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FOOD SAFETY AND LABELING LEGISLATION

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JOINT HEARINGS

BEFORE THE

SUBCOMMITTEE FOR CONSUMERS

OF THE

COMMITTEE ON COMMERCE

AND THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

ON

S. 641

TO REGULATE COMMERCE AND PROTECT CONSUMERS FROM ADULTERATED FOOD BY REQUIRING THE ESTABLISHMENT OF SURVEILLANCE REGULATIONS FOR THE DETECTION AND PREVENTION OF ADULTERATED FOOD, AND FOR OTHER PURPOSES

S. 1168

TO REGULATE COMMERCE AND PROTECT CONSUMERS BY REQUIRING IMPROVED SAFETY ASSURANCE MEASURES IN FOOD MANUFACTURE AND DISTRIBUTION AND REGISTRATION OF PRODUCERS OF FOOD

JUNE 4, 17, AND 18, 1975

Serial No. 94–25

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CONTENTS

	Page
Opening statement by Senator Moss	1
Opening statement by Senator Mondale	68
Text of bills:	
S. 641	2
S. 1168	49

CHRONOLOGICAL LIST OF WITNESSES

JUNE 4, 1975

Chasen, Nancy H., Consumers Union of the United States, Inc	90
Hanold, Terrance, chairman, executive committee, the Pillsbury Co., on behalf of the Grocery Manufacturers of America, Inc.; accompanied by Richard J. Leighton	103
Prepared statement	116
Johnson, Anita, Health Research Group	97
Schmidt, Hon. Alexander, Commissioner, Food and Drug Administration; accompanied by Sam Fine, Associate Commissioner for Compliance; Richard Merrill, Chief Counsel; Howard Roberts, Acting Director, Bureau of Foods; Stephen McNamara, Associate General Counsel for Food; and Robert Wetherell, Director, Office of Legislative Services	70
Prepared statement	83

JUNE 17, 1975

Opening statement by Senator Moss	123
Adams, John B., director, environmental and consumer affairs, National Milk Producers Federation	207
Prepared statement	213
Durling, Bruce L., president, Flavor & Extract Manufacturers Association of the United States; accompanied by Dr. Richard L. Hall, vice president and director of research for McCormick & Co., Inc.; Daniel R. Thompson, chief counsel; and William D. Appler, associate counsel	199
Imming, Bernard J., president, United Fresh Fruit & Vegetable Association	179
Prepared statement	182
Queen, Glenn J., vice president, National Association of Retail Grocers of the United States; accompanied by Henry Bison, Jr.; and Thomas Wenning, counsel	176
Somers, Dr. Ira I., executive vice president, National Canners Association; accompanied by Edward Dunkelberger, counsel	125
Prepared statement	135
Stevens, Angus, president, Stevens Canning Co	124
Williams, Edward Brown, counsel, American Frozen Food Institute	189

JUNE 18, 1975

Opening statement by Senator Moss	217
Berger, Murry, president, National Fisheries Institute; accompanied by Lee Weddig, executive director; and Dr. Roy Martin, technical director	224
Keogler, Albert, president, American Spice Trade Association; accompanied by Stewart P. Wands, executive vice president; James Sullivan, director of research and development, McCormick & Co.; George Shurman, president, Overseas Produce Corp.; and Stephen A. Weitzman, legal counsel	239

Page

McEntee, Richard, vice president, manufacturing and technical services, Nalley's Fine Foods 218
Quinlan, William A., general counsel, Associated Retail Bakers of America; accompanied by Joseph A. Becker, owner and operator, the Dixie Bake Shop 229
Prepared statement 235
Way, Raymond, director of technology and compliance, Crescent Foods 220
Zeidman, Philip F.; accompanied by John A. Knebel, on behalf of International Foodservice Manufacturers Association 246

ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

Associated Retail Bakers of America, statement 259
Bond, A. Dewey, vice president, American Meat Institute, letter of June 3, 1975 271
Brett, Abigail T., article in the Washington Post 184
Campbell, Lee, vice president, Poultry & Egg Institute of America, letter of June 19, 1975 281
Chocolate Manufacturers Association of the United States of America, statement 260
Crain, Wayne L., manager, Production and Marketing Division, Florida Fruit & Vegetable Association, statement 267
Dairy Industry Committee, statement 251
Dyson, John, Department of Agriculture and Markets, State of New York, letter of June 25, 1975 285
Gaines, J. P., executive vice president, the Rice Millers' Association, letter of June 19, 1975 281
Goodrich, William W., president, Institute of Shortening & Edible Oils, Inc., letter of June 18, 1975 277
Guggenheimer, Elinor, commissioner, Department of Consumer Affairs, City of New York, letter of June 2, 1975 292
Husbands, Fred H., executive vice president, National Cottonseed Products Association, Inc., letter of June 23, 1975 282
Imming, Bernard J., president, United Fresh Fruit & Vegetable Association, letter of June 24, 1975 285
Jackson, Ralph T., executive vice president, American Soybean Association, letter of June 27, 1975 286
Kennedy, Hon. Edward M., U.S. Senator from Massachusetts, statement 68
Millers' National Federation, statement 256
National Association of Food Chains, statement 267
National Coffee Association of U.S.A., Inc., statement 264
Ripma, S. F., president, National Association of Magarine Manufacturers, statement 253
Shoup, Floyd K., Ph. D., director, research, Far-Mar-Co., Inc., letter of June 6, 1975 273
Steingut, Stanley, speaker, Assembly of the State of New York, statement 265
Supreme Court decision, *Bigelow* v. *Virginia* 147
Sycks, Carl K., Ross Laboratories, letter of June 3, 1975 272
Way, Raymond, director of technology and compliance, Crescent Foods, letter of June 27, 1975 291
Weddig, Lee J., executive secretary, American Seafood Distributors Association, letter of July 11, 1975 293

FOOD SAFETY AND LABELING LEGISLATION

WEDNESDAY, JUNE 4, 1975

U.S. SENATE,
SUBCOMMITTEE FOR CONSUMERS,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittees met jointly at 10:55 a.m. in room 1318, Dirksen Senate Office Building, Hon. Frank E. Moss (chairman of the Subcommittee for Consumers) presiding.

OPENING STATEMENT BY SENATOR MOSS

Senator Moss. The hearing will come to order.

I do apologize for starting late. There was a conflict of scheduling with other hearings that forced us into this position, and I regret it.

I am pleased to see so many here.

Today we begin 3 days of joint hearings of the Subcommittee on Consumers and the Subcommittee on Health, to hear testimony on S. 641 and S. 1168, Food Safety and Labeling Information.

S. 641 is similar to legislation which passed the Senate last year, only to fail to be considered in the House due to the lack of time.

S. 1168 is an industry-sponsored bill, which my colleague from Alaska, Mr. Stevens, has introduced at the request of a number of different food industry groups. I understand that the number of groups is subject to some controversy as some who were announced as endorsing the proposal apparently contend that they do not endorse the proposal.

The basic objectives of the legislation are, (1) to provide consumers with greater assurance that the food they eat is safe and wholesome and, (2) to prevent consumer deception and confusion by requiring comprehensive food labeling information.

In order to achieve these objectives, the legislation sets out certain basic requirements and grants to the Secretary of Health, Education, and Welfare, additional powers to enforce the law.

We will carefully explore this legislation. The need has been clearly demonstrated through a series of general accounting office reports concerning deficiencies in the sanitation of food processing establishments, deficiencies in the authority which the Food and Drug Administration possess, and deficiencies in the information which is presented to the consumer on food labels.

Staff member assigned to these hearings: Edward A. Merlis.

[The bills follow:]

94TH CONGRESS
1ST SESSION

S. 641

IN THE SENATE OF THE UNITED STATES

FEBRUARY 11, 1975

Mr. Moss (for himself, Mr. MAGNUSON, Mr. PHILIP A. HART, Mr. KENNEDY, and Mr. JAVITS) introduced the following bill; which was read twice and referred, by unanimous consent, jointly and simultaneously to the Committees on Commerce and Labor and Public Welfare with the proviso that when one committee reports the bill the other will report as soon as possible or will be deemed discharged from said bill

A BILL

To regulate commerce and protect consumers from adulterated food by requiring the establishment of surveillance regulations for the detection and prevention of adulterated food, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Consumer Food Act of 1975".

TITLE I—FOOD SURVEILLANCE

SEC. 101. Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by inserting

after subsection (x) thereof the following two new subsections:

"(y) The term 'food processor' means any person who owns or operates any establishment in which food is processed."; and

"(z) The term 'safety assurance' includes, and is limited to, those processing factors which bear upon whether a food may be adulterated within the meaning of section 402 (a) of this Act: *Provided*, That with respect to the application of subsections (a) and (c) of section 410 of this Act to fresh fruits and vegetables in raw unpeeled form, the term includes, and is limited to, those processing factors which bear upon whether a food may be adulterated within the meaning of paragraphs (3) and (4) of such section 402 (a).".

SEC. 102. Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341–348) is amended by adding at the end thereof the following two new sections:

"FOOD SURVEILLANCE

"Safety Assurance Procedures

"SEC. 410. (a) (1) A food processor shall, unless he is exempted by the Secretary pursuant to paragraph (4) of this subsection, develop, implement, and maintain safety assurance procedures for each establishment which he owns or operates. Such procedures shall be set forth in writing (in such manner and form as the Secretary shall prescribe) and

such writings shall be available to the Secretary, within 6 months after the date of enactment of this section. In developing such procedures, a food processor shall—

"(A) identify those control points in the food processing operation carried out by any establishment owned or operated by him which are important in the prevention of adulteration, within the meaning of section 402 (a) of this chapter;

"(B) identify the hazards associated with each such point;

"(C) establish adequate controls at each such point; and

"(D) establish adequate monitoring of the controls at each such point.

"(2) The safety assurance procedures developed under paragraph (1) of this subsection shall be reviewed, and appropriate revisions made, at least annually, by the food processor involved.

"(3) Written documents required under this section shall be retained for 5 years and shall be subject to inspection, pursuant to section 704 of this Act.

"(4) A food processor shall be exempted from the requirements of this subsection if the Secretary finds by regulation that the establishment or type of establishment owned or operated by such processor is unlikely, because

of the nature or volume of its food processing, to create or contribute to a significant risk of adulteration, within the meaning of section 402 (a) of this chapter.

"Safety Assurance Plan

"(b) (1) On or before December 31 of each year, the Secretary shall prepare a safety assurance assessment report concerning existing and potential risks of adulteration, within the meaning of section 402 (a) of this chapter, which are known to him and for which safety assurance procedures, safety assurance standards, or inspection and monitoring by the Secretary appear necessary or appropriate to protect the public. Such report shall—

"(A) specify all risks identified;

"(B) rank such risks in the order of their public importance; and

"(C) state, in general terms, the means by which such risks are to be controlled (that is, by safety assurance procedures, safety assurance standards, or identified methods or procedures of inspection and monitoring).

"(2) The first safety assurance assessment report shall include a proposed safety assurance plan, in the form of a proposed regulation, which shall be designed to control the risks required to be specified in such report. Such plan shall include a specific schedule for implementation (that

is, the date by which (A) appropriate provisions shall be included in safety assurance procedures; (B) an appropriate safety assurance standard shall be developed and adopted; or (C) a particular method or procedure of inspection and monitoring—including, where appropriate, the frequency of its application—shall be implemented), in such detail as to permit reasonable evaluation by interested persons of the adequacy of the Secretary's total safety assurance effort. Subsequent safety assurance assessment reports shall include any proposed changes in the safety regulation. Such plan may be further amended at any time at the discretion of the Secretary. No such plan or amendment thereto shall contain provisions regarding safety assurance procedures or safety assurance standards applicable to processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises.

"(3) The safety assurance assessment report and the proposed safety assurance plan or amendments thereto shall be published in the Federal Register and interested persons shall be afforded an opportunity for comment pursuant to section 553 of title 5, United States Code. Any final plan or amendment shall constitute final agency action subject to judicial review, in accordance with section 701(f) of this Act.

"(4) The safety assurance plan shall provide for in-

spection at least once each year, by authorized representatives of the Secretary, of each establishment engaged in the processing of food, other than an establishment (A) which is engaged in processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises; or (B) which is of a type which the Secretary by regulation finds is unlikely, because of the nature or volume of its food processing, to create or contribute to a significant risk of adulteration, within the meaning of section 402 (a) of this chapter: *Provided*, That such plan may provide for a transfer by the Secretary of resources committed to such annual inspections to other food safety assurance activities subject to his jurisdiction upon a finding that such transfer is necessary to protect health and safety.

"(5) The safety assurance plan shall, at a minimum, be formulated so as to (A) reduce or eliminate all risks required to be specified in prior safety assurance assessment reports to the maximum extent feasible; and (B) provide reasonable assurance that within 4 years of the date of enactment of this section no risk shall constitute an unreasonable risk of adulteration, within the meaning of section 402 (a) of this chapter, unless and to the extent that the Secretary for good cause finds (and incorporates such finding and a statement of the reasons therefor in the plan) that the

realization of this objective is infeasible, impractical, or contrary to the public interest.

"Safety Assurance Standards

"(c) (1) If the Secretary finds that any food or class of food is being processed in such a manner as to present an unreasonable risk of adulteration, within the meaning of section 402 (a) of this chapter, and that existing safety assurance procedures and inspection and monitoring activities are not adequate to protect against such risk to the extent required by paragraph (8) of this subsection, he shall promulgate regulations or amendments to existing regulations in order to establish a safety assurance standard to reduce or eliminate such risk.

"(2) Regulations under this subsection shall be promulgated in accordance with section 553 of title 5, United States Code, after notice and an opportunity for a hearing: *Provided*, That (A) the Secretary shall publish in the Federal Register his findings and an adequate statement of reasons underlying the provisions adopted, including responses to objections and comments of interested persons; and (B) an order promulgating regulations or amendments to regulations under this subsection shall be subject to judicial review, in accordance with section 701 (f) of this Act.

"(3) Regulations under this subsection may be proposed by the Secretary upon his own initiative or upon the

petition of any interested person. In promulgating or modifying such regulations the Secretary shall consider the reports and recommendations of appropriate advisory committees established by the Secretary.

"(4) Regulations under this subsection shall designate—

"(A) the food or class of foods which is subject to the safety assurance standards being established;

"(B) the persons required to conduct surveillance in accordance with such standards;

"(C) the contaminants, properties, unsanitary practices, or other factors (including but not limited to micro-organisms, heavy metals, toxins, drug residues, pesticide residues, filth, and other potentially harmful constituents and practices) for which surveillance is required;

"(D) the sampling methods and methods of inspection and examination by which such surveillance shall be accomplished;

"(E) the methods of analysis by which such examinations shall be accomplished;

"(F) the circumstances under which reports of such surveillance and test results shall be submitted to the Secretary; and

"(G) the activities (including sampling, analysis,

and inspections) which the Secretary shall undertake to assure compliance with the safety assurance standards being established.

"(5) No safety assurance standard established under this subsection shall be applicable to any person who has developed, implemented, and maintained safety assurance procedures under subsection (a) of this section which the Secretary finds are adequate to protect against risks of adulteration to the extent required by paragraph (8) of this subsection.

"(6) The Secretary shall periodically evaluate the adequacy of any safety assurance standard established under this subsection and propose amendments in order to reflect new information or changes in methods of food processing.

"(7) Any person or group of persons may petition the Secretary, for an amendment of, or an exception to, regulations promulgated under this subsection, to permit the use of methods other than those specified in the regulations. Upon a showing that any alternative method is equally or more effective than the method specified in the regulations, the Secretary shall (A) approve the requested amendment or exception; or (B) refer the petition for an amendment or exception to an advisory committee established pursuant to subsection (d) of this section for its consideration and recommendation.

"(8) The safety assurance standards established pursuant to paragraphs (1) and (2) of this subsection shall be formulated and implemented so as to provide reasonable assurance that food does not present an unreasonable risk of adulteration, within the meaning of section 402(a) of this chapter. Such standards may vary, as appropriate, among different foods or classes of foods. If there is insufficient knowledge to establish such a standard for any food or class of foods, the Secretary shall immediately initiate a program to acquire sufficient knowledge and to develop such a standard.

"(9) If the Secretary finds a threat or potential threat to the public health, which requires that there be an immediate increase in the level of surveillance pursuant to safety assurance standards, with respect to any foods or classes of foods, he may direct an increase in such level (or otherwise modify the applicable safety assurance standards) to the extent that he determines necessary. Such an order may be entered without regard to any procedural prerequisites otherwise applicable, except that the Secretary shall provide an opportunity for a hearing thereon and comply with other applicable procedures as soon as practicable after the increase in the level of surveillance has been directed.

"(10) Chemical and other analyses performed under this section to determine the presence and amount of con-

tamination in food shall be performed through the use of the best instruments, technology, and trained personnel which are reasonably available.

"Advisory Committees

"(d) (1) The Secretary is authorized to appoint and organize such standing or ad hoc advisory committees as he deems necessary or appropriate to study and report to him with respect to existing and potential hazards to health and safety related to food, risks of adulteration, and recommended action to reduce such hazards or risks. Each committee so established shall provide, to the maximum extent practical, an opportunity for any interested person to submit data and views on all matters considered by such committee. The meetings of such committees shall be governed by the Federal Advisory Committee Act of 1972 (5 U.S.C. App. I). The Secretary shall cause any report submitted to him by any such committee to be published as soon as practicable in the Federal Register and shall provide interested persons an opportunity to comment thereon.

"(2) Where advisory committees are established, the members shall be individuals who are qualified, by training and experience, in food safety or in the use of statistical sampling techniques, analytical methodology, or other technical disciplines relevant to food surveillance. The provisions of chapter 11 of title 18, United States Code, shall

apply with respect to voting members of any such committee. In addition to such technical experts, any such committee shall include, as nonvoting members, a representative of consumer interests and a representative of industry interests. Committee members may be nominated by appropriate scientific, trade, and consumer organizations. The Secretary shall designate one of the members of any such committee to serve as chairman. Committee members shall, while attending meetings or conferences of the committee or otherwise engaged in its business, be compensated at per diem rates fixed by the Secretary, but not at rates in excess of the rate for grade GS–18 of the General Schedule at the time of such service, including traveltime. While serving away from their homes or regular places of business, members of such committees may be paid travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently. The Secretary shall furnish any such committee with adequate clerical and other necessary assistance, and he shall prescribe by regulation the procedures to be followed by it.

"Records and Examination

"(e) (1) Any person required to comply with the requirements of subsection (a) or (c) of this section shall

establish and maintain such records as the Secretary may by regulation require pertaining to safety assurance procedures and safety assurance standards and make such records available to the Secretary upon request.

"(2) The Secretary may require, by general or specific orders, the submission of special reports or answers in writing to specific questions containing such data and information relating to any safety assurance procedures and safety assurance standards, or the implementation thereof, or any matter relating to detection of adulterated or misbranded food, which may assist him in carrying out the purposes of this Act. The district courts of the United States shall have jurisdiction to enforce such general or specific orders and to require access to such information, upon application of the Attorney General or of the Secretary pursuant to section 309 of this Act. An action for enforcement of such orders may be brought in the district court of the United States for any judicial district in which the person or establishment involved is found or transacts business.

"Notification

"(f) (1) A food processor, upon learning, or acquiring information which supports the conclusion, that there is, with respect to food processed by him, an unreasonable risk of adulteration, within the meaning of section 402 (a)

of this chapter, shall immediately notify the Secretary of such risk, if such food has left his control. Such food processor shall also notify the Secretary of any recall of any food which is adulterated, within the meaning of section 402 (a) of this chapter, if such food has left an establishment subject to his control. No information or statements derived exclusively from any notification required under this section (except for information contained in records required to be maintained under any provision of this Act) shall be used as evidence in any proceeding brought against an individual pursuant to section 303 of this Act with respect to any alleged violation of law occurring prior to or concurrently with such notification.

"(2) The notifications required by paragraph (1) of this subsection shall contain a clear description and evaluation of the risk of such adulteration, including, but not limited to, the nature of the food affected and the quantity involved, and a statement of the measures to be taken to protect the public from such risk.

"Citizens Civil Actions

"(g) (1) Except as provided in paragraph (2) of this subsection, any person may commence a civil action for mandatory or prohibitive injunctive relief, including interim equitable relief, on his own behalf, whenever such action constitutes a case or controversy—

"(A) against any person (including the Secretary) who is alleged to be in violation of any regulation promulgated under subsection (c) (1) of this section; or

"(B) against the Secretary where there is alleged a failure of the Secretary to comply with the safety assurance plan established under subsection (b) of this section or to perform any act or duty under this section which is not discretionary with the Secretary.

The district courts of the United States shall have jurisdiction over actions brought under this section, without regard to the amount in controversy or the citizenship of the parties.

"(2) No civil action may be commenced—

"(A) under paragraph (1) (A) of this subsection—

"(i) prior to 60 days after the plaintiff has given notice of the alleged violation to the Secretary and to any alleged violator in such manner as the Secretary may by regulation require; or

"(ii) if the Attorney General or the Secretary has commenced and is diligently prosecuting proceedings with respect to such alleged violation.

"(B) under paragraph (1) (B) of this subsection, prior to 60 days after the plaintiff has given notice

to the Secretary of such alleged failure to comply with the plan or to perform an act or duty.

"(3) In any action under this subsection the Attorney General or the Secretary may intervene as a matter of right.

"(4) The court, in issuing any final order in any action brought pursuant to paragraph (1) of this subsection, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such an award is appropriate.

"(5) Nothing in this subsection shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any regulation or order or to seek any other relief.

"(6) For purposes of this subsection, the term 'person' means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State.

"Other Authority

"(h) This section shall not be construed to exempt the Secretary or any other person from any obligation imposed by any other provision of this Act or by the provisions of any other Act, nor shall this section be construed to permit the use of any substance, practice, or conduct resulting in the presence of adulterated food if such use, practice, or conduct would not have been permitted in the absence of this section.

"Exemption

"(i) This section shall not apply to—

"(1) any processing subject to the exclusive jurisdiction of the Secretary of Agriculture;

"(2) processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises, except with respect to safety assurance assessment reports and safety assurance plans prepared or established pursuant to subsection (b) of this section; or

"(3) processing of food which is not or has not been introduced into, delivered or held for introduction into, or shipped in or received or held for sale after shipment in, interstate commerce.

"Small Business Assistance

"(j) The Secretary shall cooperate with the Small Business Administration with respect to applications (under section 7(b)(5) of the Small Business Act, as amended (15 U.S.C. 631 et seq.)) for loans to assist affected small business concerns to comply with requirements under this section. The Small Business Administration shall direct that applications from such concerns, regarding proposed additions to or alterations in plant, facilities, or methods of operation which are designed to enable such concerns to comply with re-

quirements under this section, shall be reviewed by the Secretary. The Secretary shall evaluate each such application and shall report to the Administrator (or to the bank or lending institution) within 60 days as to whether such additions or alterations are appropriate to assist the applicant to comply with such requirements and whether he recommends that the loan be granted.

"FOOD CODING

"Uniform System

"SEC. 411. (a) The Secretary is authorized and directed to establish by regulation as soon as is feasible a uniform system of coding applicable to packaged foods consisting of symbols which will permit the identification of (1) the identity and plant location of each food manufacturer and packer, (2) the identity of each individual food, (3) the lot or batch number of the food, and (4) the date packed; unless the Secretary determines, by regulation, with respect to any food or class of foods, that because of the nature of the food or the volume processed, such identification of any or all such matters is not necessary to protect the public health. Such regulations for uniform coding shall not prohibit any manufacturer or packer from coding any additional information which is not inconsistent with the required information and which is necessary to effect any reasonable commercial purpose of such manufacturer or packer.

"Public Information

"(b) The Secretary shall make available to the public sufficient information to enable consumers to comprehend the basic elements of such uniform coding system established pursuant to subsection (a) of this section.

"Coding Requirements

"(c) The Secretary is authorized and directed to require by regulation, to the extent that it is technically feasible and economically practicable, that the immediate container and outside container (if any) of packaged food bear legibly and prominently thereon the symbol or symbols established in the system of coding pursuant to subsection (a) of this section.

"Distribution Records

"(d) The Secretary is authorized and directed to require by regulation, to the extent that it is technically feasible and economically practicable, that distribution records of food include such information as is adequate to reasonably permit the tracing of packaged foods coded pursuant to regulations under this section and which is helpful in effecting and monitoring recalls of such food.

"Exemption by Regulation

"(e) Upon the petition of any person, the Secretary is authorized to exempt by regulation from any requirements established pursuant to subsection (c) or (d) of this section

any packaged food or distribution records if such person demonstrates that such food or records are subject to a coding or tracing system, or type of coding or tracing system, which is adequate to meet the purposes of this section and which does not conflict with any system established by the Secretary pursuant to subsection (a) of this section. Any such exemption shall not be inconsistent with or endanger the protection of the public health.

"Availability of Records

"(f) For the purposes of establishing a coding system pursuant to subsection (a) of this section and for monitoring recalls of packaged food, the Secretary is authorized to require by regulation that manufacturers and packers of packaged foods keep records and make such records available to the Secretary on request in the manner and form he deems necessary. The Secretary is authorized to issue any general or special order which he finds is necessary in order to assemble the information necessary to establish such system of coding. The district courts of the United States shall have jurisdiction to enforce such orders upon application of the United States. An action for such enforcement may be brought in any district court of the United States where the person or establishment involved is found or transacts business.

"Exemption

"(g) This section shall not apply to manufacturing and packing of packaged food in a retail establishment for consumption on or off the premises.".

SEC. 103. Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended by adding at the end thereof the following two new subsections:

"(g) If any food is found by an authorized representative of the Secretary in any establishment or vehicle where it is held for purposes of, or during, or after distribution in interstate commerce, such food may be detained by such representative for a reasonable period, not to exceed 20 days, if such representative concludes that the facts provide a reasonable basis to show that such food is adulterated, misbranded, or otherwise in violation of this Act. Such food may be detained pending seizure action under this section or notification of any Federal, State, or other governmental authority having jurisdiction over the food, and such food shall not be moved by any person from the place at which it is located and detained (except as the Secretary may authorize), until released by the Secretary. If the food is still being processed, and has not been put in final form for shipment, processing may continue until the

food is put in final form, but detention of such food in final form may be ordered. Any person who would be entitled to claim such food if it were seized may appeal such detention to a superior official. Such official shall conduct an informal hearing on the matter and confirm or revoke such detention within 5 days of such appeal. The Secretary may extend such detention for an additional 10 days, upon making a finding (and giving appropriate notice) that such extension is necessary to institute seizure action under this section.

"(h) There is a rebuttable presumption, because virtually all food is subject to the jurisdiction of this Act, that any food found in any State is subject to seizure and condemnation pursuant to this section. The claimant or any other party to a condemnation proceeding under this section shall have the burden of establishing that the article or articles are not subject to the jurisdiction of this Act. In the absence of such a showing jurisdiction shall be deemed to be established.".

SEC. 104. Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end thereof the following two new subsections:

"(f) If it is a food which was processed other than in compliance with safety assurance procedures and appli-

cable safety assurance standards required by or pursuant to section 410 of this chapter.

"(g) If it is packaged food, and the immediate container and outside container (if any) do not bear legibly and prominently symbols which the Secretary requires to be placed thereon pursuant to section 411 of this chapter.".

SEC. 105. Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding the following three new subsections:

"(q) The failure to develop, maintain, and make accessible safety assurance procedures as required by section 410(a) of this Act, the failure to comply with safety assurance procedures or safety assurance standards required by or pursuant to section 410 of this Act, the failure to maintain or make available records or make reports required pursuant to section 410 of this Act, or the failure or the refusal to furnish notification or other information as required by or pursuant to section 410 of this Act, with respect to food subject to the jurisdiction of this Act.

"(r) The unauthorized movement of a food detained under section 304(g) of this chapter or the removal or alteration of any mark or label used to identify the food as detained.

"(s) The failure (1) to comply with any regulation

promulgated pursuant to section 411(c) or 411(d) with respect to any food or distribution records subject to such subsections, (2) to comply with the conditions of any exemption provided pursuant to section 411(e), or (3) to keep records or provide information as required by or pursuant to section 411(f).".

SEC. 106. Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331-7) is amended by adding at the end thereof the following two new sections:

"CIVIL PENALTIES

"SEC. 308. (a) Any person who is found by the Secretary, after notice and an opportunity for an adjudicative hearing in accordance with section 554 of title 5, United States Code, to have committed an act prohibited by section 301 of this chapter with respect to any food, shall be liable to the United States for a civil penalty of not more than $10,000 for each day of violation. The amount of such civil penalty shall be assessed by the Secretary, or his delegate, by written notice. In determining the amount of such penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the prohibited act or acts committed and, with respect to the person found to have committed such act or acts, any history of prior offenses, ability to pay and effect on ability to continue to do business, and such other matters as justice may require.

"(b) Any person against whom a violation is found and a civil penalty assessed under paragraph (1) of this subsection may obtain review in the appropriate court of appeals of the United States by filing a notice of appeal in such court within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such court a certified copy of the record upon which such violation was found and such penalty imposed, as provided in section 2112 of title 28, United States Code. The finding of the Secretary shall be set aside if found to be unsupported by substantial evidence, as provided by section 706(2)(e) of title 5, United States Code.

"(c) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate court of appeals has entered final judgment in favor of the Secretary, the Secretary shall recover the amount assessed in any appropriate district court of the United States. In such action, the validity and appropriateness of the final order imposing the civil penalty shall not be subject to review.

"AUTHORITY TO INITIATE LEGAL ACTIONS

"SEC. 309. Notwithstanding any other provisions of law, the Secretary may initiate, defend, or appeal any court action arising under this Act through his own legal

representative or through the Attorney General, except that the Attorney General shall have exclusive authority to initiate prosecution of persons under section 303 of this Act.".

SEC. 107. Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended by deleting "United States attorney for such district" each time it appears therein and inserting in lieu thereof "the Secretary, or the United States attorney for such district, as appropriate,".

SEC. 108. (a) Section 702 (a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372 (a)) is amended by inserting after the first sentence thereof the following new sentence: "In connection with the training by the Secretary of any individual who is not an officer or employee of the United States to prepare him to perform the duties described in the preceding sentence, the Secretary may allow such individual travel expenses to and from the place of such training, including per diem in lieu of subsistence while in travel status and during such training, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for individuals in the Government service employed intermittently: *Provided*, That the individual's training is conducted under an agreement between the Secretary and any State or any political subdivision of a State, pursuant to which such individual,

upon the completion of the training, will be employed by such State or political subdivision to conduct examinations or investigations to carry out the purposes of this Act.".

(b) Section 6(c) of the Fair Packaging and Labeling Act (15 U.S.C. 1455(c) is amended by inserting at the end thereof the following new sentence: "In connection with the training by the Secretary of any individual who is an officer or employee of any State or any political subdivision of a State, duly commissioned by the Secretary as an officer of the Department of Health, Education, and Welfare to conduct examinations, investigations, or perform other functions, for the purposes of carrying out this Act, the Secretary may allow such individual travel expenses to and from the place of such training, including per diem in lieu of subsistence while in travel status and during such training, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for individuals in the Government service employed intermittently: *Provided*, That the individual's training is conducted under an agreement between the Secretary and a State, or a political subdivision of a State, pursuant to which such individual, upon the completion of the training, will be employed by such State, or political subdivision to conduct examinations or investigations to carry out the purposes of this Act.".

SEC. 109. Section 702 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 372) is amended by adding at the end thereof the following new subsection:

"(f) For the efficient administration and enforcement of this Act as it relates to food, the provisions (including penalties but excluding annual reports) of sections 6(b), 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46(b), 49, 50) are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this Act as it relates to food and to any person, firm, or corporation with respect to whom such authority is exercised. The Secretary may prosecute any inquiry necessary to his duties under this Act in any part of the United States, and the powers conferred on the district courts of the United States by such section 6(b), 9, and 10 of the Federal Trade Commission Act may be exercised for the purposes of this Act by any such court.".

SEC. 110. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended by inserting immediately after the first sentence thereof the following two new sentences: "In the case of any establishment manufacturing, processing, preparing, packaging, or holding food, inspection shall extend to safety assurance records bearing upon whether a food may be adulterated, within the meaning of section 402(a) of this Act, and rec-

55-000 O - 75 - 3

ords bearing upon the accuracy of statements made in the labeling of food. Safety assurance records shall be limited to process flow diagrams; any analytical procedure or method used; the results obtained from tests to ascertain compliance with safety assurance standards or procedures; quality assurance instructions or manuals; complaints; any record which relates to a breakdown in or demonstrates a pattern or possible weakness in safety assurance procedures or standards; food ingredient usage records; process validation and control records; coding information; and shipping information.".

(b) Section 704(a) of such Act (21 U.S.C. 374(a)) is further amended by striking the words "second sentence" in the last sentence and inserting in lieu thereof "fourth sentence".

SEC. 111. Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end thereof the following new subsection:

"(e) (1) Every person importing, offering for importation, or otherwise responsible for importing into the United States any food or class of food shall file with the Secretary, at least 30 days prior to such importation, a certificate in such manner as the Secretary shall specify, demonstrating that the particular imported food or class of foods has been produced in accordance with safety assurance procedures and

in compliance with any applicable safety assurance standard established pursuant to section 410 of this Act.

"(2) The Secretary shall request the Secretary of the Treasury to refuse admission into the United States, pursuant to this section, of any such food or class of food which the Secretary determines has not been produced in accordance with section 410 of this Act, or where the importer has failed to file the certification required in this subsection.

"(3) Any such food refused admission shall not be admitted until such time as the Secretary may determine that the food offered for importation is not injurious to the public health. For the purpose of making such determination, the Secretary reserves the right to request that a duly authorized employee or agent of the Secretary be permitted to inspect the processing procedures employed in the production of the food or class of food offered for importation.".

SEC. 112. Section 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375) is amended by adding at the end thereof the following new subsection:

"(c) The Secretary shall not use to his own advantage, or reveal, other than to other officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any trade secret information relating to food or any other information referred to in section 1905 of title 18, United States Code, insofar as it relates to

food. With respect to information relating to food which was originated by any person other than the Secretary, whenever the Secretary determines that information which he desires to disclose is not trade secret information and is not otherwise referred to in such section 1905, he immediately shall give notice to the originator of such information that he intends to disclose such information, identifying the information in such notice with sufficient particularity to enable its originator to evaluate whether it is referred to in such section 1905, and the Secretary shall provide such originator with an opportunity, which is reasonable under the circumstances but not to exceed 15 days, to initiate a civil action to enjoin, suspend, or restrain any such intended disclosure on the ground that such information is a trade secret or is otherwise referred to in section 1905 and, therefore, is prohibited from disclosure by this subsection. The district courts of the United States shall have jurisdiction over actions brought under this subsection, without regard to the amount in controversy. The courts shall expedite the disposition of such actions and shall cause them to be conducted in a manner which is designed to protect the confidentiality of the information intended to be disclosed by the Secretary.".

SEC. 113. Section 201 (f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f)) is amended by inserting after "animals," the following: "except that in sec-

tions 402 (f), 410, and 411 of this Act such term shall not include articles used for food or drink for animals,".

SEC. 114. The amendments made by this title shall take effect upon the date of enactment of this Act, except that the first report under section 410 (b) of the Federal Food, Drug, and Cosmetic Act shall be required on or before December 31, 1976.

TITLE II—FOOD ESTABLISHMENT REGISTRATION

SEC. 201. The Congress finds and declares that—

(a) in order to make regulation of interstate commerce in food effective, it is necessary to provide for registration and inspection of all establishments in which food intended for human consumption is manufactured, processed, packaged, labeled, stored, or otherwise handled;

(b) the products of all such establishments are likely to enter the channels of interstate commerce and to affect such commerce directly; and

(c) the regulation of interstate commerce in food, without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such food, would discriminate against and depress interstate commerce in such food and ad-

versely burden, obstruct, and affect such interstate commerce.

SEC. 202. Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, is further amended by adding after section 411 the following new section:

"REGISTRATION OF FOOD ESTABLISHMENTS

"General

"SEC. 412. (a) On or before December 31 of each even-numbered year (or of such other year as the Secretary may determine), each food processor in any State shall prepare and submit to the Secretary a registration statement which shall include, but not be limited to, his name; principal place of business; the location of each establishment owned or operated by him; and, for each such establishment, a complete list, in such form as the Secretary shall by regulation prescribe, of all classes of foods processed therein. Such list shall identify the types of processing utilized for each class of food. The Secretary shall promulgate regulations defining classes of foods and types of processing, to promote uniformity and expeditious administration with respect to such registration.

"Notification

"(b) (1) Any person, upon first engaging in the processing of food in any establishment which he owns or oper-

ates in any State, shall immediately notify the Secretary and prepare and submit to him a registration statement containing the information required under subsection (a) of this section.

"(2) Any person who has duly registered under this section shall notify the Secretary if he ceases to process or discontinues the processing of any class of food in any establishment, within 90 days of such cessation or discontinuance. Such notification shall not be required in the case of any temporary cessation of processing which is necessitated by the seasonal character of operations at the particular establishment or which is caused by temporary conditions beyond the control of such person.

"(3) Every person who has submitted a registration statement in accordance with this section shall immediately notify the Secretary of any additional establishment which he acquires or at which he commences operations in any State and which involves the processing of food. Such notice shall contain a supplemental registration statement which shall include, with respect to such additional establishment, the information required by subsection (a) of this section

"Number

"(c) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section.

"Public Availability of Information

"(d) The Secretary shall make any registration statement filed pursuant to this section available for inspection by any person without charge, except to the extent that such information is a trade secret or other matter referred to in section 1905 of title 18, United States Code.

"Exemption

"(e) This section shall not apply to—

"(1) any class of food processors whom the Secretary may by regulation exempt from the application of this section upon a finding in writing that registration in accordance with this section is not necessary for the protection of the public health;

"(2) any processing subject to the exclusive jurisdiction of the Secretary of Agriculture;

"(3) any processing consisting solely of the sale of food in a retail establishment for consumption on or off the premises; or

"(4) the processing of distilled spirits, wine, or malt beverages as defined in the Federal Alcohol Administration Act (27 U.S.C. 201–211).

"Inspection

"(f) Every establishment in any State which is required to be registered with the Secretary under this section

shall be subject to inspection, pursuant to section 704 of this Act.

"Foreign Registration

"(g) The Secretary may by regulation provide for the registration of foreign establishments engaged in the processing of food intended to be offered for importation into the United States.

"Definitions

"(h) As used in this section and sections 402(f), 402(g), 403(o), 410, 801(a), and 801(e) of this Act—

"(1) 'name' includes, in the case of a partnership, the name of each partner and, in the case of a corporation, the name appearing on the corporation's charter or certificate of incorporation, the name of each principal corporate officer, and the name of any State of incorporation;

"(2) 'principal place of business' and 'location of each establishment' include mailing address and telephone number; and

"(3) 'processing' and 'processed' include manufacturing, processing, packing, labeling, storing, importing or being in any manner responsible for importing, or otherwise handling food.".

SEC. 203. Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act (21 U.S.C. 331), is

further amended by adding after subsection (s) thereof the following new subsection:

"(t) The failure to register or the failure to provide any information, as required by section 412 of this Act.".

SEC. 204. Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof the following new subsection:

"(o) If it was processed in an establishment required to be registered under section 412 of this Act and not so registered.".

SEC. 205. Section 801(a) of such Act (21 U.S.C. 381(a)) is amended by inserting "(1)" immediately after "(a)" and adding at the end thereof the following new paragraph:

"(2) The Secretary may refuse entry of any food offered for importation into the United States which has been processed in any establishment, other than an establishment registered pursuant to section 412 of this Act.".

SEC. 206. The amendments made by this title shall take effect on the first day of the seventh calendar month which commences after the date of enactment of this Act.

TITLE III—FOOD LABELING

SEC. 301. The Congress finds that the availability to consumers in a uniform manner of information regarding the dating, ingredients, and nutritional qualities of food

will enhance the health and the nutritional and economic welfare of the consumer. The presence of differing, additional, conflicting, or nonuniform labeling requirements for foods leads to consumer confusion and higher food costs by requiring for different localities separate labels for the same food; discriminates against and depresses interstate commerce in such foods; and adversely burdens, obstructs, and affects such interstate commerce.

SEC. 302. Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act (21 U.S.C. 343), is further amended by adding after subsection (o) thereof the following new subsection:

"(p) If the label or labeling bears any information regarding the dating of a food for human consumption, unless such information is in accordance with regulations promulgated by the Secretary. Regulations promulgated under this subsection shall—

"(1) identify, upon a finding of need to prevent violations of this Act, those foods or classes of food with respect to which date information must be provided, or those characteristics of a food or class of foods which necessitate the providing of date information;

"(2) require the processor of a food, with respect to which the Secretary has made a finding that date information is necessary, to place on the package or

label of such food the date by which the processor recommends that such food be sold at retail for consumption (sell date);

"(3) require that the date be stated on the package or label in a clear and conspicuous manner and in such form as will enable the consumer readily to identify the day or date, without reference to any decoding information;

"(4) require that the date be accompanied by a statement or phrase which clearly states that the date expressed is a sell date;

"(5) require a statement of the storage conditions recommended by the processor, if such storage conditions differ from ordinary room temperature;

"(6) prohibit a processor of any food with respect to which the Secretary has made a finding that date information is necessary from placing on a label or in labeling of such food any other information which may appear to the ordinary consumer to represent a sell date; and

"(7) prohibit a processor of any food with respect to which the Secretary has not made a finding that date information is necessary from placing on the label or in labeling of such food any date information which may appear to the ordinary consumer to represent a

sell date, unless such information is expressed in a manner consistent with the requirements of paragraph (2) through (6) of this subsection.".

SEC. 303. Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act (21 U.S.C. 343), is further amended by adding after subsection (p) thereof the following new subsection:

"(q) If it purports to be or is represented as a food for human consumption—

"(1) to which a nutrient or nutrients have been added; or

"(2) for which any claim of nutritional value is made on the label or in labeling, or in advertising or in promotion of such food;

unless the nutrition information on the label or in labeling is in accordance with regulations promulgated by the Secretary.".

SEC. 304. (a) Section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), is amended by striking out the fourth sentence thereof.

(b) Section 403(g) of such Act (21 U.S.C. 343(g)), is amended to read as follows:

"(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 of

this chapter, unless (1) it conforms to such definition and standard; and (2) its label bears the name of the food specified in such definition and standard.".

SEC. 305. (a) Section 403 (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (i)), is amended to read as follows:

"(i) (1) If its label fails to bear the common or usual name of the food, if there is one; and

"(2) In case the food is fabricated from two or more ingredients, if its label fails to bear—

"(A) the common or usual name of each such ingredient (in the order of its predominance); except that (i) spices and flavorings, other than those sold as such, may be designated as spices and flavorings without naming each such ingredient, if information concerning each spice and flavoring not designated on the label is available upon request from the manufacturer or distributor named on the label: *Provided*, That the Secretary may by regulation require certain spices and flavorings to be named on the labels or packages upon a finding that such disclosure is necessary to protect public health or to provide information useful to consumers; and (ii) subject to such conditions as the Secretary may by regulation provide, this provision shall not apply to the following:

"(a) a food which has been received in bulk containers at a retail establishment, if such food is displayed to the purchaser with the labeling of the bulk container plainly in view or with a counter card, sign, or other appropriate device plainly in view which prominently and conspicuously displays the information required to be stated on the label;

"(b) incidental additives that are present in a food at insignificant levels and which do not have any technical or functional effect in such food;

"(c) the label declaration of a harmless marker which is used to identify a particular manufacturer's product, in order to protect against disclosure of a trade secret;

"(d) closely related ingredients that may be declared by a general term or without regard to order of predominance in a manner that accurately states the nature of the ingredients;

"(e) a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than the establishment in which it is originally processed, labeled, or packed;

"(f) an assortment of different items of food which are packed in such a way that there are variations in the ingredients in different packages;

"(g) shipping containers or other transportation wrappings, tray pack displays, and transparent wrappers; and

"(h) inner packages in multicomponent food packages; and

"(B) a declaration of the percentage of any ingredient of any such food for human consumption if (i) the ingredient is an integral part of such food and is significant with respect to value, quality, nutrition, or acceptability of such foods, or (ii) the ingredient is required to be so declared by the Secretary by regulation upon a finding that such information would be useful to consumers.".

(b) Section 403 (k) of such Act (21 U.S.C. 343 (k)) is amended by striking out "paragraphs (g) and (i)" and inserting in lieu thereof "paragraph (i)".

(c) The Secretary of Health, Education, and Welfare shall conduct, or cause to be conducted (taking into consideration, and providing for representation of, views held by consumer, industry and health groups concerned with food labeling) a study of the need to amend the Federal Food, Drug, and Cosmetic Act to require that the common

or usual name of every spice and flavoring used in the fabrication of a food for human consumption be declared on the label of such food. Such Secretary shall transmit a report on the results of such study to the President and Congress simultaneously within 1 year after the date of enactment of this Act. This report shall assess the need of consumers for such information, the feasibility of requiring all such ingredients to be labeled, any potential beneficial or adverse economic or health consequences of such labeling, and the reasonableness of alternatives to the labeling of all such ingredients.

SEC. 306. Section 407 (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 347 (c)) is amended to read as follows:

"(c) No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless—

"(1) a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place; or

"(2) a notice that oleomargarine or margarine is served is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items; or

55-000 O - 75 - 4

"(3) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine.".

SEC. 307. Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391–2) is amended by adding at the end thereof the following new section:

"SEC. 903. (a) It is declared to be the express intent of Congress to supersede any and all laws of the States or political subdivisions thereof, insofar as they may now or hereafter provide for information on the label or in labeling of a food which is in addition to or dfferent from information required on the label or in labeling under section 403 of this Act or regulations promulgated thereunder, except as provided in subsection (b) of this section.

"(b) (1) Upon application of a State or political subdivision thereof, the Secretary is authorized to exempt from subsection (a) of this section any existing or proposed law or regulation for such jurisdiction as provided in this subsection.

"(2) An application for exemption under this subsection shall demonstrate that the implementation of the subject law or regulation in the applying jurisdiction will likely promote the interests of consumers therein without unduly burdening interstate commerce, and that such law or regulation is inappropriate for promulgation as a Federal requirement.

"(3) Upon receipt of an application for exemption, which shall be accompanied by any materials gathered by the applicant in its legislative or administrative consideration of the existing or proposed law or regulation, the Secretary shall publish such application in the Federal Register as a proposal, accompanied by a description of any supporting materials submitted therewith which, because of their voluminosity or other good and stated reason, are not suitable for publication at that time. Such supporting materials shall be available for public inspection at an appropriate location identified at the time the application is published as a proposal.

"(4) The procedure for consideration and action upon a proposed exemption shall be pursuant to section 553 of title 5, United States Code, except that the Secretary shall allow at least 60 days for public comment and shall provide interested persons with an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, and shall keep a transcript of any oral presentation.

"(5) The Secretary shall grant the proposed exemption upon finding that the subject law or regulation will likely promote the interests of consumers within the applying jurisdiction without unduly burdening interstate commerce or otherwise adversely affecting the interests of all

consumers, and such action shall be subject to judicial review pursuant to section 701 (f) of this Act.".

SEC. 308. Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act (21 U.S.C. 331), is further amended by adding after subsection (t) thereof the following new subsection:

"(u) Changing, altering, or removing before the sale of a packaged food to the ultimate consumer, any statement or information required by regulations issued under section 403 of this Act to be placed on the label or in labeling of such food.".

SEC. 309. This title shall not apply to the labeling of distilled spirits, wine or malt beverages to the extent of the application or the extension thereto of the Federal Alcohol Administration Act (27 U.S.C. 201–211).

SEC. 310. The amendments made by this title shall take effect upon the date of enactment, except that the effective date for any regulations promulgated pursuant to this title shall be no earlier than the first day of the sixth month beginning after the date regulations are published as a final order in the Federal Register with respect to all new or changed labels printed thereafter, and the first day of the eighteenth month beginning after the date the regulations are published as a final order in the Federal Register with respect to all other labels.

94TH CONGRESS
1ST SESSION

S. 1168

IN THE SENATE OF THE UNITED STATES

MARCH 12, 1975

Mr. STEVENS (by request) introduced the following bill; which was read twice and referred to the Committees on Commerce and Labor and Public Welfare, jointly by unanimous consent

A BILL

To regulate commerce and protect consumers by requiring improved safety assurance measures in food manufacture and distribution and registration of producers of food.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Safety Assurance Amendments of 1975".

TITLE I—SAFETY ASSURANCE SYSTEMS

SEC. 101. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

"SEC. 410. (a) Any person who operates any establish-

ment in which food is processed (hereinafter referred to as a 'food processor') shall develop a safety a assurance system for such establishment, unless he is exempted by the Secretary pursuant to subsection (c) of this section, or is otherwine exempt under the provisions of section 413. Such system shall be set forth in writing and accessible to the Secretary within twelve months of the date of enactment of this section in such manner and simplified, efficient format as the Secretary shall prescribe. In developing such system a food processor shall, to the best of his ability—

"(1) identify those control points in the food processing operation carried out by any establishment operated by him where he determines adequate controls are required to assure that food produced in such establishment will not be unsafe or rendered injurious to health;

"(2) identify the hazards determined by him to be associated with each such point;

"(3) establish controls which he determines are adequate at each such point; and

"(4) establish monitoring of the controls which he determines is adequate at each such point.

"(b) The safety assurance systems developed under subsection (a) of this section shall be reviewed, and appro-

priate revisions made, at least annually, by the food processor involved.

"(c) A food processor shall be exempted from the requirements of this section if the Secretary finds by regulation that the establishment or type of establishment operated by such processor is unlikely, because of the nature or volume of its food processing, to create or contribute to a significant risk that food processed therein will be unsafe or rendered injurious to health.

"(d) As used in this section 'safety assurance' includes and is limited to those processing factors which bear upon whether a food will be unsafe or rendered injurious to health within the meaning of this Act.".

SEC. 102. Section 301 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new subsection:

"(q) The failure to develop, set forth in writing, or make accessible to the Secretary safety assurance systems as required by section 410 of this Act.".

TITLE II—SAFETY ASSURANCE STANDARDS

SEC. 201. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new section:

"SEC. 411. (a) If the Secretary finds that any food (or class of food) is being processed in a significant number

of establishments in such a manner as to present an unreasonable risk that the food will be unsafe or rendered injurious to health within the meaning of this Act, he shall promulgate regulations or amendments to existing regulations establishing a safety assurance standard for the processing of such food (or class of food) in order to reduce or eliminate such risk. Such standard shall specify the food or class of food in question, the nature and scope of the risk found to exist, and the procedures, including sampling plans, found necessary for the reduction or elimination of such risk.

"(b) Regulations under this section shall be promulgated in accordance with section 553 of title 5, United States Code, except that the Secretary shall—

"(1) provide an opportunity for the oral presentation of data, views, and argument on any proposal for such regulations and have a transcript kept of any such oral presentation;

"(2) make and publish appropriate findings with respect to (A) the nature and scope of the risk referred to in subsection (a), (B) the procedures specified in the standard deemed necessary to reduce or eliminate such risk, and (C) the probable effect of such standard upon the cost and availability of such food; and

"(3) publish an adequate statement of reasons of the need and basis for the provisions adopted, including

responses to objections and comments of interested persons.

An order promulgating regulations or amendments to regulations under this subsection shall be subject to judicial review in accordance with section 701 (f) of this Act.

"(c) Any person or group of persons may petition the Secretary for an amendment of or exception to any safety assurance standard so as to permit the use of procedures other than those specified in the standard. Upon a showing that any alternative procedure is equally or more effective than the procedure specified in the standard, the Secretary shall approve the requested amendment or exception. If such a petition is submitted (1) with respect to a safety assurance standard that has been published as a proposal pursuant to subsections (a) and (b), and (2) within thirty days after such publication, then the Secretary shall take final action on such petition at the time that he issues a final order with respect to the proposed safety assurance standard, and such actions shall be reviewable in the same manner as the standard.".

SEC. 202. (a) Section 301 of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new subsection:

"(r) The failure to comply with an applicable safety assurance standard established pursuant to section 411.".

(b) Section 402 of such Act is amended by adding the following new subsection:

"(f) If it was processed other than in compliance with an applicable safety assurance standard established pursuant to section 411.".

TITLE III—REGISTRATION OF PRODUCERS OF FOOD

SEC. 301. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following section:

"SEC. 412. (a) Within ninety days after the initial promulgation of regulations under this subsection each food processor shall prepare and submit to the Secretary a registration statement which shall include his name; principal place of business; the location of each establishment operated by him; and, for each such establishment, a complete list, in such form as the Secretary shall by regulation prescribe, of all classes of foods processed therein. The Secretary may promulgate regulations defining classes of foods to promote uniformity and expeditious administration with respect to such registration.

"(b) (1) Any person, upon first engaging in the processing of food in any establishment which he operates in any State, shall within thirty days after first engaging in such processing notify the Secretary and prepare and submit to

him a registration statement containing the information required under subsection (a) of this section.

"(2) Any person who has duly registered under this section shall notify the Secretary if he ceases to process or discontinues the processing of any class of food in any establishment, within ninety days of such cessation or discontinuance. Such notification shall not be required in the case of any temporary cessation of processing which is necessitated by the seasonal character of operations at the particular establishment or which is caused by temporary conditions beyond the control of such person.

"(3) Every person who has submitted a registration statement in accordance with this subsection shall within thirty days notify the Secretary of any additional establishment which he acquires or at which he commences operations in any State and which involves the processing of food. Such notice shall contain a supplemental registration statement which shall include, with respect to such additional establishment, the information required by subsection (a) of this section.

"(c) The Secretary shall make any registration statement filed pursuant to this section available for inspection by any person without charge, except to the extent that such information is a trade secret or other matter referred to in section 1905 of title 18, United States Code.

"(d) This section shall not apply to any class of food processors whom the Secretary may by regulation exempt from the application of this section upon a finding in writing that registration in accordance with this section is not necessary for the protection of the public health.

"(e) Every establishment in any State which is required to be registered with the Secretary under this section shall be subject to inspection, pursuant to section 704 of this Act.

"(f) The Secretary may by regulation provide for the registration of foreign establishments engaged in the processing of food intended to be offered for importation into the United States. Such regulations shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country, or by inspection (including written requests for information available under section 704) of a representative of the Secretary, to determine from time to time whether food prepared, packed, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any grounds set forth in section 801 (a) of this Act.

"(g) As used in this section and sections 410, 411, 402 (f), and 801 (a) of this Act—

"(1) 'name' includes, in the case of a partnership, the name of each partner and, in the case of a corporation, the name appearing on the corporation's charter or certificate of incorporation, the name of each principal corporate officer, and the name of any State of incorporation;

"(2) 'principal place of business' and 'location of each establishment' include mailing address and telephone number; and

"(3) 'processing' and 'processed' include manufacturing, processing, packing, labeling, and storing.".

SEC. 302. (a) Section 301 of the Federal Food, Drug, and Cosmetic Act is amended by adding after subsection (r) thereof the following new subsection:

"(s) The failure to register or the failure to provide any information, as required by section 412 of this Act.".

(b) Section 403 of such Act is amended by adding after subsection (n) thereof the following new subsection:

"(o) If it was processed in an establishment not duly registered under section 412.".

SEC. 303. Section 801 (a) of such Act is amended by inserting "(1)" immediately after "(a)" and adding at the end thereof the following new paragraph:

"(2) The Secretary may refuse entry of any food offered for importation into the United States which has been

processed in any establishment, other than an establishment registered pursuant to section 412 of this Act, except as provided in subsection (b) of this section.".

SEC. 304. The amendments made by this title shall take effect on the first day of the seventh calendar month which commences after the date of enactment of this Act.

TITLE IV—FACTORY INSPECTION

SEC. 401. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act is amended to add the following two new sentences after the first sentence in that section: "In the case of any factory, warehouse, or establishment in which food for human consumption is manufactured, processed, packed, or held, the inspection may extend to such records, files, papers, and processes which are reasonably necessary for a determination whether foods that have been, are being, or are about to be manufactured, processed, or packed are unsafe or injurious to health within the meaning of this Act: *Provided, however,* That the inspection shall not extend to records, files, and papers until a statement showing a reasonable need for such access has been presented, in writing, to the owner, operator, or agent in charge and such person shall have been provided an expedited opportunity to contest the reasonableness of the inspector's demand before the Secretary's designee, who shall be a person outside the operating line of command to whom the inspector reports,

and no person shall be subject to any criminal penalty for refusal to permit access to and inspection of records, files, and papers until he has been given an opportunity to contest the reasonableness of the request before a district court of the United States, and has been ordered by such court to grant such access to and inspection of such records, files, and papers, and his rights of appeal are exhausted. In any such proceeding before the district court, where the Secretary or his designee seeks access to a manufacturer's secret formulation, the court shall not order the material disclosed unless the Secretary demonstrates (a) that he has probable cause to believe that any such food product may be adulterated, and (b) that the public health or safety requires access to such formulations, and (c) that no alternative means exist for determining that violation other than disclosure of the formula.".

(b) Section 704 (a) of such Act is further amended by striking the words "second sentence" in the last sentence and inserting in lieu thereof "fourth sentence".

(c) Section 704 of such Act is amended by adding at the end thereof the following new subsection:

"(e) Trade secrets protected from disclosure by section 301 (j) of this Act, confidential information referred to in section 1905 of title 18, United States Code, and information exempted from disclosure under section 552 (b) of title 5,

United States Code, shall not be disclosed by any officer or employee of the United States, and any request for disclosure that raises issues of fact as to disclosability shall be determined by procedures which conform, as near or may be, to the procedures of the Federal Rules of Civil Procedure, rule 34. The district courts of the United States shall have jurisdiction over actions brought under this subsection, without regard to the amount in controversy, and shall expedite the disposition of such actions.

TITLE V—DETENTION PENDING SUIT FOR FORFEITURE

SEC. 501. Section 304 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new subsection:

"(g) Any food liable to seizure may be detained, pending such seizure or notification of any Federal, State, or other governmental authority having jurisdiction over the food, by an appropriately authorized representative for a reasonable period, not to exceed twenty days, if such representative concludes that the facts provide a reasonable basis to show that such food is unsafe or injurious to health within the meaning of this Act, and such food shall not be moved by any person from the place at which it is located and detained (except as the Secretary may authorize) until released by the Secretary. If the food is still being processed, and has

not been put in final form for shipment, processing may continue until the food is put in final form, but detention of such food in final form for shipment, processing may continue until the food is put in final form, but detention of such food in final form may be ordered. Any person who would be entitled to claim such food if it were seized may appeal such detention (1) to a superior official who shall be a person outside the operating line of command to whom the representative reports, and who shall conduct an informal hearing on the matter and confirm or revoke such detention within five days of such appeal, or (2) to the district court of the United States that would have jurisdiction over such seizure.".

TITLE VI—CITIZEN SUITS

SEC. 601. Chapter III of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new section:

"SEC. 309. (a) Except as provided in paragraph (b) of this section, any person may commence a civil action for mandatory or prohibitive injunctive relief, including interim equitable relief, on his own behalf, whenever such action constitutes a case or controversy against the Secretary alleging a failure of the Secretary to perform any act or duty under this Act, without regard to the amount in controversy.

"(b) No civil action may be commenced under paragraph (a) of this section prior to sixty days after the plain-

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tiff has given notice of the alleged violation to the Secretary in such manner as the Secretary may by regulation require.

"(c) The court in issuing any final order in any action brought pursuant to paragraph (a) of this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such an award is appropriate.

"(d) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any regulation or order or to seek any other relief.

"(e) For purposes of this section, the term 'person' means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State.".

TITLE VII—EFFECT ON STATE LAWS

SEC. 701. The Congress hereby finds and declares that in order to make regulation of interstate commerce in foods effective and to avoid varying and conflicting State and local regulations which unduly burden interstate commerce it is necessary to provide for uniformity in food laws and regulations and in their enforcement by Federal, State, and local officials with respect to food, drugs, devices, and cosmetics introduced into, or held for introduction into, interstate commerce.

SEC. 702. Chapter IX of the Federal Food, Drug, and

Cosmetic Act is amended by adding at the end thereof the following new section:

"SEC. 903. (a) The requirements made by or under the authority of this Act, as now in existence and as hereafter amended, shall apply to all foods, drugs, devices, and cosmetics introduced into, held for introduction into, or held for sale after shipment in interstate commerce. The requirements of that Act may be enforced by appropriate procedures in Federal and State courts by such officers or employees as are authorized under Federal and State laws to seek or compel compliance with food, drug, device, and cosmetic legislation.

"(b) Whenever the Secretary or the Governor of any State, or his designee, proposes a change in the requirements of this Act, he shall consult his State or Federal counterparts and shall include in the petition to the Congress for such amendment or amendments a statement of the views of such counterpart officials on the proposals. Upon the request of the Governor of any State, the Secretary shall present any proposed change in the uniform food, drug, device, and cosmetic legislation to the Congress through the appropriate clearance channels within the executive branch along with the Secretary's recommendations, unless he finds that the proposal is clearly a State or local matter which, if enacted into State

or local law, would not burden or unduly interfere with interstate commerce.

"(c) No State or local law or regulation which purports to impose requirements which are in addition to or different from the requirements made by or under authority of this Act, as now in effect or as hereafter amended, may be applied to or enforced against any food, drug, device, or cosmetic which is introduced into, held for introduction into, or held for sale after shipment in interstate commerce, except that a State in which a food is processed may, for the purpose of regulating the quality of such food when produced in the State, impose quality requirements which are in addition to or higher than those set forth in the standards issued under section 401 of this Act.".

TITLE VIII—CRIMINAL AND CIVIL LIABILITY

SEC. 801. Section 303 (a) of the Federal Food, Drug, and Cosmetic Act is amended by adding the words "knowingly and willfully" before the word "violates".

SEC. 802. Chapter III of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new section:

"SEC. 308. Any person who violates a provision of section 301 shall be subject to a civil penalty of not more than $10,000 for each violation.".

TITLE IX—INGREDIENT LABELING

SEC. 901. (a) Section 401 of the Federal Food, Drug, and Cosmetic Act is amended by striking out the fourth sentence thereof.

(b) Section 403 (g) of such Act is amended to read as follows:

"(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 of this chapter, unless (1) it conforms to such definitions and standard; and (2) its label bears the name of the food specified in such definition and standard.".

SEC. 902. Section 403 (i) of the Federal Food, Drug, and Cosmetic Act is amended by striking out "if it is not subject to the provisions of paragraph (g) of this section unless its label bears" and inserting in lieu thereof "if its label fails to bear".

SEC. 903. Section 407 (c) of the Federal Food, Drug, and Cosmetic Act is amended to read as follows:

"(c) No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless—

"(1) a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to

be read and understood by the ordinary individual being served in such eating place, or

"(2) a notice that oleomargarine or margarine is served is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items; or

"(3) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine.".

TITLE X—EXEMPTIONS

SEC. 1001. (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding the following new section:

"SEC. 413. Sections 410, 411, and 412 shall not apply to—

"(a) any processing subject to the exclusive jurisdiction of the Secretary of Agriculture;

"(b) processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises;

"(c) processing of distilled spirits, wine, or malt beverages as defined in the Federal Alcohol Administration Act (27 U.S.C. 201–211);

"(d) any establishment engaged exclusively in the handling of fresh fruits and vegetables in their raw,

unpeeled form, or any vessel engaged exclusively in fishing operations.".

(b) Section 201(f) of the Federal Food, Drug, and Cosmetic Act is amended by inserting after "animals," the following: "except that in sections 410, 411, and 412 of this Act such terms shall not include articles used for food or drink for animals.".

Senator Moss. Senator Kennedy is not able to be with us this morning and asks that his remarks be placed in the record at this point.

[The statement follows:]

STATEMENT OF HON. EDWARD M. KENNEDY, U.S. SENATOR FROM MASSACHUSETTS

Today we begin hearings on S. 641, the Consumer Food Act of 1975, and S. 1168, the Food Safety Assurance Amendments of 1975.

Who would not agree with the goal that the safety and cleanliness of the American food supply must be strongly assured? The purpose of these hearings is to consider testimony from interested parties on just how we can better reach this goal.

For years now, I have joined with my esteemed colleagues, Senators Moss, Magnuson, Philip Hart and Javits, in studying the threats to food safety in food processing. In fact, last year we worked to bring a strong food safety measure through the Senate.

It's about time we get food safety in this country. The American public should no longer have to assume the risks of death and injury from mercury in fish or from a can of Bon Vivant soup. The hazards of botulism and other food poisonings must be made a risk of the past. Exposure to harmful chemicals and to rodent hairs and animal feces should no longer be tolerated.

S. 641 is landmark legislation designed to better ensure that action is taken to reduce and to eliminate risks and potential risks to health from food.

This bill contains strong measures to protect the public's freedom from contaminated and adulterated food.

It requires the Secretary of HEW to institute a safety assurance program and to develop standards throughout the industry. It requires the registration of all food establishments and the inclusion of much-needed information on food labeling to facilitate consumers' decisions.

This bill recognizes the fact that food manufacturing is a process and that there must be safety assurances from the start to the finish.

An integral part of S. 641 is that the manufacturers themselves would be primarily responsible for food surveillance, with the FDA having a role of checking up on the factories to insure industry compliance to the established standards. This is a logical posture since a manufacturer should stand behind the cleanliness and safety of his food product. If a manufacturer fails—he should be severely punished. Food is a source of health and life—not a source of sickness and death.

Senator Moss. We have a distinguished group of witnesses.

The Senator from Minnesota is sitting with the Panel this morning and indicated that he would like to make an introduction and he has to leave because he has a conflict of schedule, and I will therefore recognize him at this time.

OPENING STATEMENT BY SENATOR MONDALE

Senator MONDALE. I thank the Chairman for his remarks, first of all for calling these hearings and for his leadership in this field, and permitting me to appear out of order to make this introduction.

Mr. Chairman and members of the committee, I am delighted to introduce Mr. Terrance Hanold, who is chairman of the executive committee of the Pillsbury Co. I think he is one of the nation's leading business statesmen. He served as president of the Pillsbury Co. and as national chairman of the Board of Better Business Bureaus and as the president of Food and Drug Law Institutes, and in my opinion has proven to be one of the most enlightened leaders in

the food industry. He has demonstrated enormous sensitivity to the needs of the consumer. In particular, Mr. Hanold has been a leader in the field of nutrition labeling and it was his efforts that led the Pillsbury Co. to be the first company in the United States to start a program of full nutritional labeling on food packages. He was also instrumental in developing the first food nutrition policy.

Mr. Hanold has played a major role in the effort to improve food surveillance and has been actively pressing for the first major overhaul of the law in this area for 25 years.

I am delighted that he is with us today. I know his testimony will be of great importance and interest to our committees.

The State of Minnesota is very proud of the many contributions he has made for a more effective consumer program and I commend his testimony to the members of the committee.

Senator Moss. Thank you very much, Senator Mondale, for the introduction of Mr. Hanold and we do look forward to hearing from him. I was pleased to be introduced to him personally before the hearing got underway and we will certainly welcome hearing his testimony. The position that he holds with one of our great companies producing and distributing food in this country makes it very necessary that we hear what he has to tell us. We look forward to hearing from him and welcome him to the committee.

We are having a bit of a problem with a quorum, they tell me, and I am trying to think of the best way to resolve it.

[Discussion off the record.]

Senator Moss. Thank you.

My colleagues who sit on the committee will go and complete the quorum in another committee meeting .

There really ought to be 200 Senators so we can get all these things going at the same time. It always seems strange to me when we are accused to doing nothing, but we can't even attend all the meetings that we have with the hours there exist in the day.

Our first set of witnesses appearing here this morning are: The Honorable Alexander Schmidt, Commissioner of the Food and Drug Administration; accompanied by Sam Fine, the Associate Commissioner for Compliance; Richard Merrill, General Counsel of Food and Drug; Howard Roberts, Acting Director of the Bureau of Foods, and I don't know whether I have accounted for them all. If not, Dr. Schmidt could introduce anyone I overlooked who does not appear on my text.

Obviously, we have great pressure of time. We are pleased to have full written statements in most instances and where possible I would ask the witnesses to summarize their written statement because all of those will go in the record in full and be available to the committee for study. We would like to have the witnesses, if possible, highlight and emphasize points that they think should be underlined, particularly for the attention of the Senators who sit on the Subcommittee.

And we now recognize Commissioner Schmidt and ask him to go ahead.

STATEMENT OF HON. ALEXANDER SCHMIDT, COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY SAM FINE, ASSOCIATE COMMISSIONER FOR COMPLIANCE; RICHARD MERRILL, CHIEF COUNSEL; HOWARD ROBERTS, ACTING DIRECTOR, BUREAU OF FOODS; STEPHEN McNAMARA, ASSOCIATE GENERAL COUNSEL FOR FOOD; AND ROBERT WETHERELL, DIRECTOR, OFFICE OF LEGISLATIVE SERVICES

Mr. SCHMIDT. Thank you very much, Mr. Chairman.

On my far left is Mr. Stephen McNamara, the Associate Chief Counsel for Food and on my far right is Mr. Robert Wetherell, who is Director of our Office of Legislative Services. And everyone else you have introduced.

Senator Moss. Thank you. We welcome all of you here before the Committee.

Mr. SCHMIDT. Because our statement is fairly long, I will accept your invitation to summarize, and what I will try to go through the statement quickly and I hope not too cryptically give our feelings on these two bills.

As you mentioned, there was a bill last year similar to one of these which we discussed before you last year, and at that time we stated that the authorities we needed were for records inspection, for records reporting, including food surveillance procedures for firm registration, subpena authority, administrative detention authority, and certain provisions to expand or clarify our food labeling requirements.

At this time we still believe that the additional authorities I mentioned are needed if we are more effectively and efficiently to insure the integrity and safety of the Nation's food supply.

I might mention one or two actions during the past year which do address certain provisions in both S. 641 and S. 1168.

We have always maintained our regulations that we have issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act are substantive and do have the full force and effect of law. On the other hand, certain parts of the food industry have contested that view. Segments of the food industry have maintained that section 701(a) regulations that we have promulgated are merely interpretative statements, enforceable only on a case-by-case basis.

And here I suppose I would make my first general point, and that is that in certain areas that are addressed in the testimony we may feel that we do have the authority to do a certain thing. But in those instances in which the authority has been contested, we would feel there would be merit to our authority being confirmed and set down in the legislation. And this is a general principle that you will find throughout our statement.

So that while we do have a court of appeals decision that did uphold our interpretation of the legal effect of 701-type regulation, we would feel that our authority to adopt food safety standards—we would want to be very sure that legislation expressly conferring authority to adopt food safety assurance standards could not be interpreted as implying that FDA does not have power under section

701(a) to adopt substantive rules to enforce other provisions of the act.

Now, two other things that we have finalized during the past year, our freedom of information regulations and our procedural regulations I would call attention to and request permission to submit for the record.

These regulations, when coupled with the types of information that we provide in our annual reports and in our budget reports and in our publication and compliance programs we feel negate the need for the mandatory disclosure provisions set out in the two bills under consideration, namely in 641 the mandatory publication of an annual safety assurance plan we feel is unnecessary, as are the provisions for citizen suits against the Secretary or food processor which we feel would present some legal problems for us.

The mandatory notification with the right of appeal prior to the right of disclosure of information relating to food, the prohibition against disclosure of certain information—these last two items we feel we have addressed quite adequately in our freedom of information regulations.

Both bills recognize, as do we, that the burden of assuring the wholesomeness of foods rests primarily with the food industry, and specifically with food processors.

S. 641 requires food processors to implement, maintain, and comply with safety assurance procedures. These safety assurance procedures would apply to all matters of adulteration within the meaning of section 402(a) of our act.

I would emphasize the importance that we place on having all matters of adulteration, not just safety matters, included in any legislation passed.

We also support the provisions of title I of S. 641 for administrative detention of food, for our subpena authority, for mandatory notification of recalls that might be undertaken by the industry, the inspection of records of food establishments and records and reports authority.

It is essential that our staff possess sufficient authority to determine adequately and accurately the methods by which food is being processed. Our present authority is too limited and we need to be able to inspect pertinent records in plants and have records submitted to us.

I think it is also important that FDA be able to obtain needed information without having to send out one of our inspectors each and every time it is believed that such reports or records may shed light on a potential food hazard.

We have opposed comparable sections of S. 1168. That bill would merely provide for the establishment of a safety assurance system with no concomitant requirement that food processors maintain and comply with such a system once it has been established. Furthermore, such safety assurance systems would extend only to matters demonstrably injurious or hazardous to health, but not sanitation matters. And this is the point I made a month ago. We feel we must extend our authority into areas of filth in food and so on.

Furthermore, S. 1168 would impose unwarranted restrictions on factory records and reports, and subpena authority.

Moving on to food coding, we fully support the establishment of a uniform system of coding that would allow us to take effective regulatory action. We feel we presently do have the authority to require food coding pursuant to section 404 emergency control, our adulteration provisions, and our rulemaking authority. But again, as I pointed out in my general statement in the beginning of my remarks, we would not be opposed to having such authority expressly set out by statute and I would prefer actually that that take place.

We feel, however, the mandatory requirement to provide consumers with coding information is unnecessary since such information is readily available under our freedom of information regulations.

S. 1168, as you know, does not address food coding.

As to food labeling, we support the need for fully informative labeling as to the contents of the food that consumers buy. We don't object to having discretion to order declaration of individual spices and kavors, but we do object to the mandatory requirements to conduct a feasibility study.

We are already reviewing spices and flavors under our GRAS review and feel this would be adequate.

We also object to specific listing of exemptions from ingredients set out under the ingredient labeling provision.

And to cover a number of comments generally, we would prefer that Congress would set out the objectives we are to meet but not be as specific as some of these provisions are in either bill in directing precisely how we meet those objectives. We are concerned that some of our ability to move quickly to meet the needs of safe food might actually be hindered by expressly setting out how we must go about something.

S. 641 provides specific authority with respect to percentage ingredient labeling in an area where, again, we feel we now have general authority.

Again, we do not object to having the authority explicitly spelled out, but again we would prefer to set out details by regulation rather than by having the details set down in legislation.

As you know and as has already been referred to, we have already issued comprehensive regulations requiring a specific format for nutrition labeling, requiring nutrition labeling where nutrients are added or where nutrition claims are being made.

These provisions of the bill would serve to make explicit our current authority. This is, again, S. 641, rather than S. 1168.

S. 641 also creates a rebuttable presumption that all food is in interstate commerce for purposes of seizure. Since our experience has shown that virtually all food is in fact in interstate commerce, we would feel that this provision is good and we could conserve resources if we were relieved of the burden of having to collect documentation of interstate shipment of food.

We continue to support the proposal for food registration generally, feeling that food firm registration is important. And we spoke to this at length last year. However, in view of the present budgetary constraints and the general moratorium on new spending programs set by President Ford, we would be unable to implement

the mandatory programs in fiscal year 1976. And so, after much discussion within the administration, we feel that we must request that action on the food firm registration be deferred until such time as the administration's budgetary constraints would permit Food and Drug Administration to take on the new responsibility.

I personally regret having to ask for a deferral of such authority, but I understand the economic constraints that the President is working under and feel that there is cause to ask for a deferral.

Now, there are a number of provisions of both bills that we do oppose.

Title I of S. 641, for example, provides that in case of raw fruits and vegetables, safety assurance procedures and standards would be limited to risks of adulteration for filthy, putrid, or decomposed substances and from handling under unsanitary conditions. And we would oppose this restriction of our authority which would prevent development of producers and standards for produce relating to some very significant types of adulteration, such as aflotoxin in peanuts.

We also oppose a provision of title I of S. 1168 which limits safety assurance to include only those processing factors which bear upon whether food would be unsafe or injurious to health.

In establishing safety standards and procedures, it is important that the public be protected from all adulterated foods—and again I referred to this earlier in my remarks.

S. 1168 does not authorize the development of safety procedures and standards which relate to processing which consist solely of the sale of food in retail establishments for consumption on or off the premises. It is our understanding this language was not intended to prevent the development of standards for safe food handling in restaurants.

We oppose the publication annually of safety assurance assessment reports. We feel this would be unnecessarily burdensome to the objectives of the legislation.

For similar reasons we would oppose S. 641's 4-year plan as being unnecessary.

I think that we do now, particularly with our new procedural regulations, lay out fully the plan that we use.

We would also oppose the requirement for annual inspection of food firms as it would require an additional $19 million just for the inspection program and this would not include the cost for additional supporting activities that would have to go on.

While S. 641's advisory committee provisions are better than the old S. 2373, we feel that a statutory authorization for advisory committees would be unnecessary and might well limit the flexibility that we now have in establishing advisory committees. We have a National Food and Drug Advisory Committee. We have two or three other food advisory committees that we are now using to help us in important areas. And we believe that we have all the authority that is needed to seek the help of advisory committees. And I would assure the committee that we do use advisory committees and believe their use is important. But, again, we would prefer to have the details of how the agency would use advisory committees left to us.

On the subject of citizen civil actions, both bills would permit citizen civil actions. S. 641 would permit private plaintiffs to direct our enforcement policy and control our litigation priorities, however. And as I said earlier, this would present us with some legal difficulties.

We would have to monitor and participate in all these kinds of actions because we could not take a risk of allowing unattended private litigation to develop controlling case law in the food area. And therefore we would be concerned about these provisions.

In addition, our new procedural regulations, coupled with the availability of judicial review of our actions, provide ample opportunity for citizens to exert influence on the entire range of our activities.

