

1043

93/14
L 11/2
F 73/2
9/3

Y 4
L 11/2
F 73/2
973

FEDERAL FOOD INSPECTION ACT, 1973

GOVERNMENT

Storage

29 1974

LIBRARY
KANSAS STATE UNIVERSITY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON

LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-THIRD CONGRESS

FIRST SESSION

ON

S. 2373

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

SEPTEMBER 11, 1973



Printed for the use of the Committee on Labor and Public Welfare

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 1973

24-374 O

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION



COMMITTEE ON LABOR AND PUBLIC WELFARE

HARRISON A. WILLIAMS, Jr., New Jersey, *Chairman*

JENNINGS RANDOLPH, West Virginia
CLAIBORNE PELL, Rhode Island
EDWARD M. KENNEDY, Massachusetts
GAYLORD NELSON, Wisconsin
WALTER F. MONDALE, Minnesota
THOMAS F. EAGLETON, Missouri
ALAN CRANSTON, California
HAROLD E. HUGHES, Iowa
WILLIAM D. HATHAWAY, Maine

JACOB K. JAVITS, New York
PETER H. DOMINICK, Colorado
RICHARD S. SCHWEIKER, Pennsylvania
ROBERT TAFT, Jr., Ohio
J. GLENN BEALL, Jr., Maryland
ROBERT T. STAFFORD, Vermont

STEWART E. MCCLURE, *Chief Clerk*
ROBERT E. NAGLE, *General Counsel*
ROY H. MILLENSON, *Minority Chief Clerk*
EUGENE MITTELMAN, *Minority Counsel*

SUBCOMMITTEE ON HEALTH

EDWARD M. KENNEDY, Massachusetts, *Chairman*

HARRISON A. WILLIAMS, Jr., New Jersey
GAYLORD NELSON, Wisconsin
THOMAS F. EAGLETON, Missouri
ALAN CRANSTON, California
HAROLD E. HUGHES, Iowa
CLAIBORNE PELL, Rhode Island
WALTER F. MONDALE, Minnesota

RICHARD S. SCHWEIKER, Pennsylvania
JACOB K. JAVITS, New York
PETER H. DOMINICK, Colorado
J. GLENN BEALL, Jr., Maryland
ROBERT TAFT, Jr., Ohio

LEROY G. GOLDMAN, *Professional Staff Member*
JAY B. CUTLER, *Minority Counsel*

(II)

CONTENTS

Text of:	Page
S. 2373-----	2
Amendment No. 467 to S. 1373-----	6

CHRONOLOGICAL LIST OF WITNESSES

TUESDAY, SEPTEMBER 11, 1973

Lloyd, Tepper B., M.D., Associate Commissioner for Science of the Food and Drug Administration, accompanied by Robert Wetherell, Acting Director, Office of Legislative Services, FDA, and Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, DHEW-----	12
Jacobson, Michael, Ph. D., Center for Science in the Public Interest; Susan Sechler, Agribusiness Accountability Project, Washington, D.C., and Anita Johnson, Health Research Group, Washington, D.C.-----	47
Sechler, Susan, Assistant Director, Agribusiness Accountability Project, Washington, D.C.-----	55
Johnson, Anita, lawyer, Health Research Group, Washington, D.C.-----	91
Somers, Ira, Dr., executive vice president, National Canners Association, Washington, D.C., and Dr. Howard Bauman, Grocery Manufacturers of America, Washington, D.C., a panel-----	111
Bauman, Howard E., Ph. D., vice president for science and technology, Pillsbury Co., Minneapolis, Minn., representing the Grocery Manufacturers of America, Inc.-----	132

STATEMENTS

Bauman, Howard E., Ph. D., vice president for science and technology, Pillsbury Co., Minneapolis, Minn., representing the Grocery Manufacturers of America, Inc.-----	132
Prepared statement-----	135
Jacobson, Michael, Ph. D., Center for Science in the Public Interest; Susan Sechler, Agribusiness Accountability Project, Washington, D.C., and Anita Johnson, Health Research Group, Washington, D.C.-----	47
Prepared statement of Mr. Jacobson-----	50
Johnson, Anita, lawyer, Health Research Group, Washington, D.C.-----	91
Prepared statement (with supplemental material)-----	94
Lloyd, Tepper B., M.D., Associate Commissioner for Science of the Food and Drug Administration, accompanied by Robert Wetherell, Acting Director, Office of Legislative Services, FDA, and Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, DHEW-----	12
Prepared statement-----	28
Sechler, Susan, Assistant Director, Agribusiness Accountability Project, Washington, D.C.-----	55
Prepared statement-----	60
Somers, Ira, Dr., executive vice president, National Canners Association, Washington, D.C., and Dr. Howard Bauman, Grocery Manufacturers of America, Washington, D.C., a panel-----	111
Prepared statement-----	117

ADDITIONAL INFORMATION

Articles, publications, etc.:	
Status Report on Swordfish-----	17
Tables:	
Sources of information leading to actions on adulterated foods—fiscal year 1973-----	26

IV

APPENDIX

Text of:

S. 2373:

Page

(Committee Print No. 3) October 8, 1973, as revised in committee_	149
As reported to Senate December 7, 1973, and referred to the Com- mittee on Commerce-----	263
S. Rept. 93-605 (Committee on Labor and Public Welfare)----	228

STATEMENTS

Hanold, Terrance, chairman of the executive committee Pillsbury Co., pre- pared statement-----	168
National Association of Margarine Manufacturers, Washington, D.C., prepared statement-----	217
National Canners Association, Washington, D.C., prepared statement-----	187
Quinlan, William A., general counsel, Associated Retail Bakers of America, Annapolis, Md., prepared statement-----	206
Tolley, Everett A., executive director, Shellfish Institute of North America, Baltimore, Md., prepared statement-----	204

ADDITIONAL INFORMATION

Articles, publications, etc.:

Consumer Comments, S. 2373, by Anita Johnson, Health Research Group, Susan Sechler, Agribusiness Accountability Research Group, and Michael Jacobson, Center for Science in the Public Interest----	223
---	-----

FEDERAL FOOD INSPECTION ACT OF 1973

TUESDAY, SEPTEMBER 11, 1973

U.S. SENATE,
SUBCOMMITTEE ON HEALTH OF THE
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., room 4232, Dirksen Building, Senator Edward M. Kennedy, chairman of the subcommittee, presiding.

Present: Senator Kennedy.

Committee staff present: Jessica Dunsay Silver, subcommittee counsel; and Jay B. Cutler, minority counsel.

Senator KENNEDY. The subcommittee will come to order. Today we are holding hearings on S. 2373, a bill introduced by the distinguished chairman of the Commerce Committee, Senator Magnuson, for himself and Senator Hart, chairman of the Commerce Committee's Subcommittee on the Environment, which would require the Food and Drug Administration to formulate and publish regulations for the surveillance of our Nation's food supply to detect adulterated food and prevent it from reaching the Nation's marketplaces.

Adulterated food is a serious problem facing this Nation. The Center for Disease Control reports a total of 7,628 isolations of Salmonella for the 3d quarter of 1972—a weekly average of 587. Salmonella is only one form of foodborne disease caused by ingesting adulterated food. If those figures are projected for the year and projected figures for cases of Shigella—another form of food poisoning—are added, those two diseases alone account for 45,484 isolations of foodborne disease in 1972. The enormity of the problem is accentuated by the fact that it is acknowledged that reported incidents, as represented by these figures, significantly understate the actual instances of food poisoning. Something must be done to deal with a problem of these proportions. Both Senator Magnuson's bill and my amendment are designed to deal with this problem.

[The bill and amendment referred to follows:]

93^d CONGRESS
1ST SESSION

S. 2373

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 1973

Mr. MAGNUSON (for himself and Mr. HART) introduced the following bill; which was read twice and, by unanimous consent, referred to the Committee on Labor and Public Welfare until October 15, 1973, with instructions then to refer to the Committee on Commerce at the option of that committee

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Federal Food Inspection
4 Act of 1973".

5 SEC. 2. Chapter IV of the Federal Food, Drug, and
6 Cosmetic Act is amended by adding the following new sec-
7 tion at the end thereof:

1 "SURVEILLANCE FOR ADULTERATED FOOD

2 "Regulations

3 "SEC. 410. (a) Not more than one hundred and eighty
4 days after the enactment date of this section, the Secretary
5 shall propose regulations which shall specify the surveillance
6 procedures that he will follow for the detection and preven-
7 tion of adulterated food. The Secretary may modify or
8 amend such regulations at any time after they have be-
9 come final on his own initiative or on the petition of any
10 interested person. Initial regulations promulgated under this
11 section shall become effective no later than one year from
12 such date of enactment.

13 "Minimum Requirements

14 (b) The procedures prescribed by the Secretary un-
15 der subsection (a) shall be such procedures for sur-
16 veillance as the Secretary determines are necessary to
17 carry out his responsibilities with respect to the detection and
18 prevention of adulterated food under this and other acts ad-
19 ministered by him, but such procedures shall require, at a
20 minimum, levels of surveillance sufficient to provide reason-
21 able assurance that the presence of adulterated food does not
22 constitute an unreasonable threat to the public health or wel-
23 fare. Where no practicable procedures are available to pro-
24 vide the assurance required by this section, the Secretary
25 shall include in regulations promulgated under this section

1 (1) a program for the development of such procedures
2 within the shortest feasible time, (2) specifications as to how
3 such program is to be carried out, and (3) a timetable for
4 the completion of such program.

5 "Hearings

6 "(c) Any person adversely affected by proposed regu-
7 lations, proposed modification, or amendment of such regula-
8 tions, or the denial of a petition for any such modification
9 or amendment may upon a showing of reasonable grounds,
10 file objections with the Secretary and request a hearing
11 which shall be granted by the Secretary. All hearings con-
12 ducted under this section shall consist of the oral and written
13 presentation of data, views, or arguments in accordance with
14 provisions of section 553 of title 5, United States Code.

15 "Increase in Surveillance Levels

16 "(d) If the Secretary finds a threat to the public
17 health or welfare which requires that there be an immedi-
18 ate increase in the level of surveillance with respect to any
19 food, he may direct an increase in the level of such surveil-
20 lance to the extent that he determines necessary. Such an
21 order may be entered without regard to any requirement for
22 previous notice or opportunity for a hearing, except that the
23 Secretary shall comply with any such notice or hearing re-
24 quirement as soon as practicable after such increase in the
25 level of surveillance has been initiated.

“Methodology

1
2 “(e) Analyses performed under this section to deter-
3 mine the presence and amount of adulteration in food shall
4 be performed through the use of the best instruments, tech-
5 nology, and trained personnel which are reasonably available.

6 “Public Access to Information

7 “(f) The Secretary shall make available to the public,
8 upon identifiable request and at cost, the results of any
9 analyses or research performed under this section.

10 “Relationship to Other Laws

11 “(g) This section shall not be construed to exempt the
12 Secretary or any other person from any obligation imposed
13 by any other provision of this Act or by the provisions of
14 any other Act. Nor shall this section be construed to permit
15 the use of any substance, practice, or conduct resulting in the
16 presence of adulterated food if such use, practice, or conduct
17 would not have been permitted in the absence of this
18 section.”.

93D CONGRESS
1ST SESSION

S. 2373

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 6, 1973

Referred to the Committee on Labor and Public Welfare and ordered to be printed

AMENDMENTS

Intended to be proposed by Mr. KENNEDY to S. 2373, 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, viz:

1 On page 1, line 3, strike the words "Federal Food
2 Inspection" and insert in lieu thereof the words "Federal
3 Food Registration and Inspection".

4 On page 1, insert between lines 4 and 5, the following:

5 "SEC. 2. The Congress finds and declares that in order to
6 make regulation of interstate commerce in food effective, it
7 is necessary to provide for registration and inspection of all
8 establishments in which foods are manufactured, processed,
9 packed, labeled, or stored; that the products of all such estab-

Amdt. No. 467

1 lishments are likely to enter the channels of interstate com-
2 merce and directly affect such commerce; and that the regula-
3 tion of interstate commerce in food, without provision for
4 registration and inspection of establishments that may be
5 engaged only in intrastate commerce in such food, would
6 discriminate against and depress interstate commerce in such
7 food and adversely burden, obstruct, and affect such inter-
8 state commerce.”

9 On page 1, line 5, strike “2” and insert in lieu thereof
10 “3”.

11 On page 4, add after line 18, the following:

12 “SEC. 4. Chapter IV of the Federal Food, Drug, and
13 Cosmetic Act, as amended by this Act, is further amended
14 by adding after section 410 the following new section:

15 “REGISTRATION OF FOOD ESTABLISHMENTS

16 “Definition

17 “SEC. 411.- (a) As used in this section, the term
18 “name” includes in the case of a partnership the name of
19 each partner and in the case of a corporation the name of
20 each principal corporate officer and the State of incorporation.

21 “Biennial Registration

22 “(b) On or before December 31 of each year, every
23 person who owns or operates an establishment in any State
24 engaged in the manufacture, processing, packing, labeling,
25 or storage of food shall register with the Secretary his name,

1 principal place of business, the location of each such estab-
 2 lishment, and for each such establishment, a complete list of
 3 all foods or classes of foods manufactured, processed, packed,
 4 labeled, or stored at that establishment. Such list shall define
 5 the types of processing for each food or class of food. To
 6 achieve uniformity in the registration of classes of foods and
 7 types of processing, the Secretary shall promulgate regula-
 8 tions defining food classes and types of processing for pur-
 9 poses of the registration required by this section.

10 “ ‘New Producers

11 “ ‘(c) Any person upon first engaging in the manu-
 12 facture, processing, packing, labeling, or storage of food in
 13 any establishment which he owns or operates in any State
 14 shall immediately register with the Secretary the information
 15 required by subsection (b).

16 “ ‘Additional Establishments

17 “ ‘(d) Every person registered in accordance with sub-
 18 section (b) or (c) of this section shall immediately regis-
 19 ter with the Secretary, any additional establishment which
 20 he owns or operates in any State and in which he begins the
 21 manufacture, processing, packing, labeling, or storage of
 22 food. Such registration shall include the information required
 23 by subsection (b).

24 “ ‘Registration Number; Fees

25 “ ‘(e) The Secretary may assign a registration number

1 (or numbers) to any person registered in accordance with
2 this section.

3 “‘Availability of Registrations for Inspection

4 “‘(f) The Secretary shall make available for inspec-
5 tion to any person so requesting, any registration filed pur-
6 suant to this section.

7 “‘Exclusions From Application of Section

8 “‘(g) This section shall not apply to such classes of
9 persons as the Secretary may by regulation exempt from the
10 application of this section upon a finding that registration by
11 such classes of persons in accordance with this section is not
12 necessary for the protection of the public health.

13 “‘Inspection of Premises

14 “‘(h) Every establishment in any State registered with
15 the Secretary pursuant to this section shall be subject to
16 inspection pursuant to section 704.

17 “‘Foreign Establishments

18 “‘(i) Any establishment within any foreign country
19 engaged in the manufacture, processing, packing, labeling,
20 or storage of any food shall be permitted to register under
21 this section pursuant to regulations promulgated by the
22 Secretary. Such regulations shall require each establishment
23 to provide the information required by subsection (b).’.”

24 SEC. 5. Section 301 of the Federal Food, Drug, and

1 Cosmetic Act is amended by adding after paragraph (p)
2 the following:

3 “(q) The failure to register as required by section
4 411.”.

5 SEC. 6. Section 403 of the Federal Food, Drug, and
6 Cosmetic Act is amended by adding after paragraph (n)
7 the following:

8 “(o) If it is offered for sale or transferred from an
9 establishment which is required by section 411 (b) to reg-
10 ister, but which has not so registered under section 411.”.

11 SEC. 7. Section 801 (a) of the Food, Drug, and Cos-
12 metic Act is amended by striking the words “subsection (b)
13 of section 510 and shall request that if any” and inserting in
14 lieu thereof “sections 411 (i) and 510 (i) and shall request
15 that if any food or”.

16 SEC. 8. The amendments made by sections 4, 5, and 6 of
17 this Act shall take effect on the first day of the seventh cal-
18 endar month which begins after the month in which this Act
19 is enacted, except that the Secretary of Health, Education,
20 and Welfare shall, within ninety days of the date of the en-
21 actment of this Act, propose the regulations required by
22 section 411 of the Federal Food, Drug, and Cosmetic Act.

Senator KENNEDY. The purpose of S. 2373 is to require FDA to provide for adequate surveillance of food and food processing. That purpose is accomplished in two ways:

1. By providing a standard to guide FDA in establishing levels of surveillance and,

2. By providing a mechanism by which concerned members of the public and scientific community can participate in establishing surveillance procedures and can challenge the propriety of those regulations if they are inadequate. By opening the administrative process to outside scientists, FDA will have the benefit of their knowledge and expertise in devising testing methods and establishing inspection priorities. The public has a right to expect that adulterated food will not present an unreasonable threat to health. When surveillance measures do not provide reasonable assurance of protection, those whom the law is designed to protect must be permitted to seek relief.

In the same spirit of concern for the safety of the Nation's food supply, I have introduced an amendment to S. 2373—an amendment to require the registration of all food establishments. In part, this amendment is based upon legislation introduced in 1972 in the House by the distinguished chairman of the House Health Subcommittee, Paul Rogers. Witnesses have been requested to address their remarks to both the bill and the amendment.

The FDA is charged with enforcing the Food, Drug, and Cosmetic Act's prohibition on adulterated food and, in performance of that responsibility, the agency is empowered to inspect food plants and sample and test their products. Such inspections, sampling and testing procedures have long been considered vital to FDA's task of policing adulterated food. However, at the present time, much of FDA's effort is thwarted by its inability to locate many food establishments.

A 1972 report by the General Accounting Office on unsanitary conditions in the food manufacturing industry pointed up the problems faced by FDA because it lacks the authority to require registration of food plants. The report noted that FDA orders inspections based on its inventory of food establishments, but that that inventory is largely inaccurate. In six FDA districts, 22 percent of the plants listed on the current inventories were out of business. Is it not fair to assume that an equal number of establishments had begun operating without FDA knowledge and without being subjected to any Federal inspection? FDA sets its inspectional priorities according to relative potential for danger to health. Potential danger to health may be evaluated on the basis of the products produced, and the processing procedures. However, FDA is at the manufacturers' mercy in attempting to obtain that information. It is clear that without the authority to obtain a complete inventory, FDA cannot reach all establishments or effectively set inspection priorities; nor can it trace all the potential sources once a problem has been identified with a particular food or processing procedure.

This amendment is similar to section 510 of the Food, Drug, and Cosmetic Act requiring registration of drug manufacturers and processors and the drugs they produce. Registration of food plants and products is no less important to FDA enforcement efforts. FDA needs this authority if it is to effectively prevent adulterated food from reaching the Nation's marketplaces.

Figures provided by the Library of Congress indicate that in the 18-month period from January 1972 through July 1973, FDA actions (including recalls and seizures) of adulterated foods totaled over 600. Adulterated food is a serious problem to which Congress must turn its attention. The legislation before us today represents an effort to deal with that problem.

Our first witness today representing the administration, Dr. Lloyd Tepper. Dr. Tepper was professor of environmental health at the University of Cincinnati from 1965 to 1972. In 1972 he was named Associate Commissioner for Science of the Food and Drug Administration. In that capacity he is appearing before us today.

**STATEMENT OF LLOYD B. TEPPER, M.D., ASSOCIATE COMMISSIONER
FOR SCIENCE OF THE FOOD AND DRUG ADMINISTRATION, AC-
COMPANIED BY ROBERT WETHERELL, ACTING DIRECTOR, OFFICE
OF LEGISLATIVE SERVICES, FDA, AND PETER BARTON HUTT,
ASSISTANT GENERAL COUNSEL, FOOD AND DRUG DIVISION,
DHEW**

Dr. TEPPER. I would like to introduce, to my left, Mr. Robert Wetherell, Office of Legislative Services, Food and Drug Administration. To my right, the Department of Health, Education, and Welfare's Assistant General Counsel for Food and Drugs, Mr. Peter Hutt.

We appreciate this opportunity to appear before you this morning to discuss S. 2373, the Federal Food Inspection Act of 1973.

This bill would require the Food and Drug Administration (FDA) to conduct a surveillance program to detect and prevent adulterated food from reaching the marketplace.

S. 2373 is a revision of amendment No. 1 to S. 426, the proposed Toxic Substances Control Act. FDA testified on that amendment on March 21, 1973, before the Subcommittee on the Environment of the Senate Committee on Commerce.

S. 2373 would add a new section 410 to the Federal Food, Drug, and Cosmetic Act which would require the Secretary to conduct a surveillance program for adulterated food. Within 180 days after enactment, the Secretary would be required to propose regulations specifying the surveillance procedures he will follow for the detection and prevention of adulterated food.

The regulations shall include such procedures for surveillance as the Secretary determines are necessary to carry out his responsibilities with respect to the detection and prevention of adulterated food. They shall require, at a minimum, levels of surveillance sufficient to provide reasonable assurance that the presence of adulterated food does not constitute an unreasonable threat to the public health and welfare. Where no practicable procedures are available to provide the assurance required, the regulations shall specify a program for the development of such procedures, together with specifications for the conduct of the program and a timetable. The bill would require that analyses to determine the presence and amount of adulterated food shall be performed through the use of the best instruments, technology, and trained personnel which are reasonably available. The results of any analyses shall be made public.

The regulations shall be proposed not more than 180 days and shall become effective not more than 1 year from the date of enactment. The regulations may be amended on the initiative of the Secretary or on the petition of any interested person. Any person adversely affected by a proposed regulation or proposed amendment, or by a denial of a petition for an amendment, may file objections with the Secretary showing reasonable grounds and requesting a hearing. The Secretary would be required to afford an opportunity for a hearing on such objections. The hearing would consist of both oral and written presentation of data, views, or arguments.

The bill further provides that if the Secretary finds a threat to the public health or welfare which requires an immediate increase in surveillance levels with respect to adulterated food, he may direct an immediate increase in the level to the extent he determines necessary. Notice and an opportunity for a hearing would be provided only after the increase in surveillance takes place.

The bill further provides that it shall not be construed to exempt the Secretary or any other person from any obligation imposed by any other provision of this act or any other act, or to permit the use of any substance, practice, or conduct resulting in food becoming adulterated.

DEPARTMENT POSITION ON S. 2373

The Department opposes enactment of this legislation. The bill is not only unnecessary, but it may be construed as erecting procedural hurdles to effective action by the Food and Drug Administration to protect public health. We do not believe it is in the interest of the consuming public to inhibit FDA's ability to take action to protect consumers in order to achieve the goal of requiring FDA's entire food control program to be specified in regulation form in the Federal Register.

FDA agrees with the intention to have FDA report to Congress and to the public in detail about its plans and procedures to screen food for noncompliance with legal requirements. This information is already given in considerable detail in the Department's annual reports and in the budget request for the FDA. At the same time, we do not see that the benefits to be gained by requiring publication of such plans and procedures in regulation form would offset the possible costs in terms of reduced regulatory flexibility and impaired readiness for unforeseen emergency actions.

The Food and Drug Administration is already engaged in broad-scale efforts involving testing and analysis of food for contaminants, research on the health effects of these substances, and the development of improved methodology to detect these substances.

This bill raises a number of statutory interpretation questions which may adversely affect these actions in the interest of public health protection. For example, the bill could be read as inhibiting FDA's present programs in the area of food surveillance.

First of all, subsection (d) provides that the Secretary may immediately increase the level of surveillance if he finds a threat to the public health or welfare. FDA, however, would ordinarily increase its surveillance activities even if there were merely a potential or possible threat to health. The language of the subsection also could imply that FDA could not act in less critical situations to increase its surveillance until a proposed regulation issued and hearings were held.

Another conflicting interpretation of the bill is possible. Subsection (g) specifically provides that the bill shall not be construed to exempt the Secretary or other persons from obligations under any other provisions of law. Thus, while the hearing is going on under the proposed section 410 to determine the appropriate levels of surveillance, the Secretary could establish his own levels under present law. Indeed these levels could continue in effect even after the hearing because of the subsection (g) provision that present authority will not be affected. Thus under subsection (g) the situation could arise where FDA is initiating seizure actions under sections 402 and 403 against food which complies with the procedures established pursuant to the proposed section 410.

FDA is constantly revising its procedures, methodology, and levels of inspections as situations warrant. If these changes cannot be implemented without going through an administrative hearing, the effectiveness of FDA is compromised. But if subsection (g) means that we can ignore the new requirements of section 410 and proceed under our other authority, the bill is virtually meaningless.

In sum, the bill adds nothing to present protection, creates an administrative burden including, among other things, mandatory hearings, diminishes FDA flexibility to act, and unnecessarily raises a number of questions of interpretation.

As noted, under existing legislative authority, FDA acts even though toxic levels of a contaminant may never be reached if the quantity present exceeds the maximum no-effect level reduced by a safety factor. This level varies according to a substance's potential risk and its presence in other foods and from other exposures.

We believe the concept of "unreasonable threat to the public health or welfare" employed in the bill is a relatively imprecise criterion and is susceptible of being interpreted as more restrictive of our actions than our current preventive approach to chemicals found in food. What does this concept do to the Delaney anticancer clause, for example, or to the use of a hundredfold safety factor? Could FDA establish in a rulemaking proceeding that these requirements are needed to prevent an "unreasonable threat to public health"? We would assume that the obvious intent of this bill is not to limit our authority, and that again subsection (g) which preserves our existing authority would take precedence, and the new requirements of section 410 need not be observed. We believe this example points up the fact that we can only view the bill as undesirable legislation.

In our judgment, this bill would only mandate a flurry of administrative activity which could serve to mislead the public into believing that some simple solution had just been found to the many-faceted problems posed by environmental contaminants in food. And we believe the additional cost of this activity, almost impossible to estimate, would provide little, if any, increase in consumer protection.

CURRENT ACTIVITIES

The Food and Drug Administration has given increased emphasis and resources in the past several years to the surveillance of food for adulteration.

At the present time, FDA directs essentially all of its food budget, approximately \$60 million, to problems concerned with food safety.

These activities include surveillance for microbiological contamination and toxins, heavy metals, industrial chemicals, and mycotoxins and natural poisons. Our programs entail a variety of approaches to the various problems depending on the likelihood and degree of hazard from a given problem and its prevalence.

1. INSPECTIONS

FDA's traditional tool for maintaining surveillance over the food industry is the establishment inspection. Reflecting the administration's emphasis on consumer safety during the past few years, FDA was, in 1973, able to accomplish 16,000 inspections and 45,000 sample examination of food to detect microbial contamination problems and to reduce filth, decomposition, and other adulterants in food. This program has more than doubled since 1972. Our regulatory actions against violative products have increased markedly.

We have also entered into contracts with State agencies whereby they will perform inspections and sample analyses of bakeries, soft drink plants, food warehouses, and grain storage facilities. The primary emphasis will be plant sanitation.

2. QUALITY CONTROL

FDA's quality control program identifies those critical control points in food processing where food safety problems are likely to develop. The object is to help prevent problems before they occur, in the hope we can obviate later corrective actions such as recalls or seizures of food. This program supplements our traditional inspections. It calls for FDA to develop better information on daily compliance status of the food industry, by a three-prong check: Sampling of foods at the retail level, plant inspections by specialized quality assurance teams, and expanding the cooperative quality assurance programs.

