreign nations and the international groups to follow U. S. patterns.

Upon further discussion it appeared that the FDA proposa should be subjected to the study of a small group with a commission for further discussion with FDA. Sveral suggestions were so oriented. 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 (i) and (ii) 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 the 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 (i) and (ii) 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."

Note: A copy of the text proposed by Dr. Frawley is attached.

A committee consisting of the following was appointed by Chairman Ross C. Wilcox to implement the motion.

Jerome H. Heckman	Society of the Plastics Industry
John P. Frawley	Society of the Plastics Industry
Lewellan Burnette	Soap and Detergent Association
Max Goldfrank	Adhesive Manufacturers Association
O'Neil M. Banks	American Petroleum Institute
Einar T. Wulfsberg	American Paper Institute

In caucus, upon adjourment of the general meeting, the Committee agreed to meet on June 13, next in the office of Mr. J. Heckman.

Minutes prepared by:

Einar T. Wulfsberg

Einar T. Wulfsberg

ETW/sw

§ 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 produ 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.

ATTENDANCE SHEET

INTER-INDUSTRY COMMITTEE ON INDIRECT ADDITIVES

JUNE 3, 1969

MAYFLOWER HOTEL

PLEASE PRINT

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endance Sheet, cont...

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