We have expanded consumer protection by developing formalized work-sharing arrangements with cooperation State and local food and drug officials. We would have serious concerns that these State and local officials would not agree to join with us if they, as agents of FDA, were subjected to the liability of civil suits. Again, this is another concern on our part.

In regard to the civil money penalties, we are concerned about the substitution of civil money penalties for any of the civil sanctions now authorized by the act. We now use injunction and request recall and initiate seizures which seem to us to be adequate. In particular, recalls operate directly to eliminate violative products from the market or to stop unlawful practices. We have, however, for several years recommended increases in the present criminal penalties in order to being the criminal penalties more into line with those more recently set into legislation.

In terms of criminal liability, S. 1168 would amend the Federal Food, Drug and Cosmetic Act to provide that only when a person knowingly or willfully violates the acts will criminal penalties be applicable. This added requirement would apply to violations involving all drugs, devices and cosmetics, as well as to those involving foods. We strongly oppose this provision which would eliminate a central feature of protection presently afforded the public.

And I recently had the experience of telling a traffic policeman that I was unaware of my having been over the speed limit and that I certainly had not intended to be over the speed limit. And he was singularly unimpressed with this argument, and somehow or other we kind of feel the same way.

We have consistently exercised sound discretion, in determining when to seek imposition of criminal sanctions for violations of the act, and we have prosecuted offenders only when there has been a continuing source of violative conduct or flagrant violation of the law.

In regard to trade secrets and disclosure of information, section 112 of S. 641 would amend our act to prohibit public disclosure of trade secrets and certain other information relating to food except when relevant to judicial proceedings.

It is our experience under our regulation that we receive around 50 information requests per day, and a large percentage of our requests involve trade secrets. It is currently our practice to provide notice to the originator of the information involving a close question as to whether or not a trade secret is involved.

We feel quite strongly that we would have essentially an impossible task in the freedom of information area with the release of information were there a mandatory requirement in each and every case where someone might claim something to be a trade secret—if we had to go back and check. I have found that most of the questions are quite simple and readily resolvable and equitably resolvable by our own employees.

We have in the past asked for travel expenses for State trainees, and at this time are changing our testimony to oppose such a provision, again principally because of the money policies of the administration and the general trend toward having user charges for training activities.

We oppose the provisions S. 641 which would totally exempt from regulation under that bill the processors of alcoholic beverages to comply with the bill's food establishment registration requirement, and the exemption of these products from the labeling provisions of the bill.

We also oppose S. 1168's total exemption of these beverages from processing requirements.

We would also oppose any exemption of these products from the ingredient labeling requirements that apply to other foods.

The Department of HEW and the Treasury Department are presently working together on labeling provisions for alcoholic beverages, and we would not want to hamper such efforts.

Finally, in regard to preemption and enforcement in State courts, S. 641 would provide for preemption of all State laws except States could be granted an exemption from supersession where the State imposes a higher standard of performance.

Title VII of S. 1168 would go even further and would prohibit State or local laws or regulations which impose requirements which are different from any requirements made by or under the authority of the act, except that a State could impose quality standards for a food which are in addition to or higher than those set forth in standards issued under section 401 of the act.

We have long favored uniform Federal and State food and drug laws and regulations and we believe there are a variety of mechanisms capable of achieving this objective and that not all such methods have been exhausted at this time.

In conclusion, we share the concern of your subcommittee that our food supply must be as safe and wholesome as possible, and we appreciate your continued interest in increasing our authority to regulate the Nation's food supply. Toward this end, the administration has, during the past 4 years, provided a substantial increase in FDA's food budget and has transmitted to Congress several legislative proposals to improve the quality of foods and food labeling.

And finally, I would recognize the very great support of the entire Congress in increasing the resources the Food and Drug Administration. We are very appreciative of the support, both in the resources area and in the area of legislative authorization that has been afforded us by Congress.

Mr. Chairman, I appreciate the opportunity to present this statement. I know I have been quite cryptic in some areas and I and my col-

leagues would be pleased to try to answer any questions that you may have.

Senator Moss. Thank you very much, Mr. Commissioner. I appreciate your statement and I appreciate your summarizing it because of the time factor. We will, of course, study it in close detail as part of our record in its full form.

And I also want to say that I appreciate that you are generally supportive of the legislation that is before you, although you clearly have pointed out what you consider to be deficiencies in these two bills and have indicated parts that you would not support.

It is going to be up to the committee and the Senate and the entire Congress to weigh your views with those of other witnesses who will appear before us and finally make a decision on these legislative proposals.

Let me ask you: Will the Administration be sending up a legislative proposal, or should we take your comments in support of certain sections of S. 641 and the history of S. 3012 in the last Congress as examples of the Administration's wishes with regard to a food safety bill?

Mr. SCHMIDT. To the best of my knowledge at this time, the Administration should be sending forward some legislative proposal in this area. As of very late last night, what I have said here today and what is in our testimony and what would be proposed by the Administration are congruent, and I believe totally consistent.

Senator Moss. Well, as an example, you now say you oppose the travel expenses for State trainees, and last year the Administration sent that up to us. It was the Administration's proposal then.

Mr. SCHMIDT. That is correct. Anything that would be sent up this year would call for user charges. In other words, the State would have to pay for the travel expenses, any expenses incurred in the training of State inspectors.

In years past we felt that Federal funds used for this purpose would, in a sense, be a carrot, and would allow far more State inspectors to be trained, and we wanted to see that.

Some States obviously have their own financial problems and we could obviate those by paying these costs.

But it is a matter now of priorities, and the Administration's position is that the States should bear the cost of training State people.

Senator Moss. Maybe we should increase the revenue-sharing money we send back to them so States could pay it.

Mr. SCHMIDT. As long as it didn't come out of my budget, I wouldn't object.

Senator Moss. Do you have any concern that there would be difficulty in managing food surveillance considering the authority granted by section 410(c)(1) and the exemption authority under section 410(c)(5)? Will an inspector be in a position of not knowing whether a safety standard or safety procedure is in effect in a given plant?

Mr. MERRILL. Senator Moss, I don't see that as being a product of the proposed legislation. There certainly would be an information problem we would have to solve in seeing our inspectors were fully in-

formed of the status of particular establishments or the applicability of particular standards to foods. But I don't view the bill as it is now drafted as creating that problem. That is a logistical problem we have in getting information to the field all the time.

Senator Moss. The problem of appropriately trained inspectors and informed inspectors rather than a legislative problem then?

Mr. MERRILL. That would be my view.

Senator Moss. All right.

Your testimony, Commissioner Schmidt, is the Administration's view, as I take it, and of course your people have responsibility for assuring safety of our food supply.

With regard to subpena authority and access to records, some in the food industry suggest that these authorities be limited only to matters bearing on adulteration.

What would be the result of this situation, if we limit it just to adulteration?

Mr. SCHMIDT. Well, there are a number of different kinds of hazards that may arise, and we would be concerned about any limitation of the authority for a couple of reasons.

One is that generally the restriction has to be defined in courts, and the meaning of such limitation is the subject of legal actions challenging the Food and Drug Administration's activities.

Furthermore, as I stated, there are a variety of things ranging from naturally occurring toxicants, such as aflotoxin, on to a range of manmade hazards that may not be included in restrictive wording.

Senator Moss. So adulteration is too narrow a term; is that what you are saying?

Mr. MERRILL. We would want to be very sure that the authority we got embraces all the violations that are described as adulterations in section 402 of the statute. It seems to me there might be an administrative difficulty. You might not find the records segregable. There might be some that bear on misbranding as well.

I think our principal concern is that the adulteration concept not be shrunk and restricted to particular segments of that broad and detailed statute. I think that the limitation to adulteration, if it embraces all of the adulteration prohibitions in the statute as a legal matter, would not be a difficult one.

As a practical matter, such as getting things segregable and obtaining immediate access which is very important, that could present some problems.

Senator Moss. Well, if your authority is limited to areas solely relating to information bearing on adulteration, would not much of that information be similar or identical to information bearing on misbranding? You could use adulteration subpena authority for records access to find situations of misbranding?

Mr. SCHMIDT. I think the problem there would principally be one of definition and of challenge over and over again to our being able to do so.

Mr. MERRILL. Perhaps one solution to that concern would be very clear authorization that we had authority to prescribe the types of records that would be required bearing on the question of adulteration, so we would not be faced with resistance or refusal to disclose

on the ground that it really didn't bear on adulteration or that it included material relating to misbranding that we were not entitled to see, and we would have to wait until they sanitized it. I would like to emphasize in the case of a recall, prompt access to those records is necessary, and if you have to litigate over whether or not it is disclosable, the damage could very well be done.

Senator Moss. Commissioner, I am somewhat concerned with your objection concerning exemptions from ingredient labeling. These provisions which appear on page 42 of S. 641 were incorporated in the bill last year at the suggestion of the FDA staff working on the teechnical aspects of the bill. Your staff is far more familiar with the day-to-day aspects of the law and suggested there was a need to incorporate paragraphs (a) through (h) in the bill.

Now you say that these should be left to regulations issued by FDA.

For the record would you submit to us a statement [1] of which provisions, (a) through (h), differ from current regulations?

Mr. SCHMIDT. Yes, we would be happy to.

Senator Moss. Thank you.

Mr. MERRILL. Senator Moss, on that, our concern is not that we disagree in principle with the exceptions that are listed there, because many of them do track our regulations, but we are concerned with their solidification in statute, if I may use that phrase, that we should not, if circumstances change, be able to narrow or interpret or confine one of the exemptions that was laid out in the law.

Senator Moss. Let us talk about exemptions from title I. I appreciate your comments about alcoholic beverages and fresh fruits and vegetables. What about incorporating programs which already have effective compliance programs underway as safety-assurance procedures? I note that there is a shellfish program, a Federal-State dairy program, and the National Marine Fisheries continuous inspection program already underway.

But I would not want to limit your authority over these activities by affecting your abilities under section 410(c).

Would we not reduce the burden on industry's already effective programs by eliminating them from the requirements of section 410(a)?

Mr. MERRILL. I can't speak with familiarity; perhaps Mr. Fine can—about the operation and effect of the various programs. It seems to me one way to respond to that problem would be to put in the bill authorization for us to exempt ongoing programs of that kind, rather than attempt to identify, again by statute, which programs should qualify for the exemption.

Senator Moss. Authorize you to exempt them if they have an ongoing——

Mr. MERRILL. If we find an ongoing program meets the basic safety objectives of the law.

Mr. FINE. Senator, we have a memorandum of understanding with the National Marine and Fisheries Service of the National Oceanic and Atmospheric Agency. The kind of service they provide is inspection for a fee. We have agreed to cut back on our inspections under

[1] The statement was not received as of press time, August 6, 1975.

the terms of that agreement. We are exchanging information with them. We have the same objectives as you do. We want to eliminate duplication of effort and there is no point in their inspecting and our inspecting at the same time. We are exchanging information. They are carrying out a cooperative—kind of a cooperative quality-control program with the industry.

We have just seen it reported recently in the press that they are embossing a seal on the end of the cans of some of the fish products.

We are familiar with this. I carry on liaison with the top officials of the National Marine and Fisheries Service about this. We know what they are doing and believe we can eliminate some of the duplication that you are talking about.

Senator Moss. Rather than exempting the programs, could these standards of those programs be incorporated under the act?

I fully appreciate this necessity not to just have layers of inspection one on top of another. Obviously that would not only be wasteful but a harassment to those industries who are being inspected. I am just wondering how to handle it, whether it should be exempted entirely or whether it should be incorporated under the act—whatever standards they have?

Mr. FINE. They accept the requirements of the Food, Drug, and Cosmetic Act in so far as adulteration and misbranding are concerned, and this is also true with the Bureau of Alcohol, Tobacco, and Firearms in the Treasury Department on the alcoholic beverages.

I can say to you we have by and large delegated to the Bureau of Alcohol, Tobacco, and Firearms control of the alcoholic beverages. We don't duplicate their activities. They are modernizing the labeling of those beverages in accordance with the requirements of the Food, Drug, and Cosmetic Act. Consumers have expressed interest in this. We have had many meetings to discuss it.

Our most recent formal agreement says they will require labeling in compliance with the Food, Drug, and Cosmetic Act. But they will do it.

Senator Moss. I see.

I would like to talk now about your views on the civil penalties in S. 641 and S. 1168.

There is much concern in Congress with the application of vicarious liability. A firm should be subject to penalties for violation of the act, but many people question the fairness of subjecting a corporate executive, who is not negligent, to criminal penalties for an activity which violated the act and occurred without his knowledge.

What are your views on the application of criminal liability to one who has tried to comply with the act but without knowledge an employee committed an act which violated the Food, Drug, and Cosmetic Act?

Mr. SCHMIDT. Again, as I said, we feel quite strongly that the strict criminal liability provisions should be left alone. And the reason for that is that, number one, the subject areas we are dealing with are very important. Food safety is a terribly important subject.

Second, we feel that corporate officers have the same responsibility to be aware of their obligations as I do to watch the speedometer on my car, as I mentioned earlier, only semifacetiously.

The idea that a corporate official is not aware of his responsibility in being sure that things are done properly is not foreign to me.

Senator Moss. He might be grossly negligent in not knowing that certain things were going on, but couldn't you have a situation where something happened that was quite out of the ordinary, not in the regulations or directions, but he would have liability for what an employee did?

Mr. SCHMIDT. Yes; but again I have been looking personally at each and every recommendation for criminal prosecution that has come from the agency, and it was a very instructive experience. Because what I found generally was that when I finished reading them I was furious.

There would be in essentially each instance repeated violations of the Food, Drug, and Cosmtic Act, often repeated refusals to accept registered letters from us or repeated ignoring of regulatory warnings or letters we had issued. And I can state personally that the agency has been very responsible in not recommending prosecution for the unusual or the singular event, but really only in relatively gross instances of violations of the law.

And I feel that the agency can be responsible in exercising its authority, first of all, and, second, that the authority is necessary. Because otherwise people would hide behind a corporation and we would lose a very important way of enforcing the law.

Mr. MERRILL. Senator, if I may, as you know there is a case pending in the Supreme Court involving the applicability of the criminal liability sections of the Food and Drug Act.

In that case we argued it would be open to a defendant who could demonstrate that he was completely unaware and incapable of controlling the situation—that is, one of the unusual situations you talked about—to estabish that in court as a defense. We wouldn't object to that. What we want to be able to do is to have the rigorous effect of the criminal sanction apply in those situations where people are capable of preventing the hazards to the consumer and don't take the steps that are necessary to see that it is done.

Senator Moss. Well, if Congress modified the application of the vicarious criminal liability, wouldn't you need additional important remedies, such as the civil monetary penalty which could be applied without a finding of knowledge or intent?

Mr. SCHMIDT. Well, again we find that with seizure, injunction, and the use of recalls, we can carry out our goal of removing violative products from the marketplace. And we feel that these are more effective than a modest civil penalty would be. And we would be concerned that the civil monetary penalty would interfere with our ability that we now have to seize violative products and get an injunction. And we would rather leave the playing field without that player. I am afraid we would keep bumping into him.

Senator Moss. Commissioner, you discussed the need for registration of food establishments but then you said, "We cannot support the provision at this time."

Now, should you have that authority or shouldn't you? And how should we construe these comments along with the other points of your testimony?

Mr. SCHMIDT. Well, to answer your direct question, the answer is, "Yes," we should have them, but when we can afford them.

This is obviously, in a sense, kind of an embarrassing switch, except that I am really never embarrassed by reality.

We have learned from our Drug Listing Act that this kind of activity is very expensive. And as I look at the budget of the Food and Drug Administration, the number of things we are being asked to do, the increasing size of the job we have to do, it is clear to me that the thing I have to worry about most is to be given additional responsibilities without the additional resources necessary to carry out those responsibilities.

And we estimate it would cost a minimum of around $3 million to do a good job of registering food firms, depending on the details of the processes, and so on. And I do not now have $3 million in the agency that I could pull away from drug safety or medical devices, and so on. I do not have the ability within the agency to come up with $3 million to pay for this.

And President Ford has, as you know, declared a moratorium on new spending programs for fiscal year 1976.

So if I have, on the one hand, the necessity to pull out of some place in the agency $3 million, on the other hand, if I do get mandatory authority, then I would respectfully request that be deferred until we can afford to do it.

There are some things I ought to be doing in my family that I am not doing now because I can't afford to. And I am not embarrassed by that; it is a fact. And we are in sort of the same situation here with this.

Senator MOSS. If you are given the authority to do it but not given the funds to do it, would that be an embarrassment that you say, "There are no funds; I can't do it"?

Mr. SCHMIDT. The ideal situation would be for us to have the authority but not the mandatory provision that we do it this year.

Senator MOSS. You would like the authority without the mandate to make it effective at once?

Mr. SCHMIDT. Yes; then we could progressively implement it or we could look at how we could set it in place over the next few years.

But I would be terribly upset if we were told we had to do it next year and then we got no additional resources. Because I would get to the point where I have to ask the public, "All right, choose what you want to suffer from, because we are going to have a trade off here."

And I really don't like those trade offs.

Senator MOSS. Are there any measures or authorities that you feel would be necessary for the agency to have which are not included in S. 641?

For example, do you feel something should be done about the hearing procedures which resulted in cases such as the peanut butter fiasco?

Mr. SCHMIDT. We will have our first test of our new general counsel from Utah. Peter Hutt would be jumping up and down right now with an invitation like that. We will see what Mr. Merrill does.

Mr. MERRILL. I share Mr. Hutt's lack of enthusiasm for procedures of that kind. I think we have been pretty successful—some people would say too succsesful, in recent years—in minimizing the number of protracted hearings of that kind. And our new procedural regulations which have been submitted for the record offer and in some instances require a number of alternatives designed to permit quick and prompt exploration of the facts in controversial situations without the necessity of holding a judicial trial.

There are provisions in the bill as it is now drafted that trouble me just a little bit with respect to the procedures that are to be followed for the adoption of a plan, for the adoption of safety assurance standards. There is language in there referring to the informal rulemaking provisions of the Administrative Procedures Act, section 553. But there is also language referring to the phrase "after opportunity for a hearing."

I don't know what the drafters of the bill have in mind. I think we would prefer the authority to issue this plan and adopt these procedures through informal rulemaking which is the method we customarily adopt. We certainly would like to devise other kinds of procedures than protracted peanut butter hearings for resolving such issues.

I don't see many issues of that kind on the horizon but if the committee is interested in pursuing that I am certainly interested in sitting down and helping them tinker with the language.

Senator Moss. In the Comptroller General's report he concludes:

> We believe that a new regulatory measure, recall authority, is needed. This measure would combine the scope of voluntary rulings of the enforcement authority of seizures by adding an element of speed.

Do you think that would be desirable to add in the legislation?

Mr. SCHMIDT. Mr. Chairman, on the subject of recalls, we feel strongly that we should be notified by anyone who undertakes what we euphemistically call a voluntary recall.

We have in the past at times spoken in a kind of confused way about the subject of mandatory recall provisions.

In general, we feel that mandatory recall provisions are not necessary to be written into the law. And the reason for that is that the only substantive effect there is now is that sometimes we don't know about recalls and we need to. But when we suggest a recall, I do not have trouble in obtaining a voluntary recall from a company, in part because of the alternatives that we then present.

If recall authority were written into law, I personally am convinced that it would be described in such a way as to take away our ability to use a recall to remove products quickly from the market. And every provision I have seen written down would have an appeal procedure built in and other things built in that would delay the performance of a recall for from 3 days up to a couple of weeks.

And now what we do is negotiate very efficiently with the company their recall and recall procedures, and we can be underway literally within a couple of hours.

And I honestly don't see a major defect in that part of the recall procedure now.

We are just afraid, again, of losing flexibility, losing our ability to move quickly when things get set in concrete. And sometimes they get set in lead.

Senator Moss. You do not agree, then, with the conclusions of the GAO in this matter?

Mr. SCHMIDT. No, sir. We do not believe that there should be a mandatory recall authority with the procedures spelled out. We believe that is unnecessary.

Mr. MERRILL. Senator Moss, if I may, to be quite clear, we agree with the importance, the criticality of recall, and it is now the principal enforcement device the agency utilizes. What we are concerned about is getting saddled with a recall provision that is more restrictive than the one we have been able to effect informally.

Mr. SCHMIDT. And our own procedures need to be improved. We have worked on them in the recent past and are now working on improving and codifying them. They will be published in our set of procedural regulations.

Senator Moss. I guess Mr. Merrill should answer this.

What would be the effect of the citizen suit provisions on the State law?

Mr. MERRILL. I will be candid with you, Senator. I have not considered the impact on the State law. The citizen's suit provision causes me some difficulty for another reason, a related reason.

We are not troubled by the authorization to sue us; I think there is no agency that has been more receptive to having its actions challenged in court and even if we weren't receptive we would be there. But we have not imposed procdural obstacles.

The provision of the citizen's suit authorization in S. 641 that troubles us is the invitation to anyone to sue anyone else that they believe is violating the Federal Food, Drug, and Cosmetic Act. That would mean, it seems to me, a lot of suits, in courts all around the country, that would be troublesome for us if we were not in them, burdensome for us if we were in them, because we couldn't take the risk that somebody would litigate a suit unsuccessfully or poorly or on a theory we couldn't live with and then be stuck with that as a precedent.

Senator Moss. Well, thank you very much, gentlemen.

I am sorry the pressure of time is such that we can't pursue this further. But we do appreciate your testimony and we will consider it very carefully as we look at these two bills.

Your complete statement will be placed in the record at this point.

(The statement follows:)

STATEMENT OF ALEXANDER M. SCHMIDT, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman: We are pleased to be here today to discuss S. 641 and S. 1168, legislation intended to increase the regulatory authority of the Food and Drug Administration (FDA) over food.

While there have been several amendments to the Federal Food, Drug, and Cosmetic Act (the Act) dealing with the regulation of foods, notably the Food Additives Amendments and the Color Additive Amendments, the basic regulatory scheme established in the 1938 Act has remained virtually unchanged with respect to food processing.

During the last Congress, we discussed before your two Subcommittees several earlier versions of comprehensive amendments to the Act. Following extensive hearings, the Subcommittee on Consumer reported out a bill which incorporated many of the provisions necessary to protect the public from adulterated and misbranded food. At that time, we stated that we needed: Records inspection authority; records and reports authority, including food surveillance procedures; subpoena authority; administrative detention authority; and provisions to expand or clarify food labeling requirements.

Mr. Chairman, we still strongly believe that the additional authorities I just listed are needed if FDA is more effectively and efficiently to assure the safety of the Nation's food supply.

RECENT DEVELOPMENTS

Last year we provided your Subcommittees with a summary of some of our current food surveillance activities. Before presenting our views on the legislation currently before you, I think it would be useful to mention some actions we have taken during the past year which address certain of the provisions in S. 641 and S. 1168.

1. 701(a) Rulemaking authority

As you know, under section 701(a) of the Federal Food, Drug, and Cosmetic Act, the FDA is authorized to issue regulations for the efficient enforcement of the Act. We have always maintained that these 701(a) regulations are substantive and have the full force and effect of law. On the other hand, the food industry has contested that view. The food industry maintains that 701(a) regulations are mere "interpretive statements enforceable only on a case-by-case basis."

A recent decision by the United States Court of Appeals for the Second Circuit, in *National Nutritional Foods Association* v. *Weinberger*, Docket No. 74-1738 (February 3, 1975) explicitly upheld our interpretation of the legal effect of regulations issued pursuant to section 701(a). The Court stated that where the regulatory objective is to establish rules governing an entire industry such rules must have the force and effect of law.

We would want to be very sure that legislation expressly conferring authority to adopt food safety assurance standards could not be interpreted as implying that FDA does not have power under section 701(a) to adopt substantive rules to enforce other provisions of the Act.

Recent regulations

Mr. Chairman, two recent and significant FDA actions—the publication of milestone Freedom of Information and Procedural Regulations—relate directly to certain other provisions of the pending legislation.

Namely, under S. 641: The mandatory publication of an annual safety assurance plan; citizen Suits against the Secretary or food processor; and mandatory notification with right of appeal prior to the disclosure of information relating to food.

And under S. 1168: The prohibition against disclosure of certain information; and citizen Suits against the Secretary.

Mr. Chairman, I would like to submit for the record copies of our Freedom of Information and Procedural Regulations. Our new public information regulations permit access by the public to more than 90 percent of all information in FDA files. This should contribute to public understanding of the basis for our actions. Additionally, we believe our new Procedural Regulations will promote greater public participation in our administrative activities, and are far more detailed and inclusive than the procedural provisions, such as the civil suit provision, set out in the two bills before you.

VIEWS ON LEGISLATION

1. Food surveillance

I would like now, Mr. Chairman, to briefly discuss some of the major concepts in S. 641 and S. 1168 which the Department supports. In so doing, I will be able to point out what the Department views as deficiencies in both bills.

Both bills address three important regulatory areas: food surveillance authority, food establishment registration, and food labeling. Both bills recognize, as

does the Department, that the burden of assuring the wholesomeness of foods rests primarily with the food industry, namely the food processors.

S. 641 requires food processors to implement, maintain, and comply with safety assurance procedures. As I stated earlier, FDA presently has the authority to issue mandatory surveillance regulations as current good manufacturing practice (GMP) requirements. Thus we believe this provision of S. 641 is unnecessary.

The Department supports the provisions of title I of S. 641 for administrative detention of food, FDA subpoena authority, notification of recalls, the inspection of records in food establishments, and records and reports authority.

It is essential that FDA posess sufficient authority to determine the manner in which food is being processed. Although FDA's primary source of information in this regard is the factory inspection, present authority to inspect food processors is severely limited. An FDA inspector under our current law is limited to a visual examination of the processing in a particular establishment. He is not entitled to inspect records showing the source of materials, quality controls, or formulation of the products. This makes it virtually impossible for an FDA inspector under today's law to detect potential microbiological contamination, the addition of unapproved additives or improper amounts of approved additives, or the truthfulness of many label claims before products are entered into commerce.

It is also important that FDA be able to obtain needed information without having to send out an inspector each and every time it is believed that such records may shed light on a potential hazard posed by any particular food. To answer this need, FDA should have authority to require firms subject to the Act to maintain records and make reports necessary to assure implementation of the Act. These provisions in S. 641 are similar to those in the Department's bill submitted to the last Congress.

On the other hand, we oppose the comparable sections of S. 1168. S. 1168 provides for the establishment of a safety assurance system by food processors with no concomitant requirement that they then maintain and comply with such a system once it has been established. Furthermore, such safety assurance systems would extend only to matters demonstrably injurious or hazardous to health. Sanitation matters concerning animal, insect, and industrial contamination as well as putrid or decomposed ingredients would not be covered. Furthermore, S. 1168 would impose unwarranted restrictions on factory record examination, and makes no provision for records and reports, and subpoena authority.

2. Food coding

S. 641 directs the establishment of a uniform system of coding for packaged foods and for certain records. Further, the Secretary would be required to make available to the public sufficient information to enable consumers to understand the basic elements of such a coding system. The Department fully supports the objective of establishing a system of coding adequate to permit identification of products for efficient regulatory action. We feel that we presently have the authority to require food coding pursuant to section 404's emergency permit control, section 402's adulteration provisions, and section 701(a)'s rulemaking authority. Again we believe it is unnecessary to have such authority expressly set out by statute.

We feel that the mandatory requirement to provide consumers with coding information is unnecessary for such information would already be available under our Freedom of Information regulations.

S. 1168, on the other hand, does not address food coding.

3. Food labeling

S. 641 would also amend the Act to require certain foods to carry sell date labeling, to list nutritional information where nutritional claims are made or nutrients added, to require percentage ingredient labeling for significant ingredients, and in certain instances, would permit FDA to require the naming of spices and flavorings. The Department would also be required to conduct a feasibility study of the need to require individual designation of the common or usual name of every individual spice and flavoring in food.

The Department supports the need for fully informative labeling as to the contents of the food that consumers buy. We do not object to having discretion

to order declaration of individual spices and flavors, but we do object to the mandatory requirement to conduct a feasibility study. Spices and flavors are already being reviewed under our GRAS (Generally Recognized as Safe) substances review. We can see no economic or health benefit from such a study.

We also object to the specific listing of exemptions from ingredient labeling set out under the ingredient labeling provision. We feel that these listed exemptions should be deleted, as this is a matter appropriately left to regulations and there is no reason to believe that the FDA would abuse its present discretionary authority to grant exemptions from such labeling. The list of exemptions would, in fact, go further than present FDA regulations. The exemption for closely related ingredients could be interpreted by a cereal manufacturer to permit the listing of the single term "grains" without explicitly declaring the individual generic names of the grains.

With respect to percentage ingredient labeling, S. 641 provides specific authority in an area where the FDA presently has general authority. The FDA already has issued regulations requiring percentage labeling of characterizing ingredients in seafood cocktails and other products. We do not object to this provision but feel that such a provision should be a matter appropriately left to regulations. The FDA should have the discretionary authority to decide where and when such information will be useful to consumers. A mandatory provision may impose an economic burden on consumers for little or no public protection. Furthermore, the provision in its present form is an open invitation to protracted litigation. No standard is provided to determine when an ingredient is significant with respect to value, quality, nutrition or acceptability (an obviously vague term) so as to require its percentage listing.

We also support the "sell date" and nutrition labeling provisions. The FDA already has authority to issue regulations dealing with both matters. "Sell date" labeling may presently be required where lack of such information would result in a food's being adulterated or misbranded.

As to nutrition labeling, the FDA has already issued comprehensive regulations requiring adherence to a specified format for nutrition labeling and requiring such labeling where nutrients are added or where nutritional claims are made. These provisions of the bill would serve to make explicit our current general authority.

S. 1168 has no similar provisions.

4. Interstate commerce

Section 103 of S. 641 creates a rebuttable presumption that all food is in interstate commerce, for purposes of seizure. The FDA's experience has shown that virtually all food *is* in interstate commerce, as interpreted by the courts. The FDA could conserve resources if its inspectors were relieved of the burden of collecting documentation of interstate shipment.

5. Food establishment registration

Both bills require registration with the Secretary of the Department of Health, Education, and Welfare of all food processors. S. 641, however, requires biennial registration, while S. 1168 requires one-time registration, to be kept up to date by requiring notification to FDA of changes in operation. Of these two provisions, we prefer the S. 1168 requirement, in that paperwork would be greatly minimized. There is a real need for FDA to know the types of processing utilized by each processor as well as the classes of foods processed. We supported the idea of food firm registration in the last Congress and acknowledged the benefits that would result. We continue to support the proposal, but in light of present budgetary constraints and the President's general moratorium on new spending programs, we would be unable to implement the mandatory programs in fiscal year 1976; accordingly, we request that action be deferred until such time as budgetary conditions permit us to take on these new responsibilities.

PROVISIONS SPECIFICALLY OPPOSED

Mr. Chairman, I would now like to address myself to a number of provisions in these two bills which the Department specifically opposes. We have previously objected to many of these provisions in connection with S. 2373.

1. Food surveillance

Title I of S. 641 provides that, in the case of raw fruits and vegetables, safety assurance procedures and standards would be limited to risks of adulteration from filthy, putrid, or decomposed substances, and from handling under insanitary conditions [paragraphs (3) and (4) of Section 402(a) of the Act, 21 U.S.C. 342(a) (3) and (4)].

We oppose this restriction, which limits FDA's current authority in that it would prevent development of procedures and standards for such produce relating to several significant types of adulteration, e.g., to poisonous or deleterious substances, such as aflatoxins in peanuts.

We also oppose the provision of Title I of S. 1168 which limits the term "safety assurance" to include only those processing factors which bear upon whether a food will be "unsafe or injurious to health." In establishing safety assurance standards and procedures, it is important that the public be protected from all "*adulterated*" foods, including food which may be contaminated with filth, including rodent hair or excreta, which may be injurious to health.

We believe that any food legislation establishing procedures and standards to assure safe food handling should extend to restaurants and similar establishments.

S. 641 requires the Secretary to publish annually in the *Federal Register* a safety assurance assessment report concerning those risks of food adulteration which require regulation. To require publication of such a report in the *Federal Register* would be time-consuming, burdensome, and unnecessary in view of alternative sources of information.

In particular, we are quite troubled by the requirement of S. 641 that the original safety assurance plan, as well as any subsequent amendments, be officially published for comment, and that ultimately any plan or amendment be subject to judicial review. We believe that this requirement would greatly restrict FDA's ability to deal on a daily basis with routinely changing needs and priorities.

We certainly agree that our plans and procedures to screen food for noncompliance with legal requirements should be public. However, this information is already given in considerable detail in the Department's annual reports and in the budget request for FDA. Also, the Agency currently publishes all of its compliance programs and their evaluations annually. These are available to the public for their review and comment. Therefore for these reasons we oppose these provisions of S. 641.

In addition, the annual inspection requirement is simply not practical or reasonable given present FDA priorities. We are currently spending 30 million dollars a year to inspect processors on the average of once every three or four years. To achieve once a year inspection would require an additional 19 million per year just for the inspection and does not include the necessary supporting activities such as sample collection. We do not view this expenditure of Federal funds as necessary or appropriate given the present nature and extent of compliance. It is also highly unrealistic to expect FDA to be able to formulate a plan providing reasonable assurance that within four years of enactment of this legislation there will no longer exist "unreasonable" risks of adulteration.

2. Advisory committees

S. 641 authorizes the establishment of such standing or ad hoc advisory committees as the Secretary deems necessary. This is an improvement over previous bills which would have required the creation of a permanent food advisory committee. While we agree that the current provision allows greater flexibility, we firmly believe that there is no need for specific statutory authorization of advisory committees in this field.

Currently, FDA can and does establish such committees whenever we believe they are necessary to help us carry out our responsibilities. One example is the National Food and Drug Advisory Committee. This group serves to provide advice to the Commissioner of Food and Drugs on policy matters relating to all of our activities including our food program. The Committee's membership includes representatives of consumers and regulated industry, as well as physical and biological scientists. Additionally, we solicit guidance from other specialists as needs arise, and major studies have been made to increase participation by consumer groups in FDA activities.

In short, we believe that statutory authority for the creation of advisory committees could limit flexibility, as well as opportunity for a variety of outside groups and experts to participate in FDA decisions.

3. Citizens civil actions

Both S. 641 and S. 1168 would permit citizens civil actions. While present laws permits suits against Government officials for failure to perform non-discretionary functions (and FDA has welcomed court review of major regulatory actions), S. 641 would go much further. The bill would, for example, allow one food processor to sue another for alleged violations of safety assurance standards. FDA could not take the risk of allowing unattended private litigation to develop the controlling case law in this area.

Moreover, our new procedural regulations—coupled with the availability of judicial review of Agency actions—provide ample opportunity for citizens to exert influence on the entire range of our activities. Almost all FDA regulatory decisions are published for comment in the *Federal Register*. Any citizen can comment, and organized groups speaking for consumers, the medical and scientific communities, and industry do make comments with great frequency, often causing us to modify or amplify our decisions.

Additionally, any citizen currently may petition the Agency to initiate administrative acton based on personal research or any other data. The increasing use by consumer and other groups of this provision in the Administrative Procedure Act speaks for itself.

I would also like to add, Mr. Chairman, that FDA has expanded consumer protection by developing formalized worksharing arrangements with cooperating State and local food and drug officials. This has been accomplished through the commissioning authorities of the Federal Food, Drug, and Cosmetic Act and our current contracting program. We have serious concerns that these State and local officials would not agree to join with us in these very important extensions of the Agency's programs if they, as agents of FDA, were subjected to additional civil liability.

4. Money penalties

The Department opposes those sections in S. 641 and S. 1168 which create civil money penalties under the Federal Food, Drug, and Cosmetic Act. Further, we would oppose the substitution of civil money penalties for any of the sanctions now authorized in the Act. The Act already provides two highly effective civil remedies, seeizure and injunction, in addition to authorzing criminal prosecutions. The FDA also makes extensive use of recalls. Recalls, seizures, and injunctions offer a distinct advantage over civil money penalties in that they operate directly to eliminate violative products from the market or to stop unlawful practices. We would not want to encourage in any way the practice of imposing civil money penalties in the place of our presently effective sanctions.

Mr. Chairman, we would, however, recommend an increase in present criminal penalties. Since 1938, criminal penalties have remained $1,000 for a first offense, and $10,000 for a second offense. We recommend increasing the penalty for a first offense to $10,000 and the penalty for a second offense to $25,000. Such increases would bring the penalties in closer conformity with fines imposed by more recently enacted regulatory statutes.

5. Direct access to court

The Department defers to the Department of Justice concerning the provision in S. 641 authorizing the Secretary to initiate, defend, or appeal most court actions arising under the Act.

6. Criminal liability

S. 1168 would amend the Federal Food, Drug, and Cosmetic Act to provide that only when a person "knowingly or willfully" violates the Act will criminal penalties be applicable. This added requirement would apply to violations involving all drugs, devices and cosmetics, as well as to those involving foods. The FDA strongly opposes this provision, which would eliminate a central feature of protection presently afforded the public.

The current criminal provisions of the Federal Food, Drug, and Cosmetic Act require no showing of knowledge or intent. To be found guilty under present law, the Government need prove only that the defendant in fact acted in a way prohibited by the Act.

The courts have recognized that food and drug legislation is concerned with protecting the lives and health of human beings under circumstances in which they are unable to protect themselves. Courts have repeatedly agreed with Congress that *any* violation of such legislation should be subject to criminal sanctions.

Congress has consistently affirmed this so-called "strict liability" standard. I would note that the Supreme Court is currently considering the applicability of the criminal provisions of the Federal Food, Drug, and Cosmetic Act (*U.S.* v. *Park*, 499 F. 2d 839 (4th Cir. 1974)).

The FDA has consistently exercised sound discretion in determining when to seek imposition of criminal sanctions for violations of the Act. The FDA has primarily prosecuted offenders where there has been a continuing course of violative conduct, or a flagrant violation of the law. Trivial or technical violations have not been prosecuted. It would clearly be inadequate to impose criminal liability only for purposeful violations of the Federal Food, Drug, and Cosmetic Act. Where the health and safety of the Nation is at stake, strict standards of conduct are required.

7. Trade secrets and disclosure of information

Section 112 of S. 641 would amend the Federal Food, Drug, and Cosmetic Act to prohibit public disclosure of trade secrets and certain other information relating to food, except when relevant in judicial proceedings. It would also require the Department, prior to disclosure of *any* information relating to food originated by others, to provide sufficient advance notice to enable the originator to go to Court in an attempt to prevent disclosure. It is our experience under our Freedom of Information regulations that we receive 40 to 50 information requests per day, and a large percentage involves trade secrets. It is current FDA practice to provide notice to the originator in all cases involving a close question as to whether or not a trade secret is involved.

8. Travel expenses of State trainees

Section 108 of S. 641 would authorize the Secretary to pay transportation and per diem expenses incurred by State and local officials in connection with the training by the Secretary of such officials to carry out some of the Secretarys functions under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

Implementation of this authority would require about one million dollars per year. We have reconsidered this matter and oppose such a provision at this time on the grounds that it is generally not in keeping with the policy of Federal user charges for training activites.

9. Alcoholc beverages.

S. 641 would not require processors of distilled spirits, wine, or malt beverages to comply with the bill's food establishment registration requirement. The Department believes that this exemption is without basis, and we therefore oppose it. Similarly, we oppose the provisions of S. 1168 which would totally exempt from regulation under that bill the processing of the types of beverages noted above.

The Department also objects to the exemption of labels for these products from the labeling provisions of S. 641. We recognize that consumers have a strong interest in the composition of these beverages, and thus we oppose any exemption of these products from the ingredient labeling requirements that apply to other foods. Our Department and the Treasury Department are presently working together on labeling of alcoholic beverages.

10. Preemption and enforcement in State courts

Finally, S. 641 would provide for preemption of all State laws requiring food labeling information in addition to or different from information required under section 403 of the Federal Food, Drug, and Cosmetc Act or regulations thereunder, except that States may be granted an exemption from supersession where the State imposes a higher standard of performance.

Title VII of S. 1168 would go even further and would prohibit State or local laws or regulations which impose requirements which are different from any requirements (whether relating to food, drugs, medical devices or cosmetics) made by or under the authority of the Act, except that a State could impose quality standards for a food which are in addition to or higher than those

set forth in standards issued under Section 401 of the Act. S. 1168 would also authorize enforcement of the Act in State courts by State officials.

We strongly oppose the section of S. 1168 allowing direct petitions to Congress for State exemptions. This would force Congress to make detailed and piecemeal decisions which correctly belong in the administrative realm and could result in an inequitable application of the law among States.

The Department has long favored uniform Federal and State food and drug laws and regulations. We believe there are a variety of mechanisms capable of achieving this objective. The FDA has, for example, assisted in the development of uniform model laws and regulations and has supported in every way possible their enactment. The Agency has worked hard to coordinate its operations with the States to bolster each other's individual efforts.

CONCLUSION

The Administration shares the concern of your Subcommittee that our food supply must be as safe and wholesome as possible and appreciates your continued interest in increasing the Department's authority to regulate the Nation's food supply. Toward this end, the Administration has, during the past four years, provided a substantial increase in FDA's food budget and has transmitted to Congress several legislative proposals to improve the quality of foods and food labeling.

We would be pleased to answer any questions which you may have.

Senator Moss. Our next two witnesses will be asked to come to the table together, Nancy Chasen of the Consumers Union, and Anita Johnson of Health Research Group.

If you two witnesses would appear we will have you each give your statement and then any questions we have may be directed to either one of you, if that is satisfactory.

And I think, Nancy Chasen, we will ask you to go first.

STATEMENT OF NANCY H. CHASEN, CONSUMERS UNION OF THE UNITED STATES, INC.

Ms. CHASEN. Thank you very much, Mr. Chairman.

I will turn directly to my comments on the substance of the bill.

I might say that my comments on title I are meant more to convey to you a sense of uneasiness about the structure that they set up, more than to give you specific suggestions for the way it would be changed.

I am sorry that the FDA representatives didn't address in somewhat more detail the potential administrative burden that might develop, and so I will raise those questions, more than solve them.

Consumers Union is not opposed to a regulatory scheme that would lodge primary responsibility for developing food suveillance procedures with the food processors as long as strong backup and enforcement authority, as well as stepped up investigative capability are granted to FDA.

My name is Nancy Chasen. I am an attorney with the Washington office of Consumers Union. Consumers Union, the largest consumer organization in the world, is a nonprofit corporation established in 1936. Consumers Union publishes Consumer Reports, which has a paid circulation of approximately 2 million. The work of Consumers Union is funded solely by sales of Consumer Reports and other consumer publications which it issues from time to time; no commercial advertising or support is accepted. In addition, Consumers Union represents its several hundred thousand members in adminis-

trative, judicial, and, upon invitation, legislative proceedings of concern to consumers. Consumers Union's long-standing interest in a safe, clean food supply is frequently reflected in the pages of Consumer Reports, and we appreciate your invitation to testify at hearings on the proposed Consumer Food Act of 1975, S. 641.

Because adulteration of food is often not apparent to the naked eye or the palate, consumers cannot easily protect themselves against it. They are reliant upon the Government for protection in this field. Unfortunately, the Food and Drug Administration has relatively limited authority under present law. We therefore welcome your efforts to strengthen the Federal Food, Drug, and Cosmetic Act as it applies to food safety.

TITLE I: FOOD SURVEILLANCE PROCEDURES AND STANDARDS

Consumers Union does not oppose establishment of a regulatory scheme which lodges primary responsibility for developing food surveillance procedures with food processors, as long as strong backup and enforcement authority, as well as stepped up investigative capability, are granted to FDA.

S. 641 embodies a long overdue strengthening of FDA's enforcement and investigative capabilities. We welcome the grant to FDA of authority to issue subpenas and interrogatories, to require safety-related recordkeeping, to represent itself in civil judicial proceedings and to impose administratively substantial civil penalties for violations of the law. We are pleased that your bill embodies a commitment to a minimum of one annual inspection visit to each processor, and suggest that you amend proposed section 410(b)(4) to state that these inspection visits are to be without prior notice, as unannounced visits are likely to provide a greater incentive for self-surveillance.

These provisions should help FDA substantially in detecting and prosecuting violations of food safety laws. However, the provisions authorizing FDA to promulgate backup standards where processors have failed to adopt and conform their practices to adequate safety procedures is seriously flawed. As presently drafted, title I would create a nightmare of confusion and uncertainty, benefiting neither the processors nor the consuming public. Processors would be destined to a limbo of uncertainty as to their obligations under the law and consumers would inevitably lose in the bickering and lack of focus which this system is bound to generate.

The problems center primarily around the meaning of and relationship between sections 410(c)(1) and 410(c)(5), see pages 7 and 9. 410(c)(1) authorizes FDA to promulgate standards where existing industry-created safety assurance procedures and inspection and monitoring activities are not adequate to protect against an unreasonable risk of adulteration. These standards are apparently intended to apply industrywide, as they are to designate not particular processors but rather the food or class of food to which the standards are applicable. Under section 410(c)(1), the inadequacy of a single processor's procedures is apparently sufficient to trigger FDA's standard-setting authority, with potential impact on all processors of similar foods.

Section 410(c)(5) is apparently intended to mitigate this result. While FDA could * * * promulgate industrywide standards under section 410(c)(1), section 410(c)(5) states that:

> No safety assurance standard (promulgated by FDA) shall be applicable to any person who has developed, implemented, and maintained safety assurance procedures which the Secretary finds are adequate to provide reasonable assurance that food does not present an unreasonable risk of adulteration.

Several problems arise in this context. First, in areas where FDA has found that safety assurance standards are necessary and has promulgated such standards, the agency would be charged with administering a regulatory program under which some processors would be subject to FDA's standards and others would be subject only to their own procedures. Secondly, it is not clear at what point, and in what manner, FDA would determine that a particular processor is exempt from compliance with FDA's standard because his own safety assurance procedures are adequate. It is intended that exemptions be granted on a case by case basis, upon application of the processor, under section 410(c)(7)? Is it intended that processors be subject to FDA's standard pending approval of their procedures, as the section appears to require, or could they adhere to their own procedures until FDA finds that these procedures are not adequate?

One virtual certainty is that section 410(c)(5) will be asserted as a defense in any enforcement action or citizen civil action suit alleging violations of FDA standards. Certainly we do not want to create a system wherein endless months are wasted in court arguing about which requirements apply in a particular case of adulteration when the real issue should be whether the public interest in an unadulterated food supply has been compromised by particular processing procedures.

Thus, while Consumers Union could support some regulatory program in which FDA serves principally to prod industry into adopting acceptable safety procedures and to fill the gaps with standards where industry fails to do so, title I is presently so riddled with contradiction and confusion that the result is likely to be paralysis and needless litigation.

If I may add one more specific comment about the surveillance program, I call your attention to section 410(c)(8) which apparently recites both the standard of adequacy applicable to industry safety assurance procedures and the level of nonadulteration which FDA-promulgated standards must assure, page 10. Standards must provide reasonable assurance that food does not present an unreasonable risk of adulteration. Where an unreasonable risk it at issue, however, surely more than a reasonable assurance that such risk is not present should be required. The dual modification not only confuses the standard but undercuts what should be a commitment to eliminating all risks of adulteration which rise to the level of unreasonableness. Similarly, we urge this committee to strike the words "to reduce" from the phrase in section 410(c)(1) which provides that standards shall be promulgated to reduce or eliminate unreasonable risks of adulteration. FDA's commitment should be to the elimination of all unreasonable risks.

TITLE II: REGISTRATION OF FOOD ESTABLISHMENTS

Consumers Union believes food processors must be required to inform the Government of their existence, location, the types of foods processed, and the type of processing used for each class of food. The importance of registration was evident to all last year when FDA had to act immediately to inspect all known mushroom processors to assure the safety of canned mushrooms. It is very disturbing that FDA must now rely in such circumstances upon telephone directories, trade bulletins and the like to ferret out the names and locations of food proecssors.

TITLE III: LABELING

Title III of S. 641 would significantly increase both the quality and the quantity of information available to consumers on the labels of processed foods. This title would require, or in some instances authorize FDA to require, the labeling of processed foods with: (1) A sell date; (2) nutritional information; (3) an ingredient listing; and (4) percentage labeling of certain integral ingredients.

Consumers Union and other consumer organizations have long encouraged the fullest practical ingredient, warning, and use labeling of food and other consumer products. To state briefly our point of view, consumers have a *right to know* what they are buying and how to receive maximum benefit from their purchases, and producers have an obligation to make such information readily available. To be useful, of course, labeling information must be full, clear, and unambiguous. Exceptions to this general policy of full disclosure should be granted only where justified by valid, overriding considerations, and where no risk of harm to consumers will result.

We welcome your efforts to improve the labeling of processed foods, and offer several suggested amendments which would further the policy I have outlined.

1. Date Labeling, section 302; proposed section 403(p), page 38—while the 1974 report on a dating provision identical to proposed section 403(p) states that it applies only to perishable or semiperishable foods, Sen. Rep. 93–986, p. 11, the section on its face provides that date labeling may be required for *any* processed food identified by FDA upon a finding of need to prevent violations of this act. It is our view that date labeling should apply to all processed foods, not just perishable or semiperishable foods, as deterioration with age affects canned and frozen foods, as well as dairy products. Furthermore, because the purpose of date labeling is to provide useful information to consumers, findings as to the need to prevent violations of the law prior to mandating the use of date labels are unnecessary. We therefore propose that section 403(p)(1) be stricken from the bill and that the report reflect a broadened interpretation of the provision.

Second, Consumers Union has often stated that processed foods should be labeled with the pack date, rather than a sell date or use date, as the pack date is the one date that can be designated with certainty. If consumers are informed about, (1) the pack date, (2)

the conditions under which the product is to be maintained, and (3) the life expectancy beyond the pack date if the product is stored under proper conditions, the judgments as to when a product should be purchased, when it should be used, and when it has been stored too long can be made readily. Thus, a product label on canned goods might state: Packed June 2, 1975. This product will retain its quality for 1 year after the pack date when stored at room temperature. A label on milk might say: Bottled June 2, 1975. Refrigerate and use within 9 days of bottling date.

Third, proposed subsection 403(p) states that date labeling must conform to FDA regulations but does not require that FDA ever promulgate such regulations. Congressional intention with regard to date labeling could be thwarted by extended delay or permanent inaction by FDA. S. 641 should be amended to require the Secretary to propose date label regulations within a time certain.

2. Nutritional Labeling, section 303; proposed section 403(2), page 40—Consumers Union supports this provision which would get clear statutory authority to FDA to promulgate regulations requiring nutritional labeling of foods to which nutrients have been added or for which nutritional claims are advanced on the label or in advertisements. This section should be amended to provide additionally that, where nutritional labeling is not required but is nonetheless undertaken voluntarily, the labeling must conform to FDA regulations. This amendment would be consistent with regulations already promulgated by FDA, 21 CFR 1.17, for which clear statutory authority is necessary; it would serve to eliminate any confusion which could result from varying nutritional labeling styles.

3. Ingredient Labeling, Section 305(a); proposed section 403(i), page 41—Consumers Union supports your efforts toward the long sought consumer goal of full ingredient labeling. For a variety of reasons—allergies, religious preferences, avoidance of economic deception, and simple curiosity—consumers want to know exactly what they are eating.

S. 641 would make several much needed improvements in the current ingredient labeling law. First, it requires labeling of mandatory, as well as optional, ingredients in all foods subject to standards of identity and quality. Second, it requires labeling of specific color additives, rather than permitting nonspecific class labeling of artificial coloring, as under current law. Given the availability of F.D. & C. color designations, specific color labeling presents little practical difficulty and the presence of a full listing will allow consumers who choose to avoid specific color additives, such as Red No. 2, to do so.

Spices, too, should be included as specifically listed ingredients. As representatives of the Washington metropolitan chapter of the Allergy Foundation of America have pointed out to this committee in previous sessions, allergies to such spices as cinammon and bay leaves are not uncommon. Those suffering from these allergies need to know whether these spices are contained in the products they buy. S. 641 reflects a compromise apparently struck last year, authorizing a feasibility study of spice listing. At an absolute minimum, this provision should be retained. Section 305(c).

We also urge adoption of several amendments, relating to the categories of foods and ingredients exempted from the requirement of full ingredient listing.

The ingredient labeling provision lists several exemptions from the requirement that ingredients in foods be fully labeled. Proposed section 403(i)(2)(A)(ii), page 41. These exemptions are subject to such conditions as the Secretary may by regulation provide. However, it is unclear what kind of condition the Secretary may impose with respect to exempted foods and ingredients. Is it intended that the Secretary be empowered to revoke exemptions should the public interest so require? Can the Secretary circumscribe or merely define, the scope of these exemptions? The Secretary's latitude with respect to enlarging, restricting, or otherwise modifying the exemptions should be clarified.

Among the ingredients exempted from the full disclosure requirements are so-called, (b) incidental additives that are present in a food at insignificant levels and which do not have any technical or functional effect in such food, and (c) harmless markers which are used to identify a particular manufacturer's product, in order to protect against disclosure of a trade secret. Both exemptions run headlong into the policy which we espouse that consumers are entitled to full disclosure of ingredients, unless overriding considerations justify exceptions and where these exceptions present no risk to public health and safety.

Both of these exemptions incorporate conclusory terms to define the scope of the exemption. But who decides, and when, that an additive is incidental, that is, that it has no technical or functional effect? Similarly, who decides when a marker is harmless; is that decision made prior to marketing the product with the unidentified marker? The practice of using unidentified ingredients for purposes of disguising a formula should not be legitimized by legislation without a full analysis and evaluation of this practice by the Committee. The fact that the purpose of these ingredients is marking, does not alter the fact that they are ingredients and that they are ingested. From the consumers' point of view, there should be no difference in the way these ingredients are treated for labeling purposes.

Subsection (d) exempts from specific ingredient labeling, closely related ingredients that may be declared by a general term or without regard to order of predominance in a manner that accurately states the nature of the ingredients, page 42. This exemption has two damaging deficiencies: First, it carves a potentially massive loophole in the proposed program of full and specific ingredients labeling by reauthorizing group labeling for certain ingredients. Second, the language of the proposed exemption is so ambiguous, convoluted, and unclear as to invite years of litigation to unravel its intended meaning.

While the precise intended meaning of the phrases closely related ingredients and general term are unclear, subsection (d) appears to legitimize the continued use of such functional labeling as shelf life enhancer, flavor enhancer, preservative, sweetener, et cetera. This kind of labeling now provides virtually no guidance to consumers

who may prefer to buy or avoid products containing certain additives. Consumers do not want to know the nature of the ingredients in their food; they want to know the identity of those ingredients.

In fact, the apparent meaning and scope of this proposed exemption does not appear to comport with the Committee's own intentions with regard to ingredients labeling, as reflected in the Commerce Committee's report of last year. On page 10 of Senate report 93–985, this Committee, defining the scope of the exemption for closely related ingredients, stated:

> (M)any consumers are medically restricted in their intake of saturated fats. Products containing substitutable fats must, therefore, be required to distinguish such fats from one another. It would not be good public policy to permit fats and oils to be declared as such, since such fats and oil saturation levels vary according to their source.

It is not good policy, as the Committee recognized; but the categorical labeling of fats and oils is precisely what the present drafting of subsection (d) authorized and encourages.

Industry representatives assert that group labeling is necessary where several related ingredients may be used interchangeable depending upon cost and availability. Rather than authorizing group labeling, however, the Committee should consider allowing labels to bear the legend, May contain—with a listing of all ingredients which are interchanged. Consumers would have the advantage of specific listing and could, if desired, reject products that might contain an ingredient they want to avoid. Industry, for its part, would save the expense of printing and stocking differing labels.

A provision should be added to exemption (e) relating to food which will be repacked in an establishment other than that of the original processor, to make clear that this food is to be ingredient labeled in accordance with the requirements of section 403(i) when it is processed, labeled, or repacked at the second establishment.

Finally, the intended meaning of exemption (f), relating to assortments of different items of foods, should be clarified.

4. Percentage Ingredient Labeling, section 305(a); section 403(i)(2)(B), page 43—This subsection is apparently intended to mandate percentage labeling only to the major ingredients in certain foods. As presently drafted, however, neither FDA nor processors have any guidance as to which ingredients constitute an integral part of food products.

We recommend that this section be amended to requiring both simplified and expanded by percentage labeling of all ingredients present in an amount in excess of 2 percent of the food product. We urge that Congress provide that any ingredients present in amounts over 2 percent are by definition "integral" parts of the food and "significant" with respect to the value, quality, nutrition, or acceptability of such foods. Under such a provision, additives and other ingredients present in small or trace amounts would not be listed by percentage, although the fact of their presence in the food would be reflected in the specific ingredient listing—with the exception, as noted above, of incidental additives, harmless markers, spices, and flavorings.

As presently drafted, S. 641 would severely undermine rights enjoyed by the public under the Freedom of Information Act, 5 U.S.C. 552ff. While we are not unsympathetic of the concern of the food industry that legitimate trade secrets be protected from public disclosure, the "trade secrets" provisions in sections 112 and 202 are so broad as to virtually nullify the time limits and procedural rights embodied in the FOIA Amendments of 1974 and to severely restrict the public's right of access to Government-held information relating to food.

The FOIA permits, but does not require, the agencies to withhold access to certain categories of information, including "trade secrets and commercial and financial information obtained from a person and privileged or confidential," 5 U.S.C. 553(b)(4). In contrast, proposed section 705(c) mandates withholding of trade secrets relating to food, even where disclosure is necessary to protect the public health and safety.

Third, FDA should be required to determine whether information about to be disclosed contains trade secrets only where the originator of the information has asserted a substantiated claim of privilege for this information. This amendment would be consistent with the Freedom of Information Act under which the burden of showing that information is in fact a trade secret rests with the party seeking confidentiality.

Citizen suits, proposed section 410(a), page 14–S. 641 authorizes citizen suits for injunctive relief against either the Secretary or alleged violators of safety assurance standards. As we mentioned in our testimony last year, the private cause of action remedy has been an invaluable part of such important consumer legislation as the Consumer Product Safety Act, the Securities Act of 1933, and the Truth-in-Lending Act. Citizen groups, or even industry competitors, often become aware of practices which are adulterating food products, but the Government is not willing or, in terms of manpower is not able to take appropriate action. It is especially important that the ability to sue alleged violators be preserved, as this will allow energies now wasted by citizens suing the Government for inaction to be directed toward the alleged offender.

We appreciate this opportunity to appear before the Consumer Subcommittee, and look forward to a favorable consideration of the changes that we have suggested in S. 641.

Thank you.

Senator Moss. Thank you very much, Ms. Chasen, for that fine statement.

We will now hear from Ms. Johnson.

STATEMENT OF ANITA JOHNSON, HEALTH RESEARCH GROUP

Mr. Johnson. I think this bill provides several useful tools for law enforcement against a dirty industry. One tool is access to food plant records. Under present law, an FDA inspector may examine

the factory, equipment and food, but may not examine any records or documents. This is crippling, since the inspector must detect wrongdoing from clues present the day of the inspection. If he does not detect a barrel labeled with the name of an illegal food additive, the chances of the inspector spotting an illegal additive are small. With access to records, however, he can readily note the purchase of a certain additive, or the firm's recipe, and know what to look for in the final product.

The notification provisions of this act would be unenforceable without access to records. The accuracy of the reporting provisions would be impossible to verify.

A 1972 GAO report, "Lack of Authority Limits Consumer Protection: Problems in Identifying and Removing From the Market Products Which Violate the Law," recommended that Congress give FDA access to food plant records. As pointed out by that report, precedent exists for such access in the Federal Meat Inspection Act, the Wholesome Poultry Products Act, the Pesticide Control Act, and some State laws. FDA has had the power to inspect records of prescription drug manufacturers since 1962.

The drug provision permits inspection of the factory and

> all things therein (including records, files, papers, processes controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act [* * * except] financial data, sales data other than shipment data, pricing data, personnel data and research data (other than data relating to new drugs and antibiotic drugs, subect to reporting and inspection under regulations lawfully issued * * *) 21 U.S.C. 347.

Under this bill, FDA apparently would have to show that requested records fell under one of the permitted categories. Every time an inspector asked for access, a Covington and Burlington lawyer would appear to argue that the unseen records are not "records which demonstrate a breakdown in safety assurance procedures," and so forth. Since FDA has not seen the records, it will have to depend on the industry claim.

What is needed is a clear, predictable access provision which all can rely on, not an endless legal hassle.

A second tool provided by this bill is subpena power to get information and testimony from industry, compulsory recordkeeping by industry, registration of food factories, date coding information, and mandatory notification to FDA of food hazards. These are useful, forward looking measures.

There is one weakness in the mandatory notification provision which ought to be corrected. The provision requires the manufacturer to notify FDA of information which supports the conclusion that there is, "an unreasonable risk of adulteration within the meaning of section 402(a)" for his distributed food product and to notify FDA of recalls of any food which is "adulterated within the meaning of section 420(a)." This language requires the manufacturer to draw a legal conclusion about his product before he is obliged to notify FDA of anything. The manufacturer may not be qualified to make

such a judgment, and, if qualified, is likely—human nature being what it is—to make a judgment quite different from the judgment made by the Government. Under these circumstances, FDA would not receive the information it needs, and all would be subjected to uncertainty and dispute. We suggest that notification to the FDA occur whenever a food processor learns of the possibility of adverse effects to the consumer with respect to distributed food processed by him.

The legal immunity granted the manufacturer under this section is an inappropriate and unnecessary favor.

FREEDOM OF INFORMATION

This bill is a giant step backward for open information. Current law prohibits FDA from releasing "trade secrets" to the public, 21 U.S.C. 331(j). This bill extends the prohibition to processes, operations, style of work, apparatus, confidential statistical data, amount or source of any income, profits, losses or expenditures, and other items referred to in 18 U.S.C. 1905.

Some of these items are at the core of the safety assurance programs sought by the bill. Left to stand, this section will permanently secret the large part of safety assurance information. When industry gets information about itself secreted from the public, industry rules the agency, as we have so sadly learned from the prescription drug area. The information section, in my view, assures that S. 641 will cater to industry wishes rather than consumer needs.

The information section as written will require FDA to secret information even though the information is not confidential and is available elsewhere. FDA, for example, may be required to secret its library copy of Poore's Registry and other works openly published. By contrast, the Freedom of Information Act allows secreting only of "commercial and financial information privileged and confidential."

The information section as written will require FDA to secret information even though no damage would result from release. By contrast, the Freedom of Information Act allows secreting only upon a showing that substantial competitive harm would result. See *National Parks and Conservation Assn.* v. *Morton*, 498 F.2d 765 (D.C. Cir. 1974).

This information amendment would take the items mentioned out of the procedural protections of the Freedom of Information Act, such as opportunity for de novo judicial review for the requestor.

There are many industries and many agencies in town that would like to be exempt from the Freedom of Information Act, but Congress made the judgment that except for the narrow exemptions of the act, the ultimate public benefit in disclosure overrides the inconvenience. Congress' satisfaction with its initial judgment was reaffirmed last year when the act was amended for greater disclosure over a Presidential veto.

Different committees at the behest of different industries can slowly undo the Freedom of Information Act with provisions such as this one. If this one goes on the books, you can be sure that other industries will come in and make special pleadings. Bona fide trade

secrets—that is, confidenital information for which substantial competitive harm has been demonstrated to result from disclosure—are now protected by the Freedom of Information Act.

Another obnoxious point in this provision: if FDA proposes to release any information, it must notify the person who gave it the information and then wait 15 days so that the person can go to court to prevent release.

There is a similar provision in the Pesticide Control Act, which came out of the Senate Commerce Committee, and it has been an albatross. The health research group discovered last year that a number of household pesticides contained unlabeled vinyl chloride as a propellant, and asked EPA for a list of the brand names of such pesticides. Vinyl chloride causes cancer and thus may be dangerous at very short exposure. The EPA was willing to release the brand names so that consumers could protect themselves. But it had to wait the required hesitation period, a period which in practice far exceeds the statutory period, and in the vinyl chloride case amounted to a delay of 4 months, during which time vinyl chloride continued to be inhaled.

The provision creates a cause of action for release per se. All the industry would have to show would be that the information concerned a "style of work," and so forth, without any showing that harm would result. This committeé should not legislate such a policy departure outside of consideration of the situation as a whole, and apart from the Freedom of Information Act. Are there special considerations in the food industry which makes this desirable? Should the food industry have a special privilege that the drug industry and the automobile industry don't have? Shouldn't this be considered, if at all, in the total context of Government information?

Last, the information section annihilates the otherwise innovative citizen suit provision, since it will make most information needed to launch such a suit, secret.

Substituted for the information provision in this bill should be the strong language of a 1973 version:

> The Secretary shall make available to the public upon request and at the cost of reproduction and mailing, any and all information obtained or developed under this section except to the extent that such information constitutes a trade secret or confidential commercial or financial information which if disclosed would result in significant compettve damage to ts owner.

That version also allowed release of trade secrets and confidential commercial information to "provide reasonable protection of the public health."

S. 641 has a good chance to improve the honesty and safety of the food supply, and contains some good information provisions, but the alterations mentioned above are critical for its overall usefulness.

Senator Moss. Well, thank you very much for your good testimony.

I just have one or two questions and I will ask each of you to respond.

Some have suggested modifying the application of the strict criminal liability. What are your views about subjecting an individual to

criminal penalties without the need for a showing of negligence or knowledge by that person?

Ms. JOHNSON. I think criminal liability for corporate officials is absolutely essential for law enforcement. It is the top officials of a company who determine the tenor, tone, and priority in a business. We don't want the foreman in a specific plant having criminal liability after he had heard nothing but years and years of bad-mouthing FDA. In other words, corporate officials should be criminally liable. If you would go to industry conferences and hear the extreme concern that industry representatives have for criminal liability, I think you would realize how very important it is in making them vigilant in watching out for sanitation. They are worried about it. They don't want to be called criminals. And therefore, especially they are concerned about sanitation.

I think much of this incentive would be destroyed if the criminal liability provision were removed.

Senator Moss. Don't you think you could have a considerable miscarriage of justice in a case where the executive officers of the corporation really didn't know what was going on? If he turned his back, of course, you could show negligence and if the negligence is sufficient in that case——

Ms. JOHNSON. I think the corporate officials in charge of advertising should not be criminally liable for rodent infestation of the plant. It must be a corporate official who has responsibility, such as the vice president for sanitation, or whatever.

The Commissioner said this morning that when you look at the prosecutions that have been brought, as a practical matter they have all been cases where they were continuing violations and gross violations which could have only occurred as a matter of policy. What I am frightened of is a miscarriage of justice in that the little guy who absorbs the priorities and values of the big guys is going to get caught if the criminal liability provision is removed.

Senator Moss. Thank you. Would you respond to that?

Ms. CHASEN. I would agree with Anita's comments and those of the Commissioner. I think it is an important deterrent and I think it has been shown FDA has not used it frivolously. It has been used only rarely.

Senator Moss. Thank you.

How do you feel that the trade secret provision of the bill preempt the Freedom of Information Act? Of what concern is it to the public to have access to the flow charts, processing temperature records, and the like?

Ms. CHASEN. In the first instance, we are not certain for what kind of secrets the trade secret claim will be exerted.

But there are a number of problems with that provision. The Freedom of Information Act says an agency may withhold a trade secret but allows discretionary disclosure, so to that extent there is an implicit amendment to the Freedom of Information Act for food.

Second, there are procedural abilities under the Freedom of Information Act. This bill is drafted so broadly that FDA is required to notify an originator of information that he is about to disclose

food information even where that processor has not made a claim of confidentiality. So there is almost an implicit assumption any process could be a trade secret and there could be a second shot at it even though the originator has never suggested that is true.

In all those cases you will have the lab time and 15-day notification provision with no chance to make a change in the case of immediate requirements of public health and safety.

Certainly there are some legitimate trade secrets that the public has no right to and, second, has no interest in, but this is drafted so broadly that it includes all related food information and cuts into all the rights that you took the trouble to incorporate into the Freedom of Information Act.

If you insist on keeping it, it has to be narrowed. First of all, the case law under the Freedom of Information Act says that you need substantiation of the claim of privilege. In this bill you don't even need a claim of privilege, but, second, you don't need to substantiate it if you have the Agency withhold that information from the public.

It is a very, very broadly, uncarefully drawn provision.

Senator Moss. Do you concur in that?

Ms. JOHNSON. Suppose I wanted to know whether FDA was cleaning up filthy food? How would I go about clearing that up if I just didn't want to rely on press releases and public information reports?

I guess I would start by requesting the inspection records of the factory. Under this provision virtually all the information telling what is going on in those factories and what the inspector concluded would not be available to me because the provision goes far beyond the trade secrets. It is the style of work that is being protected, the apparatus, the machinery that cleans up or purifies food, the processes of food, and so forth.

So there is really no way that I could get any kind of information on whether or not FDA is doing its job.

Senator Moss. Thank you both very much for your testimony. We appreciate it.

We now have a time problem.

Mr. Terrance Hanold is chairman of the executive committee of The Pillsbury Co., here to testify, and I have run out of time. The bell has now summoned me to the floor. Maybe it is my fault for not having come earlier. But Mr. Hanold, if you would like, we could take your testimony now rather than trying to go over to another time and Mr. Merlis, the counsel for this subcommittee, could do that. Would that be satisfactory, sir?

Mr. HANOLD. Yes, sir.

Senator Moss. Thank you ladies, very much. Mr. Hanold is here to testify and we do appreciate his being here. We recognize that he represents one of the large food companies of the United States and he is testifying also on behalf of the grocery manufacturers, I understand. And so it is of great importance and I sincerely regret that I have to leave, although I know Mr. Merlis who has followed the legislation as closely as I, will propound questions that we want. And if we feel the need to send you written questions later, I know you will be glad to respond to that.

Mr. HANOLD. Of course, Mr. Chairman.

Mr. MERLIS. Why don't you proceed as you see fit, Mr. Hanold.

STATEMENT OF TERRANCE HANOLD, CHAIRMAN, EXECUTIVE COMMITTEE, THE PILLSBURY CO., ON BEHALF OF THE GROCERY MANUFACTURERS OF AMERICA, INC.; ACCOMPANIED BY RICHARD J. LEIGHTON

Mr. HANOLD. Mr. Chairman, I am appearing, as Senator Moss said, on behalf of the Grocery Manufacturers of America, which is a trade association to which most of the principal processors of food in this country belong.

We are, of course, pleased to be able to share our views with you again on the subject of S. 641 introduced by Chairman Moss and Senator Kennedy and S. 1168 introduced by Senators Stevens. We think that they hold the potential for landmark legislation in the food field.

As our previous testimony on this subject at other hearings on behalf of plant registration, food assurance procedures, and other features of this bill indicate, our position is that of an advocate of constructive legislation in this field. So let me emphasize at the outset that we in GMA support entirely the major aim of both bills which is further assuring the safety of foods Americans consume by the creating of increased authority to the Food and Drug Administration and the bearing of increased responsibility by food processors.

So while my testimony will be directed very much toward those few features of the bill which we oppose, I want to emphasize at the outset our general favorable position respecting legislation in this field.

While we suggest a few amendments and these are directed toward S. 641, which is the bill which passed the Senate last year, it is our judgment that either bill could be clarified so as to perform the function that all of us desire.

Our first suggestion concerns an important area not covered by S. 641, which has already received considerable discussion this morning.

Historically, interpretation of the Federal Food, Drug, and Cosmetic Act has come to provide that corporate officers should have absolute and vicarious criminal liability for the unknown acts or the omissions of their employees.

Under this interpretation, if one of hundreds or thousands of his fellow employees violates the act contrary to the procedures of the company and unknown to the executive officer, that officer is criminally liable for the unknown transgression of that employee. The officer cannot offer any defense in court if the violative conduct of his employee can be proven. We do not believe that Congress ever intended such liability to be a consequence of this law.

We recommend that the bill be amended, accordingly, to provide that any person who knowingly and willfully violates section 301 of the act—that is, the prohibited acts section—be held liable under the criminal sanctions provision. We further recommend that any corporate officer, director, or agent who negligently authorizes, orders, or performs any act or practice in violation of section 301 with respect to any food face similar criminal penalties.

The example that Dr. Schmidt offered earlier this morning, by way of analogy, has, as Senator Moss, I think, recognized, certain logical inconsistencies, or illogical consistencies to reverse the phrase.

True enough, if a man drives down the highway in an unlawful manner and is arrested, he has a very poor case to tell the arresting officer he shouldn't be arrested because his mind was on something else. He was indifferent to what he was doing.

Certainly a man who is doing something is bound to know what he reasonably ought to have done.

A more apt case would be if Dr. Schmidt is in his office one morning and a member of the police force comes to him and says, "One of your inspectors in Georgia drove an FDA car in an unlawful manner subject to criminal penalties, and we are therefore arresting you because you are his superior."

Now, Dr. Schmidt might, under those circumstances, take a more involved and personal point of view of the whole matter than he did this morning. He might say, "Well, the car was in an operable condition. It was safe. The man has been tested. He is qualified under State law to drive and he is over 21. Why are you picking on me?"

Now, Dr. Schmidt went on to say that he had reviewed the criminal prosecutions in which they had proceeded under this authority and all of them are cases which, in his judgment, required or permitted penal action. He admits, I think, by that statement, that the law so interpreted does give him despotic powers, but he is a benevolent despot and would not abuse them.

It is hardly, however, the theory of our law or the intent of Congress to say that any citizen has to throw himself on the mercy of anyone.

I am reminded of the statement of the sixth court of appeals a while ago when, in a tax case, they quoted Justice Holmes' well-known comment that in dealing with the government, the taxpayer must turn square corners. The court in this case remarked "It is also time that in these cases the government turn square corners with the taxpayer."

I would suggest reciprocity of treatment here.

If you will look at the bill you will note that all of the duties and obligations that the bill creates for the Government are placed on the Secretary. All of these duties and obligations pertain to food safety and the assurance of the safety of the food that the public eats. Is it therefore a logical consequence of Dr. Schmidt's argument that any violations of this law by Dr. Schmidt or any of his staff makes the Secretary criminally liable? Or should he be?

So, as you see, our concern goes to an individual's right to due process. We have no major concerns with the concept of holding a corporation absolutely liable for the acts of its employees nor with holding an individual officer criminally liable where there is wrongful knowledge and intent or culpable neglect. But we have grave concerns with holding innocent people criminally answerable for the acts of others where no responsibility for those acts is proven.

Perhaps that is enough on that subject.

Turning to the provisions of S. 641, beginning on page 18, the bill provides authority for requiring mandatory identification codes to be placed on all packaged foods. We heartily endorse this concept.

The purpose of such coding would be to facilitate product recalls.

GMA has devoted a considerable amount of time studying and attempting to overcome problems associated with product recalls.

You will remember that on previous occasions we have pointed to and give copies of these rather extensive Guidelines for Product Recall" to the committee and its staff [indicating document].

And we would also like, if we may, to incorporate in the record by reference the GMA testimony on Senator Nelson's recall coding proposal which was given last year; [1] because it treats this important subject at great length, and we will save time this morning.

Mr. HANOLD. Our major recommendation then and now is that care be taken to limit information in recall codes to that which is needed to accomplish their purpose. We would point out in this regard that, as to most products, it is unnecessary to encode information which would identify the type of food within a package. The label clearly shows this, and the shorter the coded message, the more efficient it is.

A large coded message is costly and perhaps difficult to imprint legibly on all food products. More importantly, needlessly complex recall codes would complicate the task of quick and easy identification of a recalled product. This is especially so for many consumers who rely in great part upon broadcast notices.

We gave examples of that in our previous testimony.

We are also concerned with the use of the same "uniform" terminology in this year's bill, to which we objected last year. If it is intended to have the same meaning as it did last year, its enactment could make recalls more difficult, not less. If it is intended to have a different meaning, this meaning should be clarified so as to prevent confusion by its legislative history. We would recommend that the term "uniform" be deleted.

We would suggest requirement of what is sometimes called a plant/batch code. This is a code which would enable a processor and FDA to trace all suspect products from a particular unit of a discrete segment of production, while at the same time enabling a legible, succinct notice to consumers and others by which they could identify individual products.

Before proceeding to title III of S. 641, there is another area in title I which we feel deserves your serious attention. It concerns the proposed governmental authority to demand and receive access to business information, including authority to require the development of information for the Government.

We support the requirement that food processors establish, maintain, and make available for FDA inspection, records pertaining to food-safety-assurance procedures and to food-safety-assurance standards as provided in this bill. On balance, we find these requirements to be appropriate even though they will result in new burdens and costs to us.

We are concerned, however, with provisions in the bill which would extend the scope of the proposed FDA investigational powers beyond their original food-safety scope into areas of economics.

This is accomplished in several ways. The proposed power to allow FDA to require processors to file written reports and answers to Government questions, on page 13 of the bill, is extended beyond the realm of food safety assurance to enable FDA to seek any information it desires.

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[1] The statement is in the committee files.

Similarly, on pages 28 and 29, the proposed power to grant FDA complete access to a company's safety assurance records is extended to cover any documents relating to label statements. This, again, amounts to virtually unlimited mandatory governmental access to business information.

Now, I should point out that there is virtually no area of business information to which one branch or another of the Government does not already have the right of access frequently exercised. We do feel, however, that in the interest of reasonable economy in the management, either of Government or of industry, that the powers so granted in the area of discovery or examination should remain pertinent to the specific objective of the agency making the inquiry. That is the basis of our argument here.