We are paying particular attention now to improving quality control in plants which can low-acid foods. As you know, those foods may, if improperly processed, present risks of toxicity from botulinum toxin. We have also developed an emergency permit control system in cooperation with the National Cannery Association to impose more stringent controls on this segment of the food industry.

The shellfish industry has also received increased attention from FDA, because of the susceptibility of shellfish to contamination from pollutants in growing areas and because of the risks of paralytic shellfish poisoning, commonly known as red tide.

Incidentally, the problem of red tide provided an excellent illustration of FDA's ability to move rapidly and respond to a risk to health from food. FDA assisted New England State officials in removing potentially hazardous shellfish from the market. As soon as we learned that potentially toxic shellfish had been distributed elsewhere, FDA alerted food control officials around the country. FDA field staff was directed to locate and remove from the market all those shipments of toxic shellfish. We also instituted a laboratory testing program to identify suspect lots. All these efforts by the States and FDA averted deaths and further poisonings which undoubtedly would otherwise have occurred.

We are also developing microbiological quality standards for food which will permit regulatory action based solely on the product's non-compliance with the standard, without need for factory inspection. Standards have been published for cream pies, edible gelatin, and bottled water. We plan to publish standards for 10 more foods in fiscal year 1974 and to conduct a survey on 25 other foods to obtain the data necessary to establish microbiological quality standards.

One integral part of the effort to reduce microbiological contamination of food is to lower the incidence of salmonella and other microbiological contaminants. Recently, FDA received the report of the FDA Task Force on Salmonella. The report recommended new emphasis on consumer education, programs for animal byproduct rendering plants, and regulatory initiatives by FDA to lessen the risks of salmonella contamination in the distribution and preparation of food. We intend to step up on our efforts in this area, which in the last 5 years have already reduced the percentage of products contaminated from salmonella in five problem food categories regulated by FDA, from almost 9 percent to less than 1 percent.

3. HEAVY METALS AND INDUSTRIAL CHEMICALS

Our programs on heavy metals involve toxicological studies with respect to mercury, lead, and cadmium as well as the development of analytical methods for mercury, lead, cadmium, arsenic, selenium, and zinc. Analysis for these six metals is now included in the total diet studies which include a "market basket" type sampling of products at the retail level.

Senator KENNEDY. May I ask you about mercury and swordfish, Doctor? I came back from Massachusetts and was meeting with some of the swordfishermen up there. Can you tell us what the latest is on that? Are you familiar with it?

Dr. TEPPER. Well, the situation basically is that the regulations depend upon an assumption of the amount of fish which might be consumed by the American public. One computes the amount of organic mercurials which would be permissible. If one knows the permissible mercurial intake and the amount of mercury in fish, this permits a computation of the amount of fish which might be permissible in the diet. A level of 0.5 parts per million of mercury is regarded as acceptable. That is, the level assures that one may eat a rather large amount of fish containing this amount of mercury, without being exposed to acceptable risk.

In the case of swordfish, the experience has been that swordfish contain a level of mercury somewhat higher than the 0.5 parts per million. And therefore this particular species of fish is not permissible if the amount consumed were to match the amount consumed of low mercury fish. Swordfish is a more hazardous species because it is higher in mercury content. If one had his choice of eating a kilogram of swordfish or kilogram of a nonswordfish species, the mercury load from the nonswordfish species would be less. Obviously this causes certain discrimination against any of the larger fish, such as swordfish which are at the end of the food chain.

Senator KENNEDY. Is there not a ban now on the swordfish?

Dr. TEPPER. There is a ban on swordfish, not because there is anything inherently troublesome about swordfish; the restriction on sword-

fish is a result of the fact that if the public were to eat the amount of swordfish as a replacement for the other kinds of fish which they now normally eat, a situation might occur in which the mercury ingestion would be above recommended levels.

Senator KENNEDY. How much are you talking about? How much swordfish would you have to eat?

Dr. TEPPER. I cannot give you that answer this morning, Senator. It represents an extreme situation.

Senator KENNEDY. I would really appreciate if you could see what could be worked out. That is an important industry up our way. Obviously none of us are interested in putting food products on the shelves that are going to be hazardous. But I think it is something that ought to be continually reviewed.

We import swordfish, though, do we not? You do not ban the importation of swordfish?

Mr. HUTT. The same rules would apply to imported swordfish as to domestic swordfish. I do not know of any imported swordfish. We would have to check that specifically.

Senator KENNEDY. You can buy—I went into a store out on Long Island, it is about \$4.50 a pound, that is how expensive it is. As I understand, it was imported. There is the question of some black marketing and other things going on. I would appreciate it if you could give us a note as to where you are. The season is effectively ending now. It ends in early October.

Dr. TEPPER. The problem is not with the swordfish; it is with the dietary consumption patterns. If we were to gear the regulation to the average fish consumption, we would be well within the safety limits. However, our regulations must always be based on the extreme case of somebody who depends to a much larger than conventional degree on this particular item in his diet. And when there is no way of controlling what dietary intake may be, then one must err on the side of conservatism and say this will not be available either to this person at one end of this spectrum or to the public at large. It is a somewhat perplexing problem.

Mr. HUTT. We would be happy to provide you a full report on the current status.

[The material referred to follows:]

STATUS REPORT ON SWORDFISH

The Food and Drug Administration established a guideline of 0.5 parts per million (ppm) for mercury in fish in 1969. This represents the level at which the Agency will charge that the fish is adulterated under the Federal Food, Drug and Cosmetic Act and will therefore initiate legal action to remove such fish from the marketplace.

This mercury in fish guideline has been re-evaluated on three separate occasions since its inception. On each occasion, the determination was made that the 0.5 ppm level was appropriate, adequate, and necessary for the protection of the public health. In addition, recent information obtained from studies of individuals in Iraq, who were poisoned as a result of eating flour made from mercury-treated grain, has provided additional support for maintenance of the guideline at its present level.

We are completing preparation of a Federal Register document in which we will propose the establishment of a formal tolerance under section 406 of the Food, Drug, and Cosmetic Act covering mercury residues in fish. This tolerance will, of course, replace our guideline but we do not anticipate any change in the allowable level (0.5 ppm) of mercury in fish.

Our position with respect to Swordfish has not changed since May 6, 1971 when the recommendation that the public stop eating swordfish was made. At that time, we indicated that an extensive survey of this nation's swordfish stocks had shown that over 90% of the fish tested contained mercury residues in excess of the 0.5 ppm guideline. We have received no new information which would indicate that the incidence of excessive levels of mercury in swordfish has decreased since that time.

It is regrettable that our policy has had an adverse effect on the swordfish industry. Nevertheless, we believe that the 0.5 ppm guideline level for mercury in fish is a reasonable and necessary regulatory measure to protect the public health.

Senator KENNEDY. You are balancing these things off about the carcinogenic factor of grilling, outdoor grilling of steak. We went all through this kind of question earlier this year, and we were talking about DES being in meats, and we had some of the experts down here saying there is a great danger if you grill your steak outside on charcoal. Obviously I am not interested, and we are not interested in putting products on the market that are going to be dangerous to the health, but I would like to get another review of this, if we could, and find out what possibly could be done, and if you would be kind enough to take another look at it and let us know.

Mr. HUTT. We will certainly do that.

Dr. TEPPER. To proceed with my statement, our Bureau of Foods also maintains surveillance of the chemical industry to determine what substances are being produced and the probability of such substances being found in food. Where a substance is on may be a contaminant of food, it is necessary for the Bureau to develop methods for detecting the substance in foods. Data must also be gathered to ascertain how harmful the substance may be, to support possible regulatory action. Where warranted, field surveys are undertaken to determine the incidence of a substance in the food supply. Regulatory actions are taken where necessary to protect the consumer.

Our activities concerned with industrial chemicals include surveillance for pesticides in the same total diet studies and field surveys of agricultural products. We are also continuing to sample and analyze for polychlorinated biphenyls (PCB's) and phthalate esters. Other materials such as chlorinated paraffins and orthophosphate esters, produced in quantities comparable to the prerestriction production of PCB's, and having a similar potential for getting into the food chain, are being investigated to see if they do, in fact, appear in foods.

4. MYCOTOXINS AND NATURAL POISONS

Activities with mycotoxins and natural poisons involve examining for aflatoxin in raw agricultural commodities—peanuts, cottonseed, corn, and nuts, in cooperation with the U.S. Department of Agriculture—and residues in animal tissue. We are also concerned with the possibility of ochratoxin in grain, patulin in applejuice, sterigmatocystin in grain, and penicillic acid in corn, dry beans, and applejuice. Recent harvesting and drying conditions for corn have contributed to molding and two possible mycotoxin problems: the T-2 toxin and zearalenone.

All of this may help to illustrate the broad range of ongoing activity that is being undertaken under existing legislative authority concerned with the surveillance of foods for adulteration.

CITIZEN PARTICIPATION

At the present time, any citizen may petition the agency for an administrative action 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.

Additionally, almost all FDA regulatory decisions are published for comment in the Federal Register. Again, anyone may comment and the high frequency of comment from organized groups speaking for consumers, the medical and scientific communities, and industry indicates the effectiveness of this means of communication.

Senator KENNEDY. Let me ask you, are your sampling or testing programs published, your particular testing programs, are they published in the Federal Register?

Dr. TEPPER. There are several components to each testing program. The actual specifics as to what samples will be collected, from what districts, how the marketbasket program will be utilized are not published. The rules do reach public record. The analytical methods which are a very important part of the sampling procedure are a matter of public record and, in fact, are developed in a collaborative program using the State laboratories, industrial laboratories, and university participants.

Mr. HUTT. Senator, I think this might be a good time to get into a little more detail of one of the problems we see with the bill and get right to the heart of the issue, because it is raised by your question. We brought along with us a sample of our plans and manuals that are involved in our total food contamination surveillance procedure. I have a list of them. I will read them off. I will ask Mr. Wetherell if he could simply hold up or point to various manuals that are involved. I will also submit for the record, but I would not burden you with, a description of each one of these manuals.

There is a "Regulatory Procedures Manual," I might add that for each one of these documents anyone may come in and either pay for it and receive a copy under the Freedom of Information Act, or read it in our offices without charge—with the single exception that there are in one or two of these documents names of specific companies or brand names where we have an investigator go out and conduct surveillance and we would delete those. Those are the only exceptions.

The second is the "Inspector Operations Manual." Then the "Inspector Programs Manual." The "Compliance Program Guidance Manual."

Each one, of these, of course, is 3 or 4 inches thick.

The "Bureau of Foods Technical Manual."

The EDRO—which is our regional operations division—the EDRO work plan. This is the plan used by the field to go about its surveillance.

The "Laboratory Operations Manual."

Senator KENNEDY. Let me take a look at one of those. What is this here?

Mr. WETHERELL. This is the work plan for our field forces throughout the country, Senator.

Senator KENNEDY. What is the point you are trying to make?

Mr. HUTT. The point I am trying to make on this, Senator, is that under the bill we would have to specify the surveillance procedures to

be followed. Now the EDRO work plan lays out the surveillance procedures for the field to follow on a yearly basis. It is renewed every year, in determining how we go about our surveillance of food factories, both processors and warehousemen, anyone belonging in the food plant.

This work manual is updated some four to six times a year. It consists of some 400 to 500 pages. We have no objection to making it available to anyone, and it is available under the Freedom of Information Act for anyone as I said to either review it or obtain a copy.

But it is a detailed work plan. In addition, under the EDRO work plan, every one of our districts has its own work plan by which in its own little regional area it carries out the central EDRO work plan. I simply did not bother to bring copies of those along.

As I say, our objection is not to make these available for scrutiny. It would be simply to having to publish them in the Federal Register and hold hearings on them, because the massive amount of material would mean an incredible number of FDA man-hours in carrying that out.

Senator KENNEDY. Could the staff get a chance to look through some of these?

Mr. HUTT. Certainly. We would be happy—

Senator KENNEDY. Why is it not possible just to provide—summaries of the information, just as you provide to Congress, in terms of budget and other things. Why can you not provide a summation of this, and publish the summary with other kinds of references as well? Why is that not possible? It seems to me you have got an awful lot of sheets in here, with a lot of little numbers, which I am sure are terribly important.

But that is not the kind of information that we are interested in trying to get out and get around. We are concerned with regulations relating to testing and analysis.

Mr. HUTT. Perhaps with the next ones I will list, and Mr. Wetherell will hold up, we will get to the heart of that problem. The next is "Laboratory Operations Manual." This contains obviously some of the detailed information about how we go about conducting the analytical work itself.

Senator KENNEDY. In this particular one [indicating], on your work plan, you only have 84 pages of actual regulations, but on inspections you also have page after page of different kinds of places where these inspections have taken place.

Mr. HUTT. That is part of the surveillance procedure. If, Senator, you are saying that it is not intended by the bill that this type of information be specified, then that would certainly be very useful.

Senator KENNEDY. We will get a chance to examine some of these.

Mr. HUTT. Another one, the "Laboratory Information Bulletins." I will go down these quickly. The "Instrument Operations Manual," et cetera.

Senator KENNEDY. We will take them.

Mr. HUTT. There are many of them, which are all in the bill as presently drafted.

Dr. TEPPER. I believe it would be pertinent to point out that each one of these documents is dynamic in character. For example, the deployment of the inspectional resources changes from week to week as a

particular problem arises. It is difficult at the outset of the year to specify what one is going to do. The "red tide," for example, the several botulism problems we have had during the past year point up the need to have considerable flexibility to move in areas where a particular threat becomes apparent. In addition, the methodologies are dynamic in character, and we have people working on the development of methods.

It is very difficult to specify these in advance in a volume, without making sure it is a looseleaf volume, deleting and inserting when necessary. These in no sense are static publications.

Senator KENNEDY. If we could summarize. We are going to start voting a little before 12, and I have some questions.

FOOD PROCESSOR REGISTRATION

Dr. TEPPER. We will skip some of the material which is specified in the printed testimony, and come right to the conclusion of the matter; we wish to point out that last week an amendment to S. 2373 was introduced to provide for the mandatory registration of food processing establishments. While we have been unable to comprehensively review all the provisions, we certainly endorse the principle of the amendment as we did in the last Congress and do have some preliminary comments which may be of interest to the subcommittee.

We believe that the lack of authority to require food processors to register with FDA seriously inhibits our ability to properly regulate the food supply of this Nation. It is impossible for FDA to adequately regulate or monitor the food supply system without full information on who is processing food and where they are located.

The inventory which FDA now maintains and upon which FDA programs its inspectional activities is incomplete. Presently, our only methods of determining the existence of new firms are by inspector surveillance, reports from cooperating State and local officials, or consumer complaints.

Our existing inventory lists approximately 60,000 firms in the food industry which are subject to inspection by FDA. Of these, some 32,000 are food manufacturing and processing plants. The scope of the food industry is vast. The agency must keep track of a growing and changing industry.

Legislation such as the amendment to S. 2373 which is pending before this committee would provide mandatory registration.

The amendment would provide for the biennial registration of establishments engaged in the processing or packing of food (including establishments engaged only in intrastate commerce). New producers would be required to register immediately upon first engaging in such activities. A person operating such an establishment would register his name, principal place of business, the location of each such establishment and a complete list of all foods or classes of foods being processed therein, and the type of processing being engaged in by the establishment. Under the bill, a registration number would be assigned. The Secretary would also have the authority to exempt classes of persons from registration if he finds that registration is not necessary to protect the public health. Every registered establishment would be subject to inspection pursuant to the Federal Food, Drug, and Cosmetic Act.

The Administration has recently submitted legislation to provide for a mandatory registration system with respect to food processing establishments. We expect this bill to be introduced within the next week and hope that it will receive consideration. The Administration's bill differs from the amendment to S. 2373 only in matters of technical detail. Its provisions were developed after careful consideration within the Administration and we strongly urge its enactment.

We would at this time answer any questions.

Senator KENNEDY. That is fine. The bill requires that the Secretary's proposed regulations specify surveillance procedures, which he will follow for detection and prevention of adulterated food.

In these publications, you have special requirements, such as how to treat the media, what percent of time you ought to be spending with certain different groups, allocation of time.

Maybe the bill should clarify what is meant by surveillance procedures that you will follow for detection and prevention of adulterated food. But how to issue press releases and things like that need not be included. I want to see if we can work out with the staff, if we move ahead on this and we plan to, at least to have it sufficiently precise so we do not have all of the information that is included in those various books, which I do not really think is relevant to the thrust of this legislation. Perhaps it is sufficiently broad now that you can interpret it that way, but I will be glad to work with you.

You have a number of concerns about the legislation, but I think we can work on that one.

Mr. HUTT. I think we can. I thought it was incumbent on us to show you the problem.

Senator KENNEDY. I think that makes a point that has to be dealt with.

You are really in support of requiring food processors to register; you believe that is essential at the present time.

Mr. HUTT. Absolutely.

Senator KENNEDY. We do not have that at the current time.

Mr. HUTT. We do not.

Senator KENNEDY. Is it your position that you are satisfied with existing machinery to go ahead and do the job, is that correct? That you are satisfied with the authority that exists within the Food and Drug Administration?

Mr. HUTT. Within the Food and Drug Administration today, to conduct food surveillance? There are probably issues. Our concern with this bill with respect to surveillance was that it would not provide any additional authority and if anything, it would hinder our current efforts. We are not at all concerned about doing additional surveillance work.

Senator KENNEDY. It inhibits them in what way?

Mr. HUTT. It inhibits them in requiring what we are concerned about, massive Federal Register publications.

There is also implicit in it the concept that the Food and Drug Administration should do all the surveillance as contrasted with our current efforts to get the industry to do the surveillance. We have under development a new program called "hazard analysis for critical control points."

What we do is we go to the industry and determine with them what the critical control points are, in that industry.

The industry is then responsible for conducting its own quality control surveillance. We merely audit that.

Now, that does a much better job, because industry is far more capable of conducting surveillance on its own products than we are to cover the whole U.S. food supply. We simply do not have the resources.

Senator KENNEDY. Where is that program at the present time?

Mr. HUTT. That program is presently in its formative stages. We started with the canning industry, because of problems that we had encountered there, and we will be expanding it as soon as we can.

Senator KENNEDY. What has been the reaction of industry so far?

Mr. HUTT. I think the reaction of industry has been quite favorable.

Senator KENNEDY. I wonder if the industry did not choose to cooperate, what kind of authority do you have to require them to cooperate?

Mr. HUTT. We at this point have no authority to require them to submit records of their surveillance activities to us. The statute says that we may enter a food establishment and look at things, but we have no records inspection authority as such.

Senator KENNEDY. Even with regard to just limited area of, say, adulterated food or food processing?

Mr. HUTT. No, sir. Only for prescription drugs. Not for any form of food.

Senator KENNEDY. What would be your reaction if you had that authority, would that be helpful in helping you meet your responsibilities?

Mr. HUTT. Well, Senator, I do not believe the administration has any position at this moment on legislation of that type.

Senator KENNEDY. But your testimony is that the industry will conduct surveillance and provide records if the industry itself wants to cooperate. They have the ability, and obviously all of us would be hopeful that they would cooperate and I am sure the great overwhelming majority of them would be willing to do so. But you do not have the authority now to look beyond the materials that they provide you?

Mr. HUTT. Not unless we pick up our own samples and conduct our own analyses, which again is imposing when you consider the great bulk of food supply in this country.

Senator KENNEDY. If they do not chose to do so, you do not have the power to require that they do so?

Mr. HUTT. Not at the present moment; no, sir.

Senator KENNEDY. Now, if you required surveillance and reporting, would it not make your job easier in terms of fulfilling your responsibility for surveillance?

Mr. HUTT. I believe it would; yes, Senator.

Senator KENNEDY. What would be the cost to the consumer?

Mr. HUTT. Let me try to tackle that in two different ways. Obviously, if the Food and Drug Administration increased its budget, this would be passed on in the form of higher taxes to the consumer. If the industry increased its surveillance, that would also be passed on to the consumer in the form of higher prices in order to pay for it.

If as you suggested, it were merely a matter of the industry records being available to us for inspection, there would be no increase in cost whatever.

Senator KENNEDY. So, you could require that the industry do the testing. You work out with particular industries the different kinds of checkpoints which you have outlined here, and you required the industry to do the surveillance along those lines. Do they do that at the present time?

Mr. HUTT. We certainly hope so. That is why we audit their quality control, to make certain they are doing that. Our experience is that for the most part they are quite willing to undertake that type of work, and the more responsible companies have been for many years.

Senator KENNEDY. For the more responsible companies, it isn't any additional kind of cost?

Mr. HUTT. I would say "No."

Senator KENNEDY. And the responsible companies would be willing to cooperate with you by giving you the results of their surveillance and the materials which lead them to their conclusions?

Mr. HUTT. I believe so. I believe there are people testifying later on this morning who can answer that more definitively.

Senator KENNEDY. I suppose the responsible companies who do the surveillance have the least instances of adulterated food?

Mr. HUTT. It is entirely a prevention matter.

Senator KENNEDY. So the real kind of thrusts are for those that either are not doing it or are unwilling to do it. You do not have at the present time the authority to require that they do it, that the industry do it, do you?

Mr. HUTT. Let me clarify that. There is nothing explicit in the statute that gives us that authority. We have from time to time issued regulations that we believe spell out what constitutes current good manufacturing practices in the industry, and some of those most recent regulations contain specific surveillance testing. The industry has argued—and we are in litigation on this point in one or two particular cases—that these are merely advisory and they are not requirements. We argue that they are requirements. That is therefore an unresolved issue at this moment.

Senator KENNEDY. Which industries?

Mr. HUTT. There was one particular case involving, I believe, the smoked fish industry.

Senator KENNEDY. They say this is advisory?

Mr. HUTT. Yes, that is not a requirement. Obviously, if it is to have any meaning, it must be a requirement. We are arguing that it is a requirement. One judge has ruled against us in a District Court in a criminal case, where I am not sure we can even appeal the issue. So it is still an unresolved issue.

Senator KENNEDY. Do you have the power to require any of the industries to keep records of their surveillance procedures?

Mr. HUTT. No. Again, we are talking solely with respect to foods, and the answer would be no, except in very limited circumstances involving a specific section of the law, section 404. This section deals with temporary permits for emergency situations, which obviously is not the vast bulk of the food supply. Again we have argued under our current good manufacturing practice regulations that such records

must be kept, as a matter of general principle, but again that has not been tested in the courts. So some of the questions you are asking simply cannot be answered. We are going as far as we believe is reasonable, and the law will permit us, in the regulations, but I think you have to realize that there are people who disagree with our view of what is proper.

Senator KENNEDY. In fulfilling your responsibility in overseeing the surveillance of various industries and protecting against adulterated food, would it not be generally useful for your people who have this responsibility to be able to require that certain records be kept?

Mr. HUTT. I would certainly think that would be reasonable, Senator.

Senator KENNEDY. How does the FDA learn that adulterated food has entered the stream of commerce?

Mr. HUTT. Basically, two ways. One is that a manufacturer may himself learn and may tell us, and a great many do. This is the way that recalls are started. The manufacturer may well come to us and say: There is a problem; we have it under control; we are sending our salesmen out to get the food back. That is one way. The other way is that the FDA or State officials or some consumer may happen upon this information in which case we go to the company and again do one of two things, either get the company to recall the product or bring regulatory action ourselves.

Dr. TEPPER. The third way of course is our own surveillance program.

Mr. HUTT. That is part of the second way, or I intended it to be.

Senator KENNEDY. How many do you spot, say this year so far? In your surveillance program, what have been the results so far?

Dr. TEPPER. The surveillance program oriented specifically toward food derives from several sources. One is the market basket program wherein some 30 times a year a sampling is procured from the normal commercial sources, that is, the marketplace, which represents a 2-week intake of a teenage boy, 15 to 20 years old, what he would eat during the course of a 2-week period. The source of these market basket samples is statistically determined to reflect food consumption across the country.

These samples are delivered to a central place. They are suitably prepared and analyzed for particular materials which are of interest at that particular point. This includes chemical adulterants—

Senator KENNEDY. This is interesting, but I want to know how many, on the basis of the surveillance you have had this year, how many adulterated foods have you discovered with your surveillance procedures?

Mr. HUTT. Specifically our inspectors? Senator, I do not believe I can possibly provide that information. We would have to go through the number of seizures, the number of legal actions we have taken, the number of recalls we have initiated.

Senator KENNEDY. Is there any requirement if manufacturers or food processors have adulterated food, that they report it to FDA?

Mr. HUTT. No, there is not.

Senator KENNEDY. Should there not be?

Mr. HUTT. Senator, again I am not in a position to recommend or comment on possible legislation other than what is before us.

Certainly one could argue that is a reasonable position, yes.
 Senator KENNEDY. Could you submit for us about the adulterated food, how much is indicated by the industries themselves, their finding it, and what percent you find?

Mr. HUTT. We would be happy to do that.

Senator KENNEDY. What are the other ways?

Mr. HUTT. State officials or individual consumers may complain.

Senator KENNEDY. OK. Would you tell us about that?

Mr. HUTT. We will certainly do that.

Senator KENNEDY. Just give a little background.

Mr. HUTT. Yes, sir.

[The information referred to follows:]

SOURCES OF INFORMATION LEADING TO ACTIONS ON

ADULTERATED FOODS - FISCAL YEAR 1973

I. Recalls

<u>Initiated by:</u>	<u>Number</u>	<u>Percent of Total</u>
FDA	23	44
State officials	5	10
Consumer	18	35
Manufacturer	2	3.8
Broker	1	1.7
Foreign Officials	2	3.8
National Canners Association	<u>1</u>	<u>1.7</u>
Total	52	100%

II. Seizures

All 392 seizures were FDA-initiated (based on FDA's own findings)

III. Corrective Actions

Approximately 4,225,000 lbs. of foods were voluntarily removed from the market by industry through product destruction, conversion to non-human use, etc.

IV. Import Detentions

All 2576 import detentions were FDA-initiated (based on FDA's own findings)

Senator KENNEDY. Should the public have access to the information obtained by the Food and Drug Administration if the industry did its own surveillance?

Mr. HUTT. You are asking a policy question, Senator. Let me try and tell you how we do it today, and perhaps we can move on into that.

We published new freedom of information regulations as a proposal in May 1972. We said that surveillance work done by FDA, our analytical work, done in our laboratories, and so forth, would be available to the public as soon as a final report is made, unless it was part of an ongoing lawsuit, and was part of the legal papers involved. In that case it would be available as soon as it was made public as part of the lawsuit. With regard to information received from industry, since we have no legal authority to require that this information be given to us, we provided that such information would be retained as confidential, if it was submitted upon a guarantee of confidentiality. This is a difficult policy situation. We could be in a sense very pure about it, which would mean everything we get we will give out, but that would mean we would not be getting anything. We have generally said if somebody will submit analytical data to us only on a confidential basis, then we will pledge confidentiality.

Now if it were required for it to be submitted to us, then that would be an entirely different issue.

Senator KENNEDY. Say we were to require the industry to do its own surveillance, what impact would that have on the Food and Drug Administration's ability to prevent adulterated food? Would this lessen your authority, do you think?

Mr. HUTT. It certainly would not lessen our authority but what it would do would be to supplement the work that we already are doing. Indeed it would probably permit us to place far greater responsibility than we do today upon the industry, because they do have greater coverage, and then we could pinpoint specific problem areas.

