JAOCS News Feature

The Food Additives Amendment and fat and oil bearing foods[1]

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Many people who are closely involved in the early stages of planning and developing research on new products have little knowledge of how the Food Additives Amendment affects what they do in the laboratory. Yet if workers at every stage of research and development had this knowledge, the results would be better planned research, better reporting of data, and better petitions submitted to FDA.

The Federal Food and Drugs Act of 1906 was the first Federal law in the U.S. dealing generally with the regulation of foods and drugs. It became a landmark of consumer protection; yet regulatory experience revealed shortcomings in protection of the public. Its successor, the 1938 Food, Drug and Cosmetic Act, required predistribution clearance for safety of all new drugs, an innovation which worked well despite widely voiced industry fears. Later developments resulted in similar provisions for premarketing clearance: the Miller Pesticide Amendment of 1954, the Color Additives Amendment of 1960, and the Food Additives Amendment of 1958, which required clearance for substances added to food. This amendment defines anything added to food as a food additive except for certain specified exceptions, of which the most important are (a) substances generally recognized as safe (GRAS), and (b) substances that had received prior sanction. The amendment provides that no food additive may legally be used in food unless and until a food additive regulation has been promulgated to provide for the desired use.

In the fat and oil bearing food industry, as a prospective new substance is being studied in the laboratory, knowledge of what information must be submitted to FDA should guide the planning of experiments to obtain the necessary data. A food additive petition must provide information to support the promulgation of a regulation that, in effect, establishes the following: (1) The conditions of use outlined by the regulations are safe. (2) The amount permitted is no higher than reasonably necessary to accomplish the intended effect. (3) The regulation will not lead to deception of the consumer. (4) The regulation will not lead to a violation of any other section of the Act.

Chemists and food technologists developing a substance for addition to food should realize that a petition to FDA will ultimately be needed and must include the following.

a) The name and all pertinent information concerning the proposed additive, including where available, its chemical identity and composition. FDA scientists need to know the method of manufacture, the purity and other specifications identifying the substance used in the tests, and the analytical methods employed to assure that the additive used in the experimental work meets the proposed specifications of the commercial product.

b) A statement of the conditions of the proposed use of the additive, including all directions, recommendations and suggestions proposed for its use and specimens of the proposed labeling. Conditions of use are an important consideration. After they have been determined, information should be developed on all metabolites, residues, etc., that result from these intended conditions.

c) All relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce the effect. Collection of data should be designed to support the effect the additive is intended to produce, e.g., recently we had to consider whether a processing technique offered for shelf-life extension should more properly have been offered for its antimycotic action. In addition, any necessary tolerance limitation must be no higher than reasonably necessary to accomplish the intended technical effect. Data should include studies designed to show that the amount sought is the reasonable minimum, i.e., an amount lower than that requested does not accomplish the intended effect and a higher amount does not significantly enhance the claimed effect.

d) A description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food because of its use, i.e., analytical methods. The method provided in the petition should be written in "cookbook" fashion so that its adequacy can be checked in FDA laboratories if necessary. A new method should be given an independent trial before it is presented in a petition. Occasionally the developer of a method is so familiar with it that he leaves out one or more important steps in his write-up; then, when we try to verify the method as received, it fails to work and we must reject the petition. Several years ago, for example, a method utilizing separation by a chromatographic column contained instructions to pack the column with a "convenient packing material." FDA analysts tried unsuccessfully to duplicate the petitioner's results. After considerable time, they found the the packing material selected at random by the petitioner's chemist was the only type that would work in the method. Another frequent failing is that data are not provided to establish the sensitivity and accuracy of the method at the levels at which the additive would be found in the food substrate.

e) Full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations. We plan to publish some guidelines for toxicological investigations for petitioners. These establish the minimum requirements for tests to be done on a

[1]Presented at the AOCS Meeting, Atlantic City, October 1971.

scale related to the expected levels in the food supply. More work will be necessary to explain any unusual or incomprehensible results or effects that suggest a significant public health risk.

Food additives as defined in the law do not include substances classed as GRAS and substances sanctioned through an action taken prior to passage of the food additives amendment. Therefore a substance so classed could be used in food without the premarketing clearance demanded of a food additive.

This does not mean that interested parties can circumvent the petition process by persuading a relatively small group of scientists to declare a substance GRAS after inspection of some data on it. Only substances in use in food under the conditions pertaining in 1958 were entitled to be considered as GRAS, and then only if sufficient information on safety was available that scientists *generally* (including FDA scientists) could recognize the safety.