The traditional argument in favor of such power discounts any proprietary protection for information developed by a business. This argument states that the Government needs more information so as to accomplish its assigned tasks more efficiently. But, even on this basis alone, it has gotten to the point that in order to make regulators more efficient we must make those whom they regulate markedly less efficient.

Let me use as an example another of our concerns over the extension of title I beyond food safety. On pages 21 and 22, the bill provides authority for any FDA inspector to stop interstate commerce by detaining foods suspected, but not known to be, in violation of any provision of the Food, Drug, and Cosmetic Act.

Federal agents do make mistakes, and a minority of them sometimes knowingly abuse their powers. We all know this. We also know that this provision, if enacted, will result at times in perfectly lawful foods being stopped in commerce while mistaken suspicions are investigated.

The food industry would support taking that certain risk where the public benefit meets or exceeds the risk. We think that to be the case where food is suspected of being unsafe. Therefore, GMA supports this provision to the extent that it would allow an FDA agent to stop commerce merely on his belief that a food may be unsafe.

We cannot, however, support the concept of granting power to a single person to halt commerce merely on his or her statement of belief that a technical violation of any of the thousands of complex FDA regulations under the act may have occurred. Such a power, as proposed in this provision, should not be delegated to one individual. If an agent has sufficient cause, there are formal actions to seize or enjoin distribution available to the agency. The proposed unilateral detention authority is harsh; it should be reserved for extraordinary siutations.

Finally let me speak to the redundant information access power in the first title of S. 641 which we also would suggest be stricken.

As already mentioned, the bill contains proposed FDA powers to require businesses to open their files and to submit reports and answers to FDA questions. These powers were tailored for FDA's mission and should be kept in the bill with the suggested modifications of their scope.

On page 28, however, the bill additionally would grant by reference to FDA the FTC's vast information access and subpena powers for the same purposes.

The FTC access and subpena powers, designed as they were for an agency which has the responsibility to explore vastly diverse economic situations, are not only redundant, they are neither desirable nor appropriate in their present form for FDA's considerably more precise functions.

Now, we have two or three other matters which are considered at great length in our statement, but in view of the request which has been made that we modify the extent of our statement, let me simply summarize our positions respecting them.

If you find the need for a new FDA ingredient percentage labeling authority—and we suggest that there is none—modify the proposed requirement so as to model it after the "characterizing ingredient" concept developed by FDA.

We think that is clear. It is capable of administration. It is capable of observance and it meets the necessity of the situation. It avoids putting into concreate, or lead as Dr. Schmidt said, matters that should be flexible in that the circumstances of the individual case should determine the required action as found by FDA.

Modify the proposed spice and flavoring labeling provision so as to make it consistent with the proposed FDA study on that subject when it is accomplished.

Delete the provision for citizen suits and conduct your own oversight of the early development under this law to assess whether there is a need for subsidizing private lawyers to exercise oversight responsibility in place of the Congress of the United States.

Correct the drafting misplacement in the proposal for civil penalties by omitting reference to daily penalties.

That is an area which, as it stands, can create nothing but confusion and has the possibility within it for unanticipated injustices of magnificent size.

Once again, GMA wishes to thank the two subcommittees for inviting us to state our views, and to commend you for making this vital legislation a priority item.

And for myself, may I state for the record my deepest appreciation to Senator Mondale of Minnesota for his gracious and, I hope, warranted introduction of me.

Thank you very much.

Mr. MERLIS. Thank you. Your entire statement will appear in the record in addition to the actual discussion we have had so far.

I have a number of questions. The staff reviewed the statement prior to the hearing and one of our questions has to do with your comment with regard to FDA's access to information concerning misbranding violations of the act.

It would seem to us to be somewhat a waste of Government resources and a barrier to competition to put manacles on FDA when it is policing for economic violations of the act. It would seem much easier to look at a record to see if someone is in violation of the act rather than perhaps to go through complex testing to determine that a person is not in violation of the act.

Mr. HANOLD. I might invite counsel to sit with me, Mr. Richard Leighton, counsel to GMA.

Mr. MERLIS. Please do.

Mr. HANOLD. This obviously involves reference to other sections of the act with which I am not really cognizant.

As I understand the situation, however, the remedies of FDA respecting misbranding are not necessarily germane to the stated subject of the bill, S. 641, and the other existing provisions of the law, it is my impression, give the FDA ample recourse or remedies or rights of access to permit the agency to discharge its duties to prevent misbranding.

But I will ask Mr. Leighton to argue the matter, perhaps with greater point.

Mr. MERLIS. Mr. Leighton.

Mr. LEIGHTON. I think you have used the argument that was questioned in the testimony. You are saying in effect it would be more efficient for FDA to discharge its responsibilities by making the particular processor less efficient by opening up his files and records and developing information on anything within FDA's purview. By including misbranding and adulteration, you are including anything within FDA's authority.

We had a throw-away line in the testimony which acknowledged that those who support opening up the files of businessmen see very little proprietary right in that information. And I won't bother with arguing that point because I have done it before unsuccessfully with you.

Let me point just to the need for balance and direction.

You have an increasingly alarming rate of requests by government agencies for information from private sources. It has gotten to the point that in many companies it is a significant expenditure to keep up with government demands to open up the files.

We would like to establish some sort of direction and balance in this. This bill started as a food safety bill. We are very much in support of it. In our opinion, you have extended the unique and extraordinary powers of discovery, that were once applicable only to food safety, to anything else an FDA agent would in effect like to see.

This concerns us because, as was stated before, these powers of investigation are delegated through a very large number of procedural steps. They go from the people to the Congress to the Secretary of the HEW, to the Commissioner, to one of his officers here in Washington, to another field officer, trickling down finally to one man. And it is very frequent these days to have a field agent coming in and saying, "I am interested in this, this, and this, and will you develop it or give this information to us."

It is hard to fulfill those requests efficiently, so if you won't accept the proprietary interest argument, we just ask you to take a look at all the other activities that are going on nowadays with government agents literally invading the offices of businesses, and see if you think that the proper balance is there, before you attempt to extend this.

You are also opening new political considerations, introducing another controversial area into an already controversial title of a bill which a good part of the food industry support in concept. At the very least, it is distractive to us.

Mr. MERLIS. Controversy is not something from which either the Committee on Commerce or the Committee on Labor and Public Welfare shrinks.

Let's pursue that a little further.

If the records are open for purposes of exploring information concerning adulteration, the Commissioner pointed to the difficulty of segregating those records. When the inspector is looking through the records he may be seeing information which has a bearing on misbranding, or alternatively he is put in the position of saying, "Oh, I know that is something bearing on adulteration," and the firm says "Oh, no, that only has bearing on misbranding."

Do you run the risk of limiting that access even if it were granted just for adulteration?

Mr. HANOLD. I would like to go at this—and I certainly agree that the subcommittees have never shrunk from controversy so we start on a common base there, I think.

But let us look at it this way, which is the way I personally look at it.

Our production people are advised—and we do establish records. We have been in the food safety assurance field for some years. We have invested a tremendous amount of funds in building a structure which we think is what food manufacturing ought to have.

We build records to make the operation of that system effective. That is, our production people are concerned with the safe production of food. And we ask them to establish a record system which gives us the best guarantee, first, that what was made is safe; second, whether there is a variance at any point or time from the established norms which would suggest that there might be something unsafe introduced into the food stream.

These people are not from Covington and Burling. These people are engineers, scientists. I guess I would exclude them from the executive and lawyer class and say they are constructive people, they are productive people; they are interested in accomplishment. They are sympathetic with the idea that what is produced is to be the best possible within the constraints of materials and economics.

We don't want to go to them and say "Look, any inadvertent statement you put in this record that somebody construes or misconstrues in another context to our detriment is something you've got to guard against."

They don't go through a semantic exercise in determining the specificity of the comment that goes into those records.

These records are there for the practical purpose for which we established them, which is: Are we on the right track? Are we doing the procedures that we set out to do? If we haven't, where is the flaw and how do we get at it right now?

If you want to obstruct and confuse and diminish the end result that this law is stated to be for, then throw these records open for their indiscriminate misinterpretation by anybody, and one immediately will see a benefit of great consequence sacrified to do a lot of material incidental to the main objective.

In other words, you sacrifice the main project to the subsidiary.

That is the whole obejctive that I've got here. We have to run a plant. We have to produce food. We want to do the kind of job that the purpose of this bill is established to do. And we don't want the people to be overly concerned that their job now becomes that of manufacturing a record rather than manufacturing food.

Mr. LEIGHTON. May I add one thing to that?

Mr. MERLIS. Yes. I was going to add one thing. Since you have safety assurance procedures in your establishments, could you explain them and give us an idea of the kind of information which might be maintained in records which you do without requirement by law, and then maybe we could have a better appreciation or understanding as to how those records have bearing upon adulteration or upon misbranding.

I don't know whether Mr. Leighton should go before you do or afterwards.

Mr. HANOLD. I don't know that I can give you a precise statement because obviously I am not that close and I am not that technically qualified. But I'll attempt simply to regenerate a feeling for what has been going on, because in past years I was very close to the efforts which were begun to establish what we thought would be the kind of a food safety assurance program that modern technology and plant practice really required—and it was something far beyond, I will say, anything that the FDA required then or now.

And I would like to say gratuitously that most manufacturers of size and stature place on themselves far higher standards than anybody else can do.

So with that self-serving statement behind me, we have four categories of safety or product controls. One of them pertains to ingredients, that is, the methods by which we receive them, test them, store them, segregate them until the tests are achieved and the results obtained.

There are inprocess tests which are usually sampling tests to determine whether there is contamination—bacterial, fungal, or any tramp articles that may, by some means, have gotten into the system—metal detection systems, other foreign material detection systems.

We have tests of finished products and final tests of the physical systems themselves: The machinery, the buildings, and the whole environment in which these processes are carried out.

Now, from one of our plants I am advised that there are 28 critical safety controls o ningredients. There is one safety control on inprocess, because it is in a closed system.

In other cases, where there are a series of processes through which the product goes before its final production, there may be dozen or 20 safety controls installed.

Two critical safety controls on finished products.

Thirty-two physical system hazard controls.

So for that one plant which manufactures a fairly limited line, we have 63 what we call critical product safety controls.

Those controls are monitored; records are kept; results are kept; records of actions taken with respect to these results are kept.

These records are kept by scientists, engineers, practical operating people. To the uninitiated they may seem cryptic. They are not scholarly and often not grammatical, but they are meaningful to the people who make them and they are meaningful to the FDA when they inspect them against that objective.

But like every other record, placed in another context, someone can read from it whatever innuendos a mind fired to pervert or a mind insensate with the litigious spirit can generate.

So no, we don't really invite litigation. That isn't the purpose of the plant. It isn't the purpose of the law. The purpose is food safety assurance. These records will further it. These practices will help to guarantee it. Nothing in this world is perfect.

That is where the emphasis of the law ought to be. That is where the emphasis of its purpose ought to rest.

Mr. MERLIS. Mr. Leighton.

Mr. LEIGHTON. In your attempt to balance the public and private interest—and there are obvious ones on both sides—as to access to information of private enterprise, I think you ought to look at the distinction between adulteration within the act and the misbranding violations you are talking about.

The misbranding violations that you think access to all private records would help locate are peculiarly, in most cases, subject to empirical observation, empirical discovery. If you are talking about whether or not a product weighs what its label says it weighs, or whether or not the type face on the product is a quarter of an inch or three-eighths of an inch as required, or questions of that sort, I think you would find it may even be more efficient to require FDA to take a look directly at the product and to determine whether it is misbranded.

But to allow a Government official to come in and say, "I am looking to see that your products are misbranded and to determine what their weights are by use of your records," I think you are reallly misstating the issues. If the present provisions are enacted, the result would be just an open door. It will be an educational process, to be sure, for FDA agents as to what is going on in the business community, but it is not a very efficient one. And I think it will divert the major purpose of this bill, that is, industry willingness to allow full Government access to highly critical, very important information where necessary to prevent unsafe adulteration.

And believe me, release of this information, be it just to FDA, scares a lot of people in the industry. There are a lot of secret formulas subject to scrutiny by FDA.

Mr. MERLIS. Let me bring out a point which may explain something.

In your procedures and recordkeeping, could the situation arise that records are kept of the introduction of a particular ingredient at a particular temperature at a certain stage in the processing—whatever the periodic time interval is. Someone notes "Yes, it is flowing right at 150 degrees."

Is that the type of thing that might be introduced in the records?

Mr. HANOLD. Yes, it is.

Mr. MERLIS. While if the ingredient is not at 150 degrees, that record would more likely have a bearing on adulteration, the fact that nothing was introduced might have a bearing on misbranding, that is, the product was formulated without the ingredient being added to it. While it is true that weighing and type faces are evident by empirical analysis—you take your ruler and measure the product and put it on the scale—it facilitates enforcement of the act if, on learning that a particular ingredient was not incorporated into the product and therefore the product was misbranded, the Agency could take appropriate remedial action.

Alternatively, the Agency has to do the laboratory or chemical analysis to determine that it wasn't in the product.

Mr. LEIGHTON. You are saying they should not do these analyses?

Mr. MERLIS. I am not saying they should not do these analyses. I am saying if the information is seen anyway—or maybe you are not seeing the information anyway—but if the information is available which has a bearing on misbranding, why should the law not be enforced using the information readily available and perhaps even preserved for public purposes?

Mr. HANOLD. You are assuming the record would show —a particular ingredient was not inserted at a particular time in the manufacturing process.

I think Dr. Schmidt stated that his inspectors actually review these things at rather distant intervals.

We are using those records every day. If the products don't have in them what is supposed to be there, they are recalled.

So the question that comes up and the question the inspector ought to be asking is not, "Is it misbranded?" but, "You have here a set of procedures which you say you are following. Did you follow them? Did you recall it?"

If he did not recall it, then you have the real issue.

Mr. MERLIS. In effect you are saying the food is adulterated food because he has not followed his own procedures.

Mr. LEIGHTON. Another point on that. If someone is going to go so far as to omit putting a listed ingredient in food, and thereby commit an obvious violation of the act; why do you assume he will make a record of it?

Mr. MERLIS. It is not a matter of assuming that he would make a record. If a technician who checks on a process notes that nothing is flowing at this time, and the technician does not go up the line and inform his superiors that there is a defect in the process, the food being produced might be misbranded.

You are quite right that anyone who intends to violate the law will violate the law no matter what kind of access you give to records.

This information could not be used in a criminal proceeding. It could be used only for the purposes of a civil proceeding or seizure or injunction.

None of it could be used in a criminal proceeding under existing safeguards.

But, if there is such a situation, does not access to records enhance the ability of the agency to enforce the law?

Mr. LEIGHTON. I submit it would not be. It would not be a continuing violation but a rather rare instance. What you are talking of is a technological mistake which may happen infrequently, and I don't think that makes it necessary to go so far as this open-up-your-files effort.

Mr. MERLIS. I was going to say with regard to the trade secret provision in this bill, that information would not be available.

Let me bring up another point. We already have detainer authority in the bill with respect to misbranding. Do you have a fear or do you run a risk that some inspector may detain food he suspects may

be misbranded? If you had in a defense that the information which you are presenting to him was under oath and that there was not a misbranding violation, he wouldn't detain it? Would the detainer authority extend to misbranding?

Mr. HANOLD. He has other remedies under the misbranding laws. Under misbranding we are assuming there is no danger to public health involved, because if there is that, there is no argument here.

If he wishes to stop the movement through commerce of a misbranded product, he has other means which permit the determination in an appropriate manner of whether it is misbranded or not.

The public is not injured because he knows where the shipment is.

The attitude of the law, in my judgment, should not be in every case that a criminal purpose and an unlawful course of conduct is the inevitable choice of the person calling the shots. We have many times, in the absence of any law, held shipments that an inspector wanted more time to look at, that he wanted to inquire of his superior about, or for any other reason. After all, production of safe food, properly branded food, is a shared responsibility.

We don't say that every inspector is about to exercise power arbitrarily. We do say that where the public health is involved we will submit to an arbitrary exercise of power whether we agree or not.

Where an arbitrary exercise is not necessary to protect the public, then we say the ordinary processes of complaint and determination —however that is done, and that can be done speedily—ought to prevail.

Mr. MERLIS. Let's pursue another area. FDA takes another position than you do as to vicarious liability.

Would you give us an example now or for the record of what you think have been questionable prosecutions of individuals, matters that could conceivably have been handled through civil penalties or in your own view you feel weren't worthy of prosecution?

The record of acquittals may indicate the judiciousness with which FDA prosecutes cases. Would you supply that for the record?

Mr. LEIGHTON. Would you accept hypotheticals rather than citations to people?

Mr. MERLIS. We would accept whatever you will provide. FDA is arguing that in its practice it has been extremely judicious and the problem with accepting hypotheticals is that FDA would say, "Oh, no; we wouldn't have prosecuted that hypothetical."

Desirable as hypotheticals might be, the actual experience would either prove or disprove FDA's contention that they have been judicious.

Mr. HANOLD. Is that the issue, though? Is it the position of Congress to grant arbitrary authority to any agency? Do you confer indiscriminately that power and say, "The man has the privilege of petition to the Star Chamber"?

Is that the theory of justice that is advocated here?

Mr. MERLIS. Obviously it is the theory with which Congress operated. If it is up to Congress to change that, it should do that based on solid data rather than just hypothetical situations.

Mr. LEIGHTON. I have two points. First, I would argue—not here —but I would argue that was not the theory of Congress when they

passed the act. There has been a development which has been slightly skewed from the original intent.

Second, it struck me when Commissioner Schmidt said, "I have personally reviewed these cases and can say I would never be arbitrary" that he is advocating an agency of men, not law.

Mr. MERLIS. These are clearly the kinds of issues before the committee. In making the determinations whether or not to change the standard, the more information you can provide, the better off it will be.

There is no question that political affiliations aside, from a civil liberties standpoint, many people are concerned with the existing situation. One does not have to be closely involved with the food industry a friend or foe, but to look at it from an abstract sense—and last year you will recall Senator Hart sided very closely with the food industry on this particular one because he had grave concerns about the constitutional protections which are otherwise afforded.

I think, though, in order to make the case one way or another, the more information we have the better off we will be.

Mr. LEIGHTON. We will be glad to supply the information. I think we will have to think about whether in recent cases, particularly those that have not been fully adjudicated——

Mr. MERLIS. I don't think you could cite them.

Mr. LEIGHTON. I have seen reference to misbranding cases where ordinary sentences, 9 years, for example, were levied for apparently minute offenses.

Mr. MERLIS. If the amendments which you suggested were made to the bill, would you support S. 641?

Mr. HANOLD. Assuming the bill with those amendments continues in its present form, yes.

Mr. MERLIS. That is interesting to hear.

What do yo uthink the effect of section 410 will be on small processors? To date larger processors have developed these systems on their own, but what is going to happen to small processors?

Mr. HANOLD. That has been a subject of recurrent concern and interest to me personally. And it was part of the reason that we urged certain of the modifications in how these procedures were proposed to be established in the first place, that is, we urged that you let the manufacturer design for himself an effective system of food safety assurance.

That means that the smaller manufacturer has the opportunity to develop both the most effective and the most economical system. In other words, he isn't bound by a general rule for the industry—as originally proposed last Congress—which might put real economic hardship on him unnecessarily.

There have been comments, personal observations, that this would be a strong burden to small processors. My own judgment in discussing this with the technical and engineering people in our staff is that it ought not to be a disproportionate burden.

I asked them what we had spent developing the system which I have referred to, and I was given what had to be pretty much of a roundhouse figure. But they said over 3 years we had spent a million dollars and perhaps a bit more.

Now, one says, "Well, that would be a pretty onerous burden for a small processor." Well, that would be true but it was applied to plants whose total output per year exceeds a half billion dollars.

Now, if one can maintain that cost in proportion, there certainly ought not to be an undue burden from this to anyone.

The point of burden, as I would see it, is that anybody who is in the food business ought to have a certain level of competence in the first place.

Now, if observing the standards set by this bill exceeds his competence, he shouldn't be there. If that kind of hardship is involved, then I think it is a necessary hardship for the public's interest.

I think if the person or persons in charge of a food processing plant are competent in their field, in 9 cases out of 10—without undue injury to themselves, they can economically comply with the law.

Mr. MERLIS. Thank you. I have one last question.

Senator Moss referred to it earlier and I would like to explore it with you as he did with Commissioner Schmidt.

As you can imagine, numerous people are interested in being exempt from one provision or another of the act. An area in which both committees have great concern—is the proliferation of Government programs and burdens.

There is in existence the national shellfish program, the national marine fisheries program, the Federal-State dairy programs, which are cooperative ventures involving various kinds of requirements—they are not all the same kind of requirements.

What are your views on incorporating some of these—I don't want to use the word "boilerplate"—but basic requirements of those procedures as meeting the safety assurance procedures requirements of this act?

Mr. HANOLD. I can't claim close acquaintance with them, sir. But the descriptions of them that I have read, mostly in trade papers, would suggest that they are generically the same as was proposed here. That is my impression.

Mr. MERLIS. Mr. Leighton.

Mr. LEIGHTON. Are you saying in effect that you will have a provision that will say "For the purposes of this act the following programs are considered to comply"?

Mr. MERLIS. No, I would not suggest that Congress make that determination about a program which is in the Code of Federal Regulations and subject to change. I don't think it should be put into the language of the act.

Mr. LEIGHTON. That was my point.

Mr. MERLIS. But I think what might be brought to the committee's attention is the potential for granting, let's say, FDA authority to certify certain programs which are its own programs, and with which many firms and particular industries may already comply, and give FDA the authority to certify that one who participates in that program need not prepare safety assurance procedures—although, of course, that industry would still be subject to safety assurance standards. This would not be to exempt them from having a high level of food safety but to reduce the necessity for them to comply with both their Federal-State dairy program, for example,

and then on top of that to prepare another set of documents explaining basically the same thing that is conceivably complied with under the existing program.

Do you have any feeling about incorporating those kinds of procedures as safety assurance procedures when determined by the FDA?

Mr. HANOLD. Isn't that recognized in the bill?

Mr. LEIGHTON. My personal feeling is a positive one, that the FDA already probably would have authority right now under S. 641.

Mr. MERLIS. One of the problems with arguing FDA authority is FDA says it has all this authority right now whereas it might be better to say explicitly in the bill that they can be certified rather than say that somewhere in the broad authority given to FDA they could be exempt.

Mr. LEIGHTON. Now we get back to your original question and my interpretation of it: You are intending to give direction to FDA and not just discretion.

Mr. MERLIS. This is off the cuff. I would think FDA would have to make a determination as to which programs are adequate so that the requirements of those programs take the place of safety assurance procedures. So it would have to be a burden on FDA to make that determination, rather than a burden on the industry—though FDA could, of course, conceivably require a higher level before it granted such a certification.

Mr. LEIGHTON. Right. But my question was: Are you going to attempt to put in the bill or its legislative history a direction that FDA do it with specific programs in mind now?

Mr. MERLIS. No, I do not think it would be appropriate at all to name any of those programs in the bill because those programs are subject to change constantly. It perhaps would be a better approach to try to describe cooperative Federal-State, or cooperative or joint programs—to describe those kinds of situations and grant FDA authority to waive the safety assurance requirements for one engaged in a program which meets those requirements.

Mr. HANOLD. I was looking at page 9, sir, and I read paragraph 7 on that page as covering that class of cases.

Mr. MERLIS. Paragraph 7 on page 9?

Mr. LEIGHTON. That is the petition authority.

Mr. MERLIS. Yes.

I appreciate your comments.

Mr. Hanold, we appreciate having you. This is the third time you have come before the committee in slightly over a year. We welcome your testimony, Mr. Leighton, and thank you.

[The statement follows:]

STATEMENT OF TERRENCE HANOLD ON BEHALF OF THE GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. Chairman and distinguished subcommittee members, my appearance here today is on behalf of the Grocery Manufacturers of America, Inc. GMA is a trade association which lists the nation's leading processors of food and related products among its membership. We are very pleased to be able to share our views with you again on this important subject.

The two bills before you—S. 641 by Chairmen Moss and Kennedy and S. 1168 by Senator Stevens (by request)—hold the potential for landmark legislation.

Lest this testimony seem negative to those not familiar with GMA's long-standing advocacy for such legislation, let me emphasize at the outset that we in GMA support entirely the major aim of both bills: Further assuring the safety of foods Americans consume by the granting of increased authority to the Food and Drug Administration and the bearing of increased responsibility by food processors.

While we shall suggest but few amendments, it is our judgment that more areas of either bill could be clarified technically. For example, we can, and do, support the Food Establishment Registration titles in both bills—Title II in S. 641 and Title III in S. 1168. But we note that, if taken literally, these provisions could be interpreted to require registration as a food processor of civic organizations holding annual free picnics or dinners.

As a final prefatory note, we shall limit our specific comments to S. 641, the more comprehensive and detailed bill which passed the Senate last year. The concepts advanced by us, however, should be considered applicable to any legislation on this subject.

REMOVAL OF ABSOLUTE CRIMINAL LIABILITY

Our first suggestion concerns an important area not covered in S. 641.[1] Historical interpretation of the Federal Food, Drug, and Cosmetic Act has come to provide that corporate officers should have absolute and vicarious criminal liability for the unknown acts or the omissions of their employees.

Under this interpretation, if one of tens of thousands of employees violate the Act, contrary to the procedures of the company, and unknown to the executive officer, that officer is criminally liable for the unknown transgression of his employee. The officer cannot offer any defense in court if the violative conduct of his employee can be proven. We do not believe that Congress ever intended such liability to be a consequence of this law.

If we are to attempt to make available sufficient foodstuffs for a consumer population of 210 million which, itself, continues to grow; if we are to attempt to meet the changing food needs of this changing population, while maintaining prices at a reasonable level; and, perhaps most relevant here, if we are to subject ourselves to a pervasive new concept of food safety control which depends on complex self-imposed legal requirements, as provided in this bill—if we are to do these things, then it becomes apparent that food companies must be allowed to delegate more, not fewer, responsibilities to competent individuals. Under such circumstances, the chilling effect of absolute criminal liability for corporate officials is unconscionable on a personal level and counterproductive on the public interest level.

We recommend that the bill be amended to provide that any person who knowingly and wilfully violates section 301 of the Act—that is, the prohibited acts section—be held liable under the criminal sanctions provision. We further recommend that any corporate officer, director or agent who negligently authorizes, orders, or performs any act or practice in violation of section 301 with respect to any food face similar criminal penalties.

As you see, our concern goes to an individual's right to due process. We have no major concerns with the concept of holding a corporation absolutely liable for the acts of its employees, nor with holding an individual criminally liable where there is wrongful knowledge and intent or culpable negligence.

FOOD CODING PROVISIONS

Turning to the provisions of S. 641 now, beginning on page 18,[2] the bill provides authority for requiring mandatory identification codes to be placed on all packaged foods. We heartily endorse this concept.

The purpose of such coding would be to facilitate product recalls. GMA has devoted a considerable amount of time studying and attempting to overcome problems associated with food recalls.

You may recall that GMA has published a detailed document on this subject. This document, titled *Guidelines for Product Recall*, was made available to the Commerce Committee last year when GMA testified on Senator Nelson's recall coding proposal. That coding provision has now been incorporated in modified form in these provisions of S. 641.

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[1] It is covered in S. 1168; see Sec. 801.
[2] Proposed FD&C Act Sec. 411.

If it would be appropriate, Mr. Chairman, we would like to submit for the record on this bill the GMA testimony on Senator Nelson's recall coding proposal, because it treats this important subject at great length.

Our major recommendation then, and now, is that care be taken to limit information in recall codes to that which is needed to accomplish their purpose. We would point out in this regard that, as to most products, it is unnecessary to encode information which would identify the type of food within a package. The label clearly shows this, and the shorter the coded message, the more efficient it is.

A large coded message is costly and perhaps difficult to imprint legibly on all food products. More importantly, needlessly complex recall codes would complicate the task of quick and easy identification of a recalled product. This is especially so for many consumers who rely in great part upon broadcast notices.

We pointed out with respect to last year's proposal that it unnecessarily would have required at least a 15-unit coded message to appear on food products. Consider the problem, for example, of a radio broadcast notice asking consumers to check their pantries for a container marked HZ8MWQD26642154; hardly a memorable 15-unit message.

The major contributing factor to this complexity in last year's proposal was the concept that recall codes be "uniform." It apparently was intended that food establishments and products would be assigned discrete numbers and symbols to be encoded on packages.

Thus, we are concerned with the use of the same "uniform" terminology in this year's bill. If it is intended to have the same meaning as it did last year, its enactment could make recalls more difficult, not less. If it is intended to have a different meaning, this meaning should be clarified so as to prevent confusion by its legislative history. We would recommend that the term uniform be deleted.

A uniform system would needlessly impose additional bookkeeping and reporting burdens on both FDA and food producers. Further, it would needlessly add to the complexity of an inherently complicated code, and would thereby diminish efficiency at the precise time that maximum efficiency is required—during a recall.

We would suggest requirement of a plant/batch code. This is a code which would enable a processor and FDA to trace all suspect products from a particular unit of a discrete segment of production, while at the same time enabling a legible, succinct notice to consumers and others by which they could identify individual products.

REASONABLE BOUNDS TO GOVERNMENTAL INFORMATION ACCESS

Before proceeding to Title III of S. 641, there is another area in Title I which we feel deserves your serious attention. It concerns the proposed Governmental authority to demand and receive access to business information, including authority to require the development of information for the Government.

We support the requirement that food processors establish, maintain and make available for FDA inspection, records pertaining to food safety assurance procedures and to food safety assurance standards as provided in this bill. On balance, we find these requirements to be appropriate even though they will result in new burdens and costs to us.

We are concerned, however, with provisions in the bill which would extend the scope of the proposed FDA investigational powers beyond their original food safety scope into areas of economics.

This is accomplished in several ways. The proposed power to allow FDA to require processors to file written reports and answers to Government questions, on page 13 of the bill, is extended beyond the realm of food safety assurance to enable FDA to seek *any* information it desires.[3]

Similarly, on pages 28 and 29, the proposed power to grant FDA complete access to a company's safety assurance records is extended to cover any documents relating to label statements. This, again, amounts to virtually unlimited mandatory Governmental access to business information.[4]

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[3] Proposed FD&C Act Sec. 410(e)(2).
[4] Bill Sec. 110(a).

At this time we are focusing only on what FDA considers to be its additional needs to find out what a business is doing. But FDA is not the only Government agency which is demanding that we formulate information for them. There is the Occupational Health and Safety Administration, the Equal Employment Opportunity Commission, the Census Bureau, the Securities and Exchange Commission, the Federal Trade Commission, and on and on one could go citing agencies whose officials have an absolutely insatiable appetite for paper.

The traditional argument in favor of such power discounts any proprietary protection for information developed by a business. This argument states that the Government needs more information so as to accomplish its assigned tasks more efficiently. But, even on this basis alone, it has gotten to the point that in order to make regulators more efficient we must make those whom they regulate markedly less efficient.

Let me use as an example another of our concerns over the extension of Title I beyond food safety. On pages 21 and 22,[5] the bill provides authority for any FDA inspector to *stop* interstate commerce by detaining foods suspected, but not known to be, in violation of any provision of the Food, Drug, and Cosmetic Act.

This provision, it would appear, at least reaches the outer boundaries of the Commerce Clause. Stopping interstate commerce is the ultimate in regulation. The power granted by the public to Congress under that clause is to be delegated to the Secretary of HEW, redelegated by him to the Commissioner of FDA, redelegated by him to an FDA official in Washington, and finally redelegated to an inspector in the field who will have the initial discretion to bring commerce to a halt based upon his suspicions.

Federal agents do make mistakes, and a minority of them sometimes knowingly abuse their powers. We all know this. We also know that this provision, if enacted, will result at times in perfectly lawful foods being stopped in commerce while mistaken suspicions are investigated.

The food industry would support taking that certain risk where the public benefit meets or exceeds the risk. We think that to be the case where food is suspected of being unsafe. Therefore, GMA supports this provision to the extent that it would allow an FDA agent to stop commerce merely on his belief that a food may be unsafe.

We cannot, however, support the concept of granting power to a single person to halt commerce merely on his or her statement of belief that a technical violation of any of the thousands of complex FDA regulations under the Act *may* have occurred. Such a power, as proposed in this provision, should not be delegated to one individual. If an agent has sufficient cause, there are formal actions to seize or enjoin distribution available to the agency. The proposed, unilateral detention authority is harsh; it should be reserved for extraordinary situations.

Finally let me speak to the redundant information access power in the first title of S. 641 which we also would suggest be stricken.

As already mentioned, the bill contains proposed FDA powers to require businesses to open their files and to submit reports and answers to FDA questions. These powers were tailored for FDA's mission and should be kept in the bill with the suggested modifications of their scope.

On page 28,[6] however, the bill additionally would grant by reference to FDA the FTC's vast information access and subpoena powers for the same purposes.

The FTC access and subpoena powers, designed as they were for an agency which has the responsibility to explore vastly diverse economic situations, are not only redundant, they are neither desirable nor appropriate in their present form for FDA's considerably more precise functions.

MODIFYING INGREDIENT PERCENTAGE LABELING PROVISION

Title III of S. 641 contains several provisions related to providing increased information on food labels. We find ourselves having significant concerns with but two of these provisions.

The first is found on page 43.[7] Subparagraph (B) on that page would require that the percentage of any ingredient of a fabricated food appear on the label

[5] Bill Sec. 103.
[6] Proposed FD&C Act Sec. 702(f).
[7] Proposed FD&C Act Sec. 403(i)(2)(B).

if the FDA decides that the percentage of the ingredient would be "useful" information to consumers.

What does "useful" mean? This term does not appear to provide FDA with a cognizable standard. We fail to perceive any reasonable constraints on the application of whatever standard this bill may be establishing for the exercise of this power.

Could the FDA, for instance, find on its own initiative or pursuant to petition that a trade secret would be information "useful" to consumers? If so, how does it balance the private and public interests at stake—or is the decision to be subject only to a discretionary application of the criterion of consumer usefulness?

GMA would urge you to create some balance and direction in this label information sphere. First, we would urge that you review FDA's existing authority and the other labeling authority proposed in this bill to assure yourself that this new authority is needed and desirable. We have our doubts that its benefits will exceed its costs.

Secondly, should you decide that FDA needs new authority to require the percentage labeling of key ingredients, we would suggest that the provision be amended to follow the established FDA terminology for what is called "characterizing ingredients." That is, that FDA would be empowered to require the percentage labeling of ingredients which it finds to have a material bearing on the cost, quality or nutritional value of a fabricated food.

Such language, we believe, would cover all areas intended to be covered by the present provision, yet would supply a standard for decisionmaking.

GMA would also suggest that flavors be specifically exempted by Congress from this provision to provide clear cut protection of formulas. We do this because it is difficult to conceive of a situation where the percentage declaration of these complex ingredients would provide useful information to anyone but a competitor.

MODIFYING SPICE AND FLAVORING PROVISION

While on the complex subject of flavors, we would like to direct your attention to the common or usual name labeling requirements proposed for ingredients, on page 41 of S. 641.[8]

The provision places a condition on the traditional exception under which spices and flavors could be labeled generically, and, in the proviso beginning on line 18, it creates an exception to that exception.

The condition is that information concerning each spice or flavoring not labeled must be made available, upon request, by the manufacturer or distributor. The exception to the exception provides that FDA could require the labeling of spices and flavorings notwithstanding the prior provision.

S. 641, beginning on the bottom of page 43,[9] directs FDA to report back to Congress within one year as to whether it would be appropriate to have FDA do just what the condition and the exception to the exception would allow FDA to do.

It would appear to us to be imprudent for Congress to impose a requirement (as it would on page 41) after recognizing the need for more information to determine whether it should impose that same requirement (as it would on pages 43 and 44).

GMA endorses the required study of this area by FDA. The results will be soon in coming, and we believe they should be awaited before deciding how to modify spice and flavoring labeling practices.

DELETE CITIZEN SUIT PROVISION

In addition to the concerns already stated about the scope of the regulatory concepts proposed in S. 641, we have two concerns with the methods of enforcement proposed in the bill.

The first problem we have is the provision for reimbursable citizen suits, as provided on pages 14 through 16 of the bill.[10]

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[8] Proposed FD&C Act Sec. 403(i)(2)(A)(i).
[9] Bill Sec. 305(c).
[10] Proposed FD&C Act Sec. 410(g).

Allowing private persons, including competitors, to bring enforcement suits at such an early point in the history of the law, we fear, will hinder the proper development of that law.

It is anticipated that this law would be enforced primarily through the interpretation of detailed regulations yet to be issued by FDA. Premature transferral of the crucial initial decisionmaking process from an emphasis on the quasi-legislative function of rulemaking to adjudication (or the threat of adjudication) in a court of law could easily result in a patchwork of precedents which could stymie fulfillment of the intent of this bill.

Assuming that an action for judicial review or in the nature of mandamus would still be available against FDA without these provisions, the provisions represent more than a mere right to sue. They represent an invitation to sue.

We would urge that a reasonable period of time should be allowed for implementation of the provisions of S. 641. If FDA and/or the food industry are not able to meet your expectations, you should consider ways to make them do so, including the propriety of provisions such as these to subsidize private practitioners of the law in the exercise of legislative oversight.

MODIFICATIONS TO CIVIL PENALTIES PROVISIONS

Finally, Mr. Chairman, we would like to call to your attention what appears to be a technical—and potentially mischievous—drafting misplacement.

This occurs on page 24 of the bill, at line 17.[11] That provision sets forth new civil penalties under the Food, Drug, and Cosmetic Act.

More particularly, it sets forth penalties on a per diem basis—"not more than $10,000 for each day of violation." The offending words are "day of."

No doubt this language was taken from provisions in other laws applicable to violations of cease and desist orders or injunctions with respect to which one can count days. We cannot conceive of how one could rationally compute a daily violation of the Food, Drug, and Cosmetic Act.

The correct approach under analogous circumstances was taken recently in the Magnuson-Moss Warranty—FTC Improvement Act which amended the FTC Act to provide maximum penalties of "$10,000 for each violation" (not day of violation).

SUMMARY

We apologize, Mr. Chairman, for the necessarily lengthy presentation. Let me conclude with a short summary.

GMA endorses the major concepts embodied in S. 641 and most of the specific language. We would urge, however, the following seven modifications:

1. Clarify the Federal Food, Drug, and Cosmetic Act by providing individual criminal liability for persons who knowingly and wilfully violate the Act or who are culpably negligent in performing responsibilities established by the Act. This would foreclose possible interpretations of absolute criminal liability of individuals for the unknown and unauthorized acts of others.

2. Delete all references to industry-wide uniformity in relation to the proposed mandatory recall code provision, and review that provision to determine if it would require the encoding of nonessential information that would be counterproductive to the need for the most succinct code possible.

3. Delete information access and detention powers proposed in the Food Surveillance title which are not related directly to processing safety.

4. If you find a need for new FDA ingredient percentage labeling authority, modify the proposed requirement so as to model it after the "characterizing ingredient" concept developed by FDA.

5. Modify the proposed spice and flavoring labeling provision so as to make it consistent with the proposed FDA study on that subject.

6. Delete the provision for citizen suits and conduct your own oversight of the early development under this law to assess whether there is a need for subsidizing private lawyers to exercise oversight responsibilities.

7. Correct the drafting misplacement in the proposal for civil penalties by omitting reference to daily penalties.

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[11] Proposed FD&C Act Sec. 308(a).

Once again, GMA wishes to thank the two subcommittees for inviting us to state our views, and to commend you for making this vital legislation a priority item.

Mr. MERLIS. The committees will next convene on the 17th of June.

Thank you.

[Whereupon, at 1:35 p.m., the hearing was adjourned, to reconvene at 10 a.m., June 17, 1975.]

FOOD SAFETY AND LABELING LEGISLATION

TUESDAY, JUNE 17, 1975

U.S. SENATE,
SUBCOMMITTEE FOR CONSUMERS,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittees met jointly at 10 a.m. in room 4232, Dirksen Senate Office Building, Hon. Frank E. Moss (chairman of the Subcommittee for Consumers) presiding.

OPENING STATEMENT BY SENATOR MOSS

Senator Moss. The hearing will come to order.

Today is our second day of hearings on S. 641 and S. 1168. These are joint hearings of the Committee on Commerce and the Committee on Labor and Public Welfare. The Consumer Committee and the Health Subcommittee of those two parent committees respectively are conducting these hearings.

We have a large number of witnesses today and are opening under time constraints imposed by the Senate as it considers the New Hampshire election, so I'm going to ask each witness to submit his statement for the record and then to summarize his statement as best he can. The statement, of course, will be in the record in full and will be available to all the members of both committees and we, I assure you, will study the record.

However, in the summary you can highlight or underscore things that you think are of unusual interest and concern and therefore want us to pay special attention to and we, of course, may have a few questions that we'd like to ask following the summary to help clarify in our minds some of the things that we are concerned about.

As I indicated, we have a number of witnesses and these are listed and not necessarily in order of appearance, so I'm going to ask Dr. Ira Somers, executive vice president of the National Canners Association, and Angus Stevens, to come forward at this time.

Angus Stevens is from my home State and president of the Stevens Canning Co. of Roy. He's one of only four surviving canners in the State of Utah. I asked him whether this indicated durability or whether it was voraciousness that had gobbled up the others, but he didn't admit to either one of them. He has been in business for 33 years and he's the past president of the Rocky Mountain Canners Association and a member of the board of directors, too.

I am very pleased to have Angus here, as I am Dr. Somers, who also is an old friend and native son, and we are pleased to have you here before the committee.

STATEMENT OF ANGUS STEVENS, PRESIDENT, STEVENS CANNING CO., ROY, UTAH

Mr. STEVENS. My name is Angus Stevens, as the Senator has told you, and I operate a small cannery in Roy, Utah.

We employ anywhere from about 10 to 75 people during the year, but in a year's operation we will have something like 200 different employees. That makes it imperative that the 10 people that we have train 200, and this gets to be quite a problem because the 200 are employed possibly over a 6-week period.

The items we pack are easy to process, being acid products, but we have a good record. We have had very, very few consumer complaints and nothing of any great amount.

As the Senator explained, there were 16 canners in 1942. There are four of us left. A lot of this decrease in numbers has been due to inability to find trained help to deal with a lot of the Government things that we have to deal with.

The last cannery that closed had a well-known Utah label and they closed simply because of their inability to keep up with the things that the Government required. The closing of this plant increased the cost to the consumers of Utah at something like $100,000, I would guess, this primarily in freight charges to bring the stuff into the state. There's probably $300,000 of money that goes out of the State for these products that was formerly kept within the State.

In addition to this, there's a loss of employment and loss of market for farm products. This is the background of our company.

In addition to this, I would like to speak about the criminal liability to officers. These small canneries that operate like we do do not have a staff of officers that are active in management of the plant. Usually, one man will be the executive officer and the rest will be people that maybe have some slight connection with the company and to make them liable to the criminal liability seems to me to be stretching it quite a ways.

In addition to this, I was impressed the other day by the acts of vandalism in the State of Utah. I don't think it's any different than any place else. To cite one, we had a canal plugged by some vandalism. They just shoved some plywood down in it and washed the hillside down and did a great deal of damage. You have a group of police officers who are supposed to make it their business to stop this. Yet it is impossible. To some extent this is true of the canning industry. You have an officer who is trying to do his job but it's just impossible to cover all of the things that are going on in the plant.

In addition to this, if one officer that's operating it gets sick and has to stay home a day or two, why, somebody else has to take care of it.

One of the other things that we face is a disgruntled Government employee and this case happened a number of years ago in Utah.

This company, some of the people that were supervisory employees got into an argument with a local State inspector. The result of the thing was that the Food and Drug seized about $100,000 worth of merchandise that had been shipped for reprocessing into the Chicago area. It took a year or so to get this through Government channels and eventually all but about 25 or 30 percent of it was completely released, but the practical effect of this seizure was that the company became insolvent in a couple of years.

The product itself had no harmful items in it. It was an adulteration to some slight extent, but the stuff that had been adulterated was not harmful in any way.

One of the things that the small canner faces is his lack of time to take care of everything. Every time we have a visit from a Government employee it takes somebody off the supervisory staff to take care of him and the recordkeeping that is involved is somewhat the same way. It takes a lot of time.

As to the coding provisions of the bills in question, as long as I can remember we have been using—in fact, ever since we started, we have been using date coding or even a shorter coding, a partial date coding. It's something that we can identify everything that we have and I can't see any particular reason why a Government uniform coding should be used.

Well, the only other comment I would make is the small canner needs as small amount of Government interference as he can possibly get by with. Anything that's necessary we're not going to object to, but we certainly think that some of the things that are being asked for us to do are not necessary at this time.

Senator Moss. Well, thank you, Angus, for that statement and telling us how it is when you run a cannery out in Utah. We appreciate it.

Dr. Somers.

STATEMENT OF DR. IRA I. SOMERS, EXECUTIVE VICE PRESIDENT, NATIONAL CANNERS ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY EDWARD DUNKELBERGER, COUNSEL

Dr. Somers. Senator, as per your request, we will make our statement brief and try to summarize what is a very lengthy statement and just hit the high points.

As you have indicated, I am Ira Somers and I am executive vice president of the National Canners Association. This statement is being submitted on behalf of our 500 members.

The subject of food surveillance legislation has of course been previously considered by both of the committees, and to a substantial extent S. 1168 and S. 641 reflect this prior discussion and consideration. During these deliberations the National Canners Association consistently supported expanded FDA authority to assure food safety, including provision for FDA access to food plant records pertinent to potential hazards to public health.

In the interval since our prior testimony, the National Canners Association and 11 other food trade associations have declared their support for S. 1168, one of the two bills now before these committees.

S. 1168 reflects the combined judgment and experience of the principal members of the American food industry.

The provisions of S. 1168 are based on extensive, careful deliberations in which FDA's need for additional authority was balanced against the weight of additional Government regulations which the food industry can be reasonably expected to bear.

First: It is clear that S. 1168 would not compromise on issues of food safety. It would explicitly provide FDA with ample food surveillance authority to provide further assurance of a safe American food supply. Second: Where nonsafety issues of sanitation and food quality or esthetics are involved, S. 1168 would strike a rational balance by insuring consumer protection without imposing excessive requirements on the food industry or making unrealistic demands on FDA's limited resources.

With that brief background, the chief aim of our testimony today is to urge passage of S. 1168, to explain the basis for each of the major provisions of S. 1168, and to comment upon the important differences between the provisions of S. 1168 and comparable provisions of S. 641. We will also comment, where appropriate, on the testimony of Commissioner Schmidt concerning these proposals.

On the matter of safety assurance systems, title I of S. 1168 would for the first time require all food companies to develop for each processing plant a safety assurance system identifying points in the processing operation where controls are required to assure food safety, identifying hazards associated with each such point, and establishing necessary controls and monitoring to assure that food will not be unsafe or rendered injurious to health.

The key to the safety assurance systems to be establishsed under S. 1168 is fundamental reliance upon industry knowledge and expertise. Although the development of such systems would be required, their content would be left to the voluntary discretion of each food establishment. This aspect of S. 1168 contrasts sharply with the analogous provision of S. 641 which would require that a food establishment comply with each element of its own safety assurance system or risk criminal punishment.

Substantial benefits would flow from the S. 1168 approach of placing primary responsibility on the individual company to determine the scope and detail of its safety assurance system and from making compliance with the system voluntary. The food processors would be encouraged to develop a broad, ambitions system designed to achieve food goals whose attainment may not always be accomplished in everyday practice. If, on the other hand, a company's failure to comply with a particular provision of its own safety assurance system were by itself to constitute a violation of the act, as S. 641 would provide, there would be a strong disincentive to develop broad systems or set ambitious food goals. Under S. 641 the safety assurance procedures would become a private criminal code. A company faced with the real risk of criminal punishment for violating a single technical provision of its own safety assurance system would inevitably tend to draw its system as narrowly as possible. Moreover, the incentive to construct a narrow safety assurance system would be particularly strong where the system was required

to cover housekeeping and sanitation practices unrelated to safety, as S. 641 would provide.

The voluntary nature of the safety assurance plans required under S. 1168 would in no way jeopardize food safety. FDA would of course retain its existing authority to proceed against any food which in FDA's judgment violated the adulteration provisions of the act. And if the Secretary determined that any food was being processed in a significant number of establishments so as to present an unreasonable risk that the food would be unsafe, he would be empowered to issue a safety assurance standard which would be fully enforceable under the act.

In addition, there are a number of existing programs, both voluntary and compulsory, which would serve as part or all of a company's safety assurance system. For example, the FDA's better process control plan for low-acid canned foods, which was jointly developed by NCA and FDA, would undoubtedly constitute the major part of a safety assurance system for processors of low-acid canned foods. Similarly, the better salmon control plan, a voluntary program worked out between NCA and FDA many years ago, would provide for the safety assurance systems of individual salmon canners. There are other voluntary and compulsory programs of this type which would either provide guidance in the development of a safety assurance system, or would themselves serve as such a system for participating processors.

A second difference between the two bills is that the scope of safety assurance procedures established under S. 641, rather than being limited to safety issues like the systems established under S. 1168, would extend to any adulteration under section 402(a) of the act, which would include so-called esthetic adulterations that pose no hazard to health and where the presence of the foreign matter is not detectable to the consumer.

It is our strong view that in a time of inflation, recession, and world food shortages, questions involving the esthetic quality of food, and attempts to achieve esthetically flawless food, should be carefully examined in light of the costs involved.

A food processor's ability to achieve a sterile plant environment and to produce an esthetically flawless product is inextricably linked to the cost of producing the product, a cost which the consumer must eventually bear. It is logical to assume that at some point the benefit of an additional degree of esthetic acceptability will be outweighed by its incremental cost. The fact is, of course, that the handling and cleaning of fresh produce in most home kitchens falls far below the levels of cleanliness and purity that are standard practice in the typical canning plant.

During this period when the President and numerous agency heads are voicing increasing concern over the artificial costs imposed by Government regulations, it is imperative that the probable impact on consumer food prices of these two bills be considered, particularly where safety issues are not involved. With these important factors in mind, it is our view that the extension of safety assurance procedures into nonsafety areas could spur an unnecessary increase in the cost of American food products and would accelerate the rate of departure of small businesses from the food industry.

On the matter of safety assurance standards, S. 1168 would authorize FDA to promulgate a safety assurance standard for a food or class of foods upon a finding that the food is being processed in a significant number of establishments in such a manner as to present an unreasonable risk that the food will be unsafe or rendered injurious to health. The failure to comply with an applicable safety assurance standard would constitute a violation of the act.

Commissioner Schmidt testified that this aspect of both bills is unnecessary because of existing FDA rulemaking authority. We share his view that existing FDA atuthority is ample for regulation of foods with respect to both safety and esthetics. Indeed, for many segments of the food industry already covered by existing programs, such as the better process control plan for low-acid canned foods, safety assurance standards would entail totally unnecessary duplication and cost for FDA, the industry, and the public.

We are going to omit our reference to the safety assurance plan and advisory committees because these are covered in the total statement to the committee.

We are also going to omit our reference to the registration of processors of food. We are already doing this and it's in the testimony before you.

On the matter of access to company records, S. 1168 would substantially enhance FDA's factory inspection authority to assure FDA access to processing records reasonably necessary for a determination whether a food is unsafe. This broadened factory inspection authority would accord FDA full power to protect consumers from unsafe foods without sanctioning unlimited forays into a food establishment's private records. Because, in our view, the records access provisions of S. 641 would license unwarranted incursions into food establishment files, we would like to delineate for the committees the principal differences between the records access provisions of the two bills and explain our support for the S. 1168 approach.

First: Under S. 1168, extended factory inspection authority would be directly linked to an existing or potential hazard to health. By contrast, S. 641 would permit FDA inspection of any food establishment records bearing upon whether a food may be adulterated within the meaning of section 402(a), as well as upon the accuracy of label statements made in the labeling of food. We oppose the expansion of FDA factory inspection records access authority beyond safety determinations for the same reasons we oppose the required inclusion of nonsafety related processing controls in registered safety assurance systems. The central concern of food surveillance legislation is, and should be, safety. Sweeping new authority to rummage through company records in search of a possible violation with respect to the esthetic quality or label accuracy of food products cannot be justified in terms of need or the protection of consumers.

Second: S. 1168 would require, as a prerequisite to factory record inspection, a presentation to the plant manager by the inspector of a written statement showing a reasonable need for record access. In addition, the plant manager could contest the reasonableness of the inspector's demand in an expedited proceeding before, first, a

designate of the Secretary outside of the inspector's chain of command, and then, if necessary, a U.S. district court. The decision of a district court would be final. In short, under S. 1168, FDA would be required to make an initial showing of need before searching plant records—a showing consistent with established constitutional principles.

Third: The factor inspection provision in S. 1168, unlike the comparable provision of S. 641, would provide necessary, explicit protection against disclosure of trade secrets. Under the expanded factory inspection authority proposed in S. 1168, a food processor cannot be compelled to disclose his secret formulations unless the Secretary demonstrates that he has probable cause to believe the food product is adulterated, that the public health or safety requires access to the formulation, and that no alternative means exist for determining the violation.

Another aspect of S. 641 that raises considerable question is the grant of authority to FDA to require the submission of special reports or answers in writing to specific questions concerning any matter relating to adulterated or misbranded foods. Here again FDA would have virtually limitless authority to demand submission of any information it deemed relevant to its administration of the act. No showing would have to be made of need or reasonableness.

The broad-based inspection of food processing records or demands for information without any initial showing of need which would be permitted by S. 641, not only contravenes the spirit of the fourth amendment, but also, to the extent that such records are employed in the prosecution of an individual, raises serious issues of self-incrimination under the fifth amendment. We have seen no demonstration of a countervailing social benefit which could arguably justify the Draconian impact of unrestricted records and information access authority coupled with absolute criminal liability. We respectfully urge that the provisions of S. 1168 in this regard form the basis for any action that the committees may take on this legislation.

On the matter of administration detection, we will skip over a couple of pages.

For the reason that administrative detention may, under any number of situations, seriously affect the company involved, we feel that the circumstances under which detention can be imposed should be subject to appropriate limitation. In this light, the S. 1168 administrative detention provision is designed to confine FDA detention authority within reasonable boundaries, whereas the comparable provision of S. 641 is virtually unrestricted.

First: Under S. 1168, an inspector could detain a suspect food for a reasonable period, not to exceed 20 days, where the inspector concluded that the facts provide a reasonable basis to show that the food is unsafe or injurious to health. Under S. 641, on the other hand, detention would be authorized in every case where a reasonable basis was shown that a food is adulterated, misbranded, or otherwise in violation of the act. Thus, under S. 641, a lot of products could be detained with attendant substantial injury to the owner, on the grounds that there was cause to believe that the labeling was inaccurate or that a single element of the owner's registered safety assurance procedure, totally unrelated to a health risk, had been

violated. FDA has ample existing authority to take prompt and effective action against misbranding, economic adulteration, and other violations of the act unrelated to safety, without investing individual inspectors with the discretionary power to cause a serious disruption of a food processor's business by ordering an administrative detention.

We're going to omit our comments on citizen suit authority because they are in the printed text.

We come next to criminal liability and civil liability. S. 1168 would enact an amendment to the Food, Drug, and Cosmetic Act specifying that criminal penalties may only be imposed for knowing and willful violations of the act.

As these committees are well aware, we have, over the years, repeatedly objected to the patnt inequity of the prevailing rule of absolute criminal liability of individuals for violations of the Food, Drug, and Cosmetic Act. However, the prospect of significant amendments to the act, enlarging FDA's enforcement powers and multiplying a food processor's duties under the act, casts an even harsher light on the rule of vicarious criminal liability and demands that the rule be reevaluated in the context of similar modern legislation.

Section 303 of the Food, Drug, and Cosmetic Act, which contains no explicit requirement that a violation of the act must be knowing or willful, was construed in the famous 1943 case of *United States* v. *Dotterweich*, 320 U.S. 277, to impose criminal liability on corporate officials for a violation of the act without a requirement that the violation be knowing or willful.

As the committees are undoubtedly aware, the Supreme Court a week ago reaffirmed this interpretation of the Food, Drug, and Cosmetic Act in *United States.* v. *John R. Park*, which involved a conviction of a food company official under the trial court's conception of the Dotterweich rule.

Our opposition to the rule of vicarious criminal liability of individuals for violations of the Food, Drug, and Cosmetic Act stands on a number of separate firm foundations.

First: Strict criminal liability is a significant departure from established principles of criminal law which require that the State demonstrate some knowledge or active participation in the prohibited act on the part of the defendant to justify his punishment in the name of the society.

Second: The evolution of the Nation's economy and food distribution systems in recent years has led to a point where most foods are produced and distributed by large corporations with multiple plants and warehouses. Consequently, the corporations which produce most American food products have long chains of management command which necessarily function by delegation of operational authority. Thus, a rule of law imposing strict criminal liability on an upper tier manager of a large corporation for the acts of an anonymous subordinate is inequitable from a modern, as well as traditional, perspective.

Third: The rule of strict criminal liability for violations of the Food, Drug, and Cosmetic Act is particularly pernicious because criminal sanctions are not confined to areas of the law involving safety and health risks. A corporate official can be prosecuted and

sent to jail for the act of a distant subordinate which resulted in a minor violation of an economic regulation.

Fourth: Strict criminal liability is acutely unfair where, as is true under the Food, Drug, and Cosmetic Act, the statute defines violative acts in broad language and the implementing agency prescribes substantive rules in voluminous, complex regulations. For example, FDA regulations now fill six volumes of the Code of Federal Regulations and, in the case of the canning industry, FDA regulations prescribe virtually every step of the canning process and are so technical and complex as to be virtually unintelligible to those without technical training. Yet, if the safety assurance procedure provision of S. 641 is passed, a high corporate official could be sent to jail for a remote subordinate's failure to observe a minor nonsafety related aspect of a plant's registered safety assurance procedure.

We know of a case in the State of Utah that Mr. Stevens and I discussed yesterday and I'd like to discuss this nightmarish experience of a fellow canner not so many years ago, in which he was prosecuted and sentenced to jail for an incident that was clearly nothing more than a packing accident or employee sabotage. Through some accident or other reason an alleged incident of a mouse in one of his canned products became a consumer complaint which was taken to the Food and Drug Administration. As I have indicated Food and Drug prosecuted the president of the firm who was not even in the United States at the time the product was packed and he was sentenced to jail and given a fine of $1,000. Also he was ordered to not go near his plant for the period of 1 year. This is an indication of what can happen to a packer in such instances.

Finally, the rule of strict criminal liability for violations of the Food, Drug, and Cosmetic Act is clearly inconsistent with numerous recently enacted public welfare and safety laws which explicitly provide that criminal sanctions—as opposed to civil sanctions—can only be imposed where it can be established that the violation is a knowing and willful act on the part of the person charged. In the case of each of these laws, after careful consideration and intensive discussion, Congress apparently concluded that it was inappropriate to depart from traditional principles of criminal law by authorizing the extreme sanctions of fine and imprisonment absent a showing of intent or knowledge.

Under the recently enacted Consumer Product Safety Act, criminal penalties are reserved for those situations where a person has knowingly and willfully violatd a provision of the act "after having received notice of noncompliance from the Commissioner."

In the case of the effect on State laws, we will omit our discussion because it's all in the prepared statement. I will turn then to ingredient labeling.

Both S. 1168 and S. 641 would require full ingredient labeling for standardized foods. The current ingredient labeling exemption for optional ingredients in standardized foods has been criticized by many consumer groups, and FDA has begun, on its own initiative, a program to amend each food standard to require the labeling of optional ingredients. Thus, an amendment to the act explicitly requiring such labeling would accord with consumer desires and cut short the slow process of amending each existing food standard of identity.

S. 641 includes several additional labeling provisions that have no counterpart in S. 1168. Our principal concern is with the proposed amendment to section 403(i)(2)(B), which would require a label declaration of the percentage of any ingredient that is significant with respect to value, quality, nutrition, or acceptability, or that is required to be declared upon an FDA finding that such information would be useful to consumers.

In his testimony on this provision, Commissioner Schmidt objected to this mandatory percentatge ingredient labeling requirement on the grounds that it might impose an economic burden on consumers for little or no public protection, and that protracted litigation would undoubtedly result from its enactment. He suggested that FDA be permitted to continue to rely on its general authority to prohibit false and misleading labeling, as it has done in requiring percentage labeling in seafood cocktails and other products.

The National Canners Association strongly endorses Commissioner Schmidt's suggested approach. The broad and ambiguous wording of S. 641 in this regard could well be interpreted to require percentage ingredient labeling when to do so would impose a substantial economic burden on food processors with no consequent consumer benefit, and with no assurance that compliance could be achieved. The varying transfer of liquids between packing medium and solid food in canned foods, for example, would in most instances make it impossible to percentage label the solid food—such as peas, peaches, or berries—and the packing medium—brine, juice, or syrup—at time of packing so as to assure that the label would remain accurate through distribution, storage, and sale.

For example, for products made by mixing ingredients in large batch containers, it is impossible to assure that every can of the finished product will have the precise amount of each of the ingredients in the proportions in which they were added to the batch. They will be close, but they won't be exact.

We urge that the committees accept the proposal of Commissioner Schmidt and leave the matter of percentage ingredient labeling to FDA under its existing general authority.

Lastly, the National Canners Association has recommended for many years that canned foods be appropriately coded to identify the plant and lot of the product. All low-acid canned foods are required to be coded under the better process control plan as jointly developed by NCA and FDA. Further, the association requires as a condition of membership that the products of a packer be adequately coded, and we are not aware of any difficulty in this regard in our industry.

Our only concern with the new section 411 as contained in S. 641 is the requirement of "uniform coding." If this language is intended to mean that the company's own system must itself be uniform among all of its products, then of course there could be no objection. But if the intention is to require that all companies use the same code, then the added costs, inconveniences, and confusion could not reasonably be justified.

In summary, we urge the committees to keep several key points in mind in considering these two proposed food surveillance bills.

First, the food industry has in its development of, and support for, S. 1168 made an affirmative, conscientious effort to strengthen the Food, Drug, and Cosmetic Act. Second, the focal point of any food surveillance legislation should be consumer safety and health, not labeling, food esthetics, or plant sanitation unrelated to health risks. Third, in authorizing expanded FDA enforcement powers, Congress must strike a reasonable balance, assuring a safe American food supply without imposing unnecessary burdens on food processors. Finally, the cost to consumers of government regulations is becoming an increasingly critical issue against which expanded agency authority must be judged. We could spend a lot of time on that point.

We hope that our comments on these two bills have been helpful to the committees and we appreciate the opportunity to present our industry's views.

Mr. Chairman, I failed to introduce Mr. Dunkelberger, who is here with us from our legal counsel of Covington and Burling. That concludes our official remarks.

Senator Moss. I should have acknowledged his presence and we are glad Mr. Dunkelberger is here.

We do thank you for your statement and it is a good, complete statement and it will be in the record in toto.

You referred to the *United States* v. *Park* case and I have the text of that. I will put that in the record, which helps to explain what the holding of the court is in that case.

You indicate, Dr. Somers, that the food processors have in existence mechanisms for insuring food safety and identifying potential hazards at various points of the processing.

How do these existing mechanisms differ from those which you would propose in S. 1168?

Dr. Somers. Well, we think the program we have for low-acid canned foods which is known to us as the better process control plan, and which is known to FDA as their part 90, 128(b) regulation—we think what is contained in that regulation would be essentially the same as what would be promulgated under this act were it passed because this FDA regulation is extremely complete and extensive in its coverage. We have now almost 2 years of experience with it and while it has caused pain to some members of our industry we, as an industry, believe it is a control that's necessary and that our industry is learning to live with it. We believe that the American canned food supply is at present very safe because of this regulation.

So what. I'm saying is that this would be part of the regulations which we think Food and Drug would adopt under this act.

Maybe Mr. Dunkelberger would want to comment further on that.

Mr. Dunkelberger. It's just thte point that the better process control plan, for example, would undoubtedly form the major part of any company's own safety assurance system. It already has the guidance for canners established in it. We're not asking for exemption from the act's provisions, as some have suggested we should, because of the complete coverage in the plan we would anticipate that we are way ahead of the bill. We have already got a better process

control plan. We think canners are compelled to adhere to it and accordingly their own safety assurance systems would follow it. This aspect of the bill would have relatively little impact on them.

Dr. SOMERS. But the plan does call for registering of the canneries so that that aspect of it is also covered.

Senator MOSS. Well, how does that vary then from S. 641?

Dr. SOMERS. Basically, the difference is that the better process control plan is aimed at product safety whereas 641 would extend FDA's authority under the new provisions into the area of esthetic adulteration.

Mr. DUNKELBERGER. We think that sanitation and esthetic matters are fully covered under the existing act, in the good manufacturing practice regulations and under other provisions of the act. Our view is that the intensive additional regulation you find in the better process control plan is justified in the interest of safety, but we don't believe it's necessary when you get beyond questions of safety, and that really is where we differ with S. 641.

Senator MOSS. You suggest that the FDA's record access powers be limited to matters directly linked to an existing or potential health hazard. How would this work? Suppose an inspector had a particular suspicion and asked to look at certain ingredients records. How would his interest in reviewing these records comply with the limitations proposed in your bill? Would he have to debate with you or appeal to a court for access to certain records and show cause why he believed these records were necessary for making his determination?

Dr. SOMERS. I'll ask Mr. Dunkelberger to comment on that.

Mr. DUNKELBERGER. I think the way we have worked the system we have established here is that the demand would be made by the inspector saying, "I think these records may be useful to determine whether there's a health or safety question." If the canner agreed —and we would expect by the way, with this new authority under the bill, that in most cases or in virtually all cases, the canner would agree—he would recognize the added FDA authority to inspect. If the canner felt the request for the records was unrelated to safety factors, he could say, "Well, I don't believe that your authority should extend that far." There would be an immediate chance to appeal the inspector's request to a superior and then an opportunity to have it tested in district court if there remained a difference of opinion concerning those records.

It is only in those rare cases that you would have that occur. I should add that for a number of years—at least in recent years—the FDA factory inspection authority was interpreted by the FDA to require a search warrant before it could demand access to food plants. We agreed that that was probably the effect of the Supreme Court's decision under the *See* and *Camara* cases. We are aware of no case in which a canner made the inspectors get a search warrant before they could inspect the food plant. The canners did not take advantage of what one might regard as an important safeguard. They acceded to the inspection request. We would expect the same pattern to govern here. W don't imagine any canner is going to be sending inspectors off to court for routine requests. It is because

of the existence of the safeguard rather than the use of the safeguard that I think it is perhaps most important to provide some limitation on the FDA inspection authority.

Senator Moss. You suggest or cite in your testimony the Federal Water Pollution Control Act which has a proviso subjecting to criminal penalties one who willfully or negligently violates the act; yet 1168 does not include a negligence test.

Do you believe that it would not be unreasonable to include a provision concerning negligence? For instance, an amendment to 303(a) providing that in addition to knowing or willful violations one might be convicted if a person negligently authorizes, orders or performs any act or practice which constitutes a violation of 301?

Mr. DUNKELBERGER. We are convinced, Mr. Chairman—again, I'll answer that because it's essentially a legal question—that the basic test of "knowing and willfulness" is the appropriate one. However, I think I can speak with confidence that if Congress were to provide for "knowing, willful or negligent" in an amendment, that would be regarded, I am confident, by the food industry as a substantial and sufficient step to bring this law in line with other consumer protection laws. And personally, I would have no objection to a reasonable "negligence" test.

If it could be shown that a corporate official didn't know or have reason to know of a violation, but because of his own negligence did it occur, then perhaps it would not be unreasonable to have the criminal sanction available.

In that regard, I might mention that although the *Park* case has been said to reflect a unanimous view of absolute criminal liability, I don't think it really reads that way. The Dissent itself suggested that a common law negligence test should apply.

So your suggestion I think is one that really bears further investigation and, personally, I think it would be acceptable to the industry.

Senator Moss. Well, thank you very much. I wish we had really more time to discuss the details, but time is pressing this morning and we must move on. We do appreciate your testimony very much.

[The statement and court decision follow:]

STATEMENT ON BEHALF OF THE NATIONAL CANNERS ASSOCIATION

This statement on S. 1168—the "Food Safety Assurance Amendments of 1975"—and on S. 641—the "Consumer Food Act of 1975"—is submitted on behalf of the National Canners Association, whose almost 500 members pack approximately 90% of the national production of canned foods. My name is Ira I. Somers; I am Executive Vice President of the Association and Director of its Research Laboratories.

The Association very much appreciates this opportunity to present the views of the canning industry on these bills. Although the two bills contain a number of substantially different provisions, both would enact a series of amendments to the Food, Drug and Cosmetic Act which would constitute the most significant revision of the food regulatory provisions of the Act since its passage in 1938.

The subject of food surveillance legislation has of course been previously considered by both of the Committees, and to a substantial extent S. 1168 and S. 641 reflect this prior discussion and consideration. Although we will not attempt to recount the legislative background of these proposals in previous Congresses, we would like to emphasize that during these deliberations the

National Canners Association consistently supported expanded FDA authority to assure food safety, including provision for FDA access to food plant records pertinent to potential hazards to public health.

In the interval since our prior testimony, the National Canners Association and a number of other food trade associations have declared their support for S. 1168, one of the two bills now before these Committees. S. 1168 reflects the combined judgment and experience of the principal members of the American food industry.

The provisions of S. 1168 are based on extensive, careful deliberations in which FDA's need for additional authority was balanced against the weight of additional government regulations which the food industry can be reasonably expected to bear.

First, it is clear that S. 1168 would *not* compromise on issues of food safety. It would explicitly provide FDA with ample food surveillance authority to provide further assurance of a safe American food supply. Second, where non-safety issues of sanitation and food quality or aesthetics are involved, S. 1168 would strike a rational balance by insuring consumer protection without imposing excessive requirements on the food industry or making unrealistic demands on FDA's limited resources.

With that brief background, the chief aim of our testimony today is to urge passage of S. 1168, to explain the basis for each of the major provisions of S. 1168, and to comment upon the important differences between the provisions of S. 1168 and comparable provisions of S. 641. We will also comment, where appropriate, on the testimony of Commissioner Schmidt concerning these proposals.

In the interest of conserving the time of the Committees, my oral testimony will be based on excerpts from our longer written statement, although I will be pleased to answer any questions you may have on any aspect of our statement. We request that our entire statement be included in the record as if it had been read at the hearings.

However, as a preface to our testimony on these two bills, we deem it appropriate to remind the Committees of the American food industry's excellent safety record. Although unfortunate isolated incidents of food adulteration have inevitably occurred, the American food supply remains among the safest and most wholesome in the world. As we have emphasized to these Committees in the past, surveillance legislation must be recognized as fundamentally preventive in nature rather than as a response to any significant existing problem.

Furthermore, while we acknowledge that the scope of FDA's food surveillance authority could appropriately be broadened in particular areas through amendments to the Act, it must not be overlooked that FDA has done an effective and commendable job under its current authority in monitoring the wholesomeness of the American food supply.

Thus, during these important hearings, we urge that a balanced perspective be preserved. The basic issues of food safety and the preventive aid of the legislative proposals should not be obscured by reference to aberrant hazards or the unattainable goal of aesthetically flawless food.

I will turn now to a discussion of S. 1168 which has the support of virtually every major segment of the food processing industry and would enact a series of amendments to the Federal Food, Drug and Cosmetic Act that will substantially strengthen and make more effective FDA regulation of the American food supply.

I. SAFETY ASSURANCE SYSTEMS

Title I of S. 1168 would for the first time require all food companies to develop for each processing plant a safety assurance system identifying points in the processing operation where controls are required to assure food safety, identifying hazards associated with each such point, and establishing necessary controls and monitoring to assure that food will not be unsafe or rendered injurious to health.

Such systems must be set forth in written form and be available for inspection by FDA. The establishment of such systems would be compulsory. It would be a violation of the Act to fail to develop, set forth in writing, or make accessible to FDA safety assurance systems.

The key to the safety assurance systems to be established under S. 1168 is fundamental reliance upon industry knowledge and expertise. Although the development of such systems would be required, their content would be left to the voluntary discretion of each food establishment. This aspect of S. 1168 contrasts sharply with the analogous provision of S. 641 which would require that a food establishment comply with each element of its own safety assurance system or risk criminal punishment.

Substantial benefits would flow from the S. 1168 approach of placing primary responsibility on the individual company to determine the scope and detail of its safety assurance system and from making compliance with the system voluntary. The food processor would be encouraged to develop a broad, ambitious system designed to achieve food goals whose attainment could not necessarily be assured in everyday practice. If, on the other hand, a company's failure to comply with a particular provision of its own safety assurance system were by itself to constitute a violation of the Act, as S. 641 would provide, there would be a strong disincentive to develop broad systems or set ambitious food goals. Under S. 641 the safety assurance procedures would become a private criminal code. A company faced with the real risk of criminal punishment for violating a single technical provision of its own safety assurance system would inevitably tend to draw its system as narrowly as possible. Moreover, the incentive to construct a narrow safety assurance system would be particularly strong where the system was required to cover housekeeping and sanitation practices unrelated to safety, as S. 641 would provide.

The voluntary nature of the safety assurance plans required under S. 1168 would in no way jeopardize food safety. FDA would of course retain its existing authority to proceed against any food which in FDA's judgment violated the adulteration provisions of the Act. And if the Secretary determined that any food was being processed in a significant number of establishments so as to present an unreasonable risk that the food would be unsafe, he would be empowered to issue a safety assurance standard which would be fully enforceable under the Act.

Furthermore, the National Canners Association Research Laboratories, and undoubtedly other food trade associations, would provide technical support to individual food processors in developing comprehensive and effective safety assurance systems. In addition, there are a number of existing programs, both voluntary and compulsory, which would serve as part or all of a company's safety assurance system. For example, the FDA's Better Process Control Plan for low acid canned foods, which was jointly developed by NCA and FDA, would undoubtedly constitute the major part of a safety assurance system for processors of low acid canned foods. Similarly, the Better Salmon Control Plan, a voluntary program worked out between NCA and FDA many years ago, would provide the basis for the safety assurance systems of individual salmon canners. There are other voluntary and compulsory programs of this type which would either provide guidance in the development of a safety assurance system, or would themselves serve as such a system for participating processors.

A second difference between the two bills is that the scope of safety assurance procedures established under S. 641, rather than being limited to safety issues like the systems established under S. 1168, would extend to any adulteration under Section 402(a) of the Act, which would include so-called aesthetic adulterations that pose no hazard to health and where the presence of the foreign matter is not detectable to the consumer.

It is our strong view that in a time of inflation, recession and world food shortages, questions involving the aesthetic quality of food, and attempts to achieve aesthetically flawless food, should be carefully examined in light of the costs involved. In a cogent paper entitled "Some Legal Aspects of Providing a Sufficient Food Supply for a Hungry Population," delivered at the Annual Meeting of the American Association for the Advancement of Science in New York City on January 29, 1975, Stephen McNamara of the FDA General Counsel's Office considered the issue of aesthetic adulteration and observed that "our traditional perceptions of 'filth' . . . may be expected to change as the world's food supply shrinks in relation to the world's population." Noting examples of the numerous natural contaminants contained in various raw foods and FDA's administrative action levels for those contaminants, Mr. McNamara

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concluded that "as we insist upon 'purer' and 'cleaner' food, rejecting that which does not meet our standards, we thereby reduce the available food supply and increase its cost. Where safety is not a factor, at some point consideration of aesthetics must give way to considerations of human need."

A food processor's ability to achieve a sterile plant environment and to produce an aesthetically flawless product is inextricably linked to the cost of producing the product, a cost which the consumer must eventually bear. It is logical to assume that at some point the benefit of an additional degree of aesthetic acceptability will be outweighed by its incremental cost. The fact is, of course, that the handling and cleaning of fresh produce in the home kitchen falls far below the levels of cleanliness and purity that are standard practice in the typical canning plant.

During this period when the President and numerous agency heads are voicing increasing concern over the artificial costs imposed by government regulation, it is imperative that the probable impact on consumer food prices of these two bills be considered, particularly where safety issues are not involved. With these important factors in mind, it is our view that the extension of safety assurance procedures into non-safety areas could spur an unnecessary increase in the cost of American food products and would accelerate the rate of departure of small businesses from the food industry.

It should not be forgotten that the impetus for these legislative proposals were concerns for food safety. In the Committee on Labor and Public Welfare's Report on S. 2373 published on December 7, 1973, the need for food surveillance legislation was based, and we think correctly, on the need to assure food safety and to prevent risks to health. These are the fundamental concerns to the American consumer, and we see no justification for extending the scope of food surveillance legislation into peripheral areas.

II. SAFETY ASSURANCE STANDARDS

S. 1168 would authorize FDA to promulgate a safety assurance standard for a food or class of foods upon a finding that the food is being processed in a significant number of establishments in such a manner as to present an unreasonable risk that the food will be unsafe or rendered injurious to health. The failure to comply with an applicable safety assurance standard would constitute a violation of the Act.

Commissioner Schmidt testified that this aspect of both bills is unnecessary because of existing FDA rulemaking authority. We share his view that existing FDA authority is ample for regulation of foods with respect to both safety and aesthetics. Indeed, for many segments of the food industry already covered by existing programs, such as the Better Process Control Plan for low-acid canned foods, safety assurance standards would entail totally unnecessary duplication and cost for FDA, the industry, and the public.

