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MCA

MANUFACTURING CHEMISTS ASSOCIATION

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January 22, 1973

To: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

Subject: S. 406 - "Food Protection Act of 1973"

Members:

Attached for your information is an excerpt from the January 16 CONGRESSIONAL RECORD containing Senator Nelson's introduction of S. 406, the bill itself, and a section analysis of it.

The bill is identical with S. 3163 of the last session. MCA's statement to the Senate Select Committee on Nutrition and Human Needs, sent to you October 5, 1972, commented on S. 3163 as well as on S. 76.

S. 406 would require third party testing of food additives at industry's expense; would prohibit the introduction of any food additive that has not been proven safe, effective, and necessary in accordance with procedures established and results approved by the HEW Secretary; would provide for factory inspection; and would set nutrition standards.

Sincerely yours,


M. M. Hoover, Secretary
Food, Drug, and Cosmetic
Chemicals Committee

MMH:gr

Attachment

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dium glutamate, and particularly, the Delaney anticancer section of the Food, Drug, and Cosmetic Act.

These controversies are carried on in the scientific community, the legal community, and by consumer laymen. The arguments promise to increase before they abate.

The bill we introduce today, the Food Protection Act, was designated S. 3163 in the last session. It grew out of the 1970 White House Conference on Food, Nutrition, and Health. Its goal is to eliminate the use of unsafe, poorly tested, and unnecessary chemicals in the food supply.

It would require proof that additives have a demonstrable benefit and are necessary, prior to governmental approval.

It calls for third-party testing of additives, so that approval can be based on data other than that supplied solely by the manufacturer and promoter of an additive.

The bill also calls for factory inspection and registration of additive producers, and requires the Federal Government to set nutritional standards for food.

It is worth noting that, according to industry and FDA figures, some 3,000 chemicals are used in food processing in this country: roughly 1,000 are used directly in food as additives; another 2,000 infiltrate through packaging materials or other indirect contacts. The use of food chemicals has more than doubled from an estimated 419 million pounds in 1955 to more than one billion pounds today, according to industry figures. The industry says the average American eats 5 pounds of additives every year.

In 1970, the FDA received 476 new applications for food additives; 62 were approved. In 1971, the FDA received 110 new additive applications; 51 were approved. In 1972, the FDA received 109 new applications; 77 were approved.

These chemicals are used as stabilizers, preservatives, disinfectants, antioxidants, extenders, tenderizers, emulsifiers, growth promoters, bleaches, sweeteners, conditioners, colors and flavors.

According to two papers presented at the American Chemical Society annual meeting in 1971, the food additives business is expected to boom in the next 10 years. The papers, one by an industry representative and one by a consultant to the industry, project that food additive sales will rise from the present \$500 million a year to \$756 million in 1980.¹

Many of the additives now used have never been adequately tested for toxic or harmful effects. Thus, the American public is a testing ground for many chemical agents.

Some 600 chemicals were generally recognized as safe under the 1958 food additives amendment to the Food, Drug and Cosmetics Act, and were exempted from testing and new approval by the

By Mr. NELSON:

S. 406. A bill to amend the Federal Food, Drug, and Cosmetic Act, relating to food additives. Referred to the Committee on Labor and Public Welfare.

FOOD ADDITIVES

Mr. NELSON. Mr. President, since two food additives bills, S. 76 and S. 3163, were introduced in the last Congress, public concern and awareness in the food additives area has increased.

Hearings conducted before the Senate Special Committee on Nutrition and Human Needs, September 19, 20, and 21, 1972, brought out a wide range of concerns on the part of scientists, consumers, and industry over use and regulation of additives.

Meanwhile, public controversy continues over such additives as saccharin, red dye No. 2, nitrates, nitrites, monoso-

¹The Future of Chemical Additives in Foods—the 1970's—A period of challenge and change for Food Additives, by Richard L. Hughes, A. D. Little Co., presented at American Chemical Society, 1971, *Congressional Record*, Feb. 14, 1972, p. S1569.