Accordingly, when President Nixon in his Consumer Message of 1969 directed FDA to reevaluate the safety of the ca. 700 items on the original GRAS list published by FDA in 1959 and 1960, we decided first to issue criteria by which any interested person could determine the eligibility of any substance for the new GRAS list. We reaffirmed the principle that no substance can be generally recognized as safe unless FDA has also considered the data on that substance. FDA will publish an inclusive list of all substances that we affirm to be GRAS. Any proposed GRAS items will be published in the Federal Register for comments before final publication, so that all interested parties, including consumer groups, will have an opportunity for review. This will establish the basis for concluding that the recognition of safety is truly general.

We have also established the principle that a substance requiring limitations in the interest of safety is not an appropriate subject for the GRAS list. The limitations upon which its safety is predicated should be described in a food additive regulation, so that any expansion of uses must be reviewed for safety prior to introduction.

In our review of safety we intend to include all prior sanctioned materials as well as GRAS items. Since the intent of the GRAS review is to subject each item so classed to the same safety considerations that apply to a new additive, we must do as much with any other substances added to food whose safety has not recently been examined.

Accordingly, we expect that a provisional regulation may appear in which it is proposed to move the authority for using BHA, BHT and other antioxidants in fats and oils from the GRAS list into the food additive regulations. Provisional regulations may be established for any substance, already in use in food, that is being subjected to scientific studies in the laboratory to determine if changes in its clearance conditions may be required. Obviously a former GRAS substance is not GRAS if laboratory experiments must be performed on it to answer some question raised by a new discovery or allegation based on related research work. Often such work merely raises questions about the substance tested; it does not provide answers, which must then be sought through additional experiments.

What can be expected from FDA in regard to the GRAS list as time goes on?

We intend to maintain a new GRAS list and to develop a published GRAS list that will reflect FDA's affirmation of such status on all substances eligible for it.

We do not intend that the review of the substances on the existing GRAS list be a *pro forma* action. We are reviewing the toxicological literature for the past 50 years to develop a complete record of the work done on all substances. We intend to subject many GRAS substances to mutagenesis and teratogenesis tests. Decision on other tests such as carcinogenicity must wait until we have reviewed the literature and determined the consumer exposure in each case.

How long this will take depends to a great extent on the funds provided by Congress and our early results on the mutagenesis and teratogenesis testing. One possible advantage of early testing is an adequate appraisal of the tests. About 50 compounds have been tested by the chick embryo technique, by mammalian teratology in four species (rat, mouse, hamster and rabbit), and by mutagenesis techniques (host-mediated assay, dominant lethal, and cytogenetics). A comparison of the results of different tests on the same substance should indicate whether some tests can be eliminated, thus extending the available funds. Certainly few, if any, proposed biological test techniques have been evaluated by such a large number of trials.

These results will be used to appraise the relationship between positive showing of mutagenesis and/or teratogenesis and the carcinogenic potential of proposed additives. The magnitude of the experimental effort provides an unprecedented opportunity to evaluate this experimental possibility.

Finally, we plan to publicize our findings. We will first publish our proposed action on each compound or group and allow time for comments; we solicit comments. Anyone who has data that may relate to the safety of a compound under review should make it available to FDA so that it can be considered in reaching the final decision.

We believe the consumer is entitled to an adequate, up-to-date review of the safety of all substances in the food supply, and that the premarket clearance of food additives coupled with our planned review of the GRAS compounds will provide this assurance.

[Received March 2, 1972]