Dr. TEPPER. It provides a more continuous kind of surveillance. If we would do this ourselves, we would enter the plant every year, every 2 years at best. If the industry has its own surveillance program, this is a daily procedure conducted during each shift of the workday.

Mr. HUTT. I might add, we would under no circumstances want to see every analytical result of every company. We would be overwhelmed with data. That would be unworkable.

Senator KENNEDY. Thank you. I want to thank you for your comments. You have been very responsive to the questions.

Mr. HUTT. Thank you, Senator. We would leave these manuals. I would ask that they not be given to people outside the staff until we can designate—

Senator KENNEDY. I think you better take them with you. We got the point. Maybe we could keep one or two.

[The prepared statement of Dr. Tepper follows:]

STATEMENT

BY

LLOYD B. TEPPER, M.D.

ASSOCIATE COMMISSIONER FOR SCIENCE

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE

THE

SUBCOMMITTEE ON HEALTH

SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

SEPTEMBER 11, 1973

Mr. Chairman:

We appreciate this opportunity to appear before you to discuss S. 2373, the "Federal Food Inspection Act of 1973." This bill would require the Food and Drug Administration (FDA) to conduct a surveillance program to detect and prevent adulterated food from reaching the marketplace.

S. 2373 is a revision of Amendment 1 to S. 426, the "Toxic Substances Control Act." FDA testified on that amendment on March 21, 1973, before the Subcommittee on the Environment of the Senate Committee on Commerce.

SUMMARY OF PROPOSED BILL

S. 2373 would add a new section 410 to the Federal Food, Drug, and Cosmetic Act which would require the Secretary to conduct a surveillance program for adulterated food. Within 180 days after enactment, the Secretary would be required to propose regulations specifying the surveillance procedures he will follow for the detection and prevention of adulterated food.

The regulations shall include such procedures for surveillance as the Secretary determines are necessary to carry out his responsibilities with respect to the detection and prevention of adulterated food, they shall require, at a minimum, levels of surveillance sufficient to provide reasonable assurance that the presence of adulterated food does not constitute an unreasonable threat to the public health and welfare. Where no practicable procedures are available to provide

- 2 -

the assurance required, the regulations shall specify a program for the development of such procedures, together with specifications and a timetable. The bill would require that analyses to determine the presence and amount of adulterated food shall be performed through the use of the best instruments, technology, and trained personnel which are reasonably available. The results of any analyses shall be made public.

The regulations shall be proposed not more than 180 days and shall become effective not more than one year from the date of enactment. The regulations may be amended on the initiative of the Secretary or on the petition of any interested person. Any person adversely affected by a proposed regulation or proposed amendment, or by a denial of a petition for an amendment, may file objections with the Secretary showing reasonable grounds and requesting a hearing. The Secretary would be required to afford an opportunity for a hearing on such objections. The hearing would consist of both oral and written presentation of data, views, or arguments.

The bill further provides that if the Secretary finds a threat to the public health or welfare which requires an immediate increase in surveillance levels with respect to adulterated food, he may direct an immediate increase in the level to the extent he determines necessary. Notice and an opportunity for a hearing would be provided only after the increase in surveillance takes place.

- 3 -

The bill further provides that it shall not be construed to exempt the Secretary or any other person from any obligation imposed by any other provision of this Act or any other Act, or to permit the use of any substance, practice, or conduct resulting in food becoming adulterated.

DEPARTMENT POSITION ON S. 2373

The Department opposes enactment of this legislation. The bill is not only unnecessary, but it may be construed as erecting procedural hurdles to effective action by the Food and Drug Administration to protect public health. We do not believe it is in the interest of the consuming public to hamstring FDA's ability to take action to protect consumers, in order to achieve the goal of requiring FDA's entire food control program to be specified in regulation form in the Federal Register.

FDA certainly agrees with the intention to have FDA report to Congress and to the public in detail about its plans and procedures to screen food for noncompliance with legal requirements. This information is already given in considerable detail in the Department's annual reports and in the budget request for the FDA. At the same time, we do not see that the benefits to be gained by requiring publication of such plans and procedures in regulation form would offset the possible costs in terms of reduced regulatory flexibility and impaired readiness for unforeseen emergency actions.

- 4 -

The Food and Drug Administration is already engaged in broad-scale efforts involving testing and analysis of food for contaminants, research on the health effects of these substances, and the development of improved methodology to detect these substances.

This bill raises a number of statutory interpretation questions which may adversely affect these actions in the interest of public health protection. For example, the bill could be read as inhibiting FDA's present programs in the area of food surveillance.

First of all, subsection (d) provides that the Secretary may immediately increase the level of surveillance if he finds a threat to the public health or welfare. FDA, however, would ordinarily increase its surveillance activities even if there was merely a potential or possible threat to health. The language of the subsection also could imply that FDA could not act in less critical situations to increase its surveillance until a proposed regulation issued and hearings were held.

Another conflicting interpretation of the bill is possible. Subsection (g) specifically provides that the bill shall not be construed to exempt the Secretary or other persons from obligations under any other provisions of law. Thus, while the hearing is going on under the proposed section 410 to determine the appropriate levels of surveillance, the Secretary

- 5 -

could establish his own levels under present law. Indeed these levels could continue in effect even after the hearing because of the subsection (g) provision that present authority will not be affected. Thus under subsection (g) the situation could arise where FDA is initiating seizure actions under sections 402 and 403 against food which complies with the procedures established pursuant to the proposed section 410.

FDA is constantly revising its procedures, methodology and levels of inspections as situations warrant. If these changes cannot be implemented without going through an administrative hearing, the effectiveness of FDA is compromised. But, if subsection (g) means that we can ignore the new requirements of section 410 and proceed under our other authority, the bill is virtually meaningless.

In sum, the bill adds nothing to present protection, creates an administrative burden including, among other things, mandatory hearings, diminishes FDA flexibility to act, and unnecessarily raises a number of questions of interpretation.

As noted, under existing legislative authority, FDA acts even though toxic levels may never be reached if the quantity present exceeds the maximum no-effect level reduced by a safety factor. This level varies according to a substance's potential risk and its presence in other foods and from other exposures.

- 6 -

We believe the concept of "unreasonable threat to the public health or welfare" employed in the bill is a relatively imprecise criterion and is susceptible of being interpreted as more restrictive than our current preventive approach to chemicals found in food. What does this concept do to the Delaney anti-cancer clause, for example, or to the use of a one hundredfold safety factor? Could FDA establish in a rulemaking proceeding that these requirements are needed to prevent an "unreasonable threat to public health?" We would assume that the obvious intent of this bill is not to limit our authority and that again subsection (g) which preserves our existing authority would take precedence and the new requirements of section 410 need not be observed. We believe this example points up the fact that we can only view the bill as undesirable legislation.

In our judgment, this bill would only mandate a flurry of administrative activity which could serve to mislead the public into believing that some simple solution had just been found to the many-faceted problems posed by environmental contaminants in food. And we believe the additional cost of this activity, almost impossible to estimate, would provide little, if any, increase in consumer protection.

CURRENT ACTIVITIES

The Food and Drug Administration has given increased emphasis and resources in the past several years to the surveillance of food for adulteration.

- 7 -

At the present time, FDA directs essentially all of its food budget, approximately 60 million dollars, to problems concerned with food safety. These activities include surveillance for microbiological contamination and toxins, heavy metals, industrial chemicals, and mycotoxins and natural poisons. Our programs entail a variety of approaches to the various problems depending on the likelihood and degree of hazard from a given problem and its prevalence.

1. Inspections: Sanitation and Quality Control

FDA's traditional tool for maintaining surveillance over the food industry is the establishment inspection. Reflecting the Administration's emphasis on consumer safety during the past few years, FDA was, in 1973, able to accomplish 16,000 inspections and 45,000 sample examinations of food to detect microbial contamination problems and to reduce filth, decomposition, and other adulterants in food. This program has more than doubled since 1972. Our regulatory actions against violative products have increased markedly.

We have also entered contracts with State agencies whereby they will perform inspections and sample analyses of bakeries, soft drink plants, food warehouses, and grain storage facilities. The primary emphasis will be plant sanitation.

- 8 -

2. Quality Control Programs: Preventing Microbial Contamination

FDA's quality control program identifies those critical control points in food processing where food safety problems are likely to develop. The object is to help prevent problems before they occur, in the hope we can obviate later corrective actions such as recalls or seizures of food. This program supplements our traditional inspections. It calls for FDA to develop better information on daily compliance status of the food industry, which a three-pronged check: sampling of foods at the retail level, plant inspections by specialized quality assurance teams, and expanding the cooperative quality assurance programs.

We are paying particular attention now to improving quality control in plants which can low-acid foods. As you know, those foods may, if improperly processed, present risks of toxicity from Botulinum toxin. We have also developed an emergency permit control system in cooperation with the National Canners Association to impose more stringent controls on this segment of the food industry.

The shellfish industry has also received increased attention from FDA, because of the susceptibility of shellfish to contamination from pollutants in growing areas and because of the risks of paralytic shellfish poisoning ("red tide").

Incidentally, the problem of "red tide" provided an excellent illustration of FDA's ability to move rapidly and respond to a risk to health from food. FDA assisted New England State officials in removing potentially hazardous shellfish from the market. As soon as we learned that

- 9 -

potentially toxic shellfish had been distributed elsewhere, FDA alerted food control officials around the country. FDA field staff was directed to locate and remove from the market all those shipments of toxic shellfish. We also instituted a laboratory-testing program to identify suspect lots. All these efforts by the States and by FDA averted any deaths and further poisonings which undoubtedly would otherwise have occurred.

We are also developing microbiological quality standards for food which will permit regulatory action based solely on the product's non-compliance with the standard, without need for factory inspection. Standards have been published for cream pies, edible gelatin, and bottled water. We plan to publish standards for ten more foods in FY 1974 and to conduct a survey on 25 other foods to obtain the data necessary to establish microbiological quality standards.

One integral part of the effort to reduce microbiological contamination of food is to lower the incidence of salmonella and other microbiological contaminants.

Recently, FDA received the report of the FDA Task Force on Salmonella. The report recommended new emphasis on consumer education, programs for animal byproduct rendering plants, and regulatory initiatives by FDA to lessen the risks of salmonella contamination in the distribution and

- 10 -

preparation of food. We intend to step up on our efforts in this area, which in the last five years, have already reduced the percentage of products contaminated from salmonella in five problem food categories, regulated by FDA, from almost nine percent to less than one percent.

3. Heavy Metals

Our programs on heavy metals involve toxicological studies with respect to mercury, lead and cadmium as well as the development of analytical methods for mercury, lead, cadmium, arsenic, selenium and zinc. Analysis for these six metals is now included in the Total Diet Studies which include a "market basket" type sampling of products at the retail level.

4. Industrial Chemicals

Our Bureau of Foods also maintains surveillance of the chemical industry to determine what substances are being produced and the probability of such substances being found in food. Where a substance is or may be a contaminant of food, it is necessary for the Bureau to develop methods for detecting the substance in foods. Data must also be gathered to ascertain how harmful the substance may be, to support possible regulatory action. Where warranted, field surveys are undertaken to determine the incidence of a substance in the food supply. Regulatory actions are taken where necessary to protect the consumer.

- 11 -

5. Industrial chemicals and pesticides

Our activities concerned with industrial chemicals include surveillance for pesticides in the same Total Diet Studies and field surveys of agricultural products. We are also continuing to sample and analyze for polychlorinated biphenyls (PCB's) and phthalate esters. Other materials such as chlorinated paraffins and orthophosphate esters, produced in quantities comparable to the prerestriction production of PCB's, and having a similar potential for getting into the food chain, are being investigated to see if they do, in fact, appear in foods.

6. Mycotoxins and natural poisons

Activities with mycotoxins and natural poisons involve examining for aflatoxin in raw agricultural commodities (peanuts, cottonseed, corn, and nuts, in cooperation with the U.S. Department of Agriculture) and residues in animal tissue. We are also concerned with the possibility of ochratoxin in grain, patulin in apple juice, sterigmatocystin in grain, and penicillic acid in corn, dry beans and apple juice. Recent harvesting and drying conditions for corn have contributed to molding and two possible mycotoxin problems: the T-2 toxin and zearalenone.

- 12 -

All of this may help to illustrate the broad range of ongoing activity concerned with the surveillance of foods for adulteration that is being undertaken under existing legislative authority.

CITIZEN PARTICIPATION

At the present time, any citizen may petition the Agency for an administrative action 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.

Additionally, almost all FDA regulatory decisions are published for comment in the Federal Register. Again, anyone can comment and the high frequency of comment from organized groups speaking for consumers, the medical and scientific communities, and industry, indicates the effectiveness of this means of communication.

The value we place on outside comment is particularly well illustrated in the case of mercury contamination of fresh water fish. The original alert received by the FDA was from Canadian authorities based on the work of a graduate student. Although preliminary studies indicated no potential hazard with salt water fish, it was Professor McDuffie at the State University of New York at Binghamton who alerted FDA to the problem with tuna and swordfish.

- 13 -

It is true that the agency may not take immediate action on a specific problem, but this is most often because the FDA is responsible for making certain that the findings are well-grounded scientifically. On occasion, time is also required for translating valid and objective scientific data into an administrative regulation which gives due consideration to potential as well as identified risks, benefits, extent of use and enforcement realities. We believe FDA has done well in this regard.

In brief, adequate opportunities for participation in FDA decisions do exist and are being used to advantage from the consumer's point of view. Legislation is not required to broaden public participation in the administrative process.

Recently a United States Court of Appeals had occasion to comment upon FDA's fairness and openness to participation by outsiders, including those who are critics.* The Court said, "the administrative process seems to have been working well in this instance," since several eminent critics had been included on the panel whose review resulted in the FDA action which they were contesting, and because communications to FDA disagreeing with its conclusions had always received a specific

*Bradley v. Weinberger, No. 73-1014 (1st Cir., July 31, 1973), in which a group of physicians were contesting FDA's proposal to require restrictive labeling for oral hypoglycemic drugs for diabetes management.

- 14 -

and complete response. The Court went on to say that, "Arguments, studies, and materials, were not ignored; difficult problems were not swept under the rug. The communications evidenced agency. . . receptivity to criticism." We will endeavor to be deserving of this reputation in our dealings with all groups, including consumer advocates and expert critics, and in all FDA regulatory programs.

LEGISLATION LIKE S. 2373 IS NOT THE ANSWER TO PUBLIC CONCERN

Public concern is a different issue. We believe public concern about adulteration of our food supply would be better served through more education than through this legislation. FDA certainly is cognizant of and shares the current concerns about the array of substances to which man is exposed through food and other environmental media. When FDA has taken action against a potential hazard, we have tried to convey to the public our assessment of the magnitude of risk involved. This, of course, may vary with the problem.

The risk of botulism from improperly prepared foods with the immediate potential consequence of illness and/or death is significantly different from concern about long-term accumulation of chemicals such as mercury in certain species of fish. Our experience with public reaction to these types of situations illustrates that considerable public confusion and misunderstanding can occur about the degree of hazard posed by a substance in a given situation.

- 15 -

We therefore consider it part of our role to educate the public to be able to appreciate that situations do occur in which scientists change their minds or disagree and when familiar products may be banned. We want the public to realize that these situations may justify appropriate action and concern, but seldom justify panic or alarm.

This is not to say that there is no need to consider additional legislation to protect the public from adulterated foods. For example, FDA does not even have a reliable means of knowing who is processing food or where. Legislation to require the registration of food processors is needed and is under active consideration by the Administration and may be forwarded to Congress within the next few weeks. Other proposals to strengthen FDA ability to prevent the distribution of adulterated or misbranded foods are also under consideration and we hope to have the various issues involved in these proposals resolved shortly so that legislation can be sent up before the end of the year.

FOOD PROCESSING REGISTRATION

Last week an amendment to S. 2373 was introduced to provide for the mandatory registration of food processing establishments. While we have been unable to comprehensively review all the provisions, we certainly endorse the principle of the amendment as we did in the last Congress and do have some preliminary comments which may be of interest to the Subcommittee.

- 16 -

We believe that the lack of authority to require food processors to register with FDA seriously inhibits our ability to properly regulate the food supply of this Nation. It is impossible for FDA to adequately regulate or monitor the food supply system without full information on who is processing food and where they are located.

The inventory which FDA now maintains and upon which FDA programs its inspectional activities is incomplete. Presently, our only methods of determining the existence of new firms are by inspector surveillance, reports from cooperating State and local officials, or consumer complaints.

Our existing inventory lists approximately 60,000 firms in the food industry which are subject to inspection by FDA. Of these, some 32,000 are food manufacturing and processing plants. The scope of the food industry is vast. The agency must keep track of a growing and changing industry.

Legislation such as the amendment to S. 2373 which is pending before this Committee would provide mandatory registration.

The amendment would provide for the annual registration of establishments engaged in the processing or packing of food (including establishments engaged only in intrastate commerce). New producers would be required to register immediately upon first engaging in such activities. A person operating such an establishment would register his name,

- 17 -

principal place of business, the location of each such establishment and a complete list of all foods or classes of foods being processed therein and the type of processing being engaged in by the establishment. Under the bill, a registration number would be assigned. The Secretary would also have the authority to exempt classes of persons from registration if he finds that registration is not necessary to protect the public health. Every registered establishment would be subject to inspection pursuant to the Federal Food, Drug, and Cosmetic Act.

The Administration has recently submitted legislation to provide for a mandatory registration system with respect to food processing establishments. We expect this bill to be introduced within the next week and hope that it will receive consideration. The Administration's bill differs from the amendment to S. 2373 only in matters of technical detail. Its provisions were developed after careful consideration within the Administration and we strongly urge its enactment.

SUMMARY

In summary, Mr. Chairman, we recommend against S. 2373 because it will not add any additional authority to the Federal Food, Drug, and Cosmetic Act or serve to increase consumer protection. While we understand the concerns behind and intent of S. 2373, it is not needed. Moreover, it could serve to weaken rather than strengthen the existing surveillance of our food supply.

- 18 -

The Administration, however, shares the Chairman's concern with assuring the safety of food as reflected in his sponsorship of legislation to provide for a much needed mandatory food processing registration system. We endorse the amendment to S. 2373 in principle but believe the language that is contained in the Administration's proposal is preferrable and still accomplishes the objective of the amendment.

My colleagues and I would be pleased to try to answer any questions you or any Members of the Subcommittee may have.

Senator KENNEDY. I would like to welcome our next panel of witnesses to the Senate Health Subcommittee. Michael Jacobson, Ph. D., has served as a research associate of the Salk Institute and as a consultant to the Center for the Study of Responsive Law in Washington, D.C. In 1970, he joined several colleagues in the formation of the Center for Science in the Public Interest, where he is presently a co-director. Susan Sechler is the assistant director of the Agribusiness Accountability Project in Washington, D.C., and Anita Johnson, from whom we have had the privilege of hearing before, is an attorney specializing in food and drug safety, and is here representing the Health Research Group.

STATEMENT OF MICHAEL JACOBSON, PH. D., CENTER FOR SCIENCE IN THE PUBLIC INTEREST; SUSAN SECHLER, AGRIBUSINESS ACCOUNTABILITY PROJECT, WASHINGTON, D.C.; AND ANITA JOHNSON, HEALTH RESEARCH GROUP, WASHINGTON, D.C.

Mr. JACOBSON. I am Michael F. Jacobson. I am codirector of the Center for Science in the Public Interest (Washington, D.C.) and have been concerned for the past several years with the quality of the American food supply. I have written books on food additives and nutrition. I welcomed the committee's invitation to testify on S. 2373, a bill intended to decrease the amount of adulterated food in the marketplace.

Despite the food industry's arguable contention that America has the purest food supply in the world, a frightfully large amount of food is adulterated during the manufacturing process with potentially harmful substances; and notwithstanding the contentions of the big food companies, not all of the contaminated products are made by the small fly-by-night outfits. Excerpts from recent FDA "weekly recall reports" illuminate well the tip of a big, dirty iceberg:

Fifteen thousand cases of Coca-Cola were contaminated with mold (February 22, 1973); 4 months later (June 21, 1973) at the same bottling plant, another 15,000 cases were contaminated (Tonawanda, N.Y.).

Seven hundred and thirty cases of Red Owl Stores' peanut butter were contaminated with aflatoxin (August 2, 1973).

Five hundred thousand pounds of Fran Mushroom Co.'s mushrooms were contaminated with clostridium botulinum, the deadly bacterium (April 5, 1973), and as a result, over 72,000 packages of A. & P. Co.'s Cap'n John Frozen Tuna Noodle Casserole were recalled (April 12, 1973).

One hundred and three thousand cases of Sunshine Biscuit Co.'s crackers and cookies were contaminated with the pesticide Ronnel (June 1, 1972).

Thirty thousand cases of Hawaiian Punch fruit drink had insect contaminate on them (December 21, 1972).

In late 1972, the Canada Dry Corp., in Pittsburgh was filling 2,500 cases of soda a day in dirty bottles.

Twenty thousand gingerbread men baked by Federal Bake Shops, Inc., Cincinnati, were blessed with rodent contamination (Jan. 11, 1973).

The list of contaminated products released weekly by FDA represents only a small fraction of contaminated products. Not every package or lot of food can be inspected and much adulteration goes undetected. In fact, the current Federal effort to prevent adulterated food from entering the lines of marketing is so meager that, on the average, FDA inspectors visit food plants only once every several years.

Food adulteration is most effectively controlled at the processing plant by quality-conscious manufacturers. This self-regulatory approach to cleanliness has been modestly successful, but the frequent discovery of large batches of adulterated food indicates that the food industry and the public would well benefit from legislation that would give the Federal Government greater authority to supervise and inspect the manufacture of this Nation's food. For that reason, I endorse S. 2373, and the amendment to it regarding the registration of food manufacturing facilities.

I do think, though, that the intent of Congress should be spelled out more clearly in the bill itself, rather than being left to the interpretation of FDA officials. As is well known, many high-ranking FDA officials were executives in or counsels to major food companies. High-ranking officials routinely leave FDA and join the industry they were charged with regulating. It may be asking a bit much to expect these men and women to issue stringent regulations and to enforce them vigorously and impartially.

I would suggest that the bill state specifically—if this is, in fact, the intent of Congress—that “surveillance procedures” referred to in the bill include general procedures, such as how often different kinds of plants are visited, and technical details, regarding analytical methods and peculiarities of certain foods or facilities.

The bill for quarterly inspections—rather than leaving this important factor to the discretion of FDA. Of course, frequent inspections would necessitate an increased budget for FDA.

Due to the enormous size of the food and beverage industry, FDA inspectors cannot be stationed in every plant during every minute of every day (as is done in slaughterhouses by the Department of Agriculture). This means that the safety and cleanliness of the food supply inevitably depends upon the conscientiousness of the workers and management. As part of their effort to maximize the quality of their products, manufacturers keep records of product contamination, spoilage, discards, et cetera. These records could be used by FDA to identify trouble-producing processes and machinery and to identify companies with poor records of cleanliness. Summaries of the inspection records could similarly enable the public to know which companies have outstandingly good records and which have poor records, thereby stimulating improved self-regulation by industry.

Senator KENNEDY. You are not suggesting that they have to give up any trade secrets or any of these types of things at all?

Mr. JACOBSON. No; just inspection records, how much of the food is dirty and how much is clean. I would recommend S. 2373, to make complete inspection records available to FDA, and summaries of these records available to the public.

Senator KENNEDY. You think we ought to give FDA the power to get those even if some of the industries do not want to give them, that they ought to have the authority?

Mr. JACOBSON. Absolutely.

Senator KENNEDY. You are suggesting that the bill should require the manufacturers to provide the inspection and surveillance themselves, and second, to keep records? And third, to make them available to Food and Drug, when Food and Drug wants it, and fourth, to make them public?

Mr. JACOBSON. Yes; it seems basic to have that. Industry should inform FDA of voluntary recalls, just as routine. If it turns out that some company is recalling food every other week, it is clear something is wrong. As it now stands, the FDA and the public have no way of knowing if there are such companies.

I would recommend that S. 2373, be amended to make complete inspection records available to FDA and summaries of these records available to the public.

It is important that the Federal Government assure the American public that the foods it is eating are not adulterated. But in closing, I would like to put the problem of adulteration in perspective by urging that the Government pay at least as much attention to the food itself as to the contaminants that may be in the food. Much illness and death in the United States and other modern nations is caused by the "modern" diet, which is high in salt, sugar, and saturated fat, and low in fiber. A rapidly growing body of evidence associates these dietary factors with tooth decay, constipation, diverticulitis, diabetes, obesity, intestinal cancer, hypertension, and heart disease. The Congress, and the Departments of Agriculture and Health, Education, and Welfare, should assist every American to consume the foods that are most conducive to good health and to avoid the foods that contribute to widespread illnesses. Taking the mold out of the soda pop, and the rodent contamination out of the gingerbread men, is laudable, but does not make these products healthful.

Thank you very much, Senator.

Senator KENNEDY. I am going to come back to the questions, but does your research show that most of the companies, what percent of the companies, food processors, actually do surveillance?

Mr. JACOBSON. I have no way of knowing.

[The prepared statement of Mr. Jacobson follows:]

Michael F. Jacobson

Center for Science in the Public Interest

1779 Church St. NW

Washington, DC 20036

Testimony on S. 2373 **adulterated food**

United States Senate Committee on Labor and Public Welfare

Health Subcommittee

September 11, 1973

I am Michael F. Jacobson. I am Co-Director of the Center for Science in the Public Interest (Washington, DC) and have been concerned for the past several years with the quality of the American food supply. I have written books on food additives and nutrition. I welcomed your invitation to testify on S. 2373, a bill intended to decrease the amount of adulterated food in the marketplace.

Despite the food industry's arguable contention that America has the purest food supply in the world, a frightfully large amount of food is adulterated during the manufacturing process with potentially harmful substances; and notwithstanding the contentions of the big food companies, not all of the contaminated products are made by the small fly-by-night outfits. Excerpts from recent FDA "weekly recall reports" illuminate well the tip of a big, dirty iceberg:

- 15,000 cases of Coca Cola were contaminated with mold (2-22-73); four months later (6-21-73) at the same bottling plant, another 15,000 cases were contaminated (Tonawanda, New York).
- 730 cases of Red Owl Stores' peanut butter were contaminated with aflatoxin (8-2-73).
- 500,000 pounds of Fran Mushroom Company's mushrooms were contaminated with Clostridium botulinum, the deadly bacterium (4-5-73)...
- ...and as a result, over 72,000 packages of A & P Company's Cap'n John Frozen Tuna Noodle Casserole were recalled (4-12-73).
- 103,000 cases of Sunshine Biscuit Company's crackers and cookies were contaminated with the pesticide Ronnel (6-1-72).
- 30,000 cases of Hawaiian Punch fruit drink were contaminated with insects (12-21-72).

-2-

- In late 1972 the Canada Dry Corporation in Pittsburgh was filling 2,500 cases of soda a day in dirty bottles.
- 20,000 gingerbread men baked by Federal Bake Shops, Inc., Cincinnati, were graced with rodent contamination (1-11-73).

The list of contaminated products released weekly by FDA represents only a small fraction of contaminated products. Not every package or lot of food can be inspected and much adulteration goes undetected. In fact, the current Federal effort to prevent adulterated food from entering the lines of marketing is so meager that, on the average, FDA inspectors visit food plants only once every several years.

