



MANUFACTURING CHEMISTS ASSOCIATION

1872 A CENTURY OF SERVICE 1972

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October 5, 1972

TO: FOOD, DRUG, AND COSMETIC CHEMICALS COMMITTEE

SUBJECT: MCA Statement to the Senate Select Committee
on Nutrition and Human Needs re S. 76 and
S. 3163

Gentlemen:

Attached is a copy of the subject statement,
which was developed by Mr. Hagan's task group.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. M. Hoover", is written over the typed name.

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

MMH:cms

Attachment

Distribution "B"

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STATEMENT
OF THE
MANUFACTURING CHEMISTS ASSOCIATION
TO THE
SENATE SELECT COMMITTEE ON NUTRITION AND HUMAN NEEDS
CONCERNING
S. 76 - FOOD ADDITIVE SAFETY ACT OF 1972
S. 3163 - FOOD PROTECTION ACT OF 1972

OCTOBER 3, 1972

The Manufacturing Chemists Association is a nonprofit trade association of 167 United States company members, representing more than 90 percent of the production capacity of basic industrial chemicals within this country. Many of our members produce substances which would be subject to these bills, especially food chemicals and color additives.

EFFECT ON FOOD SUPPLY

Immediate - It would be difficult to overstate the profound adverse effect that enactment of S. 76 and S. 3163 would have, immediately upon enactment, on the food supply of our nation. The vast bulk of our nation's food supply would be rendered unlawful by these bills. The impact would be catastrophic.

To understand how this result would come about, we discuss at the outset the inter-relationship between the revisions to Section 409(a) and Section 301 of the Food, Drug, and Cosmetic Act in S. 3163, and the revision to Section 201(s) of the Act in S. 76.

Under the revisions proposed to Section 409(a), a food additive would be deemed unsafe and, therefore, adulterated, unless the Secretary of HEW has had the additive tested as provided for in a new Section 410 contained in S. 3163, and has approved the additive for its intended use. The amendment to Section 301 prohibits the shipment in interstate commerce of any food additive, color additive, or food containing such additive, if it has not been proven "safe, effective, and necessary" in accordance with procedures established and results approved by the Secretary.

Needless to say, no food additive presently in use has been approved by the Secretary based on tests which HEW sponsored, and no food additives have been approved by the Secretary, on the basis of anyone's tests, for "necessity," since those are requirements which would be enacted into law for the first time under S. 3163. Therefore, as a matter of law, upon enactment of this bill it would be unlawful to ship

in interstate commerce any and all food additives, color additives, and food containing them, since they would all lack the type of approval required by this bill. Furthermore, under Section 301(c) of the existing Food, Drug, and Cosmetic Act, the receipt in interstate commerce of such additives and food containing them, and the delivery or proffered delivery of them, would also be prohibited.

This situation would be made even worse by Section 2 of S. 76, since it would amend Section 201(s) of the Act to eliminate the existing exemption from the definition of "food additive" for substances that are generally recognized by qualified experts as safe for their intended use. Without that exemption, hundreds of presently exempted substances, many of which have been used in food from antiquity, would fall within the definition of the term "food additive" and, on enactment of these bills, the shipment, receipt and delivery of such additives, and of food containing them, would be prohibited and unlawful. Since additives as ubiquitous as salt and pepper would become unapproved food additives, it can be readily predicted that the great bulk of our nation's food supply would violate the Food, Drug, and Cosmetic Act on enactment of this legislation.

Delayed - Even if the effective date of these bills were postponed for a very substantial period of time, their effect on our food supply would still be catastrophic because of the number of substances that would be subject to the revised definition of the term "food additive," the time it would take to conduct the required testing (and retesting) for all such substances required by S. 3163, and the overwhelming cost thereof. Even if all of our nation's animal testing facilities were devoted solely to testing of food additives, it would be many many years before this volume of testing would be completed. For each such substance, moreover, the cost of the animal testing alone would average about \$300,000.

When Congress enacted the Food Additive Amendment in 1958, it recognized this problem. It also recognized that the safety of a great many substances added to food had been established by long-term common use in food, and that the Food and Drug Administration and the Department of Agriculture had previously been satisfied as to the safety of many such substances and had specifically sanctioned or approved their use. It was for this reason that Congress, in the Food Additive Amendment of 1958, exempted from the definition of the term "food additive" substances that are generally recognized by qualified experts as safe for their intended use based on common use in food, and substances that had received such prior sanction or approval.

ADDITIONAL TESTING

Additives Already in Use - We submit that it is unwarranted and unsound to require, as S. 3163 would, that all substances which have been approved by FDA as food additives since 1958, on the basis of testing sponsored by the manufacturers, be wholly retested under the sponsorship of the Secretary. We know of no justification for such duplicate testing. Furthermore, no evidence has been presented to show that testing performed or sponsored by manufacturers has been inferior in quality to that which would be sponsored by the Secretary, or that the results of such manufacturers' tests are invalid.

New Additives - Section 410 of S. 3163 would make the Secretary responsible for all tests or investigations conducted on new food additives submitted to him for approval.

In the past, Congress has always placed with the applicant the responsibility for safety and efficacy testing of products which require premarket approval by FDA. When the Food Additives Amendment was enacted in 1958, responsibility for testing necessary to support a food additive petition was placed with the applicant. Similarly, Congress placed responsibility for testing with the applicant: for new drugs in 1938 and 1962; for antibiotic approval in 1945 and 1962; for pesti-

cide chemical tolerances on raw agricultural commodities in 1954; for color additives in 1961; and for new animal drugs in 1968.