FDA. These "gras" list items include cyclamates, now banned from all foods; MSG, which has been voluntarily removed from baby foods; saccharin, now off the "gras" list and under review; nitrates and nitrites, now under study, the latter having been restricted to certain uses by the FDA.

The scientific community increasingly raises concerns over the long range, accumulative effects of all these chemicals on the human genetic structure, their effects on the unborn, and the synergistic effects of chemicals in combination.

The list grows daily of chemicals that are discovered to have harmful effects.

Many of the chemicals widely used in the United States of America are banned or restricted in other nations or condemned by the United Nations World Health Organization—WHO—and Food and Agriculture Organization—FAO. They include BHA and BHT, antioxidants that are restricted in Britain and banned from baby foods. BHA and BHT are commonly used in U.S. baking products. Red dye No. 2, used in foods and cosmetics, has been banned in the Soviet Union. Sodium benzoate and benzoic acid is banned from many foods by the State of Wisconsin. DES—diethylstilbestrol—a cancer-causing hormone added to animal feeds, is banned in 21 countries; the FDA has banned its use in liquid and dry feed form as of January 1, 1973.

The FDA is reviewing the "gras" list and testing some of the substances. Most of them remain in common use, however.

In 1970, for the first time, Americans spent more money for processed, convenience, snack, and franchised foods than for fresh foods.

This rapid increase and proliferation of processed and convenience foods has prompted the FDA to ask industry voluntarily to meet nutritional standards in the quality of products. However, the industry is not required to comply with minimum standards—only urged to do so. This bill would require minimum nutritional standard setting which products would have to meet.

Additives cut costs to the producer, but not necessarily to the consumer. A package of instant eggs, for example, advertised as containing the equivalent of two eggs, costs 30 cents, compared to an average of 5 cents for one real egg. That means the consumer is paying three times as much per package for powdered synthetic eggs as he would pay for two real eggs.

The food industry had \$139.2 billion in sales in 1971, a 63 percent growth since 1960. It is the Nation's largest and fastest growing business. The managing editor of the trade magazine, Food Engineering, Leonard Trauberman, has written.

Convenience foods have contributed more than anything else to the growth of the food industry.

The trade magazines emphasize convenience foods and new additives which make them possible. Some examples of recent advertisements read:

Out of the laboratory comes (a synthetic) dehydrated cheese. (It) gives you real cheddar taste at a greatly reduced unit cost.

Partial or complete replacement of corn grits in direct-expansion snacks is possible

with the use of a coarse-form modified starch from (a chemical company).

Any potato product processed with (a chemical company's sodium acid pyrophosphate [SAP]) preserves the natural color.

A fabulous new food . . . TVP (textured vegetable protein) . . . could hardly look or taste better . . . or be more economical. It is available in granular, chunk, dice, strip and chip forms. It comes unseasoned, or with flavoring of almost any kind—meaty, nutty, tangy, salty, even fruit flavors. Easy to handle and to store and completely controlled in texture, flavor and color, TVP is exceptionally well suited for institutional feeding and restaurants. It's an excellent enrichment for casseroles, snacks, stews, gravies, ground meats and many convenience foods. Find out more about this fabulous new food . . . about the profit-making opportunities it affords.

Our red coloring looks so natural you'd swear it grew on a vine.

Time to increase profits! (A stabilizer) reduces cooling period required before cutting fruit pies.

One trade magazine advertised a seminar thusly:

Now ingredients and additives suppliers can reduce significantly the risk involved in selling in this vast 5 billion dollar market.

There is no question that food additives are big business. The chemical and drug industries have joined the food industry in a vast food-industrial complex that the FDA is supposed to regulate.

The result is a proliferation of food chemicals that are unnecessary, an unknown number that are unsafe, many untested, and poorly monitored.

These bills would provide for more careful regulation, monitoring, and testing of food additives.

Dr. Jean Mayer of Harvard University, President Nixon's Adviser on Nutrition, has said:

We can live perfectly well without additives.

Ogden Johnson, head of the FDA's Division of Nutrition, has said:

If the additive has no definite benefit, why use it at all?

