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September 14, 1971

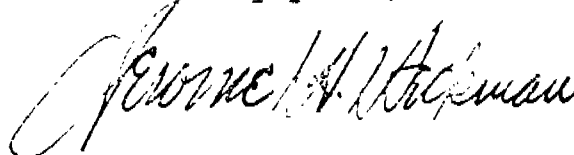
TO: All Members of the SPI Food, Drug and
Cosmetic Packaging Materials Committee

Gentlemen:

The purpose of this letter is simply to call your attention to the fact that we have now completed a long-planned move into quarters in Suite 1000 of a new office building at 1150 Seventeenth Street, N. W. Actually, we have only moved two blocks from our previous location. Our telephone number will remain the same.

We would appreciate it if you would correct your records to reflect the new address and hope that perhaps you will have an opportunity to visit us sometime soon so that we can host you on a tour of what we consider to be a very much improved facility.

Cordially yours,



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September 14, 1971

TO: SPI Food, Drug, and Cosmetics
Packaging Materials Committee

Gentlemen:

For the benefit of those of you who may not receive Food Chemical News on a regular basis, we have obtained permission from our good friend, Lou Rothschild, the publisher of the publication, to duplicate and send to you pages 6 through 13 and 26 and 27 of the current issue. I am sure you will have no difficulty whatsoever in realizing why we thought you would be interested in seeing the Food Chemical News coverage of our FDA-SPI Seminar, and also the coverage given a paper I presented at a Federal Bar Association meeting last week.

As indicated in the FCN write-up, transcripts of the Seminar will very soon be available from Joe McDermott of SPI. For those of you who attended the session on June 18, copies will be sent automatically since your registration fee covered the cost of the transcript. Those who were not present should write to Joe for their copies. Incidentally, I believe he has decided to have the document offset printed so it may yet be a few days before it is actually in the mails or available.

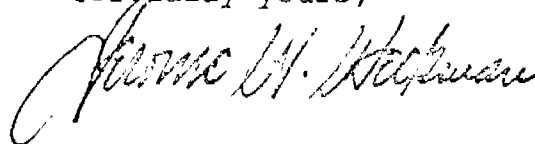
As far as my paper at the Federal Bar Association meeting is concerned, I am taking the liberty of sending each of you a copy herewith on the theory that you might find it of interest. Your comments after you have

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a chance to look the paper over would be most welcomed even if they are quite adverse. Do remember that, in this presentation, I was speaking as a lawyer and not for the Society.

Cordially yours,

A handwritten signature in cursive script, appearing to read "Jerome H. Hefner". The signature is written in dark ink and is positioned below the typed name.

STANFORD RESEARCH LINING UP 35 COMPANIES FOR PROTEIN STUDY

A half million dollar 35-company research project proposed by Stanford Research Institute is designed to foretell the market for protein enriched foods in the U.S. and a dozen other countries.

Stanford's research protocol for the study said, "The use of protein isolates (derived from natural food materials) and of synthetic protein materials in processed foods will be a key element in the future of many food related industries."

The study, which is to assess the difference between protein supply and demand through 1985, among other objectives, will concentrate on "developed" countries in addition to the United States: Japan, United Kingdom, West Germany, France, Italy, the Netherlands, Belgium, Luxemburg, Sweden, Norway, Denmark and Switzerland.

Stanford said that while the production of high quality protein has been generally sufficient for human needs in most of the advanced countries, these nations continue to be net importers of protein. The study protocol continued, "However, recent indications are that some new protein-based fabricated foods may be expected to gain in sales and be considerably more profitable."

Food and Drug Administration policies would be among the elements of the study. Others include:

- - Analysis and projection of major advancements in food-grade protein processing technology and protein production costs.
- - Identification of indigenous and imported protein materials and other ingredients required to produce protein-based food products.
- - Estimated profitability of new processing plants.
- - Summary of estimates of potential markets for each protein-based food product by country and in total.

FDA CONSULTING WITH INDUSTRY ON PACKAGING PETITION GUIDELINES

Food and Drug Administration staffers have been consulting with industry representatives in developing a revision of the Guidelines for Chemistry and Technology which spell out data required by the agency in Food Additive Petitions for packaging materials.

The revision of the Guidelines was previewed at a seminar co-sponsored by the Society of the Plastics Industry and FDA in June (See FOOD CHEMICAL NEWS, June 28, Page 10). Actually, the draft previewed at the meeting is believed to have undergone considerable re-drafting by this time.