Please turn to page 73A, this issue, for

COMPLETE PROGRAM AND ABSTRACTS

for the AOCS annual spring meeting

New Orleans, Louisiana

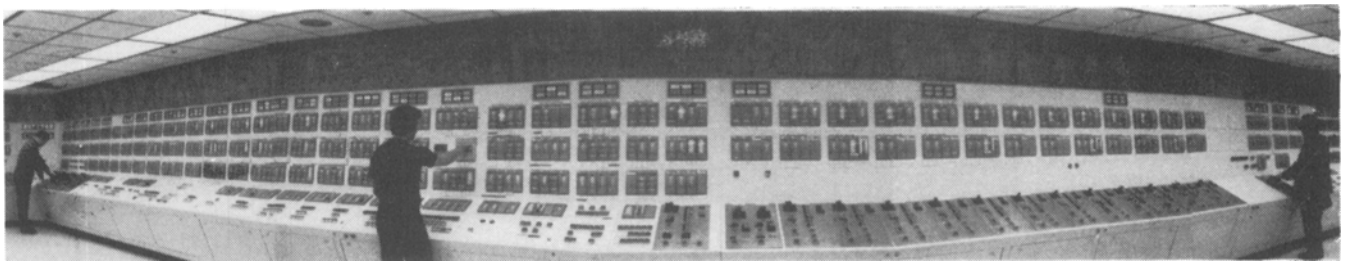
April 29-May 2, 1973

Houmas House, constructed between 1800 and 1840, derives its name from the Houmas Indians who originally held the land on which it is located. The special program, for those who accompany members on their trip to New Orleans, will include a tour of this prewar Greek revival mansion.

Plans for New Orleans meeting near completion

Bob Ory and Harold Dupuy, technical program cochairmen for the AOCS 64th Annual Meeting in New Orleans, April 29-May 2, 1973, report that arrangements for all 11 symposia are complete. The symposia will feature a group of outstanding speakers, and promises to be both rewarding and interesting. In addition, many high quality papers have been contributed to the general sessions, in the areas of oilseed processing techniques, protein properties, lipid oxidation problems, human and animal lipid metabolism, detergents, physiological changes in lipid metabolism, reactions of fats and oils and minor constitutents of vegetable oils. A total of 25 technical sessions are scheduled, all to be concluded by 6 P.M., Wednesday, May 2. The complete technical program schedule, with abstracts of papers to be presented, begins on p. 73A of this issue.

AOCS social activities, detailed in January *JAOCS*, may be supplemented by the annual New Orleans Spring Fiesta, to be held this year from April 27 to May 15. Brochures explaining the history of this celebration and the scheduled festivities will be available at the AOCS registration desk in the Jung Hotel. ■



The central control room in the main unit of Roche's new vitamin C plant is used to monitor 1200 instruments and 1800 pieces of equipment. A team of 21 chemists and technicians in the quality control department in Belvidere perform ca. 900 analytical tests daily on vitamin C during production.

Hoffmann-La Roche dedicates world's largest vitamin C plant

The world's largest vitamin C (ascorbic acid) plant was dedicated November 28, 1972, by Hoffmann-La Roche Inc. in Belvidere, N.J. The new, $65 million complex, with an annual capacity of 10,000 tons, is a highly automated and computerized plant, including a $10 million sophisticated environmental control system. Located on the east bank of the Delaware River, the plant was started in August 1968. Today the continuous-flow process can operate 24 hours a day to meet the growing demand for ascorbic acid, especially for food enrichment. By fortifying and standardizing foods with the vitamin, the nutritional value of orange and tomato juice, fruit drinks, breakfast cereals, frozen dinners, convenience foods, and many other foods is improved. As an antioxidant, ascorbic acid prevents a wide variety of fruits, vegetables, frozen foods, food products and cured meats from changing color. ■

'73 officers announced at Northern California Section meeting

The onset of the bay area cold spell coincided with the late fall meeting of the AOCS Northern California Section, held Dec. 1, 1972, at the Tiburon, Calif., office of Frank E. Sullivan. Bay area residents were joined by members and spouses from the Davis and Fresno areas in viewing Sullivan's demonstration of his latest development in automated processing of vegetable oils. Sullivan employed a working panel board showing the instruments that control continuous refining and bleaching. A projection of automated semicontinuous hydrogenation, deodorization and soap stock drying was described.

After the meeting, participants journeyed several frigid blocks to enjoy dinner at the Windjammer Restaurant, after which the results of the election of officers for 1973 were announced. Francis R. McKenna of Best Foods Div. of CPC International will act as chairman; the steering committee will include: Dick Purdy, PVO; Dave McClung, Best Foods Div., CPC International; and Cameron Lyon, Western Regional Research Lab., ARS, USDA, Albany, Calif. ■

Obituary

Henry Lehman, an AOCS member since 1953, died in December 1972. Lehman, who served on the New York City Fall Convention Committee in 1968, worked as a group leader and research chemist for PVO International Inc., Boonton, N.J. ■

AOCS Northeast Section Student Award Information

The officers and directors of the AOCS Northeast Section voted in September 1972 to allocate $200 for the Student Award in the 1972-73 period.