However, if the Committees deem it desirable to provide authority for safety assurance standards, we urge rejection of the approach in S. 641, under which FDA's authority to set safety assurance standards would be broadened to apply to any food or class of food being processed in such a manner as to present an unreasonable risk of adulteration within the meaning of Section 402(a). A safety assurance standard issued under S. 641 would, like company safety assurance plans adopted under the provisions of S. 641, govern a range of plant housekeeping and sanitation procedures unrelated to safety or health risks. For the reasons previously enumerated, we oppose the expansion of FDA's food surveillance authority into non-safety areas, as totally unnecessary and unduly costly.

III. SAFETY ASSURANCE PLAN AND ADVISORY COMMITTEES

S. 641 would enact two provisions which have no counterpart in S. 1168. One would require the promulgation of a safety assurance plan by FDA and the other would grant FDA authority to appoint advisory committees. Both provisions are in our view unwarranted, and each would, although to a different extent, unnecessarily intrude upon FDA's administrative discretion. We are in full agreement with Commissioner's Schmidt's testimony on these provisions that they are to a great extent unduly burdensome and unnecessary.

FDA's current food regulatory activities, many of which have been described in these Committees, are innovative, economical and remarkably effective. Moreover, FDA has sought and obtained close industry cooperation in developing new food surveillance techniques. An excellent example is the NCA–FDA joint development of regulations for the processing of low acid canned foods, under authority of the Emergency Permit Control provision of the Act that had not been implemented since enactment of the Federal Food, Drug and Cosmetic Act in 1938.

We are genuinely concerned that the imposition of rigid external controls on FDA's food surveillance efforts will not only confine FDA's flexibility, but also inhibit the mutual efforts of FDA and the food industry.

IV. REGISTRATION OF PROCESSORS OF FOOD

An essential foundation for effective food surveillance is mandatory food establishment registration. Throughout the consideration of food surveillance legislation we have supported an amendment to the Food, Drug and Cosmetic Act containing a food establishment registration requirement comparable to Section 510 of the Act requiring the registration of drug processors. Although S. 641 and S. 1168 contain slightly different registration provisions, the basic requirements of the two bills are the same. The principal difference is that S. 641 would require biennial registration, while S. 1168 would require one-time registration kept up to date by appropriate notification of changes to FDA.

In our view, a food establishment registration requirement is long overdue. The passage of the registration provision in S. 1168 will fill a critical gap in FDA's food surveillance authority. On the other hand, we would have no strong objection if Congress were to accede to FDA's request that action be deferred on compulsory registration until budgetary conditions become less restrictive.

V. ACCESS TO COMPANY RECORDS

S. 1168 would substantially enhance FDA's factory inspection authority to assure FDA access to processing records reasonably necessary for a determination whether a food is unsafe. This broadened factory inspection authority would accord FDA full power to protect consumers from unsafe foods without sanctioning unlimited forays into a food establishment's private records. Because, in our view, the records access provisions of S. 641 would license unwarranted incursions into food establishment files, we would like to delineate for the Committees the principal differences between the records access provisions of the two bills and explain our support for the S. 1168 approach.

First, under S. 1168, extended factory inspection authority would be directly linked to an existing or potential hazard to health. By contrast, S. 641 would permit FDA inspection of any food establishment records bearing upon whether a food may be adulterated within the meaning of Section 402(a), as well as upon the accuracy of label statements made in the labeling of food. We oppose the expansion of FDA factory inspection records access authority beyond safety determinations for the same reasons we oppose the required inclusion of non-safety related processing controls in registered safety assurance systems. The central concern of food surveillance legislation is, and should be, *safety*. Sweeping new authority to rummage through company records in search of a possible violation with respect to the aesthetic quality or label accuracy of food products cannot be justified in terms of need or the protection of consumers.

Second, S. 1168 would require, as a prerequisite to factory record inspection, a presentation to the plant manager by the inspector of a written statement showing a reasonable need for record access. In addition, the plant manager could contest the reasonableness of the inspector's demand in an expedited proceeding before, first, a designate of the Secretary outside of the inspector's chain of command, and then, if necessary, a United States district court. The decision of a district court would be final. In short, under S. 1168, FDA would be required to make an initial showing of need before searching plant records—a showing consistent with established Constitutional principles.

Under S. 641, on the other hand, no pre-inspection showing of any kind by FDA would be required. In effect, S. 641 would relieve FDA of the burden of demonstrating the need for a record search and would shift the burden to the processor to initiate litigation to contest the basis for any search. Questions concerning the scope of FDA inspection authority could be more promptly and efficiently resolved in the expedited proceeding prescribed in S. 1168. Moreover the unrestricted inspection authority in S. 641 would precipitate routine FDA fishing expeditions through company records violating privacy rights without any relation to an established need.

Third, the factory inspection provision in S. 1168, unlike the comparable provision of S. 641, would provide necessary, explicit protection against disclosure of trade secrets. Under the expanded factory inspection authority proposed in S. 1168, a food processor cannot be compelled to disclose his secret formulations unless the Secretary demonstrates that he has probable cause to believe the food product is adulterated, that the public health or safety requires access to the formulation, and that no alternative means exist for determining the violation.

Another aspect of S. 641 that raises considerable question is the grant of authority to FDA to require the submission of special reports or answers in writing to specific questions concerning any matter relating to adulterated or misbranded foods. Here again FDA would have virtually limitless authority to demand submission of any information it deemed relevant to its administration of the Act. No showing would have to be made of need or reasonableness.

In our view, the onus on the food industry of the carte blanche records and information access provisions of S. 641 must be judged in light of the prevailing rule of absolute criminal liability for corporations and individuals who violate the Food, Drug and Cosmetic Act. This extraordinary rule of vicarious criminal liability deeply concerns us and, for reasons which we will articulate later, we strongly urge an amendment to the Food, Drug and Cosmetic Act providing that criminal sanctions may only be imposed for knowing or willful violations. Beyond that, however, in the context of the sweeping FDA record inspections and information demands which would be authorized by S. 641, it would be highly inappropriate to use any records obtained under such authority in the criminal prosecution of individuals, whether or not a showing of intent is to be required.

The broadbased inspection of food processing records or demands for information without any initial showing of need which would be permitted by S. 641, not only contravenes the spirit of the Fourth Amendment, but also, to the extent that such records are employed in the prosecution of an individual raises serious issues of self-incrimination under the Fifth Amendment. We have seen no demonstration of a countervailing social benefit which could arguably justify the Draconian impact of unrestricted records and information access authority coupled with absolute criminal liability. We respectfully urge that the provisions of S. 1168 in this regard form the basis for any action that the Committees may take on this legislation.

VI. ADMINISTRATIVE DETENTION

In earlier hearings, Commissioner Schmidt testified that FDA needs additional authority administratively to detain suspect foods for up to 20 days because, in some cases in FDA's experience, a suspect food has been shipped before judicial seizures can be accomplished. While the National Canners Association is not aware of circumstances under which food processors have refused to hold goods voluntarily upon the request of an FDA inspector when there is a factual basis for believing that the goods may be in violation of the Act, we are in agreement that FDA should have authority, similar to USDA's authority with respect to meat, poultry and egg products, to detain suspect goods against the possibility, which we consider remote, that company may refuse to voluntarily withhold goods in legitimate FDA requests.

Accordingly, the National Canners Association supports the administrative detention provision of S. 1168 which would provide FDA with needed detention

authority and would contain reasonable procedural safeguards to limit the absolute discretion of individual inspectors and to minimize the risk of financial ruin of a food processor caused by the unjustified detention of his goods.

Although for some classes of foods and for some companies a 20-day detention for a suspect lot of goods would not be a heavy burden, there are a number of separate categories of food producers, comprising a significant portion of the industry, for which a 20-day detention period could create an intolerable financial strain. These include: (1) small packers for which a 20-day detention of several lots would constitute a major disruption in their production schedule; (2) packers of perishable products subject to complete or partial decomposition during the detention period; (3) packers bound to supply contracts with firm delivery dates; and (4) seasonal processors who pack their entire annual production within a span of a few weeks and must rely on prompt shipment due to limitations in warehouse space.

For the reason that administrative detention may under any number of situations seriously affect the company involved, we feel that the circumstances under which detentions can be imposed should be subject to appropriate limitation. In this light, the S. 1168 administrative detention provision is designed to confine FDA detention authority within reasonable boundaries, whereas the comparable provision of S. 641 is virtually unrestricted.

First, under S. 1168, an inspector could detain a suspect food for a reasonable period, not to exceed 20 days, where the inspector concluded that the facts provide a reasonable basis to show that the food is unsafe or injurious to health. Under S. 641, on the other hand, detention would be authorized in every case where a reasonable basis was shown that a food is adulterated, misbranded, or otherwise in violation of the Act. Thus, under S. 641, a lot of product could be detained, with attendant substantial injury to the owner, on the grounds that there was cause to believe that the labeling was inaccurate or that a single element of the owner's registered safety assurance procedure, totally unrelated to a health risk, had been violated. FDA has ample existing authority to take prompt and effective action against misbranding, economic adulteration, and other violations of the Act unrelated to safety, without investing individual inspectors with the discretionary power to cause a serious disruption of a food processor's business by ordering an administrative detention.

Second, both S. 1168 and S. 641 would provide that, if a food is still being processed, and has not been put in final form for shipment, processing may continue until the food is put in final form at which time detention may be ordered. This provision is important to our members and we urge its passage.

Third, S. 1168 would provide for the appeal of a detention order to a superior official outside of the inspector's chain of command who would conduct an expedited informal hearing or to the United States district court which would have jurisdiction over a subsequent seizure. The comparable provision of S. 641 would permit the appeal of a detention order to a superior official but would not require that the official be outside the inspector's chain of command. Nor would S. 641 recognize any alternative right of appeal to a United States district court. In view of the potentially devastating impact of an administrative detention order and the considerable discretion retained by an individual inspector in determining whether the basis for a detention exists, it is essential that a disinterested official preside at an administrative hearing and that the owner be accorded the opportunity to promptly resolve any factual disputes in the judicial forum where a subsequent seizure action would be prosecuted.

VII. CITIZEN SUIT AUTHORITY

S. 1168 would empower any citizen to bring suit, 60 days after notice to FDA, to require FDA to perform any duty under the Act. The parallel provision of S. 641 would authorize citizen suits not only against FDA, but also against companies subject to the Act.

While the National Canners Association supports the citizen suit provision in S. 1168 as an independent means of assuring that FDA carries out its responsibilities under the Act, we oppose the S. 641 provision which would authorize citizen suits against any industrial food establishments alleged to be in violation of the Act.

Our primary objection to the S. 641 citizen suit provision is that it would severely restrict FDA's enforcement flexibility and lead to non-uniform enforcement of the Act. Congress and the courts have repeatedly recognized that FDA is an expert agency with broad authority to issue regulations on complex technical and scientific issues. Moreover, in the preamble to the final regulations on FDA Administrative Practices and Procedures published in the Federal Register of May 27, 1975 (40 Fed. Reg. 22950), the Commissioner emphasizes the need for full FDA control over enforcement of the Act and for an adequate factual record where enforcement policy is tested in court.

In addition, in its efforts to streamline and reduce the cost of enforcement of the Act, FDA has recently concentrated, as also reflected in its new procedural regulations, on the passage of broad substantive regulations applicable to entire classes of food rather than on the prosecution of costly suits against individual companies. This emerging FDA policy of employing regulations to define the frontiers of enforcement policy was reflected in FDA's 1973 Annual Report which states that: "Regulations are the principal means for translating law and policy into practical guidelines and standards for compliance."

If citizens are permitted to bring suits against individual companies for alleged violations of the Food, Drug and Cosmetic Act, after FDA has concluded that suit is unwarranted or inadvisable, FDA will be faced with a Hobsons choice. It can choose not to intervene and watch helplessly as a private citizen, who may be pursuing a frivolous or fanciful claim, determines FDA enforcement priorities and compels a court to resolve important technical issues in an informational vacuum. Or, to preserve its primacy over the enforcement of the Act, FDA can intervene in such suits, as S. 641 would explicitly provide, to assure that the Act is uniformly enforced and that the court has before it all of the information necessary for a responsible judgment.

However, through this obligatory intervention process, FDA will be forced to abandon its recently successful policy of achieving enforcement, where possible, through regulations and will be compelled to invest a disproportionate share of its resources in litigation. The proporton of FDA resources presently committed to litigation is already high. FDA noted in its 1973 Annual Report the unremitting rise in the number of lawsuits in which it is involved, including numerous lawsuits filed against FDA by industry members and consumer groups. If FDA's expanding litigation costs are further multiplied by the necessity of intervening in numerous citizen suits of dubious merit, its ability to efficiently allocate its resources will be eroded and its control over the selection of enforcement priorities will be confined.

VIII. CRIMINAL AND CIVIL LIABILITY

A. Elimination of absolute criminal liability

S. 1168 would enact an amendment to the Food, Drug and Cosmetic Act specifying that criminal penalties may only be imposed for knowing and willful violations of the Act.

As these Committees are well aware, we have, over the years, repeatedly objected to the patent inequity of the prevailing rule of absolute criminal liability of individuals for violations of the Food, Drug and Cosmetic Act. However, the prospect of significant amendments to the Act, enlarging FDA's enforcement powers and multiplying a food processor's duties under the Act, casts an even harsher light on the rule of vicarious criminal liability and demands that the rule be reevaluated in the context of similar modern legislation.

Thus, we will attempt to set forth in some depth the compelling reasons for finally abandoning this unwarranted aberration of traditional principles of criminal law.

Section 303 of the Food, Drug and Cosmetic Act, which contains no explicit requirement that a violation of the Act must be knowing or willful, was construed in the famous 1943 case of *United States* v. *Dotterweich*, 320 U.S. 277, to impose criminal liability on corporate officials for a violation of the Act without a requirement that the violation be knowing or willful. Indeed, in *Dotterweich*, the corporate official whose conviction was affirmed was held

subject to prosecution even though he was not aware of the acts giving rise to the violation and took no active part in the prohibitive transaction.

As the Committees are undoubtedly aware, the Supreme Court a week ago reaffirmed this interpretation of the Food, Drug and Cosmetic Act in *United States* v. *John R. Park*, which involved a conviction of a food company official under the trial courts conception of the *Dotterweich* rule. Once again the Court emphasized that knowledge or intent are not required to be proved in criminal prosecutions of responsible corporate officials under the Act. In a key passage of its opinion, the Court stated:

"[T]he Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

We respectfully submit that whatever degree of effectiveness or fairness this statutory approach may have been thought to have in 1906, or even in 1938, the conditions of food production and processing on a massive scale in the 1970's, together with the ever increasing number and complexity of FDA regulations, make it impossible for an individual corporate official under all circumstances "to insure that violations will not occur."

Our opposition to the rule of vicarious criminal liability of individuals for violations of the Food, Drug and Cosmetic Act stands on a number of separate firm foundations.

First, strict criminal liability is a significant departure from established prniciples of criminal law which require that the state demonstrate some knowledge or active participation in the prohibited act on the part of the defendant to justify his punishment in the name of the society.

Second, the evolution of the nation's economy and food distribution systems in recent years has led to a point where most foods are produced and distributed by large corporations with multiple plants and warehouses. Consequently, the corporations which produce most American food products have long chains of management command which necessarily function by delegation of operational authority. Thus, a rule of law imposing strict criminal liability on an upper tier manager of a large corporation for the acts of an anonymous subordinate is inequitable from a modern, as well as traditional, perspective.

Third, the rule of strict criminal liability for violations of the Food, Drug and Cosmetic Act is particularly pernicious because criminal sanctions are not confined to areas of the law involving safety and health risks. A corporate official can be prosecuted and sent to jail for the act of a distant subordinate which resulted in a minor violation of an economic regulation.

Fourth, strict criminal liability is acutely unfair where, as is true under the Food, Drug and Cosmetic Act, the statute defines violative acts in broad language and the implementing agency prescribes substantive rules in voluminous, complex regulations. FDA regulations now fill six volumes of the Code of Federal Regulations and, in the case of the canning industry, FDA regulations prescribe virtually every step of the canning process and are so technical and complex as to be virtually unintelligible to those without technical training. Yet, if the safety assurance procedure provision of S. 641 is passed, a high corporate official could be sent to jail for a remote subordinate's failure to observe a minor non-safety related aspect of a plant's registered safety assurance procedure.

Moreover, the food industry can derive little comfort from the expected FDA response that criminal sanctions under the Food, Drug and Cosmetic Act are conscientiously applied and rarely abused. Because of the inevitability of technical violations based on failure to conform to one of FDA's comprehensive, technically complex, and sometimes ambiguous regulations, FDA retains the awesome power to prosecute virtually at will. Regardless of whether this power is abused, FDA's mere possession of such power contradicts the fundamental principal of a government of law and not men.

Furthermore, criminal prosecutions of individuals under the Food, Drug and Cosmetic Act are an integral part of FDA's enforcement policy. In its 1973 Annual Report, FDA stated that:

"A marked decline in the number of food seizures is expected to occur in the next fiscal year, due to a change in FDA policy. The Agency has decided to

make greater use of warning notices, product recalls, and prosecutions in dealing with insanitary foods, rather than to ask the Federal courts to seize them. Seizures will continue to be made if there is no better way to protect the public." (At p. 8.)

A recent study of the agency's enforcement activities reveals that in 1973 approximately 90 criminal cases were forwarded to U.S. attorneys for prosecution and in most, consistent with the FDA's policy, at least one individual official was charged. In a number of reported cases over the years, individual corporate defendants have been convicted under the *Dotterweich* rule absent a showing of participation in the violative acts. Mr. Stevens, a small canner from Utah, will briefly describe in his testimony the nightmare experience of a fellow canner not so many years ago, in which he was prosecuted and sentenced to jail for an incident that was clearly nothing more than a packing accident, or employee sabotage.

Finally, the rule of strict criminal liability for violations of the Food, Drug and Cosmetic Act is clearly inconsistent with numerous recently enacted public welfare and safety laws which explicitly provide that criminal sanctions—as opposed to civil sanctions—can only be imposed where it can be established that the violation is a knowing and willful act on the part of the person charged. In the case of each of these laws, after careful consideration and intensive discussion, Congress apparently concluded that it was inappropriate to depart from traditional principles of criminal law by authorizing the extreme sanctions of fine and imprisonment absent a showing of intent or knowledge.

For example, Section 113(c) of the Clean Air Act of 1970 authorizes civil injunctions for any violation, but provides that any person who *knowingly* violates the requirements of an applicable plan, or who *knowingly* fails or refuses to comply with an order of the Administrator, shall be subject to specified *criminal* sanctions. Similarly, the Federal Water Pollution Control Act authorizes civil penalties for violations of certain provisions of the Act but permits the imposition of criminal sanctions only if it can be shown that a person *willfully* or *negligently* volated the Act.

This same important distinction between the elements of criminal and civil violations is contained in the Occupational Safety and Health Act, a statute as directly concerned with health and safety as the Food, Drug and Cosmetic Act. While a violation of any standard, rule or order promulgated under OSHA may give rise to civil penalties, criminal sanctions for such violations are reserved solely for those situations in which an employer willfully violates a standard or order, and that violation causes death to an employee.

Under the recently enacted Consumer Product Safety Act, criminal penalties are reserved for those situations where a person has knowingly and willfully violated a provision of the Act "after having received notice of non-compliance from the Commissioner."

Significantly, both of these Acts, in contrast to the Food, Drug and Cosmetic Act, contain provisions exclusively concerned with health and safety. Yet, in each Act, the extreme sanction of criminal punishment is tempered by a knowing and willful requirement.

In addition, S. 776, the proposed "Toxic Substances Control Act" which was introduced by Senator Tunney on February 20, 1975, would provide in Section 17(b) that criminal penalties may only be imposed for a knowing or willful violation.

The National Canners Association submits that it is particularly appropriate at this time—when substantial amendments to the Food, Drug and Cosmetic Act are under consideration—to reassess the rule of absolute criminal liability. The Supreme Court's decision in the *Park* case—in essence making individual corporate officials insurers against the intentional or accidental misdeeds of all subordinate employees—makes it particularly important that the Food, Drug and Cosmetic Act be brought into line with modern safety and welfare legislation, and with traditional principles of fairness and due process.

B. Civil liability

Tied directly to the proposed elimination of the rule of absolute criminal liability in S. 1168 is the proposed establishment of an additional enforcement measure which would authorize civil penalties to be sought by FDA in court

actions for up to $10,000 for each violation, compared to the maximum authorized fine of $1,000 for an initial criminal violation under the current Act. This provision would enhance FDA's enforcement flexibility, as well as providing a more effective deterrent against violative acts, without exposing individuals to harsh criminal punishment based on vicarious responsibility for the acts of others.

Furthermore, separate civil and criminal penalty provisions—the first authorizing fines up to $10,000 and the second authorizing criminal sanctions where a knowing and willful violation is committed—would bring the Food, Drug and Cosmetic Act into conformity with the vast majority of modern health and welfare statutes that we have noted in which a clear distinction is maintained between civil and criminal penalty provisions and criminal sanctions are premised on intentional violations.

The civil penalty provisions of S. 641 raises two very substantial questions. That bill would authorize civil penalties to be imposed through administrative proceedings rather than by the courts. This provision would place FDA in the position of writing the laws through the promulgation of regulations, enforcing the laws as the executive branch, and deciding the cases and imposing fines. We see no reasonable basis for giving such broad authority to the agency. Certainly the courts should hear and determine all charges of violations.

Second, S. 641 would establish civil penalties of $10,000 for each day of violation rather than for each violation. We urge that the wording of S. 1168 be adopted so that monetary civil penalties be imposed for each violation.

IX. EFFECT ON STATE LAWS

In a major step towards uniformity of food regulation, S. 1168 would provide that all requirements of the Food, Drug and Cosmetic Act be made enforceable by state or local officials, as well as by FDA. Coupled with this broad encouragement of local enforcement of food regulation would be a requirement that states could not enforce provisions of their laws that imposed requirements different from or inconsistent with the Food, Drug and Cosmetic Act.

This provision would have the salutary effect of updating outmoded and inadequate state food laws and of eliminating conflicting state requirements. The unnecessary cost imposed on food processors who must now conform to a multiplicity of different state food regulations would be reduced, and optimum consumer protection would be assured by upgrading inadequate state regulations.

The comparable provision of S. 641 would have a far narrower and less beneficial impact. It would require uniformity of state regulations only with respect to food labeling, and it would not authorize legal enforcement of the Food, Drug and Cosmetic Act.

X. INGREDIENT LABELING

Both S. 1168 and S. 641 would require full ingredient labeling for standardized foods. The current ingredient labeling exemption for optional ingredients in standardized foods has been criticized by many consumer groups, and FDA has begun, on its own initiative, a program to amend each food standard to require the labeling of optional ingredients. Thus, an amendment to the Act explicitly requiring such labeling would accord with consumer desires and cut short the slow process of amending each existing food standard of identity.

S. 641 includes several additional labeling provisions that have no counterpart in S. 1168. Our principal concern is with the proposed amendment to Section 403(i)(2)(B), which would require a label declaration of the percentage of any ingredient that is significant with respect to value, quality, nutrition, or acceptability, or that is required to be declared upon an FDA finding that such information would be useful to consumers.

In his testimony on this provision, Commissioner Schmidt objected to this mandatory percentage ingredient labeling requirement on the grounds that it might impose an economic burden on consumers for little or no public protection, and that protracted litigation would undoubtedly result from its enactment. He suggested that FDA be permitted to continue to rely on its general

authority to prohibit false and misleading labeling, as it has done in requiring percentage labeling in seafood cocktails and other products.

The National Canners Association strongly endorses Commissioner Schmidt's suggested approach. The broad and ambiguous wording of S. 641 in this regard could well be interpreted to require percentage ingredient labeling when to do so would impose a substantial economic burden on food processors with no consequent consumer benefit, and with no assurance that compliance could be achieved. The varying transfer of liquids between packing medium and solid food in canned foods, for example, would in most instances make it impossible to percentage label the solid food (such as peas, peaches or berries) and the packing medium (brine, juice or syrup) at time of packing so as to assure that the label would remain accurate through distribution, storage and sale.

For products made by mixing ingredients in large batch containers, it is impossible to assure that every can of the finished product will have the precise amount of each of the ingredients in the proportions in which they were added to the batch.

Another problem would be raised for packers of private label products for a number of different buyers, each of whom would supply his own labels with slight differences in ingredient percentages. The added costs of such a situation could be expected to provide one more burden to the canners of all sizes who must pack private label goods if they are to continue to survive.

We urge that the Committees accept the proposal of Commissioner Schmidt and leave the matter of percentage ingredient labeling to FDA under its existing general authority.

XI. UNIFORM CODING

The National Canners Association has recommended for many years that canned foods be appropriately coded to identify the plant and lot of the product. All low acid canned foods are required to be coded under the Better Process Control Plan as jointly developed by NCA and FDA. Further, the Association requires as a condition of membership that the products of a packer be adequately coded, and we are not aware of any difficulty in this regard in our industry.

Our only concern with the new Section 411 as contained in S. 641 is the requirement of "uniform coding." If this language is intended to mean that the company's own system must itself be uniform among all of its products. then of course there could be no objection. But if the intention is to require that all companies use the same code, then the added costs, inconveniences, and confusion could not reasonably be justified.

We note that Commissioner Schmidt suggests that no new regulatory authority is necessary in this regard. Because we are satisfied that canned foods are now adequately coded, our only concern is that if the coding requirements of S. 641 are to be retained, they be clarified to make clear that all companies need not adopt the same coding system.

XII. SUMMARY

In summary, we urge the Committees to keep several key points in mind in considering these two proposed food surveillance bills. First, the food industry has in its development of, and support for, S. 1168 made an affirmative, conscientious effort to strengthen the Food, Drug and Cosmetic Act. Second, the focal point of any food surveillance legislation should be consumer safety and health, not labeling, food aesthetics, or plant sanitation unrelated to health risks. Third, in authorizing expanded FDA enforcement powers, Congress must strike a reasonable balance, assuring a safe American food supply without imposing unnecessary burdens on food processors. Finally, the cost to consumers of government regulations is becoming an increasingly critical issue against which expanded agency authority must be judged.

We hope that our comments on these two blls have been helpful to the Committees and we appreciate the opportunity to present our industry's views.

(Slip Opinion)

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Lumber Co.*, 200 U.S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BIGELOW *v.* VIRGINIA

APPEAL FROM THE SUPREME COURT OF VIRGINIA

No. 73–1309. Argued December 18, 1974—Decided June 16, 1975

Appellant, the managing editor of a weekly newspaper published in Virginia, as the result of publishing a New York City organization's advertisement announcing that it would arrange low-cost placements for women with unwanted pregnancies in accredited hospitals and clinics in New York (where abortions were legal and there were no residency requirements), was convicted of violating a Virginia statute making it a misdemeanor, by the sale or circulation of any publication, to encourage or prompt the processing of an abortion. The trial court had rejected appellant's claim that the statute was unconstitutional under the First Amendment as made applicable to the States by the Fourteenth as being facially overbroad and as applied to appellant. The Virginia Supreme Court affirmed the conviction, also rejecting appellant's First Amendment claim and holding that the advertisement was a commercial one which could be constitutionally prohibited under the State's police power, and that because appellant himself lacked a legitimate First Amendment interest inasmuch as his activity "was of a purely commercial nature," he had no standing to challenge the statute as being facially overbroad. *Held:*

1. Though an intervening amendment of the statute as a practical matter moots the overbreadth issue for the future, the Virginia courts erred in denying appellant standing to raise that issue since "pure speech" rather than conduct was involved and no consideration was given to whether or not the alleged overbreadth was substantial. Pp. 5–8.

2. The statute as applied to appellant infringed constitutionally protected speech under the First Amendment. Pp. 8–19.

(a) The Virginia courts erred in assuming that advertising, as such, was entitled to no First Amendment protection and that appellant had no legitimate First Amendment interest, since

speech is not stripped of First Amendment protection merely because it appears in the form of a paid commercial advertisement, and the fact that the advertisement in question had commercial aspects or reflected the advertiser's commercial interests did not negate all First Amendment guarantees. Pp. 8–11.

(b) Viewed in its entirety, the advertisement conveyed information of potential interest and value to a diverse audience consisting of not only readers possibly in need of the services offered, but also those concerned with the subject matter or the law of another State, and readers seeking reform in Virginia; and thus appellant's First Amendment interests coincided with the constitutional interests of the general public. Pp. 11–12.

(c) A State does not acquire power or supervision over another State's internal affairs merely because its own citizens' welfare and health may be affected when they travel to the other State, and while a State may seek to disseminate information so as to enable its citizens to make better informed decisions when they leave, it may not, under the guise of exercising internal police powers, bar a citizen of another State from disseminating information about an activity that is legal in that State, as the placement services here were at the time they were advertised. Pp. 12–14.

(d) Virginia's asserted interest in regulating what Virginians may *hear* or *read* about the New York services or in shielding its citizens from information about activities outside Virginia's borders (which Virginia's police powers do not reach) is entitled to little, if any, weight under the circumstances. Pp. 16–17.

214 Va. 341, 200 S. E. 2d 680, reversed.

BLACKMUN, J., delivered the opinion of the Court, in which BURGER, C. J., and DOUGLAS, BRENNAN, STEWART, MARSHALL, and POWELL, JJ., joined. REHNQUIST, J., filed a dissenting opinion, in which WHITE, J., joined.

NOTICE : This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D.C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 73–1309

Jeffrey Cole Bigelow, Appellant, *v.* Commonwealth of Virginia. | On Appeal from the Supreme Court of Virginia.

[June 16, 1975]

MR. JUSTICE BLACKMUN delivered the opinion of the Court.

An advertisement carried in appellant's newspaper led to his conviction for a violation of a Virginia statute that made it a misdemeanor, by the sale or circulation of any publication, to encourage or prompt the procuring of an abortion. The issue here is whether the editor-appellant's First Amendment rights were unconstitutionally abridged by the statute. The First Amendment, of course, is applicable to the States through the Fourteenth Amendment. *Schneider* v. *State*, 308 U. S. 147, 160 (1939).

I

The Virginia Weekly was a newspaper published by the Virginia Weekly Associates of Charlottesville. It was issued in that city and circulated in Albemarle County, with particular focus on the campus of the University of Virginia. Appellant, Jeffrey C. Bigelow, was a director and the managing editor and responsible officer of the newspaper.[1]

[1] His brief describes the publication as an "underground newspaper." Brief for Appellant 3. The appellee states that there is no evidence in the record to support that description. Brief for Appellee 3 n. 1.

On February 8, 1971, the Weekly's Volume V, Number 6, was published and circulated under the direct responsibility of the appellant. On p. 2 of that issue was the following advertisement:

"UNWANTED PREGNANCY
LET US HELP YOU
Abortions are now legal in New York.
There are no residency requirements.
FOR IMMEDIATE PLACEMENT IN ACCREDITED
HOSPITALS AND CLINICS AT LOW COST
Contact
WOMEN'S PAVILION
515 Madison Avenue
New York, N. Y. 10022
or call any time
(212) 371–6670 or (212) 371–6650
AVAILABLE 7 DAYS A WEEK
STRICTLY CONFIDENTIAL. We will make
all arrangements for you and help you
with information and counseling."

It is to be observed that the advertisement announced that the Women's Pavilion of New York City would help women with unwanted pregnancies to obtain "immediate placement in accredited hospitals and clinics at low cost" and would "make all arrangements" on a "strictly confidential" basis; that it offered "information and counseling"; that it gave the organization's address and telephone numbers; and that it stated that abortions "are now legal in New York" and there "are no residency requirements." Although the advertisement did not contain the name of any licensed physician, the "placement" to which it referred was to "accredited hospitals and clinics."

On May 13 Bigelow was charged with violating Va. Code § 18.1–63. The statute at that time read:

> "If any person by publication, lecture, advertisement, or by the sale or circulation of any publica-

> tion, or in any other manner, encourage or prompt the procuring of abortion or miscarriage, he shall be guilty of a misdemeanor." [2]

Shortly after the statute was utilized in Bigelow's case, and apparently before it was ever used again, the Virginia Legislature amended it and changed its prior application and scope.[3]

Appellant was first tried and convicted in the County Court of Albemarle County. He appealed to the Circuit Court of that county where he was entitled to a *de novo* trial. Va. Code §§ 16.1–132 and 16.1–136. In the Circuit Court he waived a jury and in July 1971 was tried to the judge. The evidence consisted of stipulated facts; an excerpt, containing the advertisement in ques-

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[2] We were advised by the State at oral argument that the statute dated back to 1878, and that Bigelow's was the first prosecution under the statute "in modern times," and perhaps the only prosecution under it "at any time." Tr. of Oral Arg. 40. The statute appears to have its origin in Va. Acts 1877–1878, p. 281, c. 2, § 8.

[3] The statute, as amended by Va. Acts 1972, c. 725, now reads:

"18.1–63. If any person, by publication, lecture, advertisement, or by the sale or circulation of any publication, or through the use of a referral agency for profit, or in any other manner, encourage or promote the processing of an abortion or miscarriage to be performed in this State which is prohibited under this article, he shall be guilty of a misdemeanor."

It is to be observed that the amendment restricts the statute's application, with respect to advertising, to an abortion illegal in Virginia and to be performed there. Since the State's statutes purport to define those abortions that are legal when performed in the State, see Va. Code §§ 18.1–62.1 and 18.1–62.3 (Supp. 1974), the State at oral argument described the pre-1972 form of § 18.1–63 as "effectively repealed by amendment," and, citing *Roe* v. *Wade*, 410 U. S. 113 (1973), and *Doe* v. *Bolton*, 410 U. S. 179 (1973), the statute, as amended, as limited to an abortion performed by a nonphysician. Tr. of Oral Arg. 38–39. In any event, there is no dispute here that the amended statute would *not* reach appellant's advertisement.

tion, from the Weekly's issue of February 8, 1971; and the June 1971 issue of Redbook Magazine, containing abortion information and distributed in Virginia and in Albemarle County. App. 3, 8. The court rejected appellant's claim that the statute was unconstitutional and adjudged him guilty. He was sentenced to pay a fine of $500, with $350 thereof suspended "conditioned upon no further violation" of the statute. App. 4–5.

The Supreme Court of Virginia granted review and, by a 4–2 vote, affirmed Bigelow's conviction. 213 Va. 191, 191 S. E. 2d 173 (1972). The court first rejected the appellant's claim that the advertisement was purely informational and thus was not within the "encourage or prompt" language of the statute. It held, instead, that the advertisement "clearly exceeded an informational status" and "constituted an active offer to perform a service, rather than a passive statement of fact." *Id.*, at 193, 191 S. E. 2d, at 174. It then rejected Bigelow's First Amendment claim. This, the court said, was a "commercial advertisement" and, as such, "may be constitutionally prohibited by the state," particularly "where, as here, the advertising relates to the medical-health field." *Id.*, at 193–195, 191 S. E. 2d, at 174–176. The issue, in the court's view, was whether the statute was a valid exercise of the State's police power. It answered this question in the affirmative, noting that the statute's goal was "to ensure that pregnant women in Virginia who decided to have abortions come to their decisions without the commercial advertising pressure usually incidental to the sale of a box of soap powder." *Id.*, at 196, 191 S. E. 2d, at 176. The court then turned to Bigelow's claim of overbreadth. It held that because the appellant himself lacked a legitimate First Amendment interest, inasmuch as his activity "was of a purely commercial nature," he had no "standing to rely upon the

hypothetical rights of those in the noncommercial zone." *Id.*, at 198, 191 S. E. 2d, at 177–178.

Bigelow took a timely appeal to this Court. During the pendency of his appeal, *Roe* v. *Wade*, 410 U. S. 113 (1973), and *Doe* v. *Bolton*, 410 U. S. 179 (1973), were decided. We subsequently vacated Bigelow's judgment of conviction and remanded the case for further consideration in the light of *Roe* and *Doe*. 413 U. S. 909 (1973).[4]

The Supreme Court of Virginia, on such reconsideration, but without further oral argument, again affirmed appellant's conviction, observing that neither *Roe* nor *Doe* "mentioned the subject of abortion advertising" and finding nothing in those decisions "which in any way affects our earlier view." [5] 214 Va. 341, 342, 200 S. E. 2d 680 (1973). Once again, Bigelow appealed. We noted probable jurisdiction in order to review the important First Amendment issue presented. 418 U. S. 909 (1974).

II

This Court often has recognized that a defendant's standing to challenge a statute on First Amendment grounds as facially overbroad does not depend upon whether his own activity is shown to be constitutionally privileged. The Court consistently has permitted "attacks on overly broad statutes with no requirement that the person making the attack demonstrate that his own conduct could not be regulated by a statute drawn with the requisite narrow specificity." *Dombrowski* v. *Pfister*, 380 U. S. 479, 486 (1965). See also *Grayned* v. *City of Rockford*, 408 U. S. 104, 114 (1972); *Gooding* v. *Wilson*,

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[4] See Note, The First Amendment and Commercial Advertising: *Bigelow* v. *Commonwealth*, 60 Va. L. Rev. 154 (1974).

[5] Virginia asserts, rightfully we feel, that this is "a First Amendment case" and "not an abortion case." Brief for Appellee 15 n. 6; Tr. of Oral Arg. 26.

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405 U. S. 518, 520–521 (1972); *Coates* v. *City of Cincinnati,* 402 U. S. 611, 616 (1971), and *id.,* at 619–620 (WHITE, J., dissenting); *NAACP* v. *Button,* 371 U. S. 415, 432 (1963); *Thornhill* v. *Alabama,* 310 U. S. 88, 97–98 (1940). The Supreme Court of Virginia itself recognized this principle when it recently stated that "persons who engage in non-privileged conduct are not precluded from attacking a statute under which they were convicted." *Owens* v. *Commonwealth,* 211 Va. 633, 638–639, 179 S. E. 2d 477, 481 (1971). "For in appraising a statute's inhibitory effect upon [First Amendment] rights, this Court has not hesitated to take into account possible applications of the statute in other factual contexts besides that at bar." *NAACP* v. *Button,* 371 U. S., at 432. See generally Note, The First Amendment Overbreadth Doctrine, 83 Harv. L. Rev. 844, 847–848 (1970).

This "exception to the usual rules governing standing," *Dombrowski* v. *Pfister,* 380 U. S., at 486, reflects the transcendent value to all society of constitutionally protected expression. We give a defendant standing to challenge a statute on grounds that it is facially overbroad, regardless of whether his own conduct could be regulated by a more narrowly drawn statute, because of the "danger of tolerating, in the area of First Amendment freedoms, the existence of a penal statute susceptible of sweeping and improper application." *NAACP* v. *Button,* 371 U. S., at 433.

Of course, in order to have standing, an individual must present more than "allegations of a subjective chill." There must be a "claim of specific present objective harm or a threat of specific future harm." *Laird* v. *Tatum,* 408 U. S. 1, 13–14 (1972). That requirement, however, surely is met under the circumstances of this case, where the threat of prosecution already has blossomed into the reality of a conviction, and where there can be

no doubt concerning the appellant's personal stake in the outcome of the controversy. See *Baker* v. *Carr,* 369 U. S. 186, 204 (1966). The injury of which appellant complains is one to him as an editor and publisher of a newspaper; he is not seeking to raise the hypothetical rights of others. See *Moose Lodge No. 107* v. *Irvis,* 407 U. S. 163, 166 (1972); *Breard* v. *Alexandria,* 341 U. S. 622, 641 (1951). Indeed, unlike some cases in which the standing issue similarly has been raised, the facts of this case well illustrate "the statute's potential for sweeping and improper applications." *Gooding* v. *Wilson,* 405 U. S., at 532–533 (BURGER, C. J., dissenting).

Declaring a statute facially unconstitutional because of overbreadth "is, manifestly, strong medicine," and "has been employed by the Court sparingly and only as a last resort." *Broadrick* v. *Oklahoma,* 413 U. S. 601, 613 (1973). But we conclude that the Virginia courts erred in denying Bigelow standing to make this claim, where "pure speech" rather than conduct was involved, without any consideration of whether the alleged overbreadth was or was not substantial. *Broadrick* v. *Oklahoma,* 413 U. S., at 615, 616. The Supreme Court of Virginia placed no effective limiting construction on the statute. Indeed, it characterized the rights of doctors, husbands, and lecturers as "hypothetical," and thus seemed to imply that, although these were in the noncommercial zone, the statute might apply to them, too.

In view of the statute's amendment since Bigelow's conviction in such a way as "effectively to repeal" its prior application, there is no possibility now that the statute's pre-1972 form will be applied again to appellant or will chill the rights of others. As a practical matter, the issue of its overbreadth has become moot for the

future. We therefore decline to rest our decision on overbreadth and we pass on to the further inquiry, of greater moment not only for Bigelow but for others, whether the statute as applied to appellant infringed constitutionally protected speech.

III

A. The central assumption made by the Supreme Court of Virginia was that the First Amendment guarantees of speech and press are inapplicable to paid commercial advertisements. Our cases, however, clearly establish that speech is not stripped of First Amendment protection merely because it appears in that form. *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relation,* 413 U. S. 376, 384 (1973); *New York Times Co.* v. *Sullivan,* 376 U. S. 254, 266 (1964).

The fact that the particular advertisement in appellant's newspaper had commercial aspects or reflected the advertiser's commercial interests did not negate all First Amendment guarantees. The State was not free of constitutional restraint merely because the advertisement involved sales or "solicitations," *Murdock* v. *Pennsylvania,* 319 U. S. 105, 110–111 (1943), or because appellant was paid for printing it, *New York Times Co.* v. *Sullivan,* 376 U. S., at 266, *Smith* v. *California,* 361 U. S. 147, 150 (1959), or because appellant's motive or the motive of the advertiser may have involved financial gain, *Thomas* v. *Collins,* 323 U. S. 516, 531 (1945). The existence of "commercial activity, in itself, is no justification for narrowing the protection of expression secured by the First Amendment." *Ginzburg* v. *United States,* 383 U. S. 463, 474 (1966).

Although other categories of speech—such as fighting words, *Chaplinski* v. *New Hampshire,* 315 U. S. 568, 572 (1942), or obscenity, *Roth* v. *United States,* 354 U. S.

476, 481–485 (1957), *Miller* v. *California,* 413 U. S. 15, 23 (1973), or libel, *Gertz* v. *Robert Welch, Inc.,* 418 U. S. 323 (1974), or incitement, *Brandenburg* v. *Ohio,* 395 U. S. 444 (1969)—have been held unprotected, no contention has been made that the particular speech embraced in the advertisement in question is within any of these categories.

The appellee, as did the Supreme Court of Virginia, relies on *Valentine* v. *Chrestensen,* 316 U. S. 52 (1942), where a unanimous Court, in a brief opinion, sustained an ordinance which had been interpreted to ban the distribution of a handbill advertising the exhibition of a submarine. The handbill solicited customers to tour the ship for a fee. The promoter-advertiser had first attempted to distribute a single-faced handbill consisting only of the advertisement, and was denied permission to do so. He then had printed, on the reverse side of the handbill, a protest against official conduct refusing him the use of wharfage facilities. The Court found that the message of asserted "public interest" was appended solely for the purpose of evading the ordinance and therefore did not constitute an "exercise of the freedom of communicating information and disseminating opinion." *Id.,* at 54. It said:

> "We are equally clear that the Constitution imposes no such restraint on government as respects purely commercial advertising." *Ibid.*

But the holding is distinctly a limited one: the ordinance was upheld as a reasonable regulation of the manner in which commercial advertising could be distributed. The fact that it had the effect of banning a particular handbill does not mean that *Chrestensen* is authority for the proposition that all statutes regulating commercial advertising are immune from constitutional challenge. The case obviously does not support any

sweeping proposition that advertising is unprotected *per se*.[6]

This Court's cases decided since *Chrestensen* clearly demonstrate as untenable any reading of that case that would give it so broad an effect. In *New York Times Co.* v. *Sullivan, supra,* a city official instituted a civil libel action against four clergymen and the New York Times. The suit was based on an advertisement carried in the newspaper criticizing police action against members of the civil rights movement and soliciting contributions for the movement. The Court held that this advertisement, although containing factually erroneous defamatory content, was entitled to the same degree of constitutional protection as ordinary speech. It said:

> "That the Times was paid for publishing the advertisement is as immaterial in this connection as is the fact that newspapers and books are sold." 376 U. S., at 266.

Chrestensen was distinguished on the ground that the handbill advertisement there did no more than propose a purely commercial transaction, whereas the one in *New York Times*

> "communicated information, expressed opinion, re-

[6] MR. JUSTICE DOUGLAS, who was a Member of the Court when *Chrestensen* was decided and who joined that opinion, has observed, "The ruling was casual, almost offhand. And it has not survived reflection." *Cammarano* v. *United States,* 358 U. S. 498, 514 (1959) (concurring opinion). MR. JUSTICE BRENNAN, joined by STEWART, MARSHALL, and POWELL, JJ., has observed, "There is some doubt concerning whether the 'commercial speech' distinction announced in *Valentine* v. *Chrestensen* . . . retains continuing validity." *Lehman* v. *City of Shaker Heights,* 418 U. S. 298, 314 n. 6 (1974) (dissenting opinion). See also *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations,* 413 U. S. 376, 393 (1973) (BURGER, C. J., dissenting); *id.,* at 398 (DOUGLAS, J., dissenting); *id.,* at 401 (STEWART, J., dissenting).

> cited grievances, protested claimed abuses, and sought financial support on behalf of a movement whose existence and objectives are matters of the highest public interest and concern." *Ibid.*

The principle that commercial advertising enjoys a degree of First Amendment protection was reaffirmed in *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations,* 413 U. S. 376 (1973). There, the Court, although divided, sustained an ordinance that had been construed to forbid newspapers to carry help-wanted advertisements in sex-designated columns except where based upon a bona fide occupational exemption. The Court did describe the advertisements at issue as "classic examples of commercial speech," for each was "no more than a proposal of possible employment." *Id.,* at 385. But the Court indicated that the advertisements would have received some degree of First Amendment protection if the commercial proposal had been legal. The illegality of the advertised activity was particularly stressed:

> "Any First Amendment interest which might be served by advertising an ordinary commercial proposal and which might arguably outweigh the governmental interests supporting the regulation is altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity." *Id.,* at 389.

B. The legitimacy of appellant's First Amendment claim in the present case is demonstrated by the important differences between the advertisement presently at issue and those involved in *Chrestensen* and in *Pittsburgh Press.* The advertisement published in appellant's newspaper did more than simply propose a com-

mercial transaction. It contained factual material of clear "public interest." Portions of its message, most prominently the lines, "Abortions are now legal in New York. There are no residency requirements," involve the exercise of the freedom of communicating information and disseminating opinion.

Viewed in its entirety, the advertisement conveyed information of potential interest and value to a diverse audience—not only to readers possibly in need of the services offered, but also to those with a general curiosity about, or genuine interest in, the subject matter or the law of another State and its development, and to readers seeking reform in Virginia. The mere existence of the Women's Pavilion in New York City, with the possibility of its being typical of other organizations there, and the availability of the services offered, were not unnewsworthy. Also, the activity advertised pertained to constitutional interests. See *Roe* v. *Wade, supra,* and *Doe* v. *Bolton, supra.* Thus, in this case, appellant's First Amendment interests coincided with the constitutional interests of the general public.[7]

Moreover, the placement services advertised in appellant's newspaper were legally provided in New York at that time.[8] The Virginia Legislature could not have

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[7] It was argued, too, that under the circumstances the appearance of the advertisement in the appellant's newspaper was "an implicit editorial endorsement" of its message. Brief for Appellant 29.

[8] Subsequent to Bigelow's publication of the advertisement in February 1971, New York adopted Laws 1971, c. 725, effective July 1, 1971, now codified as Article 45 of the State's Public Health Law. Section 4500 contains a legislative finding:

"Medical referral services, organized as profit making enterprises within this state, have been . . . in violation of the standards of ethics and public policy applicable to the practice of medicine and which would be violations of standards of professional conduct if

regulated the advertiser's activity in New York, and obviously could not have proscribed the activity in that State.[9] *Huntington* v. *Attrill*, 146 U. S. 657, 669 (1892).

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the acts were performed by physicians. . . . It is hereby declared to be the public policy of this state . . . that such profit making medical referral service organizations be declared to be invalid and unlawful in this state."

Section 4501.1 provides:

"No person, firm, partnership, association or corporation or agent or employee thereof, shall engage in for profit any business or service which in whole or in part includes the referral or recommendation of persons to a physician, hospital, health related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition. The imposition of a fee or charge for any such referral or recommendation shall create a presumption that the business or service is engaged in for profit."

A violation of the statute is a misdemeanor punishable by imprisonment for not longer than one year or a fine of not more than $5,000 or both. § 4502.1. Article 45 expressly is made inapplicable to a nonprofit corporation exempt from federal income taxation under § 501 (c) of the Internal Revenue Code of 1954, 26 U. S. C. § 501 (c). § 4503.

The 1971 statute has been upheld against constitutional challenge. *S. P. S. Consultants, Inc.* v. *Lefkowitz*, 333 F. Supp. 1373 (SDNY 1971).

[9] In 1972, after Bigelow's prosecution was begun, Virginia adopted Acts 1972, c. 642, now codified as Va. Code § 18.1–417.2. This statute is similar to the New York statute described in n. 8, *supra*, and is directed at for-profit medical referrals within Virginia. The statute prohibits engaging for profit "in any business which in whole or in part includes the referral or recommendation of persons to a physician, hospital, health related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition." Acceptance of a fee for any such referral or recommendation "shall create a presumption that the business is engaged in such service for profit." Violation of the statute is a misdemeanor punishable by imprisonment for not longer than one year or a fine of not more than $5,000, or both.

By a 1973 amendment, Acts 1973, c. 529, to its statute dealing with unprofessional conduct by a member of the medical or a re-

Neither could Virginia prevent its residents from traveling to New York to obtain those services or, as the State conceded, Tr. of Oral Arg. 29, prosecute them for going there. See *United States* v. *Guest,* 383 U. S. 745, 757–759 (1966); *Shapiro* v. *Thompson,* 394 U. S. 618, 629–631 (1969); *Doe* v. *Bolton,* 410 U. S., at 200. Virginia possessed no authority to regulate the services provided in New York—the skills and credentials of the New York physicians and of the New York professionals who assisted them, the standards of the New York hospitals and clinics to which patients were referred, or the practices and charges of the New York referral services.

A State does not acquire power or supervision over the internal affairs of another State merely because the welfare and health of its own citizens may be affected when they travel to that State. It may seek to disseminate information so as to enable its citizens to make better informed decisions when they leave. But it may not, under the guise of exercising internal police powers, bar a citizen of another State from disseminating information about an activity that is legal in that State.

C. We conclude, therefore, that the Virginia courts erred in their assumptions that advertising, as such, was entitled to no First Amendment protection and that ap-

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lated profession, Virginia prohibits advertising by a physician. Specifically, Va. Code § 54–317 now provides:

"Any practioner of medicine . . . shall be considered guilty of unprofessional conduct if he:

. . . . . .

"(13) Advertises to the general public directly or indirectly in any manner his professional services, their costs, prices, fees, credit terms or quality."

See also Va. Code §§ 54–278.1 and 54–317 (4), (5), and (6).

We, of course, have no occasion to comment here on whatever constitutional issue, if any, may be raised with respect to these statutes.

pellant Bigelow had no legitimate First Amendment interest. We need not decide in this case the precise extent to which the First Amendment permits regulation of advertising that is related to activities the State may legitimately regulate or even prohibit.[10]

Advertising, like all public expression, may be subject to reasonable regulation that serves a legitimate public interest. See *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations, supra; Lehman* v. *City of Shaker*

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[10] We have no occasion, therefore, to comment on decisions of lower courts concerning regulation of advertising in readily distinguishable fact situations. Wholly apart from the respective rationales that may have been developed by the courts in those cases, their results are not inconsistent with our holding here. In those cases there usually existed a clear relationship between the advertising in question and an activity that the government was legitimately regulating. See, *e. g., United States* v. *Bob Lawrence Realty, Inc.*, 474 F. 2d 115, 121 (CA5), cert. denied, 414 U. S. 826 (1973). *Rockville Reminder, Inc.* v. *United States Postal Service*, 480 F. 2d 4 (CA2 1973); *United States* v. *Hunter*, 459 F. 2d 205 (CA4), cert. denied, 409 U. S. 934 (1972).

Nor need we comment here on the First Amendment ramifications of legislative prohibitions of certain kinds of advertising in the electronic media, where the "unique characteristics" of this form of communication "make it especially subject to regulation in the public interest." *Capital Broadcasting Co.* v. *Mitchell*, 333 F. Supp. 582, 584 (DC 1971), aff'd 405 U. S. 1000 (1972). See also *Banzhaf* v. *FCC*, 132 U. S. App. D. C. 14, 405 F. 2d 1082 (1968), cert. denied, *sub nom. Tobacco Institute, Inc.* v. *FCC*, 396 U. S. 842 (1969); *Columbia Broadcasting System, Inc.* v. *Democratic National Committee*, 412 U. S. 94 (1973).

Our decision also is in no way inconsistent with our holdings in the Fourteenth Amendment cases that concern the regulation of professional activity. See *North Dakota Pharmacy Bd.* v. *Snyder's Stores*, 414 U. S. 156 (1973); *Head* v. *New Mexico Board*, 374 U. S. 424 (1963); *Williamson* v. *Lee Optical Co.*, 348 U. S. 483 (1955); *Barsky* v. *Board of Regents*, 347 U. S. 442 (1954); *Semler* v. *Dental Examiners*, 294 U. S. 608 (1935).

Heights, 418 U. S. 298 (1974).[11] To the extent that commercial activity is subject to regulation, the relationship of speech to that activity may be one factor, among others, to be considered in weighing the First Amendment interest against the governmental interest alleged. Advertising is not thereby stripped of all First Amendment protection. The relationship of speech to the marketplace of products or of services does not make it valueless in the marketplace of ideas.

The Court has stated that "a State cannot foreclose the exercise of constitutional rights by mere labels." *NAACP* v. *Button,* 371 U. S., at 429. Regardless of the particular label asserted by the State—whether it calls speech "commercial" or "commercial advertising" or "solicitation"—a court may not escape the task of assessing the First Amendment interest at stake and weighing it against the public interest allegedly served by the regulation. The diverse motives, means, and messages of advertising may make speech "commercial" in widely varying degrees. We need not decide here the extent to which constitutional protection is afforded commercial advertising under all circumstances and in the face of all kinds of regulation.

IV

The task of balancing the interests at stake here was one that should have been undertaken by the Virginia courts before they reached their decision. We need not remand for that purpose, however, because the outcome is readily apparent from what has been said above.

In support of the statute, the appellee contends that the commercial operations of abortion referral agencies

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[11] See also *Adderley* v. *Florida,* 385 U. S. 39, 46–48 (1966); *Cox* v. *Louisiana,* 379 U. S. 536, 554 (1965); *Poulos* v. *New Hampshire,* 345 U. S. 395, 405 (1953); *Kunz* v. *New York,* 340 U. S. 290, 293–294 (1951); *Cox* v. *New Hampshire,* 312 U. S. 569, 575–576 (1941).

are associated with practices, such as fee splitting, that tend to diminish, or at least adversely affect, the quality of medical care, and that advertising of these operations will lead women to seek services from those who are interested only or mainly in financial gain apart from professional integrity and responsibility.

The State, of course, has a legitimate interest in maintaining the quality of medical care provided within its borders. *Barsky* v. *Board of Regents,* 347 U. S. 442, 451 (1954). No claim has been made, however, that this particular advertisement in any way affected the quality of medical services within Virginia. As applied to Bigelow's case, the statute was directed at the publishing of informative material relating to services offered in another State and was not directed at advertising by a referral agency or a practitioner whose activity Virginia had authority or power to regulate.

To be sure, the agency-advertiser's practices, although not then illegal, may later have proved to be at least "inimical to the public interest" in New York. *S. P. S. Consultants, Inc.* v. *Lefkowitz,* 333 F. Supp. 1373, 1378 (SDNY 1971).[12] But this development would not justify a Virginia statute that forbids Virginians from using in New York the then legal services of a local New York agency. Here, Virginia is really asserting an interest in regulating what Virginians may *hear* or *read* about the New York services. It is, in effect, advancing an interest in shielding its citizens from information about activities outside Virginia's borders, activities that Virginia's police powers do not reach. This asserted interest, even if understandable, was entitled to little, if any, weight under the circumstances.

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[12] See *State* v. *Abortion Information Agency, Inc.,* 323 N. Y. S. 2d 597 (Sup. Ct. 1971); see also *Mitchell Family Planning Inc.* v. *City of Royal Oak,* 335 F. Supp. 738 (ED Mich. 1972).

No claim has been made, nor could any be supported on this record, that the advertisement was deceptive or fraudulent,[13] or that it related to a commodity or service that was then illegal in either Virginia or in New York, or that it otherwise furthered a criminal scheme in Virginia.[14] There was no possibility that appellant's activity would invade the privacy of other citizens, *Breard* v. *Alexandria, supra,* or infringe on other rights. Observers would not have the advertiser's message thrust upon them as a captive audience. *Lehman* v. *City of Shaker Heights, supra; Packer Corp.* v. *Utah,* 285 U. S. 105, 110 (1932).

The strength of appellant's interest was augmented by the fact that the statute was applied against him as publisher and editor of a newspaper, not against the advertiser or a referral agency or a practitioner. The prosecution thus incurred more serious First Amendment overtones.

If application of this statute were upheld under these circumstances, Virginia might exert the power sought here over a wide variety of national publications or interstate newspapers carrying advertisements similar to the one that appeared in Bigelow's newspaper or containing articles on the general subject matter to which the advertisement referred.[15] Other States might do the

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[13] See Note, Freedom of Expression in a Commercial Context, 78 Harv. L. Rev. 1191, 1197–1198 (1965); Developments in the Law—Deceptive Advertising, 80 Harv. L. Rev. 1005, 1010–1015 (1967).

[14] We are not required to decide here what the First Amendment consequences would be if the Virginia advertisement promoted an activity in New York which was then illegal in New York. An example would be an advertisement announcing the availability of narcotics in New York City when the possession and sale of narcotics was proscribed in the State of New York.

[15] The State so indicated at oral argument. Tr. of Oral Arg. 37–38. It, however, was never so applied. In the light of its "effective

same. The burdens thereby imposed on publications would impair, perhaps severely, their proper functioning. See *Miami Herald Publishing Co.* v. *Tornillo,* 418 U. S. 241, 257–258 (1974). We know from experience that "liberty of the press is in peril as soon as the government tries to compel what is to go into a newspaper." 2 Z. Chafee, Jr., Government and Mass Communications 633 (1947). The policy of the First Amendment favors dissemination of information and opinion, and "[t]he guarantees of freedom of speech and press were not designed to prevent 'the censorship of the press merely, but any action of the government by means of which it might prevent such free and general discussion of public matters as seems absolutely essential . . .' 2 Cooley, Constitutional Limitations 886 (8th ed.)." *Curtis Publishing Co.* v. *Butts,* 388 U. S. 130, 150 (1967) (opinion of Harlan, J.).

We conclude that Virginia could not apply Va. Code § 18.1–63, as it read in 1971, to appellant's publication of the advertisement in question without unconstitutionally infringing upon his First Amendment rights. The judgment of the Supreme Court of Virginia is therefore reversed.

It is so ordered.

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repeal," as the State's counsel observed during the oral argument, "[w]e will never know" how far, under appellee's theory, it might have reached. *Id.,* at 38.

SUPREME COURT OF THE UNITED STATES

No. 73–1309

Jeffrey Cole Bigelow, Appellant, *v.* Commonwealth of Virginia. | On Appeal from the Supreme Court of Virginia.

[June 16, 1975]

MR. JUSTICE REHNQUIST, with whom MR. JUSTICE WHITE joins, dissenting.

The Court's opinion does not confront head-on the question which this case poses, but makes contact with it only in a series of verbal sideswipes. The result is the fashioning of a doctrine which appears designed to obtain reversal of this judgment, but at the same time to save harmless from the effects of that doctrine the many prior cases of this Court which are inconsistent with it.

I am in agreement with the Court, *ante,* at 8, that Virginia's statute cannot properly be invalidated on grounds of overbreadth [1] given that the sole prosecution which has ever been brought under this now substantially altered statute is that now in issue. "It is the law as applied that we review, not the abstract, academic questions which it might raise in some more doubtful case." *Saia* v. *New York,* 334 U. S. 558, 571 (1948) (Jackson, J., dissenting).

Since the Court concludes, apparently from two lines

[1] The Court, *ante,* at 7, states that the Virginia Supreme Court placed no limiting interpretation on its statute and that it implied that the statute might apply to doctors, husbands, and lecturers. The Court is in error: the Virginia Supreme Court stated that it would not interpret the statute to encompass such situations. *Bigelow* v. *Commonwealth,* 191 S. E. 2d 173, 177 (1972).

of the advertisement, *ante,* at 2, that it conveyed information of value to those interested in the "subject matter or the law of another state and its development" and to those "seeking reform in Virginia" and since the ad relates to abortion, elevated to constitutional stature by the Court, it concludes that this advertisement is entitled to something more than the limited constitutional protection traditionally accorded commercial advertising. See slip op., *ante,* at 12, 15 n. 10. Although recognizing that "[a]dvertising, like all public expression, may be subject to reasonable regulation that serves a legitimate public interest," *ante,* at 15, the Court for reasons not entirely clear to me concludes that Virginia's interest is of "little, if any, weight."

If the Court's decision does indeed turn upon its conclusion that the advertisement here in question was protected by the First and Fourteenth Amendments, the subject of the advertisement ought to make no difference. It will not do to say, as the Court does, that this advertisement conveyed information about the "subject matter of the law of another state and its development" to those "seeking reform in Virginia," and that it related to abortion, as if these factors somehow put it on a different footing from other commercial advertising. This was a proposal to furnish services on a commercial basis, and since we have always refused to distinguish for First Amendment purposes on the basis of content, it is no different than an advertisement for a bucket shop operation or a Ponzi scheme which has its headquarters in New York. If Virginia may not regulate advertising of commercial abortion agencies because of the interest of those seeking to reform Virginia's abortion laws, it is difficult to see why it is not likewise precluded from regulating advertising for an out-of-state bucket shop on the ground that such information might be of interest

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to those interested in repealing Virginia's "blue sky" laws.

As a threshold matter the advertisement appears to me, as it did to the courts below, to be a classic commercial proposition directed towards the exchange of services rather than the exchange of ideas. It was apparently also so interpreted by the newspaper which published it which stated in apparent apology in its following issue that the *"Weekly* collective has since learned that this abortion agency as well as a number of other commercial groups are charging women a fee for a service which is done free by Women's Liberation, Planned Parenthood, and others." *Bigelow* v. *Commonwealth,* 191 S. E. 2d 173, 174–175 (Va. 1972). Whatever slight factual content the advertisement may contain and whatever expression of opinion may be laboriously drawn from it does not alter its predominantly commercial content. "If that evasion were successful, every merchant who desires to broadcast . . . need only append a civic appeal, or a moral platitude, to achieve immunity from the law's command." *Valentine* v. *Chrestensen,* 316 U. S. 52, 55 (1942). See, *e. g., Ginzburg* v. *United States,* 383 U. S. 463, 474 n. 17 (1966). I am unable to perceive any relationship between the instant advertisement and that for example in issue in *New York Times* v. *Sullivan,* 376 U. S. 254, 292 (1964). Nor am I able to distinguish this commercial proposition from that held to be purely commercial in *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations,* 413 U. S. 376 (1973). As the Court recognizes, *ante,* at 9–10, a purely commercial proposal is entitled to little constitutional protection.

Assuming *arguendo* that this advertisement is something more than a normal commercial proposal, I am unable to see why Virginia does not have a legitimate

public interest in its regulation. The Court apparently concedes, *ante,* at 15 n. 10, and our cases have long held, that the States have a strong interest in the prevention of commercial advertising in the health field—both in order to maintain high ethical standards in the medical profession and to protect the public from unscrupulous practices. See, *e. g., Semler* v. *Dental Examiners,* 294 U. S. 608, 612 (1935); *Williamson* v. *Lee Optical Co.,* 348 U. S. 483, 490–491 (1935); *North Dakota Pharmacy Bd.* v. *Snyder's Stores,* 414 U. S. 156 (1973). And the interest asserted by the Supreme Court of Virginia in the Virginia statute was the prevention of commercial exploitation of those women who elect to have an abortion:

> "It is clearly within the police power of the state to enact reasonable measures to ensure that pregnant women in Virginia who decide to have abortions come to their decisions without the commercial advertising pressure usually incident to the sale of a box of soap powder. And the state is rightfully interested in seeing that Virginia women who do decide to have abortions obtain proper medical care and do not fall into the hands of those interested only in financial gain, and not in the welfare of the patient." 191 S. E. 2d, at 176.

The concern of the Virginia Supreme Court was not a purely hypothetical one. As the Court notes, *ante,* at 12 n. 8, although New York at the time of this advertisement allowed profitmaking abortion referral agencies, it soon thereafter passed legislation prohibiting commercial advertisement of the type here in issue. The court in *S. P. S. Consultants, Inc.* v. *Lefkowitz,* 333 F. Supp. 1373, 1378 (SDNY 1971) quoted the author of that legislation on the reasons for its passage:

> "Because New York State has the most liberal abortion statute within the Continental United States,

> thousands of women from all over the country are coming into New York State . . . . [M]ost of these women came here through referral agencies who advertise nationally. These agencies, for a sizeable fee, make all abortion arrangemnets for a patient. We also learned that certain hospitals give discounts to these lucrative profit-making organizations. Thus at the expense of desperate, frightened women these agencies are making a huge profit—some, such a huge profit that our Committee members were actually shocked." See, *e. g., State* v. *Mitchell,* 321 N. Y. S. 2d 756 (1971); *State* v. *Abortion Information Agency,* 323 N. Y. S. 2d 597 (1971).

Without denying the power of either New York or Virginia to prohibit advertising such as that in issue where both publication of the advertised activity and the activity itself occur in the same state, the Court instead focuses on the multistate nature of this transaction, concluding that a state "may not under the guise of exercising internal police powers, bar a citizen of another State from disseminating information about an activity that is legal in that State." Slip op., *ante,* at 14. And the Court goes so far as to suggest that it is an open question whether a state may constitutionally prohibit an advertisement containing an invitation or offer to engage in activity which is criminal both in the state of publication and in the proposed situs of the crime. See slip op., *ante,* at 18 n. 14.

The source of this rigid territorial limitation on the power of the States in our federal system to safeguard the health and welfare of their citizens is not revealed. It is surely not to be found in cases from this court.[2]

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[2] The Court, *ante,* at 12–13, relies on *Huntington* v. *Attrill,* 146 U. S. 657, 669 (1892), for its major premise that Virginia could not regulate the relations of the advertiser with its residents since these

Beginning at least with our decision in *Delamater* v. *South Dakota,* 205 U. S. 93, 100 (1907), we have consistently recognized that irrespective of a State's power to regulate extraterritorial commercial transactions in which its citizens participate it retains an independent power to regulate the business of commercial solicitation and advertising within its borders. Thus for example in *Head v. New Mexico Board,* 374 U. S. 424 (1963), we upheld the power of New Mexico to prohibit commercial advertising by a New Mexico radio station of optometrist services provided in Texas. Mr. JUSTICE BRENNAN, concurring in that opinion, noted that a contrary result might well produce "a 'no-man's land' . . . in which there would be at best selective policing of the various adver-

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occurred in New York. To the extent that the Court reads *Huntington* to impose a rigid and unthinking territorial limitation, whose constitutional source is unspecified, on the power of the States to regulate conduct, it is plainly wrong. The passage referred to by the Court in the *Huntington* opinion is dicta and appears to be a statement of then-prevalent common law rules rather a constitutional holding. And the attempt to impose such a rigid limitation on the power of the States was first rejected by Mr. Justice Holmes, writing for the Court in *Strassheim* v. *Daily,* 221 U. S. 281, 284–285 (1911):

"Acts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a State in punishing the cause of the harm as if he had been present at the effect. . . ."

Mr. Justice McKeena in *Hyde* v. *United States,* 225 U. S. 347, 362–363 (1912), observed that "this must be so if we would fit the laws and their administration to the acts of men and not be led away by mere "bookish theorick.'" See, *e. g., Skiriotes* v. *Florida,* 313 U. S. 69, 74–75 (1941); *Ford* v. *United States,* 273 U. S. 593, 620–621 (1927). To the extent that the Court's conclusion that Virginia has a neglible interest in its statute proceeds from the assumption that the State was without power to regulate the extraterritorial activities of the advertiser involving Virginia residents, it is quite at war with our prior cases.

tising abuses and excesses which are now very extensively regulated by state law." *Id.*, at 446 (Opinion of BRENNAN, J., concurring). See, *e. g., Packer Corp.* v. *Utah,* 285 U. S. 105 (1932); *Breard* v. *Alexandria,* 341 U. S. 622 (1951).

Were the Court's statements taken literally, they would presage a standard of the lowest common denominator for commercial ethics and business conduct. Securities issuers could circumvent the established Blue Sky laws of States which had carefully drawn laws for the protection of their citizens by establishing as a situs for transactions those States without such regulations, while spreading offers throughout the country. Loan sharks might well choose States with unregulated small loan industries, luring the unwary with immune commercial advertisements. And imagination would place the only limit on the use of such a "no-man's land" together with artificially created territorial contacts to bilk the public and circumvent long established State schemes of regulation.

Since the Court saves harmless from its present opinion our prior cases in this area, *ante,* at 15 n. 10, it may be fairly inferred that it does not intend the results which might otherwise come from a literal reading of its opinion. But solely on the facts before it, I think the Court today simply errs in assessing Virginia's interest in its statute because it does not focus on the impact of the practices in question on the State. Cf. *Young* v. *Masci,* 289 U. S. 253 (1933). Although the commercial referral agency, whose advertisement in Virginia was barred, was physically located outside the State, this physical contact says little about Virginia's concern for the touted practices. Virginia's interest in this statute lies in preventing commercial exploitation of the health needs of its citizens. So long as the statute bans commercial adver-

tising by publications within the State, the extraterritorial location at which the services are actually provided does not diminish that interest.

Since the statute in question is a "reasonable regulation that serves a legitimate public interest," *ante,* at 15, I would affirm the judgment of the Supreme Court of Virginia.

Senator Moss. Is Mr. Glenn Queen, vice president of the National Association of Retail Grocers of the United States present and ready?

We are pleased to have you, Mr. Queen, and if you would identify the gentlemen who are with you we would appreciate that.

STATEMENT OF GLENN J. QUEEN, VICE PRESIDENT, NATIONAL ASSOCIATION OF RETAIL GROCERS OF THE UNITED STATES; ACCOMPANIED BY HENRY BISON, JR.; AND THOMAS WENNING, COUNSEL

Mr. QUEEN. On my left is Mr. Henry Bison, Jr., counsel. On my right is Mr. Thomas Wenning, also counsel.

Senator Moss. We welcome you gentlemen to the committee. You may proceed if you will please.

Mr. QUEEN. Mr. Chairman and committee members, I am Glenn J. Queen, president of Foodland Super Markets in Huntington, W. Va. I have been in the retail food business for almost 30 years. I also have the privilege of presently serving as vice president of th National Association of Retail Grocers of the United States—NARGUS—on whose behalf this statement is presented. NARGUS is a national nonprofit trade association representing owners and operators, like myself, of local retail food stores. NARGUS has approximately 40,000 members in all States in the Union and approximately 37 affiliated State and local associations. Members operate retail grocery stores including smaller outlets, convenience stores, and supermarkets.

Owners, like myself, of local retail food establishments have a vital stake in the community we serve. I'm extremely proud of the people I serve. In the almost 30 years I have been in the retail business I've loved every minute of it. There is no greater satisfaction for me than to offer my friends and neighbors safe and wholesome food at a reasonable price. Unfortunately in the last 2 years inflation has played havoc with food prices. Providing safe and wholesome food will always remain a principal concern. Why? Because my reputation in the community and my business success depend on customer satisfaction. Local food retailers cannot afford to lose customers to competitors.

The major purpose of S. 641 as stated in the bill is to protect consumers from adulterated food. Now no reasonable person is going to disagree with such a desirable purpose. Everyone favors doing what is necessary to assure our food is safe and wholesome. We are not going to fail doing whatever this purpose requires. To be effective, we must act reasonably and responsibly.

It's been my experience in dealing with most kinds of problems, you have to be selective, doing first that which needs doing the most. You can't do everything at once, all at the same time.

While I'm speaking of experience let me tell you what I've noticed to be a growing trend, particularly in recent years. More and more there is the thought that every problem requires a new law, or government regulation from Washington, D.C. Away from Washington, D.C. not all problems are as major as they are made out

to be. Nor is there a cry for more government, but rather for less unnecessary government intervention. Maybe that is my goal here today more than anything else, to assist in assuring consumers safe and wholesome food with the minimum burden on consumers, taxpayers, the food industry, and government resources to accomplish the job.

NARGUS has followed the development of S. 641 since 1973 when S. 2373 was originally introduced. Last year in testifying on S. 2373, NARGUS pointed out that food retailers and FDA would have been unnecessarily burdened by various provisions in that bill. Food and Drug Commissioner, Dr. Alexander Schmidt, stated that, the scope of registration provisions is extremely broad, and that FDA could not immediately extend the registration that broadly. Commissioner Schmidt stated there were approximately 80,000 processors, those directly adding substances, repackers, and relabelers, and an estimated 500,000 retail stores. Being in the retail food business as long as I have, I can appreciate how unnecessary and burdensome registration would be. The amount of information required to be filed would be a major problem considering the number of ownership changes, new openings, closed outlets, and constant altering of food product categories handled by half a million retailers.

The overall reach of S. 2373 would have required many thousands of retailers to register with the Federal Government and greatly exceeded the government's ability to utilize the information in any useful manner.

S. 641 is similar to S. 2373 as was passed by the Senate last year. The unnecessary coverage of retail establishments is attempted to be remedied by an exemption under title I, food surveillance procedures, and under title II, food establishment registration. I say attempted because I am informed by NARGUS counsel that the retail establishment exemption now in S. 641 does not fully accomplish its intended purpose.

Both title I, food surveillance, and title II, food establishment registration, in S. 641 contain retail exemptions that state that the sections shall not apply to processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises. Processing and processed are defined to include manufacturing, processing, packing, labeling, storing, importing or being in any manner responsible for importing, or otherwise handling food.

The proposed retail establishment exemption is limited to processing which consists solely of the sale of food. However, many things which go on in a retail food store do not consist solely of the sale of food. Many activities in retail food establishments involve various kinds of processing operations prior to the sale of food.

Since there is a desire to exempt retail establishments under title I, food surveillance, and from title II, food establishment registration, in S. 641, NARGUS recommends that the language of the retail establishment exemption in the bill be improved by deleting the words, which consists solely of the sale in title I and deleting the words, consisting solely of the sale in title II. The exemption would then apply to processing of food in a retail establishment for consumption on or off the premises, except under title I to safety

assurance assessment reports and to safety assurance plans. This proposal would harmonize the retail exemption in food surveillance and food establishment registration with the food coding retail exemption. With such changes, the intent to exempt retail establishments under title I and II would be achieved, and NARGUS would be in a position to support S. 641 as it affects retail food establishments.

NARGUS also recommends deletion of the provision authorizing commencement of citizens suits. S. 641 provides a major extension of Federal regulations covering the food industry. Permitting citizens suits would unnecessarily burden and disrupt the food industry and FDA while the new law progresses through a developmental stage. Many of the safety assurance procedures will take time to develop and improve. Inclusion of citizens suits would disrupt and delay efficient implementation of the new law in its early stages.

Finally, we are concerned about a policymaking company executives criminally liable for violation of the Federal Food, Drug and Cosmetic Act based on the fact that such executives hold a position of authority and responsibility. It seems to me that when a violation of the law occurs the president of a company ought not to be held criminally accountable for that violation unless he was conscious of the wrongdoing, or unless it can be shown that he acted with substantial disregard for meeting the standards of care reasonably expected in such a situation.

Presidents of firms should not be criminally prosecuted for misdeeds of employees simply because the president is the boss and is therefore held responsible for what employees do or don't do while on the job. That kind of policy it seems to me is too harsh.

Every organization—and not just business organizations—operates on the basis of the person in charge delegating some responsibilities to subordinates. Sometimes those delegated a responsibility fail in the performance of their duty. In that case we say, if the executive has made a reasonable effort to satisfy the law, he should not be criminally prosecuted. Before a company executive is convicted of a criminal offense, it should be necessary to show he engaged in a wrongful action prohibited by the law. It's not wrongful to be an officer in charge of a business concern. If this is not the case today, I hope you will help change the law so a rule of fairness is restored.

In conclusion, let me thank you for this opportunity to express these views. I hope all of us can work together to improve the law where it is needed, and make it effective for everyone concerned. Our common goal is to protect consumers while preserving efficient competitive enterprise in food processing. We hope to be able to support enactment of S. 641, and to that end we pledge our willingness to cooperate to the fullest extent possible.

Senator Moss. Well, thank you, Mr. Queen, for your good statement. I assure you that we welcome your comments and your willingness to work with us in trying to fashion a suitable piece of legislation. I can assure you that we are very sympathetic with that problem of absolute criminal liability and we are giving great attention to that. Your comment on that is very persuasive and I think

that we can probably pretty well accommodate the views that the retailers have expressed.

Mr. QUEEN. Thank you, sir.

Senator Moss. Thank you, sir, and thank you, gentlemen, for being present.