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Transcripts of the all-day meeting, which was vitally important for the indirect additives industry, have now been made available from SPI at \$15 per copy. They are available from Joseph S. McDermott, The Society of the Plastics Industry, Inc., 250 Park Avenue, New York, New York 10017.

Inviting comments from SPI and its members, Albert Holtz, of FDA's Division of Chemistry and Physics, said at the seminar, "If any of the data we said should be submitted for the various categories is excessive, superfluous, we would like to hear from you and know why you think so."

Nathaniel L. Geary, director of FDA's Division of Petition Processing, said:

" . . . We would like . . . to invite SPI to sit down and . . . roll up your sleeves with us, and let's hash over them (the Guidelines), because what we want is something that is practical, something that is useable and something that industry can live with.

"At the same time we have to recognize that FDA will not sacrifice anything with respect to safety and I am sure the industry feels the same way that FDA should not. . . But I agree with you that the information that we request should be the information that we need, not information that would just be nice to have. . . . We set a target date to get procedural guidelines in this particular area, chemistry and technology, out by the first of October."

In an exchange with SPI Attorney Jerome H. Heckman, of Keller and Heckman, Geary indicated that the theory of "toxicological insignificance" may not be dead, but may be negotiated after the FDA issues its toxicological criteria for food additives. This is to be a more formal document than the informal Guidelines for Chemistry and Technology, which are simply to be "how to" documents on how to prepare Petitions.

Heckman postulated that for a specific indirect additive migration is no more than 0.05 p.p.m., and that "toxicology is sufficiently familiar . . . so that it would have no problem if 0.05 p.p.m. were extracted . . ." The lawyer asked if "under these circumstances would you be prone to issue a letter agreeing that that was a non-food additive?"

Dr. Joseph McLaughlin, Jr., of FDA's Reproductive Physiology Branch in the Division of Toxicology replied: "The answer would probably be at this time you would not get a letter." Asked why, the FDA-er added:

"Because we still would consider that there is possible migration up to 0.05 p.p.m. Now, if we took the other approach, and with a sensitivity, say, down to somewhat lower, then you might get such a letter. You see, this is the crux right now as we read the law. In any

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"For that reason, I think we should be able to establish some Guidelines in Chemistry and Technology as well as in toxicology that can permit us to conclude the degree of migration is . . . insignificant in some areas, and . . . very low order of magnitude in others without going back and repeating on every food packaging component the same sort of thing, and going through the detail, the chemical documentation for this low level of migration.

"With 12 years of experience, I would think that the FDA could come up with some guidelines. That a certain product isn't going to contribute any more than 2 p.p.m. to the food without going over again what has been done on a half a dozen antioxidants or similar physical products. It seems we are perpetuating this overkill and I was hoping these Guidelines would give us simplified procedures . . ."

Heckman urged that the "Guidelines should not only say what data should be required, but to some degree should state narratively what the objective is and why you are doing these things." He suggested that the Guidelines explain "the difference between the kind of testing you need to do to satisfy Petition requirements and point out how sometimes that testing is much more extensive than what is in an end-test regulation, because the end-test regulation is really something you come up with as a quick and dirty way only after you are satisfied that it will correlate with the basic work."

Discussing the possibility of FDA issuing letters regarding the status of specific indirect additives, McLaughlin said, "If your product complies with the regulation as spelled out, you are entitled to write and advise your customer you are covered according to the regulations." He added, "If you . . . wish to come in with a product and ask if we will put in writing that your product definitely is covered by the regulation" data must be provided "to back it up."

Heckman responded that in the light of these comments, "my own personal recommendation would be that if you determine that your product complies with the regulation, you so advise your customer - - and not go near the FDA to ask any of these silly questions." The attorney explained that "it is obvious that if you do ask those questions, you are going to be asked some questions in return." Heckman said that "the answer-a-question-with-a-question bit . . . can go on forever and often does at FDA."

Holtz said that a major change in the revised Guidelines, as they were drafted at the time of the seminar, is that "we will request detailed information only for the petitioned additive." He explained, "We would, therefore, suggest that petitioners formulate food contact surfaces for extractions only from regulated pertinent materials where extractants would interfere as little as possible with analysis for the petitioned additive."