Food adulteration is most effectively controlled at the processing plant by quality-conscious manufacturers. This self-regulatory approach to cleanliness has been moderately successful, but the frequent discovery of large batches of adulterated food indicates that the food industry and the public could well benefit from legislation that would give the Federal government greater authority to supervise and inspect the manufacture of this nation's food. For that reason I endorse S. 2373 and the amendment to it regarding the registration of food manufacturing facilities.

I do think, though, that the intent of Congress should be spelled out more clearly in the bill itself, rather than being left to the interpretation of FDA officials. As is well known, many high-ranking FDA officials were executives in or counsels to major food companies. High-ranking officials routinely leave FDA and join the industry they were charged with regulating. It may be asking a bit much to expect these men and women to issue stringent regulations and to enforce them vigorously and impartially.

-3-

I would suggest that the bill state specifically--if this is in fact the intent of Congress--that "surveillance procedures" referred to in the bill include general procedures, such as how often different kinds of plants are visited, and technical details, regarding analytical methods and peculiarities of certain foods or facilities. The bill should dictate the maximum interval between inspections--I would argue for quarterly inspections--rather than leaving this important factor to the discretion of FDA. Of course, frequent inspections would necessitate an increased budget for FDA.

Due to the enormous size of the food and beverage industry, FDA inspectors cannot be stationed in every plant during every minute of every day (as is done in slaughterhouses by the Department of Agriculture). This means that the safety and cleanliness of the food supply inevitably depends upon the conscientiousness of the workers and management in the industry. As part of their effort to maximize the quality of their products, manufacturers keep records of product contamination, spoilage, discards, etc. These records could be used by FDA to identify trouble-producing processes and machinery and to identify companies with poor histories of cleanliness. Summaries of the inspection records could similarly enable the public to know which companies have outstandingly good records and which have poor records, thereby stimulating improved self-regulation by industry. I would recommend that S. 2373 be amended to make complete inspection records available to FDA and summaries of these records available to the public.

It is important that the Federal government assure the American public that the foods it is eating are not adulterated. But, in closing, I would like to put the problem of adulteration in perspective by urging

-4-

that the government pay at least as much attention to the food itself as to the contaminants that may be in the food. Much illness and death in the United States and other modern nations are caused to a large extent by the "modern" diet, which is high in salt, sugar, and saturated fat, and low in fiber. A rapidly growing body of evidence associates these dietary factors with tooth decay, constipation, diverticulitis, diabetes, obesity, intestinal cancer, hypertension, and heart disease. The Congress and the Departments of Agriculture and Health, Education, and Welfare should assist every American to consume the foods that are most conducive to good health and to avoid the foods that contribute to widespread illnesses. Taking the mold out of the soda pop and the rodent contamination out of the gingerbread men is laudable, but does not make these products any more healthful.

Senator KENNEDY. Ms. Sechler.

STATEMENT OF SUSAN SECHLER, ASSISTANT DIRECTOR, AGRIBUSINESS ACCOUNTABILITY PROJECT, WASHINGTON, D.C.

Ms. SECHLER. Thank you very much for the opportunity to present testimony today in support of S. 2373 and Senator Kennedy's amendment thereto.

My name is Susan Sechler, and I am the assistant director of the Agribusiness Accountability Project (AAP). We are a public interest research group concerned with the impact of corporate agribusiness in this country.

The project was founded in 1969 and is mainly supported by grants from the Field Foundation and the Stern Fund. Our publications include monographs on tax-loss farming, various corporations in agriculture, farmworkers, pesticides, and two book-length publications: "Hard Tomatoes, Hard Times"; and "The Great American Grain Robbery."

S. 2373 is an important first step toward establishing Federal food inspection policy which will provide adequate consumer protection against contaminated foods. In a speech entitled "Consumerism in the 70's," the chief legal counsel of the National Canners Association bemoans the rise of what he calls "rampant consumerism," "the increase in the tempo of agitation by scientifically uninformed critics," and "the constant harassment by congressional committees of the Food and Drug Administration."

The speech goes on to say that the food industry needs more intelligent and intensive public education to, among other things, tell the public how the industry "polices its own house * * * We must also do a better job of communicating with various levels of government. We must make known our readiness to cooperate and our willingness to take voluntary action to correct any difficulties that may exist. We must call their attention to our success at self regulation."

With FDA inspection of processing facilities averaging only one in 3 years, it seems that the consumer's only hope is "self-regulation" and I wish we could agree with the industry's claim of success. However, our evidence suggests that FDA's laissez faire practices have led to some pretty loose policies in the food industry.

For example, as part of our food action campaign, the AAP recently undertook a study of the Del Monte Corp. With sales of over \$947 million in 1972, Del Monte is the world's largest canner of fruits and vegetables—larger than its two closest competitors combined (Stokley-Van Camp and Libby, McNeill & Libby).

Del Monte's \$15 million annual advertising budget, the Del Monte red shield and the slogan, "The more you know about peaches, the better for Del Monte," have linked the company's familiar products with an assurance of quality for many consumers.

During our study of Del Monte, we obtained the corporation's 1969-71 plant inspection records. These reports are not a reassuring testimonial for either "self-regulation" or "readiness to cooperate."

Del Monte Corp., Burley, Idaho: In his summary, the inspector says:

This is the initial inspection of this corn and pea canning plant. Current inspection shows this firm to be packing corn in a plant still under construction, which is not tight to insects or windborn contaminants. Wash water and condensate was seen falling into raw materials and finished products. Loose pieces of metal solder were found in cans being filled with corn. The firm is using water from an untested private well in finished products and as cooling water in their retorts; it has not been chlorinated. Management refused formulation, coding information, photographs and to permit review of product quality control records.

In his "discussion with management," the inspector goes on to say:

Concerning the fact that the firm was operating in a building that was still under construction, "X" said that he was given orders by his superior to start the plant, even though he acknowledged he was personally aware that it was probably illegal under the Food, Drug, and Cosmetic Act to do so at this time. He stated that he was aware that it was illegal to process foods under conditions whereby they may become contaminated, but he said that he had to follow orders.

In his section on "guarantees," the inspector wryly concludes:

This firm requires a Food and Drug guarantee from every grower they buy their corn from. "X" stated that he did not know if any customers who bought their canned corn required any guarantees from them, as this would be handled out in the main office in San Francisco.

Del Monte Corp., Crystal City, Tex.: In the inspection of this plant, the inspector says:

"X" refused to tell me how much calcium chloride was being added to canned potatoes. "X" refused me the coding structure, and would not allow me to see other quality checks without a specific request for the exact code I wanted to see.

And in reference to Del Monte's own quality checks:

Either the foreman on the floor or the mechanic at the beginning of the morning pulls four cans and tears them down the seams and checks them. This is done again at noon, again in the evening and again at night—four times a day.

At the end of his report, the inspector mildly states:

No other recommendations were made other than that the firm could possibly check and tear down can seams a little more often than four times a day.

DEL MONTE CORP., SAN JOSE, CALIF.

FDA has consumer complaints on file reporting these findings in Del Monte cans; rusty hairpin, dead bird, corncob, whole dead mouse, and wooden sticks. In investigating one of these complaints the inspector says:

The cans are conveyed for long distances in an open condition prior to reaching the seamers. During this travel, foreign material could possibly fall into the cans or could easily be placed into the cans by an employee if he so desired. During my inspection of this form when they were canning spinach on 3/30/70 (one year before) I pointed out this objectionable condition.

DEL MONTE DE PUERTO RICO, MAYAGUEZ, PUERTO RICO

According to the report, the main part of the inspector's time was spent tracking down the reason for retort indicator tags which were not changing color, and which would therefore not register whether the individual basket had been through the retort or not, and retort production records which did not show a true chart reading but were being recorded at 242°F regardless of chart readings. However, the

inspector also noted "some areas which could cause a bacteriological buildup in the product prior to retorting. For example: The female employees were not washing or sanitizing hands before returning to work following breaks; wooden-handled knives are being used for cleaning of tuna and these knives are not cleaned or sanitized during the production day."

These reports are shared with the committee as evidence we found which would point to the need for more inspections. We are not talking about protecting the public against esoteric strains of bacteria, but rather against outrageously shabby sanitary practices—simple dirt and insects being blown in while a facility is still under construction, an untested, unchlorinated well, quality control which consists of opening four cans four times a day, and employees not washing their hands after breaks.

But the average consumer didn't need either the Agribusiness Accountability Project or the FDA to tell them that the food industry needs more regulation. According to a recent survey cited by the National Canners in the speech I referred to earlier, 40 percent of the public believed that a food manufacturer that deceives the public may get away with it for a long time; 50 percent had concluded that food labels were more designed to deceive than to inform, and almost 70 percent of consumers interviewed wanted more Federal legislation, looked for new agencies to test products, believed that testing by the Government would be more reliable and dependable than testing by the food industry, and felt a need for massive detailed Government regulation.

The AAP agrees that a public monitor can do better than self-regulation. Therefore, we support S. 2373. We would also like to recommend the following specific changes in the FDA regulations affecting inspection procedures:

1. That the FDA inspector have access to any and all records and information that may be necessary to fulfill his mandate to protect the public. (Current law does not give inspectors access to records, even in a case of contamination, and—as shown earlier—access to records is not necessarily volunteered.)

2. That the FDA be given the right to require temporary detention of food which the agency has reason to believe is contaminated, before final authority for seizure has been obtained. (Here again, FDA is dependent on voluntary cooperation of the food processor. For example, a recent GAO report revealed that, during one of the more recent botulism episodes, before the authority to seize the suspected goods was final, the food processor agreed voluntarily to delay shipment. However, the report says, "... they were unable to honor that promise because of fiscal considerations . . ." The FDA was therefore required to seize the product at over 100 different locations.)

We also support Senator Kennedy's registration amendment, but would suggest additions which we think are of importance.

1. That a food firm or plant, canning or packing food under several labels, register all labels under which its products are sold and that the complete information required by the legislation be provided for each of the private labels.

2. Every package or can should have on its label the name and place of business of the true manufacturer, packager, and distributor. (The

importance of this requirement cannot be overemphasized. In the well known botulism incident with Bon Vivant soups, the fact that Bon Vivant canned soup under 35 different private labels complicated seizure efforts considerably. Had the real manufacturer's name and location been on the can, tracking down the contaminated goods would have been easier and consumers could immediately have identified for themselves any they had already purchased.)

Thank you.

Senator KENNEDY. Those are good suggestions. What ever happened to Del Monte? What ever happened after these reports by the Food and Drug Administration and these other discoveries came about? What was the bottom line on that investigation?

Ms. SECHLER. Our project receives the FDA reports as part of an ongoing investigation of the Del Monte Corp. as an example of the impact of a corporate leader in the highly concentrated food industry. We are currently working with a number of consumer, farmer, and labor groups on a number of agribusiness issues brought out in the Del Monte study.

Senator KENNEDY. I was wondering with regard to these particular discoveries and the reports, has the Food and Drug Administration given any kind of reaction to it or have you spoken to them about it?

Ms. SECHLER. No; however, I do know that none of the specific examples I cited led to seizure, although during the past 5 years the FDA has twice seized Del Monte shipments found "packed under unsanitary conditions." If a report does not lead to a seizure action, I do not know if FDA does anything else.

Senator KENNEDY. You can let us know.

Ms. SECHLER. I think FDA can let you know easier than I could. They are more familiar with the subtleties of their own procedures and have easy access to the records—

Senator KENNEDY. I am interested in what your organization does. If you find these things out, where does it end? Do you just reveal them to the Congress or Senate or do you go out and press them? That is my question. It is a legitimate one.

If you do not have the answer, I do not want an answer that you can go to the FDA—

Ms. SECHLER. I misunderstood you.

Senator KENNEDY. You make these allegations. Those are serious charges. I want to know what the followup is. You make these allegations and charges. Do you leave them there or what do you do with them?

You have listed four or five different things that have happened. You have listed what happened out in Burley, Idaho, with Del Monte Corp., and you have given what has happened in Crystal City, Tex., and San Jose with regard to Del Monte. What I am interested in is what you do about them, what have been the results.

Ms. SECHLER. Del Monte was an example of a leader in the food industry. Our purpose in singling out one corporation was just as an example.

One of our main efforts at the project is to make public information about corporate policy and practices in the agricultural sector of the economy that the public might not otherwise have access to. This includes the impact agribusiness corporations are having on consumers, farmers, and rural America as a whole. Various remedies to the problems described are suggested and in some circumstances they are implemented, in others they are not.

I am testifying here today to bring this information to your attention, and I would hope that it will be useful to you.

[The prepared statement of Ms. Sechler, with accompanying material follow:]

STATEMENT OF THE AGRIBUSINESS ACCOUNTABILITY PROJECT
IN SUPPORT OF S2373
AND SENATOR KENNEDY's Amendment to *S.2373*
September 11, 1973

Thanks you very much for the opportunity to present testimony today in support of S.2373 and Senator Kennedy's amendment thereto.

My name is Susan Sechler and I am the assistant director of the Agribusiness Accountability Project (AAP). We are a public interest research group concerned with the impact of corporate agribusiness in this country. The Project was founded in 1969 and is mainly supported by grants from The Field Foundation and the Stern Fund. Our publications include monographs on tax-loss farming, various corporations in agriculture, farmworkers, pesticides, and two book-length publications: Hard Tomatoes, Hard Times; and The Great American Grain Robbery.

S.2373 is an important first step toward establishing Federal food inspection policy which will provide adequate consumer protection against contaminated foods. In a speech entitled, "Consumerism in the 70's," the Chief Legal Counsel of the National Canners' Association bemoans the rise of what he calls "rampant consumerism," "the increase in the tempo of agitation by scientifically uninformed critics," and "the constant harrassment by Congressional Committees of the Food and Drug Administion." The speech goes on to say that the food industry needs more intelligent and intensive public education to, among other things, tell the public how the industry "polices its own house"... "We must also do a better job of communicating with various levels of government. We must make known our readiness to cooperate and our willingness to take voluntary action to correct any difficulties that may exist. We must call their attention to our success at self regulation."

With FDA inspection of processing facilities averaging only one in three years, it seems that the consumer's only hope is "self-regulation" and I wish we could agree with the industry's claim of success. However, our evidence suggests that FDA's laissez faire practices have led to some pretty loose policies in the food industry.

For example, as part of our FOOD ACTION CAMPAIGN, the AAP recently undertook a study of the Del Monte Corporation. With sales of over \$947 million in 1972, Del Monte is the world's largest canner of fruits and vegetables--larger than its two closest competitors combined (Stokely-Van Camp and Libby, McNeill and Libby). Del Monte's \$15 million annual advertising budget, the Del Monte red shield, and the slogan, "the more you know about _____ (the product), the better for Del Monte," have linked the company's familiar products with an assurance of quality for many consumers.

During our study of Del Monte we obtained the corporation's 1969-71 plant inspection records. These reports are not a reassuring testimonial for either "self-regulation" or "readiness to cooperate."

Del Monte Corporation, Burley, Idaho

In his summary, the inspector says:

"This is the initial inspection of this corn and pea canning plant. Current inspection shows this firm to be packing corn in a plant still under construction, which is not tight to insects or windborn contaminants. Wash water and condensate was seen falling into raw materials and finished products. Loose pieces of metal solder were found in cans being filled with corn. The firm is using water from an untested private well in finished products and as cooling water in their retorts: it has not been chlorinated. Management refused formulation, coding information, photographs and to permit review of product quality control records."

In his "discussion with Management," the inspector goes on to say:

"Concerning the fact that the firm was operating in a building that was still under construction, () said that he was given orders by his superior to start the plant, even though he acknowledged he was personally aware that it was probably illegal under the Food, Drug and Cosmetic Act to do so at this time. He stated that he was aware that it was illegal to process foods under conditions whereby they may become contaminated, but he said that he had to follow orders."

In his section on "guarantees", the inspector wryly concludes:

"This firm requires a Food and Drug guarantee from every grower they buy their corn from. () stated that he did not know if any customers who bought their canned corn required any guarantees from them and this would be handed out in the main office in San Francisco."

Wm, as

Del Monte Corporation, Crystal City, Texas

In the inspection of this plant, the inspector says,

"... () refused to tell me how much calcium chloride was being added to canned potatoes. () refused me the coding structure, and would not allow me to see other quality checks without a specific request for the exact code I wanted to see."

And, in reference to Del Monte's own quality checks:

"Either the foreman on the floor or the mechanic at the beginning of the morning pulls four cans and tears them down the seams and checks them. This is done again at noon, again in the evening and again at night--four times a day."

At the end of his report, the inspector mildly states: "No other recommendations were made other than that the firm could possibly check and tear down can seams a little more often than 4 times a day."

Del Monte Corporation, San Jose, California

FDA has consumer complaints on file reporting these findings in Del Monte cans: rusty hair pins, dead bird, corn cob, whole dead mouse and wooden sticks. In investigating one of these complaints the inspector says:

"The cans are conveyed for long distances in an open condition prior to reaching the seamers. During this travel, foreign material could possibly fall into the cans or could easily be placed into the cans by an employee if he so desired. During my inspection of this firm when they were canning spinach on 3/30/70 (one year before) I pointed out this objectionable condition ().

Del Monte de Puerto Rico, Mayaguez Puerto Rico.

According to the report, the main part of the inspector's time was spent tracking down the reason for retort indicator tags which were not changing color, and which would therefore not register whether the individual basket had been through the retort or not, and retort production records which did not show a true chart reading but were being recorded at 242 F regardless of chart readings. However, the inspector also noted "some areas which could cause a bacteriological build-up in the product prior to retorting. For example. The female employees were not washing or sanitizing hands before returning to

work following breaks, wooden handled knives are being used for cleaning of tuna and these knives are not cleaned or sanitized during the production day."

These reports are shared with the Committee as evidence we found which would point to the need for more inspections. We are not talking about protecting the public against essoteric strains of bacteria, but rather against outrageously shabby sanitary practices --simple dirt and insects being blown in while a facility is still under construction, an untested, unchlorinated well, quality control which consists of opening four cans four times a day, and employees not washing their hands after breaks.

But the average consumer didn't need either the Agribusiness Accountability Project or the FDA to tell them that the food industry needs more regulation. According to a recent survey cited by the National Canners in the speech I referred to earlier, 40% of the public believed that a food manufacturer that deceives the public may get away with it for a long time; 50% had concluded that food labels were more designed to deceive than to inform, and almost 70% of consumers interviewed wanted more Federal legislation, looked for new agencies to test products believed that testing by the government would be more reliable and dependable than testing by the food industry, and felt a need for massive detailed government regulation."

The AAP agrees that a public monitor can do better than self-regulation. Therefore, we support S.2373. We would also like to recommend the following specific changes in the FDA regulations affecting inspection procedures:

1. That the FDA inspector have access to any and all records and information that may be necessary to fulfill his mandate to protect the public. (Current law does not give inspectors access to records, even in a case of contamination, and--as shown earlier --access to records is not necessarily volunteered.)

2. That the FDA be given the right to require temporary detention of food which the Agency has reason to believe is contaminated, before final authority for seizure has been obtained. (Here again, FDA is dependent on voluntary cooperation of the food processor. For example, a recent GAO report revealed that, during one of the more recent botulism episodes, before the authority to seize the

suspected goods was final, the food processor agreed voluntarily to delay shipment. However, the report says, "... they were unable to honor that promise because of fiscal considerations. . ." The FDA was therefore required to seize the product at over 100 different locations.)

We also support Senator Kennedy's registration amendment, but would suggest additions which we think are of importance.

1. That a food firm or plant, canning or packing food under several different labels register all labels under which its products are sold and that the complete information required by the legislation be provided for each of the private labels.

2. Every package or can should have on its label the name and place of business of the true manufacturer, packager and distributor. (The importance of this requirement cannot be overemphasized. In the well known botulism incident with Bon Vivant soups, the fact that Bon Vivant canned soup under 35 different private labels complicated seizure efforts considerably. Had the real manufacturer's name and location been on the can, tracking down the contaminated goods would have been easier and consumers could immediately have identified for themselves any they had already purchased.)

Thank you.

-2-

Del Monte Corp.
 Burley, Idaho
 Insp. George D. Victor
 9/19/68

SUMMARY OF FINDINGS:

This is the initial inspection of this corn and pea canning plant. Current inspection shows this firm to be packing corn in a plant still under construction, which is not tight to insects or windborn contaminants. Wash water and condense water was seen falling into raw materials and finished products. Loose pieces of metal solder were found in cans being filled with corn. The firm is using water from an untested private well to use in finished products and as cooling water in their retorts; it has not been chlorinated. Management refused formulation, coding information, photographs, and to permit review of product quality control records. Factory sample Inv 069-693 C of cream style corn was collected for examination for contamination with foreign material and bacteria.

HISTORY OF BUSINESS:

This firm is a New York corporation, with its headquarters located in San Francisco, Calif. Its president whose office is in San Francisco, and vice president for U.S. production is Dick Landis, whose office is in San Francisco. Management did not know who either the secretary or the treasurer was.

This firm just started operation about 3 weeks ago. From approximately July 1st through August 10th, the firm will can peas and then from Sept. 1st through Sept. 30th, the firm will can cream style and whole kernel corn. Management stated that they will not warehouse any other type of canned foods. All of their own label canned peas and corn will be sold under the Del Monte brand name. Management stated that they anticipated putting up some corn and peas under various private labels at some later date, but that they have not done so at this time.

INDIVIDUAL RESPONSIBILITY:

is general manager of this firm. He is the most responsible individual at this plant. During this inspection I saw him give orders to various individuals whom he said were supervisors at this plant. He stated that his immediate supervisor was y, Mountain States Division production manager for Del Monte Corp.

-3-

Del Monte Corp.
Burley, Ida.
GDV - 9/19/68

PERSONS INTERVIEWED:

Credentials were shown and Notice of Inspection was issued to [] general manager. [] provided all of the business and operational information contained in this report and accompanied me throughout the entire inspection. Post inspection discussion was held with [] No other individuals were interviewed during this inspection.

OTHER INSPECTIONS:

[] stated that at this time no other governmental agencies have made any inspection of his plant. He said that he anticipated that at some time in the future the U.S. Army Veterinary Corps and the Idaho State Health authorities would probably be around to inspect this plant.

GUARANTEES:

This firm requires a Food and Drug guarantee from every grower they buy their corn from. [] stated that he did not know if any customers who bought their canned corn required any guarantees from them, as this would be handled out of the main office in San Francisco.

BUILDING AND ENVIRONMENT:

This plant is a metal frame, metal covered building with a concrete floor. Exhibit #1 attached to the back of this report shows the layout of this plant.

There is no wall along the west side of the north side of the building where a wing of the plant is still under construction. A tarp covers a portion of this open gap in the plant, but the section of the 2nd floor had no covering at all.

RAW MATERIALS:

-4-

Del Monte Corp.
 Burley, Ida.
 GDV - 9/19/68

MANUFACTURING OPERATIONS:

Exhibit #2 attached to the back of this report is a schematic diagram of the flow plan for this firm's corn packing operations.

FORMULATION:

[] refused to provide the quantitative formulation for this firm's whole kernel and cream style corn. He stated that he was refusing this information on the basis of orders he received from [] Division Manager at Ogden, Utah.

CODING:

[] stated that he could not provide coding information to me on the basis of instructions he received from [] Division Manager at Ogden, Utah. He did tell me that their code told the date, hour and line that the product was packed on, as well as the product's variety and plant where it was packed.

The cream style corn that the firm was packing the afternoon of this inspection, was coded 532 on the top line and R3Q24 on the bottom line. The whole kernel corn being packed that afternoon was coded W52VI on the top line and R3Q14 on the bottom line.

CONTROLS:

[] stated that their quality controls permit them to follow through on any particular batch of corn from the field it was grown on to the final customer who received the finished canned product. He said that some of their quality controls included checking fill of containers, net weight, consistency, foreign material, and other checks. [] stated that [] division manager at Ogden, Utah had given him orders not to show product quality control records to me.

-5-

Del Monte Corp.
Burley, Ida.
GDV - 9/19/68

CAN SEAMS:

This firm makes a visual examination of two cans during every half hour period to check for seam defects. Once every hour the firm tears down a seam of one can completely to examine it. Attached as exhibit #3 to the back of this report is a form which the firm uses to record their can seam findings.

Throughout this inspection, I examined approximately 200 cans coming off the firm's packing line, and I did not observe any seam defects in them. I did not observe any employees adjusting the can seam heads during this inspection.

CAN COOLING:

-6-

Del Monte Corp.
 Burley, Ida.
 CDV - 9/12/68

DEFECTIVE CANS:

About 4:30 the afternoon of this inspection, I was examining the firm's empty cans that they were placing on their conveyor line to go to the filling lines. I observed that there were loose pieces of metal solder inside some of these cans which the firm was not pulling out. I found that these pieces of solder were showing up in from 1 in 25 cans to about 1 in 150 cans. These pieces of solder could be pried loose easily with a finger. I finally ordered that this batch of cans be removed from their active stock and by 5 o'clock the firm was using another batch of cans which did not appear to have this defect.

I supplied the following information about the batch of defective cans I observed during this inspection. He said that it was a shipment of 137,280 cans the date received during the week of August 5th. He said the shipment was received in railcar UP165012. He said that coding information on the boxes of cans showed that they were manufactured on June 12th, 1968. I stated that these cans were made at the Del Monte Corp. plant located at 501 Main St., Smithfield, Utah.

I stated that he was going to have employees examine the remaining portion of this shipment of cans to be able to isolate those cans which had solder in them. He said that approximately 68,000 cans remained of this original 137,000 can shipment. He stated that he believed the approximately 70,000 cans which were used up were used up on the day of this inspection. I refused to give me the codes that were used during this day, other than to tell me that they would be quite similar to the 2 codes that I reported under coding information for corn being packed that afternoon.

SANITATION:

Some objectionable sanitary conditions were encountered during this inspection, and these were reported to on the Food and Drug form FD 483, left with him at the conclusion of this inspection. These conditions observed are discussed in the following paragraphs below.

The west section of the north wall had not been built and construction of a wing was taking place outside the plant. The portion

-7-

Del Monte Corp.
Burley, Ida.
GDV - 9/19/68

of the wall that was missing was in an area next to where actual canning operations were taking place.

During this inspection, I saw an estimated 10 live flies in the plant. I observed these flies to land on the corn being received at the plant prior to cutting.

This firm had placed fine screens over the base of all their light fixtures in the plant. I found a wide variety of various dead insects resting on the screens. These light fixtures were directly over some of the canning equipment. Wind blowing in through the uncompleted wall could dislodge these insects and blow them down into the product. I did not observe this take place while I was in the plant however.

The firm has their brine and syrup mixing tanks on the first floor, and the brine and syrup holding tanks on the 2nd floor of the plant. These tanks were all uncovered and two of them were located within 2' of the uncovered wall outside the plant where dust and other contaminants could be expected to blow into them. There is a metal filter for both the brine and syrup holding vats that would filter out any large pieces of contaminant that might have been blown into the product. I was only able to examine one of these filters and I did not observe any dead insects in the trapped particles.

I observed water splashing off equipment during cleanup operations to be splashing into the uncovered syrup and brine holding vats and also onto uncovered bags of salt, sugar and starch stored on the 1st floor, thoroughly soaking these bags.