FDA Commissioner Charles Edwards, has stated:

If I am reading consumer complaint correctly, among other things, they are saying that at least for some foods, there must be a positive gain or benefit in the food, or, in the case of food additives, there must be a positive reason for its use."

Mr. President, I ask unanimous consent that the text of the bill be printed in the Record, along with a section-by-section analysis, following these remarks.

There being no objection, the bill and analysis were ordered to be printed in the Record, as follows:

S. 406

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act shall be known as the "Food Protection Act of 1973."

FOOD ADDITIVE TESTING

SEC. 2. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding immediately after section 409 a new section as follows:

"TESTING OF FOOD ADDITIVES

"SEC. 410. (a) (1) The Secretary shall be responsible for all tests or investigations conducted on all new food additives sub-

mitted to him for approval under this Act for the purpose of determining whether or not such additives may be used in food, and shall be responsible for having new tests or investigations conducted on additives which have been approved prior to the enactment of this section, in order to determine whether or not approval of such additives should be withdrawn.

"(2) The Secretary, in carrying out the provisions of paragraph (1), shall not conduct tests or investigations, but shall contract with qualified individuals, organizations, but shall contract with qualified individuals, organizations, or institutions to conduct such tests or investigations.

"(b) Whenever the Secretary receives an application from any person for approval of a new food additive pursuant to this section, he shall, as soon as practicable, provide for the necessary testing or investigation of such food additive.

"(c) It shall be the responsibility of the Secretary to insure that the testing or investigation of such food additive is conducted by experts (certified by the Secretary in accordance with rules and regulations promulgated by him) qualified to investigate and evaluate the safety and effectiveness of food additives. In the preparation of specifications for the conducting of tests or investigations of any food additive under this section, the Secretary shall consider the food in or on which the additive is proposed to be used and shall consider, among other relevant factors, those factors prescribed in section 409(c) (5).

"(d) In any case in which the Secretary determines that a period of more than one year is necessary to develop the necessary data to support or deny approval of any food additive for which approval has been requested, he shall notify the applicant to that effect and indicate the amount of additional time needed for such purpose.

"(e) The sponsor of any food additive submitted to the Secretary for testing and investigation shall, upon request, be provided with the pertinent facts relating to the testing or investigation of the food additive, including the procedures being used in such testing or investigating. If the sponsor objects to the manner, scope, or procedures used by the Secretary in testing, evaluating, or investigating the food additive, or a determination made under subsection (d), he may notify the Secretary of his objections and request a hearing on the record to adjudicate the matter.

"(f) Whenever a food additive has been submitted to the Secretary by a sponsor for approval, the sponsor, at his own expense, shall make available such amount of the food additive and the food in or on which such additive is proposed to be used as the Secretary determines is necessary for adequate testing and investigation.

"(g) The testing or evaluation of any food additive shall be terminated as promptly as practicable by the Secretary upon receipt by him of a written request from the sponsor of such food additive to discontinue such testing or investigation; and the sponsor shall be liable for the payment of all costs attributable to the termination of such testing or investigation.

"(h) (1) The sponsor of any new food additive submitted to the Secretary for testing or investigation under this section shall be liable for the direct costs incurred in carrying out such testing or investigation. The Secretary shall prescribe by regulation the manner in which charges shall be computed for the testing or investigation of any food additive.

"(2) If any amount of the charges for testing or investigating a food additive under this section is unpaid after the due date thereof, as prescribed by regulations, interest shall accrue thereon at the rate of 6 per

centum per annum. Past due charges and interest thereon shall be recoverable by civil action brought in the name of the United States in the appropriate district court of the United States.

"(i) In administering the provisions of this section, the Secretary is authorized to utilize the services and facilities of any other agency of the Federal Government and of any institution, organization, or individual in accordance with appropriate agreements, and to pay for such services either in advance or by way of reimbursement as may be agreed upon.

"(j) A request by the sponsor of any food additive for termination of the testing or investigation of such food additive at any time prior to one year from the date such food additive was submitted to the Secretary for testing shall constitute sufficient basis for the denial of approval for such food additive.