The current Guidelines, Holtz explained, "had questions on everything that was used in the food contacting surface," whereas the revision will ask only "for the necessary information for the petitioned additive."

Holtz made it clear that there will be separate Guidelines for paper and paperboard components, saying that a separate seminar on paper extractives will be held in cooperation with the American Paper Institute and/or TAPPI.

The FDA-er said that paper applications "do not generally lend themselves to equilibrium extraction requirements," so that "we are faced with a great variety of interpretation of migration conditions which have in the past not been readily fitted with uniform extraction guideline programs."

Geary said that, "What we want to do is, rather than confuse the Guidelines for paper or plastics in the same sets, put one out for the plastics industry in particular."

Most of the changes in the proposed revision of the Guidelines would concern extraction testing. Holtz outlined the major changes, as follows:

" . . . Our Guideline comments will be mainly directed toward practical packaging applications which permit sufficient storage time to result in equilibrium extractions as exemplified by single use containers.

" . . . A second type of equilibrium extractions which we will discuss are those represented by repeated uses resulting from food contact surfaces used in food handling and processing operations."

Discussing deficiencies frequently encountered in Petitions, Holtz said the Petition often "proposes a broad regulation without any limits and then proceeds to perform extractions which seem to cover the most likely uses but these fall short of the unlimited coverage requested by the regulation." He suggested that if a Petitioner "is uncertain concerning the extraction data which he will need to obtain the coverage he desires, it would be best that he contact the proper FDA sources to assure himself that complete details and a full understanding of the Petition requirements have been reached."

Another deficiency, Holtz said, results from Petitioners being "unaware of" or misinterpreting the current Guidelines, particularly as regards extraction testing requirements.

Misunderstanding of extraction requirements, Holtz said, "frequently results in extractions being run as listed under the particular regulation end-test which the Petitioner is seeking." These end-test extractions are included in §121.2514 for resinous and polymeric coatings and §121.2526 for components of paper and paperboard in contact with aqueous and fatty foods. The FDA-er said "these ASI-PR 0001070 conditions and all end-tests apply only to already regulated materials and not

to newly Petitioned additives." He said the end-tests "are generally rapid tests which are intended to show that formulations of regulated materials or compositions comply with the intended conditions of use."

Petitions often are delayed because of questions concerning the food contact surfaces, Holtz said, explaining: "These formulations are often submitted with trade names of components, instead of the chemical identification used in our regulations. These result in excessive time and correspondence before the compositions are properly presented for detailed evaluation."

Dr. Edward O. Haenni, Director of the Division of Chemistry and Physics discussed methodology, as follows:

" . . . From the standpoint of regulatory practicability I think it is obvious that a method is normally needed that can be used in most laboratories involved in this problem. In the particular phase concerned with establishing basic data for us, this is not quite so important. It may be an entirely in-house operation for the purpose of generating such basic data. We have no quarrel with that. If the method in fact, however, is intended as a control method it is practicable in that it uses equipment commercially available and not too highly specialized."

Holtz said the Guidelines are being simplified in that "we are telling you exactly what we want." He added: "You think that this is excessive. If you can show us in any simpler way that nothing is coming out, we will be glad to accept that presentation."

Previewing the Guidelines, Holtz said that extraction tests should be run "(1) under the most severe anticipated temperature conditions; (2) using the highest concentration of the petitioned additive; (3) in the maximum contemplated thickness of food contact surface; (4) with the foods (or simulants) requested in the Petition coverage. For complete food coverage the simulants are water, 3% acetic acid, 50% ethanol and heptane."

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"Although in some cases limited solvent extraction may seem desirable," Holtz said, "we recommend that extractions be run with all . . ." He explained that: "(a) the availability of extraction and analytical material and equipment at the time of Petition avoids a later reassembly; (b) very few foods are represented by single solvents; (c) . . . we have attempted to reduce the necessary testing by limiting the acetic and alcoholic testing to the single sample and time period of water equilibrium; (d) in most previous limited extraction regulations, Petitioners soon apply for broader coverage."