I observed condensate on the ceiling that was directly over the uncovered brine and syrup holding tanks on the 2nd floor, and directly over the portion of the line of the can conveyor where filled cans of cream style corn were going to the canner. I observed the condensate falling from the ceiling where the filled, uncapped cans of cream style corn were moving, to splash around these cans. I did not actually see any drops fall directly into the can, but this could occur.

The last item on the Report of Observations lists the loose pieces of solder noted in some of the cans being filled with corn during this inspection that was discussed under an earlier heading.

The above seven observations were the only ones listed on the FD 483 left with . . . During this inspection, I did not observe

-8-

Del Monte Corp.
 Burley, Ida.
 ODV - 9/19/68

any evidence of rodent activity in the plant. I looked at the firm's sort and trim line and saw that the firm appeared to be segregating out all defective ears of corn. The line appeared to be moving slowly enough for the women to be able to adequately inspect each ear as it passed by them.

PEST CONTROL:

[] stated that all pest control would be handled by his own firm. He stated that at this time they had not set out any type of rodent control in the plant and I did not observe any mechanical traps or baits to be set out in the firm. He said that they were not using any kind of insect controls within the plant but around the exterior of the plant, particularly in their refuse dump areas, they were spraying diazinon applied with a hand pressure sprayer.

CLEANUP OPERATIONS:

This firm uses one of two cleaners in their wash water, both made by Oakite Products, Inc. The two products are Eisan HD, which has a statement warning that this product contains highly alkaline ingredients, and the other product is Chlor-Tergent, containing 5% Tri Chloro-S-Triazinetrione.

[] stated that they run 3 shifts in this plant and the plant is open all night, though canning operations are not always in progress. He said that there is approximately a 1 hour cleanup between shifts and a 4 hour cleanup that takes place roughly between 3 a.m. and 7 a.m. each morning. I observed the cleanup operations that took place during one change of shifts and saw that the 1 hour cleanup removed the visible residues from the outsides of all equipment that I examined. High pressure hoses are used to wash this equipment off.

PHOTOS:

[] refused to permit me to take photos of the insanitary conditions I observed during this inspection. He stated that his superior division manager of Ogden, Utah had given him these orders.

SAMPLES:

During this inspection, factory sample Inv. 069-603 C was collected to be examined for foreign material and bacterial contamination. The sample consisted of about six empty cans which were found

-9-

Del Monte Corp.
 Burley, Ida.
 GDV - 9/19/68

to contain loose pieces of solder in them, and 8 cases of cream style corn that were packed that afternoon, using the batch of cans which contained the loose solder. These 8 cases of cans were from a lot of 493 cases of creamed corn that were noted on the 1st line 532 and on the 2nd line R3Q24.

SHIPMENTS:

_____ stated that they have not sold any corn as of this date. _____ stated that the firm had already decided in advance before production started that they would not ship any of the products packed at this firm out of the state, because of problems they believed might exist at this firm. _____ stated that none of their corn would be shipped out of the state until management at higher levels decided that the product was ok and legal to be shipped.

_____ stated that once they did begin shipments he believed that a portion of their products would be shipped to the Del Monte Corp., Freeport Center, Clearfield, Utah for distribution throughout the country.

COMPLAINTS:

_____ stated there could be no complaints as none of their product has yet been sold.

DISCUSSION WITH MANAGEMENT:

At the conclusion of this inspection, a Report of Observations and a Receipt for Samples was issued to _____. _____ had the following comments to make about the conditions noted on the Report of Observations:

Concerning the fact that the firm was operating in a building that was still under construction, he said that he was given orders by his superior to start the plant in operation even though he acknowledged he was personally aware that it was probably illegal under the Food, Drug & Cosmetic Act to do so at this time. He stated that he was aware that it was illegal to process foods under conditions whereby they may become contaminated, but he said that he had to follow orders. He said he did not know exactly who the individuals were that had given the orders to start the plant operations. He said that the firm was supposed to be finished earlier this year, but that construction problems prevented its completion. While I was at the plant I saw him call up the

-10-

Del Monte Corp.
Burley, Ida.
GDV - 9/19/68

contractor and tell him to begin constructing the upper portion of the missing wall the next day.

For the 2nd problem listed, [] stated that there would be nothing he could really do about live flies in the plant until the wall was finished. He said that when the plant was finished, it would be operated under a positive pressure inside the plant, which would keep air flowing out of the plant at all times and tend to restrict insects from getting into the plant.

For the 3rd item, [] said that there would not be much he could do there, until the wall was in.

For the 4th item, [] stated that he would have lids on all 4 tanks the next day.

For the 5th item, [] stated that getting lids on the vats would take care of part of the problem and that he would instruct his men to be more careful with the bags of salt, sugar and starch on the 1st floor in the future.

For the 6th item, [] stated that there would not be much he could do about this until the plant was finished and they had their positive air pressure ventilation system installed. He said at the time that was done he thought it would take care of any condensate problems.

For the 7th item, [] changed the batch of cans that was in use at the time this was reported to him, and the other batch of cans he was using were found to be free of any significant amounts of solder. [] collected a duplicate sample of cans that I collected of the cream style corn packed that afternoon, and said that his company would check out that sample. The creamed corn that was sampled on that date as well as the batch that was made immediately prior to that and the whole kernel corn that was made that afternoon, were all packed in unlabeled cases and no labels were put on the cans. The cream style corn that was packed at this time was coded 532 on the top line and R3Q24 on the 2nd line. There were approximately 10,000 cans in that batch. The whole kernel corn that was packed that afternoon was coded W52VI on the top line and R3Q14 on the bottom line and consisted of 75 cases of 24 #303 cans. The cream style corn that was packed immediately prior to the one mentioned above, was coded 532 on the 1st line and R3Q23 on the 2nd line. [] stated that if they found any evidence that metal solder had gotten into the batch of cream style corn that I sampled, then they would start checking all of

-11- Del Monte Corp.
 Burley, Ida.
 GDV - 9/19/68

the batches made prior to that with other codes on them until they found that the problem was eliminated.

I questioned [] as to why he was using non-chlorinated cooling water in his retorts to cool down the cans in view of the fact that they might breathe in some of the water, and this water might contaminate the product. [] agreed that he knew this was a bad practice but that there wasn't anything he could do about it until their chlorinator got there.

DISCUSSION WITH CO-OPERATING IDAHO STATE DEPT. OF HEALTH AUTHORITIES:

On 9/20/68, I contacted Mr. J. R. Ingalls, supervisory sanitarian for the south central district health department in Twin Falls, Idaho. I reported to Mr. Ingalls the objectionable sanitary conditions I encountered in the plant, and also told him that the firm was using water which management told me had not been tested by state authorities. I also told him that they were not chlorinating their cooling water in the retorts. Mr. Ingalls requested a copy of my FD 483 and I let him take a photocopy of it after informing him that the law required that this information be kept confidential, and that he should keep the copy of the report to himself.

I told Mr. Ingalls that at this time the firm was not shipping any of their product interstate in order to avoid giving FDA jurisdiction of their product. Mr. Ingalls stated that he was not sure if he could do anything either if the firm was not offering any of their product for sale within Idaho, as that was required before they had jurisdiction. Mr. Ingalls stated that he would inform the sanitarian responsible for firms in Cassia County and that he was sure they would make an inspection of the plant to see if the firm made the corrections they have promised to make. I thanked Mr. Ingalls for any attention that he might be able to give to this firm.

EXHIBITS:

There are four exhibits attached to the back of this report. They are:

1. A diagram of the layout of the plant.
2. A flow chart showing how the products are manufactured in the firm.

-4-

DEL MONTE DE PUERTO RICO
Mayaguez, Puerto Rico
EX 1-20/21-70 TEM & DLS

OBJECTIONABLE CONDITIONS:

During the inspection it was noted that the firm was having problems in their retort area. We noted that the firm was using retort tags that were of a brownish color prior to going into the retort. These tags should have been of a purple color. After the tags had been through the retort they remained the brownish color and did not change to the green color as they are supposed to.

Because of this lack of color change in the retort tags there was no positive way of telling whether the individual basket had been through the retort or not.

We pointed out this problem to management as soon as we noted it. [] then decided that he would check his stock of retort tags which were stored in the office which is completely air-conditioned. We checked approximately 25 books of 1,000 tags which they had on hand from the same shipment. These tags had been received in March 1969. All of these books were in sealed plastic bags. Upon checking the books most of the pages were brown in color rather than the purplish color they should have been. These books did not appear to have been exposed to any type of moisture. The firm also had a later shipment of these books on hand stored in the same area and these books were all of the correct color. These books are manufactured by Cannery Controls Co., 712 Tuna St., Terminal Island, Calif.

Management of Del Monte immediately called the firm in California and told them about the problem. The firm told them not to use the retort tags and that this was a common problem in that if they were stored under conditions where there may be high heat and humidity that they would change color. The firm indicated to Del Monte that they received complaints of this type quite often.

-6-

DEL MONTE DE PUERTO RICO
Mayaguez, Puerto Rico
EI 1-20/21-70 TBM & DLS

1. During the inspection it was noted that female employees were not washing or sanitizing their hands before returning to work following breaks. We observed the women who were returning following lunch and also returning following coffee breaks. Some of them would walk directly from the cafeteria to the production line and start handling the product without washing or sanitizing their hands.

2. The female employees were using multi-piece wooden handled knives for the cleaning of the tuna. Because of the porous nature of the handles on the knives they would be hard to clean or sanitize. These knives are not cleaned or sanitized during the production day but are cleaned and soaked in a sanitizing solution over night. Because of the lack of cleanup of the knives during the day a bacteriological buildup could occur in the static material on the knives.

3. During the inspection 7 female employees were noted wearing cloth finger cots and working directly with the tuna. These finger cots are placed over bandages. Because these are cloth and of a porous nature any infection from the cut the bandage is covering could work its way through the bandage and through the cot and come in contact with the tuna itself.

No other objectionable conditions were noted during this inspection.

JUICE & NECTAR OPERATION:

The juice and nectar canning operation remains the same as reported during the previous inspection. During this inspection it was noted that the firm is using pineapple concentrate which they receive from Hawaii to manufacture pineapple juice. This is in direct violation of the standards in that it is not allowable ingredient of pineapple juice.

The firm declares the ingredient on the label but the label is still stated as pineapple juice.

The label for this product is submitted with this report.

DISTRIBUTION:

This firm ships all of their products to Del Monte distribution warehouses located throughout the states. Following is a list of the cities in which these warehouses are located.

-7-

DEL MONTE DE PUERTO RICO
 Mayaguez, Puerto Rico
 EI 1-20/21-70 TM & DLS

This is the only tuna cannery owned by this firm and all Del Monte tuna on the market is manufactured by this plant. The firm would not give specific shipments but stated that their products were sent to all of the above listed warehouses.

SAMPLES COLLECTED:

During this inspection sample numbers INV 064-104D and INV 064-105D were collected of finished product. These samples were collected to check on the can seams and for standards. Sample number INV 064-104D consisted of 2 cases of 48 cans of 6 1/2 oz. tuna taken from closing machine F. One case was taken from production of 1-20-70 and was coded XBFF/FLP54 and the other case was taken from production of 1-12-70 coded XBFF/HP5P4.

Sample number INV 064-105D consisted of 2 cases of 48/6 1/2 oz. cans taken from closing line C. Cans coded XBFC/SLP53 taken from production of 1-20-70 and cans coded XBFC/HP5D2 were taken from production of 1-12-70.

DISCUSSION WITH MANAGEMENT:

At the conclusion of the inspection we issued FD 483 to Operations Manager. We discussed the FD 483 with Plant Manager. All items on the FD 483 had been pointed out to prior to this discussion and each item was gone over individually during the discussion with.

A great deal of time was spent on the retort control and kept questioning why these items were listed on the 483 and that they were not supposed to be handled in this manner. He stated that if the controls had been working as they were set up this report would not have been issued. made no excuses nor did he argue with the items listed. He stated that they would be corrected immediately. Mr.

stated that the chains had already been replaced on the retorts and that new retort tags were obtained to eliminate this problem. He stated that they had already placed an order for new mercury thermometers and they would be placed on immediately. He stated that they also would have a meeting with all employees to make sure they knew what they were supposed to be doing as far as control records were concerned.

No other discussion was held with management during this inspection.

Terry B. Mueson
 Terry B. Mueson (329)
 Inspector, San Juan Section
 New York District

David L. Stephens
 David L. Stephens (376)
 Microbiologist, San Juan Section
 New York District

Page 4

Del Monte Foods, Inc.

August 12-13, 1971

Plant Superintendent, answered all questions concerning the firm's processes except those which he was strictly instructed not to answer by the firm's Operations Manual. These items will be discussed under "Refusals."

No other individuals were interviewed during this inspection.

REFUSALS:

The following information was refused to me by [redacted] The firm's annual volume, their manufacturing codes, and allowing me to take photographs during the inspection. [redacted] also would not tell me how much calcium chloride was being added to the canned potatoes.

[redacted] refused me the following information: their coding structure, and the amount of calcium chloride added to the canned potatoes.

GUARANTEES AND LABELING AGREEMENTS:

[redacted] stated that he did not know of any guarantees or labeling agreements, but if there was such, they would be on file with the Legal Department in San Francisco.

RAW MATERIALS:

The only raw materials in use during this inspection were calcium chloride and salt, as well as the white potatoes being canned. No other food additives or any color additives were being used during this inspection.

FIRM'S EQUIPMENT AND PROCESSES:

Page 7

Del Monte Foods, Inc.

August 12-13, 1971

SANITARY CONDITIONS:

The only objectionable condition one related to a consumer complaint in a consumer found a rusty hair pin in a can of the female employees during this inspection pins in their hair, most to hold on the bouffant style hair do's.

No evidence of insects or rodents. The firm's premises appeared to be in a state of repair and the weeds were being controlled around the firm's

No evidence of dripping pipes or in the canning plant during the canning

during this inspection was complaint alleged that the blonde spinach. I checked and they indeed all had hair pins and some to hold on large

seen during the inspection. state of repair and the weeds ty.

ing of this nature was seen s.

COMPLAINT FILE REVIEW:

[1] stated that they keep a Plant, but all complaints are sent to

there at the Crystal City cisco to the Legal Department.

RECENT CONSUMER COMPLAINTS:

Page 8

Del Monte Foods, Inc.

August 12-13, 1971

I brought all of the above complaints to the attention of [redacted] and told [redacted] that I would like copies of the cook charts, retort logs and can seam inspection charts for the last 2 lots mentioned, the spinach and green beans. He complied with this and these copies are submitted as exhibits 2-17. I reviewed all of these charts and logs and could not find any discrepancies for these lots. Complete distribution was obtained for the Double Luck Cut Green Beans for the year 1968. Of approximately 68,000 cans, only a little over 5,000 were shipped out of the state of Texas. [redacted] told me that for the Midland area, the shipment would have been made to Lubbock for this is the area serviced out of Lubbock. There was only 1 consignee in Lubbock, that being the Waples Platter Co. The list of distribution is attached at the end of this report as exhibit 16.

During the inspection I went to the warehouse to collect samples of the code of spinach involved in the above complaint. They had 1350 cases of spinach with a lower code U4AA7. The upper line were mixed as to the line on which the cans were actually canned. I obtained 2 samples, one manufactured on line 1 and 1 manufactured on line 4. These samples consisted of 48 cans each taken 4 cans from each of 12 different cases. In total, I opened and examined more than 50 cases of this lot and found no abnormal cans. Samples were collected from 24 cases.

I checked stocks of the Double Luck Cut Green Beans in the warehouse and found no abnormal cans. The firm does not have any of the codes mentioned on hand and these codes were manufactured on March 10, 1968, and the last shipment of 1968 merchandise left this plant on April 24, 1969. I did, however, collect 2 samples of 2 different lots codes C35/A432 and C36/A3A51. These were both coded during the last season in 1970.

Pot Monte Foods, Inc.

August 12-13, 1971

I asked [redacted] if he had any response to make to any of the other complaints mentioned and he said that he could not understand the high incidents of complaints other than in 1963 he remembers the firm having a problem with sabotage. It seems that a disgruntled employee was purposely putting things into cans. He said that they would take a look into this possibility at this time.

QUALITY CONTROL:

The Quality Control Laboratory routinely takes samples of the cans and runs them for gross weight, net weight, drained weight, vacuum, head space, quality check of the contents and the salt content done by titration. The records for these tests are submitted to San Francisco with a copy being kept in Crystal City. [redacted] let me look at the record for the potatoes being run the day of the inspection, and everything appeared to be within limits. He would not allow me to see other quality checks without a specific request for the exact code I wanted to see.

Either the foreman on the floor or the mechanic at the beginning of the morning pulled 4 cans and tears down the seams and checks them. This is done again at noon, again in the evening and again at night. 4 times per day. They pull 4 cans at each time and the results are recorded on the firm's double seen inspection chart. A copy of which is attached on the exhibits.

CAN MANUFACTURING PLANT:

The firm manufactures their own cans. I observed this process and did not see any unusual practices. The can side seams are checked for routinely every 30 minutes and the bottoms being put on the cans are checked as are the double seams before the can sealers. They are checked 4 times per day. Also 6 cans are taken every week and sent to San Francisco for examination. I checked several cans myself and could find no cans which were out of tolerance.

DISCUSSION WITH MANAGEMENT:

FD-483/4 were presented to [redacted] Division Manager, at the conclusion of the inspection. The one item on the FD-483 was discussed with [redacted] and he said that they would pay more particular attention to this. It was at this time that [redacted] mentioned the incident in 1963, in which they had a problem of employee sabotage and it was at this time that he said they would check into this possibility also. No other recommendations were made other than that the firm could possibly check and tear down can seams a little more often than 4 times a day. It was determined at this time that each canner had 4 heads and seam of 4 cans were checked on these 4 times a day. No other suggestions or recommendations were made to management at this time.

Page 10

Del Monte Foods, Inc.

August 12-13, 1971

PHOTOGRAPHS AND EXHIBITION:EXHIBITS:*Notes received 9-13-71*

Exhibits are submitted for this report to aid in the evaluation of the firm's processes.

Exhibit 1 consists of the blank forms of the firm's cook checks.

Exhibits 2-16 consist of records covering 2 products, Spinach and Green Beans. These are copies of cook charts, retort records and seam inspection logs.

Exhibit 18 is the distribution of the lot of green beans in question.

Exhibit 19 are some copies of the firm's labels.

James R. Chankin
Inspector

JRC/nt

Typed from IBM 8/23/71

-5-

D&I Monte Corp. #3
 San Jose, Ca.
 EIR 1/25/71 JNC

No reported injuries were involved in any of these complaints.

DISCUSSION WITH MANAGEMENT:

[] and I followed the flow of the spinach through the processing plant and also the flow of the cans prior to and after filling. The cans are received from the Oakland's plant and go through a depalletizer, up an elevator and then through a water fall which inverts the cans. The cans are then transported across the plant to the spinach packing area where in 1970 the cans were placed inverted into a vibrator device where they were vibrated to eliminate the possibility of any dust or any foreign material being in the cans immediately prior to their entering the packing lines. After the cans are packed with spinach, they are transported from the packing area on cable conveyers through various sections of the plant to the staging and seaming area where the water and salt is added and the cans are sealed prior to being conveyed to the cookers.

The cans are conveyed for long distances in an open condition prior to reaching the seamers. During this travel, foreign material could possibly fall into the cans or could easily be placed into the cans by an employee if he so desired. During my inspection of this firm when they were canning spinach on 3/30/70, I pointed out this objectionable condition to _____. During that inspection, I did not notice anyone inspecting the cans prior to the seamers. The following is a quote under the heading, Discussion with Management, from my EIR of 3/30/70:

-6-

Del Monte Corp. #3
 San Jose, Ca.
 EIR 1/25/71 JNC

"The only thing pointed out to management that could lead to possible problems was the fact that they have an excessive distance from can filling operations to the fillers (Madia) and seamers, thus, cans travel open across the plant and are not inspected prior to seamer."

[] stated that the entire distance from the packing area to the seamers is cleaned and repainted overhead prior to the spinach operation. He stated that this is to eliminate the possibility of anything such as paint falling from the ceiling into the open cans of spinach below. Most of the distance across the plant that the spinach travels in open cans is at an elevation of approximately 7 or 8 ft. The spinach conveyer cables and hoses are easily accessible due to various catwalks and platforms along the route.

The only explanation for the consumer complaints given by Mr. Bergstrom was the fact that some disgruntled employee must have placed the foreign material in the cans deliberately prior to the seaming operation. He stated that they have an inspector who is supposed to check the cans prior to the seamer. He stated that the seamer operators are also supposed to examine the cans as they enter the seamer. He could not explain how the cans with the foreign materials in them got by the inspectors, particularly the cans with the sticks in them where the sticks would have to stick out into the headspace of the can and would be easily visible.

[] stated that he doubted if they could find the person responsible for this problem. He stated that during the 1971 pack, they would try to cut down the access to the open cans by employees and place more inspectors in the staging area prior to the seamers.

On February 8, 1971, I contacted [] to determine if they had received any more consumer complaints and to see what plans they had come up with to eliminate this problem during their 1971 pack.

[] stated that he was not aware of any new consumer complaints. He stated that he had had a meeting with the supervisors and floor ladies so that they would all be aware of this problem and would be alert for any condition which could lead to contamination of their products by one of their employees. He stated that during the 1971 pack, the inspectors along the line at the staging area immediately prior to the seamers would be operating and would be the

upgraded

-7-

Del Monte Corp. #3
 San Jose, Ca.
 EIR 1/25/71 JNC

only persons who were very reliable and had worked for Del Monte for a considerable period of time and that they would be employees they had not had problems with in the past. He stated that they had not come up with any good ideas yet as to how to cover the open can line from the packing area to the sealers themselves. He did state that they would have limited access to the areas of the plant involved so that employees could not indiscriminately wander through the area.

Agreed that the sealing operation should be close to the packing line and stated that in this plant it was impossible due to the plant construction. Mr. Bergstrom stated that he would contact me if he received any new consumer complaints.

DISTRIBUTION:

At the time of this inspection the firm only had one large block of the 1970 spinach pack left in his warehouse. None of the codes involved in these complaints were found in this block.

EXHIBITS:

Copies of all these consumer complaints (five involved in the 1970 pack and one involving 1969 pack) are attached to this EIR.

James R. Chantler
 JAMES R. CHANTLER, 038
 Inspector, San Jose

HARRISON A. WILLIAMS, JR., N.J., CHAIRMAN
 JENNINGS RANDOLPH, W. VA.
 CLAIRBORNE PELL, R.I.
 EDWARD M. KENNEDY, MASS.
 GAYLORD NELSON, WIS.
 WALTER F. MONDALE, MINN.
 THOMAS F. EAGLETON, MO.
 ALAN CRANSTON, CALIF.
 HAROLD E. HUGHES, IOWA
 WILLIAM D. HATHAWAY, MAINE

STEWART E. MCCLURE, STAFF DIRECTOR
 ROBERT E. NAGLE, GENERAL COUNSEL

JACOB K. JAVITS, N.Y.
 PETER H. DOMINICK, COLO.
 RICHARD S. SCHWEIKER, PA.
 ROBERT TAIT, JR., OHIO
 J. GLENN BEALL, JR., MD.
 ROBERT T. STAFFORD, VT.

United States Senate

COMMITTEE ON
 LABOR AND PUBLIC WELFARE
 WASHINGTON, D.C. 20510

September 14, 1973

Mr. Alfred W. Eames, Jr.
 Chairman of the Board
 Del Monte Corporation
 P.O. Box 3575
 San Francisco, California 94119

Dear Mr. Eames:

On September 11, the Subcommittee on Health, of the Senate Committee on Labor and Public Welfare, held a hearing on S.2373, a bill to require the establishment of surveillance regulations for the detection and prevention of adulterated food.

The testimony of one of the witnesses at that hearing, Ms. Susan Sechler of the Agribusiness Accountability Project, included allegations concerning reports of Food and Drug Administration inspections of several of the processing facilities operated by your company. A copy of her testimony is enclosed.

Although, at this time we do not plan to hold further hearings on food surveillance, I believe you should have the opportunity to respond to those allegations. Therefore, if you wish to submit a statement we will be happy to include it in the record of the hearings. Since the record is already in the process of being printed, I must ask that you have your statement to the Health Subcommittee staff by September 28.

Sincerely,

Edward M. Kennedy, Chairman
 Senate Health Subcommittee

Enclosure

COPY

Del Monte Corporation, 215 Fremont St., Box 3575, San Francisco, CA 94119

Alfred W. Eames, Jr.
Chairman of the Board
Chief Executive Officer

September 27, 1973

The Honorable Edward M. Kennedy
The United States Senate
Washington, D.C. 20510

Dear Senator Kennedy:

Thank you very much for the opportunity to respond to certain testimony received by your Senate Health Subcommittee at its September 11 hearing on S. 2373. Your interest in hearing from both sides is commendable and should enhance the quality of testimony that will be considered by your subcommittee.

Though Del Monte Corporation shares the concern of the National Canners Association about certain provisions of S. 2373, I support your amendment requiring the registration of all food establishments. The principle of registration is very sound, and we have endorsed it in the past: Del Monte was a leader in the implementation of a Better Processing Control Plan which required producers of low-acid foods to register with the Food and Drug Administration.

I am personally proud of the overall performance of Del Monte's food processing plants. Our record for producing safe, wholesome foods is a good one. It, therefore, is disappointing that witnesses before your subcommittee should seize upon isolated incidents at a handful of our plants in an effort to purport evidence of a general breakdown of sanitary practices.

Never in its 57 years has Del Monte permitted or condoned unsanitary conditions in its processing plants. Our plant management is under strict orders to take quick, decisive action whenever unfavorable conditions are noted. As a double-check, we have long made a routine practice of sending company inspectors from the home office to conduct in-depth audits on the performance of our plants. These inspection reports are filed directly with our senior management. Additionally, we have numerous on-going control programs to assure wholesomeness.

When regulatory inspections are made, it is FDA's policy to have the inspector note only those conditions (on FDA Form #483) which are "unfavorable". Many of the inspections of Del Monte Corporation plants result in no unfavorable findings; hence no inspection report is left at the plant.

As happens with other companies and industries, our best efforts sometimes fall short of perfection. It is the shortcoming -- not the satisfactory or normal condition -- that is noted in inspection reports filed by the Food and Drug Administration. For all its merits, this policy tends to magnify the inevitable results of human error.

In an unending effort to assure safety and wholesomeness, Del Monte has consistently and vigorously supported programs designed to assure the production of safe, wholesome foods. Here are a few examples:

- Del Monte spearheaded the development of the National Cannery Association's Better Processing Control Plan. This resulted in development of FDA regulations designed to provide greater assurance of safety in the canning of low-acid foods.
- We gave early and continuing support and assisted in the development of FDA's Good Manufacturing Practices regulations for the food industry.
- We have actively supported development of the joint FDA-NCA Canned Salmon Control Plan for rigid enforcement of sanitary processing conditions.
- We have assisted FDA in the training of inspectors for a new inspection program based on recognizing and evaluating the critical control points in food processing.
- Within Del Monte, we have adopted extensive production control procedures with emphasis on critical control points to provide even greater assurance of safe and wholesome products.
- Del Monte promoted the State of California's adoption in the 1920's of a stringent control program for the processing of low-acid foods. We then adopted the program at all our U.S. production facilities outside California.