We submit that industry has fulfilled its responsibility well with respect to testing of food additives, and we know of no reason why the responsibility for food additive testing should be handled differently than for the other types of products which require FDA approval prior to marketing.

As a practical matter, the proposed revision of Section 409(b)(2) would, to a large extent, result in duplication of testing of new food additives. For a company which develops such an additive to be in a position to reach a decision as to whether it wishes to seek FDA approval of a food additive petition, it must have information as to the safety, performance, etc. of the additive. Therefore, the company itself would have to sponsor most, if not all of the testing that the Secretary would also sponsor after receipt of the food additive petition. The applicant, thus, would be paying twice for the testing of its product.

PROOF OF NECESSITY

We note the provision of Section 301(g) that would require that all substances added to food be proved both effective and necessary, and approved as such by FDA. Section

409(b) (2) (C) of the Act currently requires that food additive petitions contain all relevant data bearing on the physical or other technical effect the additive is intended to produce. To this extent, "efficacy" of food additives is required under the present statute. We are not sure of exactly what the word "effective" in the revision to Section 301(g) is intended to add, if anything.

We take strong exception to the proposed requirement that food additives be proved and approved as "necessary." By what standard is necessity to be judged? Does this mean that additives which make food more attractive, more palatable, or better tasting, are to be prohibited? For example, are all food colors to be banned, even though they are safe, and though they add markedly to the attractiveness of foods?

It seems to us that it would not be a proper function of the Congress to deny to the American public such benefits of food technology.

EXPANSION OF DELANEY CLAUSE

Section 3 of S. 76 would amend the Delaney clause in the Food, Drug, and Cosmetic Act (Section 409(c) (3) (a)) to make it applicable to any chronic biological injury or damage, including induction of congenital deformities and genetic

mutation, as well as cancer. This section would also make the Delaney clause applicable for the first time to substances used in food that are exempt from the definition of the term "food additive."

When Congress enacted the Food, Drug, and Cosmetic Act in 1938, the Act contained a per se prohibition against any poison or deleterious additive to foods. By this we mean that the addition of such a substance to food would render it adulterated, regardless of whether it had been shown to be totally safe in the quantity and under the conditions of its intended use. When Congress, after a number of years of hearings, passed the Food Additives Amendment in 1958, it recognized that "safety under the conditions of intended use" should be the relevant test for acceptability of food additives, with the one exception of the per se prohibition contained in the Delaney clause.

With increasing frequency, eminent scientists in and outside of government have been speaking against the per se nature of the existing Delaney clause since it forecloses the application of scientific knowledge to the determination of whether substances now subject to that clause are safe under the conditions of intended use.

Biologic scientists have developed unique toxicological testing techniques as the result of which, given the right species, dosage form, timing and method of application, almost any substance can be found to induce a tumor of some type whether benign or malignant - a result which, however meaningless, could require the Secretary to refuse approval or to ban the substance. The same thing can be said with respect to testing for congenital deformities and mutagenesis.

In our view, Section 3, if enacted, would be a disaster since it would make unlawful almost all food additives, including table salt.* This derives from the fact that toxicity is a function of dose. Indeed, Paracelsus wrote in the year 1531 that "Dosis sola facit venenum" or "The dose alone makes a poison." On this basis, any substance (including table salt) in sufficient dose will produce a chronic biological injury. The occurrence of such injury at an exaggerated dose does not

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- * 1. "Chronic Sodium Chloride Toxicity in the Albino Rat-I. Growth on a Purified Diet Containing Various Levels of Sodium Chloride" - Meneely, G. R., Tacher, R. G., and Darby, W. J., J. Nutr. 48, 489, 1952.
2. "Chronic Sodium Chloride Toxicity in the Albino Rat-II. Occurrence of Hypertension and of a Syndrome of Edema and Renal Failure" - Meneely, G. R., Tacher, R. G., Darby, W. J., and Auerbach, S. H., J. Exper. Med. 98, 71, 1953.

mean that the material is unsafe for its normal intended use at a lower dose. This is implied in 40 CFR Part 180 "Pesticide Chemical Safety - Proposed Toxicology Guidelines" (Federal Register, September 20, 1972, p. 19383) which requires for subacute toxicity (A.2.d. Dosage): "At least three dosage levels plus a control group. One dosage level should manifest severe pharmacological effects and one level should be 'no effect.' "

To further illustrate the impact of Section 3, it would, if taken literally, prevent fortification of food stuffs with vitamins A and D, since both have been shown to produce congenital deformities in experimental animals.

We recommend, therefore, that the Secretary continue to be allowed to exercise his judgment when, in his opinion, an additive would be safe under intended conditions of use even though it might under exaggerated dose conditions cause chronic biological injury including teratogenesis or mutagenesis, and that the law be amended to allow him to exercise such judgment with respect to carcinogenesis as well.

EXPANDED INSPECTION

In closing, we comment briefly on the revisions to Section 704(a) of the Act proposed in S. 3163. Those revisions

would expand the factory inspection authority of FDA with respect to foods and food additives to the degree now authorized only with respect to prescription drugs. Needless to say, prescription drugs by their very nature are biologically active substances and it is difficult to see why FDA would need the same inspection authority over food and food additive manufacturing facilities as it possesses for prescription drugs.

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