Noting that "test samples should not be discarded until there is no further question of their need," Holtz said the tests "should be run over a time period to reach equilibrium, or maximum extractability, as gauged by at least three equivalent determinations." He said polymer samples having the lowest molecular weight anticipated in production should be used, and that identification of pertinent

The extraction data, the FDA-er said, should be collected in a table which should list: "(1) the time-temperature cycles used for extraction to reach equilibrium; (2) the type of sample, area size, thickness, film coating, container. This table should list a detailed composition of the substrate showing level of petitioned additive in the tested substrate; (3) state method of extraction and ratio of simulated solvent to extractive area and material, if the area used in migration calculations is that of one side or both sides of the extracted sample."

Noting that use of the ASIM cell is satisfactory for extractions, Holtz said "it may be desirable to resort to an immersion extraction" using larger areas. He said that, "These larger samples provide more material for testing and can help to increase the sensitivity of analysis." For aqueous solvents, Holtz said, the exposure time "must total at least 72 hours, and for heptane at least 6 hours."

All extracts using food simulants should be characterized by determining the total nonvolatile extractives, Holtz said, and "it may be necessary to show the distribution between organic and inorganic fractions by solvent fractionation . . ." Test results should also identify the nature of extractables, he added, for example, monomers or low molecular weight fractions.

Where regulations already have existing end tests, Holtz said, the Petition extraction tests should show "whether these practicable tests are adequate for the new substance or whether other end tests are needed to limit to safe amounts the migration to the food of the additive from practical packaging materials."

Holtz said that "all families of polymers that are to be used with a new adjuvant should be tested," and that if the adjuvant is a catalyst, the Petitioner should furnish "complete details covering the chemical nature, heavy metal composition, if any, function (and composition), intended uses and desired level, decomposition products, catalyst rate and other pertinent data relative to potential migration."

The FDA-er said that room temperature extractions are to be run at 120° F. "to evaluate high temperature storage conditions encountered in warehouse and shipping."

For repeated use articles, Holtz said, "the data must show the likely level of migratory additives contributed to the food during the first use of the articles and the level likely to be added during subsequent use." He added:

"Such details may be obtained from a continuous extraction setup . . . under the most severe conditions of the product and with the proper simulated solvents. Periodically samples would be removed for identity and quantitative analyses covering first uses or batches and other significant periods until equilibria are obtained. The . . . testing area should be related to the exposed area during actual use. The weight or volume ratio of food handled over the useful life of the food contact surface should be submitted or estimated. Calculation based on the above data will consider the

equilibria migration levels as distributed over the entire quantity of food processed unless certain data dictate otherwise."

The Guidelines requirements for identifying an additive, Holtz said, would include: (1) a common, trade and/or trade name, if any; (2) the chemical name, utilizing the Chemical Abstracts nomenclature system; (3) structural formula; (4) molecular weight; (5) description of the manufacturing process, including a list of all substances used, their concentrations and specifications, and equations for all chemical reactions involved, plus any production controls used; and (6) physical, chemical and/or biological properties of the additive.

The Guidelines would require the following data on the proposed use of the indirect additive: (1) food types if limited; (2) maximum temperature and time range of use; (3) maximum use level in desired substrates and maximum thickness; and (4) minimum size package or maximum food contact area.

Regarding intended technical effect, Holtz said FDA would require a description of the intended effect, plus data showing that the intended effect is accomplished or "certification from customer usage." The FDA also said data should be submitted showing that "the proposed level of use is an amount not more than that required to accomplish the intended effect."

For methodology, Holtz said the Petition should contain the following:

- (1) Outline of pertinent procedural methods or complete reference to standard accepted one;
- (2) sensitivity of the method expressed in weight figures;
- (3) samples of calibration curves and information on how they were developed;
- (4) details of how calibration is done;
- (5) samples of curves used for analysis;
- (6) sample calculations based on the analytical curves and showing factors used to convert to mg. per square inch or p.p.m.;
- (7) conversion of mg. per square inch extractant to p.p.m. obtained by using a factor of 100, based on 10 grams of being in contact with one square inch of package surface;
- (8) maximum extraction levels for different food simulants;
- (9) heptane extraction values corrected by the permitted factor of 5; and
- (10) for some additives, a determination of the extractability relationship between edible oil and heptane.

GIANT LAUNCHES NUTRITION LABELING TEST WITH FULL FANFARE

Nutritional labeling costs very little, the President of Giant Food told a Sept. 8 press conference in which the food chain's cooperative experiment with the Food and Drug Administration was brought into the full glare of a publicity spotlight.