Mr. Bernard Imming, president of the United Fresh Fruit and Vegetable Association, We are glad to have you come before the committee, sir, and we have your written statement and it will be in the record.

STATEMENT OF BERNARD J. IMMING PRESIDENT, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Mr. IMMING. Thank you, Senator. I appreciate the opportunity to be here to present our views.

My name is Bernard J. Imming. I am president of the United Fresh Fruit and Vegetable Association, a national trade association with headquarters at 1019 19th Street NW., Washington, D.C. We have more than 2,500 member companies throughout the United States who are engaged in the production and distribution of fresh fruits and vegetables, as well as providing goods and services to the industry. In the aggregate, they handle approximately 75 percent of the Nation's tonnage of commercially produced fresh fruits and vegetables.

Mr. Chairman, I am here today to speak in support of an exemption for the fresh fruit and vegetable industry from S. 641, a bill designed to protect consumers from adulterated food by requiring establishment of surveillance regulations for the detection and prevention of adulterated food. We do not oppose S. 1168, the second bill designed to protect consumers by requiring approved safety assurance measures in food manufacture and distribution and registration of producers of food. This bill does contain an exemption from the Federal Food, Drug, and Cosmetic Act for any establishment engaged exclusively in the handling of fresh fruits and vegetables in their raw, unpeeled form.

The primary purpose of S. 641 is to protect consumers from adulterated food. This has no direct application to fresh fruits and vegetables since these perishable products are not subject to adulteration in their raw, unpeeled form.

The exclusion outlined at line 9, page 2 of S. 641 requires some clarification. The exclusion limits application of the bill to "processing factors." In the case of fresh fruits and vegetables there is no "processing"; rather they are only culled, graded, washed, sometimes waxed and packed. It would appear that fresh fruits and vegetables could be unequivocally excluded.

Again, with respect to this exemption, inclusion of the fresh fruit and vegetable industry within the parameters of the safety assurance section of S. 641 is unnecessary. Fresh fruits and vegetables in their raw, unpeeled form present no hazard with regard to microorganisms, toxins, and other harmful constituents. Reliable scientific data verify the fact that no fresh fruit or vegetable has ever been incriminated as a source of food poisoning such as salmonellosis,

botulism, streptococcus or staphyococcus. The reason is that fresh fruits and vegetables do not constitute a substrate on which such microorganisms thrive and multiply.

In the case of botulism, the organism cannot elaborate its toxin except in airless conditions, a condition in which fresh fruits and vegetables by their nature cannot exist.

It should further be understood that while microorganisms such as clostridium botulinum may be present in the soil in which fresh fruits and vegetables are grown, they are not a hazard. Their presence, so far as fresh fruits and vegetables are concerned, does not constitute a danger. This is a generally accepted microbiological principle.

Consequently, surveillance procedures with regard to fresh fruit and vegetable packing and wholesaling houses is a needless elaboration of regulatory procedures.

There should be a complete and unequivocal exemption of fresh fruit and vegetable packinghouses and warehouses from food-plant-surveillance procedures.

With regard to the food-coding provisions of the proposed legislation, again there should be a complete and unequivocal exemption for packaged fresh fruits and vegetables. The basis for this is simply that there is nothing in the packaging process that changes the form of a fresh fruit or vegetable which would thus require food coding.

Another major area addressed by the proposed legislation is food labeling. The FDA currently has jurisdiction over food labeling and it has proposed regulations relating specifically to fresh fruits and vegetables. Although these regulations have not been promulgated, they have been opened for comment. The United Fresh Fruit and Vegetable Association has filed comment with the FDA. It is well worth noting that the proposed Food and Drug regulations call for voluntary compliance, with mandatory compliance only under certain conditions. S. 641 would require mandatory nutrition and ingredient labeling across the board.

The United Fresh Fruit and Vegetable Association has further, with the approval of the FDA, set up a task force of experts to advise with regard to matters relating to food and nutrition advertising and labeling. It is our intention to gain insight from the task force to help the association develop a handbook that will enable those in the industry who want to use nutrition labeling to take the necessary steps to comply with both existing and future regulations.

The subject of food labeling is indeed a difficult one. The chief difficulty lies in the determination of an acceptable average basis on which nutrients in each species and variety of fruit or vegetable from each growing area can be determined. The problems are formidable, and solutions are not yet in sight. What seems more readily apparent is that since fresh fruits and vegetables do not have "ingredients" they should be completely exempt from any mandatory disclosure of composition.

The final area on which we would like to comment is that of "sell date," that is, a date after which a package should not be sold. We

have no objection to the voluntary use of some kind of dating of packaged produce by retailers of fresh fruit and vegetables, if they see fit to offer such information to the public. In fact, we know of instances where retailers employ such a program, and it is reportedly well received. Consumers are said to appreciate the "freshness" assurance represented by the "sell date," which is determined by the retailer and applied to the package.

However, about half the fresh produce sold at retail is not packaged, and many consumers—perhaps the majority—say they prefer nonpackaged produce. Moreover, there is no agreed upon procedure nor scientific body of information, no set of tables, which can be applied to a particular lot of a fresh fruit or a fresh vegetable to determine with certainty a valid sell date for that particular lot. There are so many variables relating to genetic characteristics, horticultural practices, weather, growing and marketing diseases, temperature control, care and handling throughout storage, transportation, warehousing, and packaging procedures that each lot must be dated on the basis of the judgment of some person who may or may not be aware of what has happened to that commodity or, I might add, what has not happened to that commodity. We believe that in many instances, even if fresh produce were all packaged, a sell date on fresh fruits and vegetables would have no real information value for the consumer, but perhaps would be misleading instead.

Most consumer purchase decisions involving fresh fruits and vegetables are based on appearance of the product and other factors which influence the individual purchaser. And again, although it is possible for some retailers to apply a sell date or freshness date, as one major retailer calls it, to some packaged fresh fruits and vegetables offered for sale and we applaud their doing so, at the same time we believe it would be a difficult if not impossible matter for other retailers to do so. Accordingly, we oppose mandatory date labeling for raw agricultural products which are sold at retail in their fresh, unprocessed form.

The facts that I have outlined here today readily support our request for a complete exemption for the fresh fruit and vegetable industry from the food surveillance bill S. 641.

The United Fresh Fruit and Vegetable Association will be more than happy to make all of its facilities and resources available to the committees and their staffs to provide additional research on these most perplexing problems.

Senator Moss. Thank you, Mr. Imming, for your statement. It's very good to have the viewpoint of the fresh fruit and vegetable industry in this matter and how you are affected.

FDA, as well as some other witnesses, have spoken of the breadth of FDA rulemaking authority under existing law. Do you think the FDA has such extensive rulemaking authority as it has claimed?

Mr. Imming. I believe so. At least we have been working under that assumption.

Senator Moss. The FDA in its testimony referred to aflatoxins and in addition an article appeared in the Washington Post Sunday and spoke at great length about microtoxins which spread when a

commodity is stored. Are these toxins potential problems which can already be dealt with under FDA's existing authority?

Mr. IMMING. With respect to fresh fruits and vegetables, they are not problems because, as I said in my statement, fresh fruits and vegetables in their unprocessed forms present no substrate on which such microorganisms can thrive and multiply.

Senator MOSS. Do you think the language in S. 641 would limit the existing authority of FDA in this area we're talking about?

Mr. IMMING. Whether it would limit their responsibility or jurisdiction in this area, frankly, I'm not prepared to say.

Senator MOSS. Of course, it would take a legal answer perhaps and I was just asking whether you had an opinion on it and if you haven't had time to look at it you'd have a hard time forming an opinion.

Mr. IMMING. I haven't had time to go through any analysis of that in comparison.

Senator MOSS. Very good. Well, thank you, Mr. Imming. We appreciate your testimony.

[The statement follows:]

STATEMENT OF BERNARD J. IMMING, PRESIDENT, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION, WASHINGTON, D.C.

Mr. Chairman and Members of the Committee; My name is Bernard J. Imming. I am president of the United Fresh Fruit and Vegetable Association, a national trade association with headquarters at 1019 Nineteenth Street, N.W., Washington, D.C. 20036, having more than 2,500 member companies throughout the United States, who are engaged in the production and distribution of fresh fruits and vegetables, as well as providing goods and services to the industry. In the aggregate, they handle approximately 75 percent of the nation's tonnage of commercially produced fresh fruits and vegetables.

Mr. Chairman, I am here today to speak in support of an exemption for the fresh fruit and vegetable industry from S. 641, a bill designed to protect consumers from adulterated food by requiring establishing of surveillance regulations for the detection and prevention of adulterated food. We do not oppose S. 1168, the second bill designed to protect consumers by requiring approved safety assurance measures in food manufacture and distribution and registration of producers of food. This bill does contain an exemption from the Federal Food, Drug and Cosmetic Act for any establishment engaged exclusively in the handling of fresh fruits and vegetables in their raw, unpeeled form.

The primary purpose of S. 641 is to protect consumers from adulterated food. This has no direct application to fresh fruits and vegetables since these perishable products are not subject to adulteration in their raw, unpeeled form. Leafy vegetables, for example, can be sprinkled or iced to prevent evaporation; however, it seems inconceivable that this is the kind of adulteration perceived in the purview of this bill, since this form of protection does not change the product and is performed for the sole purpose of avoiding dehydration.

The exclusion outlined at line 9, page 2 of S. 641 requires some clarification. The exclusion limits application of the bill to "processing factors." In the case of fresh fruits and vegetables there is no "processing;" rather they are only culled, washed, sometimes waxed and packed. It would appear that fresh fruits and vegetables could be unequivocally excluded.

Again, inclusion of the fresh fruit and vegetable industry within the parameters of the safety assurance section of S. 641 is unnecessary. Fresh fruits and vegetables in their raw, unpeeled form present no hazard with regard to microorganisms, toxins, and other harmful constituents. Reliable scientific data verify the fact that no fresh fruit or vegetable has ever been incriminated as a source of food poisoning such as salmonellosis, botulism, streptococcus or staphylococcus. The reason is that fresh fruits and vegetables do not constitute a substrate on which such microorganisms thrive and multiply.

In the case of botulism, the organism cannot elaborate its toxin except in airless conditions, a condition in which fresh fruits and vegetables by their nature cannot exist.

These various microrganisms above do, in fact, contribute to food poisoning; however, they thrive on types of foods other than fresh fruits and vegetables such as meats, fish, poultry, custards, and various creamed dishes.

It is of interest to note that the Food Protection Committee of the National Academy of Sciences states that "there are reasons for believing that the bacterial hazards associated with mildly processed products are greater than corresponding unprocessed items." (Reference: National Academy of Science Publication 1195, Evaluation of Public Health Hazards.)

It should further be understood that while microorganisms such as clostridium botulinum may be present in the soil in which fresh fruits and vegetables are grown, they are *not* a hazard. Clostridium botulinum and clostridium welchii are commonly found in garden soil and dust, but their presence, so far as fresh fruits and vegetables are concerned, does not constitute a danger. This is a generally accepted microbiological principle.

Fresh fruits and vegetables are subject to many kinds of diseases, it is true, but these are *plant diseases*, not diseases that affect human beings. A disease that causes an apple to rot, for example, affects only the apple and is so obvious that the apple is not bought or is discarded. Such rot is not a danger to humans. Consequently, surveillance procedures with regard to fresh fruit and vegetable packing and wholesaling houses is a needless elaboration of regulatory procedures.

There should be a complete and unequivocal exemption of fresh fruit and vegetable packing houses and warehouses from food plant surveillance procedures.

The Food Protection Committee of the National Academy of Sciences points out that "microbiological criteria established for foods should: (1) accomplish what they purport to do, that is reduce public health hazards; (2) be technically feasible, that is attainable under conditions of good commercial practice; and (3) to be administratively feasible." (Reference: National Academy of Science Publication 1195, Evaluation of Public Health Hazards.)

With regard to the food coding provisions of the proposed legislation, again there should be a complete and unequivocaal exemption for packaged fresh fruits and vegetables. The basis for this is simply that there is nothing in the packaging process that changes the form of a fresh fruit or vegetable which would thus require food coding.

Another major area addressed by the proposed legislation is food labeling. The Federal Food and Drug Administration currently has jurisdiction over food labeling and it has proposed regulations relating specifically to fresh fruits and vegetables. Although these regulations have not been promulgated, they have been opened for comment. The United Fresh Fruit and Vegetable Association has filed comment with the Food and Drug Administration. It is well worth noting that the proposed Food and Drug regulations call for *voluntary* compliance, with mandatory compliance only under certain conditions. S. 641 would require mandatory nutrition and ingredient labeling across the board.

The United Fresh Fruit and Vegetable Association has further, with the approval of the Food and Drug Administration, set up a task force of experts to advise with regard to matters relating to food and nutrition advertising and labeling. It is our intention to gain insight from the task force to help the association develop a handbook that will enable those in the industry who want to use nutrition labeling to take the necessary steps to comply with both existing and future regulations.

The subject of food labeling is indeed a difficult one. There are many special problems which require a slow and deliberate course on the part of both the Food and Drug Administration and the fresh fruit and vegetable industry.

The chief difficulty lies in the determination of an acceptable average basis on which nutrients in each species and variety of fruit or vegetable from each growing area can be determined. The problems are formidable, and solutions are not yet in sight. What seems more readily apparent is that since fresh fruits and vegetables do not have "ingredients" they should be completely exempt from any mandatory disclosure of composition.

The final area on which we would like to comment is that of "sell date." We have no objection to the voluntary use of some kind of dating of packaged produce by retailers of fresh fruits and vegetables, if they see fit to offer such information to the public. In fact, we know of instances where retailers employ such a program, and it is reportedly well received. Consumers are said to appreciate the "freshness" assurance represented by the "sell date," which is determined by the retailer and applied to the package.

However, about half the fresh produce sold at retail is *not* packaged, and many consumers say they prefer non-packaged produce. Moreover, there is no agreed upon procedure nor scientific body of information, no set of tables, which can be applied to a particular lot of a fresh fruit or a fresh vegetable to determine with certainty a valid sell date for that particular lot. There are so many variables relating to genetic characteristics, horticultural practices, weather, growing and marketing diseases, temperature control, care and handling throughout storage, transportation, warehousing, and packaging procedures that each lot must be dated on the basis of the judgment of some person who may or may not be aware of what has happened to that commodity. For one example, a fresh fruit or vegetable which may deteriorate rapidly at 75 degrees Fahrenheit may last for many dates and even weeks in some cases at 32 degrees Fahrenheit.

Since the primary beneficiary of any legislation such as S. 641 is the consumer, it would appear that there is a genuine danger in making mandatory the placing of an arbitrary date on fresh produce which indicates the date after which it may not be sold. We believe that in many instances, even if fresh produce were all packaged, a sell date on fresh fruits and vegetables would have no real information value for the consumer, but perhaps would be misleading instead.

Most consumer purchase decisions involving *fresh* fruits and vegetables are based on appearance of the product and other factors which influence the individual purchaser. And again, although it is possible for some retailers to apply a sell date or "freshness date" to some packaged fresh fruits and vegetables offered for sale and we applaud their doing so, at the same time we believe it would be a difficult if not impossible matter for other retailers to do so. Accordingly, we oppose *mandatory* date labeling for raw agricultural products which are sold at retail in their fresh, unprocessed form.

The facts that I have outlined here today readily support our request for a complete exemption for the fresh fruit and vegetable industry from the food surveillance bill S. 641. We also wish to further state that the United Fresh Fruit and Vegetable Association takes the position of not opposing S. 1168.

The United Fresh Fruit and Vegetable Association will be more than happy to make all of its facilities and resources available to the committees and their staffs to provide additional research on these most perplexing problems.

[From the Washington Post, June 15, 1975]

Molds in the Corn

(By Abigail Trafford Brett)

In the fall of 1972, stories began to circulate that the corn harvest was not going well in the Midwest. There was a tremendous amount of rain; plants were beaten down in the fields and farmers couldn't get in to harvest the crops. To make matters worse, the energy crisis cut off supplies of natural gas, limiting the amount of corn that could be dried by artificial methods once it was harvested.

Meanwhile, the country's agri-business was turned upside down by the famous billion-dollar grain deal with the Soviets. While vast amounts of wheat purchased by the Soviets were rushed to ports in the southern United States for export, transportation of other grains to the elevators was reportedly tied up.

As a result, the corn was left in piles in the fields or in the streets, alternately covered with snow, warmed by the sun and then soaked with rain.

So critical was the situation that, in the summer of 1973, acting director Sherwin Gardner of the Food and Drug Administration (FDA) wrote to the Office of Emergency Preparedness: "I would like to bring to your attention a national problem." The letter continued, ". . . In the fall and winter of 1972,

farmers in parts of the corn belt experienced considerable difficulties in harvesting and storing their corn crops. The Food and Drug Administration has determined that because of these difficulties a portion of the crop became contaminated with certain molds and chemical substances which may represent human and animal health hazards."

The FDA's so-called "soft alert" on the corn crop of 1972–73 never reached the public. If at that time the U.S. taxpayer was still smarting over the idea that the Russians had bought too much wheat for too little money, there were those in government and industry who were growing increasingly concerned over a more far-reaching problem posed by the "certatin molds and chemical substances" referred to in the FDA alert.

FEDERAL CONCERN

That concern has been more than justified. Two months ago the Soviets complained that the latest shipment of corn to Russia contained a high percentage of broken kernels. While the complaint focused on faulty U.S. grade standards, it was clear to agricultural circles that a major reason for the complaint is that a broken kernel is an open invitation to those molds and chemical substances the FDA warned about in 1973.

If corn—and other grains—are contaminated at high enough levels, they are unsafe. More than the apparent quality is at stake and, given the very loose and superficial inspection of U.S. grains both for export and domestic use, there is no systematic way without sophisticated chemical analysis to control these poisonous mold substances in grain, or even to know if they are there.

The FDA has identified these molds as a major health problem in food and is in the process of stiffening existing regulations and in some cases setting new ones. It is also investigating several key mold poisons to determine the long term effects of these toxic substances on test animals.

These poisons are called mycotoxins. They are highly toxic and in some cases carcinogenic, or cancer-causing, substances produced naturally by ordinary fungi that grow on nuts and grains. These molds attack the plant while it is growing and spread while it is stored. What exacerbates the problem with mold toxins is that contamination is not always apparent. In many cases, all visible evidence of the fungus disappears and the chemical lingers on in the plant like a phantom.

Corn is one of the commodities most susceptible to these molds. When news reached Washington that the 1972 corn harvest was going badly, the FDA worried about three mycotoxins in particular: affatoxin B–1, considered a powerful carcinogen and the only mycotoxin currently regulated by the FDA; zearalenone, a potent substance whose hormonal effects on human beings are not understood but which causes abortions in animals; and T–2 trichothecene toxin which in high amounts causes heart failure.

In the spring of 1973, the FDA decided to make a special survey of the corn crop. Samples were taken both from food processing establishments and terminal elevators. The FDA didn't expect to find much affatoxin since the mold producing that compound only grows in warm moist climates and as yet the weather had been too cold. But scientists knew that T–2 and zearalenong thrive in freezing conditions and it was these that FDA was worried about—with good reason, it developed.

The survey results confirmed that the corn crop was seriously contaminated. Out of 223 samples tested, FDA scientists found zearalenone in 38; out of 173 samples, they found evidence of T–2 in 94 samples and high levels of T–2 in 16 samples. What's more, a number of toxin-ridden samples had been intended for conversion to human foodstuffs as opposed to animal feed—and both types of mycotoxin were found in corn destined for export.

A few months later, scientists at the Agriculture Department's Northern Regional Laboratory in Peoria conducted additional spot surveys. By then, it was warm enough for aflatoxin and in one lot of corn generally contaminated with zearalenone, scientists found hot spots of the carcinogenic compound as well. In fact, the levels average *1600 parts per billion*—as opposed to the *15 parts per billion* level currently proposed for federal regulation and the same amount that produces cancer in rats 100 percent of the time.

In July, the FDA brought the whole matter of mycotoxin contamination to the attention of the Office of Emergency Preparedness. A special interagency

meeting was held with representatives of the Agriculture Department, the Department of the Army, the Federal Power Commission, the FDA, the Office of Oil and Gas and the Department of Transportation.

The meeting's purpose was to present the results of the FDA survey and to discuss the agricultural conditions which lead to the growth of these poisonous molds. The amount of moisture in a crop is a key factor and the FDA asked that a fuel priority be set so that farmers could dry their crops artificially, the most effective way to keep the mycotoxin problem from getting out of hand as it had in that 1972–73 crisis.

By then, however, it was August. The 1972–73 corn crop was gone. The energy crisis had abated and the 1973–74 crop looked good. The matter was apparently dropped.

INTERNATIONAL REPERCUSSIONS

Meanwhile, the Soviets had received a billion dollars worth of grain from the United States, most of it wheat. Although government officials knew how badly the corn crop had been contaminated no special analyses were made on the wheat for mycotoxins despite the fact that it was the presence of one of these same mold compounds, T–2 trichothecene toxin, in wheat and millet that probably caused an epidemic in Russia 30 years earlier during World War II.

There are no official statistics but estimates range between 10,000 and 100,000 deaths in the Soviet Union and untold loss of animals from mold grains in that epidemic. The men were away at war. The wheat and millet were left in the fields covered with snow. By the time crops were finally harvested, the grains were very moldy and highly contaminated. At its peak in 1944, in some areas the epidemic wiped out 10 percent of the population.

The Soviets, concerned over recurring outbreaks of mold-borne diseases, have established an epidemiology institute with a special laboratory to investigate mold toxins. But the U.S. Agriculture Department is not known for its sensitivity to historic ironies. As far as the government was concerned, the billion-dollar grain deal was just a private matter between grain companies and Soviet buyers.

Inspection of the grains that went to Russia was handled in the usual way. "All we would supply are the grade standards," explains Edward B. Liebe, in charge of grain grading at U.S.D.A. "There would be nothing extra. We have an implied responsibility that no poisonous material goes out but many times we don't know the origin or the destination of the grain. We will be told (by the inspector at the loading terminal) what the grade is and then, a week later, we might find out it went to Russia or China or someplace."

Publicly, the Soviets only complained after that billion-dollar grain deal that the lots they received were infested with bugs and the quality was poor. But behind the scenes, mycotoxins were becoming an important issue in international agri-business.

The year before the famous grain deal, the U.S. sent its first shipment of corn to Russia. Word goes back that the corn was analyzed there for several mycotoxins and the Russians claimed that the corn was contaminated with T–2, a disquieting reminder of the wartime epidemic. Apparently, the Soviets tried unsuccessfully to return the corn. According to sources in the Agriculture Department, the combination of the T–2 toxin in the first corn shipment and the presence of aflatoxin in cornmeal seized by the FDA months earlier in this country may have contributed to the Soviet decision to buy predominantely wheat in that 1972–73 deal.

As a general rule, wheat is less susceptible to mycotoxins because it is harvested earlier than corn. But wheat is not immune, as surveys in this country show—not to mention the Soviet wartime experience. And in fact, the Chinese actually refused to unload two of six wheat shipments because the grain was contaminated with a certain type of smut. Smut is a fungal disease which in itself is not toxic but which scinetists believe makes the wheat more susceptible to molds that are.

A NUMBER ONE PROBLEM

Suddenly, everybody is talking about molds. "Up to three years ago, we didn't have anybody who would listen to us about mycotoxins," U.S.D.A.'s Liebe says. "It's surprising how many friends we've got all of a sudden."

Farmers consider molds a number one problem both for their crops and for the animals that feed on meal susceptible to mycotoxins. International grain

traders talk of mycotoxins in terms of market value, and a consumer-oriented public is growing concerned over the safety of foods.

And for good reason: The sheer volume of the food industry that could be affected by these molds is sufficient to suggest a major impact on U.S. agribusiness if the problem gets out of hand.

More than 185 million metric tons of corn are grown in the United States every year. Roughly 80 percent goes into feed, which means that if there is a mold problem, animals will get the brunt of it. But the FDA is concerned that people will be exposed to mycotoxins in the milk, eggs, liver and perhaps even the meat of animals and poultry raised on contaminated feed.

The corn that is not used for feed—more than 35 million metric tons—is processed into 25 different products such as corn syrup or corn starch and converted into food in the form of corn flakes or hominy grits. Sweet corn—corn on the cob—is not affected by these mycotoxins, but the question facing the FDA is to what degree these toxins exist in cereals and other processed foods.

Both government and industry are concerned. The U.S.D.A. is trying to get a handle at least on the levels of mycotoxins that exist in U.S. grains, especially corn. The major problem is the sheer volume of the corn crop. As one Agriculture Department official has commented, it would be "an impossible task" to analyze all the corn grown in the United States. Furthermore, it takes sophisticated chemical methods to scan for mycotoxins and as yet these are expensive and time-consuming. New techniques, however, are being developed and, after three years of research, the U.S.D.A. is ready to try a quick screening method for aflatoxin.

LAX INSPECTION

Another problem is the grain inspection system itself. In no other country does the government have so little control over inspection. In many instances, grains here are not inspected at all. For domestic use, processors can contract directly with local farmers and the grain does not have to be graded according to federal standards.

Even if grain is inspected, the examination is superficial. "Odor and appearance—these are the two keys to determine grades at the present time," Liebe says. With export grains, the U.S. does issue a Phytosanitary Certificate which includes basic chemical analyses for noxious weeds, but molds are not considered. And no other routine chemical tests are made on corn or any other grains.

Meanwhile, industry is developing its own in-house monitoring system. As one industrial representative points out: "There is a moral obligation not to sell grains contaminated with mycotoxins and a practical consideration: industry can't afford to have the FDA find them."

In the final analysis, however, the mold problem begins in the field and that's where government agriculturalists think it should end. Several conditions favor mold growth. Some scientists suggest that the overuse of herbicides in the soil and antibiotics in animal feeds lowers the resistance of both plants and animals to the invasion of mycotoxin-producing molds.

In general, the amount of moisture is the critical factor. If there is a lot of rain and the harvest is delayed, then there is bound to be a problem with mycotoxins.

Ironically, the more advanced and more automated the methods of harvesting employed, the higher the content of moisture and the more likely the growth of molds. With the use of giant self-propelled harvesting mtachines and automatic corn pickers, the grain must be harvested slightly wet.

Harvesting corn with a higher moisture content makes it imperative that the farmer dry the grain properly afterward, requiring the expensive use of artificial drying equipment and natural gas.

Dr. Colin Campbell, biochemist at Virginia Polytechnic Institute, believes the mold problem here has increased as "an outgrowth of technological development. Machines on the farm may have saved labor at first," said Campbell, "but they've introduced new costs and new problems" as well.

* * * AND IN OTHER FOODS

The Food and Drug Administration is investigating several key poisons produced by certain molds in food and is also preparing to set new regulations for these elusive but toxic chemical substances.

Called mycotoxins, these compounds belong to a class of about 15 poisons which vary greatly in chemical structure and type of toxic effect. They can cause cancer (aflatoxin), abortions (zearalenone and ergot), respiratory failure (patulin), heart failure (trichothecenes), muscle paralysis and tremors (cyclopiasonic acid) and nerve disorders (citreovidin.)

Mycotoxins have also been responsible for several great historical epidemics—St. Anthony's Fire in Europe (ergot in bread), Yellow Rice Disease in Japan, China and Korea (a combination of toxins in rice), and Alimentary Toxic Aleukia in the Soviet Union (trichothecenes in wheat).

The molds that produce these compounds grow on almost all nuts and grains. While corn and peanuts seem to be the most susceptible, these toxins are also found in apples, oats, wheat, barley, millet, pisctachio nuts, Brazil nuts—even garlic and coffee.

Until the 1960's, mold-borne diseases in the United States were considered primarily a veterinary problem. But as scientific research identified the potent biochemical properties of these compounds and linked some of them to cancer in experimental animals, the question of human safety was raised.

"These things just haven't disappeared and we know they can get into food in the United States," explains organic chemist Joseph V. Rodricks who is in charge of FDA mycotoxin research. "We're probably not going to get any kind of epidemic situation but we don't want to get anywhere near that.

"If these compounds contaminate food at lower levels, what is the hazard to human health?"

To answer this question, the FDA is testing three particular mycotoxins in addition to aflatoxin: patulin, T–2 (trichothecene) toxin and zearalenone. Over the next four years, the agency will spend more than $2 million to determine the chronic effects of these poisons in test animals.

Patulin is a mycotoxin of great concern to the FDA because it is found in apple juice and apple cider, consumed in great quantities especially by children. Over 50 million gallons of apple juice are produced in this country a year.

In a recent survey of commercial products, the FDA found that 37 percent of the 140 samples were contaminated, which the FDA considers a high incidence of contamination. Early experiments show that patulin produces tumors when injected into mice at the site of injection, and in large amounts it is known to cause respiratory failure.

What patulin does when it reaches the intestines is to destroy all the micro-organisms there; the immediate result is diarrhea. Curiously, however, it leaves one micro-organism alone, a gas-producer which then takes over in the intestines, forcing the liquid back up through the trachea and into the lungs. The end result is respiratory failure.

The mold that produces patulin is the rot in apples, and all it takes is one rotten apple to spoil the juice. Patulin is not found in apple slices or apple sauce if the apple skins have been removed, which suggests that the toxin is formed close to or in the skin.

Preliminary studies indicate that there is no danger of patulin poisoning from apple juice grown in the United States, but the FDA is concerned about the chronic effects of the low levels of patulin currently found in commercial products. Apple processors are being "encouraged" to screen out bruised as well as rotton apples in making juice and cider.

Zearalenone is another mycotoxin of interest to the FDA. This estrogenic compound is prevelant in corn and, curiously, affects swine but not cattle or poultry. It enlarges the genitalia in male hogs and causes the animals to vomit. In female swine, it prevents conception and causes abortion.

Very little is known about how this compound works and, given the dramatic changes zearalenone produces in swine, medical researchers are concerned about its effect on human beings. A key question is whether it survives food processing and persists in such commodities as corn flakes and corn meal. If it does, the hormonal effect is a matter for concern; perhaps, subtle physical changes are stimulated by low levels of this toxin over a long period of time. Acute doses could have a more dramatic effect. As one U.S.D.A. official remarks: "A woman suddenly aborts—how is she is know it's from mold toxin in her food?"

The T–2 toxin is a very complex compound belonging to the trichothecene family which scientists believe causes Alimentary Toxic Aleukia, the recurring disease that plagued the Soviet Uuion and Eastern Europe since the 19th century.

After experiencing skin rashes, bleeding from the mouth, and internal hemorrhages, victims of ATA finally suffer heart failure. The disease affects animals as well as people.

"All of these chemical compounds (aflatoxin, patulin, zearalenone, T–2) have extremely toxic properties," explains biochemist T. Colin Campbell of Virginia Polytechnic Institute in Blacksburg, Virginia. "The problem is you don't know how toxic these things really are and it takes a lot of experimental work with animals to extrapolate back to the human situation.

"The real toxicity that exists in this country may be chronic and we may already be seeing the effects of mycotoxins in illnesses and diseases for which we don't know how to list the cause."

Senator Moss. Mr. Edward Brown Williams, counsel for the American Frozen Food Institute. Is Mr. Williams here? Would you come forward, sir.

We appreciate your being here to testify and we have your statement and now we will put it in the record in full and ask you to proceed.

STATEMENT OF EDWARD BROWN WILLIAMS, COUNSEL, AMERICAN FROZEN FOOD INSTITUTE, WASHINGTON, D.C.

Mr. Williams. Thank you, Mr. Chairman. I want to express the appreciation of the American Frozen Food Institute for the opportunity to appear at this join hearing on S. 641 and S. 1168. The members of the institute process 85 to 90 percent of this country's production of frozen foods.

S. 1168, the industry bill, in the preparation of which the institute collaborated with others, reflects the outer limits of new regulatory provisions in the field of food surveillance which we can support. As will appear hereinafter, we find some fundamental defects in S. 641 which require that the frozen food industry oppose that bill as now drafted.

We support the requirement of registration with FDA by food processors. Like Dr. Schmidt, the Commissioner of Food and Drugs, however, we consider that one-time registration provided for by S. 1168, title III, page 6, as more reasonable and appropriate than the biennial registrations which would be required by S. 641. We also support the extension to foods standardized under section 401 of the requirement that ingredients be declared on the label, in the form set forth in title I– of S. 1168 amending sections 401, 403(g), and 403(i) of the present act.

We have an essential difficulty with the concept which one must assume underlies the support for the extensive regulatory provisions of S. 641; namely, that food in this country is not being made available to consumers in a safe and wholesome condition. All of the evidence of which we know demonstrates that this is not true, with exceptional situations which are now being dealt with by the Food and Drug Administration. One was referred to by Mr. Dunkelberger, and the Food and Drug Administration has repeatedly declared that our food supply is the safest and the best in the world.

There have of course been some problems. This is hardly surprising in a nation of more than 200 million people, with a vast

food industry. But it is noticeable that, in the testimony of FDA, no suggestion is made that there are any serious problems of safety or wholesomeness of foods. On the contrary, in such sensitive areas of the regulation being proposed as so-called safety procedures and standards, open date labeling, and percentage labeling, among other provisions, FDA seems to believe that it has adequate authority under the present act.

In fact, it has alreday exercised extensive regulatory authority under section 404, the "Emergency Permit Control" provision of the act. It is fair to state that the identifiable problems in connection with the safety and wholesomeness of the food supply are being actively dealt with by FDA and the U.S. Department of Agriculture with the cooperation of industry.

Insofar as frozen foods are concerned, it is well known and conceded by experts in food technology that the public health record of the frozen food industry has been outstanding. The point is documented in a footnote on page 3 of our testimony on S. 2373 in the last Congress.

We urge that these considerations be carefully weighed before a bill is enacted which will create additional and unnecessary burdens upon industry and Government and which will surely increase the price of foods to consumers.

SAFETY ASSURANCE PROCEDURES, PLANS, AND STANDARDS

The safety assurance procedures, plans, and standards which would be provided for by S. 641 would extend to any adulteration under section 402(a) of the act, new section 410, pages 2 and 7 of the bill. Most adulterations, by far, do not involve matters of safety at all. This has long been and is now recognized by FDA. The use of the term "safety" in the designation of the procedures and standards in question is therefore inaccurate and may, indeed, mislead Members of Congress who are not familiar with the complexities of the statute, but who must vote upon the legislation.

The problem is emphasized by a statement in the second paragraph of the report of the Committee on Commerce on S. 2373, the predecessor of S. 641, in the 93d Congress that:

> The Consumer Food Act of 1974 requires food processors to develop comprehensive safety assurance systems and empowers the Secretary of Health, Education, and Welfare (HEW) (acting through the Food and Drug Administration (FDA)) to develop safety assurance standards for systems that fail to assure adequate protection.

Senate Report No. 93–985, 93d Cong., 2d sess.—One: The Committee on Labor & Public Welfare, in its report on S. 2373 in the 93d Con., 1st sess., lends even more emphasis to the point. That report stated:

> The Secretary must establish surveillance procedures which are "sufficient to reduce or eliminate existing or potential health hazards" and "to provide reasonable assurance that the food does not present an unreasonable risk to the public health." (S. Rept. No. 93–605, 93d Cong., 1st sess.)

S. 1168, on the other hand, limits the applicability of such procedures and standards to situations which present an unreasonable

risk that the food will be unsafe or injurious to health. This, we submit, should be the essential purpose of the legislation. The scope of S. 641, however, is such that not only unsafe but also safe food will be encompassed within the procedures and standards contemplated.

The scope of the so-called safety assurance provisions of S. 641 is far too broad, in our opinion. Given the immense size and scope of the food processing and related industries, the economic and other practical problems involved, and the sheer burden of surveillance, regardless of economics, such provisions should be limited to the aim of assuring safety in situations where FDA finds that there is a potential hazard to public health.

If the legislation is not so limited we are convinced that the bureaucracy created will be counterproductive in terms of the damage and expense to business, the expense to Government, and the prolifereation of nonhealth issues of serious concern to business, but of little practical significance to consumers.

The "safety assurance" standards provisions of S. 641, section 102, adding section 410 to the act, would authorize FDA to require the keeping of records, designate the personnel required to conduct surveillance operations, sampling methods, methods of inspection, and the methods of analysis by which such surveillance should be accomplished; they would authorize FDA to require, by general or specific orders, the submission of annual or special reports or answers in writing to specific questions relating to the surveillance procedures or to any matter relating to the detection of adulteration or misbranded foods.

To these provisions section 108 adds the broad subpena and investigatory authority of the Federal Trade Commission.

We read these provisions as conferring upon FDA the power to step in and run substantial areas of the business of the food industry.

Even those provisions of the 1962 Drug Amendments applicable to all drugs, which present far more serious problems of safety than do foods, did not grant such authority to FDA. We cannot see how such legislation can be justified for foods.

It is no comfort to say that the Agency is expected to exercise its discretion in administering the statute. The very existence of the great authority contemplated is an effective invitation to exercise it, as we all know well from experience; and no consideration of these matters can ignore the fact that, under present law, criminal penalties can be imposed upon both corporations and individuals without any regard to whether the violative act is knowing or willful.

FACTORY INSPECTION

Section 110 of S. 641 would extend FDA inspection authority to "safety assurance records bearing upon whether a food may be adulterated, within the meaning of section 402(a) of this act, and records bearing upon the accuracy of statements made in the labeling of food."

This authority as spelled out in the same provision of the bill is so encompassing that we must strenuously object to it.

Not only is it an unjustifiable authority for a fishing expedition into industry files, but, again, it adds another layer of authority for the Agency which is beyond its financial and personnel capabilities to exercise equitably in the food industry.

Section IV of S. 1168, which limits inspection to records, files, papers, and processes reasonably necessary for a determination of whether foods may be unsafe or injurious to health, is more reasonable and more likely to be within the capabilities of the Agency.

TRADE SECRETS

The prohibition of disclosure of trade secrets in title IV of S. 1168 is the minimal protection to which industry is entitled. Dr. Schmidt objected to the trade secret protection provision of section 112 of S. 641, apparently on the principal ground that it is current FDA practice to provide notice to the processor concerned in all cases involving "a close question" as to whether or not a trade secret is involved. This is a matter of too great importance to leave to the discretion of FDA.

FDA TESTIMONY ON SAFETY ASSURANCE

Commissioner schmidt stated, in his testimony, that:

> We would want to be very sure that legislation expressly conferring authority to adopt food safety assurance standards could not be interpreted as implying that FDA does not have power under section 701(a) to adopt substantive rules to enforce other provisions of the act.

Commissioner Schmidt also stated that:

> FDA presently has the authority to issue mandatory surveillance regulations as current food manufacturing practice (GMP) regulations.

Thus, he believed and stated, that the requirements of S. 641 for the establishment of safety assurance procedures by individual processors are unnecessary, new section 410(a), page 2, of S. 641.

There are two observations which we should like to make about this portion of Dr. Schmidt's testimony.

First: If as FDA seems to believe, section 701(a) of the act, the general regulationmaking authority, is sufficient basis for safety assurance standards, it is difficult to understand why specific authority for such standards should be included in the bill at all; and it is equally difficult to see how a provision preserving such authority as now exists under section 701(a) would offer any support to FDA's concept of that section's scope.

Second: We do not disagree with FDA's view that section 701(a) regulations have the effect of law, with this important condition—that the regulation is authorized by the statute. Thus, a GMP regulation dealing with sanitation in a reasonable manner would be authorized by the statute and therefore enforceable in the courts. We know of no case that holds otherwise, including the *National Nutritional Foods* case cited in Dr. Schmidt's testimony. *National Nutritional Foods Association* v. *Weinberger*, 2d Cir., February 3, 1975. In that case other provisions of the statute, sections 401 and 503(b) supported the section 701(a) regulations.

We do object to the FDA's characterization of section 701(a) regulations as "substantive," because use of the term substitutes semantics for content. Even interpretative regulations have the effect of law if authorized by the statute and are therefore enforceable.

Like Dr. Schmidt, we object to the provision of S. 641 requiring individual safety assurance systems. A failure by a processor to comply with his own system would be a violation of the act subject to the sanctions of the act, including criminal prosecution. We can see no logic in punishing a processor for failure to comply with his own procedures. The result, we think, would be that processors would be reluctant, and probably would refuse, to establish adequate procedures.

To us the provision seems inconsistent with salient purpose of the bill, to place upon the industry the primary burden of safety assurance.

Furthermore, it is our belief that to require that the procedures contemplated by section 102 of the bill be adopted within 6 months is unrealistic. Certainly it would be beyond the capabilities of small- or medium-sized processors, who comprise most of the thousands of processors in the United States.

The American Frozen Food Institute has been and is conducting programs which provide information to processors on good quality control procedures and guidelines for good manufacturing practice. As we stated in our testimony on S. 2373 in the last Congress, however, adequate quality control systems cannot be achieved except upon a developmental basis, not in 6 months. This applies equally to the provisions of S. 641.

We therefore support the provisions for individual safety assurance systems of S. 1168, which avoid the problems which would arise under S. 641. Under S. 1168, FDA's authority to enforce appropriate GMP regulations would not be disturbed and the Secretary could, if he found it necessary, establish safety assurance standards.

PERCENTAGE LABELING

Section 305(a) of S. 641 would amend section 403(i) of the act to require, in a new paragraph (B), a declaration of the percentage of any ingredient of a food for human consumption if:

(i) the ingredient is an integral part of such food and is significant with respect to its value, quality, nutrition, or acceptability of such food, or (ii) the ingredient is required to be so declared by the Secretary by regulation upon a finding such regulation would be useful to consumers.

The Commissioner of Food and Drugs, Dr. Schmidt, in his testimony on June 4, stated: "We do not object to this provision but feel that such a provision should appropriately be left to regulations", that FDA should be authorized to decide when such information will be useful to consumers; that a mandatory provision may impose an economic burden on consumers for little or no public protection; that the provision is an open invitation to protracted litigation—presumably because of its vagueness—and that no standard is provided to determine when an ingredient is significant with respect to value, quality, nutrition, or acceptability.

Basically the Commissioner seems to feel that the percentage labeling provision is unnecessary because it deals with an area in which, he stated in his testimony, "FDA presently has general authority."

Apparently the Commissioner is content to let the courts decide upon the existence or extent of FDA's so-called general authority in this area. We are in accord with this approach as we understand it, and we agree also with the Commissioner's criticisms of the provision in question.

It may be added that the second part of added paragraph (B), requiring a percentage declaration where the Secretary finds that such information would be useful to consumers, offers no standard of usefulness to guide the Agency, leaving it an authority virtually without limitaiton.

It is our hope that the committees also will consider the impact of the provision in question upon the costs of percentage labeling which, of course, will ultimately fall upon consumers. Each change in the quantity of any ingredient as well as in size of a container would involve a new label, in addition to the initial expense entailed. At the least, any legislation requiring percentage labeling should be limited to cases where, without it, there is sound basis for a determination that consumers would be misled.

There is no such restriction upon the applicable provisions of S. 641.

CRIMINAL PENALTIES

Title VIII of S. 1168 [p 16] would amend section 303(a) of the Federal Food, Drug and Cosmetic Act by restricting criminal penalities to violations of the act which are knowing and willful. The bill would also add a civil penalty of $10,000 for each violation.

S. 641 would provide for a civil penalty of $10,000 for "each day of violation." The penalty would be assessed not by the courts, as under S. 1168, but by the Secretary, subject to appeal to the appropriate court of appeals.

We can see no basis for changing the present provision of the statute penalizing each violation to a provision for a penalty for "each day of violation." The concept of "day of violation" is so vague that it probably could not withstand attack in the courts.

Administrative imposition of fines is entirely foreign to the enforcement philosophy underlying the Food, Drug and Cosmetic Act. It is particularly objectionable where, as the statute is now interpreted, a violation can be found regardless of the knowledge or fault of an individual defendant.

Under other recently enacted statutes, such as the Consumer Product Safety Act—CPSA—not even a civil penalty or fine is imposed unless the accused person, including corporations, knowingly commits the violation. A corporation is not subject to criminal penalties under the CPSA unless it knowingly and willfully commits an offense after having received notice of noncompliance from the Commission. Likewise, an individual director, officer, or agent of a corporation is subject to criminal penalties only if he knowingly and willfully authorizes, orders, or performs an act in violation of

the CPSA and has knowledge of a notice of noncompliance from the Commission.

These carefully circumscribed provisions are in stark contrast to the absolute liability without fault provisions of the Food, Drug and Cosmetic Act.

The Food, Drug and Cosmetic Act provisions apply, moreover, not simply to violations involving safety or injury to the public health, but to all violations of the act, including, for example, minor misbrandings, by responsible individuals who are officers or agents of corporations as well as by the corporations themselves.

The National Emission Standards Act—42 U.S.C. 1857–f–4—provides specifically for a civil as distinguished from a criminal penalty and carries with it no sanction of imprisonment, as does the FDC Act.

Other recent legislation, such as the Occupational Safety and Health Act and the Federal Water Pollution Control Act, also provides only for civil penalties, except for willfull, negligent, or knowing violations.

These statutes strongly suggest that civil penalities should be provided for violations of the FDC Act enforceable through the courts, and that criminal penalities should be available, as under the CPSA, only for knowing and willful violations.

Under the recent Supreme Court decision in the Park case *(United States* v. *Park*, No. 72–215, June 9, 1975) an offense is committed by all who have a responsible share in the furtherance of the transaction which the statute outlaws *(United States* v. *Dotterweich*, 320 U.S. 277, 282–283), regardless of actual knowledge or intent to commit a prohibited act.

This simply means that large business enterprises processing or handling foods are subjected to a standard which cannot consistently be met by the individuals who manage them.

We hope that the implications of this approach for business in this country and for its ability to recruit effective managerial talent will be carefully scrutinized by Congress.

OPEN DATING

Section 302 of S. 641 would amend section 403 of the Federal Food, Drug, and Cosmetic Act to require so-called open dating of foods, in accordance with FDA regulations, if the label or labeling bears any information regarding the dating of a food for human consumption.

Among the provisions which are authorized for inclusion in the regulations is a clear statement of the storage conditions recommended by the processor, if they differ from ordinary room temperature.

It is now well understood and accepted generally that temperature during storage and handling is the critical factor in the quality of life of frozen foods. This factor is the key to the problem of open dating of such foods. Frozen foods are a substantial growing and well-established segment of the food industry, and millions of consumers depend upon them as an important source of their food supply.

It must be recognized, however, that if a particular frozen commodity is subjected to substantial temperature variance a sell or pull date based upon its normal storage life could be misleading rather than informative.

The correct handling of frozen foods is actively being advocated by extensive industry publicity. Complementary efforts to the same end are found in the frozen food handling code of the Association of Food and Drug Officials of the United States and the draft code of practice for the processing and handling of frozen food of the Codex Alimentarius which is now under active development.

Since it is clear that not time, but product temperature is the basic factor which affects the quality of frozen foods, we consider it premature to include such foods in the provision of S. 641 concerning date labeling.

ADMINISTRATIVE DETENTION

Section 103 of S. 641 provides for administrative detention of food for not to exceed 20 days by an authorized representative of the Secretary, if such representative concludes that "the facts provide a reasonable basis to show that such food is adulterated, misbranded, or otherwise in violation" of the Act.

If detained, the article "shall not be moved by any person from the place at which it is located and detained" unless released by the Secretary. An amendment to section 301 would prohibit the "movement" of a detained article or the removal of any identifying mark or label upon the detained food (section 105, adding section 301(n) to the act).

The detention authority is not accompanied by limitation to foods which are believed to be unsafe or injurious to health or by specific provision for appeal to the courts by a person who would be entitled to claim such food if it were seized. S. 1168 contains such provisions (title V, pp. 12–13).

The testimony of FDA offered no specific reason for supporting the detention provision. We suggest that there is good reason for eliminating any detention authority or, at the very least, for providing the limitations specified in S. 1168 and the safeguard of appeal to the courts which is included in that bill.

If not limited to safety factors, detainer activities could overwhelm FDA and would certainly be a basis for harassment of industry. If there is any doubt at all whether an article should be seized, it would be surprising if an inspector, out of an abundance of caution, did not detain it until a decisoin whether to seize the product could be made by his superior.

CITIZENS' SUITS

FDA, in its testimony, opposed the provisions of S. 641 authorizing the bringing of suits against the Secretary or any other person who violates a safety assurance standard (new section 410(c)) and against the Secretary for failure to comply with the safety assurance plan established under new 410(b).

The Commissioner opposed these provision. We agree that they are unnecessary and would be needlessly burdensome for both the Secretary and the industry.

FOOD CODING

The Commissioner testified that it was unnecessary to require a uniform system of food coding as provided by S. 641. Again, we agree that such a system is unnecessary. Present industry practices in this area have proved generally adequate. In any event, a uniform system would be impractical, and disruptive of present practices, requiring that processors revise their present codes to achieve a uniformity which may be expected to cause confusion between the products of different processors and to burden processors with additional unjustified expenses.

For the particular concerns of the frozen food industry we refer the committee to the testimony of O. A. Cerutti of the John Inglis Frozen Food Co. on Senate amendment 1838 to S. 2373 in the last Congress.

PREEMPTION

We urge also that the preemption provision of S. 1168 (title VII) be adopted rather than that of S. 641, which is limited to labeling. The food industry operates in every State of the country. The pressures of State and local laws and regulations which differ from Federal laws are becoming more and more burdensome. Relief of the type proposed in S. 1168 is imperative if the industry is to function effectively in the future.

CONCLUSION

We have stated, in these comments and in our testimony on S. 2373, in the 93rd Congress, that insofar as frozen foods are concerned, it is well-known and conceded by experts in the field that the public health record of the frozen food industry has been highly satisfactory, indeed outstanding; and we have noted that thsi statement was documented in our testimony on S. 2373. Consequently, we can perceive no benefits to the public in imposing the severe regulatory restrictions of S. 641 upon this industry. We think the industry performance dictates that such onerous obligations and regulations should not be thrust upon it. As we have heretofore indicated, the most regulation which we could support at all is that provided in S. 1168.

Thank you, Mr. Chairman.

Senator Moss. Thank you, Mr. Williams, for you statement. We appreciate it and appreciate having the views of the frozen food industry.

Under optimum conditions, are there shelf life limitations on frozen foods?

Mr. Williams. The shelf life of frozen foods differs with the food.

Senator Moss. So there is a limitation.

Mr. WILLIAMS. Yes, that is correct, there are limitations.

Senator Moss. What factors would cause the percentage ingredient labeling requirements to increase costs?

You said it would increase costs. What factor would cause that?

Mr. WILLIAMS. I think I mentioned, Mr. Chairman, that there would be of course the initial cost of changing the label. Second, there would be the cost of changing the label each time an ingredient was changed, or the proportion of an ingredient was changed.

Senator Moss. Of course the labeling would be reprinted periodically, so that the percentage that might be lost would not be large, would it not?

Mr. WILLIAMS. The percentage of what?

Senator Moss. You say if the ingredients changed, then the labels would have to change, and that means certain ones of them would be outdated. But would that be a large factor?

Mr. WILLIAMS. It would with the big companies in particular, and it would be onerous upon the small companies because of their financial limitations.

When you order labels for a year in advance, and suddenly you are confronted with a necessity for changing them because of the percentage labeling provisions, I think you can see that there are difficulties there.

Senator Moss. Don't you think it is a bit severe to advocate total preemption on the States for food, drugs and cosmetics, as is the case with S. 1168?

Mr. WILLIAMS. Well, I didn't think so, because the provision of S. 1168 contemplates that the State, if its law permits, can enforce the Federal provisions as well as its own provisions. It seemed to me to be rather reasonable.

Senator Moss. But the variation that might occur in a state area would be preempted away from the State if that provision were there.

Mr. WILLIAMS. That is correct. That is one of the biggest problems that the whole food industry faces, the various types of regulations and the differing regulations in the various States and localities.

Senator Moss. It seems to me the provision also is wide in that it takes in food, drugs and cosmetics, not just food.

Isn't that a bit broad?

Mr. WILLIAMS. It seems reasonable as applied to all, but I can't speak for the drug industry, I have no idea how they feel about it.

Senator Moss. Well, thank you, Mr. Wiliams. We appreciate your coming to testify before us.

Mr. Bruce Durling, president of the Flavor and Extract Manufacturers' Association.

If you would introduce those accompanying you at the table, Mr. Durling, we would appreciate it.

Your statements that have been offered are all placed in the record, and will be there in full, and we will ask you to do as our previous witnesses have, to highlight and summarize to the extent that you can.

STATEMENT OF BRUCE L. DURLING, PRESIDENT, FLAVOR & EXTRACT MANUFACTURERS' ASSOCIATION OF THE UNITED STATES; ACCOMPANIED BY DR. RICHARD L. HALL, VICE PRESIDENT AND DIRECTOR OF RESEARCH FOR McCORMICK & CO., INC.; DANIEL R. THOMPSON, CHIEF COUNSEL; AND WILLIAM D. APPLER, ASSOCIATE COUNSEL

Mr. Chairman, Distinguished Subcommittee Members, and members of the staffs of the Consumer and Health Subcommittees:

We appreciate the opportunity given the Flavor & Extract Manufacturers' Association [FEMA] to comment upon S. 641, the Consumer Food Act of 1975. I am Bruce L. Durling, chairman of the board of Stange Co. and president of FEMA. With me today are Dr. Richard L. Hall, vice president and director of research for McCormick & Co.; Daniel R. Thompson, FEMA chief counsel; and William D. Appler, associate counsel.

We will direct our remarks to two areas in S. 641 where our expertise as flavor manufacturers may be useful to the committee. These are: (1) The possibility of compelled disclosure of formulas under several sections of the bill broadening FDA's information-gathering powers; and (2) review of the flavor and spice labeling exemption. Both Dr. Hall and I will keep our remarks brief, since a more detailed presentation—to which we will occasionally refer—has been submitted by FEMA for the record.

By commenting critically on these two areas, however, we do not mean to suggest that we oppose the balance of S. 641. To the contrary, FEMA generally supports the remaining substantive provisions of this legislation intended to insure the safety of food products, and would like to go on record with this support.

FEMA has a long and productive history of close cooperation with the FDA to meet our common goal of a safe food supply. We have testified in favor of the 1958 Food Additives Amendments, developed accurate analytical testing methods for flavors, and worked closely with a panel of independent experts who evaluate the safety of flavoring substances. We are now preparing, under a cost-reimbursable contract with FDA, a series of scientific literature reviews of several hundred flavoring substances. Thus, the overall focus of our association's activities, since 1958, has been on scientific matters in general, and on safety in particular.

Our member companies make a substantial contribution to the variety and flavor of the foods we all enjoy, a contribution that will increase in importance as we come to rely more and more upon less traditional sources of nourisment—in response to the deepening world food shortage. These member companies are generally small in size—over half our active members have annual sales of less than $1 million. They use sophisticated technology and costly, continuing research to develop the highly individualized and complex formulations that are the heart of our industry.

Our formulas play a vital and unique role in the flavor industry. To other food processors formulas are of comparatively little concern, because their products are less sophisticated. But to firms in the flavoring industry, their formulas are absolutely vital. Formulas are the embodiment of our creative response to the needs and demands of customers and consumers in a competitive market economy; formulas and service are what we have to sell our customers.

The FDA itself recently recognized in its labeling regulations that flavor formulas are extremely valuable trade secrets which deserve special protection. This is because they represent a substantial investment—hundreds of thousands of dollars in research and development work—on the part of the manufacturer. Even a small company will have several thousand differing formulations; large companies may have 100,000 current formulas.

This investment is carefully protected through the extreme precautions that are taken to safeguard the confidential nature of the formulas. They are broken into subassemblies and in many cases coded into computers. As FDA has acknowledged, "because of the secret nature of flavor formulas * * * only certain company personnel may be authorized to handle them." While the Coca-Cola Co. has earned a national reputation for closely guarding its formulas, that same concern for secrecy and protection characterizes the entire flavor industry.

FEMA has long opposed FDA efforts to compel the disclosure of flavor formulas. Because of the importance of such trade secrets in promoting creative, competitive responses to the needs of consumers and food processors, Congress has, in the past, repeatedly sustained this position, as our formal submission demonstrates. Therefore we urge that to the extent S. 641 may authorize the FDA to obtain flavor formulas, it should be amended. The amendments we propose have been submitted for your consideration as an appendix to our submission.

FDA DOES NOT NEED THE AUTHORITY TO INSPECT FLAVOR FORMULAS TO CARRY OUT THE PURPOSE OF THE FOOD, DRUG, AND COSMETIC ACT

The salient fact is that, in its testimony before this committee both this year and last, FDA has failed to state any persuasive reason why it should be given the unprecedented power to inspect flavor formulas. In fact, Commissioner Schmidt has publicly stated that "in terms of demonstrated hazard, the least important health concern in the food area is that from "food additives, the materials used in food in small amounts to maintain * * * flavor." Dr. Virgil O. Wodika, until last November Director of FDA's Bureau of Foods, has stated—concerning flavors—that:

> [M]ost of the substances now in the food supply, including the regulated direct additives and the materials on the GRAS list, have been in use in foods for more than a single lifetime. It would be extremely difficult to document damage to health that they have produced.

Indeed, FDA's specific testimony on the bill last year revealed that it was not aware that any demonstrated cases exist of any health hazard from flavors. This conclusion is supported not only by human

experience, but also by data in animal studies and other scientific investigations.

Against this background, it is not surprising that FDA, in its testimony before this committee just 2 weeks ago, did not even suggest that public health or safety considerations motivate its desire to obtain statutory authority to inspect formulas. And the reasons actually advanced by FDA as to why it needs formula inspection authority focus on problems which are either unrelated to flavor formula inspection or clearly covered by current statutory authority.

The first problem for which formula disclosure was necessary, according to Commissioner Schmidt, was potential microbiological contamination. Concern for such contamination, however, is centered entirely on nonflavor ingredients, and therefore obtaining a flavor formula will throw no light on microbiological contamination.

Another problem cited by FDA as necessitating formula disclosure was its desire to verify the truthfulness of many label claims. I should like to direct the attention of the committee to the fact that new and extensive labeling regulations, dealing expressly with the truthfulness of flavor labeling, will go into effect in 2 weeks on July 1. These regulations were not even in existence when S. 2373, the predecessor to S. 641, was orignally drafted.

Pursuant to the new flavor labeling regulations, food products must reflect, either in the ingredient statement or in the name of the product, the presence of artificial and natural flavors. Bulk shipments of flavors are similarly regulated. Thus, the FDA certainly does not need additional statutory powers to resolve the truthfulness of label claims regarding flavors.

Apparently the major problem which FDA believes requires formula inspection authority is the detection of unapproved additives or improper amounts of approved additives. However, in this area in particular, present statutory authority is completely adequate to protect the public health and safety.

The provisions of the Food Additives Amendments of 1958, combined with: (1) The authority to inspect materials, containers, and labeling—section 704; and (2) the power to draw samples, analyze them and seize adulterated or misbranded products—sections 304 and 702, are effective means for detecting any improper additives in food products.

More importantly, all flavor substances used in food fall into one of two broad categories. A flavor ingredient may be approved for use under the Food, Drug, and Cosmetic Act because it has been generally recognized as safe, section 201(s), or because it is a regulated food additive. If the latter, it must be precleared by FDA to determine whether, and at what levels, it may be safely used.

The Food and Drug Administration, not the manufacturer, makes this ultimate determination. In doing this, the FDA has been directed by Congress: (1) To forbid use of any additive unless its "proposed use * * * will be safe"; (2) to set tolerance levels at an amount no higher than "reasonably required to accomplish the * * * effect for which such additive is intended"; and (3) to establish the manner in which the additive can be labeled, packaged and used safely.

55-000—75——14

The Food Additives Amendments also give FDA the authority to insure that safe tolerance levels have not been exceeded in actual use. Every food additive petition proposing a tolerance level must contain "practical methods for determining the quantity of such additive in * * * food"—section 4096. This enables FDA to determine by analysis whether improper levels of such additives are contained in a food product.

It is, therefore, clear that FDA already has ample authority to meet its stated needs. While formula disclosure might possibly make FDA's operations a little easier, that fact standing alone surely is no justification for exposing flavor manufacturer's confidential trade secrets. For as Senator Hart pointed out last year in these hearings, "It is always easier for enforcement procedures to sweep, but that doesn't justify it"—especially when preserving these trade secrets serves an important public policy favoring creative ingenuity and free enterprise competition with minimum Government interventions.

For these reasons, we urge the committee to continue the long standing congressional policy against formula disclosure under the Food, Drug, and Cosmetic Act. This policy has reflected the sound congressional judgement expressed by Senator Inouye, who testified against an earlier effort by FDA to obtain confidential food formulas as follows:

> This unprecedented grant of authority to a Government agency to pry into the files and records of private commercial enterprises on a regular and recurring basis is * * * unwarranted and totally unnecessary * * *. No evidence has been produced to establish the need for this drastic proposal. On the contrary, there is compelling evidence to establish that this unlimited authority in a Federal agency to enter food manufacturing establishments at will and rifle through their files may well seriously interfere with the efforts of reputable, progressive companies to produce high-quality, wholesome foods on a volume basis at a reasonable price to consumers.

These concerns are no less applicable today.

Our specific suggestions for amending S. 641 to remove any possibility that FDA has been given formula disclosure authority are set forth in an attachment to our formal submission to the committee. Now it is my pleasure to introduce Dr. Richard Hall, vice president for Research of McCormick & Co., who will discuss FEMA's opposition to certain changes in the act's flavor and spice labeling exemption.

Senator Moss. Thany you. I wish to welcome Senator Stafford from Vermont who represents the Labor and Welfare Committee in this hearing. I am glad he has joined us now.

We will hear your statement, ask you to summarize as best you can, and then we will ask any questions that ocur to us.

Dr. Hall. Thank you, Mr. chairman. I, too, am pleased to have the opportunity to present to this committee FEMA's position on provisions in S. 641 which would restrict the spice and flavoring labeling exemption long contained in the Food, Drug, and Cosmetic Act, and would direct the FDA to undertake a mandatory expedited study of this exemption. Neither of these provisions can be justified on the basis of any evidence presented to the committee thus far, and neither would accomplish the apparent goals of S. 641 sponsors.

The flavor and spice labeling provisions of the act permit these substances to be designated generically on food product labels, ratehr than being named individually. Section 305 of S. 641 would limit or do away with this provision unless the manufacturer revealed ingredients or perhaps formulas in response to consumers' questions about the particular product. Even then, whenever FDA felt that eliminating the exemption would provide information useful to the consumer, flavors would have to be named on the label. These provisions are not in the interest of either the consumer or the manufacturer.

FDA itself opposed any requirement that flavors and spices be declared by name on food labels when it testified before the consumer subcommittee last year. FDA made it plain that there are no demonstrated cases of health hazards requiring flavors and spices to be named on labels, and should such cases occur, it had sufficient authority to deal with them.

But FDA's principal reason for opposing the removal of the labeling provision was provided by Deputy Commissioner Gardner, who explained that the disclosure of these ingredients would not help the consumer, and specific designations of spices and flavorings would not really be practical.

Dr. Wodicka further said in the quote before you, that the common name of a natural ingredient tells the consumer nothing of its components, and that the listing of ingredients of artificial flavors would be cumbersome and impractical. Because flavors are combinations of dozens of ingredients, FDA said it would not be feasible in many instances to publish that on the label, it would take up too much room.

It is precisely for these reasons, the large number of flavoring substances, their complex or unfamiliar names, the length of the listing involved, and most importantly, the lack of any value to the consumer from such listing and the reasons mentioned earlier by Mr. Durling, that the spice- and flavor-labeling provision was established in the act. These same considerations require its continuance, without the amendments proposed by S. 641.

We thought the committee might find it useful if we fleshed out FDA's previous testimony with some representative examples to illustrate the scope of the problem, if the flavor labeling provision were modified or removed. There are about 1,524 different flavoring ingredients and almost any number of these may be contained in a particular flavor. For example, our exhibit 1 gives the 20 flavoring ingredients in a simple imitation brandy extract.

Obviously there is no practical way to include these on a 1-ounce carton, much less on the bottle label. Moreover, most flavors, particularly the individual chemical substances, have no common or usual name to put on a label. And the listing of the chemical components would not convey to anyone except a flavor expert any sense of the taste or aroma of the product.

Our exhibit 2 shows the composition of a very typical dry flavoring mixture such as would be used in pudding of frosting mixes. The most prominent flavoring ingredient which might be recognized by at least some consumers would be the fourth one down, amyl

acetate, sometimes called banana oil, and vanillin, which is an ingredient of and resembles vanilla.

But actually that list of ingredients is a list of the ingredients of a rather simple typical raspberry flavor, and here is a sample of it, in a 1-ounce bottle, for you to examine.

Senator STAFFORD. Don't you have more than one sample?

Dr. HALL. Further, depending upon the product, and the objective of the flavor chemist, a number of additional ingredients, some artificial, some natural, perhaps twice as many, might be added to provide the best flavor for the particular product and the processing involved. A raspberry flavor might contain rose essence or oil of clove, and yet not in any way be flowery or spicy.

If this raspberry flavoring listed on exhibit 2 seems somewhat complex, it is really not so. These ingredients are carefully chosen not only to produce the desirable flavor, but to have the necessary characteristics of stability, safety, economy, and compatability with processing which a national food distribution system requires, and which are often lacking in the natural product.

It is interesting to compare this rather short list of ingredients in exhibit 2 with the far larger number of substances so far found in the flavor of raspberry juice itself. Moreover, many of these natural components you see before you are variable, sometimes present, sometimes absent, sometimes in different amounts. Many of them are without value and some may be undesirable in other ways. Near the bottom of the last chart you will see coumarin which is contained naturally in raspberries, but is banned as an ingredient in food.

Those substances on this list in front of you which are actually useful in raspberry flavoring are marked appropriately with a raspberry on exhibit 2. Gum arabic is an encapsulating agent and propylene glycol a solvent, but vanillin and the other three are ingredients of other natural foods, mainly fruits and vegetables. It appears to us that whatever small interest or concern there may be among consumers in the names of flavoring ingredients springs principally from a lack of appreciation of the complexity and the variability of nature.

If, despite the demonstrated safety to which Mr. Durling alluded, there should appear some particular problem, FDA has testified it has sufficient authority to deal with it under its present statute. And certainly if any specific health problem were presented under competent medical auspices, I find it inconceivable that the flavor industry and the particular company involved, which has the greatest possible interest in the safety and reputation of its products, would not react responsively and appropriately to that specific hazard. Certainly none of us who have devoted our professional lives to the flavor industry would be content with inadequate action.

We therefore see no reason whatever to remove or amend the present provisions of flavor and spice labeling in section 403 of the Food, Drug, and Cosmetic Act.

One final point. We also join FDA in objecting to the mandatory requirement to conduct a feasibility study of the flavor-labeling provisions. FDA simply has far more important things to do.

We appreciate this opportunity and would be pleased to answer your questions, or work further with you in any way.

Thank you.

[The exhibits follow:]

EXHIBIT 1

APPROXIMATE LIST OF FLAVOR INGREDIENTS IN IMITATION BRANDY EXTRACT

Ethyl formate
Ethyl acetate
Ethyl propionate
Ethyl lactate
Ethyl laurate
Ethyl heptylate
Ethyl butyrate
Ethyl hexanoate
Ethyl octanoate
Ethyl decylate
Ethyl undecanoate
Methyl salicylate
Methyl hexanoate
Methyl decylate
Oil of clove bud
Oil of rue
Phenyl ethyl alcohol
Amyl formate
Vanillin
Undecyl cinnamic aldehyde

EXHIBIT 2

ARTIFICIAL RASPBERRY FLAVOR

Gum arabic
Benzyl alcohol
Propylene glycol
Amyl acetate (common name, "banana oil")
Vanillin
1-(4-Hydroxyphenyl butan-3-one
Eugenol methyl ether
Butyl acetate
Benzaldehyde
Octanoic acid
γ-Undecalactone
Phenylethyl alcohol
Maltol
Diacetyl
Citral
β-Ionone
Acetaldehyde
Dimethyl sulfide

EXHIBIT 3

FLAVORING INGREDIENTS SO FAR FOUND TO OCCUR NATURALLY IN RASPBERRIES

Hydrocarbons
naphthalene
2-methylnaphtalene
acenaphthene

Alcohols
methanol
ethanol
2-methylpropan-1-01
1-butanol
2-butanol
trans-2-buten-1-01
2-methylbutan-1-01
3-methylbutan-1-01
3-methylbut-2-en-1-01
3-methylbut-3-en-1-01
1-pentanol
trans-2-penten-1-01
1-penten-3-01
1-hexanol
cis-3-hexen-1-01
1-heptanol
2-heptanol
1-octanol
cis-2-octen-1-01
1-nonanol
geraniol

Carbonyls
acetaldehyde
propanal
2-propenal (acrolein)
2-methylpropanal
3-methylbut-2-enal
3-methylbutanal
2-pentenal
hexanal
2-hexenal
cis-3-hexenal
geranial
neral
benzaldehyde
2-propanone
3-hydroxybutan-2-one
2, 3-butanedione (diacetyl)
2-pentanone
3-pentanone
2-heptanone
2-nonanone
menthone
carvone
1-(4-hydroxyphenyl)-butan-3-one
camphor
α-ionone
Nerol

EXHIBIT 3—Continued

FLAVORING INGREDIENTS SO FAR FOUND TO OCCUR NATURALLY IN RASPBERRIES—Continued

Carbonyls—Continued
linalool
cyclohexanol
benzyl alcohol
2-phenylethanol
4-hydroxyphenylethanol (tyrosol)
menthol
2-methen-1-ol
α-terpineol
terpineol-4
3-methylbut-2-ol-2

Esters
methyl acetate
ethyl acetate
butyl acetate
amyl acetate
isoamyl acetate
hexyl acetate
3-hexenyl acetate
butyl propanoate
ethyl propenoate
ethyl butanoate
ethyl 3-methylbutanoate
methyl hexanoate
β-ionone
β-dihydro-ionone
epoxy- -ionone
α-irone
acetophenone
1-(2, 6, 6-trimethyl-1, 3-cyclohexadien-1-yl)-2-buten-1-one (damascenone)
piperitone
furfural
5-methylfurfural

Acids
formic
acetic
propanoic
2-methylpropanoic
butanoic
3-methylbutanoic
pentanoic
hexanoic
2-hexenoic
3-hexenoic
octanoic
9-octadecenoic (oleic)
ethyl hexanoate
ethyl octanoate
ethyl salicylate
5-hydroxyhexanoic acid lactone
5-hydroxy-2-hexenoic acid lactone
4-hydroxydecanoic acid lactone
5-hydroxydecanoic acid lactone

Miscellaneous
1,1-dimethoxyethane
1,1-diethoxyethane
4-methylphenol
dimethoxyallylbenzene
coumarin
1,2-dihydroxybenzene (catechol)
theaspirane
benzoic
4-hydroxybenzoic

Senator Moss. Thank you very much, Dr. Hall. We do appreciate your testimony, and looking at all the ingredients that is in raspberry flavoring boggles my mind. I think you have made your point pretty well in that respect.

We have suggested some possible amendments that might make the bill acceptable. I am going to ask my staff assistant to propound these amendments to you to see if you think they would meet your situation.

I am going to be required to leave very shortly, as will Senator Stafford, as we have a joint session and that time is immutable and we have to go.

I am going to ask Mr. Merlis if he would receive the testimony of the final witness and get it in our record, so we can complete it today.

I hope you understand the constraints that require that. So I will ask Mr. Merlis to propound these questions and then to call Mr. John Adams, who will be our final witness today.

Do you have any questions or comments, Senator?

Senator STAFFORD. I have no questions. Like you, Mr. Chairman, I am amazed at the complexity of the chemicals that are in a real raspberry and the somewhat similar artificial means of devising the same flavor.

Senator Moss. I will enjoy raspberries with more reverence now.

Mr. MERIS. We have drafted two amendments and if you have a copy of S. 641, perhaps we could go over the language and see whether or not these meet the kinds of objections which you have.

In no way do these suggested amendments represent any position which either of the two subcommittees has taken.

I think the objective in drafting these is to try to see whether this language does meet the objections you have addressed.

On page 41, lines 11 through 23, if they were to read as follows, what is your view:

(a) The common or usual name of each such ingredient in the order of its predominance except that spices and flavorings other than those sold as such may be designated as spices and flavorings, without naming each such ingredient, provided the Secretary may by regulation require a certain spice or flavoring to be named on the labels or packages upon a finding that such disclosure is necessary to protect public health.

That meets one of your objections, I take it?

Mr. DURLING. Correct.

Mr. MERLIS. The second one is on page 43.

We suggest striking lines 11 through 16 and beginning at line 9 it would read: "A declaration of the percentage of any ingredient of any such food for human consumption, if the Secretary determines that the ingredient is a characterizing part of such food, in that it has a material bearing on the cost, quality, or nutrition, provided that a spice or flavoring may not be considered a characterizing part of such food unless the food itself is a spice or flavoring."

That goes a long way too——

Dr. HALL. That is very good, yes.

Mr. MERLIS. I don't have any further questions. Obviously your comments about the study will be taken in line with the Commissioner's comments about both the GRAS study and the practical aspects of having a study regarding labeling before a study regarding the GRAS existence of items is completed.

It would be a little difficult to require labeling of something that subsequently might be stricken from the GRAS list.

Would it be possible to obtain reduced size versions of these exhibits, or are they attached to your statement?

Dr. HALL. They are attached to the statement we submitted.

Mr. MERLIS. Fine. They should be put in the record for all to see.

Thank you very much, gentlemen.

Our next witness will be Mr. John Adams, director environmental and consumer affairs, National Milk Producers Federation.

Mr. Adams, you have a fairly brief statement, but to the extent you feel appropriate, why don't you summarize it?

STATEMENT OF JOHN B. ADAMS, DIRECTOR, ENVIRONMENTAL AND CONSUMER AFFAIRS, NATIONAL MILK PRODUCERS FEDERATION

Mr. ADAMS. I will do so. I first want to thank you for this opportunity to reappear before this subcommittee and express our views on this legislation before you.

I made the point last year in testifying before the committee that the dairy industry, perhaps the most regulated of all segments

of the food industry, and we are again today prepared, and I would like to ask your permission to submit four things for the committee's reference. It is quite lengthy, and I am not asking it be put in the record, but I would like to comment on it briefly to lay a basis for the suggestions that we have brought in our testimony for changing the language in title I and title II of this bill, S. 641.

Mr. MERLIS. Those materials will be retained in the committe files and possibly—I have not looked at them—there may be some items that will go into the printed record.

Mr. ADAMS. Right. The first item deals with the Grade A Pasteurized Milk Ordinance and the supplement covering dry milk products, which is a recommended ordinance to State milk control authorities, developed by the Food and Drug Administration, U.S. Public Health Service.

This is an extensive grade A milk ordinance and code regulating milk from the farm through the plant and distribution. it provides detailed quality assurance procedures for all critical control points, such as is contemplated in title I of this particular bill.

The second item deals with a publication of the Food and Drug Administration which details the milk certification ratings of milk supplies throughout the country, grade A milk supplies, which comply with this basic milk ordinance and code.

The next item relates to the USDA grading and inspection program, for manufacturing dairy plants and it details the various services offered under this program and specifically I would like to call to the committee's attention the granddaddy of all good manufacturing practices in the dairy industry, the proposed general specifications for approved dairy plants and standards for grades of dairy products.

This is again a very detailed manufacturing practice, procedure and program, which all plants which commit themselves to the grading and inspection program must meet before they can receive the benefits of the grading service. The final item I brought with me for reference of the committee deals with the memorandum of understanding between the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Division, and the Food and Drug Administration regarding the salmonella inspection program, the policies of agreement, procedures and sampling which these two Agencies cooperate on in order to assure protection of the consumers for a wholesome milk supply from the manufacturing facility.

Now, turning to our statement, as I indicated previously, we have several suggested language changes that would recognize the benefit derived from the cooperative Federal-State program for milk sanitation of interstate milk shippers.

We believe this unique cooperative Federal-State structure should be retained and recognized as an offsetting type of safety assurance procedure envisioned under title I of the Consumer Food Act. Since it is a widely accepted and recognized program for Grade A milk sanitation throughout the Nation, we believe it is the most effective means for continuing to assure a safe and high quality milk supply for consumers. We therefore wish to recommend several amendments to title I of the Food Surveillance Act.

The first amendment would be inserted on page 3 of S. 641, following section 410(a)(1) as a new item (5) and would read as follows:

The Secretary shall exempt food processing operations regulated under Federal-State cooperative programs which establish assurance procedures and enforcement policies which afford the same public health protection as those enumerated in paragraph (1) of this subsection.

Mr. MERLIS. You used the term "the same public health protection."

In looking at section 410(a)(1), I don't believe those words appear. Do you mean that the term, "the same public health protection" is any different than the concept embodied in 410(a)?

Mr. ADAMS. No; we do not.

Mr. MERLIS. So both the sanitation and safety would be incorporated?

Mr. ADAMS. Right.

The cooperative Federal-State program for certification of Interstate Milk Shippers does indeed meet those criteria enumerated on page 3 of S. 641 which detail the safety assurance procedures of food processor shall develop, implement, and maintain. The PMO identifies those control points in the milk processing operation which are important in preventing adulteration within the meaning of section 402(a) of the Food, Drug, and Cosmetic Act and the hazards associated with each such point.

It also establishes adequate controls at each such point, as well as adequate monitoring of the controls of each such point.