Testimony before your subcommittee cites FDA inspection reports at four of our 46 domestic canning operations. So that this letter be as responsive as possible, I will comment on each of those instances.

Burley, Idaho

A 1968 FDA inspection report was critical of the fact that we operated this plant before completion of construction which was delayed by construction industry labor problems not related to Del Monte. Though informed by the FDA of this criticism, an inspector for the Idaho Department of Public Health visited this plant five days later, found conditions satisfactory, and said he did not agree with the FDA report.

The Honorable Edward M. Kennedy

-3-

September 27, 1973

Careful thought was given to the decision to operate the plant while construction continued. After much study, management became convinced we could operate in such a way as to fully meet FDA standards in the production of a safe and wholesome product.

Two contributing factors figured in the decision. Crops were becoming ripe, and our growers would have suffered economically if we had not been able to accept their product for processing; and we felt it necessary to honor a commitment to the local community, which supplies a majority of our work force during the canning season.

San Jose #3

An FDA inspector suggested that cans at this plant are conveyed for "long distances" in an open condition that would make it possible for foreign material to fall -- or be placed -- into cans. Our plant management is fully aware of the situation, and it is our practice to protect cans from contamination prior to closure. Contrary to the FDA report, we believe this is a safe and sanitary operating practice.

Every food processor has recorded incidents of employee pranks or sabotage that result in placement of foreign objects in food containers. We were aware of incidents prior to an FDA inspection of consumer complaints and have taken appropriate action.

During the packing season, we employ many young people, a goodly number of whom are defraying the costs of education. Unfortunately, there have been isolated instances of pranks -- notwithstanding our best efforts to prevent such incidents by employee training and other means. We are still working toward a goal of 100 percent effectiveness.

Crystal City, Texas

Food processors, like manufacturers in other industries, regard certain product information as proprietary. Its disclosure could put a company at a competitive disadvantage. Information of a proprietary nature includes our product formulations, code systems for quickly identifying the place and time of processing, and in-company quality assurance records. An FDA inspector objected to these policies during a visit to the Crystal City plant.

With reference to product formulations, the quantity of any food additive used in our products is well within FDA tolerances; an analysis of a product would reveal this fact. As for the code system, it is our practice and policy to provide regulatory officials with information conveyed by any code in which they are interested.

The inspector also commented on the frequency of our container quality checks. Del Monte strictly abides by National Cannery Association recommendations for procedures and frequency of the evaluation of can seams. These procedures are endorsed by FDA.

The Honorable Edward M. Kennedy

-4-

September 27, 1973

Mayaguez, Puerto Rico

We disagree with an FDA inspection report asserting that retort indicator tags were not changing color and, therefore, did not provide adequate evidence that product was processed. (Exposed to the heat of the cooking process, the tag changes color, indicating product has passed through the retort.)

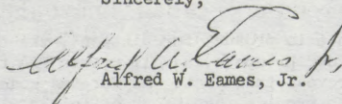
Our investigation shows that the tags were changing color, though not to the degree they usually do. However, any change in color is sufficient to provide totally reliable evidence that processing has been achieved. It should be noted that use of heat indicator tags is a voluntary safety procedure which Del Monte has used for many years as an additional check on the safety of its products. We augment this procedure with the use of heat indicator paint on each container.

An FDA inspector indicated that our retort form showed that a cook was done at 242° F. and this did not exactly coincide with the true temperature. We train our people to record the true temperature in all instances. However, in order to be absolutely certain that a retort has achieved a proper process, we rely on automatic temperature recorders. After each cook and prior to shipment, the automatic temperature chart is examined to insure that the temperature was properly maintained throughout the duration of the cook. It is inexcusable for an employee to estimate on the retort form the temperature of the cook and we do everything in our power to preclude these occurrences. However, since the final determinant is the automatic temperature recorder, the safety of the product is assured.

Through employee training, the use of signs, and direct supervision, every effort is made to assure that employees follow prescribed sanitary practices. We believe the incidents reported by the FDA inspector were isolated exceptions to customary practice. We are continually working to prevent human error.

Thank you again for allowing us to provide this information for consideration by your subcommittee.

Sincerely,


Alfred W. Eames, Jr.

AWE:mls

✓cc: Mrs. Jessica Silver

Senator KENNEDY. Thank you.
Next is Anita Johnson.

**STATEMENT OF ANITA JOHNSON, LAWYER, HEALTH RESEARCH
GROUP, WASHINGTON, D.C.**

Ms. JOHNSON. I am Anita Johnson, a lawyer with Health Research Group here in Washington.

As I understand it, S. 2373, was created to meet three needs: To require FDA to actively assess public health hazards from food and plan procedures to deal with them; to direct FDA to consult and discuss general food safety matters with parties other than the regulated industries; and to create the possibility of substantive court surveillance of FDA activities in the food safety area.

These intentions merit support, and they are founded on gross deficiencies FDA has in the food safety area. Any agency with regulatory responsibilities for a \$150 billion industry with funds of only \$62 million is maimed from the start. Add to this handicap, a tradition of drawing its leadership directly from the regulated industry, and a law which requires a day-to-day contact with industry officials but not with the public sector, and you get an agency sunk in good-natured somnolence toward the hazards it was created to combat.

A 1972 GAO study reported that of 97 representative food manufacturing plants, about 40 percent were operating under conditions that were insanitary or worse. The GAO concluded: "A serious problem of insanitary conditions exists in the food manufacturing industry—sanitary conditions in the food industry are deteriorating." Kenton L. Harris, a former FDA official now a private consultant, stated in a recent speech that FDA is making less seizures and prosecutions throughout the entire country than used to be made in one district alone.

Last year, FDA publicized what it called "unavoidable" levels of contaminants in food. It announced that filth such as rodent excreta, mould, et cetera, would be overlooked by FDA inspectors provided the filth did not exceed the so-called "unavoidable" levels.

The policy of announcing in advance that filth will be tolerated has considerably lowered industry incentive to produce clean food. The foolishness of FDA's policy is heightened by the high levels of filth declared acceptable, levels so high that one commentator called them "fraudulent" and even the Grocery Manufacturers Association itself has stated publicly that they are far above what the industry would tolerate.

As of 1971, FDA inspected food plants only once every 5-7 years. After the Bon Vivant and other incidents, Congress has directed FDA to hire more inspectors and has provided money for them. The full number of inspectors requested by Congress were not all hired. The number of inspections has increased, but I question whether a change in how FDA reports what constitutes an inspection, is responsible for much of the increase.

FDA abhors the idea that it is policing food, and prefers to extol the virtues of "voluntary compliance," as it did here this morning. One of the latest ventures is its "self-certification" program, which removes Federal food inspectors from food plants except in an infrequent, advisory capacity.

Surely this policy is one where the fox has persuaded the farmer that he can guard the chicken coop. FDA is even considering granting a "seal of approval" for promotional use by participants in this non-inspected program.

Virgil Wodicka, Director of the Bureau of Foods and formerly a Hunt-Wesson executive, summed it all up in a 1972 FDA papers article: "I don't know that the FDA has necessarily learned anything from this botulism episode. Something went wrong; it was an abnormal situation but this sort of thing is essentially unavoidable by any sort of regulatory approach or, for that matter, industrial approach."

Once again FDA labeled the matter "unavoidable." A rash of botulism incidents has struck since then.

S. 2373's attempt to inject the possibility of more public participation in FDA performance, is overdue. It directs FDA to make its food adulteration surveillance procedures public and allow public hearings upon objection to them. This is excellent. However, I fear that in treating the procedures as formal regulations, FDA may be cemented into outmoded procedures when—and if—it is ready to improve itself.

If FDA gets a new method of food analysis, for example, or decides to step up inspection frequency, it may be inhibited by the procedures this bill requires, and particularly by the hearing procedure, which industry has and will use for extraordinary disputation and delay.

This hearing procedure is not as appropriate as it might be for the expression of views by public interest groups because it is set up for objection to specific regulations rather than broad policy matters and priorities, and because the public interest groups do not like to risk the delay in implementing procedures which they may view as weak but nevertheless improvement.

I believe that the court review S. 2373 attempts to make available—that the procedures do not "provide reasonable assurance that the presence of adulterated food does not constitute an unreasonable threat to the public health or welfare"—would not, in view of the great weight accorded FDA in substantive matters by the courts, provide a realistic new avenue for improving FDA performance for the consumer.

My proposed amendment to S. 2373 may more directly push FDA to better performance and allow public input. A copy of my amendment follows my prepared statement which I'll submit for the record at the end of my testimony.

I would amend the bill to require FDA to propose every year an annual comprehensive program which would identify the main hazards from foods, propose plans for acquiring information about them and combating them, and state practical procedures for inspection and analysis.

The annual comprehensive program would be open to public comment and informal hearing at the request of any parties, after which FDA would be required to assess and comment upon serious objections raised in its final promulgation of the program.

Thereafter, FDA would be free to improve the procedures in the program, but a cause of action would be created for failure to carry out at least the standards of the program, and upon proof that the FDA did not perform at least the requirements of the program, one plaintiff could recover \$5,000 or legal costs.

The cause of action is realistic because the courts would have the performance standard spelled out by the annual comprehensive program, and would have to decide merely whether the agency performed up to its stated standard. Thus, the amendment would force FDA to initiate assessment of overall food hazards, force it to state what it can and can't do, and would annually fund a private party to investigate its performance in detail—a task that no congressional staff could hope to do, and no executive branch personnel could honestly do, but one which would enormously increase the performance and accountability of the agency to the public.

* Should this committee decline to consider this proposed amendment, it might report out instead of S. 2373, a bill to make plant records open to FDA inspectors when they do inspect. Food plants are not now required to show FDA inspectors formula data, production and quality control records, or complaint files, although this material would appear to be crucial to a thorough, efficient inspection, since it would pinpoint what problems to look for.

A 1972 GAO report found that 46 percent of plants asked for formula data by inspectors wanting to know what was in the products, refused to reveal this information. The authority to look at such records is an urgent need, and one Congress already has given FDA in the drug area.

Finally, registration of food establishments would make it more likely that all food plants were eventually inspected, and would make communication and handling of routine and crisis situations much easier for FDA. This legislation was recommended by the White House Conference on Food, Nutrition, and Health. I will insert into the record the other White House Conference recommendations in this area.

In addition to registering types of foods processed, food establishments should be required to identify the brand names their products are sold under, so that if FDA identifies a serious hazard from a product, it can immediately trace the place of production and identify the cause and existence, if any, of hazards from the product marketed under another name. Thank you.

[The prepared statement of Ms. Johnson, with accompanying material subsequently supplied for the record follows:]

TESTIMONY OF ANITA JOHNSON
HEALTH RESEARCH GROUP
Washington, D.C.
BEFORE SENATE SUBCOMMITTEE ON HEALTH
September 11, 1973

As I understand it, S. 2373 was created to meet three needs: to require FDA to actively assess public health hazards from food and plan procedures to deal with them; to direct FDA to consult and discuss general food safety matters with parties other than the regulated industries; and to create the possibility of substantive court surveillance of FDA activities in the food safety area.

These intentions merit support, and they are founded on gross deficiencies FDA has in the food safety area. Any agency with regulatory responsibilities for a \$150 billion industry with funds of only \$62 million is maimed from the start. Add to this handicap, a tradition of drawing its leadership directly from the regulated industry, and a law which requires a day to day contact with industry officials but not with the public sector, and you get an agency sunk in good-natured somnolence toward the hazards it was created to combat.

That FDA fits this somnolent mold is already documented in hearings before the Congress (See, for eg., Senate Select Committee on Hunger and Human Needs, Hearing Sept. 1972; House Subcomm. on Public Health and Environment, Hearings Sept., 1971).

2.

A 1972 GAO study reported that of 97 representative food manufacturing plants, about 40% were operating under conditions that were insanitary or worse. The GAO concluded: "A serious problem of insanitary conditions exists in the food manufacturing industry...sanitary conditions in the food industry are deteriorating." (p. 2.) Kenton L. Harris a former FDA official now a private consultant stated in a recent speech that FDA is making less seizures and prosecutions throughout the entire country than used to be made in one district alone.

This year, FDA publicized what it called "unavoidable" levels of contaminants in food. It announced that filth such as rodent excreta, mould, etc., would be overlooked by FDA inspectors provided the filth did not exceed the so-called "unavoidable" levels. The policy of announcing in advance that filth will be tolerated has considerably lowered industry incentive to produce clean food. The foolishness of FDA's policy is heightened by the high levels of filth declared acceptable, levels so high that Mr. Harris called them "fraudulent" and even the GMA itself has stated publicly that they are far above what the industry would tolerate.

As of 1971, FDA inspected food plants only once every 5-7 years. After the Bon Vivant and Campbell botulism incidents, Congress has directed FDA to hire more inspectors and has provided money for them. The full number of inspectors requested by

3.

were not all hired. The number of inspections has increased, but I question whether a change in how FDA reports what constitutes an inspection is responsible for the increase. FDA abhors the idea that it is policing food, and prefers to extol the virtues of "voluntary compliance," one of the latest ventures being its "self-certification" program which removes federal food inspectors from food plants except in an infrequent, advisory capacity. Surely this policy is one where the fox has persuaded the farmer that he can guard the chicken coop. FDA is even considering granting a "seal of approval" for promotional use by participants in this non-inspected program.

Virgil Wodicka, director of the Bureau of Foods and formerly a Hunt-Wesson executive, summed it all up in a 1972 FDA Papers article: "I don't know that the FDA has necessarily learned anything from this [Bon Vivant] botulism episode. Something went wrong; it was an abnormal situation but this sort of thing is essentially unavoidable by any sort of regulatory approach or, for that matter, industrial approach." Once again FDA labeled the matter "unavoidable." A rash of botulism incidents has struck since then.

In the chemical pollution area, FDA's failings, again are on the record (see the Commerce Committee hearings on this Bill, "Toxic Substances Act 1973"). The meat supply increasingly offers us carcinogens, sensitivity-producing antibiotics and other hazards. FDA's survey of pesticide residues is inadequate. FDA has destroyed the 1958 Food Additives Amendment, which requires proof of safety of food additives, by exempting the great bulk of additives from it.

4.

The review of "generally recognized as safe" food additives-- the GRAS review-- instigated by Congress and the White House Conference on Food, Nutrition and Health, is an attempt to redress this error. Even here the FDA cannot shake off the voluntary compliance urge and has contracted out the safety review of food flavor additives to manufacturers themselves, the Flavor Extract Manufacturers Association, allowing industry not only to decide for itself whether it complies with the law, but to decide the law itself.

S. 2373's attempt to inject the possibility of more public participation in FDA performance, is overdue. It directs FDA to make its food adulteration surveillance procedures public and allow public hearings upon objection to them. This is excellent. However, I fear that in treating the procedures as formal regulations, FDA may be cemented into outmoded procedures when-- and if--it is ready to improve itself. If FDA gets a new method of food analysis, for example, or decides to step up inspection frequency, it may be inhibited by the procedures this Bill requires, and particularly by the Hearing procedure, which industry has and will use for extraordinary disputation and delay. This hearing procedure is not as appropriate as it might be for the expression of views by public interest groups because it is set up for objection to specific regulations rather than broad policy matters and priorities, and because the public interest groups do not like to risk the delay in implementing procedures which they may view as weak but nevertheless an improvement.

5.

I believe that the court review S. 2373 attempts to make available-that the procedures do not "provide reasonable assurance that the presence of adulterated food does not constitute an unreasonable threat to the public health or welfare"-would not, in view of the great weight accorded FDA in substantive matters by the courts, provide a realistic new avenue for improving FDA performance for the consumer.

My amendment to S. 2373 may more directly push FDA to better performance and allow public input. I would amend the Bill to require FDA to propose every year an annual comprehensive program which would identify the main hazards from foods; propose plans for acquiring information about them and combatting them; and state practical procedures for inspection and analysis. The annual comprehensive program would be open to public comment and informal hearing at the request of any parties, after which FDA would be required to assess and comment upon serious objections raised in its final promulgation of the program. Thereafter, FDA would be free to improve the procedures in the program, but a cause of action would be created for failure to carry out at least the standards of the program, and upon proof that the FDA did not perform at least the requirements of the program, one plaintiff could recover \$5000 or legal costs.

6.

The cause of action is realistic because the Courts would have the performance standard spelled out by the annual comprehensive program, and would have to decide merely whether the agency performed up to its stated standard. Thus the amendment would force FDA to initiate assessment of over-all food hazards, force it to state what it can and can't do, and would annually fund a private party to investigate its performance in detail--a task that no Congressional staff could hope to do, and no executive branch personnel could honestly do, but one which would enormously increase the performance and accountability of the agency to the public.

Should this Committee decline to consider this proposed amendment, it might report out instead of S. 2373 a Bill to make plant records open to FDA inspectors when they do inspect. Food plants are not now required to show FDA inspectors formula data, production and quality control records or complaint files, although this material would appear to be crucial to a thorough, efficient inspection since it would pinpoint what problems to look for. A 1972 GAO report found that 46% of plants asked for formula data by inspectors wanting to know what was in the products, refused to reveal this information. The authority to look at such records is an urgent need, and one Congress already has given FDA in the drug area.

7.

Finally, registration of food establishments would make it more likely that all food plants were eventually inspected, and would make communication and handling of routine and crisis situations much easier for FDA. This legislation was recommended by the White House Conference on Food, Nutrition and Health. In addition to registering types of foods processed, food establishments should be required to identify the brand names their products are sold under, so that if FDA identifies a serious hazard from a product, it can immediately trace the place of production and identify the cause and existence, if any, of hazards from the product marketed under another name.

Proposed amendment to S. 2373SURVEILLANCE FOR ADULTERATED FOOD
COMPREHENSIVE PROGRAM

Not more than one hundred and eighty days after the enactment date of this section, and annually thereafter, the Secretary shall propose a comprehensive program for the detection and prevention of adulterated food. The program shall include identification of health and welfare hazards from adulterated food together with potential hazards, setting of priorities for prevention and detection of such hazards with reasons for setting such priorities. The program shall include specific surveillance procedures necessary for the detection and prevention of adulterated food and shall require that the food supply be surveyed with the frequency and methods sufficient to provide assurance that the public suffers no unreasonable risk to its health or welfare from adulterated food, and shall require that analyses performed to determine the presence of adulteration in food be performed through use of the best instruments, technology and trained personnel reasonably available. Each annual comprehensive program shall include all specific surveillance procedure changes since promulgation of the last annual comprehensive program; and shall identify all health and welfare hazards arising since the last annual comprehensive program but not identified in that program; and all recalls and seizures occurring since promulgation of the last program.

Where no practical surveillance procedure is available to detect and/or prevent certain food adulteration, the Secretary shall so state in the comprehensive program and he shall then

- 2 -

include in said program (1) a plan for the development of practical surveillance procedures within the shortest feasible time, (2) specifications as to how such plan is to be carried out, and (3) a timetable for the completion of such plan.

PROCEDURE

The comprehensive program for the detection and prevention of adulterated food and all annual comprehensive programs under this Act, shall be published in the Federal Register and open to written public comment and to informal public hearings at the request of any interested party, including agency employees, before promulgation. If issues are raised in written public comments or hearings which question the adequacy of the program to prevent unreasonable risk from food adulteration, the program as promulgated shall include a description of the issues raised, together with the Secretary's disposition of the issues and the reasons therefore.

When the Secretary has stated that no practical procedures exist for a particular food adulteration, and has included in a prior annual comprehensive program, a plan and timetable for developing such procedures, he shall with the next annual comprehensive program report on the progress of said plan, report on new information available to him on the subject, and update the timetable of the plan, if it has not been completed.

MINIMUM REQUIREMENT

The annual comprehensive program shall include such surveillance procedures as the Secretary determines are necessary to carry out his responsibilities with respect to the detection and pre-

- 3 -

vention of adulterated food, but such procedures shall require, at a minimum, levels of surveillance sufficient to provide assurance that the public suffers no unreasonable risk to the public health or welfare.

CAUSE OF ACTION

Any citizen may within one year after expiration of an annual comprehensive program bring an action in the U.S. District Court against the Secretary for failure to carry out the comprehensive program, and may upon proof that the Secretary failed, recover \$5000 or the costs of suit, whichever is greater, provided that such amount shall not be recovered if the failure is minor, or if the failure involves a plan for developing a practical procedure not already available, or if the government has already paid such sum to another party because of failure to carry out the annual comprehensive program for the same year. The Secretary is not liable for such monies if it was not in his power to carry out the annual comprehensive program and he could not have known it at the time he promulgated it.

PUBLIC ACCESS TO INFORMATION

The Secretary shall make available to the public, at the cost of copying, upon identifiable request all records in the possession of the agency, provided they are the finished work product of an employee and provided they are not secret formulas or manufacturing processes, or confidential or privileged commercial or financial information.

May 30, 1972

Hearing Clerk
Room 6-88
5600 Fishers Lane
Rockville, Md., 20852

Dear Madam:

I hereby submit my comments to the proposed "Defect Levels in Foods" published in the Federal Register March 30, 1972.

A GAO report released April 18, 1972, "Dimensions of Unsanitary Conditions in the Food Manufacturing Industry" found that 40% of the food plants in this country are operating under insanitary conditions. It further found that only 30% of the plants inspected were operating in compliance with Good Manufacturing Practice for the sanitary manufacture of food (21 C.F.R. 128). The GMP guidelines entail such elementary cleanliness requirements as: adequate hand-washing facilities, training employees to prepare foods in a sanitary manner; using effective cleaning and sanitizing procedures; inspecting incoming raw materials and rejecting any decomposed raw materials; destroying bacteria during processing by approved methods; and handling finished packaged products in a way that avoids contamination.

The GAO report documented such conditions as:

- rodent excreta and urine, cockroach and other insect infestation, and non-edible materials found in or around raw materials, finished products and processing equipment.
- improper use of pesticides in close proximity to food-processing areas.
- use of insanitary equipment.
- dirty and poorly maintained areas over and around food-processing locations.

The GAO report, together with FDA's own inspection records showing a general decline in food industry sanitation practices¹ indicates that the cleanliness expectations that the

¹Statement by Commissioner Edwards, FDA news release, May 8, 1972.

2.

consumer has of his food have been seriously undermined by the food industry; and that the Food, Drug and Cosmetic Act has been flagrantly disobeyed."

The Food, Drug and Cosmetic Act forbids the sale in interstate commerce of adulterated foodstuffs (Section 301(b)). It calls any food adulterated if the food contains "any filthy, putrid, or decomposed substance" (Section 402 (3)). It makes no allowances for "safe" levels of filth, putridity or decomposition.

According to Commissioner Edwards, financial limitations restrict FDA inspections of food plants to only once every five to seven years.²

Given the food industry's serious filth problems, and given FDA's inhibited inspection ability, the FDA should foster fear of criminal prosecution to get the food cleaned up. The proposed "Defect Levels" do exactly the opposite. They are part of FDA's misguided "partnership" program, designed to end the anxiety of food manufacturers in noncompliance with the law, rather than to maximize the police functions of a consumer protector. The major purpose of a criminal statute is deterrence of anti-social behavior. No governmental body can prosecute all violations of the criminal law, since it lacks the resources. It depends, rather, on the threat of prosecution for public adherence to criminal code standards. If the government announces that it will prosecute only some criminal conduct, it is giving up much of the power for social control available to it. The advantage in making such an announcement is that it allows part of the criminal population to act criminally without anxiety. For example, the state might announce that it intended to prosecute larcenies only if they involved goods worth over \$500. In so doing, the state destroys the deterrence value of the law which prohibits all larcenies for larcenies under \$500. All incentive for obeying the law completely has been destroyed.

Similarly with these Defect Levels. When FDA decides to prosecute only foods containing over, for example, ten insect fragments, it is destroying all incentive to gain perfect compliance with the law. The ten fragments become the "target," not completely clean food.

The Defect Levels are all the more a mistake because they are

²Testimony, Subcommittee on Public Health of the House Commerce Committee, August 3, 1971.

3.

apparently very lax. FDA itself states: "all of the product defect levels have existed for some time, and...some pre-date enactment of the 1938 statute."³ It is literally incredible that technological capacity for clean food production has not increased since 1938, or that it has not increased yearly. This is supported by the fact that the Grocery Manufacturing Association--prime food industry spokesman--has stated publicly that the FDA filth tolerance levels are greater than what the industry itself tolerates.⁴

An example of a standard which uses "lowest common denominator" food sanitation is the peanut butter tolerance. With the Defect Levels, the FDA pledges not to prosecute any producer whose peanut butter averages 50 insect fragments per 100 grams, or averages 2 rodent hairs per 100 grams, or more than 35 milligrams per 100 grams of insoluble inorganic residue. In announcing this tolerance, FDA states that the levels are unavoidable. However, Consumers Reports, did a study of peanut butter⁵ and found that only 14 percent of the samples tested contained insect fragments or rodent hairs. Eighty-six percent of their samples contained none of this filth. It is difficult for FDA to argue that its presence is "unavoidable" when 86% of manufacturers avoid it. The report also stated that peanut butter need not contain any "insoluble inorganic residue" (otherwise known as grit) since properly cleaned peanuts are virtually free of it.

In summary, if FDA wishes to encourage the food industry to strive for clean food, it will abolish these limits on the prosecution of adulterated food. The guidelines it has set not only remove incentive for trying to manufacture clean food, but will in many cases cause increased filth, since the standards will invariably become the new targets, replacing zero filth levels.

FDA justifies the Defect Levels on the grounds that they are 1. unavoidable and 2. present no health hazard.

1. For the reasons stated above, it is probable that the levels are in many cases avoidable.

2. Without full investigation, the FDA cannot conclude that a health hazard is absent. The burden would seem to be on the

³Federal Register, March 30, 1972, p. 6498

⁴As reported in Supermarket News, April 3, 1972

⁵May, 1972, p. 287.

4.

FDA to so present, since the agency is in effect saying that filth in amounts above the tolerated levels do present a health hazard, and since there is abundant and increasing evidence that the filth in question does threaten health. The literature is increasing on mycotoxins widely present in molds on lentils, grains, potatoes, and nuts. An increasing number of foods, as wide ranging as fish and pepper, appear to carry harmful mycotoxins when mouldy.⁶ These mycotoxins apparently inflict severe liver damage and/or cancer. The number of such organisms identified and the variety of foods containing them, indicate potential problems of considerable importance to health.

The presence of excreta, rodent hairs, insect parts, etc. have traditionally been regarded as clues to the presence of numerous varieties of pathogens. The significance of their presence in any quantity can hardly be dismissed out of hand as aesthetics alone.

FDA is cavalier in its flat recitation that the defects present no health hazard. In dismissing without apparent evidence the potential hazards of the tolerated defects, FDA is really dismissing its own obligation to assure safety--and its obligation to enforce the law. It has shifted the burden of proof to the public, saying "unless the public can show otherwise, the defects are not hazardous." The law prohibits the presence of any filth in food products, and this shift of responsibility for safety to the public from the industry and the FDA is inappropriate and careless of the public health.