Joseph Danzansky of Giant was accompanied by Giant consumer advisor Esther Peterson, Harvard's Dr. Jean Mayer, Sen. Hart (D-Mich.), FDA's Dr. Ogden Johnson, Director of the Division of Nutrition, James Turner, author of *The Chemical Feast*, and others in a full-scale press conference. Giant also splurged on full page newspaper ads and a half-hour television show.

Hitting the source declaration proposal as unnecessary in view of the fatty acid labeling proposal, Armour said, "Our discussion with concerned customers finds an almost unanimous opinion that they will specify shortening that will fit their label rather than buy the most economical shortening if the proposed section of the regulations becomes the rule," resulting in higher prices.

The American National Cattleman's Association urged that FDA require only "practical information" on labels. Saying that some manufacturing techniques alter the chemical structure of fats whether they are of animal or vegetable origin, ANCA wrote, "This means that what appears on the label may not be identical to what originally went into the product because of changes brought on by manufacturing processes."

The Association also said that "there is quite a variation as to location and percentage of saturated, monounsaturated and polyunsaturated fats within an animal carcass," so that it would "be difficult, if not impossible to accurately reflect the percentages of fat content on a label . . ."

Source labeling was also opposed by Guy's Foods and by Fairmont Foods, both of which said it would raise difficulties in manufacturing potato chips.

FDA NEEDS MORE LAWYER INVOLVEMENT, INDUSTRY ATTORNEY SAYS

The Food and Drug Administration came under fire from an industry lawyer during a Sept. 9 session of the Federal Bar Association for the agency's failure to involve lawyers in staff decisions and its lack of any general counsel of its own.

Washington attorney Jerome H. Heckman, speaking at the session in New Orleans, pointed out that the man often referred to as FDA's General Counsel is, in fact, an HEW General Counsel. Heckman continued:

"Indeed, since FDA's top legal advisor does not serve at the pleasure of the agency's Commissioner, he has sometimes been viewed as a sort of super-Commissioner who survives the frequent FDA reorganizations unscathed and unaffected."

FDA lawyers, Heckman said, are never in evidence when important questions of procedure, legality of requests for supplementary information and the like are brought up. He continued:

"With all due deference to some very dedicated staff people, we believe this type of FDA 'legal work' has led to the grossest type of distortion of Congressional intent, misuse of scarce scientific talent, and sets of regulations which are almost always so confusing as to make them meaningless to many experts in the field, much less the public."

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Much of what FDA handles as rulemaking, Hochman charged, is or should be carried on as a licensing function under "the instructions commonly understood by administrative lawyers with respect to these two areas."

Hochman suggested that the use of lawyers by FDA "in the less celebrated cases" could "plunge the agency and 'dilute the virtues of predictability and consistency to FDA regulations.'"

The "disregard" which has set FDA apart, Hochman said, "is its paucity of legal expertise at the Bureau and lower staff levels." Finding the reasons for this in FDA's historical growth, he said:

"Unlike other agencies, and contrary to some popular belief, when the need for legislation and rules to deal with problems prospectively, instead of by prosecution for embezzling, arose, FDA was not overly bothered with administrators or lawyers who did not understand the fundamental concepts of administrative law . . . In short, the agency knew how to deal with the small-number minority, but not with the silent majority of ethical performers."

"For example, FDA did not show, and still does not always show, sufficient concern for self-limiting its jurisdictional problems . . . It has then had an impossible time attempting to carry out its self-imposed new missions."

As an example of the difficulty arising, he noted that the average time to process a Food Additive Petition is 134 days, instead of 90 or "even the 180 allowed as an absolute maximum."

TWO STATES GET "EQUAL TO" POULTRY INSPECTION POWER

The Department of Agriculture certified two state poultry inspection programs as being "equal to" federal inspection last week, bringing the total of states in the program to 12. The new states were Nevada and Indiana.

Both states, USDA said, had to develop poultry inspection laws and regulations, as well as inspection capability, in order to qualify.

The Department also announced last week that it will hereafter make available to the public warning letters to firms "suspected" of violating meat and poultry laws.

Also to be released are records of meat and poultry detained under federal law.

Noting that the U.S. District Court in Baltimore and a U.S. Court of Appeals had mandated the action following a Freedom of Information Act suit, USDA stressed that the warning letters "are sent to firms suspected of minor violations of federal meat and poultry inspection laws" and "are sent without conclusive judgment that the firm is actually guilty of a violation."

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