"(k) Nothing in this section shall be construed as prohibiting the sponsor of any food additive from conducting tests or investigations with such food additive in accordance with other provisions of this Act.

"(l) The results of all tests and investigations conducted under this section with any new food additive shall be made public by the Secretary in accordance with section 552 of title 5, United States Code."

Sec. 3(a) Section 301 of such Act is amended by adding to the end thereof the following new subsections:

"(q) The introduction or delivery for introduction into interstate commerce of any food additive, color additive, or any food containing a food additive or color additive, which has not been proven to be safe, effective, and necessary in accordance with procedures established and results approved by the Secretary, in the production of food, or unavoidable by good manufacturing practices for use under the conditions prescribed."

(b) Section 409(a) of such Act is amended by renumbering clauses (1) and (2) as (2) and (3), respectively, and inserting a new clause (1) as follows:

"(1) it has been tested or investigated pursuant to section 410 and approved by the Secretary for its intended use;"

(c) Section 409(c)(2) is amended by inserting before the period at the end thereof the following: ", but in any case where testing or investigation is required under section 410 the provisions of that section shall apply".

(d) Section 510(b) of such Act is amended by inserting after the word "drugs" the following "or of a food additive or food additives".

(e) Section 704(a) of such Act is amended by—

(1) inserting in clause (1) after the word "food," each time it appears therein, the words "food additives".

(2) inserting in the second sentence after the word "which" the first time it appears therein, the following: "food, food additives, or".

Sec. 4. (a) Section 401 of such Act is amended by inserting after the word "container" the first time it appears therein a comma and the following: "and reasonable standards of nutritional value".

(b) Section 402(c) of such Act is amended by inserting before the period at the end thereof the following: "or which is unnecessary for the maintenance of the nutritional value or preservation of such food".

(c) Section 403(e) of such Act is amended by striking out "and" at the end of clause (1) and striking out the colon preceding the proviso in clause (2) and inserting in lieu thereof the following: "; and (3) an accurate statement of the nutritional value of the contents:".

SECTION-BY-SECTION ANALYSIS OF FOOD ADDITIVES BILL

SEC. 1. Title: The "Food Protection Act of 1973."

SEC. 2. Food additive testing.

Amends Chapter IV of the Food, Drug and Cosmetic Act, giving HEW authority and responsibility for all tests or investigations conducted on all new food additives submitted for approval for use in food. The Secretary shall also be responsible for having new tests conducted on additives that were approved prior to enactment of this bill, to determine whether they should be withdrawn.

The Secretary shall contract with qualified third-party laboratories to conduct such tests.

Such tests shall be conducted by experts certified by the Secretary.

Sponsor of food additives for testing may receive pertinent facts relating to the testing procedure, and, if he objects to the procedures, may request a hearing on the matter.

Sponsor shall provide the necessary material for testing, and shall pay all costs of testing, with charges to be recoverable by civil action if unpaid after the due date.

Secretary may use services and facilities of any other agency in the federal government and of any institution, organization, or individual for testing.

Sponsor may request termination of testing prior to one year from date of application, which request shall constitute sufficient basis for denial of approval of such additive.

Nothing prohibits sponsor of any additive from conducting tests of his own.

The results of tests conducted under this section shall be made public.

SEC. 3. Prohibited acts, registration of producers, factory inspection.

A new section added to Sec. 301 of the Food, Drug and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of any food, food additive or color additive or food containing additives that have not been proven to be safe, effective and necessary in accordance with procedures established and results approved by the Secretary, in the production of food, or unavoidable by good manufacturing practices for use under the conditions prescribed.

Extends of Sec. 704(a) of the Food, Drug and Cosmetic Act to allow any factory, warehouse or establishment in which food additives are manufactured, processed, packed or held to be inspected by HEW employees.

SEC. 4. Nutrition standards.

Nutritional value is added to definitions and standards for food, under Sections 401, 402(c) and 403(e) of the Food, Drug and Cosmetic Act. The Secretary shall set reasonable standards of nutritional value for food.