Finally, FDA shows bad faith in disowning responsibility for food contaminants it deems merely "aesthetic". FDA has traditionally shown high concern for food cosmetics. It encourages the use of cosmetics such as artificial flavors, colors and textures. Its usual justification for this support is that additives make food more pleasing so that the consumer will eat it and acquire the proper nutrients. One could expect FDA to be consistent and follow the same logic with respect to filth: if consumers find filth disgusting, FDA should take steps to remove it from the food supply so that consumers will not have difficulty in finding pleasant food to satisfy their nutritional needs.

Yours sincerely,

Anita Johnson
Associate attorney

⁶Brook, P.J. et al, "Fungus Toxins Affecting Mammals," A. Rev. Phytopath., 4, 171 (1969).

Christensen, "Microflora of Black and Red Pepper," Applied Microbiology (1967) reprinted in Cong Rec., March 29, 1972; and references cited therein.

Shank, et al, "Dietary Aflatoxins and Human Liver Cancer," Food and Cosmetics Toxicology, February 1972, pp. 51-82; April 1972, pp. 171-192.

Uraguchi et al, "Chronic Toxicity and Carcinogenicity in Mice of the Purified Mycotoxins, Luteoskyrin and Cyclochlorotine," Food and Cosmetics Toxicology, April 1972, pp. 193-208.

MORE EFFECTIVE SYSTEM OF FOOD PLANT INSPECTION

Additional legal authority and resources are urgently needed to expand and improve inspection of food plants.

Recommendations

1. That greatly increased appropriations be made to obtain a sufficient number of adequately trained personnel and supporting facilities to make plant inspections under existing laws.
2. That all plants which manufacture, prepare, propagate, process or repackage any foods be required to register biannually.
3. That food processors and distributors be required to report on a reasonably periodic basis cases of illness or other adverse effects allegedly attributable to any food or component thereof.
4. Where the necessary provisions for effective inspections are inadequate or nonexistent at the State and local level, such authority should be assumed by the appropriate Federal agencies.
5. That additional legislation be enacted to provide effective control of egg and fish processing operations.

Senator KENNEDY. As I understand the position, it is, first of all, you would like the Food and Drug Administration to establish some procedures for surveillance and inspection on these quality questions, and those regulations ought to be developed through open hearings, in which consumer groups ought to be able to testify and those ought to be published. Is that one aspect? Would that be one of your suggestions?

Ms. JOHNSON. Beyond that, I would ask that FDA develop and publish an assessment of the overall problems of the food supply. Part of that assessment would include making public, and inviting open criticism of, the specific surveillance procedures.

Senator KENNEDY. You would require the industry to go ahead and follow those particular regulations in terms of quality control?

Ms. JOHNSON. The regulations, so-called surveillance procedures, mean to me the methods that FDA uses to survey industry.

Senator KENNEDY. Would you not include in those that the industry do some as well? Do you think it ought to be left up to the FDA? Should they not both do it?

Ms. JOHNSON. I think that the idea of a manufacturing plant producing human food without any quality surveillance of its own, is beyond belief.

Senator KENNEDY. I would imagine that the good ones do it, and the ones that are really dangerous probably do not. As I understand, you think there ought to be both—there ought to be regulations published about what the FDA is going to do, in its inspection of various food processes and also the requirement that food processors have surveillance and keep their records, make them available to the Food and Drug Administration and to the public?

Ms. JOHNSON. That is perfectly reasonable. The problem I have with FDA, is that it is mortified at the idea that some food manufacturers might be disobeying the law.

FDA succumbs to the feeling that white-collar people cannot be criminal and white-collar people cannot disobey the law. That is why it is unwilling to do a proper job of policing for violations.

Instead, its attitude is we will help industry along, we will help industry to police itself. FDA would never use the word "police" though; it uses words like "self-certification."

Senator KENNEDY. My question is not the attitude of FDA with regard to the legislation, it is the specifics.

Ms. JOHNSON. I think FDA can easily advise industry in setting up programs; that is fine. But if this means that it is going to suspend regulatory inspection of these plants as it plans to do, I say no.

Senator KENNEDY. It should not be a substitute, they ought to have both. Do you think there is a danger to have both, independent inspection by food and drug and also requirements for the industry?

Ms. JOHNSON. I think there are many food industry people who are very aggressive and intelligent and perfectly capable of working out for themselves the procedure that they require for producing clean foods. Why should we pay civil servants for doing industry's job?

Senator KENNEDY. Should we leave it up to industry?

Ms. JOHNSON. I think the job of the Food and Drug Administration is to police cleanliness of food. If they can incidentally advise people to set up their own standards, I think that is wonderful. However,

it is not the job of FDA to consult with industry on things they should be doing themselves.

Senator KENNEDY. I am concerned about setting up requirements. That they be required to maintain certain records and conduct quality control in certain ways given the particular kind of industry, and in the process of the surveillance by Food and Drug that those records and information be available to the Food and Drug Administration, as a matter of right and obligation as well.

Ms. JOHNSON. I would say that is a major point; yes.

Senator KENNEDY. Would you like to give any kind of reaction to that, Mr. Jacobson?

Mr. JACOBSON. I would go along with what you just said. I think it would be important that those specifics be included in the bill. As the bill now stands, the bill strikes me as being very, very vague. I think it should specify what those surveillance procedures consist of.

The bill should say that FDA will promulgate regulations requiring companies to carry out certain kinds of inspections to make their records available and so on. I also agree with what Ms. Johnson was making a major point about, namely at the beginning of the year or ever so often the FDA should describe its priorities in the food inspection area, saying what it sees as major problems and how it is going to conquer those problems.

Those are the things consumer groups would be most interested in comments on.

Senator KENNEDY. You do not have available to you any sort of overview as to the way the Food and Drug Administration is attacking the problem, the lines of priorities, how they are going to proceed over the next year, that sort of thing?

Mr. JACOBSON. That is right. I do not have any feeling for that. It would be nice to see that spelled out very clearly, that these kinds of plants are the plants that should receive priority. These plants should be inspected every week, every year. These plants have not been a problem, et cetera. Pesticides are a problem, et cetera; not a problem, and so on.

Consumer groups, I think, do not have the staff or manpower to comment—

Senator KENNEDY. We could amend the legislation to require that Food and Drug submit a kind of annual report to Congress that would sort of outline this as to the way they are going to proceed along, including some of the points you made here, could we not, that could be in addition?

Mr. JACOBSON. I think that would be valuable.

Senator KENNEDY. Maybe you could help us in drafting that and submit it to us.

Mr. JACOBSON. Maybe we would between us.

Senator KENNEDY. Maybe we could help.

Mr. JACOBSON. I think right now the bill suffers from being so vague that it can be interpreted any way by Government officials, and I do not think that is what is needed.

Senator KENNEDY. Ms. Sechler?

Ms. SECHLER. I agree with both Mr. Jacobson and Ms. Johnson.

Senator KENNEDY. Thank you very much. You have been very helpful.

Our final panel of witnesses today consists of Dr. Ira I. Somers, representing the National Canners Association, and Dr. Howard E. Bauman, representing the Grocery Manufacturers Association of America.

Dr. Somers has performed a great deal of distinguished service in the food area. He has served as a member of the board of directors of the Research and Development Associates for Military Food and Packaging Systems, Inc. He is presently executive vice president of the National Canners Association.

Dr. Bauman is vice president of science and technology for the Pillsbury Co. He is a microbiologist by training and has made significant contributions to the area of Government-industry cooperation.

Gentlemen, welcome to the Health Subcommittee.

**STATEMENT OF DR. IRA SOMERS, EXECUTIVE VICE PRESIDENT,
NATIONAL CANNERS ASSOCIATION, WASHINGTON, D.C., AND DR.
HOWARD BAUMAN, GROCERY MANUFACTURERS OF AMERICA,
WASHINGTON, D.C., A PANEL**

Mr. SOMERS. It is a pleasure for us to be here this morning to participate in the discussion of this bill.

This statement on S. 2373, with the proposed amendment by Senator Kennedy—to be entitled the “Federal Food Establishment Registration and Inspection Act of 1973”—is submitted on behalf of the National Canners Association, a nonprofit trade association of more than 500 members from all parts of the country.

Members of the association pack approximately 85 to 90 percent of the national production of canned fruits, vegetables, juices, specialties, meat, and fish.

The National Canners Association appreciates this invitation to present its views on S. 2373, and particularly to support the proposed addition of a new section 411 to the Federal Food, Drug, and Cosmetic Act to provide for registration of all food establishments in the country, as well as foreign establishments processing or storing food and shipment to the United States.

Our statement will be directed primarily to the registration provisions of the bill before the subcommittee, but we will also briefly discuss the proposed new section 410 to provide for surveillance for adulterated foods.

The proposed new section 411 to the Food, Drug, and Cosmetics Act would establish a system of compulsory registration for all establishments in the United States engaged in the manufacture, processing, packing, labeling, or storing of food, in much the same manner that section 510 of the Food, Drug, and Cosmetics Act now provides for registration of drug establishments.

The registration is to include the registrant's name, the principal place of business, the location of each establishment, as well as a complete list of all foods or classes of foods manufactured, processed, packed, labeled, or stored at that establishment. In addition, the list must define the types of processing for each food or class of food, and the Secretary is directed to promulgate regulations defining types of processing for food for purposes of registration.

Additional provisions of proposed section 411 would require that new producers of foods register immediately with the Secretary, and that any registrant opening a new establishment also register that establishment immediately.

The Secretary is authorized to issue registration numbers to registrants and is directed to make available for inspection to any person any registration filed. The Secretary may by regulation exempt from the registration requirement classes of persons upon a finding that registration by such classes is not necessary for the protection of the public health. Each registered establishment will be subject to factory inspection pursuant to section 704 of the present act.

Under section 411(i), registration would also be provided for food establishments within any foreign country.

These registration provisions would be made effective by further amendments to the enforcement provisions of the act. Section 301 of the act lists a series of acts which are prohibited under the act and which may give rise to enforcement action. This section would be amended to provide specifically that "the failure to register as required by section 411" would constitute the act.

The effect of this inclusion would authorize the Secretary to seek appropriate enforcement by injunction proceedings under section 302 or by criminal proceedings under section 303. Thus, the failure to register would subject the owner or operator of an establishment to imprisonment for not more than 1 year, or a fine of not more than \$1,000, or both, for an initial violation. Even more stringent penalties are provided for subsequent violations.

Enforcement would be further facilitated by amending section 403 of the Food, Drug, and Cosmetic Act to provide that a food shall be deemed to be misbranded "if it is offered for sale or transferred from an establishment which is required to register under section 411(b) but which has not so registered under section 411." The principal effect of this amendment would be to render such food subject to seizure and condemnation under section 304 of the act.

Finally, section 801(a) of the act would be amended to provide for effective enforcement of the registration provisions with respect to imports.

The National Canners Association is convinced that these registration provisions will have a salutary effect, and in fact will operate to the benefit of the consuming public, the Food and Drug Administration, and the food industry.

As has been frequently pointed out, it is anomalous for the Food, Drug, and Cosmetic Act to provide for inspection of food establishments and yet to provide no effective reliable means for the identification of those plants in which food are manufactured, packed, or stored.

To that end the National Canners Association for many years published a directory of canners identifying their operations and the products packed. At the present time questions concerning the number and nature of other types of food establishments in the country can be answered only in general fashion, and solely on the basis of estimates and inadequate information.

Our support for a food plant registration requirement has also been reflected in past positions taken by the association with respect to legis-

lation and administrative action. In previous Congresses, legislation was considered that would have imposed special regulatory provisions applicable solely to fish processing establishments.

Although there were a number of good faith differences of opinion as to the specific provisions of those bills, the National Canners Association did not oppose such legislation in principle, and indeed expressed support for reasonably drafted legislation along this line.

We expressed the view then that plant registration provisions for fish plants along the lines of those set forth in section 510 of the F. D. & C. Act with respect to drug plants would be appropriate and would serve a beneficial public purpose.

Since October 1971 the National Canners Association has been working closely with the Federal Food and Drug Administration on the development of a better processing control plan for thermally processed low-acid canned foods.

The initiation for such a plan developed within NCA, and it was our proposal submitted to FDA that set the administrative process in motion.

I should like to submit for the record that original NCA proposal, as published in the Federal Register on November 12, 1971, which embodied required plant registration. I understand that has been made available.

Here again there have been some differences concerning details of this plan, but throughout the association proposed and urged the necessity for plant registration for all processors of those low-acid canned foods. Indeed, 21 C.F.R. paragraph 90.20(c)(1), requiring registration for plants processing low acid foods, was contained in a final order promulgated by FDA last May, was not objected to by NCA or affected companies, and thus became fully effective in June. All processors of thermally processed low-acid canned foods were required to register with the Food and Drug Administration by July 13 on forms developed with the agency, indicating the name, principal place of business, the location of each establishment, and a list of the canned foods packed in each such establishment. We are submitting for the record a copy of FD form 2541 covering that program of food canning establishment registration. This is, of course, essentially the same information that would be required for all food plants under the proposed section 411 of the bill before this subcommittee today.

Thus, a major segment of our industry is already in actual compliance with the currently operative registration provision. In our view, the benefits from this approach should reasonably be extended to the entire food industry and for this reason we support the proposed new section 411 of the F.D. & C. Act.

We have several comments concerning specific details of the proposed language of new section 411.

An initial point of particular interest is that proposed section 411 would follow the pattern established by section 510 for drugs in that it would require registration not only of plants now subject to the F. D. & C. Act by reason of the fact that they ship food products in interstate commerce, but also to purely local food plants whose products do not cross State lines.

Thus, for the first time significant provisions of the F.D. & C. Act would be applicable to many intrastate food operations. There are,

of course, a number of precedents that support this approach, in addition to section 510 itself.

For example, the oleomargarine regulatory provisions in section 407 of the act apply to intrastate as well as interstate sales. And of course the Meat and Poultry Inspection Acts have been amended in recent years also to extend to intrastate activities, because of the relationship between intrastate and interstate sales. As far as the Meat and Poultry Act is concerned, we think what you are proposing would be parallel to that, and not in lieu thereof.

Under any circumstances, we have every reason to believe that all members of the National Canners Association and most other commercial canners distribute their products in interstate commerce and would thus not be affected one way or the other.

The principal significance for our industry would probably be that it would require registration by so-called custom packers, and perhaps thereby subject those operations to a greater degree of control than now exists. Accordingly, we support this aspect of the amendment.

Section 411(b) would require annual registration, which would be required to include a complete list of all foods and all classes of foods manufactured in the establishment. For purposes of clarity and for particular application to seasonal industries such as ours, we believe it might be desirable to add the words "during the preceding year" at the end of the first sentence, so that it would be made clear that registration would require a listing of all products packed in the establishment during the last 12 months.

There would, of course, be no utility in requiring the listing of products packed longer ago than that, and we see no purpose that would be served by requiring a company to speculate as to possible changes in its product mix in the year ahead. We assume that the regulations could provide for amendment of a registration if a company decided to pack a product not listed in its annual registration form.

In the subheading to section 411(e), there is a reference to "fees," but there is no requirement of a fee in that provision. We assume that the subheading is in error.

At any rate, we believe it would be desirable to adhere to the section 510 practice of not imposing a fee upon companies registering in accordance with the act.

The provision for exclusions from the requirement of registration in section 411(g) is undoubtedly necessary, for there may well be some classes for which registration would serve no useful purpose.

For example, it is not entirely clear whether farmers raising and selling raw products to processors would come within the coverage of the section, but we see little or no advantage in requiring every food farmer in the United States to register as a food establishment under this section. Indeed, it might be desirable to provide a statutory exclusion for farmers who are themselves not engaged in the processing, in much the same way that section 510 provides for statutory exclusions for pharmacies, physicians, and research laboratories.

We have not developed any specific proposal in this regard, however, for the issue has no direct impact upon our industry. Perhaps the subcommittee may want to consider this point with affected industry groups.

Another class for which a specific exclusion might be appropriate is food service establishments, which also might technically be re-

garded as coming within the broad definition of coverage in section 411(g).

We note that the registration requirements would apply to foreign as well as domestic food companies processing foods for distribution in the United States. It has frequently been observed that the regulatory provisions of the F.D. & C. Act do not fall equally on foreign and domestic processors. The former are substantially free of the rigorous factory inspection provisions of the act, and the sanitation and other processing requirements set forth in various FDA regulations. The requirement of registration for these plants is in our view desirable.

There are two procedural provisions to which the subcommittee might well give further consideration. As I have previously pointed out, section 302 of the act authorizes the FDA by injunction to compel plant registration. As the subcommittee is aware, the criminal provisions of the act are enforced under the doctrine of absolute criminal liability—which means that no knowledge or intent is required. Any individual officer or employee of any company may thus be criminally prosecuted even though he had no knowledge of any failure fully to comply with the registration requirements of the amendment or any intent to do so.

We suggest that it will suffice for the enforcement of the amendment to provide for injunctive action alone. To that end, we would suggest that in section 5 the prohibited act read on “the willful or knowing failure to register as required by section 411.” There seems to be no reason to require indictments and jury trials when an effective and prompt remedy is available.

I would now like to turn briefly to the language of S. 2373 which provides for the establishment of what are denominated “surveillance procedures” by the Secretary for adulterated foods. We found this confusing, and we would have to agree with the testimony of the Food and Drug Administration as to what it would accomplish and what we see the intent of it to be.

When I was asked by the subcommittee to testify on S. 2373, the logical first step was to review the provisions of the bill as introduced in order to determine what it provides and what its impact would be upon the consuming public, the industry, and the agency.

I must confess that I was unable to determine what was intended by the proposed section 410, how it would operate, and just what it would do. The association’s legal counsel could not provide me with any clarification in this regard. I mention this background so that the subcommittee will understand our difficulty in preparing meaningful comments on the surveillance provisions of the bill.

The proposed new section 410 would require that the Secretary adopt regulations to specify “surveillance procedures” that he would follow for the detection of adulterated foods. Just what would be involved in those procedures and just what the proponents have in mind is not clear.

We are convinced, however, that the expenditure of substantial energy and time on behalf of the agency, the regulated industries, and interested consumers in an administrative proceeding designed to specify surveillance procedures would be far better directed toward providing additional support for existing FDA programs.

At the present time the FDA is free, within budgetary and stationary limits, to establish whatever inspection procedures it deems to be ap-

appropriate to carry out its responsibilities under the F.D. & C. Act. Where a problem or potential problem is thought to exist, the FDA may focus its energies and resources in that direction and develop a specific program that will assure the protection of the consumer.

We cannot conceive what utility there would be in requiring FDA to undertake extensive administrative proceedings to specify, and possibly to limit, the surveillance procedures it will use for its enforcement of section 402 of the act. The task itself will be almost endless in view of the myriads of substances that might be involved. The FDA and other interested persons could find themselves engaged in totally unnecessary proceedings to establish and argue about procedures involving controversies that perhaps need never arise with respect to hypothetical situations that may never occur. Administrative flexibility essential in this area would be impaired.

The National Canners Association is well aware of the efforts by FDA, industry and association laboratories and others to develop methods of analysis for a wide variety of adulterants and potential adulterants. The association laboratories have been intensively active in that work for more than six decades and have cooperated with the FDA in developing and improving procedures, in exchanging views on techniques, analyzing check samples, and the like.

We are at a loss to understand what problem or kind of problems are thought to exist that would justify the initiation of unwieldy administrative procedures that could do little more than describe what FDA is now doing, but at great cost in time and energy to everyone involved.

For these reasons and because of the very fundamental ambiguity of the provisions of section 410, the National Canners Association believes that it would not be in the public interest for Congress to enact section 410, certainly as presently drafted. It is our view that corrective legislation addressed to a perceived need may often be desirable, but we urge that it is not in the public interest for Congress to enact vague general directives, aimed at no identified need, that will burden the agency and the industry and will apparently have little effect in helping the agency accomplish its objectives.

In conclusion, we strongly support the enactment of proposed section 411 in the Kennedy amendment to S. 2373, and must firmly oppose the enactment of the basic text of that bill which provides for the enactment of the section 410 so-called surveillance procedures.

Thank you.

Senator KENNEDY. Thank you very much.

[The prepared statement of Dr. Somers follows:]

Statement of Dr. Ira I. Somers
On Behalf of the
National Canners Association
On S. 2373, with Proposed Kennedy Amendment
"Federal Food Establishment Registration
and Inspection Act of 1973"
before the
Health Subcommittee of the
Senate Committee on Labor and Public Welfare
September 11, 1973

This statement on S. 2373, with the proposed amendment by Senator Kennedy -- to be entitled the "Federal Food Establishment Registration and Inspection Act of 1973" -- is submitted on behalf of the National Canners Association, a nonprofit trade association of more than 500 members from all parts of the country. Members of the Association pack approximately 85 to 90 percent of the national production of canned fruits, vegetables, juices, specialties, meat and fish.

The National Canners Association appreciates this invitation to present its views on S. 2373, and particularly to support the proposed addition of a new Section 411 to the Federal Food, Drug, and Cosmetic Act to provide for registration of all food establishments in the country, as well as foreign establishments processing or storing food for shipment to the United States. Our statement will be directed primarily to the registration provisions of the bill before the

Subcommittee, but we will also briefly discuss the proposed new Section 410 to provide for surveillance for adulterated foods.

The proposed new Section 411 to the FD&C Act would establish a system of compulsory registration for all establishments in the United States engaged in the manufacture, processing, packing, labeling, or storing of food, in much the same manner that Section 510 of the FD&C Act now provides for registration of drug establishments. The registration is to include the registrant's name, the principal place of business, the location of each establishment, as well as a complete list of all foods or classes of foods manufactured, processed, packed, labeled or stored at that establishment. In addition, the list must define the types of processing for each food or class of food and the Secretary is directed to promulgate regulations defining types of processing for food for purposes of registration.

Additional provisions of proposed Section 411 would require that new producers of foods register immediately with the Secretary, and that any registrant opening a new establishment also register that establishment immediately. The Secretary is authorized to issue

registration numbers to registrants and is directed to make available for inspection to any person any registration filed. The Secretary may by regulation exempt from the registration requirement classes of persons upon a finding that registration by such classes is not necessary for the protection of the public health. Each registered establishment will be subject to factory inspection pursuant to Section 704 of the present Act.

Under Section 411(i), registration would also be provided for food establishments within any foreign country.

These registration provisions would be made effective by further amendments to the enforcement provisions of the Act. Section 301 of the Act lists a series of acts which are prohibited under the Act and which may give rise to enforcement action. This Section would be amended to provide specifically that "the failure to register as required by section 411" would constitute a prohibited act. The effect of this inclusion would authorize the Secretary to seek appropriate enforcement by injunction proceedings under Section 302 or by criminal proceedings under Section 303. Thus, the failure to register would subject the owner or operator

- 4 -

of an establishment to imprisonment for not more than one year, or a fine of not more than \$1,000, or both, for an initial violation. Even more stringent penalties are provided for subsequent violations.

Enforcement would be further facilitated by amending Section 403 of the FD&C Act to provide that a food shall be deemed to be misbranded

"if it is offered for sale or transferred from an establishment which is required to register under section 411(b) but which has not so registered under section 411."

The principal effect of this amendment would be to render such food subject to seizure and condemnation under Section 304 of the Act.

Finally, Section 801(a) of the Act would be amended to provide for effective enforcement of the registration provisions with respect to imports.

The National Canners Association is convinced that these registration provisions will have a salutary effect, and in fact will operate to the benefit of the consuming public, the Food and Drug Administration, and the food industry. As has been frequently pointed out, it is anomalous for the FD&C Act to provide for inspection of food establishments and yet to provide no effective reliable means for the identification of those

plants in which foods are manufactured, packed or stored. To that end the National Cannery Association for many years published a directory of canners identifying their operations and the products packed. At the present time questions concerning the number and nature of other types of food establishments in the country can be answered only in general fashion, and solely on the basis of estimates and inadequate information.

Our support for a food plant registration requirement has also been reflected in past positions taken by the Association with respect to legislation and administrative action. In previous Congresses legislation was considered that would have imposed special regulatory provisions applicable solely to fish processing establishments. Although there were a number of good faith differences of opinion as to the specific provisions of those bills, the National Cannery Association did not oppose such legislation in principle, and indeed expressed support for reasonably drafted legislation along this line. We expressed the view then that plant registration provisions for fish plants along the lines of those set forth in Section 510 of the FD&C Act with respect to drug plants would be appropriate and would serve a beneficial public purpose.

Since October 1971 the National Canners Association has been working closely with the Federal Food and Drug Administration on the development of a Better Processing Control Plan for thermally processed low acid canned foods. The initiation for such a plan developed within NCA, and it was our proposal submitted to FDA that set the administrative process in motion. I should like to submit for the record that original NCA proposal, as published in the Federal Register on November 12, 1971, which embodied required plant registration.

Here again there have been some differences concerning details of this plan, but throughout the Association proposed and urged the necessity for plant registration for all processors of those low acid canned foods. Indeed, 21 C.F.R. § 90.20(c)(1), requiring registration for plants processing low acid foods, was contained in a final order promulgated by FDA last May, was not objected to by NCA or affected companies, and thus became fully effective in June. All processors of thermally processed low acid canned foods were required to register with the Food and Drug Administration by July 13 on forms developed with the agency, indicating the name, principal place of business, the location of

- 7 -

each establishment, and a list of the canned foods packed in each such establishment. We are submitting for the record a copy of FD Form 2541 covering that program of Food Canning Establishment Registration. This is of course essentially the same information that would be required for all food plants under the proposed Section 411 of the bill before this Subcommittee today.

Thus, a major segment of our industry is already in actual compliance with the currently operative registration provision. In our view, the benefits from this approach should reasonably be extended to the entire food industry and for this reason we support the proposed new Section 411 of the FD&C Act.

We have several comments concerning specific details of the proposed language of new Section 411.

An initial point of particular interest is that proposed Section 411 would follow the pattern established by Section 510 for drugs in that it would require registration not only of plants now subject to the FD&C Act by reason of the fact that they ship food products in interstate commerce, but also to purely local food plants whose products do not cross state lines. Thus, for the first time significant provisions of the FD&C Act would be applicable to many intrastate food

operations. There are of course a number of precedents that support this approach, in addition to Section 510 itself. For example, the oleomargarine regulatory provisions in Section 407 of the Act apply to intrastate as well as interstate sales. And of course the Meat and Poultry Inspection Acts have been amended in recent years also to extend to intrastate activities, because of the relationship between intrastate and interstate sales. Under any circumstances, we have every reason to believe that all members of the National Canners Association and most other commercial canners distribute their products in interstate commerce and would thus not be affected one way or the other. The principal significance for our industry would probably be that it would require registration by so-called custom packers, and perhaps thereby subject those operations to a greater degree of control than now exists. Accordingly, we support this aspect of the amendment.

Section 411(b) would require annual registration, which would be required to include a complete list of all foods and all classes of foods manufactured in the establishment. For purposes of clarity and for particular application to seasonal industries such as ours, we believe it might be desirable to add the words

- 9 -

"during the preceding year" at the end of the first sentence, so that it would be made clear that registration would require a listing of all products packed in the establishment during the last 12 months. There would of course be no utility in requiring the listing of products packed longer ago than that, and we see no purpose that would be served by requiring a company to speculate as to possible changes in its product mix in the year ahead. We assume that the regulations could provide for amendment of a registration if a company decided to pack a product not listed in its annual registration form.