Specifically, in regard to those items enumerated, I would call, as an example of the type of quality assurance procedures, your attention to page 68 of the Grade A Pasteurized Milk Ordinance which details the safety procedures involved in the high-temperature, short-time critical control points of pasteurization.

Now in carrying forward the amendment to 401(A)(1), section 410 (c), page 9 of S. 641, we would also offer the following amendment to item (5) as follows:

Insert the words "or who operates under Federal-State cooperative programs pursuant to subsection (a) of this section" on line 7 after the word "section" and before the word "which."

Again this amendment is recommended to provide that those persons who now are regulated under PMO standards would not be subject to additionally providing for the development of safety assurance standards under section 410(c)(1) of this act.

Since we also operate our milk plant facilities, a great majority of which operate under the USDA Grading and Inspection Program, we would like to bring to the Committee's attention the unique and effective program of dairy inspection offered by the Department of Agriculture.

This program is a voluntary program for inspection and grading of dairy products such as butter, Chedder cheese, and nonfat dry milk. These services are designed to help improve the quality, wholesomeness, manufacture, and distribution of dairy products. Testimony to their value is the fact that they are widely used by dairy producers, wholesalers, buyers, restaurant owners, and others involved in the production and marketing of dairy products.

I also mentioned previously that the Department of Agriculture, Agricultural Marketing Service, Dairy Division, which administers this program, has entered into an agreement with the Food and Drug Administration covering Salmonella surveillence and other procedures of quality assurance, and this item appears in the Federal Register notice of March 3, 1975. Both the plant inspection program and resident inspection and grading program of the USDA utilize these general specifications for dairy plants approved for USDA inspection and grading.

The plant specifications are specifically detailed safety and quality assurance standards for processing of manufactured dairy products as contemplated in section 410(a)(1) of this act. These standards must be met before a dairy manufacturing plant can qualify for grading service. Therefore, in recognition of the fact that a great majority of manufacturing milk plants utilize the grading and inspection program of USDA, we offer for your consideration an amendment to section 410 (i)(1) on page 17.

Beginning on line 4, following the word "Agriculture", add the following: "or to any segment of processing committed to operating under inspection and grading programs administered by the Secretary of Agriculture or covered by memorandums of understanding between the Secretary of Agriculture and the Commissioner of the Food and Drug Administration."

It is important to note that a dairy plant operating under the grading and inspection program of USDA subjects itself to meeting quality assurance procedures such as contemplated in title I of the Consumer Food Act before being accepted as an approved plant for purposes of receiving the benefits of the USDA grading service.

Furthermore, as the "memorandum of understanding" so states in regard to salmonella surveillance, FDA is not precluded from "inspections of any plant for problems other than salmonella, whether or not such plant produces dry milk products under USDA inspection or the sampling of their products, including dry milk products, for problems other that salmonella."

SECTION III

The Federation wishes to endorse the provisions of section III of S. 641 which requires importers of "any food or class of food" to file a certificate with FDA which demonstrates that the imported food has been produced in accordance with safety assurance procedures and standards prescribed by this act.

This provision is absolutely necessary when huge volumes of imported dairy products enter this country as they did in 1974, and greatly tax the ability of FDA laboratories to keep pace with the number of analyses of import samples.

We believe the provisions contained in section III of this act will provide FDA with greater assurance that imported foods are not prepared, packed, or held under unsanitary conditions, whereby such food may have been rendered injurious to health in violation of the Federal Food, Drug, and Cosmetic Act.

TITLE II—FOOD ESTABLISHMENT REGISTRATION

Our final suggestion for amendment of S. 641 involves title II and the requirement for food establishment registration. We would call to the committee's attention that grade A dairy plants are now required to be registered with the States under the cooperative Federal-State IMS program. Each plant is assigned a number by the State and this number appears on the quarterly "FDA Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers" beside the name of the plant.

It would, therefore, be unnecessary and a duplication of regulation to require such plant to also be registered pursuant to title II of this act. We therefore recommend that on page 35, under section 201(e), paragraph number (2) be renumbered paragraph (3) and a new paragraph (2) be inserted to read as follows:

The Secretary shall exempt any food processor registered under a Federal-State cooperative program.

Paragraphs presented number (3) and (4) would then be renumbered (4) and (5) respectively.

CONCLUSION

Mr. Chairman, we have detailed those amendments to S. 641 which we believe provide for the necessary exemption of dairy plants already operating under offsetting types of quality control assurance programs which provide for the detailed quality assurance procedures contemplated in title I of this act.

Both the grade A milk plant operations regulated under the cooperative Federal-State IMS program and dairy manufacturing plants committed to the USDA grading and inspection programs must follow stringent quality control and milk safety assurance procedures which have been designed to protect consumers from milk-borne disease. Both programs should be recognized for their effectiveness in providing this Nation with a safe and wholesome supply of milk and dairy products. For this reason we commend to your consideration the amendments which we have proposed to S. 641.

Thank you.

Mr. MERLIS. Thank you, Mr. Adams. I have a number of questions I would like to pose.

If a milk processor does not comply with the requirements of the grade A milk procedures, what is the liability which he is subject to?

Mr. ADAMS. He is subject to losing his permit, and this can mean substantial economic loss. And he is given a reasonable chance to make the corrections, if it involves sanitation.

If it involves adulteration, he is subject to immediate permit suspension, and this is a very effective tool, which is enforced by the States, and of course under this program as I have indicated, FDA validates that this enforcement and compliance is taking place.

Mr. MERLIS. FDA today I would assume also has authority if it wanted to, to enforce this?

Mr. ADAMS. That is correct. I think the point should be made that FDA has really never had to exercise its good manufacturing practice authority under the Food, Drug, and Cosmetic Act because of their cooperation and involvement in this extensive Federal-State structure and their oversight authority involvement with it.

Mr. MERLIS. So if someone were to fail to comply with the requirements, and be producing adulterated milk, nothwithstanding whatever the particular State inspector might require, FDA could come in and enforce the Food, Drug, and Cosmetic Act?

Mr. ADAMS. Right. There is nothing in the cooperative Federal-State program that overrules the authority food and drug has always had under the act to control milk and dairy products in interstate commerce.

Mr. MERLIS. What programs other than the milk program are you aware of which operate on a similar basis, where the Federal Government and the State government and food processors share the responsibility for insuring safety assurance?

Mr. Adams. Well, the only two I am aware of are the shellfish program, and the national marine fisheries program.

Mr. MERLIS. In addition to the program you have?

Mr. ADAMS. Yes, in addition to the milk program.

Mr. MERLIS. Are there any milk processors who don't have permits?

Mr. ADAMS. Not to my knowledge.

Mr. MERLIS. So everyone does participate?

Mr. ADAMS. Everyone has a license. Every grade A plant participates in this program.

Now the manufacturing plants are regulated by the States through State Statute, but, as I say, the overwhelming majority of the manufacturing plants voluntarily subject themselves to the USDA grading and inspection program, in order that they qualify for the services of grading, sampling, inspection, and laboratory work which they, by the way, pay for.

Mr. MERLIS. They pay for it themselves.

In testimony by Dr. Summers he referred to the fact that 11, I think it was, food organizations had endorsed S. 1168. Was your organization one of those?

Mr. ADAMS. No, I don't believe we were, but we do; we haven't officially endorsed it, but we generally agree with the provisions contained in S. 1168 and we have no objections to it.

Mr. MERLIS. If the changes which you recommended were made in S. 641, would you then endorse S. 641?

Mr. ADAMS. I believe we would, yes.

Mr. MERLIS. Now let me pursue with you another way of wording that first amendment which I think is really the key amendment, which appears in your text.

You speak in terms of exemption, and exemption sometimes is a difficult term for people to swallow. A food processor who was complying with your Federal-State cooperative program is not really exempt from anything, other than some paper requirements.

I am going to read some language to you which is nowhere near final form, but I would like to have your off-the-cuff opinion of it.

Instead of reading as yours does, if it were to read:

A food processing operation regulated under Federal-State cooperative programs which establishes assurance procedures and enforcement policies which afford the same protection as those enumerated in paragraph (1) of this subsection, shall be deemed by the Secretary to have complied with the requirements of section 410(a).

It is a way of saying the same thing, except without the word "exemption." It says you have already met the requirement.

Mr. ADAMS. This would be acceptable.

Mr. MERLIS. Well, I thank you very much. We will be interested in hearing from others who are in a similar position of Federal-State cooperative programs, to see whether that is an approach they find acceptable also.

Mr. ADAMS. Thank you.

[The statement follows:]

STATEMENT OF JOHN B. ADAMS, DIRECTOR OF ENVIRONMENTAL AND CONSUMER AFFAIRS, NATIONAL MILK PRODUCERS FEDERATION

Mr. Chairman, my name is John B. Adams. I am Director of Environmental and Consumer Affairs for the National Milk Producers Federation. It is a pleasure to have this opportunity to present the views of the National Milk Producers Federation on S. 641, the Consumer Food Act of 1975.

THE FEDERATION

The National Milk Producers Federation is a farm commodity organization representing dairy farmers and their cooperative marketing associations which they own and operate. Our interest in the food surveillance legislation before this Committee stems from the fact that practically every form of dairy product produced in any substantial volume in the United States is produced, processed and/or marketed by dairy cooperatives represented by the Federation.

THE FEDERATION'S POSITION ON TITLE I OF S. 641

Traditionally, the dairy industry has been the most regulated of all segments of the food industry. Before this Subcommittee in March of 1974, we presented our views and explanations of why we did not believe the provisions of Title I of the Consumer Food Act should be applied to the Grade "A" milk industry and other segments of the dairy industry which already function under effective public health enforcement programs and plant surveillance systems. We would like to reiterate our case today, and briefly explain why a requirement to develop, implement and maintain safety assurance procedures in Grade "A" milk operations and plants already under routine resident inspections of the U.S. Department of Agriculture would be counterproductive in terms of providing little additional protection to consumers, while resulting in duplicated efforts of inspection and higher costs for the dairy industry.

REGULATION OF GRADE "A" MILK

Due to the obvious public health importance of milk-borne diseases, regulation of the Grade "A" fluid milk industry has traditionally developed around local and state public health agencies with the U.S. Public Health Service cooperating at the Federal level.

In 1924, a model Grade "A" milk sanitation ordinance was developed for adoption by state and local governments. This document today is known as the Grade "A" Pasteurized Milk Ordinance (PMO). All 50 states have adopted the PMO or its equivalent. This document is characterized by its detailed requirements covering adulteration, bacterial, temperature, transportation, equipment, and handling standards in producing and processing Grade "A" milk and milk products. It is used by the Food and Drug Administration for the regulation of milk and milk products on interstate carriers. It is incorporated by reference in government specifications for the procurement of milk and milk products. Most importantly, the PMO affords strong consumer protection as

the basic standard governing the Cooperative-Public Health Service Program for Certification of Interstate Milk Shippers.

This unique cooperative Federal-State program provides the procedures for state milk control authorities and the Food and Drug Administration to certify the validity of milk safety and sanitation compliance with the standards spelled out in the PMO. Operating under this Cooperative Public Health Program for Certification of Interstate Milk Shippers, known as IMS, the state milk control authorities certify to FDA the compliance ratings they have given milk supplies—both farms and plants.

The Food and Drug Administration validates state compliance survey ratings through a system of check ratings which provide a compliance vehicle for evaluating and endorsing state programs. The FDA also publishes a quarterly list of certified interstate milk shippers which is used as an approved list by interstate carriers, Veterans Administration, and the Department of Defense, in the purchase of milk and milk products.

While the Cooperative-PHS Interstate Milk Shippers Program does not replace any statutory authority of the FDA to regulate milk and milk products in interstate commerce, it does fully utilize state and local regulatory agencies in providing close and efficient supervision of all milk supplies.

It is this close supervision, coupled with the existence of an effective industry-wide food surveillance document in the form of the PMO, that have been responsible for the conquest of milk-borne disease in the United States and the development of advanced sanitary and quality assurance practices in the dairy industry.

FEDERATION RECOMMENDATIONS FOR AMENDING TITLE I

We believe this unique cooperative Federal-State structure should be retained and recognized as an offsetting type of safety assurance procedure envisioned under Title I of the Consumer Food Act. Since it is a widely accepted and recognized program for Grade "A" milk sanitation throughout the nation, we believe it is the most effective means for continuing to assure a safe and high quality milk supply for consumers. We, therefore, wish to recommend several amendments to Title I of the Food Surveillance Act.

The first amendment would be inserted on page 3 of S. 641 following Section 410(a)(1) as a new item (5) and would read as follows:

"The Secretary shall exempt food processing operations regulated under Federal-State cooperative programs which establish assurance procedures and enforcement policies which afford the same public health protection as those enumerated in paragraph (1) of this subsection."

Mr. Chairman, the cooperative Federal-State program for certification of Interstate Milk Shippers does indeed meet those criteria enumerated on page 3 of S. 641 which detail the safety assurance procedures a food processor shall develop, implement and maintain. The PMO identifies those control points in the milk processing operation which are important in the prevention of adulteration within the meaning of Section 402(a) of the Food, Drug and Cosmetic Act and the hazards associated with each such point. It also establishes adequate controls at each such point, as well as adequate monitoring of the controls of each such point.

It should be pointed out that the PMO represents a document which requires close quality control supervision and scrutiny at all critical control points in the handling and processing of fluid milk from farm to market.

In carrying forward the amendment recommended above to Section 410(c) on page 9 of S. 641, we would also offer the following amendment to item (5) as follows:

Insert the words "or who operates under Federal-State cooperative programs pursuant to subsection (a) of this section" on line 7 after the word "section" and before the word "which."

Again, Mr. Chairman, this amendment is recommended to provide that those persons who now are regulated under PMO standards would not be subject to additionally providing for the development of safety assurance standards under Section 410(c)(1) of this Act.

DAIRY INSPECTION AND GRADING PROGRAMS

Since the basic purpose of the Consumer Food Act is to regulate commerce and protect consumers from adulterated food by requiring the establishment of surveillance regulations for the detection and prevention of adulterated food

and for other purposes, we would like to bring to the attention of the Committees another unique and effective program of dairy inspection offered by the U.S. Department of Agriculture. This program is a voluntary program for inspection and grading of dairy products such as butter, Cheddar cheese and nonfat dry milk. These services are designed to help improve the quality, wholesomeness, manufacture and distribution of dairy products. Testimony to their value is the fact that they are widely used by dairy producers, wholesalers, buyers, restaurant owners and others involved in the production and marketing of dairy products.

While the inspection and grading services are exclusively under the jurisdiction of the Dairy Division of the USDA's Agricultural Marketing Service and are offered to industry on a voluntary basis, the program is used as a vehicle for enforcement by the Food and Drug Administration under a Memorandum of Understanding between the Agricultural Marketing Service-USDA and the Food and Drug Administration (copy of March 3, 1975 Memorandum submitted for record). Agreement between these two agencies has been in effect since May 1968 in order to avoid duplication of efforts in the Salmonella inspection and sampling coverage of dry milk products plants. The background of these agreements and the type of inspection programs involved, as well as the description of work to be performed, are outlined in the *Federal Register* notice submitted for the record.

It should be pointed out that the *Federal Register* notice describes the two types of plant inspection programs administered by the U.S. Department of Agriculture. Both the Plant Inspection Program and the Resident Inspection and Grading Program utilize the General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service. The plant specifications are specifically detailed safety and quality assurance standards for processing of manufactured dairy products as contemplated in Section 410(a)(1) of this Act. These standards must be met before a dairy manufacturing plant can qualify for grading service. Therefore, in recognition of the fact that a great majority of manufacturing milk plants utilize the Grading and Inspection Program of USDA, we offer for your consideration an amendment to Section 410(i)(1) on page 17.

Beginning on line 4 following the word "Agriculture", add the following—"or to any segment of processing committed to operating under inspection and grading programs administered by the Secretary of Agriculture or covered by Memorandums of Understanding between the Secretary of Agriculture and the Commissioner of the Food and Drug Administration."

It is important to note that a dairy plant operating under the grading and inspection program of USDA subjects itself to meeting quality assurance procedures such as contemplated in Title I of the Consumer Food Act before being accepted as an approved plant for purposes of receiving the benefits of the USDA grading service. Furthermore, as the Memorandum of Understanding so states in regard to Salmonella surveillance, FDA is not precluded from "inspections of any plant for problems other than Salmonella, whether or not such plant produces dry milk products under USDA inspection, or the sampling of their products, including dry milk products, for problems other than Salmonella."

SEC. III

The Federation wishes to endorse the provisions of Section III of S. 641, which requires importers of "any food or class of food" to file a certificate with FDA which demonstrates that the imported food has been produced in accordance with safety assurance procedures and standards prescribed by this Act. This provision is absolutely necessary when huge volumes of imported dairy products enter this country as they did in 1974, and greatly tax the ability of FDA laboratories to keep pace with the number of analyses of import samples.

We believe the provisions contained in Section III of this Act will provide FDA with greater assurance that imported foods are not prepared, packed or held under unsanitary conditions, whereby such food may have been rendered injurious to health in violation of the Federal Food, Drug and Cosmetic Act.

TITLE II—FOOD ESTABLISHMENT REGISTRATION

Our final suggestion for amendment of S. 641 involves Title II and the requirement for food establishment registration. We would call to the Committees' attention that Grade "A" dairy plants are now required to be registered with the states under the cooperative Federal-State IMS program. Each plant

is assigned a number by the state and this number appears on the quarterly FDA Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers beside the name of the plant. It would, therefore, be unnecessary and a duplication of regulation to require such plant to also be registered pursuant to Title II of this Act. We, therefore, recommend that on page 35 under Sec. 201(e), paragraph number (2) be renumbered paragraph (3) and a new paragraph (2) be inserted to read as follows:

"The Secretary shall exempt any food processor registered under a Federal-State Cooperative Program." Paragraphs presently numbered (3) and (4) would then be renumbered (4) and (5), respectively.

CONCLUSION

Mr. Chairman, we have detailed those amendments to S. 641 which we believe provide for the necessary exemption of dairy plants already operating under offsetting types of quality control assurance programs which provide for the detailed quality assurance procedures contemplated in Title I of this Act. Both the Grade "A" milk plant operations regulated under the cooperative Federal-State IMS Program and dairy manufacturing plants committed to the USDA Grading and Inspection Programs must follow stringent quality control and milk safety assurance procedures which have been designed to protect consumers from milk-borne diseases. Both programs should be recognized for their effectiveness in providing this nation with a safe and wholesome supply of milk and dairy products. For this reason we commend to your consideration the amendments which we have proposed to S. 641.

Thank you for this opportunity to appear and present the views of the National Milk Producers Federation on S. 641, and I shall be happy to answer any questions you may wish to address to me at this time.

Thank you.

[Thereupon, at 12:25 p.m. the hearing was recessed, to reconvene at 10 a.m. the following day.]

FOOD SAFETY AND LABELING LEGISLATION

WEDNESDAY, JUNE 18, 1975

U.S. SENATE,
SUBCOMMITTEE FOR CONSUMERS,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittees met jointly at 10 a.m. in room 4232, Dirksen Senate Office Building, Hon. Frank E. Moss (chairman of the Subcommitte for Consumers) prisiding.

OPENING STATEMENT BY SENATOR MOSS

Senator Moss. The hearing will come to order.

This is the last scheduled day of hearings on the Consumer Food Act of 1975, S. 641; and the Food Safety Assurance Amendments of 1975, S. 1168. These hearings are being held jointly by the Subcommittee for Consumers of the Committee on Commerce and the Subcommittee on Health of the Committee on Labor and Public Welfare.

We have some important witnesses to hear today. We have compiled an excellent record up till now and I'm sure today's hearing will add to it. Once the record is complete, the committees will sit down and look at the two bills and begin the process we call markup to determine what these two committees would like to submit to the floor for consideration of the Senate.

We are very pleased to have my colleague from Maryland, Senator Beall, here this morning and I hope others may come in, but I would like to emphasize so it is not misunderstood, other Senators who are not here this morning will see the record. The important objective is to get into the record what should be placed there by those who have a concern of any sort about the legislation being proposed.

In the interest of time we usually suggest that witnesses who have prepared testimony summarize what they have to say because we will place the whole statement in the record, of everything that's written and they may summarize or emphasize parts that they think should be called particularly to our attention. Under the rules of the Senate we have only a limited time in which we can sit in hearings and we want everybody who's on the list to be able to appear and get into the record what he has to bring us this morning.

Senator Beall, do you have any statements?

55-000—75——15

Senator BEALL. No, I have no statement, Mr. Chairman.

Senator Moss. Thank you.

We will call as our first witness Mr. Raymond Way, director of technology and compliance for Crescent Foods of Seattle, Wash.; and Mr. Richard McEntee, vice president of research and development of Nalley's Fine Foods of Tacoma, Wash.

You two gentlemen have come a long way to testify before us. We welcome you before the committee and you may proceed in whatever manner you would like. I will place your statement in the record in full.

STATEMENT OF RICHARD McENTEE, VICE PRESIDENT, MANUFACTURING AND TECHNICAL SERVICES, NALLEY'S FINE FOODS, TACOMA, WASH.

Mr. McENTEE. Thank you, Mr. Chairman.

I am Richard McEntee, and for the record I am vice president of Manufacturing & Technical Services for Nalley's Fine Foods in Tacoma, Wash.; and Mr. Way is also along. We are appearing jointly here. We are here on behalf of a group of concerned individuals representing the food and agricultural community in the States of Washington, Oregon and Idaho. Our group, which was brought together out of a common concern for Senate bill 641, encompasses the entire spectrum of the food growing, processing, warehousing and retailing industry in our beautiful Pacific Northwest—an industry which directly or indirectly accounts for two-thirds of the economy of that region.

At the outset, let me state that we in the Northwest support the goals and basic provisions of S. 641. The establishment of safety assurance monitoring systems and the requirement that all food plants register will help assure the continued wholesomeness of the American food supply.

There are however, serious difficulties in S. 641 which will reduce its effectiveness. These difficulties are significant enough to have caused our group to come together in the first place and to dispatch us 3,000 miles to present our concerns to these subcommittees.

Now, Mr. Chairman, we are somewhat unfamiliar with the ways of the Senate. We do hope you will allow us to proceed through with our joint testimony, each of us discussing half of the specific suggestions made by our group in the Northwest.

Senator Moss. That will be satisfactory to do that.

Mr. McENTEE. Our first suggestion is something which should be included in S. 641 but is presently absent. That is, an amendment to the Federal Food, Drug and Cosmetic Act that redefines criminal liability.

Right now the Food and Drug Act allows corporate officials to be considered liable for a violation of the act when, although they are ultimately responsible for their entire business, they neither wanted nor knew about the violation.

When you are dealing with an item as fundamental as the food we consume, we can agree to holding a person criminally responsible

for actions over which he has control. We do question, however, the fairness of a system which provides that a corporate official can go to jail as a common criminal for the acts or omissions of employees working out in the plant. What is even more frightening is the fact that this criminal conviction may be gained without proving intent or even knowledge of the wrongdoing.

Mr. Chairman, we are not attorneys, but we are food processors who will be personally affected. As such, we are greatly concerned about the basic justice of a law which can make an individual a criminal because an employee whom he may never have seen, let alone directly supervised, acted improperly.

S. 641 is the most extensive revision of the Food, Drug and Cosmetic Act to be considered in almost 40 years. As such, it is the perfect means for removing from the act a provision which runs counter to our philosophy of fairness under the law.

The food industry in the Northwest strongly encourages these subcommittees to amend the Food, Drug and Cosmetic Act to remove the vicarious liability provisions while retaining criminal liability for knowing and willful or negligent violations.

While we are discussing penalties, may we point out what might have been an oversight in the drafting of S.641. Section 308 of the bill provides for a civil penalty of "not more than $10,000 for each day of violation."

This is a tenfold increase in current civil penalties—an increase which we can support. But the per day nature of the penalties seems, to us, a bit much.

For one thing, how are you going to calculate the number of days? Does the counting begin the day the product was manufactured, the day it left the plant, or the day the government took action?

It may be possible to count days for violations of an injunction or the like, but such is not the case for food distribution. We would urge the subcommittees to drop the per day nature of the penalty.

S. 641 also authorizes citizens to bring suit against the FDA or an individual food company for certain alleged violations of the act.

My first reaction when I heard this was that my competitors are also citizens and would be entitled to sue my company. That sounds like a strange new form of warfare which will benefit the legal fraternity but have very little positive impact on the safety of the food supply.

Second, our group is of the "walk before you run" philosophy. S. 641 requires the implementation of systems which are quite complicated and will take some time to perfect. The important working relationship between FDA and the food processors implementing the law will be impeded if everyone is suddenly able to act as a "mini-FDA" by bringing suit and throwing the whole issue into the courts. We would urge that at least for the period of the initial introduction of the safety assurance systems, that the authority to sue under the law be limited to FDA.

I should also mention in passing that it is our understanding that at least one State agency in our area which enforces the Federal regulations under contract to FDA has indicated it will cease to do so if in so doing it subjects itself to citizen suits.

Mr. Chairman, that is a brief discussion of a few of the key concerns of the food industry in the Northwest. At this point, and with your permission, I'd like to turn this over to Ray Way for a discussion of other issues of concern to our group.

Senator Moss. All right. Thank you. Mr. Way, we will be glad to hear you.

STATEMENT OF RAYMOND WAY, DIRECTOR OF TECHNOLOGY AND COMPLIANCE FOR CRESCENT FOODS, SEATTLE, WASH.

Mr. WAY. Thank you, Mr. Chairman.

I am Raymond Way, director of technology and compliance for Crescent Foods of Seattle, Wash.

Let me preface my remarks by seconding what Dick McEntee said about the honor of appearing before you today. I also want to reiterate his point that we are in accord with the goals and purposes of S. 641 and are suggesting amendments which, we feel, would make it a better, more workable piece of legislation.

With this in mind, then, I'd like to touch on three additional points of concern to our Northwest food industries group.

New section 411 would provide that all food products should be encoded so as to identify the plant, lot, and date applicable to that product as well as the identity of the food. We support such a code as a meaningful method of facilitating product recalls. In my experience, most responsible food processors are doing this under existing regulations.

Unfortunately, one word has crept into proposed section 411 which alters the entire thrust of the section as well as quite possibly defeats the purpose for which the code was intended.

That word is "uniform." If taken to mean that the coded inscription should be uniform within individual products, we have no problem.

If, however, "uniform" means that the tens of thousands of food products in the marketplace should all be coded alike you have opened Pandora's Box and inhibited the ability of the code to communicate meaningful recall information to the trade and to consumers.

The problem is basically a mathematical one. If each of the thousands upon thousands of food products is to have a discrete code which adheres to a uniform system, that code is going to be quite lengthy.

If, on the other hand, the word "uniform" is dropped, or is interpreted to mean uniform within individual products, the mathematical problem disappears and the code can be concise and easily communicated to and used by consumers and the trade.

We also have great concern over the fact that S. 641, which purports to be a food safety bill, contains a few "sleeper" provisions relating to purely economic matters such as the inspection of records bearing upon the accuracy of labeling statements.

One point should be made at the outset. If a label statement has an impact on the safety of the consumer, S. 641 and current law pro-

vide the means of assuring that food is removed from the marketplace.

Additionally, we should point out that we support the FDA's right of access to records affecting safety. Unfortunately, sections 109 and 110 of S. 641, in extending FDA's records access powers, do not differentiate between safety and nonfood safety related records.

Mr. Chairman, we are here in an attempt to respond in a responsible manner to a serious issue—food safety—and a legislative attempt to assure safe food for all. Must we also contend with granting the Federal Government authority to delve into our nonfood safety data, gunning for an obscure document totally unrelated to the safety of the product?

We understand that, with regard to some provisions of this bill, the FDA has expressed concern over whether they have or can get the necessary funds. We are all on tight budgets now—doesn't it make more sense to have FDA spending its resources to protect the safety of the consumer, rather than fishing through files to try and catch us violating some labeling provision which they could catch anyway without diving into our records?

And speaking of labeling, our final major concern regarding S. 641 is the proposed authority to authorize the percentage labeling of every ingredient in every food product.

Frankly, getting into any percentage statement is tricky business. Different ingredient blends can produce the same product with the same taste and nutrition but with different ingredient perecntages. Must we keep labels on hand for every conceivable blending combination?

It would seem to us that the information which will help the consumer is not that cheese pizza contains 0.02 percent oregano, but rather, how much cheese it contains.

Make no mistake about it, either, a statement of the percentage of significant ingredients will not be the easiest thing with which to comply. In fact, we'd rather see no percentage requirement at all. If, however, the Congress in its wisdom determines that the benefits of percentage information outweigh the obvious costs, we urge that information be limietd to that which is most important to consumers and not extended to cover every minute component of every food product.

Mr. Chairman, in behalf of our group back in Washington, we thank you for this opportunity to appear before you.

We have noted that your witness list to date has been comprised chiefly of industry trade associations. While we have great respect for and confidence in our associations, they are professionals in how laws are made.

We, on the other hand, are professionals in how food is made. Dick McEntee and myself are the ones who will have to implement the law you pass.

We felt we owed it to the group back home and to you to share with you the frontline feelings of people who will be directly affected by every word you write.

Thank you for your interest. We would be pleased to respond to any questions you may have.

Senator Moss. Well, thank you very much, gentlemen, for your statements.

You represent people that are in the food canning business is that it; or is it broader than just canners?

Mr. McEntee. If I can respond, Mr. Chairman, those that we met with in the few weeks prior to our coming here are people in all parts of the food processing business in the State of Washington and States of Oregon and Idaho as well, from the Washington beekeepers to the representatives of the 56,000 farm families who operate farming operations in those areas, to canners and large processors; and involves a wide range of food interests both in the argicultural and food processing areas.

Senator Moss. I see. You wouldn't represent dairy farmers, for instance. You do not represent them, do you?

Mr. McEntee. There are some in the processing area in the Northwest who are involved in dairy operations and some of those people were in the groups that we spoke with.

Senator Moss. Well, the points that you made on the parts of the bill to which you addressed yourselves have been raised before and I assure you we are going to deal with them and make sure we try to fashion a bill that will not have the onerous effects that you pointed out might come from the present language.

What's written now isn't necessarily the language that will come out of the committee. In fact, that's the reason we have the hearings, so that we can tailor it not to cause damage and yet achieve the objective which both of you said that you support.

Do you also support the requirements of section 410 which would have the processors establish their own safety assurance procedures?

Mr. McEntee. As stated at the outset we support the basic provisions in establishing safety assurance systems, those provisions of the bill. We are not attorneys, of course, and the exact language that come out in the final analysis in the markup of the bill would be something that we'd like to look at and perhaps have our attorneys look at.

Senator Moss. But do you like that idea of having the processors establish their own safety assurance procedures?

Mr. Way. Yes, in principle; and for this reason, Senator: I believe that every responsible food processor is doing this to a more or less extent at the present.

Senator Moss. That's what many of them said who have come before us.

Senator Beall. On that point, Mr. Chairman—do you all have a plan now, a quality assurance plan, a safety assurance plan?

Mr. Way. Yes, sir. That is commensurate with our operation. As Senator Moss' question was do we represent a narrow part of the food business or a very broad one, we do represent a very broad one. For instance, in our industry, rather than discuss foods, I think we should discuss food components by and large, and safety assurance there is different than it would be in——

Senator BEALL. If we pass this act, what changes would you have to make in your current safety assurance program?

Mr. MCENTEE. Well, I can only speak for my own company and I'm sure Mr. Way only for his. Our safety assurance systems, particularly since my company has two of its eight plants registered as establishments under the Meat Inspection Act, we applied many of the same systems which exist there, in addition to those which have been promulgated in the past by FDA and our own safety assurance systems within our own operations, and we feel that these are adequate and complete. But some of the others——

Senator BEALL. If we passed this act, it won't require you to do anything differently than you are now doing?

Mr. MCENTEE. I can't imagine that it would unless under the provision that allows the Secretary of HEW or the Commissioner to issue regulations—I'm not sure what those regulations might say, whether they would be in conflict with what we consider to be good safety assurance, which we are following right now. In addition, I would say that some exemptions would have to exist. I mentioned the Washington State beekeepers, for example. These people are greatly concerned at our meetings because they are mostly groups of one or two or three or four, just family operations, where they collect honey and clean it and process it to a minor extent. How they would react to some of the provisions, whether they would be exempt and so on and so forth would be of concern to us, also, in taking information back to these people.

Senator BEALL. You talked about the trouble that the word "uniform" gives you, Mr. Way. Are you looking at the word "uniform" by itself or does it trouble you when taken into consideration with the four points that are enumerated after the use of the word 'uniform" in section 411? In other words, section 411, as it now reads—if I can find it—says: "They shall have a uniform system of coding applicable to"—then four different areas; the identity and plant location of the manufacturer, the identity of the food by lot and batch, and date of the food and the date packaged.

Does that trouble you? Does that produce the mathematical problem or is it the creation of the additional information in addition to the four points here create the mathematical problems?

Mr. WAY. I believe the difficulty with it has to do with the word "uniform" itself and how it's to be interpreted. You see, it would be very nice if in food procesing all food were processed by batch; then you have a discrete entity on which you can fix a number and then possibly uniformity would have a meaning under this kind of a system.

But, unfortunately, food is not only procesesd by batches. It's processed continously and it's also processed in combination of batches continuously. So then the word "uniform" has to do more close—has to be more closely defined. If it were eliminated, I think then the regulation could be written much more concise that it would allow a processor to put meaningful information on his food package so then recall, when necessary—and hopefully it would never be necessary—could be done with the greatest of expediency.

Senator Moss. I think it was our intent to have uniform apply to the individual manufacturer and not to the entire industry. Now would that still give you trouble if it were made clear and qualified?

Mr. WAY. No, and I think this is one of the better interpretations. But we need, I feel, the assurance that further down the road that intent is carried along in some manner.

Senator Moss. Well, we will consider that carefully when we look at the language.

Thank you, gentlemen. We appreciate your testimony and we are glad to have you come all the way across the continent to see us.

Mr. MCENTEE. Thank you, Mr. Chairman.

Mr. WAY. Thank you.

Senator Moss. Mr. Murry Berger, president, National Fisheries Institute, will be our next witness. Would you come forward, please, Mr. Berger.

We will place your statement in the record in full and ask you to proceed as expeditiously as possible.

Would you identify the gentlemen who have accompanied you to the table, please?

STATEMENT OF MURRY BERGER, PRESIDENT, NATIONAL FISHERIES INSTITUTE, WASHINGTON, D.C.; ACCOMPANIED BY LEE WEDDIG, EXECUTIVE DIRECTOR; AND DR. ROY MARTIN, TECHNICAL DIRECTOR

Mr. BERGER. Yes, Mr. Chairman. I am Murry Berger, president of the National Fisheries Institute. With me on my right is Lee Weddig, our executive director; and on my left is Dr. Roy Martin, our technical directors. So we will be able to answer questions on all sides for you.

Our association has presented its views on food inspection legislation to this committee on numerous occasions during he past 8 years. We believe we have been consistent in our testimony, beginning with the initial hearing on the Fishery Products Protection Act of 1967.

At that time, we said we supported a program specifically designed to the requirements of the fish and seafood industry; one that would cover domestic and foreign products equitably; and one that would be applied to all facets of the industry.

Our position today remains the same.

We support the principles of improved food surveillance as proposed in legislation being considered in this hearing. However, the existence of teh voluntary inspection program now administered by the National Marine Fisheries Service and our need for a specific mandatory fishery products inspection program complicate our position.

The proposed program and the requirement for fishery products inspection are not incompatible. We believe that with appropriate amendments, the legislation could serve the long standing need for an improved fishery products inspection system.

We would like to comment in these areas: (1) Concerns with S.641 and S.1168; (2) relationship of the proposed surveillance program

to the national marine fisheries service voluntary program, and (3) need for further development of a specific fishery products inspection program.

Our concerns with S.641 parallel those of other food industries. Very generally, we believe S.1168 is a more reasonable and practical approach than S.641.

A. S. 1168's amendment to existing law, which would limit criminal liability of corporate officers to knowing and willful violations, is a needed clarification of the act. The thousands of details that make up the daily operation of a plant cannot come under the personal supervision of a corporate officer. Thus, it is not just that corporate officials be personally liable in a criminal sense for violations that are done contrary to their direction and will.

B. We believe S.1168 outlines a more workable company safety assurance system. The scope of the system, any standards, records inspection, and detention provisions should be limited to matters of health and safety, as provided in Sec. 402(a) 1 and 2 of the act.

C. We favor a requirement to register food establishments but believe a one time registration would be adequate, rather than biennial registration as called for in S.641.

D. We believe the provision of S.1168 allowing initiation of citizens' suits against the Secretary only is adequate.

E. Civil penalty of $10,000 per violation should be adequate financial incentive to assure compliance, rather than the excessive provision of $10,000 per day as called for in S.641. Also, such penalties should be imposed through court action rather than administrative procedure.

F. We believe product coding should be required, but see no need for uniformity since the purpose of such coding would be served just as well by use of company designed systems. We oppose any additional labeling requirements, believing that current law provides for all necessary labeling information.

A major concern is with the exemption section. Both proposed bills provide for exemptions for certain classes of industry. The fish and seafood industry has been utilizing the voluntary inspection service offered by the National Marine Fisheries Service for many years. While the number of companies using the program is small in relationship to the total number of processors in the industry, the quantity of product packed in plants using the service is rather sizable. Most of the companies using this program are members of the National Fisheries Institute. We encourage our members to use this program and believe that the interests of the consumer and industry, as well as those of the taxpayer, would be served by exempting firms using the NMFS program from the provisions of the food surveilance bill.

We suggest that the following clause be added to the exemption section of the bill: "Any processing conducted under contract inspection or otherwise certified by the Secretary of Commerce."

The NMFS inspection program provides for primary inspection of procesing facilities, assuring that it has the capabilities of producing a wholesome product. Secondly, it provides for inspection of product and, more importantly, of the product quality assurance

system, by trained U.S. Department of Commerce employees. The system employed here is more stringent than that provided for in the proposed legislation. We believe that exempting those companies using the voluntary system from the provisions of the new bill, would provide tremendous incentive for more companies to take on the service. There is another incentive. This is the ability to utilize an inspection mark on the product. This certification is quite important in many of the institutional markets, and we believe it will become a significant factor in the retail market in coming years. Certainly, the taxpayer will benefit by the avoidance of duplication of inspection programs.

While we strongly urge the inclusion of an exemption clause in this new legislation, we would like to use this opportunity to provide for additional authorities to the U.S. Department of Commerce to strengthen the fishery products inspection program.

The present system has a weakness in that the Department does not have the authority to provide for inspection of products overseas. Since almost 60 percent of the fishery products is originally produced at overseas plants, a meaningful inspection system must establish procedures whereby foreign governments can provide for inspection according to our standards.

Meat and poultry produced overseas for export to the United States is inspected under such a system. There is no reason why the NMFS could not certify systems operated by overseas governments, provided such systems were equal to that used in this country in terms of the protection provided to the consuming public. This additional authority would have to include the issuance of a special mark for the package to denote that the product was produced in an inspected plant. Much of the seafood product consumed in this country comes from Canada, Iceland, and Scandinavian countries who already have inspection systems in operation. All that is needed is an extension of authority to the Secretary of Commerce to investigate the inspection systems of countries desiring to export fishery products to the United States, and upon verification of the adequacy of those systems, certify their compliance with the standards. We would envision consistent monitoring of the effectiveness of the system at the port of entry.

Extension of such authority to the Department of Commerce would be one more step in the development of a truly effective, equitable fishery products inspection program.

Since fish is one of the basic animal protein foods, we are in direct competition with the meat and poultry industry. While we are overshadowed by these two industries in terms of total product consumed, our products nevertheless are important to the total diet of the public.

Since we are in competition with meat and poultry, we believe it is only proper that there be equity in the area of Government support for the industry. Presently, the fish and seafood industry must pay for the NMFS inspection service. Meat and poultry inspection is provided at the expense of the taxpayer.

Many of our small plants would like to employ the services of the National Marine Fisheries Service inspectors, but cannot afford

it. Thus, they are not able to market products showing the Government-inspected shield. The National Fisheries Institute would like to see the expansion of the NMFS inspection service to the point where it covers all plants in the industry, as well as providing a certification system for overseas producing plants as described earlier. We think this total service should be paid for by general revenue, to the same extent that meat and poultry inspection is paid for by the taxpayer.

The NFI knows very well that attempts to develop a specific fishery products inspection program in the past have not passed the Congress. However, we believe progress toward such a goal can be achieved by modifying the present food surveillance legislation to include three important steps. We have mentioned two of them: Namely an exemption from the new surveillance program for those companies using the more stringent NMFS voluntary program; second, we believe the authority of the National Marine Fisheries Service in the area of inspection should be extended so that foreign government inspection to our standards would be recognized.

The third recommendation is to establish a timetable for the implementation of a comprehensive, mandatory fishery products inspection program, one that would extend the present voluntary program to the entire industry. The timetable would call for the Secretary of Commerce to report to this committee in 1 year on the status of the voluntary program, providing a detailed plan, including proposed regulations for the mandatory extension of that program to all companies in the industry. This plan would incorporate a detailed cost projection, including explanation of departmental overhead charges. It would have to detail any additional legislated authority needed. It would have to cover the relationship of the program to the National Shellfish Sanitation activity and spell out cooperative responsibilities of the NMFS and those of the Food and Drug Administration.

The congressional charge to the Department would be to develop the plan to implement a comprehensive inspection service with costs to be covered by general revenues to the same degree as meat and poultry inspection, and not to determine if such a program is needed or desirable.

We recommend that this planning be conducted in conjunction with a committee to include representatives of the companies now using the inspection program and their associations.

The National Fisheries Institute thanks the committee for the opportunity of commenting on these proposals. We urge the committee to take this opportunity to strengthen the existing fishery products inspection program by putting in motion the recommendations we have made. We offer our assistance to the full extent of our capabilities.

Senator Moss. Well, thank you very much, Mr. Berger.

I appreciate your testimony and I say it's not often that an industry comes before the committee and asks for legislation mandating a higher degree of performance of its members, and your recommendations are good and I would appreciate it if you could

supply draft language that you think would accomplish the objectives that you have set out here for us concerning mandatory fish inspection.

I agree especially on the overseas inspection. Since we require of our own processors certain standards, we ought to be sure that it's being done on imported goods at least as high as we have in our own country.

We have had a number of witnesses appear before us covering some of the same topics which you covered, so I'd like to pose the following question which goes to, I think, your substantive objections.

If the bill were amended to change the criminal libility to provide for knowledge or negligence, if only one-time food plant registration provisions were incorporated, if the civil penalty provision were modified to $10,000 per violation instead of per day violation, and if the coding requirement dropped the word "uniform," and if a provision were incorporated to make participation in a program such as the National Marine Fisheries Service program sufficient for compliance with section 410(A) of the act, would the National Fisheries Institute then feel they could support section 641?

Mr. BERGER. I'm going to let Mr. Weddig answer that one.

Mr. WEDDIG. I think you hit most of the things that we have concerns with on S. 641 even though you didn't mention modification in the area of the recordkeeping provision or in the basic establishment of the quality assurance system that also gives us some trouble, as it does most other parts of the food industry. Even though in our respect, if the plants were using the Marine Fisheries program they would meet these requirements, I think we would be in a somewhat different position than many other industries, but we do share their basic views that the way the quality assurance system is drafted in 1168 is more acceptable to our way of thinking, especially the area of recordkeeping.

Senator MOSS. I see. These other matters that I read, though, do comply pretty much to the objections that you have raised?

Mr. WEDDIG. Yes, sir.

Mr. BERGER. I think we can live with those, Senator. I still would feel that the committee should take some more time to learn about—as much about the present problems of the food industry as you can and learn what is being done in the food industry to help make this bill more meaningful.

Senator MOSS. Well, we do appreciate your helpful comments and testimony on the bill and your offers of cooperation are greatly appreciated and we hope that you can continue to help us as we work on the final version of the bill.

Thank you very much, gentlemen.

Mr. BERGER. Thank you, Senator.

Senator MOSS. Mr. William Quinlan, general counsel of the Associated Retail Bakers of America, from Annapolis. Mr. Quinlin you have a long statement prepared for us. It looks like it's a good one. We'll have it in the record in full and ask you to proceed if you can by summarizing to the extent possible and still get over your points that you want to make to us.

STATEMENT OF WILLIAM A. QUINLAN, GENERAL COUNSEL, ASSOCIATED RETAIL BAKERS OF AMERICA, ANNAPOLIS, MD.; ACCOMPANIED BY JOSEPH A. BECKER, OWNER AND OPERATOR OF THE DIXIE BAKE SHOP, SIOUX FALLS, S. DAK.

Mr. QUINLIN. Thank you, Mr. Chairman.

A number of the pages which you have are appendices to the statement. We condensed our comments and I will condense them further.

Senator Moss. Thank you.

Mr. QUINLIN. I would appreciate it, Mr. Chairman, if when the prepared statement is included in the record the reporter will include the page and line numbers referring to the bill. I think that would be helpful.

Senator Moss. All right.

Mr. QUINLIN. With me, Mr. Chairman, is Mr. Joseph A. Becker, owner and operator of the Dixie Bake Shop, Sioux Falls, S. Dak.

Senator Moss. We are glad to have you, Mr. Becker.

Mr. QUINLIN. He is a member of the board of directors of our association and chairman of its Committee on Sanitation, Safety, and Health. He's a practical operating retail baker of wide experience.

We greatly appreciate this opportunity to testify, Mr. Chairman. The retail bakers are the ones who prepare their own bakery foods and sell directly to the consumer across their own counters. A picture is worth the proverbial 10,000 words, so I'd like to show you, sir, what a retail bakery is. I'm sure you're familiar with it, but to be sure there's no mistake as to what we're talking about.

Senator Moss. I like your product.

Mr. QUINLIN. Thank you, sir. Mr. Becker, first of all, has three prints of the exterior of a typical single unit retail bakery. That happens to be Schupp's Bakery in the District of Columbia on Connecticut Avenue near Chevy Chase Circle. Second: Three prints of the interior of the store; and third; three prints of the interior of the bake shop in the rear. We have more prints, Mr. Chairman, should you want them.

Senator Moss. Thank you.

Mr. QUINLIN. Our immediate concern and reason for being here are that S. 641 is appropriate, if at all, for wholesale food factories or plants but not for food retailers such as retail bakeries. We hope it's the intent of the bill to exempt such retailers, but it does not appear to exempt them or, at best, the exemption isn't clear.

These establishments vary in size, volume of sales and number of employees, but most of them are extremely small, even in comparison with other kinds of retailers.

For example, over 6,000 of them have no employees at all. Their owners do all the work. They are local establishments making and selling fresh baked products daily and seldom do any of their products move in interstate commerce. An example is Schupp's Bakery. Occasionally they will take a wedding cake across the District line into Maryland, but that's the extent of any interstate commerce in their finished products.

But all of these establishments, even the smallest ones that have no interstate outgoing products, no employees at all, would be subject to the food surveillance provisions of S. 641 unless they qualify for one of the express exemptions. Those exemptions include "processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises." We hope it's the intent of that language to exempt retail establishments such as retail bakeries which produce or prepare the foods they sell but what is "processing which consists only of the sale"? That unusual terminology seems to be related to the broadness of the definition of processing, for purpose of the food surveillance and registration provisions, as including "manufacturing, processing, packing, labeling, storing, importing or being in any manner responsible for importing, or otherwise handling food."

Processing being so broadly defined, however, it does not appear that there could in fact be any such thing as "processing which consists solely of the sale." Every retailer handles, as well as sells. Most pack, label, and/or store. Many, like retail bakeries, retail candy and ice cream shops, grocery supermarkets, in their meat departments, and retail druggists, at their lunch counters, also manufacture or process. It is therefore difficult to think of any retail establishment that would be exempted by the exemption of "processing which consists solely of the sale."

In my prepared statement, Mr. Chairman, I didn't mention this, but perhaps I should at this point. That exemption which is now in the bill on page 17, lines 5 through 10, exempts "processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises," but it then goes on "except with respect to safety assurance assessment reports and safety assurance plan prepared or established pursuant to subsection (b) of this section." In other words, it says that retail establishments are not exempted from the safety assurance plan requirements, but then, if you go back to subsection (b) on page 5, lines 12 through 16, the bill says that "No such plan or amendment thereto shall contain provisions regarding safety assurance procedures or safety assurance standards applicable to processing which consists solely of the sale" and so on. So retail establishments seem to be in and then out on page 17 and then in again on page 17 and then out again on page 5. I think that's a confusing series of provisions that needs clarification.

We think the bill uses better language in its exemption from the food coding provisions of "manufacturing and packing of packaged food in a retail establishment for consumption on or off the premises." That exempts only manufacturing and packing of packaged food because those are the only activities covered by the food coding provisions to begin with.

The food surveillance provisions, on the other hand, cover all "processing" as broadly defined. We therefore suggest that consistent with the food coding exemption the food surveillance provisions should exempt "processing of food in a retail establishment for consumption on or off the premises." That suggested language would be substituted for the present lines 5 throug 10 on page 17, "processing which consists solely of the sale" and so on.

In passing, we note that the food surveillance provisions also exempt "processing of food which is not or has not been introduced into, delivered or held for introduction into, or shipped in or received or held for sale after shipment in, interstate commerce." At first glance that might seem to exempt local retailers, including retail bakers, but it does not; the previous interstate movement of their goods or materials denies them this exemption, and we have cited the *Hipolite Egg* and *Sullivan* cases. I think it could almost be stated flately that every food retailer handles food which at some time has moved in interstate commerce, and under these cases any movement in interstate commerce triggers the jurisdiction of the Food and Drug Administration forever after, even though such food may later move through a series of hands in purely intrastate commerce.

The bill also gives those who would administer it discretion to grant exemptions but we find little comfort or assurance in that discretion.

The "food establishment registration" provisions of S. 641 also exempt "any processing consisting solely of the sale of food in a retil establishment for consumption on or off the premises." We suggest that this too be changed, like the food surveillance exemption, to read: "processing of food in a retail establishment for consumption on or off the premises."

The "food labeling" provisions of S. 641 would provide no exemption for retailers as such other than the exemption from the label ingredient declaration of food received in bulk containers at a retail establishment—page 42, lines 1–8.

Most retail bakery foods are displayed and sold unpackaged in display cases and placed in a bag, wrapper, or box after the customer has made her selection. Some, however, are prepackaged by the baker.

The difficulties of placing required labeling including ingredient declarations on packaged products in a retail bakery would be overwhelming. Certainly they would inhibit variety and changing of retail bakery foods to such an extent as to make impossible the continued operation of retail bakeries as they are known to today's consumers.

The Federal labeling requirements presently apply only to foods moving in interstate commerce but if there's to be any further legislation this would be a good time, especially in view of reported claims now by Food and Drug Administration officials to jurisdiction over labeling of interstate foods on the ground that their ingredients at one time moved in interstate commerce, a good time to exempt from the labeling provisions, other than those which prohibit misleading labeling, "food sold by a retail establishment which manufactures or processes such food for consumption on or off the premises."

If retail establishments including retail bakeries are not exempted from the various provisions of S. 641 and if the bill becomes law, there will be a succession of unintended and unfortunate results.

The "food surveillance" procedures are unsuitable for retail establishments, including retail bakeries and their handcraft or

semihandcraft operations. I wil not belabor the point but ask you to read those provisions while visualizing a retail bakery in your neighborhood. The baker probably would have to sell his bakery to pay the civil penalties of up to $10,000 a day, if he could find a buyer.

Requiring all food "processors," including retailers, to register with the Federal Government has a certain plausibility but we ask you to examine that very critically.

We believe that once a regulator gets a register of enterprises subject to his authority his instinct will be to communicate with them frequently and that his communications are likely to take the form of more regulations and reporting and recordkeeping requirements. Business enterprise, and especially small business, is already surfeited with those. Anything that would tend to increase them unnecessarily should be avoided. We see nothing worthwhile to be accomplished by Federal registration and much danger in it, at least as it applies to the retailer who sells his own products directly to the consumer.

We refer in our prepared statement to the authority that would be given the Secretary to prescribe classes of food and types of processing to promote uniformity and expeditious administration with respect to registration and this concerns us deeply. Variety and quality of products and processing, rather than uniformity, are the lifeblood of retail bakeries. The retail baker is a craftsman and his bakery is a handcraft or semihandcraft shop rather than a plant or a factory.

In our appendix A we have given you a list of typical retail bakery products. It's not complete but you can see that it's a very extensive list. These products and the recipes, sizes, shapes, fillings, and toppings, differing from those of other bakeries, are varied by the retail baker deliberately depending upon the preferences of his customers, the season, the day of the week, the wathr, and othr influences on consumer acceptance.

Uniformity would destroy his small business and deprive the consumer of his individualized and continually changing variety of bakery foods, and we say this with the interest of the consumer in mind, not just of the retail baker. It would be relatively easy if the retail baker could produce a small number of uniform products, but that's not the nature of his handcraft business.

No reliance should be placed on any administrative assurance that registration requirements would be simplified or that small food establishments would be exempted by administrative rulemaking. History tells us that the Congress must limit these grants of authority or they will eventually be abused. We can see where ultimately, in order to conform our operations to the administrative requirements of registration, we might be subjected to an administrative straightjacket rather than conforming the requirements of registration to the realities of the retail bakery business.

If registration of all food purveyors with the Federal Food and Drug Administration is required it would logically follow that they and all other Americans should also register with every other Federal agency having regulatory authority over their activities.

Surely that prospect with its implications is a frightening one.

The "open dating" provisions of S. 641 seem at first to say merely that if food labeling bears any dating it must comply with the regulations, but there's danger, we think, that they would be construed to authorize the Secretary to require dating. Such a requirement wouldn't be appropriate for retailers selling directly to consumers in their own stores the foods that they themselves produce.

In my prepared statement I refer to the report by our committee on open dating, Mr. Chairman. Those copies didn't reach me today. I expect to have them when I get back to my office. With your leave, I'd like to submit copies of that report.

Senator Moss. They may be submitted and it will appear in the record.[1]

Mr. QUINLAN. Further, S. 641 would authorize the Secretary to prescribe nutrition labeling for a food "to which a nutrient or nutrients have been added" or "for which any claim of nutritional value is made—page 40, lines 4 to 17.

"Nutrient" is undefined but presumably would include anything nutritious, so as literally to cover all foods. "Any claim of nutritional value" also is undefined but literally would include saying that our products are 'delicious and nutritious."

So we think that provision needs much refining and safeguarding against administrative abuse.

The bill also would require a food label to bear a declaration of the percentage of each ingredient, subject to some state qualifications which do not appear significant—page 43, lines 9 to 16.

I don't know how the retail baker, with his numerous products and ingredients and constantly striving for change and variety, could possibly comply with that requirement.

Again, in appendix B we have given you a somewhat extensive list of typical bakery ingredients.

Going to the other bill, S. 168, it does not include open dating, nutrition labeling or ingredient percentage declaration requirements but does include food surveillance—"safety assurance"—and registration provisions, subject to an exemption, as in S. 641, of "processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises"—page 18, lines 18 to 20. Our comments and suggestions on S. 641 apply also to those provisions of S. 1168.

Because he still is able to cater to the demanding and changing tastes of consumers for fresh, eye-pleasing, delicious bakery foods the retail baker has so far managed to survive the burdens of government taxation and regulation. His is one of the few kinds of small business still remaining on the American scene. We urge you to leave him free enough to do the work we believe he is doing well.

Thank you, Mr. Chairman, for this opportunity to testify and for your consideration. I would appreciate it if you would give Mr. Becker an opportunity to add a few strictly practical observations.

Senator Moss. We will be glad to hear that. Thank you, Mr. Quinlan. We will hear from Mr. Becker briefly.

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[1] See p. 258.

Mr. BECKER. Mr. Chairman, I am an operating small retail baker. We now put in approximately 14, 16, 18 hours every day. This has come about by a lot of bookwork that we have had to do due to regulations over the past 10 or 15 years. We try to keep people in our small communities working. We try to give the people the type of product they desire and I would like to state here that a retail bakery is similar to a kitchen. All it is really is an enlarged kitchen and if we wouldn't put out the product to compete with the housewife she wouldn't buy it. It has to be as good. It has to be better. This is why she buys our product.

So I say we have the greatest competition in the world in the housewife.

Second, we have today in my bakery, because we do get ingredients in from out of State, we have the FDA check us several times a year. We have the State people check us. We have the city health department check us. We have OSHA check us. We have so many checks that it's unbelievable.

The foods that we make are all baked at over 400°. The custard fillings that we had in the past have been eliminated to a large degree because of regulations. Where we used to use milk, we used to use eggs, we used to use butter—these have been taken out strictly for safety. So the consumer again has lost something that I believe would be very nutritional.

All I'm saying is it would be a sad day that the second oldest profession that's known to mankind—second only to agriculture, would be destroyed by regulations of this type.

Mr. QUINLAN. Mr. Chairman, I'd like to add one thing. Mr. Becker can correct me if I'm wrong. When he spoke of eliminating the milk and so on, you were referring to custards?

Mr. BECKER. Right.

Mr. QUINLAN. The only dangerous product that had been produced in retail bakeries was custards. The finer the custards were, the richer they were, the better culture they were for staphyiococcus bacteria. So our association, in cooperation with the American Bakers Association, the American Institute of Baking, and the University of Chicago many years ago conducted a research project which ended in a program to pasteurize custards and to give the consumer information as to how custards should be handled—that they should be kept refrigerated and so on.

Now, going beyond that, Mr. Becker has indicated that even some of the fine ingredients that we and the consumer like to have in custard were taken out to be sure you wouldn't even need to pasteurize and refrigerate them. But that's the only product I'm aware of in retail bakeries that had any danger of contamination and that danger has, for all practical purposes, been eliminated.

Mr. BECKER. Mr. Chairman, I would like to state, if I haven't before, that in my little bakery alone we average between 5 and 600 varities each week of different products.

Senator MOSS. The products that you bake and sell?

Mr. BECKER. Right.

Senator MOSS. Do you believe that the processing in a retail bakery should be treated in the same way as a retail food store or a restaurant?

Mr. BECKER. Well, restaurant and a bakery, a small retail handcraft bakery, there isn't very much difference.

Mr. QUINLAN. Many of our retail bakeries now are in food stores in that we have in-store bakeries, so-called in supermarkets, and their situation would be just like the bakerery that's in a store by itself. They perform the same operations. It's a kitchen handcraft type of operation.

Senator Moss. Well, we appreciate your coming to give us this information about the bakers and how you think the bill would impact upon them. I certainly agree with you that we ought not to place any unneeded burdens on small units of an industry like the bakers and hopefully we will be able to draft the bill so it will not be burdensome or onerous at all.

Our objective is to assure that foods are wholesome when sold to the public and we try to keep at a minimum any of the detail necessary to get this assurance.

Mr. BECKER. Mr. Chairman, may I add that in a small bakery where the owner and his wife do all the bookkeeping and so forth, if we had to keep a record of 5 to 700 varieties each week it would require the aid of a bookkeeper or somebody and, of course, in the end the consumer will have to pay more for the product because it would be added expense. It would be an impossibility today with the load that the small baker has to add more to it. It would just be an impossibility.

Mr. QUINLAN. But the objectives are the same. We can't survive if our products aren't wholesome.

Senator Moss. Well, thank you very much, Mr. Quinlan and Mr. Becker. We appreciate your testimony.

[The statement follows:]

STATEMENT BY WILLIAM A. QUINLAN, GENERAL COUNSEL, ASSOCIATED RETAIL BAKERS OF AMERICA

I am William A. Quinlan, of Annapolis, Maryland, appearing as General Counsel of the Associated Retail Bakers of America to testify on the food registration and regulation bills S. 641 and S. 1168.

With me is Mr. Joseph A. Becker, owner and operator of the Dixie Bake Shop, Sioux Falls, South Dakota, a member of the Board of Directors of our association and Chairman of its Committee on Sanitation, Safety and Health.

We greatly appreciate this opportunity to testify. To conserve your time my prepared statement is as short and specific as possible.

The Associated Retail Bakers of America ("ARBA") is the national nonprofit membership association of retail bakers—those who sell across their own counters directly to consumers the bakery foods which they prepare. There are about 25,000 retail bakeries. Most of them are very small, neighborhood shops.

I have been associated with bakers in various capacities during all of my working life, and with ARBA during most of it.

Our immediate concern and reason for being here are that S. 641 is appropriate, if at all, for wholesale food factories or plants but not for food retailers such as retail bakers, that we hope it is the intent of the bill to exempt such retailers, but that it does not appear to exempt them or at best the exemption is not clear.

The approximately 25,000 retail bakeries, according to the latest (1972) Census of Business and Census of Manufactures, include 19,203 independent establishments baking and selling on the same premises, about 5,000 grocery supermarket bakeries baking and selling on the same premises, 98 multiple unit retail bakeries which sell through their own separate retail bakery stores, and retail donut and pie shops making up the remainder.

They vary in size, volume of sales and number of employees, but most of them are extremely small, even in comparison with other kinds of retailers.

Of the 19,203 independent establishments 12,870 had one or more employees each and had average gross weekly sales of only $1,958—that was the average gross, to cover all costs—ingredients, wages and salaries, overhead and profit. The 6,333 which had no employees—their owners did all the work—had average gross weekly sales of only $522 to cover everything.

They are local establishments making and selling fresh-baked products daily. Seldom do any of their products move in interstate commerce—for example, when a retail baker near a state line may deliver a special wedding cake order across the line in his car or station wagon.

CLARIFICATION OF THE RETAILER EXEMPTION

All of them, however, would be subject to the complex "food surveillance" provisions of S. 641 unless they qualify for one of the express exemptions.

Those provisions exempt "* * * processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises * * *" (S. 641, page 17, lines 5–10; see also page 5, lines 12–16, page 6, lines 3–6).

We hope it is the intent of that language to exempt retail establishments such as retail bakeries which produce or prepare the foods they sell. But what is "processing which consists solely of the sale"?

That unusual terminology seems to be related to the broadness of definition of "processing," for purposes of the food surveillance and registration provisions (page 36, lines 20–23), to include "manufacturing, processing, packing, labeling, storing, importing or being in any manner responsible for importing, or otherwise handling food." "Processing" being so broadly defined, however, it does not appear that there could in fact be any such thing as "processing which consists solely of the sale." Every retailer "handles" as well as sells. Most "pack," "label" and/or "store." Many, like retail bakeries, retail candy and ice cream shops, grocery supermarkets (in their meat departments) and retail druggists (at their lunch counters), also "manufacture" or "process." It is therefore difficult to think of any retail establishment that would be exempted by the exemption of "processing which consists solely of the sale."

The bill uses better language in its exemption, from the "food coding" provisions, of "* * * manufacturing and packing of packaged food in a retail establishment for consumption on or off the premises" (page 21, lines 2–4)

That exempts only "manufacturing and packing of packaged food" because those are the only activities covered by the food coding provisions to begin with.

The food surveillance provisions, on the other hand, cover all "processing" as broadly defined. We therefore suggest that, consistent with the food coding exemption, the food surveillance provisions should exempt "processing of food in a retail establishment for consumption on or off the premises"

That language would be substituted for the present "processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises."

In passing, we note that the food surveillance provisions also exempt "processing of food which is not or has not been introduced into, delivered or held for introduction into, or shipped in or received or held for sale after shipment in, interstate commerce" (page 17, lines 11–14). At first glance that might seem to exempt local retailers including retail bakers, but it does not; the previous interstate movement of their goods or materials denies them this exemption. See *Hipolite Egg Co.* v. *United States*, 220 U.S. 45 (1911), *United States* v. *Sullivan*, 332 U.S. 689 (1948).

The bill also gives those who would administer its discretion to grant exemptions but we find little comfort or assurance in that discretion.

The "food establishment registration" provisions of S. 641 also exempt "any processing consisting solely of the sale of food in a retail establishment for consumption on or off the premises" (page 35, lines 16–18). We suggest that this too be changed, like the food surveillance exemption, to read "processing of food in a retail establishment for consumption on or off the premises"

The "food labeling" provisions of S. 641 (pages 37–47) provide no exemption for retailers as such other than the exemption from the label ingredient declaration of food received in bulk containers at a retail establishment (page 42, lines 1–8).

Most retail bakery foods are displayed and sold unpackaged in display cases and placed in a bag, wrapper or box after the customer has made her selection. Some, however, are pre-packaged.

The difficulties of placing required labeling including ingredient declarations on packaged products in a retail bakery would be overwhelming. Certainly they would inhibit variety and changing of retail bakery foods to such an extent as to make impossible the continued operation of retail bakeries as they are known to today's consumers.

The Federal labeling requirements presently apply only to foods moving in interstate commerce but if there is to be any further legislation this would be a good time (especially in view of reported claims by Food and Drug Administration officials to jurisdiction over labeling of intrastate commerce) to exempt from the labeling provisions, other than those which prohibit misleading labeling: "food sold by a retail establishment which manufactures or processes such food for consumption on or off the premises"

IMPORTANCE OF THE RETAILER EXEMPTION

If retail establishments including retail bakeries are not exempted from the various provisions of S. 641 and if the bill becomes law, there will be a succession of unintended and unfortunate results.

The "food surveillance" procedures are unsuitable for retail establishments, including retail bakeries and their handcraft or semi-handcraft operations. I will not belabor the point but ask you to read those provisions while visualizing a retail bakery in your neighborhood. The baker probably would have to sell his bakery to pay the civil penalties of up to $10,000 a day, if he could find a buyer.

Requiring all food "processors," including retailers, to register with the Federal Government has a certain plausibility, but we ask you to examine that very critically.

We believe that once a regulator gets a register of enterprises subject to his authority his instinct will be to communicate with them frequently and that his communications are likely to take the form of more regulations and reporting and record-keeping requirements. Business enterprise, and especially small business, is already surfeited with those. Anything that would tend to increase them unnecessarily should be avoided. We see nothing worthwhile to be accomplished by Federal registration and much danger in it.

In our case, for example, the registration would (page 33, lines 12–21) "include, but not be limited to, * * * for each * * * establishment, a complete list, in such form as the Secretary shall by regulation prescribe, of all classes of foods processed therein. Such list shall identify the types of processing utilized for each class of food. The Secretary shall promulgate regulations defining classes of foods and types of processing, to promote uniformity and expeditious administration with respect to such registration."

Variety and quality of products and processing, rather than uniformity, are the lifeblood of retail bakeries.

The retail baker is a craftsman and his bakery is a handcraft or semi-handcraft shop rather than a plant or factory.

The attached "Appendix A" will give some idea of the foods prepared in retail bakeries, although it is not complete or static. On any given day a retail baker offers a myriad of such items, and of recipes, sizes, shapes, fillings and toppings, differing from those of other bakeries, and he varies them from day to day, depending on the preferences of his customers, the season, the day of the week, the weather, and other influences on consumer acceptance.

Uniformity would destroy his small business and deprive the consumer of his individualized and continually changing variety of bakery foods.

It is the interest of the consumer, not that of the retail baker, which demands freedom to provide unlimited, unclassified and un-prelisted varieties of bakery foods. It would be relatively easy for the retail baker to provide a few, uniformly classified, unchanging products. In a totalitarian regime the consumer would be satisfied with them, or at least would not complain. In America, the consumer would not be satisfied and would complain.

No reliance should be placed on any administrative assurances that registration requirements will be simplified or that small food establishments will be exempted by administrative rule-making. The lessons of history tell us that

the Congress must provide against unnecessary extremes of regulation and intervention. Sooner or later, the proposed authority for the Food and Drug Administration to "promulgate regulations defining classes of foods and types of processing" would be too great a temptation for the administrators, computerizers and statisticians to conform bakery foods to their own notions and purposes rather than the needs, desires and preferences of consumers.

If registration of all food purveyors with the Federal Food and Drug Administration is required it would logically follow that they and all other Americans should also register with every other Federal agency having regulatory authority over their activities. Surely that prospect with its implications is a frightening one.

As a member of the bar, sworn to uphold the Constitution, I am required to say I believe the findings in the bill (page 32, line 10, through page 33, line 2) that all intrastate commerce in food must be registered and inspected in order to make regulation of interstate commerce effective is an unconstitutional perversion of the Commerce Clause, which would render meaningless the Constitutional limitation of Federal regulatory power to interstate and foreign commerce.

The "open dating" provisions of S. 641 seem at first to say merely that if food labeling bears any dating it must comply with regulations to be promulgated by the Secretary (page 38, lines 13–16).

There is danger, however, that they would be construed to authorize the Secretary to require dating (page 38, line 18, through page 39, line 3).

Such a requirement would not be appropriate for retailers selling directly to consumers in their own stores the foods which they themselves produce.

We respectfully submit for your record a report by our ARBA Committee on Open Dating which summarizes reasons against applying an open dating requirement to such retailers.

S. 641 also would authorize the Secretary to prescribe nutrition labeling for a food "to which a nutrient or nutrients have been added" or "for which any claim of nutritional value is made * * *" (page 40, lines 4–17).

"Nutrient" is undefined but presumably would include anything nutritious, so as literally to cover all foods. Any "claim of nutritional value" also is undefined but literally would include saying that our products are "delicious and nutritious."

That provision, we respectfully submit, needs much refining and safeguarding against administrative abuse.

The bill also would require a food label to bear a declaration of the percentage of each ingredient, subject to some stated qualifications which do not appear significant (page 43, lines 9–16).

I don't know how the retail baker, with his numerous products and ingredients and constantly striving for change and variety, could possibly comply with that requirement.

The attached "Exhibit B" will give some idea of the ingredients used by retail bakers, although it is not complete or static.

The bill S. 1168 does not include open dating, nutrition labeling or ingredient percentage declaration requirements but does include food surveillance ("safety assurance") and registration provisions, subject to an exception, as in S. 641, of "processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises" (page 18, lines 18–20). Our comments and suggestions on S. 641 apply also to those provisions of S. 1168.

Because he still is able to cater to the demanding and changing tastes of consumers for fresh, eye-pleasing, delicious bakery foods the retail baker has so far managed to survive the burdens of Government taxation and regulation. His is one of the few kinds of small business still remaining on the American scene. We urge you to leave him free enough to do the work we believe he is doing well.

Thank you, Mr. Chairman and Members of the Committee, for this opportunity to testify and for your consideration.

Senator Moss. Mr. Albert Keogler, president, American Spice Trade Association, will be our next witness. We are pleased to have you, sir, and we look forward to hearing your testimony.

STATEMENT OF ALBERT KEOGLER, PRESIDENT, AMERICAN SPICE TRADE ASSOCIATION, ENGLEWOOD CLIFFS, N.J.; ACCOMPANIED BY STEWART P. WANDS, EXECUTIVE VICE PRESIDENT; JAMES SULLIVAN, DIRECTOR OF RESEARCH AND DEVELOPMENT OF McCORMICK & CO.; GEORGE SHURMAN, PRESIDENT OF THE OVERSEAS PRODUCE CORP.; AND STEPHEN A. WEITZMAN, LEGAL COUNSEL

Mr. KEOGLER. Senator Moss, my name is Albert E. Keogler. I am a vice president of Brooke Bond Foods, Inc., I also serve as the president of the American Spice Trade Association, on whose behalf I am appearing today. Present with me are Mr. Stewart P. Wands, executive vice president of ASTA, Mr. James Sullivan, director of Research and Development of McCormick & Co., and a member of ASTA's Technical Committee, Mr. George Shurman, president of the Overseas Product Corp., and Mr. Stephen A. Weitzman, legal counsel to the association on this matter.

Senator Moss. We welcome all of you gentlemen. I will be out of the room just for a few moments. I wish you would go right ahead and I will ask the staff counsel here to conduct the hearing. I have to go and make a quorum. That's my problem, but you go right ahead.

Mr. KEOGLER. The American Spice Trade Association has been in existence since 1906, being one of the country's early trade organizations. The association was created because of the end for arbitration facilities where questions of quality and condition of imported spices, seeds, and herbs could be settled at the industry level.

The association has some 280 members, representing all segments of the worldwide spice industry, located not only in the United States, but in most spice producing countries as well. We include among our members many spice importers, as well as a number of food manufacturing firms which are large users of spices, and a number of companies which supply the industry with products and services. The association's members represent approximately 80 percent of the total volume of spices traded and processed in the United States.

We would like to discuss with you today some of our concerns about S. 641, namely the provision dealing with imported food products; the provision concerning disclosure and listing of spices and flavorings on product labels; and the records inspection authority.

Section 111 requires that an importer of food products file a certificate with the Secretary 30 days prior to importation, stating that the foods were produced in accordance with domestic safety assurance procedures and standards.

It would be extremely difficult, if not impossible, for the spice industry to meet these requirements.

In 1974, 46 different spices, seeds, herbs, and seasoning materials were imported into the United States from 76 different countries. A list of these exporting countries is attached to this statement. In 1974, imports into the United States amounted to 306 million pounds, valued at over $138 million.

Many foreign producers still harvest and dry spices in traditional ways. Spices may be from the bark of a jungle tree, the leaves of a wild plant, or the root of some remote plantation crop. They are frequently grown by small peasant farmers. In some areas, the products are harvested in small quantities by families, left in the sun to dry and then taken to the first collection station. The product may pass through three or four collection centers before it reaches the final dealer at the port of shipment. This method of gathering products for export is almost universally used. The foreign producers trade these products as a major cash crop and they are not intending to provide a processed food product. It is the existing practice that when these products are entered into the United States they are processed for ultimate use.

The 30-day notice provision is impractical. In order to keep costs down, merchandise is imported whenever there is demand. There are spices which can be delivered within a short period after ordered—such as allspice from Jamaica, 3 to 5 days; pepper from Brazil, 2 weeks; poppy and caraway seed from Holland, 10 days. If the importer must wait 30 days he would incur unnecessary warehouse and interest costs, or demurrage charges, which would increase the cost to consumers for no reason.

The American importer, even when dealing with the most reliable exporting firms, can have no knowledge as to the condition of the spices prior to entry examination. All spice imports received in this country are currently subject to FDA inspection at the point of entry into the United States, as well as to the cleanliness specifications developed and enforced by members of the American Spice Trade Association through its trading contract. ASTA specifications require an independent laboratory analysis, from which the importer can determine whether or not a product meets the association's requirements and those of the Food and Drug Administration. The current FDA procedures for examining imported spices provide adequate assurance of a wholesome product. Under existing procedures the American consumer is well protected. In all cases, the manufacturer subjects the merchandise to additional cleaning prior to its ultimate sale and delivery to the consumer. These actions taken by the U.S. grinder cannot be duplicated by an exporter to this country.

We urge that section 111 be rewritten (1) to exempt spices which are subject to further processing in the United States in accordance with this legislation, and (2) to eliminate the prior notice to reflect the very short timetable under which the spice trade operates.

Second, in reviewing the statement of FDA Commissioner Schmidt before this joint subcommittee, and the statement presented by FEMA yesterday, we find we are in agreement with them in regard to the statement that there is no need for a mandatory requirement to conduct a feasibility study as to the necessity of having complete declaration of individual spices on every food product label. The survey of GRAS substances currently underway will establish whether any additives might present problems to the consuming public. To require a second study covering spices and flavoring labeling would be wasteful.

Proposed section 305 gives the Secretary the authority to require by regulation the listing of spices and flavorings on product labels if such listing is found to be "necessary to protect public health or to provide information useful to consumers."

We certainly agree that information about a particular ingredient or product may be necessary for some consumers and should be available in cases involving the public health. However, we object to the wording "useful to consumers," as being far too vague and subject to any manner of interpretation.

Product formula is one of the most valuable competitive properties of the food industry, and spices and flavorings are often the most important component of such formulas. Spice blends often represent significant investments by spice manufacturers in the areas of research and new product development. To require the disclosure of such ingredients to the FDA or the public would be severely detrimental to our industry, of no practical value to the consumer, and is therefore unjustified.

We have included with our testimony, as a means of informing the subcommittees, copies of publications which describe the actions which the association and its members have taken to assure that the American consumer is receiving today the highest quality and most wholesome seasonings the world has known.

We thank you very much for your time and would be happy to answer any questions you may have.

I would like very much first to have Mr. Weitzman make his own brief statement.

Mr. MERLIS. Proceed, Mr. Weitzman.

Mr. WEITZMAN. Rather than go over points made by other trade associations, we decided to prepare this short statement, and I would like to supplement those remarks made in the past few days by the other trade associations and the FDA.

[The following comments on criminal liability are the personal views of Mr. Weitzman].

Mr. WEITZMAN. With regard to criminal liability, I think that after reading the facts in the *Park* case and assuring that there was no concealment of the FDA inspection from the chief executive officer would agree with the decisions of the Supreme Court. I think we should note that in the *Park* case according to the court, it was clear, at least in my opinion, that the test of "knowingly and willfully" violating the Food and Drug Act was met. I think that the notice that FDA provided before the last inspection should have put the company on notice that they had to take action.

I think that the notice procedure of the Agency of violations is commendable and I think it should become a part of the requirements of the law.

Mr. MERLIS. May I just interject one point right there?

Mr. WEITZMAN. Certainly.

Mr. MERLIS. From your reading of the case, would you or could you also assume, let's say, that even without knowledge he was negligent?

Mr. WEITZMAN. In negligence you would have to say to yourself, what is the reasonable businessman supposed to do. Once you have

established a duty on the part of the companies I think absolute liability for negligence is correct. But vicarious liability is wrong where one has delegated his authority and his personnel have decided not to pass on inspection reports, or someone in the chain of command is lying to the president, covering up their own deficiencies. A company president may have some means of auditing, but he can't audit every plant every day of the week. Suppose an FDA inspector walks in before an audit that's scheduled in that company, plant, and finds it to be in a dilapidated state and in violation of the act. Do you want to put the president in jail then? I don't think so.

