APPENDIX B

THE FOOD ADDITIVE PROBLEM OF PLASTICS USED IN FOOD PACKAGING*

by

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I welcome the opportunity here this afternoon to review with you some of the regulatory developments in the area of indirect food additives, which, of course, include the migratory substances from plastics used in food packaging.

In response to industry's need we developed and issued a document in August 1966 entitled "FDA Guidelines for Chemistry and Technology Requirements of Food Additive Petitions." You are undoubtedly familiar with it. The purpose of this document was to elaborate and clarify the regulations with respect to the chemistry and technology data required for the clearance of not only direct food additives but also indirect food additives. The document, itself, made it clear that it was not to be construed as a regulation, that it set forth guidelines, not inflexible requirements.

In the Federal Register of August 8, 1967, FDA published a proposal to revise its procedural regulations for food additive petitions. Quoting from this publication:

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"The Commissioner of Food and Drugs proposes that the procedural food additive regulations be revised as set forth below to obtain improvement in the quality and organization of food additive petitions submitted and to expedite their scientific review by the Food and Drug Administration. The need for such revision is based on the following:

A. Almost half of the food additive petitions as originally submitted to the Food and Drug Administration have been incomplete or have not adequately supported the regulation requested and, therefore, have required subsequent supplementation, amendment, withdrawal, or denial.

B. Scientific review of deficient and poorly organized petitions is an unnecessary burden that wastes the time and efforts of both Administration and industry scientists."

This proposal prescribes the format and content of the petition and its organization in greater detail than previously, requires adequate indexing, and requires a summary of the petition. We received 53 communications, including one from the Society of Plastics Industry, commenting upon this proposal. Some of these communications were rather voluminous, the opposing point of view being argued in detail and at some length. Three major issues were evident from these comments:

1. Whether the analytical method and a summary of the toxicological information upon which a regulation has issued can properly be considered public information.

2. Whether it is proper to require that 10 year old data or older must be resubmitted.

to listen, to obtain your views and recommendations (1) with regard to possible changes that can be made in FDA petition requirements and the criteria for evaluating the safety of the indirect additives from food packaging materials and food processing equipment, and (2) with regard to any possible changes in the scientific or administrative handling of this whole area of indirect food additives. We cannot, of course, accept any recommendations which sacrifice the consumer protection afforded by the Food Additives Amendment against unsafe amounts of foreign substances in the country's food supply. And perhaps this is the crux of the whole problem, how much of a health risk should the consumer be subjected to, for the risk from indirect food additives, however slight, cannot be summarily dismissed; it is merely a matter of degree. Absolute safety, like the absolute zero, can never be unequivocally demonstrated although in many instances it can be approached ever so closely. We are indeed hopeful that we shall receive some practical and specific suggestions during this conference, suggestions that are both scientifically and administratively sound."

At this conference, Dr. Frawley reiterated his proposal as follows:

"Thus, we propose three categories of food packaging components: 1) those used at 0.2% or less which cannot 'reasonably be expected' to become components of food, and these should be exempt, 2) those used above 0.2% which may 'reasonably be expected' to become a component of food, 'but in fact do not,' and these should be considered nonmigratory, and 3) those used above 0.2% which are indeed food additives and should be subject to appropriate examination for safety and regulation under the law."

3. Whether it is proper to require details of the manufacturing process for every additive.

In addition and aside from the procedural regulations the Society of Plastics Industry seized upon this opportunity to recommend a major change in the handling of indirect food additive petitions involving trace amounts of food additives. Pointing to a paper presented by Dr. John P. Frawley at the national meeting of the American Chemical Society in New York, September 1966, the SPI objected strongly to the need for migration and toxicology studies where the usage level of a substance in the packaging material was less than 0.2%, with certain exceptions. About this time, the dissatisfaction of a part of the food packaging industry with FDA's requirements for clearance of indirect food additives also came to the attention of a congressional committee.