All senior students who are engaged in the advanced studies of oils, fatty acids, lipids, or their technology, and have published a copy of their work in the form of a thesis or technical publication are eligible for the award. The students must be enrolled at universities in the states of New England, New York, New Jersey, Maryland, Delaware, District of Columbia or Pennsylvania. The relatives of AOCS members will be given preference in consideration for the award.

How to Apply

A student applying for the award must supply letters of support from two faculty members of concerned colleges, one letter from a member of the AOCS Northeast Section and a copy of the publication for review by the Student Award Committee. The application must be sent to:

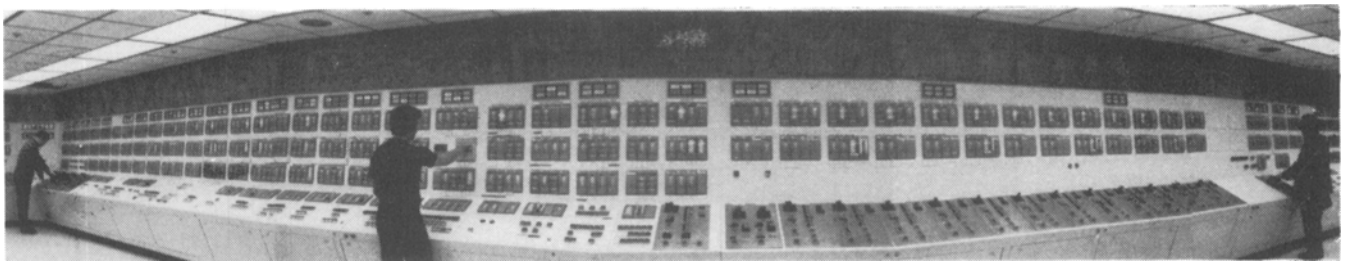
Hans Kaunitz, Chairman of Student Award Committee
Columbia University
630 West 168th Street
New York, N.Y. 10032

A copy of the application should be sent to:

S. Dominik, President, AOCS Northeast Section
Baker Castor Oil Co.
40 Avenue A
Bayonne, N.J. 07002
Telephone: (201) 436-8800

Kaunitz and his committee will select the best qualified recipient of the Award.

Nominations should be submitted prior to March 1, 1973. ■



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Nominations should be submitted prior to March 1, 1973. ■

Robert Suffis, John Munson, Hoffmann-La Roche, Mrs. Suffis, Kak-yuen Tao of W.A. Cleary, treasurer of Northeast Section, and Mrs. Munson.

Rita and Jack Marcus, The Theobald Industries, Suresh Shah, Sunshine Biscuit Co., and Mr. and Mrs. Lawrence Brickman of PVO International.

Mennen tour highlights Northeast Section meeting

The AOCS Northeast Section convened Dec. 5, 1972, for a tour of the Mennen Co., Morristown, N.J., arranged by John B. Munson, meeting chairman. During the plant tour, members and guests were familiarized with modern methods of the production of cosmetics, and especially with the high speed packaging lines of Mennen products.

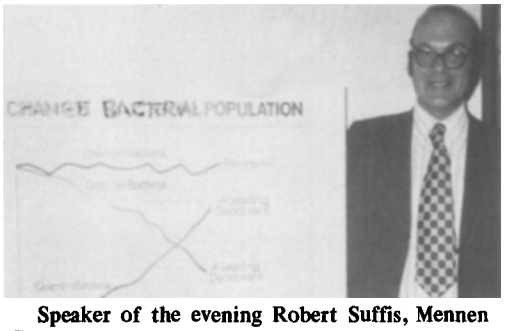
The program, preceded by a dinner at the Black Bull Restaurant, was presented by Robert Suffis, who lectured on vitamin E as a deodorant. Suffis, director of research and development at Mennen, elaborated on the uses, testing and applications of vitamin E in this new field.

During the business meeting, President Stan Dominik announced that the April 10th Symposium on Palm Oil will be chaired by Manny Eijadi of PVO Corp. and cochaired by Peter Kalustian of Kalustian Associates. ■

Mrs. Bernard Kipperman, Mrs. Louis Amaducci and Mrs. Anthony Novelline.

Left to right: Manny Eijadi, PVO International, chairman of April 1973 symposium, Stan Dominik, Baker Castor Oil, president of Northeast Section, and Pete Kalustian, of Kalustian Associates, cochairman of April 1973 symposium.

Dorothy Rathmann and Louise Morrow of CPC International, and Mr. and Mrs. Lew Wayne of Hoffmann -La Roche.



Speaker of the evening Robert Suffis, Mennen Co.