I think that if the company has a normal system—should have a normal system of checking on its own plants, but I think if the President's not receiving his information like Mr. Merrill said, he may be powerless.

Mr. MERLIS. Isn't the negligence on the part of the person who didn't pass that information on? If the case is brought against that person, that person is the negligent person, not Mr. Park.

Mr. WEITZMAN. I'm concerned with the chief executive officer. In this case as the facts were presented, I think this chief executive officer met that test of "knowing" what was going on. I think the man in the plant that covered up met the test of "knowing" what was going on and I think a letter to the chief executive officer is one of the finest and fairest procedures the Agency has ever followed of sending you a letter and saying, "There's something wrong with this plant." If the chief executive has not been receiving the information from his people in the ranks he's going to call somebody in and, if necessary, fire him and replace him with somebody else.

Mr. MERLIS. The last point to pursue on that, did you, as you read the facts in the case, think Mr. Park acted reasonably or unreasonably, as a negligent test is based on reasonableness?

Mr. WEITZMAN. I think anybody in the food industry will tell you that a 12-day inspection of a facility is probably a record, at least of a food facility, and the conditions of that plant—he should have had people who reported up to him as to the seriousness of the violation. I think in that case there was negligence on the part of the plant personnel.

Mr. MERLIS. Thank you. Proceed. I'm sorry to interrupt you but it seemed to me an appropriate place.

Mr. WEITZMAN. Let me go on to the question of rulemaking authority. The other day Commissioner Schmidt stated that the food industry maintains that FDA regulations: (1) are not substantive; (2) do not have the force and effect of law; and (3) enforcement of the law must be on a case-by-case basis.

I do not subscribe to this statement and I do not believe that most of the food industry does. Some people in the *National Nutritional Foods* cases contended this in some lawsuits and I think they were resoundingly wrong.

FDA regulations issued pursuant to the delegated authority of the Congress under the law are substantive regulations, but substantive means legislative in nature. Those substantive rules were enumerated in section 701(e) which prescribes a hearing. In the legislative his-

tory of the act, Congress said it couldn't promulgate standards one by one. For example, Congress couldn't get involved in reviewing new drug applications one by one and it passed on to the Agency the duty of "filling in the law" in the enumerated subject areas.

FDA rules do have the force and effect of law if they are issued under section 701(e), after a properly conducted hearing. Those rules are substantive. FDA can go out and enforce them. There is no challenge from anybody in the food industry on that. Even the rules issued under section 701(a), which says that the Agency may issue regulations for the "efficient enforcement of the act, which interpret the provisions of the law have the force and effect of law if they correctly interpreted that law, and do not contradict the law as passed by Congress.

If you look at the *Hynson* case, FDA interpreted the new drug provisions of the law and in the *Vitamin Mineral* case FDA again interpreted provisions of the law which was specifically enumerated. This is not to say that FDA has a "necessary and proper" clause in section 701(a), a license to do anything it wants to. It can only interpret the law Congress gave it. It can execute provisions in the law that Congress delegated to it, to enact "administrative legislation."

Third: We do not believe FDA needs to proceed on a case-by-case basis, but FDA should proceed by rulemaking. That is clearly preferable.

What is our dispute? I think the core of our dispute is the unarticulated one that FDA doesn't want to deal with the hearing process that Congress mandated it to deal with under certain circumstances. FDA argues that hearings are too long and they are partially correct. Certainly the hearings held in the *Peanut Butter* case or the *Vitamin Mineral* case were too long. They were atrocious. But the fault lies with the hearing examiner who did not prevent abuses of the hearing process both by FDA counsel and by representatives of some of the industry. Redundant cross-examination should be cut off. Parties should be consolidated. The administrative law judges must exercise control.

Senator Moss, your procedures under the warranty bill are admirable and could even be adopted, I believe, with minor changes, requesting cross-examination, as the FDA hearing process under section 701(e).

We don't resolve the problem by calling a food standard a "common or usual" name regulations in order to avoid the hearing process. Clearly, the legislative mandate under the food standard provisions, as an example, is far more sweeping than the prohibition against deception which is outlined in section 403(a). Section 401 regulations are established both to promote "honesty and fair–with emphasis added—dealing in the interest of consumers." I think that you can do more under section 401 than simply correct a misbranding under section 403(a). I think we should correct the problem in FDA's poor management of the hearing process: first, by possibly establishing a judicial officer with a staff of examiners, with some funds to administer these hearings and also by adopting some sane rules for the hearing process itself.

I have one further point. I would like to elaborate on the statements made regarding constitutional rights, the fourth amendment, and so forth, relating to Agency inspections or subpena authority.

Monday, in the case of *Bigelow* v. *Virginia*, the Supreme Court severely limited the interpretation of the *Valentine* v. *Christenson* doctrine that there is no such thing as commercial free speech. The Court stated that commercial speech is protected under the first amendment. The Court substituted a balancing text much like the one used in that ninth circuit opinion a few weeks ago regarding prescription drug price advertising.

I think, Senator Moss, you're going to be very interested in reading the case. I'm having copies made. The Court has not printed the case yet, but I think it's going to be very enjoyable reading for you.

Senator Moss. Good.

Mr. WEITZMAN. In my opinion, the balancing test should apply to subpena authority and records inspection. In regard to records inspection, we should weigh on balance the constitutional protections against "fishing expeditions" into files when there's no public need. Clearly, when safety or public health is involved, there is a need, but not in the other cases.

Senator, because much of the statement that I have made here was supplemental to some of the answers to questions of others and also involves the recent case, I have not yet had it typed and I would like to submit it formally in the record in a few days.

Senator Moss. The record will be held open for that purpose. We will be glad to have it in the record and we will include it in the record. We appreciate your comments and those of Mr. Keogler, whom I didn't get to hear fully. My associate, Mr. Merlis, sat through it, so maybe I'll have him ask any questions that occurred to him.

Mr. MERLIS. Thank you, Senator.

Yesterday, when the flavor and extract manufacturers appeared before the committee some language was suggested, and since flavorings and spices seem to go hand in hand throughout this act I'd like to read that to you and get your opinion.

The language has to do with both the ingredients identification and the percentage ingredients identification, and let me read first the proposed language as it would apply to listing of ingredients.

On page 41, line 11 of S. 641—it would be section 305(A). The common or usual name of each such ingredient in the order of its predominance except—reading—without naming each such ingredient providing that the Secretary may by regulation provide certain spice or flavoring be labeled—reading—such disclosure is necessary to protect public health, and then, the deletion of "to provide information useful to consumers" and the deletion of the "available upon request" provision.

How does that strike you?

Mr. WEITZMAN. It strikes me as being very satisfactory. I would, of course, like to examine this. We plan to work with Mr. Thompson, whom we are in touch with, on this amendment. I think it goes a long way.

Mr. MERLIS. Okay. The same concept was embodied in percentage ingredient, but let me pursue comments about importation. There are

many spices—and I may be picking something which isn't a spice—is whole angelica root considered a spice?

Mr. WANDS. It's botanical.

Mr. MERLIS. Ginger?

Mr. WANDS. Yes, very much so.

Mr. MERLIS. The nature of your objection is if it's subject to reprocessing, then it would not be subject to import detention as long as following the reprocessing it met all requirements of the act. Is that a paraphrase of your suggestion?

Mr. KEOGLER. Import detention by the FDA.

Mr. MERLIS. I guess it's Treasury which detains.

Mr. KEOGLER. Food and Drug does inspect spice and they detain and we have no issue with that at all. We want that continued.

Mr. MERLIS. What I was trying to get at was the change in the import provisions proposed in S. 641, and how they would either reduce or increase the existing level of import inspection.

Now the one area that clearly would be increased is that the importer would have to certify that it met a safety assurance procedure. Would any other of the import requirements be vitiated by the language that's in S. 641 or would the same kinds of detentions that go on still be able to go on?

Mr. WEITZMAN. Yes, our basic problem with the addition of the import languege is that the current import provision is very stern. It gives the Treasury absolute authority to stop any adulteration or misbranding. You now define adulteration in S. 641 to include the absence of a safety assurance system. I think the existing provision of the law, section 801, covers it.

I think the one problem that we do have regarding timing and 30 days notice and provisions like this is that it is just going to increase paperwork. There is notice. FDA maintains at every port of entry a staff to go over the import slips as they are brought in by the broker.

FDA goes out and surveys the docks to see the actual shipments and they have laboratories in trucks now that do examinations right on the dock, a tremendous time saving. You add on this paper burden and the person in the truck is going to have to look at the paper. He doesn't want to look at the paper any more. The idea was to send him down to the dock and let him see what's coming in on a day to day basis and not hamper trade, not have the trade in the ports slowed up by waiting for an FDA inspector to come down for a week or 2 weeks and handle the merchandise. You're going to have ships sitting in the port or a product held overseas for 30 days in warehouses and things of this nature happen.

Mr. MERLIS. Okay. Thank you very much.

Senator MOSS. Well, thank you, gentlemen, for your testimony and your responses to questions. We appreciate having it in our record and we will include the additional material when it is submitted to us.

Mr. KEOGLER. Thank you, Senator.

Senator MOSS. Mr. Kenneth E. Fulton, Vice Chairman of Government Relations, Committee of International Food Service Manufacturers Association.

You have a long title, sir. We are very pleased to have you, Mr. Fulton.

Mr. ZEIDMAN. Mr. Chairman, not only is it a long title but in this case it's the wrong name because Mr. Fulton is somewhere circling overhead. We have just received word that his plane has not been able to land. It's been detained for over an hour for some reason over National Airport and we have been asked to appear in lieu of him. Hopefully he will walk in any minute.

Senator MOSS. I hope he gets here for two reasons: One, I want him to get down safely, and the other is we'd like to have him testify.

STATEMENT OF PHILIP F. ZEIDMAN; ACCOMPANIED BY JOHN A. KNEBEL, BROWNSTEIN, ZEIDMAN, SCHOMER AND CHASE, ATTORNEYS, ON BEHALF OF INTERNATIONAL FOODSERVICE MANUFACTURERS ASSOCIATION

Mr. ZEIDMAN. My name is Philip F. Zeidman, of the Washington law firm of Brownstein, Zeidman, Schomer and Chase. Mr. John Knebel of the same law firm is with me. We serve as Washington counsel for the International Foodservice Manufacturers Association and have had the opportunity to work with Mr. Merlis and others in connection with this legislation over recent weeks.

Mr. Kenneth Fulton, whose statement we will be presenting today, is a vice president of General Foods, head of its institutional foods division and a member of the board and vice president of the Government Relations Committee of the International Foodservice Manufacturers Association.

IFMA is a trade association comprised of more than 300 of the nation's leading companies engaged in the manufacture and distribution of food, equipment, and supplies to the institutional away-from-home eating market. While we share many of the views of the other associations which are presenting testimony during these hearings, I will speak only to the points of S. 641 which most directly affect the food service part of the industry.

At the outset, it should be understood that IFMA supports the premise on which the legislation is based. The food processing industry, with IFMA members in its vanguard, strives to insure that American consumers' food supply is the best and safest in the world. The record of cooperation between food service processors and the Federal Government in this regard has been outstanding. The American consumer benefits from this industry cooperation with the Food and Drug Administration in such vital areas of common concern as food safety, nutrition education, and the establishment of industry standards. We believe this industry-Government relationship can be enhanced—and the protection of the American consumer furthered—if S. 641 is enacted with amendment or other clarifications in certain respects. But if S. 641 were to be enacted in its present form, we believe the results could prove disruptive, could foster protracted litigation, and would represent a setback for both the consumer and the FDA-industry efforts.

If we could turn, then, to some suggestions with respect to the legislation—first, on title I, food surveillance:

America's food processors have consistently provided her consuming public with the safest and best products in the world. Much attention is given to food recall for safety reasons, infrequent as these incidents are, in large part because of the massive publicity our industry directs toward recalls in order to accomplish them effectively. However, it would be unfortunate if the publnc attention necessarily drawn to these infrequent incidents were to be used as a yardstick for the need to legislate food safety plans. IFMA supports the concept of safety assurance procedures embodied in title I of the bill, but we do have some concerns about the way the procedures are to be set up. We share the FDA's own concern about it having sufficient staff to make annual inspections that will be effective. We are also concerned about the exact procedure to be used by inspectors in citing violations.

As I have indicated, we will be pleased to work with the committee and the staff with respect to whatever modifications may take place.

We believe there are certain modifications that can be made to S. 641 to clarify congressional intent and thus minimize uncertainty, unnecessary litigation and undue diversion of the FDA's efforts to protect the public health.

Food surveillance and safety assurance plans are matters with which responsible processors concern themselves on a daily basis. Ongoing efforts with the FDA have produced industry standards in many areas. Other areas are presently working with the FDA toward that end. These efforts, we believe, are what prompted the FDA to brand as unnecessary the requirement for a safety assurance plan submission by each processor.

Let's turn to some specifics in this regard—first, to criminal liability. Any legislation reported by these subcommittees amending the Federal Food, Drug, and Cosmetic Act should clearly state the intent of the Congress in such terms as to effeceively preclude expansion of the judicial concept which ascribes absolute and vicarious criminal liability to corporate officers for the unknown acts or omissions of their employees. The recent decision of the Supreme Court in the case of *United States* v. *Park* on June 9, 1975, dictates the imposition of some limits. The chilling effect this will have on decisionmaking in the executive suite does not need further elaboration. Recent congressional enactments, including the Occupational Safety and Health Act and the Federal Water Pollution Control Act, provide only for civil penalties, except in the case of willful, negligent, or knowing violations. Further, the Consumer Product Safety Act does not even provide for a civil penalty or fine for a violation, including corporate, unless the offense is knowingly committed. So our concern is that the expansion of traditional concepts unknowingly and unfairly affect decisionmaking in this area.

Let's turn to subpena power and FDA remedies. The crux of the legislation from the standpoint of new authority for the FDA is the subpena power authorized by section 410(e)(2) of S. 641. As presently written, the bill enables the Secretary to order any processor to provide answers to any questions which would help him carry out the purpose of the act. Subpena authority comparable to that required by the Federal Trade Commission to conduct an economic

inquest is simply not intended to enforce a statute whose aim is to insure the purity of food. Subpena powers, and, similarly, the record-keeping requirement authority of the Secretary under the bill should be limited to matters affecting public safety and should not encompass economic and trade secret material.

Just as the subpena power is too broad, so too is the use of per diem fines. While a daily fine can properly be applied for failure to file a safety assurance program, maintain records, answer questions posed by the Secretary or adopt the prescribed coding system, this type of penalty is not readily applicable to labeling violations or other infractions which are not susceptible to remedy by injunctive order. We therefore recommend the words "day of" should be deleted from line 17, page 24 of the bill, in order to correct what we view as this excessively broad approach.

Turning to the uniform coding system, section 411 of the bill authorizes and directs the Secretary to implement a uniform coding system which will, in the interest of public health, permit identification of (1) the plant location and packer, (2) the product, (3) lot or batch number, and (4) date packed. While most IFMA processor-members presently have a coding system in operation, few, if any, have one as detailed as the statute would require (in large part because a great deal of the information already appears, uncoded, printed out on food product labels. It is estimated that a 15-digit number would be required to properly encode all data under the four categories specified in the bill. The use of a symbol with this many characters greatly increases both the cost of compliance, which is necessarily passed on to consumers, and the chance of error in transmission of the number in a recall operation—the prime occasion for using the coding requirements. Industry recall procedures, operated in concert with the FDA and the news media, have proved reliable in the past. We wonder if the price we pay for uniformity will be the substitutions of confusion for success. There is no reason for a long code which yields information that does not bear directly on the problem at hand—a recall of food from a particular batch or plant. IFMA urges the subcommittees to permit manufacturers to use their own existing coding procedures which can accomplish a satisfactory product recall.

Turning to importation certification, section III of the bill would amend section 801 of the Food, Drug, and Cosmetic Act by requiring every processor or importer to notify the Secretary at least 30 days prior to the importation of any food and provide assurances that the food has been processed in a plant which would comply with the safety assurances procedures prescribed by S. 641. This would mean that corporate officers of importing firms would have to make a physical inspection of every batch of food their firms import from abroad—even though all such shipments are now subject to seizure by the FDA at port of entry if they are adulterated. In short, section III transforms what has been an FDA responsibility into an expanded element of potential criminal liability for corporate officers. We disagree with the need for and logic of such an extension and urge that the bill be clarified so as to limit corporate responsbility to providing notice of importation to the Secretary.

Turning to title II, registration, IFMA fully supports the premise that a current registry of food processors should be maintained by the Federal Government for use by the Secondary when he needs it. But the FDA has indicated that, in view of its own budgetary restraints and the Presidential moratorium on the institution of new programs, it could not implement the establishment and maintenance of such a registry. We believe that this registry information is presently in the hands of the Federal Government—with part or all of it—existing in such places as the Bureau of the Census and the Bureau of Labor Statistics. If statutes controlling access to any or all of these sources of data were amended, the material could be released for use by the Secretary without creating a new program. Additionally, use of employer identification numbers would seem logical to avoid the issuance of yet another governmental number.

Turning finally to title III, labeling, as noted at the outset of the testimony, IFMA endorses the principle of providing information to the consumer for whatever legitimate reason he seeks it—dietary, religious, educational, or simple curiosity. But title III significantly amends the misbranding provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 343(i). Sell dating, storage requirements, nutritional claims, itemization of ingredients, and percentage declarations are proposed for inclusion in the law in a most ambigiuous fashion.

The "sell date" information proposed by section 302 of the bill presents a special problem for the processors and users of institutional foods. If congressional intent with respect to title III is the need to inform the consumer, this, in and of itself, suggests exemption for bulk institutional packages with which the consumer does not come in contact. Any dating of such food containeres has to be for the guidance of the kitchen help or the restaurant manager. And, since in the institutional food industry processed foods are shipped either in bulk form or in full cases, the outside of the bulk container or the shipping cartons is the logical place for such information to appear.

The date itself presents a special problem in the institutional food field. Does "sell date" mean the date the processor sells it to the commissary supplier of the institution or retail establishment that serves the consumer? Or the date the supplier sells it to the retail establishment? Or does it mean the date the retail establishment actually opens the packages and uses its contents in a recipe formulation? Or the date the patron of the establishment purchases the finished product? A more meaningful date would be a "use" date—to indicate the limit of time during which the product can be served to the ultimate consumer.

Section 305(a)(2)(B) would require percentage ingredient labeling on foods if such listing would be significant "with respect to value, quality, nutrition, or acceptability of such foods." We have a serious concern as to the benefit to consumers of this requirement when measured against the additional costs to consumers and the complexity of conformance by manufacturers. We are concerned with its application to institutional food packages particularly, because the Secretary on finding that the information "would be useful to consumers" would have to require a percentage listing for all ingredients or all packages. Consumers almost never come in contact with or

all packages. Consumers almost never come in contact with institutional packages and therefore would receive no benefit from percentage labeling of institutional packages. Yet the cost would have to be passed on to the hospitals, schools, and restaurants which buy these products. There are no exemption possibilities under subsection (B); hence, from the standpoint of statutory construction, the percentage requirement, would of necessity apply to bulk containers and other classes of food irrespective of how the bulk container exemption might otherwise be interpreted. We believe, at a minimum, that institutional foods should be exempt from this provision.

Finally, it should be noted that many IFMA processors substitute certain interchangeable ingredients from batch to batch. This practice occurs most frequently with respect to vegetable oils, spices, flavorings, and colorings. Itemization of items in these categories would effectively prohibit the manufacturers from taking advantage of seasonal price variations of many ingredients, particularly oils, and the resulting cost increases would most likely be passed along to the consumer.

IFMA is satisfied that the intention of these subcommittees is to report legislation which can become law, will be enforceable, will not compromise FDA efforts to protect the public health and will provide a meaningful approach to fulfilling the need for consumer information. These objectives are share by IFMA and its members. To this end, we will be pleased to provide whatever assistance is indicated in the preparation of clarifying amendments.

Thank you.

Senator Moss. Thank you, Mr. Zeidman, and we accept your offer of cooperation with the staff in working out language that accomplishes the things that you mentioned here and others that may pose problems for the food processors and packagers.

Our objective, as you well said, is really just to try to provide assurance of wholesome food to the consumer and give him the advantage of being able to know what he's buying and be informed when he makes his decision and we certainly want to avoid in every way we can placing impediments upon the processors and distributors of food because that's an element of cost and it all costs too much right now. We want to hold down in every way we can on any further inflation in prices. So I think our objectives coincide.

I think your testimony or the testimony that you read for your organization is very thoughtful and well placed and it's going to be helpful to us.

I really don't have any questions. I think you stated very clearly and concisely what your point of view is.

Mr. Zeidman. Thank you very much, Mr. Chairman.

Senator Moss. Thank you, gentlemen.

This completes our list of witnesses this morning and at this time we do not contemplate further public hearings. However, if in the next 10 days there are matters which should be brought to our attention we might still include them in the record. I have granted permission on two or three instances for material to be supplied before the record is printed up and then we will proceed on to the markup phase after our record is complete.

We stand adjourned.

[Whereupon, at 11:55 a.m., the hearing was adjourned.]

ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

STATEMENT OF THE DAIRY INDUSTRY COMMITTEE

This statement is submitted in behalf of the Dairy Industry Committee, an organization whose members consist of the following trade associations: American Butter Institute, American Dry Milk Institute, Dairy & Food Industries Supply Assoc., Evaporated Milk Association, International Assoc. of Ice Cream Mfrs., Milk Industry Foundation, National Cheese Institute, and Whey Products Institute.

The associations represent the processors of the various dairy products indicated in the name of the associations and the companies that furnish equipment, supplies and services to the dairy and food industries.

THE DAIRY INDUSTRY—SAFETY ASSURANCE

The Dairy Industry has long been the leader in the food industry of the United States in adopting processing techniques and distribution practices that assure Americans a safe and adequate supply of health giving dairy products.

At the same time, the dairy industry in the United States is undoubtedly the most regulated of all segments of the food industry. The enduring and legal keystone of this regulation is the present Food, Drug and Cosmetic Act. The Dairy Industry Committee is of the opinion that the present act, as enforced by the Commissioner, has adequately protected the consumers of America.

In presenting testimony before the Senate Subcommittee on the Consumer on March 25 on S. 2373, DIC then indicated the magnitude of the regulatory impact upon the dairy products industry. In addition to the Food, Drug and Cosmetic Act, it was pointed out that 49 of the states and over 11,000 local communities have adopted the Pasteurized Milk Ordinance recommended by the U.S. Public Health Service.

This is done through the IMS Conference built on compacts between the states and federal government. All plants with suitable sanitary ratings are listed and published quarterly by FDA and the plants with adequate sanitation ratings may ship their milk products in interstate commerce and sell their products to interstate carriers serving food.

All of the states in which the production of milk is important and in which manufactured dairy products such as evaporated milk, dry milk, butter and cheese are produced, have adopted state regulations setting forth the sanitary conditions in which those products must be produced in those states.

In addition, any processing plants wishing to sell dairy products to the federal government through programs of the United States Department of Agriculture must subject the processing plant to the rigorous sanitary inspection controls of USDA.

NO NEW REGULATION NEEDED

Based upon the long history of this leadership of the field of sanitation and in the production of clean, healthful products in the United States, and upon the adequate enforcement of the present Food, Drug and Cosmetic Act, and upon the regulations of the 49 states and some 11,000 local communities under which bottled milk is regulated, and based upon the extensive regulations governing the production of dairy products in the fifty states and upon the large number of plants that are presently submitting voluntarily to the sanitary control programs and Department of Agriculture, DIC submits that the dairy industry in the United States is in no need of further regulation to assure an adequate and safe supply of healthful dairy products for American consumers.

LEGISLATIVE PROPOSALS

If the Congress in its wisdom does not agree with this premise, we would urge modifications in the pending legislation.

First, we would urge that the safety assurance provision be aligned to situations presenting an unreasonable risk that food will be unsafe or injurious to health. This is certainly the case in the dairy industry. To accomplish this, we urge the adoption of language of S. 1168 regarding safety assurance provisions.

CIVIL PENALTIES

The provisions of S. 641 provide a civil penalty of "$10,000 for each day of violation." This amount would be assessed by the Secretary which then may be appealed in an "appropriate Court of Appeals."

DIC believes this penalty is unreasonably harsh and should be levied only when there is "knowing and willful violation" which could and would be assessed by the court and not by the Secretary. We believe it would be unreasonable to alter the present provisions of the Statute assessing penalties for each violation rather than each day of violation. DIC urges that the language in S. 1168 is more compatible in this regard.

CITIZEN SUITS

The Federal Food, Drug and Cosmetic Act now provides to citizens the right to take legal action against the Secretary if he does not fulfill his obligations of maintaining a safe and wholesome food supply. We believe that the same authority should be extended to safety assurance provisions. We oppose that section of S. 641 which provides citizens the right to take legal action against the Secretary as well as company officials.

CONTAINER CODING

Members of the Dairy Industry Committee have been in support of the concept of container coding for many years. Coding expedites product identification for recall purposes whenever this becomes necessary. DIC opposes the section of S. 641 that sets forth the uniform code with firm belief that the Commissioner now has the authority to require necessary product coding.

PLANT REGISTRATION

S. 641 requires that food processing plants register with the Federal Food and Drug Administration every two years. The registrants must indicate the type of processing taking place in these plants. The Dairy Industry Committee has no objection to plant registration, however, we would support that section of S. 1168 regarding plant registration as being more reasonable and correct and applicable to the dairy industry.

LABELING

The Dairy Industry Committee believes there is no need to extend the Secretary additional authority in the area of labeling. Basically, practically all of the provisions enumerated in S. 641 are already being accomplished or are being considered voluntarily by the product associations of the Dairy Industry Committee.

Nutritional labeling has been instituted by the American Dry Milk Institute, Evaporated Milk Association, Milk Industry Foundation and The National Cheese Institute. Voluntarily, the ice cream and frozen dessert industry has petitioned FDA for the adoption of a program of ingredient labeling. At the same time, the ice cream industry is also voluntarily conducting nutrient assay studies to be able to properly nutritionally label ice cream and other frozen desserts made by the industry. There is no need to provide statutory authority since FDA is presently exercising these powers and the goals are being accomplished. For example, by the simple expedient of issuing a regulation having the force and effect of law, FDA requires mandatory nutritional labeling if a nutrient is added or a nutritional claim is made or implied on the carton and this is being done under a program stated to be and regarded by many as voluntary.

In regard to open dating, all aspects of the perishable dairy products industry is now open dated by either a pull or sell bydate on dairy products. Since this

is being accomplished voluntarily, we see no reason for federal legislation on this subject.

INGREDIENT LABELING

Ingredient labeling now appears on all non-standardized dairy products and on many of the standardized dairy products. A petition has been submitted to FDA on behalf of the ice cream industry to provide for ingredient labeling of those frozen dairy products. Again, DIC sees no reason for additional legislation.

UNIFORMITY OF STATE REGULATIONS

An area where the Dairy Industry Committee asks the Congress to focus its attention and support is to those sections of S. 641 and S. 1168 which provide for uniformity of federal and state laws and regulations. There are many dairy processors who operate in more than one state. Inconsistent state rules and regulations as well as conflicts in federal regulations are constantly increasing in number. The Dairy Industry Committee wholeheartedly urges the adoption of those provisions of S. 1168 which would provide the needed uniform approach for federal and state enforcement authority.

PROPOSED AMENDMENTS

As the Committee has already been made aware, the milk industry is without question the most regulated segment of the food industry today. Over 11,000 local communities and some 49 states enforce the United States Public Health Services Recommended Pasteurized Milk Ordinance or its sanitary equivalent. This is an excellent example of a Federal-State Cooperative Program that has worked successfully in the consumer interest. The Pasteurized Milk Ordinance has achieved an outstanding record for assuring safe food products reaching the consumer.

To accomplish the recognition of this existing program and fulfilling the obligations of the safety assurance programs, plants and standards, the Dairy Industry Committee submits the following proposed amendment to S. 641: On Page 4, after line 3, insert.

"(5) The Secretary shall exempt food processing operations regulated under Federal-State Cooperative Programs which establish assurance procedures and enforcement policies which afford the same public health protection as those enumerated in paragraph one of this subsection."

On Page 9, line 7, after the word "section" insert "or who operated under Federal-State Cooperative Programs pursuant to subsection (a) of this section."

Furthermore, to prevent the unnecessary duplication of plant registrations, especially plants operating under Federal-State Cooperative Programs, the Dairy Industry urges the adoption of the following proposed amendment to S. 641: On Page 35, after line 13, add a new section:

"(2) The Secretary shall exempt any food processor registered under a Federal-State Cooperative Program."

And, on Page 35, renumber Sections (2), (3), and (4), to (3), (4), and (5).

CONCLUSION

The Dairy Industry Committee believes that the dairy products now reaching the American consumer are of excellent quality and sanitary condition and pose no public health hazard to the American public. The Committee believes that the many voluntary programs, the Federal-State Cooperative Programs, and the present Food, Drug and Cosmetic Act account for this fine record.

While the Dairy Industry Committee feels that the present regulatory system is more than adequate to protect the public health, if the Congress in its wisdom deems that general legislation is needed than we urge the adoption of proposed amendments that would recognize the present Federal-State Cooperative Programs.

STATEMENT OF S. F. RIEPMA, PRESIDENT, ON BEHALF OF THE NATIONAL ASSOCIATION OF MARGARINE MANUFACTURERS

Mr. Chairman and distinguished members of the Committee: The National Association of Margarine Manufacturers respectfully submits, for the Committee's hearing record, its comments on S. 641, "Consumer Food Act of 1975", and S. 1168, the "Food Safety Amendments of 1975". We appreciate this oppor-

tunity to present our views. Since the present hearing, and previous hearings, have brought together comprehensive suggestions concerning this legislation, our comments are selective.

The Association represents the manufacturers of a majority of the margarine consumed in the United States. The proposals before the Committee would affect directly the manufacturers of vegetable margarine, which is under the regulation of the Food and Drug Administration.

The two bills would amend the Food, Drug and Cosmetic Act (as amended) to give the Food and Drug Administration added powers for the prevention of unhealthful and unsafe food. We concur with the spirit of this proposed legislation, although we know of no significant problem involving the healthfulness or safety of margarine.

A number of improvements in the proposed legislation have been suggested by other food industry representatives. We think these changes are justified. We endorse them as they are set forth in the alternate proposal S. 1168, and in particular in the testimony you have received from the American Frozen Food Institute and the Institute of Edible Oils and Shortening.

However, I respectfully offer the following further suggestions for improvement of S. 641:

(1) Simplification of notice requirements for margarine in public eating places. S. 641—Sec. 306, pages 44–5.

We endorse these provisions. The existing law, Sec. 407(c) of the Act, is unnecessarily complicated. They are not being enforced. We believe compliance and enforcement alike will be made easier by the provisions in the bills and appreciate your inclusion of them.

The identical language passed the Senate last year as part of S. 2373, and has twice passed the House. Justifications are set forth in the Senate hearing report.[1]

(2) Removal of a conflict between S. 641 and the Act. S. 641—Sec. 305(a), page 43.

The proposal would amend Sec. 403(i)(1)(A)(h) of the Act to exempt inner units of multicomponent food packages from labeling the common or usual name of the food.

We endorse this proviso. But we note that it does not harmonize with the Act, Sec. 407(b)(4), which requires the name "margarine" or "oleomargarine" to be on the wrapper of inner units.

The latter provision adds nothing to consumer protection where, as is almost always the case, the inner units of margarine are not intended by the manufacturer to be sold separately. Indeed the Sec. 407(b)(4) requirement is obsolete in view of the detailed labeling required on margarine outer packages. Sec. 407(b)(4) itself is not comprehensive—it deals with the product name only, not with other parts of margarine labeling required to appear on the outer package label (ingredients, nutrition).[2] Thus, at best Sec. 407(b)(4) is a requirement for only a portion of total outer package labeling.

It is appropriate to remove this conflict. That may be accomplished by addition simply of: "Sec. 407(b)(4) of the Act is repealed". We urge this be done to harmonize the new legislation with existing law.

If the Committee wishes to assure in the statute that margarine inner units intended to be sold as separate packages should be fully labeled, it can add language to that effect. However, we believe that this is better accomplished by a suitable Food and Drug Administration regulation which would require such separately-sold inner units to be labeled fully, as separate packages, just like other foods.

(3) Preemption of state laws. S. 641—Sec. 307, page 45; S. 1168—Sec. 702, page 15.

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[1] U.S. Senate, Subcommittee on Health of the Committee on Labor and Public Welfare, *Hearing . . . on S. 438 . . . H. R. 2166 . . . November 1, 1971* (Washington, 1971); *U.S. Senate, Consumer Food Act of 1974. Report of the Senate Committee on Commerce on S. 2373 . . . July 8, 1974* (Washington, 1974), p. 63.

[2] Under present federal law and regulations, vegetable margarine package labels are required to state: Product name; fats/oils ingredients specifically, in order of predominance; other ingredients specifically, except for colorings and flavorings which may at present be stated in approved general language; net weight in pounds/ounces; nutrition statement; manufacturer's/distributor's name and address. Many margarines also label fat, fatty acid, and cholesterol content and give the weight in metric terms. Many packages also bear the Universal Product Code.

We endorse these provisos. However, it is not perfectly clear that this provision would implement the notification provisions of Sec. 306, which amount to a type of labeling. We believe such application of the principle of uniformity reflects the Committee's thinking. Therefore we urge that Sec. 307 worded to state (page 45, line 12—new words underlined) : ". . . in labeling *or notification* under Sections 403 *and 407* of this Act . . ."

The Committee may decide it is better to restrict the bill's Section 306, in which case we suggest adding this language to that Section.

(4) Extension of "safety matters. S. 641—Sec. 410, pages 1 *et seq.*

We share the widespread concern, reflected by other testimony to the Committee, that Title I of S. 641 establishes an unnecessary extension of authority for the purposes of "safety assurance procedures" beyond the assurance of health and safety.

This extension would give large powers of detention, records inspection, and subpoena where they have not been shown to be necessary to protect public health and safety. S. 641 thereby projects into matters of sanitation, misbranding, economic adulteration, and simple plant housekeeping. Seizure should be for reasonable evidence of danger to health and safety under Sec. 304 of the Act, not for noncompliance with assurance procedures as such. In this particular respect we note and endorse the comments to you on June 4th of Mr. Terrance Hanold, pages 6–9.

Also, while we certainly agree that recalled food offering a risk to public health should be subject to the notification provision, recalls for other reasons need not be. Food processors often recall for purposes other than health.

We therefore respectfully suggest that the provisions of S. 1168, Sec. 101, pages 1–6, be substituted for those of Sec. 410. They serve the same objective with respect to the central issue, which is health and safety.

(5) Split jurisdiction of margarine. S. 641—Sec. 410(i), page 17. S. 641 deals only with food regulated under the Food, Drug and Cosmetic Act. The Act covers vegetable margarine. It does not include margarine made with animal fat and regulated under the meat inspection laws. Thus, one system would exist for one type, and another, for the other type of margarine. Plants making both kinds will have to operate with two different sets of assurance procedures and regulations.

S. 641 seems to include both types of margarine in its assurance procedures provisos, since the bill exempts only products not under the "exclusive jurisdiction" of the Secretary of Agriculture. However, to secure uniformity this should be clarified in the bill or in the report.

(6) Percentage ingredients labeling S. 641—Sec. 305(a)(2)(B), page 43.

It is not clear if this provision means that each ingredient should be labeled with its percent of the total product weight. To do so would impose a most serious burden, for the percent of a given ingredient in margarine (and other foods) may often change. To print new labels with each change of ingredients is to incur an unacceptable cost to all concerned, including consumers.

We think it reasonable to ask that margarine be exempted from the provision. It is presently required by law to label the major ingredients, the oils or fats, in order of predominance. It is also required by law and Standards to contain a minimum of 80% fat. All regular margarines do.

To require that the Food and Drug Administration order such labeling if it considers it to be "useful" to consumers is to open the door to burdensome interpretations of that word. The information now required on a margarine label is all, and more, than reasonably could be called "useful".

To require margarine to label its "characterizing ingredient" is to raise the question of what the characterizing ingredient is. There is no single specific characterizing ingredient of margarine. If the fat content as a whole is so identified, it is already known by virtue of being a Standard minimum requirement.

Therefore, we respectfully suggest this provision be worded so as to exempt products that, like margarine, must frequently change ingredients and have no specific single "characterizing ingredient."

I thank the Committee for their consideration of these comments, and for the opportunity to make them available. I am pleased to provide further information as the Committee may require and insofar as it may be available.

STATEMENT OF MILLERS' NATIONAL FEDERATION

The Millers' National Federation is pleased to have this opportunity to submit for the record these views of the wheat flour milling industry in regard to food surveillance as embodied in S. 641 and S. 1168. The 67 member firms of the Federation operate over 150 mills in 37 states and account for 85 percent of the flour produced in the country. These firms range in size from individual owned and operated family enterprises to multinational corporations and, thus, represent a significant economic and processing link in the food production chain.

In offering comments on these two bills, both of which would enact amendments to the Food, Drug, and Cosmetic Act—substantially revising food regulatory provisions, may we state at the outset that the Federation is supportive of the general intent of such legislation: to further guarantee the safety of food to the consumer by increasing the authority of FDA and by further emphasizing the responsibility of food processors. Given the Federation's joint effort with FDA in developing one of the nation's first food standards—that for flour in 1942,—none of the comments as to provisions in the proposed legislation should be construed as negativism on the part of the industry. The Federation is among those food trade associations who have declared their support for S. 1168. In our opinion, the bill represents a considered approach to the two-fold purpose of providing additional authority for assuring food safety to FDA while imposing an increased regulatory burden which industry can reasonably be expected to bear. We will direct our comments on these two bills primarily to those sections with which the milling industry has had particular experience which may be of use to the Committee.

SAFETY ASSURANCE SYSTEMS

Under Title I of S. 1168, food processors would be required to establish a safety assurance system for each plant operated. Such a system would delineate the processing operations, identify those points where controls are necessary to assure food safety, describe the hazards associated with such points, and recommend controls and monitoring of controls to insure the wholesomeness of the product. Once set forth in writing, these safety assurance systems would be available to FDA. Failure to develop such systems would constitute a violation of the Act.

The Federation would welcome the opportunity to participate in developing safety assurance systems. Many millers have operated under similar systems for some time, and the technical expertise is available to create a positive procedure to which the actual milling process readily would lend itself. The above proposed systems as envisioned by S. 1168 are designed to assure food safety, namely those factors determining whether food is rendered "unsafe or injurious to health." The provisions of S. 641, however, would extend safety assurance systems to include *any* adulteration defined in the Food, Drug, and Cosmetic Act and would encompass plant sanitation and factors unrelated to food safety and already thoroughly covered by other FDA inspection programs and Good Manufacturing Practice (GMP) regulations. Such extensive safety assurance system parameters would appear to be unnecessarily duplicative in our opinion.

In his testimony before the joint subcommittees on June 4, FDA Commissioner Dr. Alexander Schmidt outlined current FDA authority for issuing GMP's and stated that additional safety assurance procedures were unnecessary. Realizing that the processing industry must take a positive approach to assuming responsibility for the wholesomeness of foods, the Federation endorses safety assurance systems limited to food safety as in S. 1168, but concurs with Dr. Schmidt in believing that such systems should not include sanitation and non-safety items, thereby encroaching upon present FDA GMP authority, as S. 641 would mandate. Flour being one of the first foods for which a standard was promulgated, milling is case in point of a process highly regulated. The two-fold incentive of standardization and GMP's has produced market advances in milling technology over the years. Thus we maintain that the broad safety assurance systems proposed by S. 641 are redundant and unnecessary.

COMPULSORY EFFECT OF SAFETY ASSURANCE SYSTEMS (SAS)

We are particularly concerned that the safety assurance provisions contained within S. 641 would turn a company SAS, once established, into a private criminal code, unequivocably binding upon the processor. According to the bill, failure of the firm to comply with its own system would constitute a violation of the Act, sanctionable by prosecution, seizure, or injunction. We would question the wisdom of such an approach, since the bill invests a certain dependence on industry knowledge and expertise as its foundation in formulation of adequate and ambitious safety assurance systems. The strict adherence provisions of S. 641 would be counterproductive to a processor's accepting primary responsibility for determining the guidelines and detail of its safety assurance system. Under onerous mandatory compliance provisions, the drafter of a company SAS would be inclined to draw narrowly the parameters for such a system, thereby negating any incentive for a creative, exacting, or ambitious standard for which a processor could strive under voluntary compliance such as that proposed by Title I of S. 1168. Under S. 1168, Title II, should a company fail to observe its SAS or if such SAS should prove inadequate, FDA still has recourse in that it may promulgate its own safety assurance standard to eliminate risk for that particular food or class of food.

Although milling has become a highly automated process, there are control points at various stages in the mill stream where the personal judgment and consequential actions of the head miller, based on long experience, figure prominently into the production of the final product. An allowance for this human factor would be a primary consideration in formulating any company SAS and would provide the necessary latitude required for the miller to exercise his judgment. Under the mandatory compliance provisions of S. 641, however, writing a standard so precisely as to provide for any contingency on the part of the miller—with the view that he will be held strictly accountable for any variation—would disallow this important input of professional talent.

RECORDS ACCESS

The Federation supports the records access provisions of Title IV, S. 1168 which would grant FDA authority to extend its inspection to company files and processes which are "reasonably necessary" for a determination whether foods are being rendered "unsafe or injurious to health." Our support of the amendment would be contingent upon maintaining the language in the bill which would provide recourse to a company in protecting its records—the language requires that an FDA inspector show reasonable need for record access and that the company have the opportunity to contest an inspector's demand, through the courts, if necessary.

On the other hand, analogous provisions of S. 641 require no predetermination for the necessity of records access by FDA, nor do they limit records access to matters directly linked to potential health hazards. Such a position would be untenable, we believe. Milling is a highly competitive industry, traditionally operating on particularly narrow margins—often not more than 1–2 percent. Furthermore, although the generic milling procedure is not secret in nature, certain individual company processes constitute trade secrets, as do the formulation for certain mixes, refrigerated doughs, and the wheat starch gluten process. Consequently, Federation members are particularly sensitive to the release of production figures, positions taken in the cash wheat or commodity futures market, or formulae of specialized products. Unrestricted records access provisions of S. 641 raise the spector of fishing expeditions through company files, detention of product on the assumption that minor misbranding may have occurred for reasons unrelated to safety or health, and the weakening of a company's competitive position. Past experience has shown that the Federation and individual members have cooperated fully with FDA officials in instances of short weight, rail car sanitation, and similar areas of FDA concern. We see no reason why such cooperations may not be expected to continue. However we specifically support having recourse provisions available to protect trade secrets and similar sensitive information.

DETENTION

Although we know of no instance in which a miller refused to comply with an FDA request to hold product voluntarily in light of a reasonable belief that the product was in violation of the Act, we concur that FDA should have the authority to detain goods if the inspector concludes that the facts warrant a "reasonable basis" to show that the food is "unsafe or injurious to health within the meaning of the Act." S. 1168 would provide such a mechanism and sets out a "reasonable period", not to exceed 20 days, for such detention.

Since millers often book bakery flour orders as much as four months in advance, since on-time flour delivery is crucial to bakery production runs, and since failure to meet shipping dates can result in cancellation of contracts or other financial loss, the Federation supports the reasonable procedural safeguards of S. 1168 to limit or at least provide a check upon the autonomous powers of individual inspectors.

ABSOLUTE CRIMINAL LIABILITY

Others, we feel, have argued persuasively before the Committees the issue of absolute criminal liability. The implications of the Park case recently decided by the Supreme Court will make themselves apparent repeatedly in future Food and Drug Administration actions. In this regard, the Federation wholeheartedly supports that section of S. 1168 which proposes to amend the Food, Drug, and Cosmetic Act to place it in conformance with other public safety laws which provide that criminal sanctions only can be imposed when it is proven that a violation is a knowing and willful act on the part of the person charged. Given the diversity of the production and distribution system of many of the Federation's larger members, application of strict criminal liability provisions against upper management levels, absent any willful or knowing violation, would appear to us to be inequitable to the extreme.

EFFECT ON STATE LAWS

Title VII of S. 1168 provides for uniformity in state and local regulations to ease any burden in the free operation of interstate commerce where such regulations conflict with Federal statute. It has been the finding of the Federation through experience with a Model State Enrichment Law for flour and flour products that provisions for uniformity are well received, often easing the burden upon state legislators and state Food and Drug officials. Therefore we support the uniformity provided by S. 1168.

UNIFORM CODING

S. 1168 does not speak to the specifics of food coding for recall purposes. Commissioner Schmidt supported in his testimony the objective of establishing a system of coding adequate to permit identification of products for efficient regulatory action, but he maintained that FDA has sufficient authority at present to require coding. Consequently, he labeled the coding provisions of S. 641 as unnecessary.

Millers have coded for years, on an individual company basis. The objection of the Federation to the coding provisions of S. 641 lies in that they may be construed to require a *uniform* system applicable to *all* millers or even to the *entire* processing industry. Such mandatory uniformity would be unacceptable to the Federation in that it would be economically unsound from a cost/benefit viewpoint and competitively debilitating as it affects the confidentiality of production statistics. Consequently, we would support mandatory coding, should the Committee feel it necessary, but would caution against provisions that would require uniformity.

In summary, the Federation would appreciate favorable Committee consideration of S. 1168, with particular attention to those provisions emphasized above. The overall record of the flour milling industry is excellent, particularly as concerns cooperation between the industry and government. Such cooperation, we believe, would be enhanced—to the mutual benefit of the consumer, FDA, and industry—by enactment of the moderate, yet effective, provisions contained in S. 1168. Conversely, the provisions of S. 641 which would augment

the regulatory burden would prove disruptive to industry, expensive to the consumer, logistically unmanageable for FDA, and counterproductive to the economy. We would recommend against its enactment without extensive amendment.

[The following information was referred to on p. 233:]

STATEMENT OF ASSOCIATED RETAIL BAKERS OF AMERICA

REPORT OF THE COMMITTEE ON OPEN DATING

The Retail Bakery Business is a unique manufacturing business. All of its divisions, whether a mama-papa bakery, a large individual bake shop that may hire up to 10–20 employees, an MUR bakery (one that bakes at one location and sells through a number of its retail stores), an on-premise supermarket bakery, or a donut shop, sell directly to the consumer.

They are dependent upon the customer's confidence and good will to bring her into their store several times a week for fresh bakery foods. Most of their variety is baked under their own supervision and sold unpackaged. Most items have a one day shelf life; a few items may be sold the second day. If not so sold, the bakery foods are then drastically reduced in price and sold in a "day old" department or a separate "thrift" store. There is never any confusion in the consumer's mind as to the freshness of the bakery foods she is buying.

These bakers bake their products fresh every day, 5 or 6 or 7 days a week, depending on the number of days their stores are open. Their operation differs from the wholesale baker who sells to the markets by salesmen, and whose bakery foods are left on the shelves either until they are sold, or go beyond their own private code date. We do not know of any reason why a retail baker should ever code date his products. Some bakers might wrap or package bread, cookies, buns and similar items for their customers' convenience, but these bakery foods are subject to the same freshness check and sale as the hundreds of other items the retail baker makes each week.

Consolidating the reasons for execpting the retatil baker from the provisions of a proposed "Open Dating" Act, they are:

1. Retail bakers bake primarily for sale only the day the item is placed on sale.

2. The retail baker's customers have confidence in the bakery store where they do their shopping. The baker is dependent on that confidence.

3. Only a small percentage of the hundreds of varieties produced each week are packaged.

4. Those items that are prepackaged are wrapped mostly by hand and the baker cannot support the sophisticated equipment needed for dating.

5. To label a product "Not to be sold after _____" or "Not fit for consumption after _____" would upset the retail bakery selling the items as "day old" in a thrift store or department. Since retail bakers usually operate on an 8%–10% of so called stales, the recovery from the sale of these foods is sometimes the entire net profit for the bakery. We know of no baker who would sell a perishable food, such as cream or custard goods, the second day.

6. The number of small businesses in the retail bakery field has been rapidly diminishing through the years. Most large cities such as New York, Chicago, Philadelphia, Cleveland, etc., have only about 15% to 20% the number of retail bakers they had a decade or two ago. Constant legislation and reports, with an altruistic background, have become a harrassment that discourages the most stouthearted individual businessman.

7. The retail branch of the Baking industry is unique from the other type of operations and should be made exempt from the proposed law.

8. Use of retarders and freezers for unbaked items permits the retailer to better regulate production to daily needs.

9. Evidence of the high standing of the consumers' preference for retail bakery shopping is found in the advertising of one of the prominent national bakers who says, "Our baking is just as fresh as the Retail Bakers."

10. There is no more discriminating judge of freshness than the housewife who regularly goes out of her way to shop our stores.

We definitely believe that for these reasons the Retail Bakers, including all facets of the Retail Baking Industry, should be exempt from the provisions of legislation on "Open Dating", such as H.R. 8417 and similar proposed laws. The consumer will best be served by permitting the Retatil Baker to build his own fine reputation for freshness and quality of his products without having a "pull date" to prolong the date of sale "for consumption without a high risk of spoilage or significant loss of nutritional value or palatability."

Respectfully submitted,

COMMITTEE ON OPEN DATING
ASSOCIATED RETAIL BAKERS OF AMERICA,
ARTHUR E. PILE, *Chairman,*
Hough Bakeries, Inc., Cleveland, Ohio.
DONALD A. KILWIN,
Kilwin's Bakery, Petoskey, Mich.
CLIFTON A. MYHR,
Myhr's Bakery, Minneoapolis, Minn.
JOHN JUBELT, *Ex officio,*
Jubelt's Variety Bakeries, Mount Olive, Ill.

This Report was reviewed by the Board of Directors and approved at the meeting of the Board in Denver, Colorado, on April 26, 1972.

RICHARD C. GOHLA,
Executive Vice President and Secretary,
Associated Retail Bakers of America.

STATEMENT OF THE CHOCOLATE MANUFACTURERS ASSOCIATION OF THE UNITED STATES OF AMERICA

We appreciate the opportunity to present the views of the Chocolate Manufacturers Association of the United States of America on S. 641 and S. 1168. The membership of the Association consists of fifteen companies which produce a substantial portion of the chocolate and cocoa products in the United States.

The members of the CMA are producers of quality chocolate and cocoa products for conversion into finished products or for sale to other food processors in semi-finished form.

We will direct our comments mainly to S. 641 and limit these comments to areas we believe are of major significance to our membership.

In general, the Chocolate Manufacturers Association approves the development of legislation or regulations where necessary to provide the consumer with a product produced under sanitary conditions.

The Chocolate Manufacturers Association will accept the development of quality assurance procedures by its membership as a means of improving the safe and sanitary operations of food processing plants. We would also agree to permanent registration of plants and the requirements to notify the Secretary when additional products are processed in covered operations.

We have additional specific comments on certain provisions of the proposed legislation, and we will discuss them on a section-by-section basis.

SAFETY ASSURANCE PROCEDURES

The principal issue on safety assurance is what additional authority the Food and Drug Administration needs to enable it to carry out its responsibilities in providing safe food products to the American public.

We have stated that we agree with the development of safety assurance procedures to aid in the enforcement of the act. Nevertheless, we believe those procedures should be limited to safety if the principal objective of the Act is to provide the consumer with a safe product produced under sanitary conditions.

There is already authority to seize adulterated food prepared under insanitary conditions in the Act and to inspect plants to insure that such sanitary conditions exist.

We favor the amending of the Food, Drug and Cosmetic Act to include in Section 410 subsections (a), (b), (c), (d), (e), and (f) (with a reservation for subsection (f)) as proposed in Title I of S. 641. These subsections will assist Food and Drug in carrying out its responsibilities.

FTC POWERS UNNECESSARY

The Chocolate Manufacturers Association does not believe the Food and Drug Administration needs to be granted powers held by other agencies, particularly the Federal Trade Commission. It is not necessary for the FDA to develop certain economic data in order to insure safe food products for the consumer, nor do we believe FTC penalties should be added to the penalties now contained in the Food, Drug and Cosmetic Act or proposed in this legislation.

We believe there should be a sharp distinction between the safety and economic principles involved in this legislation. We do not believe the food processor covered by the provisions of this Act should be held accountable for inadvertent failure or omission of a supplier to follow the letter of regulations concerning technical labeling and other conditions when the product offered by the supplier is otherwise perfectly safe and fit for use as a food. Unless an amendment is made to this Act, a food processor will be criminally and civilly liable for those events over which he has no control. We, therefore, offer the following as amendments to subsections (f) and (g) of Section 104 of the bill and to Section 402 of the Food, Drug and Cosmetic Act: "*provided, however, a food containing an ingredient received by the processor from third parties shall not be deemed to be adulterated solely because the ingredient would be deemed to be adulterated for failure to comply with this subsection.*"

RECORD-KEEPING AND AVAILABILITY

We believe it is necessary if this proposed legislation becomes law that adequate records be kept by the food processor covered undr the Act. Records will be necessary and essential for the FDA to carry out the new provisions of the bill. It will also be necessary for certain records to be accessible to the Food and Drug Administration to insure effective enforcement.

It is essential that, in addition to the protection of 18 U.S.C. 1905, and Section 301(j) of the Federal Food, Drug and Cosmetic Act, the trade secret exemption under 5 U.S.C. 552(b) needs to be maintained. Should an issue arise on what information should be disclosed, then appropriate Federal Rules of Civil Procedure should be utilized to determine the issue.

Leaving the trade secret provision in the section as proposed in S. 641 would invite litigation. It would be more appropriate to place the issue of trade secret in Section 704 and under the known restraints of 18 U.S.C. 1905.

EFFECTIVE DATE PROVISIONS

We are concerned about the relatively brief period under which those covered in this Act will have an opportunity to develop and implement safety assurance procedures required by this legislation. We would recommend that processors covered by this Act be allowed at least one year to complete and implement procedures. We believe this is necessary because conformity to this Act will be time-consuming and extremely costly to those covered by the Act, particularly if it involves construction or replacement of equipment. We are submitting an amendment to proposed Section 410(a)(1) (Section 102 of the bill) as follows: "Section 410(a)(1) A food processor shall, unless he is exempted by the Secretary pursuant to paragraph (4) of this subsection, develop [, implement, and maintain] safety assurance procedures for each establishment which he owns or operates. Such procedures shall be set forth in writing (in such manner and form as the Secretary shall prescribe), [and] such writings shall be available to the Secretary, within six (6) months after the date of enactment of this section *and such procedures shall be implemented within one year after the date of enactment of this section and shall thereafter be maintained.* In developing such procedures, a food processor shall——. . ."

We urge consideration of this provision even though some of our members are already participating in the self-certification of quality assurance program under FDA and the Good Manufacturing Practices for the Cacao Products and Confectionery Industries which were issued on June 4, 1975. The latter will aid significantly in reading compliance under the proposed quality assurance procedures; but if these procedures are to be implemented properly, they must be undertaken carefully and without haste.

CITIZEN SUITS

We believe there should be some system of civil action to redress grievances under this legislation, but we are concerned about the provision on citizen civil suits in S. 641.

As Section 410(g) is now written in S. 641, food processors covered by this Act could be placed in a position of legal harassment for any and all violations of their own procedures. The legal expense for defense against such actions will only increase the price of food to the consumer and will have little positive effect in the carrying out of the provisions of the Act to provide a safe product for public consumption.

The enforcement of this Act is the responsibility of a federal government agency, not the members of the public-at-large.

Therefore, if relief is to be obtained for citizens seeking such relief, it should be directed to the Administrator of this Act.

FOOD CODING

The Chocolate Manufacturers Association agrees there is a necessity for an adequate system of coding packages for foods. Our members already comply with identification of food and a system to determine when and where the food is processed. It is not clear in this legislation whether present company coding systems will be accepted. We believe they should be. As we interpret Section 411(a), present company coding systems will be accepted if they meet the standards developed by the Secretary.

If our interpretation is correct, Section 401(a) is satisfactory; but we believe the committee report should be enunciate the system(s) the Secretary will accept.

One concern we have is the confusion likely to be in the minds of the consumer if the "pack date" and "sell date" are both clearly identified on the same package. In addition, sell dates themselves also raise confusion. The American consumer generally has been educated by the film manufacturers, among others, that where a date appears on a package it signifies the date after which the product should not be used. We, therefore, would recommend that if a date must appear on the package it should be the "sell date" which is the one most important to the consumer's safety.

DISTRIBUTION RECORDS

We believe there is need for a proposed new section clarification under Section 411(d) on the information the Secretary will require in regard to distribution of records. As this section is now proposed, there are no limitations or parameters for the amount of information the Secretary may require, including records of invoices or other information accompanying each shipment. For recall purposes it should be necessary to show the coding information which would permit the identification of the product when it was produced, where it was produced, and to whom it was sold.

DETENTION

We recognize that FDA needs authority to detain products it believes are adulterated. This is in the interest of providing a safe product for the consumer. We question the length of twenty days which the FDA could detain a food as required by this Act.

We also do not believe that safe foods which are either misbranded or otherwise in violation of the Act, other than products deemed to be adulterated, should be detained by the FDA for such an extended period of time, if correction can be made promptly.

Food in violation of the Act unrelated to adulteration could be returned to the processing plant, rewrapped or changed in a way to be in compliance with the Act, and returned to the market in satisfactory compliance.

CIVIL PENALTIES

As the proposed legislation now reads in proposed new Section 308(a) of the Act (Section 106 of the bill), the Secretary (or his delegate) is the prosecuting attorney, Judge, jury, and the one who establishes the civil penalties.

We do not believe, as a matter of good principle or good law, that one agency should have this all-encompassing power. There should be a means of separating the prosecutorial and judicial functions in this legislation to provide a fairer and more impartial guarantee of justice for those prosecuted under the provisions of the Act.

We, therefore, recommend the following amendment to Section 308(a) of the bill with our amendments underscored as follows: "Section 308(a) Any person who is found by the Secretary after notice and an opportunity to be heard within ten (10) days from service of notice, [for an adjudicative hearing in accordance with Section 554 of Title 5 United States Code,] to have committed an act prohibited by the Section 301 of this chapter with respect to any food, shall be liable to the United States for a civil penalty of not more than $10,000 for each [day of] violation. The amount of such civil penalty shall be assessed by the [Secretary] *compliance branch of the Bureau of Foods of the Food and Drug Administration*, or [his] its delegate, by written notice. In determining the amount of such penalty, [the Secretary] *there* shall [take] *be taken* into account the nature, circumstances, extent, and gravity of the prohibited act or acts committed and, with respect to the person found to have committed such act or acts, any history of prior offenses, ability to pay and effect on ability to continue to do business, and such other matters as justice may require. *The Secretary shall establish a Board, without the Food and Drug Administration, consisting of three Administrative Law Judges, which Board shall be known as the Food SAFETY REVIEW BOARD. Any person who wishes to appeal a civil penalty assessed by the compliance branch of the Food and Drug Administration shall, within thirty (30) days of such assessment, file a request for a hearing by the Board and shall be entitled to a hearing by the Board in accordance with Section 554 of Title 5, United States Code, in which proceeding the compliance branch shall have the burden of proving the acts complained of by a preponderance of the evidence and the factors set out above shall govern the Board's determination of whether a penalty shall be imposed and the amount, if any, of such penalty.*"

There needs to be legislative history developed in regard to the civil penalties in Section 308(a). We believe that the fine should be based on each violation and not on each day. We also believe it should be clarified that if a dozen chocolate bars are misbranded that this does not constitute a dozen violations.

We further question the justification of adding a civil penalty on top of criminal liability for the same violation.

REGISTRATION OF FOREIGN PLANTS

The basic commodity for chocolate is the cocoa bean. It is a tropical crop grown in equatorial countries, primarily those classified as developing. There is a growing trend in these developing countries producing cocoa to establish processing plants to convert cocoa beans into semi-finished chocolate and cocoa products.

We support the registration of these plants, but our great concern is the time period in which foreign plants will be required to be in compliance with the provisions of this Act. There has not been a significant problem in safety of these semi-finished products entering the United States as they relate to the processing procedures in foreign countries. Therefore, we believe it is reasonable, since many of these producing countries do not have a large number of qualified personnel to have a number of years to adjust to these procedures. This will be necessary because the first step in bringing the processing plants in developing countries into compliance will be an educational program to train personnel to carry out required procedures.

We specifically request that the following amendment be included in the bill under Section 206 of Title II as follows: "*In countries classified as developing nations, compliance with the provisions of this Act shall be extended for a period of five (5) years from the day of enactment.*"

NUTRITIONAL LABELING

As we interpret Section 303 of this bill which adds Section 403(q) to the Act, if a food processor does not add nutrients to a product, such as chocolate products as defined in Part 14, 21 C.F.R., nor make any nutritional claims, nor advertise the nutritional value of such food, then such food processors

would not be required to provide nutritional information on the label and the food would not be deemed to be misbranded under Section 403(q) if no such claims were made and no nutritional information appeared on the food product label.

If our interpretation is correct, this meets the policy of the Chocolate Manufacturers Association which favors voluntary nutritional labeling whenever nutrients are added or nutritional claims made on the label or in advertising.

INGREDIENT LABELING

We believe the consumer has a right to know what is contained in the product, whether the product be a standardized or non-standardized food. We do not favor the percentage ingredient labeling for formulated foods. This is done not to disguise ingredient information about the product, because the consumers will know what is in the product, in order of predominance, by reading the ingredient statement. Listing percentages of ingredients is equivalent to making public secret formulas, which are protected under law and the protection of trade secrets are specifically mentioned in this legislation. We favor the deletion of the amendment proposed for Section 403(i)(2)(b) of the Act as contained in Section 305(a) of S. 641.

UNIFORMITY

We believe it is imperative that provisions be included in this proposed legislation to require the establishment of uniform state, federal, and local requirements for compliance with the labeling provisions.

ECONOMIC IMPACT

Prior to further consideration of this legislation, the Chocolate Manufacturers Association recommends to these subcommittees that the FDA be required to report to the subcommittees the economic impact and cost of adjustment of the industries for the inmplementation of this Act should it become law. We believe the public has a right to know what it is going to cost in increased food prices as a result of the food processing industry making necessary adjustments to the law and regulations anticipated by this legislation.

We thank the combined subcommittees for the opportunity to present the views of the Chocolate Manufacturers Association of the United States of America on S. 641 and S. 1168.

STATEMENT OF NATIONAL COFFEE ASSOCIATION OF U.S.A., INC.

The National Coffee Association of U.S.A., Inc., respectfully submits the following comments and recommendations concerning S. 641: The National Coffee Association (NCA) is a trade association which represents United States coffee importers (green or raw coffee), coffee roasters, and instant coffee manufacturers. NCA's members account for approximately 85% of the total volume of coffee imported into the United States. Coffee is the largest agricultural commodity imported into the United States.

The coffee industry of the United States, which annually imports raw coffee and processes and sells coffee products with annual wholesale value of about $2.5 billion to the American consumer, is proud of its record of manufacturing and marketing wholesome food products under the current Good Manufacturing Practice and Food Inspection Procedures. In this spirit, we support prudent and reasonable efforts to improve the system of consumer protection. At the same time, taking into account economic, proprietory and legal considerations, overkill should be avoided.

We feel that some provisions of S. 641 are worthy and desirable, some unnecessary but harmless, and some entirely undesirable.

Therefore, we submit the following comments on specific provisions:

A. IMPORTANT TO RETAIN

Sec. 102—The principle of making the food processor responsible for developing, implementing and maintaining safety assurance procedures is proper and reasonable and places the responsibility where it should be. This feature should be retained in the Bill.

Sec. 112—The specific prohibition against disclosure of trade secrets by the FDA is very important and any amendments that are made in this section should be for the purpose of making the protection as fool-proof as possible. The greater the assurance given to industry in this regard, the more companies will be come pro-active in cooperating with FDA.

Sec. 307—In view of the myriad of diverse state and municipal laws and regulations in effect or under legislative consideration with respect to food labeling, we consider it imperative that the Federal regulations preempt any such laws. Since the vast majority of the food business in the United States is interstate commerce, the industry must be relieved of the costly necessity of making its labels conform to as many different requirements as the number of political subdivisions in which it distributes.

B. AMEND OR DELETE

Sec. 106 & 107—It is absolutely impossible for a corporate officer in a large food company to be aware of every detail with respect to the compliance with the Food & Drug Law. In order to be so informed he would have to spend all his time being briefed on that aspect of the business and even this would not prevent the possibility of a violation occurring without his knowledge. Therefore, we consider it unconscionable to provide for criminal prosecution in this Bill and request that these sections be amended to provide that there is no absolute and vicarious criminal liability of an individual for the wrongful deeds of his employees, provided that individual himself did not knowingly and willfully violate the Act nor negligently authorize, order or perform a violative act.

Sec. 308—The civil penalty of $10,000 per day of violation is inappropriate because of the difficulty of determining a per day term of a violation. This section should be amended to provide a maximum penalty of $10,000 for *each* violation, rather than each day of violation.

Sec. 102—We feel that the FDA should have absolute authority to enforce this law because of the many, new, innovative concepts contained in it. Industry should not be subject to the harassment of possible citizen suits, at least for the first few years while the new requirements are being implemented. This provision allowing Citizens Civil Actions should be deleted in its entirety.

Sec. 111—It is obvious from a reading of *S. 641* that its main thrust is to protect the public from health risks from consumption of adulterated foods. Indeed, Sec. 111 contains language that would grant authority to the Secretary of the Treasury to refuse entry of any such food or class of food which the Secretary determines had not been produced in accordance with any safety assurance standard under Sec. 401 of the Act.

It also seems obvious that the Bill was not conceived or intended to protect the consumer against imported raw agricultural products which the Food & Drug Administration and U.S. Department of Agriculture already have the authority to inspect under existing law. We feel then that raw agricultural commodities should be exempted from the provisions of this section.

A special situation exists with green (raw) coffee which, as a raw agricultural product, is also not consumable in that form. Imported raw coffee must be roasted, and in the case of instant coffee manufacturing, further processed before it is consumable for use in preparing the beverage. The green (raw) coffee is inspected before it is passed for entry by F.D.A. and is further subject to Good Manufacturing Practices throughout the manufacturing process. Such manufacturing would come under the control of the new food surveillance authority provisions contained in the Bill.

Therefore, we feel that raw agricultural products in general, and in particular, such products as raw coffee that are imported in non-consumable form requiring processing in the United States, should be exempted from this section on imported products.

STATEMENT OF STANLEY STEINGUT, SPEAKER OF THE ASSEMBLY OF THE STATE OF NEW YORK

As Speaker of the Assembly of the State of New York, I am pleased to submit this statement in support of federal legislation designed to protect consumers from unsafe food. Provisions to increase the F.D.A.'s authority, by

granting the F.D.A. power to subpoena information, to detain adulterated foods, to require food processors to notify the agency of any recalls and to require them to keep records of processing procedures which the agency could examine, are appropriate and worthwhile legislative measures.

Of the two bills before you now, S. 641 and S. 1168, S. 641 is clearly a stronger measure to achieve the desired goals of the Congress, to protect consumers from unsafe food. However, certain provisions of the bills will have an adverse affect on New York State is left unamended. Following a detailed analysis of these two measures, John Dyson, Commissioner of the New York State Department of Agriculture, submitted a statement to you pointing out four major areas where changes in the bills are recommended. I support and would like to reinforce Commissioner Dyson's recommendations.

(1) *We request a maximum exemption clause to preclude the supercession of state label laws which are equal to or higher than federal standards.*

S. 641 provides for preemption of all state label laws requiring information which is in addition to or different from information required under the Act. This may adversely affect our current food enrichment laws as well as regulations governing the labeling of money and maple syrup products. Labeling requirements of the Kosher Food program may also be affected along with certain Milk Control regulations such as plant identification on milk products, special cheese labeling requirements and melloream standards. S. 641 calls for the approval by the Secretary of Health, Education and Welfare of state labeling requirements in addition to or different from federal standards. In addition to being cumbersome and time consuming, this type of federal review of state action is not likely to be responsive to the peculiar needs of a large state having a diversified population. The states should be permitted to establish labeling standards which provide a higher degree of consumer protection than federal standards. S. 1168 is too restrictive in that it actually prohibits state laws or regulations from imposing requirements that are in addition to or different from any requirements of the Act.

(2) *We request a modification of the provision permitting any person to commence a civil action against any other person who is alleged to be in violation of inspection and monitoring responsibilities.*

Since S. 641 provides very broad opportunities for any person to sue the F.D.A. and since the New York State Department of Agriculture and Markets is now engaged in many contracts with the F.D.A., the Department could very easily be dragged into irrelevant proceedings. Without modification of the civil action clause, the department could be dragged into costly, time consuming litigation in areas in which it is only peripherally involved through its contracts with the F.D.A. The department has had good work sharing agreements with the F.D.A. to date and future contracts seem desirable from the standpoint of continued Federal-State cooperation. Therefore, the civil action clause should be re-drafted so that cooperating state agencies would not be drawn into lawsuits that do not involve them in any substantial way.

(3) *We request an amendment allowing state registration or licensing of food processors in lieu of the proposed federal registration program.*

S. 641 requires a national biennial registration of food processors by the F.D.A. while S. 1168 requires one-time registration, to be kept up to date by requiring notification to the F.D.A. of changes in operation. Either of these registration procedures would duplicate New York's licensing activities under Agriculture and Markets Law, Articles 20–B and 20–C, which are actually broader than the proposed federal program, since we also license retail establishments. The federal legislation should contain provisions that clearly indicate that there will be no preemption of state licensing or registration of food processing establishments in those states that are doing an adequate job.

(4) *If the F.D.A. is to inspect state food processors annually, the Department of Agriculture and Markets' inspections should be accepted by the F.D.A. as equal to federal inspections.*

S. 641 requires an annual inspection by the F.D.A. of all food processors subject to the Act. The F.D.A. currently inspects processors on the average of once every three or four years. Should this ratio be reduced to one inspection per year, it would conflict with the same inspection ratio pursued by the New York State Department of Agriculture and Markets, resulting in both a duplication of effort and the possibility of over-regulation.

STATEMENT OF WAYNE L. CRAIN, MANAGER, PRODUCTION AND MARKETING DIVISION OF THE FLORIDA FRUIT & VEGETABLE ASSOCIATION

Mr. Chairman and Members of the Committee: My name is Wayne Crain. I am manager of the Production & Marketing Division of the Florida Fruit & Vegetable Association, 4401 East Colonial Drive, Orlando, Florida 32814. Our Association is a grower organization whose members produce a substantial volume of the fruits and vegetables grown in the state of Florida. Many of our members are disturbed by the broad implications of S. 641, The Consumer Food Act of 1975, should this bill pass and become law in its present form.

I request that this statement, with its comments on S. 641 and S. 1168, be made a part of the permanent record in the hearings due to begin in mid-June, since it will not be possible for me to make a personal appearance.

The Florida Fruit & Vegetable Association opposes S. 641 because its proposals would burden our industry with unnecessary and impractical regulations that in our opinion need not be so imposed under the assumption that our products cause or may cause consumer food poisoning. The majority of our growers produce fruits and vegetables primarily for the fresh consumptive market, and are not subject to adulteration in their raw, unpeeled form. Those growers who do produce crops for processors likewise deliver their products to the processors in a raw, unpeeled state. There is no factual evidence available that backs up claims that consumers have been subjected to food poisoning organisms from raw unpeeled fruits and vegetables at the farm level. The reason that fresh fruits and vegetables do not constitute a consumer food poisoning fear is the fact that these raw products do not provide a substrate on which such harmful microorganisms thrive and multiply.

The National Academy of Science Publication 1195,—Evaluation of Public Health Hazards—backs our claims as does the Vegetable Crops Department at the University of Florida. Based on this information, we see no need to include fresh fruit and vegetable packing and wholesale facilities to the surveillance procedures and regulations of S. 641. There should be complete and unequivocal exemption of fresh fruit and vegetable packing houses and warehouses from food plant surveillance procedures similar to the exemption expressed in S. 1168.

Our fruit and vegetable growers here in Florida are under great stress and pressure from a multitude of existing government regulations that already hamper production capabilities and reduce economic returns. The government regulations, recession and inflation factors all combine to restrict their production which only tends to decrease supply and increase food costs to consumers. There is no sure solution to the recession and inflation factors, but there is positive action that can be taken by government legislators and that is good legislation which will solve particular problem areas without burdening innocent people or industries. Senate Bill S. 641 may solve the overall problems of food contamination or adulteration but its all inclusive broad coverage features include our fruit and vegetable growers whom we feel are innocent as to source of contamination and should be exempted from surveillance.

The Association is optimistic enough to believe that this committee will seriously consider our comments on S. 641 and those from our "agricultural partners" nationwide—who feel as we do—and grant our fresh fruit and vegetable industries exemption from needless food plant surveillance procedures. We also want to state that the Florida Fruit & Vegetable Association does not oppose S. 1168 which gives our producers a clear-cut exemption from the Federal Food, Drug and Cosmetic Act for any establishment engaged exclusively in the handling of fresh fruits and vegetables in their raw, unpeeled form.

In closing, the Association wants you to know that we wholly support the views and comments of Mr. Bernard J. Imming, President of the United Fresh Fruit and Vegetable Association, Washington, D.C. of whose association we are an active member.

Thank you for the opportunity to express our comments on S. 641 and S. 1168 and we respectfully request that our fresh fruit and vegetable producers be exempt from food surveillance procedures under S. 641.

STATEMENT OF THE NATIONAL ASSOCIATION OF FOOD CHAINS

The National Association of Food Chains is a Washington-headquartered organization representing more than 200 supermarket chains, both large and small, located in all parts of the United States.

In submitting this statement to the Consumer Subcommittee of the Senate Committee on Commerce and the Health Subcommittee of the Senate Committee on Labor and Public Welfare, NAFC will focus attention on four issue areas related to S. 641.

Specifically, the food retail industry is concerned with: (1) retail exemption language as it applies to surveillance and registration requirements; (2) absolute criminal liability; (3) civil penalties provisions; and (4) open dating.

I. RETAIL EXEMPTION LANGUAGE

The development of efficient food retailing through supermarkets has been one of the notable achievements of this Nation during the last 50 years. The growth and development of supermarkets have produced significant improvements in the efficiency, economy, and sanitation with which food is handled. As supermarkets have developed, more and more food has been sold in packaged form, and less and less is ever touched by human hands in the retail store. Prepared foods are delivered in the same package from the processor to the retailer to the consumer. And, the trend toward more and better packaging continues. In fact, up to 70% of food products sold are untouched by retail handlers.

At the present time the meat and produce departments are the two principal areas where food is packaged at the store. There is a great tendency for more and more meat and poultry to be prepackaged under Department of Agriculture inspection, wherever labor contracts permit this more efficient practice. Many stores purchase prepackaged produce. Others rightly believe that consumers prefer to select produce in unpackaged form and therefore provide it in that manner. Whether produce is packaged or not, consumers will tend to reject fruits and vegetables which are off-condition. The greatest hazard of the overripe banana is to the reputation of the store which displays it.

We believe that food retailers have an outstanding record in food safety. We are not aware of any outbreaks of illness which have ever emanated from a retail store. We further believe we would know of any such outbreak, because it would be inherently traceable to its source.

At the present time, food retailers are subject to a variety of regulations. To the extent that retail food stores operate warehouses. bakeries, and similar facilities, these are subject to FDA inspection under the Federal Food, Drug and Cosmetic Act. Food retailers have always given full cooperation to both the Food and Drug Administration and the United States Department of Agriculture in the implementation of food recalls. Where food retailers package meat and poultry at a central location, such operations are subject to inspection under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

While FDA has jurisdiction over retail stores to the extent that they are in interstate commerce, state and local authorities have traditionally been more involved in health and safety regulations at the store level. This is both logical and appropriate. According to Food and Drug Administration estimates, there ase 80,000 food processors, 30,000 primary distributors (including warehouses), 500,000 retail stores, and 500,000 restaurants in the country. Registration or surveillance over retail stores and restaurants would increase the FDA workload tenfold. Fortunately, state and local food and health authorities have traditionally borne the administrative burden of overseeing retail stores and restaurants. And, the record will clearly show that this system has worked.

Further, the type of alleged undetected problems discussed at hearings in 1974 on S. 2373 and this year on S. 641 is totally unique to the manufacturing phase, and has no relationship to the retail outlet.

Finally, it is significant that FDA already has the authority to come into a retail food store and inspect food products on our shelves. If the food is found to be adulterated, FDA already has the authority to remove such products from the shelves.

To summarize, the nature of the surveillance function with its concurrent recordkeeping and subpoena authorities may well be appropriate to the processing phase, but would place an unjustified burden on retail stores.

In 1974 the Senate of the United States Congress affirmed that same conclusion when it passed S. 2373, which contained language exempting food retail outlets from surveillance and registration sections. S. 641 is similar to S. 2373 as passed by the Senate in the 93rd Congress.

However, a closer analysis of the exemption provision reveals the need for a technical change in the bill, as the current language falls short of accomplishing its intended purpose.

Titles I and II in S. 641 contain language stating that the sections shall not apply to processing which consists solely of the sale of food in a retail establishment for consumption on or off the premises. But, there are numerous activities related to the handling of food in a retail store which do not consist solely of the sale of food. The phrase "consists solely of the sale" is unduly restrictive, and could contradict the original intent of the exemption provisions. Thus, we recommend the following technical change: that the words "which consists solely of the sale" be deleted from Title I and Title II in S. 641.