In order to provide an opportunity for the industry and other interested groups to review and discuss with FDA the scientific basis for its policy with respect to indirect food additives, the FDA scheduled a National Conference on Indirect Food Additives. This conference was held in Washington, D. C., on February 13-14, 1968. It was well attended and while representatives of your organization did not appear on the program, I believe your industry was well represented by speakers for The Society of the Plastics Industry, Inc. The representatives from FDA explained our present policy and reviewed the scientific basis for it. They made it clear, however, that FDA came primarily seeking information and advice. Quoting from the paper I presented: "In conclusion I would only remind you that we in the FDA are here primarily

He explained further that a level of 0.2% or less of a component in the packaging material or in the food contact surface would not be expected to contribute more than 0.1 ppm of an individual substance to the total diet of man and he regarded this as insignificant toxicologically. He would exclude heavy metals and pesticides, however, from this concept of safety at 0.1 ppm.

The industry speakers at the conference generally endorsed the essence of Dr. Frawley's proposal.

Following this national conference we in FDA undertook a reappraisal of our requirements and procedures for the indirect food additives in light of the recommendations and suggestions of industry and in light of our own experience during a decade of administration of the Food Additives Amendment. This reappraisal was initiated to determine whether any changes should be made.

While our own study was underway we were informed that a task force on Toxicologic Insignificance had been established by the Food Protection Committee of the Food and Nutrition Board, NAS-NRC, to study the broad problem of the safety of minute amounts of substances in man's diet. The NAS-NRC report entitled "Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Food" is the result of this study and has just been published. We delayed the development of any proposal until we could have the benefit of this report. However, we were furnished a pre-publication copy by the Academy on a confidential basis several months ago and used it in the development of an in-house (Bureau of Science) proposal. A draft of this proposal was sent to the industries

represented at the National Conference for comment and for discussion with us. We concluded those discussions on the proposal with the industry this past September.

This in-house proposal would amend the regulations to permit the use of substances (except heavy metals, carcinogens, and other substances that have been demonstrated to produce toxic reactions when present at levels of 40 ppm or less in the diet of man or animals) in food packaging materials and other food contact surfaces as follows:

(1) As components of food-contact articles provided any substance so used contributes no more than 0.05 ppm to the contacted food;

(2) As components of articles for use in contact with dry, non-fatty food;

(3) As components of articles intended for repeated use in contact with bulk quantities of food.

(4) As components of defoaming agents employed in the manufacture of paper and paperboard intended for use in contact with food.

(5) As components of food-packaging adhesives.

We have not yet reached a decision on whether or not to publish the proposal formally in the Federal Register; and, of course, I am unable to make any reliable prediction in this regard.

We do intend to finalize a revision of the food additive procedural regulations mentioned earlier, and we expect to adopt some of the suggestions received which we have evaluated and found to be sound.

Let's turn our attention now to the processing of food additive petitions. In spite of the Guidelines and the proposed revision of the procedural regulations, we continue to receive a high percentage of deficient petitions. The most common deficiency is a lack of adequate extraction data from which to estimate the likely migration of packaging components to food. Another common deficiency is a failure to identify fully the proposed packaging component by its Chemical Abstracts name and by physical and chemical specifications. Identity is, as you undoubtedly appreciate, basic to our consideration. We also urge you to provide a general summary of any petition you submit which will include among other things the following: the expected quantity of the food additive in individual foods or classes of foods under the proposed conditions of use, the maximum as well as the average quantity to be expected in the total daily diet of the consumer, and the margin of safety provided by the animal feeding studies.

The submission of an inadequate petition imposes an unnecessary burden upon our scientific staff and more importantly from your viewpoint results in costly delays in time for you. I would urge you to make every effort to assure yourself that the petition you submit is indeed fully supported by the necessary data and information when it is submitted.

About one half of all food additive petitions received are in the indirect area. During the period July 1, 1968, to June 30, 1969, we received a total of 121 food additive petitions; 61 of these were for indirect additives. The receipts of petitions since last June are continuing at about the same rate.

Currently, with only an occasional exception, food additive petitions are being handled within the statutory time limits. This work is accorded high priority and we expect to maintain this level of performance in the future. Your cooperation in observing the Guidelines and the regulations in preparing sound, well organized food additive petitions will help assure the realization of an important mutual goal of industry and FDA, the prompt processing of the petitions.

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