II. ABSOLUTE CRIMINAL LIABILITY

We recommend also that the standards of criminal liability applicable to individuals under the Food, Drug and Cosmetic Act be revised and clarified. At the present time the nature of these standards is not clear, and the present statutory language has been construed as imposing absolute liability on a company's officers and employees, regardless of their lack of knowledge of or participation in an offense. To the extent that the Act can be or has been judicially construed in this manner, it operates to impose harsh and unrealistic criteria on individuals, such that they could be criminally convicted of an offense which they did every act reasonably within their power to prevent.

The objectives of the Act do not evoke such a stringent scheme of culpability. There are presently a multiplicity of legal requirements which have been added over the years since 1906. Regulations have been devised, containing numerous further requirements, and the principal features of the legislation presently being considered would also append major new obligations to the Act. Every obligation, many of these highly technical in nature, would be punishable by criminal sanction.

There is no basis for applying these sanctions to individuals where they are both unaware of the condtions resulting in the offense and have not participated in its commission, either by affirmative act or through some omission in the performance of responsibilities.

Compliance with the Federal Food, Drug and Cosmetic Act is an increasingly complex activity which requires the delegation of authority and responsibility, even in relatively small companies. The corporate manager can and should direct that his employees comply with each of the detailed requirements designed to prevent adulteration and misbranding, and he can and should monitor to ascertain that compliance is being achieved. However, the manager cannot inspect each batch of product or sweep every warehouse every day. He should strive for perfection, but he should not be treated as the guarantor that each company employee will perform perfectly each day.

The Committee is, of course, aware of the Supreme Court's recent decision in *United States* v. *Park*, No. 74–215 (June 9, 1975). This case represents the most significant explication of criminal liability standards under the Food, Drug and Cosmetic Act since *United States* v. *Dotterwich*, 320 U.S. 277 (1943). Unfortunately, the *Park* decision may have created more problems than it has resolved. In some respects its language appears only to impose a duty of due care on company officials and, indeed, the dissent characterizes the majority opinion as adopting a standard of "common-law negligence." Other language, however, appears to announce a remorseless strict liability standard requiring individuals to "implement measures that will insure that violations will not occur." If lower courts take hold of the latter words, individuals will assume positions of responsibility in the food industry on peril of criminal liability notwithstanding their earnest, diligent and good faith efforts to effect compliance. This result would neither be fair nor consistent with the purposes of the statute. Accordingly, we recommend that criminal liability for individuals under the Act be limited to willfull, knowing or culpably negligent violations.

This approach is consistent with recent Congressional enactments affecting health and safety. For example, the Clean Air Act of 1970 authorizes criminal penalties only where a person knowingly violates requirements of an applicable plan or knowingly fails or refuses to comply with an order of the Administrator. The Federal Water Pollution Control Act permits criminal sanctions only if it can be shown that a person willfully or negligently violated the Act. The Occupa-

tional Safety and Health Act authorizes criminal sanctions only where an employer willfully violates a standard or order, and that violation causes the death of an employee. The imposition of criminal liability under the Federal Food, Drug and Cosmetic Act should be placed on a basis consistent with the policy contained in these other more recent regulatory statutes.

III. CIVIL PENALTIES PROVISIONS

New provisions authorizing the imposition of civil penalties for violations of the Federal Food, Drug and Cosmetic Act would be added by S. 641. The concept of providing an added enforcement tool to assure compliance with the Act may be meritorious; the calculation of penalties on a daily basis is not. As presently drafted, S. 641 (at page 24, line 17) would allow the Secretary of Health, Education, and Welfare to impose penalties of up to "$10,000 per day of violation." This language is apparently drawn from other statutes where it is possible to calculate the days during which a violation occurs. We do not know how such a calculation could rationally be made for violations of the Federal Food, Drug and Cosmetic Act. In addition, the rapid cumulation of maximum penalties ($3,650,000 per year for a single continuing violation) would have a chilling effect on the willingness of alleged violators to defend themselves. Given the choice between asserting innocence and thereby risking multi-million dollar penalties or admitting guilt and accepting a token penalty, most accused violators would choose the latter and less-expensive course. Thus, the availability of large penalties calculated on a daily basis would encourage plea-bargaining and tend to coerce persons subject to the Act not to assert the legal defenses properly available to them.

IV. OPEN DATING

Title III, Section 302, would allow FDA to mandate open dating for perishable or semiperishable foods. The voluntary efforts of the retail food industry demonstrate that such authority is not needed. Several years ago the NAFC Board of Directors took a position in favor of voluntary open dating on perishable private label foods and millions of dollars have been spent in developing this vital consumer service for our customers. Today, over two-thirds of the stores of food chains and coops in this country put a pull date on all of their private label perishable and semiperishable goods.

In view of the voluntary initiative taken by the industry in the area of open dating, we strongly urge that the Subcommittees view Section 302 in a manner that will not negatively impact on those companies who are now open dating. Such action would certainly discourage further voluntary initiatives in the future, and would not be in the best interests of the consumer.

Thus, first, as indicated above, we question the need for the creation of statutory and regulatory date labeling requirements.

But, secondly, specific provisions of Section 302, as currently drafted, would negatively impact on many companies who are currently open dating.

Recall that over two-thirds of the stores of food chains and coops in this country put a pull date on their private label perishable and semiperishable goods. These company open dating programs have been accompanied by extensive educational campaigns that have explained the nature of the (pull-sell) date.

But, Section 302 would amend Section 403 of the Federal Food, Drug and Cosmetic Act by adding Subsection (p) (4) and Subsection (p) (5). Subsection (p) (4) would require that the date be accompanied by a statement or phrase which clearly states that the date expressed is a sell date.

As the pull date-sell date concept is not new and has been accompanied by comprehensive educational programs, such a requirement represents an unnecessary burden on food chains who have voluntarily used the simple pull date on their products.

Thus, NAFC recommends that the language in Subsection (p) (4) be deleted from the bill.

We make the same recommendation with reference to subsection (p) (5) which would require a statement of the storage conditions recommended by the processor, if such storage conditions differ from ordinary room temperature. It is our understanding that the act is intended to cover a variety of perishable and semiperishable food products. By definition consumers realize and commonly refrain from storing perishable and semiperishable food products at room temperature.

A law isn't needed to remind consumers that milk, for example, should be stored in the refrigerator.

Finally, we suggest that fresh fruits and vegetable be exempt from any mandatory open dating requirement. To date, it is technically impossible to determine with any degree of certainty a valid sell date for a particular lot of a fresh fruit or a fresh vegetable. As the United Fresh Fruit and Vegetable Association testified on June 17, 1975, "there are so many variables relating to genetic characteristics, horticulture practices, weather, growing and marketing diseases, temperature control, care and handling throughout storage, transportation, warehousing, and packaging procedures that each lot may be dated on the basis of the judgment of some person who may not be aware of what happened to that commodity."

AMERICAN MEAT INSTITUTE,
Washington, D.C., June 3, 1975.

Hon. FRANK E. MOSS,
Chairman, Subcommittee on Consumer,
Senate Commerce Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MOSS: As evidenced by the enclosed committee report, it was the apparent intent of the drafters of S. 641 and S. 1168 to exempt products subject to the Federal Meat Inspection Act. This statute provides a comprehensive system for assuring the wholesomeness of meat and meat food products and at the same time establishes authority for the Secretary of Agriculture to exercise a degree of control over product labeling that is not found in the general food laws.

It seems clear that there was no intent, in the drafting of the food surveillance bills, to dilute the authority of the Secretary of Agriculture or to create an overlapping jurisdiction in areas where Agriculture provides a comprehensive program for consumer protection.

It appears, however, that the exemptions found in Title I and Title II of S. 641 and in Title X of S. 1168 do not fully recognize the functions that now are the responsibility of the Secretary of Agriculture. In the case of S. 641, the exemption provisions read: "This section shall not apply to any processing subject to the exclusive jurisdiction of the Secretary of Agriculture." These exemptions would apply to the food surveillance and food establishment registration provisions, but may impose on meat packing and processing establishments all the food labeling provisions of the bill despite the fact that such establishments already are subject to the rigorous regulations of USDA.

In the case of S. 1168, the exemption provision reads: "Sections 410, 411, and 412 shall not apply to any processing subject to the exclusive jurisdiction of the Secretary of Agriculture." This omits any reference to Title IV, Title V, Title VI, Title VII, Title VIII, and Title IX of the bill. We suggest that the meat packing and processing industry, being already covered by a comprehensive system of inspection, surveillance and label control, does not require further regulation by a second agency of government and that the limited exemption found in these two bills would only create confusion and uncertainty.

We, therefore, urge that, to remove this confuction and uncertainly, whatever measure may be finally adopted contain an exemption applicable to each section.

We have been somewhat concerned about the language of the exemption where in it is stated that it applies to "any processing subject to the *exclusive* jurisdiction of the Secretary of Agriculture." Being mindful of the fact that other Federal agencies, including the Occupational Safety and Health Administration and the Environmental Protection Agency, have some limited jurisdiction over processing activities of the meat industry, we would have preferred specific reference to the Federal Meat Inspction Act. However, this general reference may be preferable because it would include a few other Federal statutes. The committee report enclosed should eliminate any doubt so far as meat inspection is concerned, and we urge that the exemption be included in the legislation without the present limitations as to sections.

We emphasize that we are not seeking any exemption from proper regulatory authority. We do ask that the clear authority now residing with the Secretary of Agriculture not be weakened or confused by exemption provisions that are not sufficiently specific.

Sincerely yours,

A. DEWEY BOND, *Vice President.*

ROSS LABORATORIES,
Sturgis, Mich., June 3, 1975.

HON. PHILIP A. HART,
U.S. Senate,
Washington, D.C.

DEAR SENATOR HART: The purpose of this letter is to express the concerns of Ross Laboratories with certain of the provisions contained in S. 641 entitled the "Consumer Food Act of 1975." Ross Laboratories, Columbus, Ohio, and Sturgis, Michigan, manufacture a number of food products and, therefore, would be greately affected by S. 641. While Ross is in complete accord with the general principle that this bill seeks to achieve, namely the assurance of a safer food supply for the American public, we are most concerned that certain unduly restrictive and over-burdensome provisions in the bill may deter from this basic purpose. For this reason, we are setting forth below a number of suggested changes we would respectfully request be taken into consideration during your deliberations on S. 641.

1. The Federal Food, Drug and Cosmetic Act has been interpreted by the Food and Drug Administration as placing absolute and vicarious criminal liability on corporate officers for the acts or omissions of their employees. Today's mass marketing, while providing lower cost foods, prevents company officers from being informed on every little detail. Placing such corporate officers in a position of criminal liability for unknown and unauthorized acts of employees is not only unconscionable but also has a chilling affect on decision making and innovation. In view of this, it is essential that S. 641 be amended to make it clear that under the Federal Food, Drug and Cosmetic Act there is no absolute and vicarious criminal liability of an individual for the wrongful deeds of his employees, provided that individual himself did not knowingly and willfully violate the act or negligently authorize, order or perform a violative act.

2. S. 641 provides for a uniform system of coding, while the need for uniformity clearly has not been established. What is important and what S. 641 should provide is that each manufacturer and packer be allowed to establish his own coding system to identify the information required under S. 641.

3. S. 641 authorizes the Food and Drug Administration to impose civil penalties of up to $10,000 per day for violations of the Federal Food, Drug, and Cosmetic Act. Unlike other laws applicable to injunctions or cease and desist orders there is no daily violation of the Federal Food, Drug, and Cosmetic Act. In view of this, it is essential that S. 641 be amended so that the proposed penalties provided are a maximum of $10,000 for each violation of the Act.

4. S. 641 provides that the Food and Drug Administration shall be granted investigative authority to issue subpoenas, to require reports and answers to interrogatories. Such information gathering is entirely too broad and must be limited to the food safety provisions of this bill. Access to information for the purpose of detecting non-food safety economic violations is unwarranted and will have virtually no effect on insuring the safety of the U.S. food supply.

5. S. 641 provides that anyone may institute a civil action against a food processor of the FDA to require or prohibit action with regard to certain activities required of the FDA under S. 641. These provisions are new concepts with which the government and industry are not yet familiar. Allowing private persons (including competitors) to bring such enforcement may prove counterproductive. S. 641 should be amended to delete entirely the authorization of citizen suits.

6. S. 641 provides the authority to the FDA to require percentage labeling whenever it might be useful. Such authority is entirely too broad and must be limited to those situations where FDA determines that a particular ingredient is a characterizing part of the food and has a material bearing on the cost, quality or nutrition of such food.

It is our sincere hope that the thoughts we have shared with you in this letter will be useful and will assist you in developing legislation which will help provide a safer food supply for the American people.

Sincerely,

CARL K. SYCKS.

FAR-MAR-CO., INC.,
Hutchinson, Kans., June 6, 1975.

Senator WARREN G. MAGNUSON,
Russell Office Building,
Washington, D.C.

DEAR SENATOR MAGNUSON: Please find enclosed a position statement by FAR-MAR-CO., Inc. regarding the U.S. Senate Bill S. 641. We urge you to share our concern over the immense magnitude of this legislation as it relates to the restriction of the regulatory flexibility of the FDA, the restrictions it imposes on the flexibility of industry to change safety assurance programs in processes that are in constant flux, the monetary impact on the FDA, industry and of course ultimately the consumer, and the many areas outlined in the attached statement.

As you may or may not know, FAR-MAR-CO is devoted to Research and its Quality Assurance programs. It is our professional opinion that this legislation adds nothing to the objective of providing quality products to the consumer. It is this opinion that prompts us to ask your careful and critical consideration of this bill and its impact on FDA, the Food Industry and the Consumer.

Sincerely,

FLOYD K. SHOUP, Ph.D.
Director, Research.

FAR-MAR-CO., INC.,
Hutchinson, Kans., June 6, 1975.

Subject: Position Statement on S. 641.

GENTLEMEN: This statement of position put forth by the FAR-MAR-CO., INC. Foods Division is intended to delineate our interpretations and opinions of S. 641.

FAR-MAR-CO Food Operations were created to fill a need which was perceived in marketing products which our respective shareholders produce. Toward that end FAR-MAR-CO has attempted to develop an organization committed to ethical and competent business practice in the food ingredient field. FAR-MAR-CO, at the division headquarters, has a research laboratory committed to the technical enrichment of this field and practices involved therein. FAR-MAR-CO is submitting this statement in response to what is perceived as a situation of immense magnitude as is embodied in S. 641.

POSITION STATEMENT

FAR-MAR-CO Foods Division wishes to enter, for the record, its opposition to legislation proposed in S. 641 and S. 1168.

While FAR-MAR-CO, INC. agrees with the purposes and ideals of the bill, it does oppose the manner and form set forth in the bill to direct implementation of specific processes to achieve those goals.

SECTIONAL DELINEATION

Title I—Food Surveillance: Sec. 101 (Amendment to Sec. 201)(y).

The definition of food processor is vague as to what processing is. Perhaps —The term 'food processor' means any person who owns or any establishment which is engaged in the manufacture of food which at some point in the process itself shall be subject to change by that process.

As the definition now stands, it is a description of itself. It does not make clear just what a food processor is and what constitutes that definition.

Also, in subsequent sections of the bill focus liability in civil suit action on food processors. As is stated in the bill, the responsibility for any given employee misconduct perpetrated without the knowledge of the "owner" or operator would subject those people to legal liability and fines. This statutory placement of burden upon personnel not necessarily informed of each and every employee conduct borders on the elimination of certain civil rights to which that person is entitled.

Sec. 102 Chapter IV "Food Surveillance"; "Safety Assurance Procedure."
Sec. 410 "Safety Assurance Plan"; "Safety Assurance Standards."

FAR-MAR-CO tends to agree with Dr. Alexander Schmidt of the Food and Drug Administration in his overall views relating to these sections of the bill. The very specification of the details involved removes from both the FDA and industry the ability to be flexible in handling quality assurance.

The FDA now, through the good manufacturing procedures and other authorities, has the ability to work meaningful quality assurance programs into practice and concurrently retain the flexibility to implement change when needed.

As Dr. Schmidt also pointed out, any legislative definitions promulgated to date has been incomplete in some manner or form. In dealing with ongoing techniques, procedural research, product improvement, the FDA must retain the inherent flexibility to progress with technological advances. To legislate such strict procedural aspects as put forth in S. 641 would tend to impose restraint in forward progress in product advancement by requiring methodology and procedure to be adhered to which might be totally inappropriate to the situation.

Due to the very nature of this proposed action, the government is intending to oversee and restrict a process in industry which is in constant flux. Any changes necessary would be limited to those which the government issued approvals to. Time delays included would complicate or eliminate any effective changes or any trials of in-process procedures.

Quality assurance monitoring can and should be a dynamic process. A program should have the ability to focus on areas which require more attention than others.

When, after a period of observance, that area of manufacture that requires attention stabilizes, the level of surveillance should be decreased and the concentration shifted to those other areas less consistent. This would apply in cases of new equipment new processes, process changes, raw material problem, etc.

In light of the inherent philosophy of "good manufacturing" procedures which the FDA promulgates, it appears that all industry is automatically assumed by S. 641 to be unreliable and consciously attempting to produce inferior products which are willfully distributed.

The FDA, via seizure and prosecution, could place the manufacturer in a position such that quality assurance records would be presented in court cases. In that event, all records would become public knowledge. The open records provision in S. 641 does not, in and of itself, automatically prevent products—adulterated or misbranded—from entering interstate commerce. It merely opens another unnecessary control point.

"Notification." S. 641 states that information derived from notification relevant to adulterated products shall not be used as evidence in the event of criminal prosecution. In paragraph 2 the notification is delineated with no limitation on information input.

Therefore it could be construed that by a very precise, totally encompassing notification relative to the events involved in adulteration and release, all criminal liability would be waived due to the specific exclusion made in paragraph one.

"Citizens Civil Actions." Due to the provisions allowing for civil suits against the Secretary of HEW for failure to "comply with the safety assurance plan established under section (b) of this section or to perform any act or duty under this section. . . ." vis a vis subsection b(4), page 5–6, lines 25–3 which requires a yearly inspection of all establishments engaged in food processing—if *any* one establishment, regardless of that establishments size, is not inspected in a given 12 month period, the Secretary is liable to prosecution.

Further, due to the judicial system's reliance on precedence, the allowance for civil suits would cause immense legal problems for the FDA. Any citizen (whether independently or as an agent of a company) could bring suit against a "food processor." The FDA is not, by prerequisite, involved. However, due to the possible ramifications of a decision, the FDA should have some input into the proceedings. This could conceivably become an immense network of legality which might never be resolved.

Due to the voluminous numbers of food establishments engaged in processing food, it is obvious that significant manpower requirements will emanate from this legislation. Also due to the bureaucratic tendency involved, any effective enforcement program also obviates significant personnel to be involved above

those conducting field inspections. This would be necessary to merely protect the Secretary's legislative liability.

Such enforcement would be a prerequisite to immense field personnel expansion.

"Food Coding"; "Uniform System." There exists no real definition of the word "uniform"—is this to be interpretative relative to its application as meaning (either)

1. Uniform—on a nationwide scale with each processor having FDA requirements to meet relative to coding sequence and meanings, or

2. Uniform—within a given company such that said company can identify and distinguish its own products and also that the FDA is made aware of the code and interpretations thereof, or

3. Uniform—within subsections of food industries involved, each given class of foods will have uniform coding requirements nationwide.

Also in the event that any given processor has a program which generates hundreds of formulae for new products used in commercial channels, then each product, regardless of its longevity, would require a code number. Such code numbering would require a complex and large volume of numbering systems to cover the gamit of any given individual food made by any processor.

The provision which would allow each processing company to have its own systems if deemed adequate to permit reasonable tracing of food product distribution (pages 19–20, lines 23–8) [subsection (e)] would result in an unenforceable proliferation of numerical systems pursuant to all other specified sections of the act. Also, as Dr. Schmidt pointed out in his comments, the FDA already has authority to enact a coding system under existing laws.

"Civil Penalties." FAR-MAR-CO feels that the $10,000 per day penalty is going to be an unworkable situation. We tend to agree with Mr. T. Hanold's June 4th statement that it would be difficult to "compute a daily violation" based on current food manufacturing systems and distribution schemes.

"Availability of Records." This section provides open access to nearly every facet of business which a company might be engaged in. It would in effect make any companies' records subject to public knowledge.

The direct application to the bill in terms of safety assurance is unclear at this point. It appears that what is wanted is more data not particularly relevant to a safety assurance procedure.

We would reiterate those statements made by Mr. Terrance Hanold regarding the section in his June 4th statement titled "Reasonable Bounds to Governmental Information Access".

Sec. 111 Section 801(e)(1)(2) & (3). Import Adherence to the Quality Assurance Provisions of S. 641.

Any and all raw ingredients used and imported, e.g., spices, would be drastically affected due to the economic and technical requirements of the act.

The net effect would be either mass prohibition of importation of a wide variety of materials or a complete breakdown in enforcement to allow such importation.

The entire section is infeasible without specific delineations which are not provided.

FAR-MAR-CO has serious questions as to the possible extension by statute of this bill to cover every food importation situation. In particular, we are concerned with the extension to such items as spices. In the case of, for example, black pepper, it seems somewhat unreasonable for the small Indian field grower to institute quality assurance procedures (ne. HAACP) to his crop.

It would seem to be unreasonable to impose, or attempt to impose this type of regulation on totally unenforceable systems.

Sec. 112 Section 705(c). This section provides the Secretary with the discretion to make public any information which he, on his own initiative, deems nonsecretive relative to an organizations internal functions.

Whereas provision is made for rebuttal, it is still an unacceptable proposal. In the event that a court action is initiated and the party involved wins nondisclosure rights, said party still is liable to pay costs involved to prevent an unjust act from occurring. Therefore the burden of proof lies with the processor in all instances, the Secretary has no inherent restraints to restrict or augment judgment.

FAR-MAR-CO., INC. agrees in principle with this segment of S. 641. However, it does find the limits of statutory imposition totally inappropriate. As FDA Commissioner Schmidt pointed out in his June 4th statement, FDA already has the authority to implement food establishment regulation. S. 641 merely puts a time imposition in, also causing monetary problems.

As Dr. Schmidt stated, it will cost the FDA about 3 million dollars just to initiate this segment of the act. This figure does not take into account the cost to industry. President Ford's moratorium on new spending is for the federal government, but it also in fact tends to encompass impacts derived from new spending.

"Registration of Food Establishments." General. Sec. 412(a). It is absolutely necessary for the Secretary to promulgate the defining of food classes. In as much as a specific time requirement is placed on the registration provisions of this section, they should be exempted until such time as the Secretary published the list defining the food classes in order to facilitate expeditious and concise statements of registration.

"Foreign Registration." (g) Is this merely provision for or requirement of foreign registration?

If it is construed to mean requirement of, it becomes quite infeasible vis a vis arguments in previous sections.

Also this ambiguity if further promulgated on page 37, lines 15–18(2). "The Secretary *may* refuse entry" indicating a discretionary power which circumvents certain regulatory requirements.

"Open Dating." Sec. 302 Section 403. This section requires: (1) Open dating listing the sale date requirements for retail consumption, (2) conspicuous package printed date information, (3) statements which expressly state that the date is a sale date, (4) storage conditions. This would tend to place in-line process control from one processor to another to ensure adequate product distribution to avoid any processing delay overlap which might result in out of date product distribution. (Specifically in those products which will be consumed in product preparation for retail sale (spices, etc.).)

Such in-line reliance would put responsibility for any violation of adulteration by dating in a state of limited liability and confusion.

"Nutrient Labeling." No clear definition of nutrient—therefore, any food which has a nutritional value of any sort or function can be considered misbranded unless specific claims are made to the contrary.

Sec. 304 Section 403(g). This new addition leaves off, "and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such foods" from the existing labeling regulations.

This regulation therefore declares that there must be specific declaration of individual spices on a label of a food with a standard of identity which requires label information. The purpose of individual spice declaration is not clear or obvious nor is it herein specified as being exempted as before in the existing regulation.

In view of the current studies being conducted, this section is relatively obscure as to what realized benefits will be obtained from spice delineation.

Sec. 305(a) Section 403(i). Spice and Flavoring Labeling. In general, this section should be deleted as there is presently an ongoing FDA study into the relative GRAS status of spices and flavorings which would promote more significant knowledge toward legal labeling status of such ingredients.

FAR-MAR-CO is also concerned with the statement, "if information concerning each spice and flavoring not designated on the label is available upon request from the manufacturer or distributor named on the label."

Any information considered proprietary by our company would have to be divulged to our customers, allowing competition/competitors to have access, at the customers discretion/or their request, to predominance listings of spices in any given seasoning blend which would eliminate any trade secret combination of spices which yields products indigenous to our specific business.

Sec. 305(a) Section 403(i). Part B. No clear definition of value or purpose (e.g., monetarily, nutritionally, functionally, etc.) is made in relation to percentage declaration criteria.

Sec. 305(a) Section 403(k). *Study to Require the Name Listing of Every Spice and Flavoring Listed Specifically*

The one year restriction is probably insufficient time to make conclusions which will allow adequate compilation of data to precede any recommendation. This provision is also redundant in view of studies currently being conducted by the FDA.

As a summarizing statement, we merely wish to reiterate our opening statement which indicates our opposition to S. 641. We do agree with the concept of providing quality products to the American consumer and we are constantly striving to upgrade the performance of the food industry. We do feel, however, that S. 641 is counter-productive toward achieving this goal.

We appreciate the opportunity to express our views and appreciate your efforts on behalf of the American consumer.

Sincerely,

DEREK PARK,
Technical Service.
WAYNE E. HENRY, Ph.D.
Vice President, Food Operations.
FLOYD K. SHOUP, Ph.D.
Director, Research.

INSTITUTE OF SHORTENING & EDIBLE OILS, INC.,
Washington, D.C., June 18, 1975.

Hon. FRANK E. MOSS,
Chairman, Subcommittee on the Consumer, Senate Committee on Commerce, Washington, D.C.
Hon. EDWARD M. KENNEDY,
Chairman, Subcommittee on Health, Senate Committee on Labor and Public Welfare, Washington, D.C.

DEAR MR. CHAIRMEN: We are writing in support of S. 1168, a bill to regulate interstate commerce and protect consumers by requiring improved safety assurance measures in food manufacture and distribution and registration of producers of food. This bill, drafted by a group on industry representatives, was introduced by Senator Stevens, by request, so that it might be considered along with S. 641, prepared and introduced by you, Senator Magnuson, Senator Hart and Senator Javits.

It seems in order first to explain how we came to draft S. 1168, and why we favor it over S. 641.

When S. 2373 was under consideration in the 93rd Congress, we addressed ourselves to the public policy issues with which it was concerned. We found that while there were several points in the bill that we could and would support, it was nonetheless objectionable because it required or permitted an unnecessary (and in our view inappropriate) intervention of the regulatory agency (FDA) into the specifics of how foods are produced and processed for interstate distribution and how the safety of those foods is assured in the public interest. Further, we were concerned about the expansive inspection authority and subpoena power that the bill would have conferred, and we believed that the criminal provisions of existing law are too harsh.

We concluded that it would be desirable to propose a reasonable alternative to S. 2373, in the hope of achieving a consensus that all concerned could support and could bring to early enactment.

Specifically, we found S. 2373 (and S. 641) objectionable because it called upon food processors to prepare and place in operation safety assurance programs meeting certain detailed specifications (e.g., to identify critical control points and to describe the controls and monitoring steps required for safety assurance), and then made the inadvertent deviation from the safety assurance plan itself an adulteration of the food, as well as a basis for criminal action against the processor. Thus, each processor's plan became, for him, a private criminal code. This would have forced each processor to seek the lowest common denominator, because any effort to achieve a higher order of safety assurance would have subjected the processor to a higher risk of criminal action against himself.

S. 2373 (and S. 641) then called upon the Secretary of HEW to prepare an annual safety assurance report, which would include a proposed safety assurance plan in the form of regulations designed to control any risks identified in the report. As envisaged by the bill, this report would specify the date by which certain safety assurance steps would have to be taken, and would detail

the particular methods of inspection and monitoring to be carried out. The plan would have to provide for at least annual inspections of each food processing establishment; and the annual reports would be followed up by the promulgation of regulations embodying safety assurance standards. These standards would cover such details as the specific "contaminants, properties, unsanitary practices, and other factors" to be attended to by surveillance, as well as the sampling methods, methods of analysis, type of instrumentation, etc. to be observed.

We were not surprised that Dr. Schmidt has said that it would not be possible for FDA to carry out such an ambitious program. We submit that such a program is unnecessary to assure food safety, and that it would so bind food processing in governmental red tape as to transfer responsibility for food safety from the processor to the Government, because processors would be forced, under threat of criminal law, to follow mandated procedures.

Further, we found S. 2373 (and S. 641) objectionable because of the breadth of unrestrained inspection authority and other regulatory mechanisms that were included.

The alternative we proposed in S. 1168 was to require the processor to prepare, record, and place in operation a safety assurance program for his plant, and provided that a failure to have such an ongoing plan described in writing, or to produce it at the request of the Secretary, would be a prohibited act, punishable by criminal action and enforceable by injunction.

The basic difference in the bills is that inadvertent deviations in detail from the surveillance plan would not themselves be criminal acts, but the processor's failure to have in operation an appropriate safety assurance plan, available for the Secretary's inspection, would be an offense.

Further, S. 1168 provides that the Secretary could require, upon finding that a significant number of establishments were producing food in a manner to present an unreasonable risk that the food would be unsafe or rendered injurious to health, that that segment of the industry conform to a safety assurance standard prescribed by regulations. Upon promulgation of the standard, in accordance with the Administrative Procedure Act, processing in violation would be an offense.

We believe that our alternative fixes the responsibility for safety assurance primarily upon the processor, where it properly belongs, but allows the Secretary to intervene by regulations into particular situations needing control by regulations, rather than giving FDA overall supervisory responsibility for food safety surveillance industry wide.

A point has been made that our alternative does not go far enough because it deals with safety—not sanitation. In considering this point, it must be kept in mind that matters of food sanitaiton are already adequately regulated—in the opinion of some, over-regulated. Under existing law, food is adulterated if it consists in whole or in part of any filth, putrid, or decomposed substance. It is also adulterated, even though it contains no filth, if it has been prepared, packed, or held under unsanitary conditions whereby it *may* have become contaminated with filth or whereby it *may* have been rendered injurious to health.

Adulteration which occurs at the point of production of the raw materials, of finished food, or even at the point of storage in a warehouse or display at retail can give rise to seizure, injunction, or criminal prosecution of any person who stands in a responsible relationship to the violation—even though he may be wholly innocent of any criminal intent or criminal awareness of the causes of the adulteration.

In like manner, food is adulterated if it bears or contains any added poisonous or deleterious substance that may render the food injurious to the health of any part of the consuming public—the old or the young, the well or the sick, the weak or the strong. Not only that, any substance used in food handling or preparation—whether an intentional additive or an indirect additive—which is not either generally recognized as safe among qualified experts or proven safe by scientific studies and allowed by affirmative FDA action—is classified as an adulterant with all the regulatory consequences we have described.

Beginning with a decision by the Court of Appeals for the 7th Circuit in the 50's, FDA was encouraged to, and did, adopt regulations describing the conditions of current good manufacturing practice. The violation of these regulations, according to the Agency and very respectable judicial authority, makes the food so produced an adulterated food.

With this impressive legal armamentarium one can not help but wonder what else the FDA could possibly need to carry out a rigorous sanitary and safety surveillance program. It must be kept in mind that the new legislation proposed does not repeal, modify, or supplant existing authority. It is not written on a clean slate, but instead is amendatory of the basic Federal Food, Drug and Cosmetic Act which contains the provisions we have summarized.

Since S. 1168 was prepared, Dr. Schmidt has testified before your Subcommittees that FDA does not seek new statutory authority to promulgate food surveillance regulations. The Commissioner stated that FDA already has ample authority to promulgate binding regulations relevant to food safety surveillance. Thus, we conclude that Title I and II of S. 1168 (as well as Section 410(a), (b), (c), and (d) of Title I of S. 641) are not supported by the FDA, and we do not press the provisions of S. 1168 that we devised on food surveillance over the FDA's wishes.

Title III of S. 1168 addressed the issue of registration of producers of food. We support registration, and we have sought to make it as inexpensive and effective for FDA, as possible. Commissioner Schmidt testified that the Agency could not allocate the funds to carry out the registration responsibility. Again, we will defer to the Agency's wishes on this point.

Dr. Schmidt's goals for food legislation were confined to better inspection authority, to record keeping and reporting by industry processors, to administrative subpoena power, administrative detention authority pending the initiation of seizure actions, and to the clarification and expansion of certain food labeling requirements.

INSPECTION AUTHORITY, SUBPOENA POWER AND ADMINISTRATIVE DETENTION

S. 1168 addresses the inspection authority, subpoena power, detention issues. We support (Title IV of S. 1168) additional inspection authority. We request the addition of provisions that would give the food processor the explicit right to contest, at both the administrative and judicial level, any demands for inspection rights that he believed unreasonable, before the processor could be charged with a criminal offense for refusing inspection. The Supreme Court, in *See* v. *Seattle*, 387 U.S. 541, decided only a few years ago (1967) held that this right was a constitutional right. The Supreme Court there said that books and records subject to subpoena may not be inspected without judicial review of the reasonableness of the demand. That principle also applied to inspection without a subpoena. We want this constitutional right written into the law so as to minimize or eliminate friction when the inspector makes a judgment on the spot in the plant that he must have access to material the processor believes is not subject to inspection. The processor should at that point have the right to appeal to the Agency and, if necessary, to the Courts to challenge the reasonableness of the inspector's demand.

As to the product detention pending seizure, we find no fault with that—indeed, we endorse it. We request only a right to an expedited hearing on the detention, when there is reason to bring the issue to a determination quickly.

Subpoena power of the type exercised by the Federal Trade Commission was requested by Dr. Schmidt.

We submit that the expanded inspection authority, which we endorse, provides ample authority for FDA. FTC is concerned with economic and deceptive practices, with respect to which subpoena authority is more appropriate. Therefore, we oppose this additional authority on the ground that adequate inspection authority would give the Agency all the power it needs to enforce the law.

We do not object to the provision for record keeping and reporting to supplement the Agency's inspection authority. Again, we would want a right to challenge unduly broad reporting demands.

S. 1168 restricts access to records to matters involving safety. Sanitation inspection is a physical inspection which does not require access to records as a routine matter. The exceptional case where record access may be needed can be handled under existing law. Also S. 1168 provides appropriate protection to trade secret and confidential commercial information, the same way the Freedom of Information Act does.

We do not object to a provision for citizen suits to require the enforcement agency to exercise non-discretionary duties. We do object—as does FDA—to private enforcement suits.

ADDITIONAL LABELING REQUIREMENTS

As to the added labeling authority proposed by S. 641, we offer the following comment:

Coding. We do not object to a requirement of product coding. We agree with FDA that a uniform system of coding, published in the manner prescribed by Section 411 of S. 641, would be very expensive and unnecessary to enable the Agency to determine the manufacturing history of the coded lot of food.

Produrt Dating. We believe this provision should be restricted to products that are perishable or semi-perishable, and thus require an out-date. It should not apply to products that are hermetically sealed to prevent deterioration or to other products with an indefinite shelf life long enough to assure retention of quality during their expected shelf life and use after purchase.

Nutrition Labeling. We find no objection to FDA's program of voluntary nutrition labeling. But Sec. 303 of S. 641, which is intended to codify the current requirements, is subject to misapplication. This is because it would require nutrition labeling for any food to which a nutrient or nutrients are added. Literally this would include any food which contained any fat, protein, or carbohydrate, those being the essential nutrients. What FDA means by "nutrient" in its current program is added vitamins, minerals, amino-acids; not fat or carbohydrate.

Ingredient Labeling. We do not object to requiring standardized foods, as well as unstandardized ones, to bear ingredient statements.

Percentage Labeling. Where this type declaration is required to avoid misleading the public, it can properly be required.

Criminal and Civil Penalties. We believe that criminal penalties should be restricted to knowing and willful violations of law, not to inadvertent or negligent ones. Civil penalties are appropriate for the inadvertent or negligent violations.

FEDERAL-STATE UNIFORMITY

Both S. 641 and S. 1168 address this important issue. S. 641, Section 303, declares it the Congressional intent to supersede any and all state and local laws that provide for information on the label or in the labeling of food that is in addition to or different from the information required by or under Section 403 of the Federal Food, Drug, and Cosmetic Act, as amended.

Provision is made for the State and local authorities to seek exemption from the Secretary of Health, Education and Welfare.

S. 1168, on the other hand, would not supersede State and local laws. It would mandate uniformity, then leaving it within the authority of State, local, and Federal officials to enforce the uniform requirements.

We strongly favor National uniformity in food, drug, cosmetic and medical device labeling. It is impossible to conduct a National distribution program when special products with special labels have to be prepared to meet the different demands of Federal, State, and local laws and ordinances. Food is a commodity of National distribution, for the most part, so uniformity of legal requirements is a must.

We have undertaken to mandate uniformity in this fashion. All requirements made by or under authority of the Federal Food, Drug, and Cosmetic Act would be declared enforceable by Federal and State authorities in both Federal and State Courts. This is similar to the approach taken in S. 642, which Senator Moss introduced.

It has these advantages. For consumers, it assures them the up-to-date protection of a comprehensive food and drug law, without regard to the interstate character of the food. For State officials, it has the advantage of updating a number of State laws, some of which are based upon the 1906 Food and Drugs Act, and none of which is wholly uniform with the Federal law. For industry it provides a uniform code.

It will be said that this takes away the power of the States to adopt innovative amendments to the food and drug laws. S. 1168 provides a mechanism through which any State official could initiate a change in the uniform law and could be heard on it. Such a change would have to go through the National legislature—The Congress—to preserve the National uniformity policy so essential for the public interest.

We will be pleased to discuss any part of this letter with you, with your staff, or with the Committee staff, should you see fit to call upon us.

Respectfully,

WILLIAM W. GOODRICH, *President.*

POULTRY & EGG INSTITUTE OF AMERICA,
Washington, D.C., June 19, 1975.

Hon. FRANK E. MOSS,
Chairman, Consumer Subcommittee, Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR SENATOR MOSS: Your subcommittee is currently considering S. 641 and S. 1168 on Food Surveillance. We feel sure it is the intent of the sponsors of this legislation, and we hope of the committee, not to require duplicate registration and inspection of food establishments which are required to be inspected continuously by the Department of Agriculture pursuant to such statutes as the Federal Meat Inspection Act, Poultry Products Inspection Act and the Egg Products Inspection Act.

It is our opinion that Section 24 of the Poultry Products Inspection Act, as amended, exempts from the provisions of the Federal Food, Drug and Cosmetic Act every establishment at which the inspection of the slaughter of poultry, or processing of poultry products, is maintained under the authority of the Poultry Products Inspection Act, as amended.

Further, it is our opinion that Section 23 of the Egg Products Inspection Act confers exclusive jurisdiction in the Secretary of Agriculture over official plants processing egg products and operations thereof and exempts such plants and operations from the provisions of the Federal Food, Drug and Cosmetic Act as to all matters within the scope of the Egg Products Inspection Act.

Though we do not speak for the meat industry, it is our opinion that the same exemption exists in the Federal Meat Inspection Act.

To require duplicate registration and inspection of such establishments would be burdensome upon and expensive to industry and costly to taxpayers without added benefit to consumers.

Both of the proposed bills do exempt plants under the "exclusive jurisdiction" of the Secretary of Agriculture. But we are concerned about any ambiguity that might exist in that phrasing. It is clear to us, the Congress decided that jurisdiction for poultry and egg inspection, as well as meat inspection, is clearly in the Secretary of Agriculture. Congress should continue to establish that policy, we believe.

We respectfully suggest that the following language be considered instead of the "exclusive jurisdiction" language: "Poultry and poultry products, meat and meat products and eggs and egg products shall be exempt from the provision of the Act to the extent of the application or extension thereto of the provisions of either the Poultry Products Inspection Act, as amended or the Federal Meat Inspection Act, as amended, or the Egg Products Inspection Act, as amended."

Thank you for your consideration.

Sincerely,

LEE CAMPBELL,
Vice President.

THE RICE MILLERS' ASSOCIATION,
Washington, D.C., June 19, 1975.

Hon. WARREN G. MAGNUSON,
Chairman, Senate Commerce Committee,
Washington, D.C.

DEAR SENATOR MAGNUSON: The Rice Millers' Association wishes to go on record in opposition to Senate bill 641, the Consumer Food Act of 1975.

The Rice Millers' Association is the trade association of the nation's rice milling industry. Headquarters of the Association are in Washington. D.C.

There are 30 rice milling companies in The Rice Millers' Association—27 in the southern states of Arkansas, Louisiana, Mississippi, and Texas—and 3 in California. Members of the Association process 100 percent of the rice produced in the South, where about 80 percent of all U.S.A. rice is produced, and about 25 percent of the rice produced in California. Both independent rice milling companies and rive grower cooperatives are members of the Association.

We believe S. 641 is unnecessary and would simply add to the pyramiding number of federal agencies and federal reporting requirements affecting business in general, and particularly the food industry.

All rice processing plants are currently subject to daily inspections by rice inspectors of the Department of Agriculture, who work closely with the Food

and Drug Administration. We believe the USDA, and the Food and Drug Administration are currently performing adequate surveillance of rice processing plants, and are very adequately protecting the interests of consumers.

In our opinion, there is a greater need for a complete review of the federal regulatory system rather than enactment of new laws and establishment of new regulatory agencies. The burdensome requirements of current unnecessary regulations are adding to the cost of foods to the consumer and making it increasingly difficult for small business to operate.

A review will show a quagmire of regulatory requirements involved in OSHA, EPA, FDA, USDA, and the Department of Commerce. The Committee would do the consumer and food processor a great favor if current regulations could be made more simple and more realistic. We hope this will come out of your current hearing.

We wish to request the views of The Rice Millers' Association be placed on the record of hearings on S. 641.

Sincerely,

J. P. GAINES, *Executive Vice-President.*

NATIONAL COTTONSEED PRODUCTS ASSOCIATION, INC.,
Memphis, Tenn., June 23, 1975.

Hon. FRANK E. MOSS,
Chairman, Subcommittee on the Consumer,
Senate Committee on Commerce, Washington, D.C.
Hon. EDWARD M. KENNEDY,
Chairman, Subcommittee on Health,
Senate Committee on Labor and Public Welfare, Washington, D.C.

DEAR SENATORS MOSS AND KENNEDY: This communication seeks to make known to you the views of the National Cottonseed Products Association, Inc.,[1] on food surveillance legislation (S. 641, "Consumer Food Act of 1975" and S. 1168, "Food Safety Assurance Amendments of 1975") which is being jointly considered by you and the other distinguished members of the subcommittees.

We address ourselves to the subject of adequacy of the existing Federal Food, Drug and Costmetic Act (Act) and to the contrasting provisions of S. 641 and S. 1168. We believe that the existing Act gives FDA completely adequate authority to protect the safety and wholesomeness of the American food supply and that FDA has employed this authority effectively. If the Congress, in its wisdom, finds it desirable to amend the Act, we strongly support S. 1168 in preference to S. 641 for the welfare of consumers, effective administration by FDA, and fair and reasonable operation of the food industry.

STATUS OF FOOD SAFETY

We submit that United States citizens have the most safe, nutritious, economical and abundant food supply known in the history of man. We believe that the Congress will carefully evaluate the probable effects of any amendments to the Act upon each of these factors.

We strongly support the concept that food safety and health must be considered foremost. However, considering the high degree of wholesomeness which has been achieved, we believe that food economy and abundance must be considered as vital issues. It is axiomatic that the cost of compliance with regulatory requirements eventually becomes a part of food costs at the retail level. It is too seldom recognized that regulatory costs pyramid from step to step through the food chain.

The greatest danger which exists is that governmental regulation will proceed to the point that food costs will increase to such degree that a significant sector of the consuming public will be unable to maintain an adequate level of nutrition. The spectre of economic imposed malnutrition is the most horrible of food safety risks.

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[1] The National Cottonseed Products Association, Inc., is a national trade association whose members process more than ninety percent of the cottonseed produced in the United States. The industry is deemed by the Food and Drug Administration to be engaged in food processing because it produces crude cottonseed oil which, after further extensive processing by other manufacturing plants in other industries, becomes an edible product. Cottonseed oil is second in volume only to soybean oil as a domestic source of oils and fats. The members of this Association operate plants in each of the fourteen cotton-growing states.

Yes, incidents—minor to the picture of widespread food safety—have occurred and will continue to occur infrequently regardless of the degree of regulatory restrictions which may be enacted. We are deeply distressed that testimony given in support of various amendments to the Act have unduly magnified and even distorted food safety dangers. The Commissioner of Food and Drugs, a truly dedicated and knowledgeable advocate of strict regulation, testified to you on May 4, 1975 that it is "highly unrealistic" to require FDA to formulate a plan which would guarantee complete freedom from food safety risks within four years. That is probably the most profound statement which has been made during the many hearings on these amendments.

VIEWS ON PROPOSED LEGISLATION

The food industry has an inherent obligation to regulate its own processing controls in such manner that the consumer is provided safe, non-injurious food. We believe (1) that this is effectively done under the existing Act, and (2) that S. 641 denies industry the privilege of effective, economical prevention of hazards. S. 1168, while it adds to both Government and industry costs unnecessarily, would not remove from industry needed self-regulation.

This Association strongly supports S. 1168 over S. 641.

Issue No. 1—Unsafe or Injurious vs. Adulterated:

S. 1168 addresses itself to safe, unharmful food, whereas S. 641 encompasses the entire category of adulteration. We submit that only food safety can be the issue at stake in consideration of the proposed amendments. FDA has very specific authority under the existing Act to prevent the practices of insanitary procedures, misbranding, etc.

Issue No. 2—Safety Assurance Procedures or Systems:

We concur that food processing plants should develop, maintain, and follow effective food safety systems and that FDA should have access to such documents. In fact, this Association worked extensively in the development of crude cottonseed oil sanitation guidelines in coordination with FDA. Thus, we can support Title I of S. 1168 which provides for precisely what we have done.

In contrast, we believe that the safety assurance procedures imposed by Title I of S. 641 are unworkable and an infringement on the Constitutional rights of food processors. These "procedures" constitute a self-imposed penal code upon the processor because any departure therefrom constitutes a prohibited act subject to criminal proceeding. Thus, the safety assurance procedures drafted by any processor will be far less exacting than his normal safety control program and will be degrading to efforts to produce safe, non-injurious food. Further, the very requirement that a food processor subject himself to a self-imposed penal code is an outrageous violation of his rights.

The Commissioner of Food and Drugs has testified in opposition to the requirement of either safety assurance procedures or safety assurance systems and his advice should be followed.

Issue No. 3—Safety Assurance Plan:

The proponents of S. 641 are completely unrealistic in their attempts to require the Secretary to publish a plan and an assessment report which will completely eliminate unreasonable risk of adulteration within four years. The Commissioner of Food and Drugs would have been less than honest and not worthy of the trust placed in him if he had not testified (June 4, 1975) that such is "highly unrealistic." Since FDA finds that such a plan would be time-consuming, burdensome, and unnecessary, the Congress should not so hinder the Agency by enacting the requirements therefor.

Issue No. 4—Safety Assurance Standards:

The Standards provided for in S. 1168 relate to the subject of safety and hazards which the proponents of amendments have defined as the need for legislation. In contrast, the standards provided for under S. 641 relate to the all inclusive designation of "adulteration" which is unnecessary as stated under Issue No. 1. The Commissioner of Food and Drugs is fully justified in his concern that enactment of specific authority to publish these standards with the full force and effect of law may adversely affect its authority for rule making and invite prolonged litigation.

Issue No. 5—Plant Registration:

This Association does not object to plant registration, as provided for in S. 1168, if FDA finds it is needed to enforce the existing Act. Apparently, the Commissioner believes such registration would be unduly costly and would hinder ongoing enforcement programs. We suggest that the Congress accept his considered professional assessment.

Issue No. 6—Citizen Suits:

The Commissioner is precisely correct that citizens now have adequate avenues for judicial relief and opportunity to participate in rule making. He demonstrates keen perception in pointing out that the citizen civil actions provisions of S. 641 would encourage one processor to sue another for alleged violations. From an industry standpoint, this provision would be intolerable and could result in legalized restraint of trade.

Issue No. 7—Detention:

S. 641 would unjustifiably permit an FDA inspector to detain foods solely upon his opinion, or even bias, without adequate administrative or judicial recourse to the food processor. In contrast, S. 1168 gives FDA authority to detain foods which may be subject to seizure because there are facts to indicate that they are hazardous. S. 1168 rightfully gives the food processor the privilege to appeal to a superior official within FDA who is outside the operating line of command for the inspector who moves for detention. Surely this is only reasonable and fair procedure.

Issue No. 8—Record Inspection:

S. 641 grants an FDA inspector unstified and unreasonable authority to demand broad inspection of records without giving the food processor the right to contest the unreasonableness of the request. In contrast, S. 1168 grants adequate authority to inspect records which may be unreasonably expected to relate to food hazards. Further, S. 1168 grants the processor the right to contest the demand to inspect records which the processor believes to be unreasonable. The Supreme Court decided (*See* v. *Seattle*, 387 U.S. 541) in 1967 that books and records subject to subpoena may not be inspected without judicial review of the reasonableness of the demand. Thus, it is entirely correct that this principle be written into any law which relates to record inspection.

Issue No. 9—Reports and Replies to Questions:

S. 641 requires food processors to make any reports and reply to any questions which may be demanded by FDA. Such requirement approaches self-incrimination, and would be unnecessarily costly to both FDA and food processors.

Issue No. 10—Subpoena Powers:

S. 641 grants FDA the power of subpoena which is of the kind granted to the Federal Trade Commission. We submit that, whereas it may be necessary for FTC to have such power in order to deal with deceptive and far-reaching economic matters, it is unreasonable and unnecessary to grant such powers to FDA because it has adequate authority to regulate food safety.

Issue No. 11—Interstate Commerce:

S. 641 explicitly states that it is a rebuttable resumption that any food found in any state is subject to seizure and condemnation. This places unreasonable burden upon food processors and handlers. It is unnecessary since FDA has the power to seize and condemn any violative food should it move into interstate commerce.

Issue No. 12—Criminal Liability:

The existing Act is unjustifiably harsh in providing for criminal liability without knowledge or intent. We strongly support S. 1168 which amends the Act to limit criminal liability to knowing and willful violation.

Respectfully,

FRED H. HUSBANDS,
Executive Vice President.

UNITED FRESH FRUIT & VEGETABLE ASSOCIATION,
Washington, D.C., June 24, 1975.

HON. FRANK E. MOSS,
Chairman, Subcommittee for Consumers,
Committee on Commerce, U.S. Senate, Washington, D.C.

DEAR SENATOR MOSS: Thank you for your inquiry of June 20 regarding my testimony before the joint Commerce and Labor and Public Welfare Committees on S. 641.

You ask whether it is our contention that aflatoxins, mycotoxins and microorganisms about which the Washington Post article of Sunday, June 15, 1975 spoke do not appear in fresh fruits and vegetables?

Any microorganisms which live in the soil can and do appear on fresh fruits and vegetables but organisms which are toxic to humans are not effectively transmitted by fresh fruits and vegetables because they do not multiply sufficiently on these products. We do not include soy beans, peanuts or other nuts in the fruit and vegetable class. So far as food poisoning is concerned, fresh fruits and vegetables in their original form (and not including any dishes to which there have been such additions as mayonnaise, milk, eggs etc.) have not been a medical problem. In my testimony I meant specifically to state that fresh fruits and vegetables have not caused such food poisoning as botulism, salmonellosis or staphylococcus poisoning.

We do not contend that there are no toxins of any kind in fresh fruits and vegetables. Virtually all foods have some naturally occurring toxins, as set forth by the National Academy of Sciences in the book "Toxicants Occurring Naturally in Foods." My testimony was addressed to the issue of whether any legislation is necessary to protect the public against any form of poisoning from fresh fruits and vegetables. Our conclusion is that there is no such necessity, because these products are in no way a menace to the public due to microorganisms.

My understanding is that problems with aflatoxins have been mainly related to moldy peanuts although they may also relate to moldy cereals; and problems with mycotoxins have been mainly related to moldy cereals.

I have reviewed the transcript of my testimony, made a few structural and grammatic changes and already returned it to the Committee.

Sincerely,

BERNARD J. IMMING, *President.*

STATE OF NEW YORK,
DEPARTMENT OF AGRICULTURE AND MARKETS,
Albany, June 25, 1975.

HON. FRANK E. MOSS,
Chairman, Consumers Subcommittee,
U.S. Senate, Washington, D.C.

DEAR SENATOR MOSS: We are pleased to have the opportunity to offer our views on proposed Senate Bills S–641 and S–1168.

We acknowledge the worthy intent of both bills to protect consumers from unsafe food by increasing the regulatory authority of the Food and Drug Administration. Provisions that would grant the FDA authority to notify the agency of any recalls and require them to keep records of processing procedures which the agency could examine are recognized by us as appropriate and desirable legislative measures.

It is our opinion that Senate Bill S–641 most clearly acknowledges the intended objective of strengthening the FDA's regulatory procedure. There are, however, certain provisions of this Bill, as well as S–1168, which are not acceptable to the Department of Agriculture and Markets either in whole or in part. Each of the provisions in question is discussed below.

1. *Provision:* S–641 provides for preemption of all state label laws requiring information which is in addition to or different from information required under the Act. Such preemption may adversely affect our current food enrichment laws as well as regulations governing the labeling of honey and maple syrup products. Labeling requirements of the Kasher Food program may also be affected along with certain Milk Control regulations such as plant identification on milk products, special cheese labeling requirements and melloream standards.

The Bill provides for the Secretary of Health, Education and Welfare approval of state labeling requirements in addition to or different from Federal standards. This type of Federal review of state action is cumbersome, time-consuming and not likely to be responsive to the peculiar needs of a large state having a richly diversified population. All states should be free to establish labeling standards which afford a higher degree of consumer protection than Federal standards.

S–1168 goes even further than S–641, in that it would prohibit state laws or regulations which impose requirements that are in addition to or different from any requirements of the Act.

Resolution: The Department requests the imposition of a maximum exception clause which would preclude the supersession of state laws which are equal to or higher than Federal standards.

2. *Provision:* S–641 provides for any person to commence a civil action against any other person who is alleged to be in violation of Section 410(c)(1) of the proposed law which includes inspection and monitoring responsibilities. Since we are now and may later be engaged in surveillance contracts with FDA, the Department could be subject to suit by any party for alleged inspection inadequacies.

Resolution: The Department requests the modification or deletion of the civil action clause to eliminate the threat of suits challenging the regulatory decisions. We have had good work sharing agreements with the Food and Drug Administration to date and future contracts are desirable from the standpoint of continued Federal-State cooperation.

3. *Provision:* S–641 requires a national biennial registration of food processors by FDA while S–1168 requires one-time registration. Either of these registration procedures would duplicate our Article 20–B and 20–C licensing activities.

Resolution: The Department strongly recommends an amendment allowing state registration or licensing programs in lieu of the Federal programs. (Our current registration program is actually broader than the proposed Federal program since we also license retail establishments.) It is our opinion the Bill should contain a clause which clearly disclaims an intent to preempt state licensing or registration of food processing establishments.

4. *Provision:* S–641 requires an annual inspection by the Food and Drug Administration of all food processors subject to the Act. FDA currently inspects processors on the average of once every three or four years. Should this ratio be reduced to one inspection per year, it would conflict with the same inspection ratio we pursue, resulting in both a duplication of effort and the possibility of over-regulation.

Resolution: If FDA is to inspect state food processors annually, the Department will either withdraw inspection from the affected establishments or petition the Food and Drug Administration to accept our inspections as equal to the Federal.

We again wish to thank you for the opportunity to submit our views on S–641 and S–1168. We support the concern of your committee that our food supply be rendered as safe and wholesome as possible. Should you desire any further comment on our part, we will gladly provide it.

Sincerely,

JOHN S. DYSON.

AMERICAN SOYBEAN ASSOCIATION,
Hudson, Iowa, June 27, 1975.

Hon. FRANK E. MOSS,
Senate Committee on Commerce,
Washington, D.C.

DEAR SENATOR MOSS: Enclosed are copies of correspondence between this office and the Federal Food and Drug Administration. I have taken the liberty to mark parts of the letters pertinent to the question of whether U.S. consumers have the right to know what they are eating. The Food and Drug Administration is still following a letter written in 1940—several years prior to research connecting fatty acid consumption to heart attacks.

Palm oil contains 51.9 percent saturated fatty acids and coconut oil with 91.5 percent can freely be substituted in shortenings without label identification.

Although federal law requires label identification, FDA continues to allow shortening manufacturers to use the catch-all term "vegetable oil." Soybean oil and corn oil contain only 13.7 percent of saturated fats versus 85.1 unsaturated.

I sincerely hope that you can and will use all of your considerable influence to help us rectify this deplorable situation.

Sincerely yours,

RALPH T. JACKSON,
Executive Vice President.

Enclosures.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., June 3, 1975.

Mr. RALPH T. JACKSON,
Executive Vice President, American Soybean Association,
Hudson, Iowa.

DEAR MR. JACKSON: This replies to your letter of April 18, 1975, concerning the labeling of shortening and other edible oil products.

As we previously advised you, the labels of shortening and other edible oil products should identify the specific fats and/or oils contained therein. Failure to do so would constitute a violation of the Federal Food, Drug, and Cosmetic Act.

We will promptly investigate your charges that there are shortening and other edible oil products on the market which are not so labeled. We would appreciate any specific information you may have concerning the identity of these products.

Sincerely yours,

ALEXANDER M. SCHMIDT, M.D.,
Commissioner of Food and Drugs.

AMERICAN SOYBEAN ASSOCIATION,
Hudson, Iowa, June 27, 1975.

Dr. ALEXANDER M. SCHMIDT,
Commissioner, Food and Drug Administration, Department of Health, Education and Welfare, Rockville, Md.

DEAR DR. SCHMIDT: We have your letters of June 3 and March 26, 1975, advising that "labels of shortening and other edible oil products should identify the specific fats and oils contained therein" and the "failure to do so would constitute a violation of the Federal Food, Drug and Cosmetic Act." We also have Associate Commissioner Fine's letter of June 20, 1975, reversing this advice on the basis of trade correspondence letter 62 of February 15, 1940, and stating that FDA "cannot object at the present time if hydrogenated vegetable, animal and/or marine oils are declared as such without naming each." Commissioner Fine also advises of a proposal made on June 14, 1974, but still not in effect to rescind the trade correspondence letter of 1940.

The American Soybean Association calls on you again to enforce the law which requires that labels identify specific fats and oils. We call on you to hasten revocation of trade correspondence letter 62 as we proposed over a year ago. We look forward to an explanation for the inordinate delay in effecting such revocation.

Dr. Schmidt, I need not tell you as a physician of the advances made in recent years in knowledge of the relationship of saturated fatty acids to cardiovascular disease. It is incongruous and archaic for a letter written 35 years ago to be operative today in face of (1) the law, (2) what is known now about saturated fatty acids, and (3) the advice given by many physicians to cardiovascular patients to avoid saturated fatty acids—advice which they cannot follow if products are not labeled as to specific oil content.

In light of the medical advice given many consumers and in any case their basic right to know what they are eating, there is a demonstrated need now for full disclosure of specific oils on labels as the Congress intended—not only disclosure for shortening but also salad oils and high oil content foods which today do not enjoy such labeling to the detriment of the consumer. In addition, as I said in my letter of April 18, such full disclosure is important to open a fair competition among the different fats and oils.

We understand the problems of the oil industry with regard to reprinting labels and would favor a reasonable time for change over, say six months.

The American Soybean Association would appreciate meeting with you within the next two weeks at your convenience to discuss this situation.

Sincerely yours,

RALPH T. JACKSON, *Executive Vice President.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., June 20, 1975.

MR. WILLIAM KLING,
American Soybean Association,
Washington, D.C.

DEAR MR. KLING: This replies to your letter of June 10, 1975 concerning the labeling of shortening and other edible oil products. I am also furnishing certain information you requested in the course of our telephone conversation on June 19, 1975.

Our letters of March 26 to you and June 3 to Mr. Ralph Jackson indicated that all shortening and liquid oil products must identify the specific fat or oil components by their common or usual names. We have given further consideration to the question of shortenings and, in the light of the opinion expressed in Trade Correspondence Letter 62 (TC–62), we can not object at the present time if hydrogenated vegetable, animal and/or marine oils are declared as such without naming each. While we have proposed to rescind this opinion (*Federal Register*, June 14, 1974), this is not final. We are advising the Institute of Shortening and Edible Oils that shortening products must be labeled as prescribed by TC–62 or be considered in violation of the Federal Food, Drug, and Cosmetic Act and subject to regulatory action. This means that those oils which have been hydrogenated must be identified as "hardened" (or "hydrogenated") vegetable, animal and/or marine oil(s). All non-hydrogenated oil products must, of course, bear the specific common or usual name of each oil ingredient.

We are aware that many foods, such as bakery products, do not identify their specific fat or oil ingredients. However, we did not mean to imply in our letters of March 26 or June 3 that we were now in a position to object to such labeling. The use of the term "shortening" on the labels of such things as bakery products and "vegetable oil" (or "vegetable shortening") on the labels of potato chips and sticks was authorized in other trade correspondence, TC–94 and TC–209, both of which were proposed to be rescinded in the June 14 proposal.

As I informed you in our June 19, 1975 telephone conversation, our Bureau of Foods has advised me that it will forward to the Commissioner in about 3 months a draft order ruling on the June 14, 1974 proposal.

Sincerely yours,

SAM D. FINE,
Associate Commissioner for Compliance.

SHORTENINGS—LABEL DECLARATION OF INGREDIENTS

Held, under circumstances presented, that labels such as "made exclusively from Hardened Vegetable Oils," etc., may be considered as satisfactorily meeting the branding requirements of Section 403(i)(2) with respect to listing ingredients of certain shortenings.

TC–62—FEBRUARY 15, 1940.

(Letter dated April 12, 1939, signed by Acting Secretary of Agriculture).

"On March 24, 1939, your committee presented a petition for the issuance of a regulation under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act exempting shortenings of the type manufactured by the Institute of Shortening Manufacturers, Inc. from the requirement that the names of the individual animal, vegetable, and marine animal oils and fats entering into the composition of these products be declared upon the labels. You were accorded a hearing on March 29, 1939.

"At this hearing your committee discussed orally and elaborated upon the statements made in the petition which accompanied your letter of March 24, 1939. This petition was supplemented also by a further memorandum submitted by Mr.

James G. Parry of your committee on March 30, 1939. It is noted that your products fall into three general types: (1) vegetable shortenings composed wholly or mixtures of edible vegetable oils, which have been subjected to a chemical hardening process known as hydrogenation; (2) mixtures of vegetable oils with or without varying proportions of hardened vegetable oils and with edible animal fats; and (3) hydrogenated mixtures of vegetable oils and marine animal oils. The products under group 2 are in general manufactured under inspection by the Bureau of Animal Industry. The products included in class 1 are labeled 'Vegetable Shortening' or 'Made exclusively from Vegetable Oils'; those in class 3 as 'Made from Marine Oils and Vegetable Oils.' Since, according to our understanding, all the ingredients, in types 1 and 3 are subjected to hydrogenation which has the effect of changing the identity of the ingredients, it is the present conclusion of the Department that labels such as 'Made exclusively from Hardened Vegetable Oils' or 'Made exclusively from Hardened Mixtures of Marine Animal Oils and Vegetable Oils' may be considered as satisfactorily meeting the branding requirements of Section 403(i)(2) of the Act. It is our understanding that the industry is entirely willing to employ this type of branding. Under these circumstances an exempting regulation with respect to these classes of products need not be considered.

"The same reasoning applies to products in class 2 where the entire mixture has been subjected to a hydrogenation process. The Department has reached the conclusion that where such mixtures contain animal fats or vegetable oils which have not had their identity changed by hydrogenation, there is no justification for exempting the products from the requirement that the specific names of these unaltered animal fats or vegetable oils be declared on the labeling.

"In advising you that the vegetable shortenings and the vegetable and marine animal oil shortenings, and those vegetable and animal oil shortenings which have been subjected to the hardening process may be labeled as 'Made from Hardened Vegetable Oils,' or 'Made from Hardened Mixtures of Animal Oils and Vegetable Oils' as the case may be, we are discussing exclusively the fats and oils used. Should any non-fat constituents be incorporated, their declaration may be necessary. In addition, the articles should comply with all the other provisions of the statute. Should it later develop that the form of labeling discussed herein either results in deceiving the public or in withholding any substantial information of the kind guaranteed to the consumer by Section 403(i)(2) of the Food, Drug, and Cosmetic Act, the Department reserves the right, on appropriate notice to the industry, to modify this opinion."

AMERICAN SOYBEAN ASSOCIATION,
Washington, D.C., June 10, 1975.

MR. SAM FINE,
Assistant Commissioner for Compliance,
Food and Drug Administration, Rockville, Md.

DEAR MR. FINE: Further to our telephone conversation and to Commissioner Schmidt's letter to Mr. Ralph Jackson of June 3, enclosed is a list of products that do not identify specific oils on labels as gathered by a staff member of our Association at a supermarket in Iowa. I have had the same experience in Washington, D.C., and Falls Church, Virginia.

The American Soybean Association appreciates your assistance.

Sincerely yours,

WILLIAM KLING, *Washington Representative.*

AMERICAN SOYBEAN ASSOCIATION,
Hudson, Iowa, April 18, 1975.

DR. ALEXANDER M. SCHMIDT,
Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Rockville, Md.

DEAR DR. SCHMIDT: The American Soybean Association resolved at its semi-annual meeting in Waterloo, Iowa on April 4, 1975 to request that your Bureau enforce existing labeling regulations with respect to generic names of oils in shortening and other edible oil products. This is essential because of the medical aspects of oil consumption, particularly the health needs of many people who are advised to consume oils that are low in saturated fatty acids.

We are informed by your staff that existing labeling regulations require that generic names of oils be listed on labels, as per attached letter from Mr. M. L. Gates of your Bureau. However, examination of stocks on grocery shelves reveals that labels do not provide such information, most shortenings referring only to "hydrogenated vegetable oil" as to content.

At present large quantities of palm and similar oils are being imported into the U.S. to be blended, in shortenings especially. Palm oil has an extremely high saturated fatty acid content but consumers will be unaware of their consumption of palm oil.

Please be assured that we are pursuing this matter in the interests of open and fair competition. We believe that soybean oil should compete with other oils on the basis of full disclosure. The policy of the American Soybean Association is to foster open and growing international trade. We do not seek to impose import restrictions on palm oil. We do seek to require that imported oils, just as U.S. produced oils, be bound by labeling requirements that inform consumers of oil content in the interest of their health and in the interest of trade which must be fully informed if competition is to be equitable and effective.

If you are unable to enforce the existing regulations to this end, then the American Soybean Association will recommend that a stronger labeling law be enacted by the Congress.

I would appreciate an early reply so that I can report on this problem to the National Board of our Association.

Sincerely yours,

RALPH T. JACKSON, *Executive Vice President.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., March 26, 1975.

Mr. WILLIAM KLING,
American Soybean Association,
Washington, D.C.

DEAR MR. KLING: This replies to your letter of March 18, 1975, concerning the labeling of shortening, cooking and salad oils, margarine, etc.

Section 403(i)(1) and (2) of the Federal Food, Drug and Cosmetics Act requires that the labels of foods bear the common or usual name of the food and, if fabricated from two or more ingredients and not covered by a standard of identity, a declaration of all ingredients by their common or usual names. Accordingly, the name of a food consisting of soybean oil (one ingredient) is "Soybean Oil". A blend of oils may bear the name "Salad Oil," "Vegetable Shortening", etc., but the label should identify all ingredients, eg. "soybean oil, cottonseed oil and peanut oil". Margarine is covered by a standard of identity, and the standard requires a label declaraton of all ingredients, including the specific common or usual name of the oil ingredient.

We have not objected (in the past) to the declaration of a vegetable oil ingredient as "vegetable oil" when present as an ingredient in another food, eg. bread. A proposed new regulation, however, would require specific identification of the oil ingredient in all foods. We have always required that the labels of oil sold as such (shortening, salad or cooking oil etc.) bear the specific common or usual name(s) of the oil(s), either in the name of the food or in the declaration of ingredients.

Sincerely yours,

M. L. GATES,
Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods.

AMERICAN SOYBEAN ASSOCIATION,
Washington, D.C., March 18, 1975.

Mr. M. L. GATES,
Division of Regulatory Guidance, Bureau of Food, Food and Drug Administration, Washington, D.C.

DEAR MR. GATES: As discussed on the phone, we would much appreciate your advice as soon as possible concerning the labeling of shortening, cooking and

salad oils, margarine, etc., regarding specific types of vegetable oil content, i.e., soybean oil, palm oil, cottonseed oil, etc. A description of the legal requirements and the practice would be most helpful for a meeting of our Association.

Sincerely,

WILLIAM KING, *Washington Representative.*

CRESCENT FOODS,
Seattle, Wash., June 27, 1975.

Hon. FRANK E. MOSS,
U.S. Senate,
Washington, D.C.

DEAR SENATOR MOSS: The testimonies presented before the Consumer Subcommittee of the Senate Commerce Committee and the Subcommittee on Health of the Senate Labor and Public Health Committee on June 17 and June 18 have prompted me to add the following to the testimony presented by myself on June 18.

These additional observations have to do with very practical difficulties with labeling food components by their so-called "common or usual" names. While testimony has brought to your attention the complexity of flavoring mixtures and the unfamiliar names associated with them, I have not seen any reference to what is a basic flaw in the logic of using such terminology in light of present-day food science and technology.

In 1938 when the Food, Drug and Cosmetic Act was passed, it was realistic to consider food ingredients by their "common or usual" names. If the product contained sugar, it was so named as "sugar" not "sucrose." If it contained flour, this was indicated by its common or usual name. If it contained alcohol, this word was used, not "ethanol." Essentially all of these things were known by the majority of consumers and thus were common or usual.

The 1958 amendments to the Act changed all of this. Suddenly a large number of people, professional and laymen, became aware of the fact that some hundreds of chemicals were commonly used to flavor foods, but did not have "common or usual" names as generally understood by the average consumer. They became aware of the fact that a large number of substances, exhibiting no hazard to man, were used in foods for their functional properties. These now had to have "common or usual" names, but common or usual to whom? The FDA attempted to solve the problem, in part, by using the phrase: "flavor enhancers." Clearly this phrase does not convey the knowledge that is suggested by "common or usual" names. However, such words as flavors, spices, emulsifiers, fat preservatives, etc., convey the knowledge to the purchasers that the product contains these categories of substances. If the purchaser has sufficient need or interest, there are ways for him to determine in more detail what these substances may be. To present to him an unfamiliar name—one which he cannot find in his dictionary—and not give him a reference to what the term means is an exercise in futility—and an expensive one.

Some have suggested that the expression "common or usual" for most of these substances can be established from the GRAS reaffirmation program now being conducted by the FDA. I submit that this program will not establish "common or usual" names, but only "safe and suitable" substances. 90% plus of the several hundred substances under study will still be foreign to the layman.

There is one additional point that must be explored in the hypothesis that the expression "common or usual" conveys useful information to the layman. If one, by mandate, must label the ingredients of a food by their so-called "common or usual" name, does not this preclude the development and marketing of foods of the future?. By definition the components of these foods cannot be common or usual. What, then, shall they be called? If they cannot be placed upon the market, by what mechanism can their components become "common or usual" in order to satisfy the mandate?

I submit a possible solution would be to list these substances by their functional use in the food. Declaration by functional categories provides consumers with more information than a name which is neither common or usual.

I regret to say I cannot offer answers to all the questions I have raised regarding the labeling of food ingredients anymore than I could answer similar questions regarding the labeling of ingredients of compounded medicines by their common or usual names. Medicine, by its very nature, transcends the experience of laymen. Production of food has also transcended the experience of

laymen and those in the profession of food science and technology must assume the responsibility and burden of providing for the future a wholesome food supply, not unlike the responsibility of the medical practitioner.

RAYMOND WAY,
Director of Technology and Compliance.

THE CITY OF NEW YORK,
DEPARTMENT OF CONSUMER AFFAIRS,
New York, N.Y., June 2, 1975.

Hon. WARREN G. MAGNUSON,
Senate Committee of Commerce,
Washington, D.C.

DEAR SENATOR MAGNUSON: I would like to offer my comments on two food safety and labeling bills (S. 641 and S. 1168) under consideration by your committee.

This Department has become concerned with the safety as well as the fair pricing and disclosure of essential information by labeling of food. Through the New York Unit Pricing Law and this Department's regulations requiring process labeling of certain foods, we have seen an increase in protection for the consumer in these areas. It is clear, however, that a major effort on the Federal level to assure safety in food processing and uniform coding of essential information is needed and supported by this Department.

After comparing the two bills, I feel strongly that Senator Moss' bill (S. 641) is superior. It contains the important food coding system and provides for suits by governmental agencies as well as citizens. Furthermore, the Moss bill contains preferable ingredient labeling requirements as to listing in order of predominance and availability of complete spice and flavoring information.

I would like to make the following specific comments and criticisms of the bills:

1. The Moss bill (Section 302) requires that where date information is determined to be necessary the date used shall be the "sell date." While dating of foods is certainly a positive development, I would strongly urge consideration of mandating the use of a "use date" which should be identified on the package accompanied by words such as "use by . . ." Sell dates help the consumer to determine if food was fresh when purchased; the problem remains as to how long the food may be kept at home. A "use date" would clearly set the outside time limit for safe consumption from the consumer's point of view. The Secretary should be empowered to investigate the correctness of such use dates. A natural and essential companion bill requiring that food sellers remove open dated foods from the shelves upon expiration should also be considered by your Committee.

2. Under the Food Coding sections of the Moss bill (Section 411a) the Secretary is empowered to exempt foods by regulation from the coding requirements. It is my opinion that this power to exempt should be limited by requiring that the Secretary make a finding of exemption after application and a hearing or public comment on the issue of necessity. These requirements would parallel those in effect for the granting of exemptions from the labeling requirements of Section 307 of this bill.

3. We support the Moss bill provisions raising the maximum penalties for violations. I would like to suggest, however, minimum penalties as well as maximums be set for more effective enforcement.

4. We support the ingredient labeling requirements set out by the Moss bill including the required disclosure of spice and flavoring information on request as an alternative to mandatory labeling. The labeling section (Section 403(i)(2)(B)(i) which requires labels where the ingredient is an integral part of the food is extremely vague and an attempt should be made to clarify the meaning of "integral."

5. We urge that consumers' interests be represented by voting membership on all advisory committees that are established pursuant to Section 410(d). Having established the principle of consumer participation on such committees, it seems incongruous to deny such members the voting power of full membership.

6. The establishment of a private cause of action for citizens and the empowerment of governmental agencies to sue under the regulations promulgated by the

Secretary by the Moss bill is an excellent development. My only comment is that Section 201(g)(2)(A)(ii) should be tightened to exclude such civil actions only where the Attorney General or Secretary had taken action before the filing of the private suit and is diligently prosecuting the action rather than automatically foreclosing private suit if official action is pending.

7. Finally, I would urge that appropriate funding be made to the appropriate inspection and enforcement authorities to cover the additional tasks established by the proposed bills. It is indisputable that even the best legislative purposes are vitiated by the failure to implement them fully.

Thank you for affording me the opportunity to voice my general support of S. 641 as well as my concerns. I trust that thoughtful consideration will be given to the points I have raised on this important piece of consumer legislation.

Sincerely yours,

ELINOR GUGGENHEIMER, *Commissioner.*

AMERICAN SEAFOOD DISTRIBUTORS ASSOCIATION,
Washington, D.C., July 11, 1975.

Hon. FRANK E. MOSS,
Senate Committee on Commerce, Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR MOSS: The American Seafood Distributors Association is an organization of 100 companies involved in the importation of seafood products. The United States depends on overseas sources for more than 60% of fish and seafood consumed. Accordingly, the matter of imports is far more important in the fish industry than in other parts of the food business.

ASDA functions as an autonomous division of the National Fisheries Institute and as such supports the principles of the testimony presented by the NFI on these legislative proposals.

ASDA suggests that Section 111(e)(1) of S. 641 be clarified. As written, it appears that a certificate be required 30 days prior to each imported shipment. This would be unrealistic in view of the thousands of shipments which occur each month.

We suggest that certification cover the product from a plant over an extended period of time. This is logical in that the certification is to assure usage of safety assurance procedures.

ASDA also points out that much product may come from modern plants in nations whose governments are not equipped to provide the necessary certification. For this reason, we recommend that Section 111(e)(3) provide for rapid port-of-entry inspection of uncertified product to provide assurance that product is not injurious to public health. We do not believe that inspection of the processing procedures should be necessary to provide this assurance. Certainly, laboratory tests on a given lot of food should be adequate to determine its wholesomeness. Accordingly, we request that the last sentence of the paragraph be eliminated.

In conclusion, ASDA indicates its support for development of an inspection program specifically designed for seafood products, equitable for imported and domestic product alike. We would welcome an opportunity to discuss specific requirements of importers as this legislation develops.

Sincerely,

LEE J. WEDDIG, *Executive Secretary.*

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