In the subheading to Section 411(e), there is a reference to "fees," but there is no requirement of a fee in that provision. We assume that the subheading is in error. At any rate, we believe it would be desirable to adhere to the Section 510 practice of not imposing a fee upon companies registering in accordance with the Act.

The provision for exclusions from the requirement of registration in Section 411(g) is undoubtedly necessary, for there may well be some classes for which registration would serve no useful purpose. For example, it is not entirely clear whether

- 10 -

farmers raising and selling raw products to processors would come within the coverage of the Section, but we see little or no advantage in requiring every food farmer in the United States to register as a food establishment under this Section. Indeed, it might be desirable to provide a statutory exclusion for farmers who are themselves not engaged in the processing, in much the same way that Section 510 provides for statutory exclusions for pharmacies, physicians and research laboratories. We have not developed any specific proposal in this regard, however, for the issue has no direct impact upon our industry. Perhaps the Subcommittee may want to consider this point with affected industry groups.

Another class for which a specific exclusion might be appropriate is food service establishments, which also might technically be regarded as coming within the broad definition of coverage in Section 411 (g).

We note that the registration requirements would apply to foreign as well as domestic food companies processing foods for distribution in the United States. It has frequently been observed that the regulatory provisions of the FD&C Act do not fall equally on foreign and domestic processors. The former are substantially

- 11 -

free of the rigorous factory inspection provisions of the Act, and the sanitation and other processing requirements set forth in various FDA regulations. The requirement of registration for these plants is in our view desirable.

There are two procedural provisions to which the Subcommittee might well give further consideration. As I have previously pointed out, Section 302 of the Act authorizes the FDA by injunction to compel plant registration. As the Subcommittee is aware, the criminal provisions of the Act are enforced under the doctrine of absolute criminal liability -- which means that no knowledge or intent is required. Any individual officer or employee of any company may thus be criminally prosecuted even though he had no knowledge of any failure fully to comply with the registration requirements of the Amendment or any intent to do so.

We suggest that it will suffice for the enforcement of the Amendment to provide for injunctive action alone. To that end, we would suggest that in Section 5 the prohibited act read on "the wilfull or knowing failure to register as required by section 411." There seems to be no reason to require indictments and jury trials when an effective and prompt injunctive remedy is available.

- 12 -

I would now like to turn briefly to the language of S. 2372 which provides for the establishment of what are denominated "surveillance procedures" by the Secretary for adulterated foods. When I was asked by the Subcommittee to testify on S. 2372, the logical first step was to review the provisions of the bill as introduced in order to determine what it provides and what its impact would be upon the consuming public, the industry, and the agency.

I must confess that I was unable to determine what was intended by the proposed Section 410, how it would operate, and just what it would do. The Association's legal counsel could not provide me with any clarification in this regard. I mention this background so that the Subcommittee will understand our difficulty in preparing meaningful comments on the surveillance provisions of the bill. The proposed new Section 410 would require that the Secretary adopt regulations to specify "surveillance procedures" that he would follow for the detection of adulterated foods. Just what would be involved in those procedures and just what the proponents have in mind is not clear.

- 13 -

We are convinced, however, that the expenditure of substantial energy and time on behalf of the agency, the regulated industries, and interested consumers in an administrative proceeding designed to specify surveillance procedures would be far better directed toward providing additional support for existing FDA programs.

At the present time the FDA is free, within budgetary and statutory limits, to establish whatever inspection procedures it deems to be appropriate to carry out its responsibilities under the FD&C Act. Where a problem or potential problem is thought to exist, the FDA may focus its energies and resources in that direction and develop a specific program that will assure the protection of the consumer. We cannot conceive what utility there would be in requiring FDA to undertake extensive administrative proceedings to specify, and possibly to limit, the surveillance procedures it will use for its enforcement of Section 402 of the Act. The task itself will be almost endless in view of the myriads of substances that might be involved. The FDA and other interested persons could find themselves engaged in totally

- 14 -

unnecessary proceedings to establish and argue about procedures involving controversies that perhaps need never arise with respect to hypothetical situations that may never occur. Administrative flexibility essential in this area would be impaired.

The National Canners Association is well aware of the efforts by FDA, industry and Association laboratories and others to develop methods of analysis for a wide variety of adulterants and potential adulterants. The Association laboratories have been intensively active in that work for more than six decades and have cooperated with the FDA in developing and improving procedures, in exchanging views on techniques, analyzing check samples, and the like. We are at a loss to understand what problem or kind of problems are thought to exist that would justify the initiation of unwieldy administrative procedures that could do little more than describe what FDA is now doing, but at great cost in time and energy to everyone involved.

For these reasons and because of the very fundamental ambiguity of the provisions of Section 410, the National Canners Association believes that it would not be in the public interest for Congress to enact

- 15 -

Section 410, certainly as presently drafted. It is our view that corrective legislation addressed to a perceived need may often be desirable, but we urge that it is not in the public interest for Congress to enact vague general directives, aimed at no identified need, that will burden the agency and the industry and will apparently have little effect in helping the agency accomplish its objectives.

In conclusion, we strongly support the enactment of proposed Section 411 in the Kennedy Amendment to S. 2373, and must firmly oppose the enactment of the basic text of that bill which provides for the enactment of the Section 410 so-called surveillance procedures.

Thank you.

Senator KENNEDY. Dr. Bauman, you have a separate statement?

**STATEMENT OF HOWARD E. BAUMAN, PH. D., VICE PRESIDENT
FOR SCIENCE AND TECHNOLOGY, PILLSBURY CO., MINNEAPOLIS,
MINN., REPRESENTING THE GROCERY MANUFACTURERS OF
AMERICA, INC.**

Dr. BAUMAN. Yes, Mr. Chairman. I am Howard Bauman, vice president for science and technology, the Pillsbury Co., Minneapolis, Minn. I appear before you today on behalf of the Grocery Manufacturers of America, Inc. (GMA). GMA is the trade association of the Nation's leading manufacturers of food and grocery products. The membership of GMA, approximately 160 in number, manufactures a major percentage of the total volume of processed foods produced in this country.

Mr. Chairman, we will limit our comments today to a discussion of the registration aspects of S. 2373. GMA, as an association, has not formalized a position at this time on the "surveillance" aspects of the bill.

I might add, if the chairman is interested, I would comment on a personal basis on any question.

Two years ago, in September of 1971, the GMA board of directors adopted a position supporting a continuing registration of all food plants. This board position called for registration of all food plants including information on name, address, and products produced. We believe that registration is one of three steps necessary to improve FDA's monitoring of sanitation in food production and distribution. The other needed steps include adequate resources and improvement and upgrading of current resources.

GMA firmly supports an effective and capable Food and Drug Administration (FDA) and endorses the need for adequate funding and staff for this regulatory arm of government.

Indeed, in 1971 and again in 1972, GMA testified in support of increased resources for the FDA. It is encouraging to note that additional resources were allocated to this agency in each of the last 3 fiscal years. The need for increased resources was presented in 1971 when then Commissioner Edwards testified that the frequency of food plant inspection was approximately once every 7 years. With the increased resources granted the FDA for this past fiscal year, this figure has changed to approximately one inspection every 3 to 4 years.

This increase has come about through the addition of 500 new inspectors. To increase the inspection level to one inspection per plant per year would require a further increase in the number of inspectors by 700-1,000, or about double the current number of inspectors.

To be a more effective agency, the FDA needs not only adequate funding, but also properly trained inspection personnel. In September of 1972, The Pillsbury Co. conducted a 2-week training course on food quality assurance under contract with the FDA. The 20 FDA inspectors participating in this program were trained in hazard analysis and critical control point techniques. This degree of sophistication for FDA inspectors has become necessary in light of the rapid technological developments in food processing methods. FDA has since conducted two additional training schools.

However, even with properly trained personnel, the essential problem is that the number and location of food establishments within FDA's jurisdiction are not precisely known. The FDA estimates that the food industry in the United States comprises some 60,000 establishments, including approximately 32,000 manufacturing and processing plants and 28,000 establishments of other types, such as warehouses and repacking and relabeling plants from bulk to consumer size packages.

These estimates are based on published statistics from the Bureau of the Census of the Department of Commerce. The Census Bureau has the most accurate and extensive listing of known food manufacturers in its files, but this listing is confidential and not available to FDA or most other Government agencies.

The Bureau compiles this listing from the Social Security Administration records of manufacturers. All manufacturers, when they enter into business, must contact the Social Security Administration for an employer identification number to be used when reporting employees' social security information.

The most current census figures for processing plants and wholesalers are attached. A copy of the annual survey form sent to a sample of the food processing industry by the Bureau of the Census is also attached to this statement.

In this connection, one of the problems facing FDA is becoming aware of new food manufacturers and new products. Currently, FDA must rely upon chance observations by inspectors, reports from existing companies, consumer complaints, State reports, requests for label approvals or other types of inquiries from new firms. We believe that mandatory plant registration is the answer to this problem.

But registration must be more than simply mandatory. It must be uniform. The FDA should develop, in cooperation with other regulatory agencies, a model registration form to be used as the standard by all jurisdictions. This standardized form for plant registration should be uncomplicated, concise and easily integrated to a computer system. We believe this is an achievable objective and GMA would be willing to work with FDA on the registration form.

Pertinent data on each manufacturer and types of product, when computerized, would be easily accessible. When necessary, all firms that manufacture a particular product could be quickly identified. By utilizing this computer-stored information, FDA could target specific projects to discrete segments of the food industry with greater facility.

In regard to plant registration as set forth in S. 2373, GMA is in agreement with the general provisions of the bill. We have only a few specific comments on certain provisions of this proposed legislation.

GMA agrees with the requirement for listing of the name, principal place of business, location of each food establishment, and list of all foods or classes of foods manufactured in each establishment. We believe that this requirement would provide useful information to FDA without undue burden on the food manufacturing industry. Should not the heading "biennial registration" read "annual" registration, based on the text following that heading?

However, GMA believes that a requirement for listing the "type of processing" at each establishment does raise some practical difficulties, since a precise description of the types of processing is in many cases

regarded as a trade secret and confidential business information. Disclosure of the specific type of processing could make public certain information concerning new processed foods that a manufacturer would ordinarily deem to be confidential.

GMA believes that "type of processing" should be clearly defined to mean a general description of the processes used, for example, baking, canning, freezing, and the like. Education and/or enforcement programs could then be tailored to product classes or to manufacturers engaged in similar types of processing.

With further respect to the registration provision itself, GMA particularly agrees with the requirement that the Secretary shall promulgate regulations defining food classes for the purposes of registration. This will help to avoid uncertainty under that provision and to provide a clear and simple method of providing useful information. Based on FDA's current approach to food classes, as proposed in the Federal Register of July 26, 38 F.R. 20035, GMA is confident that a workable and logical definition of food classes can be achieved.

GMA has some question as to whether a registration number is useful or necessary under this provision. There are many other registration numbers and other identification numbers currently used including the Universal Product Code, USDA registration number for meat and poultry processing establishments and the registration required by State agencies.

Another identification number would appear to further add to the complications without any commensurate benefits. If any such number is adopted in the legislation, GMA recommends that a universal Federal numbering system be established to avoid further unnecessary duplication.

In conclusion, GMA believes that the purpose and the general substance of the registration aspects of this bill will have a salutary effect on the FDA's exercise of its statutory responsibilities and duties with respect to the food industry.

To summarize:

(1) GMA supports legislation that provides for continuing reasonable registration of all food establishments. All manufacturers should be required to annually register their name, principal place of business, location of each food establishment, and foods or classes of foods produced.

(2) A standard registration form should be developed by FDA in conjunction with other Federal regulation agencies as well as State and local governments. This universal form could then be used by all jurisdictions to register food manufacturers.

(3) All registration information should be made in computer-available form, that is, the registration form should be precoded so the information can be directly keypunched.

(4) Six months or one year after enactment of mandatory registration, FDA should report to Congress on its progress in meeting the requirements of this provision, specifically the extent and effectiveness of computerization of the data.

Thank you.

Senator KENNEDY. Thank you very much.

[The prepared statement of Dr. Bauman follows:]

TESTIMONY OF HOWARD E. BAUMAN, PH.D.
ON BEHALF OF
THE GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. Chairman, members of the Subcommittee on Health, I am Howard Bauman, Vice President for Science and Technology, The Pillsbury Company, Minneapolis, Minnesota. I appear before you today on behalf of the Grocery Manufacturers of America, Inc. (GMA). GMA is the trade association of the nation's leading manufacturers of food and grocery products. The membership of GMA, approximately 160 in number, manufactures a major percentage of the total volume of processed foods produced in this country.

Mr. Chairman, we will limit our comments today to a discussion of the registration aspects of S. 2373. GMA, as an association, has not formalized a position at this time on the "surveillance" aspects of the bill.

Two years ago, in September of 1971, the GMA Board of Directors adopted a position supporting a continuing registration of all food plants. This Board Position called for registration of all food plants including information on name, address and products produced. We believe that registration is one of three steps necessary to improve FDA's monitoring of sanitation in food production and distribution. The other needed steps include adequate resources and improvement and upgrading of current resources.

GMA firmly supports an effective and capable Food and Drug Administration (FDA) and endorses the need for adequate funding and staff for this regulatory arm

Testimony given on September 11, 1973 to the Subcommittee on Health, Senate Committee on Labor and Public Welfare.

of government. Indeed, in 1971 and again in 1972, GMA testified in support of increased resources for the FDA. It is encouraging to note that additional resources were allocated to this Agency in each of the last three fiscal years. The need for increased resources was presented in 1971 when then-Commissioner Edwards testified that the frequency of food plant inspection was approximately once every seven years. With the increased resources granted the FDA for this past fiscal year, this figure has changed to approximately one inspection every three to four years. This increase has come about through the addition of 500 new inspectors. To increase the inspection level to one inspection per plant per year would require a further increase in the number of inspectors by 700-1000, or about double the current number of inspectors.

To be a more effective agency, the FDA needs not only adequate funding, but also properly trained inspection personnel. In September of 1972, The Pillsbury Company conducted a two-week training course on food quality assurance under contract with the FDA. The twenty FDA inspectors participating in this program were trained in hazard analysis and critical control point techniques. This degree of sophistication for FDA inspectors has become necessary in light of the rapid technological developments in food processing methods. FDA has since conducted two additional training schools.

However, even with properly trained personnel, the essential problem is that the number and location of food establishments within FDA's jurisdiction are not precisely known. The FDA estimates that the food industry in the U.S. comprises some 60,000 establishments, including approximately 32,000 manufacturing and processing plants and 28,000 establishments of other types, such as warehouses and repacking and relabeling plants from bulk to consumer size packages.

These estimates are based on published statistics from the Bureau of the Census of the Department of Commerce. The Census Bureau has the most accurate and extensive listing of known food manufacturers in its files, but this listing is confidential and not available to FDA or most other government agencies. The Bureau compiles this listing from the Social Security Administration records of manufacturers. All manufacturers, when they enter into business, must contact the Social Security Administration for an employer identification number to be used when reporting employees' social security information. (The most current census figures for processing plants and wholesalers are attached. A copy of the annual survey form sent to a sample of the food processing industry by the Bureau of the Census is also attached to this statement.)

In this connection, one of the problems facing FDA is becoming aware of new food manufacturers and new products. Currently, FDA must rely upon chance observations by inspectors, reports from existing companies, consumer complaints, state reports, requests for label approvals or other types of inquiries from new firms. We believe that mandatory plant registration is the answer to this problem.

But registration must be more than simply mandatory. It must be uniform. The FDA should develop, in cooperation with other regulatory agencies, a model registration form to be used as the standard by all jurisdictions. This standardized form for plant registration should be uncomplicated, concise and easily integrated to a computer system. We believe this is an achievable objective and GMA would be willing to work with FDA on the registration form. Pertinent data on each manufacturer and types of product, when computerized, would be easily accessible.

When necessary, all firms that manufacture a particular product could be quickly identified. By utilizing this computer-stored information, FDA could target specific projects to discrete segments of the food industry with greater facility.

In regard to plant registration as set forth in S. 2373, GMA is in agreement with the general provisions of the bill. We have only a few specific comments on certain provisions of this proposed legislation.

GMA agrees with the requirement for listing of the name, principal place of business, location of each food establishment, and list of all foods or classes of foods manufactured in each establishment. We believe that this requirement would provide useful information to FDA without undue burden on the food manufacturing industry. (Should not the heading "biennial registration" read "annual" registration, based on the text following that heading?)

However, GMA believes that a requirement for listing the "type of processing" at each establishment does raise some practical difficulties, since a precise description of the types of processing is in many cases regarded as a trade secret and confidential business information. Disclosure of the specific type of processing could make public certain information concerning new processed foods that a manufacturer would ordinarily deem to be confidential. GMA believes that "type of processing" should be clearly defined to mean a general description of the processes used, for example, baking, canning, freezing, and the like. Education and/or enforcement programs could then be tailored to product classes or to manufacturers engaged in similar types of processing.

With further respect to the registration provision itself, GMA particularly agrees with the requirement that the Secretary shall promulgate regulations defining

food classes for the purposes of registration. This will help to avoid uncertainty under that provision and to provide a clear and simple method of providing useful information. Based on FDA's current approach to food classes, as proposed in the Federal Register of July 26 (38 F.R. 20035), GMA is confident that a workable and logical definition of food classes can be achieved.

GMA has some question as to whether a registration number is useful or necessary under this provision. There are many other registration numbers and other identification numbers currently used including the Universal Product Code, USDA registration number for meat and poultry processing establishments and the registration required by state agencies. Another identification number would appear to further add to the complications without any commensurate benefits. If any such number is adopted in the legislation, GMA recommends that a universal federal numbering system be established to avoid further unnecessary duplication.

In conclusion, GMA believes that the purpose and the general substance of the registration aspects of this bill will have a salutary effect on the FDA's exercise of its statutory responsibilities and duties with respect to the food industry.

To summarize:

(1) GMA supports legislation that provides for continuing reasonable registration of all food establishments. All manufacturers should be required to annually register their name, principal place of business, location of each food establishment, and foods or classes of foods produced.

(2) A standard registration form should be developed by FDA in conjunction with other federal regulatory agencies as well as state and local governments. This universal form could then be used by all jurisdictions to register food manufacturers.

(3) All registration information should be made in computer-available form, that is, the registration form should be pre-coded so the information can be directly keypunched.

(4) Six months or one year after enactment of mandatory registration, FDA should report to Congress on its progress in meeting the requirements of this provision, specifically the extent and effectiveness of computerization of the data.

STATISTICS FROM THE BUREAU OF CENSUSFood and Kindred Products

Total Number of Establishments (Processing Plants) -- 32,518

Sub-categories (and corresponding number of establishments) included in Food and Kindred Products:

Meat Products	4,914
Dairy Products	6,188
Canned, Cured, and Frozen Foods	3,528
Grain Mill Products	3,202
Bakery Products	4,390
Sugar	182
Confectionery and Related Products	1,240
Beverages	4,376
Miscellaneous Foods and Kindred Products	4,498

TOTAL 32,518 establishments

Reference: U. S. Bureau of the Census, Census of Manufacturers, 1967.

Groceries and Related Products

Total Number of Establishments (Merchant Wholesalers) -- 29,051

Sub-categories (and corresponding number of establishments) included in Groceries and Related Products:

Groceries, General Line	2,543
Frozen Foods	1,365
Dairy Products	2,785
Poultry and Poultry Products	2,022
Confectionery	1,998
Fish and Seafoods	1,534
Meat and Meat Products	5,041
Fresh Fruits and Vegetables	5,284
Groceries and Related Products	6,479

TOTAL 29,051 establishments

Reference: U. S. Bureau of the Census, Census of Business, 1967.

PENALTIES FOR FAILURE TO REPORT DUE DATE: FEBRUARY 15, 1973

Form Approved: OMB No. 41-S7110

Form MA-100

1972 ANNUAL SURVEY OF MANUFACTURES

(For 1972 this is the first sheet of the 1972 Census of Manufactures form)

RETURN THIS COPY TO

Bureau of the Census

Jeffersonville, Indiana 47130

Physical location and Employer identification Number

Complete a, b, and c.

110

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

61

62

63

64

65

66

67

68

69

70

71

72

73

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

95

96

97

98

99

100

101

102

103

104

105

106

107

108

109

110

111

112

113

114

115

116

117

118

119

120

121

122

123

124

125

126

127

128

129

130

131

132

133

134

135

136

137

138

139

140

141

142

143

144

145

146

147

148

149

150

151

152

153

154

155

156

157

158

159

160

161

162

163

164

165

166

167

168

169

170

171

172

173

174

175

176

177

178

179

180

181

182

183

184

185

186

187

188

189

190

191

192

193

194

195

196

197

198

199

200

201

202

203

204

205

206

207

208

209

210

211

212

213

214

215

216

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243

244

245

246

247

248

249

250

251

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

270

271

272

273

274

275

276

277

278

279

280

281

282

283

284

285

286

287

288

289

290

291

292

293

294

295

296

297

298

299

300

301

302

303

304

305

306

307

308

309

310

311

312

313

314

315

316

317

318

319

320

321

322

323

324

325

326

327

328

329

330

331

332

333

334

335

336

337

338

339

340

341

342

343

344

345

346

347

ITEM 9		Additional products of this establishment (Describe) (a)		Product class code (b) (See manual)	Unit of quantity (c)	Quantity (d)	Value (\$100) (e)
Continued Quantity and value of products shipped and other receipts (\$100)	a.			581		582	583
	b.			581		582	583
	c.			581		582	583
	d.			581		582	583
	e.	TOTAL (Transfer to page 1, item 9, line 1)					
ITEM 12 Not applicable this year							
ITEM 13 MARK ONE BOX							
1 ☐ No change in operator or operations							
2 ☐ Reorganized - Describe in "Remarks," e.g., partnership change or change in corporate status							
3 ☐ Started new business - Date							
4 ☐ Plant dismantled, abandoned, or destroyed on - Date							
5 ☐ Plant idle or inactive but still owned - Date							
6 ☐ This establishment was purchased or leased from another company - Complete the following information							
Name of former operator or owner				Address (Number, street, city, State, ZIP code)		EI Number (9 digits)	
Date							
7 ☐ This establishment was sold or leased to another company - Complete the following information							
Name of new operator or owner				Address (Number, street, city, State, ZIP code)		EI Number (9 digits)	
Date							
ITEM 14 Is the FIRST DIGIT of your Census File Number (Imprinted in the address box) a Zero "0"? ☐ YES - Complete item 14A, a through d ☐ NO - Skip to Item 15 below							
ITEM 14A 113 Is this company owned or controlled by another company? ☐ YES - Complete the following information ☐ NO							
Company affiliation and organization		Name, address, and Employer Identification Number of owning or controlling company		Activity of owning or controlling company (Describe, e.g., manufacture, retail, wholesale, etc., and chief products sold)		1972 payroll and sales (\$100)	
		Employer Identification Number				Payroll \$	
						Sales \$	
						Payroll \$	
						Sales \$	
ITEM 14B 114 Does this company own or control any other companies? ☐ YES ☐ NO							
115 Does this company operate more than one establishment? ☐ YES ☐ NO							
116 Did this company have any manufacturing plants under construction but not in operation at the end of the year? ☐ YES ☐ NO							
ITEM 14B Other companies owned or establishments operated		Name, address, and Employer Identification Number		Activity (Describe, e.g., manufacturing, retail, wholesale, etc., and chief products sold)		1972 payroll and sales (\$100)	
Complete only if item 14A b or c is marked "YES."		Employer Identification Number				Payroll \$	
						Sales \$	
		Employer Identification Number				Payroll \$	
						Sales \$	
ITEM 15 CHECKS The Census Bureau reviews your report for omissions, inconsistencies, and unusual ratios. To save you future correspondence about these problems, please make the following checks before returning your report.							
(1) Review the report carefully to see that no items are omitted for the year being covered.							
(2) Calculate and enter figures for the four "reasonableness" checks below, and review the results.							
(3) Correct your report for any errors you find and explain unusual figures in "Remarks."							
For most manufacturing establishments, the figures computed usually fall within the ranges indicated.							
"Reasonableness" checks		Calculation required for each check		Figures for 1972		Usual range	
a. Average hourly wages per production worker	Item 3Aa (Production workers' wages) ÷ Item 4e (Total man-hours)			\$		51 - \$11	
b. Hours worked per week per production worker	Item 4e (Total man-hours) ÷ 20 ÷ Item 2f (Average number of production workers)			Hrs.		20 - 60	
c. Salaries and wages per dollar of shipments	Item 3Ac (Total payroll) ÷ Item 9p (Total value of shipments)			¢		05¢ - 5¢	
d. Materials cost per dollar of shipments	Item 5f (Total materials cost) ÷ Item 9p (Total value of shipments)			¢		05¢ - 95¢	
e. Is the total for Value of Shipments (Item 9p) greater than the sum for Payroll (Item 3Ac) plus total Cost of Materials, etc. (Item 5D)? ☐ YES ☐ NO - Explain in "Remarks"							
f. Is the gross value of depreciable assets (Item 10c) minus total capital expenditures (Item 7D), within 5% of gross depreciable assets at the beginning of the survey year? ☐ YES ☐ NO - Explain in "Remarks"							
Remarks							

Senator KENNEDY. I would be interested if you could describe rather briefly what is being done in the respective industries now in terms of their surveillance?

Dr. SOMERS. Speaking for the canning industry, which is the industry I represent, all canners of course have quality control programs. Records are kept. Records are made and records are kept.

There is very close surveillance of the product as it goes through the processing line and of the product after it has been manufactured.

In the area of processing, we have provided what we have called the better process control plant which has been implemented by the Food and Drug Administration and which does provide for the Food and Drug Administration to have access to all records pertaining to the processing of canned foods, so that not only is the industry reviewing and surveying that aspect of our operations, but those records are made available to the Food and Drug Administration.

Furthermore, the industry is very much involved in the hazard analysis and critical control program as is being operated by Food and Drug. Dr. Bauman talked about participating in the first school. We participated in the next two schools. We have assisted in that training. We have prepared a booklet, after consulting with Food and Drug, and the many ramifications of that program are explained in the booklet. It is a booklet which advises them how to proceed. They know what to expect and how to make these programs most effective. We could go on, but I think that is sufficient for now.

Senator KENNEDY. Dr. Bauman.

Dr. BAUMAN. There really are three different kinds of surveillance that are currently undertaken by FDA.

Senator KENNEDY. I am interested in the industry.

Dr. BAUMAN. What the industry is doing, all right. I can speak for the Pillsbury Corp., which reflects a number of them. We currently have seven of our plants under the cooperative quality insurance program within FDA. Within this system, a complete hazard analysis is done of the plants and all of the critical points within the process, ingredients, whatever it may be, and these areas are monitored.

The agreement with FDA is that these records are available to them for inspection, to determine whether or not we are staying within the controls as established.

Further than that, once reports are submitted to FDA, if anything goes wrong in the plant, we are to advise FDA of it and also as to the disposition of any products that may be faulty from the system.

Senator KENNEDY. I suppose, Dr. Somers, the degree of quality control or surveillance varies with different manufacturers, like any other kind of industrywide program?

Dr. SOMERS. Yes; that would be expected.

Senator KENNEDY. Has the association worked out any type of standard of quality control, surveillance procedures?

Dr. SOMERS. As I said, in the area of processing, which is the prime critical area in the canning industry, yes; we do have this.

Senator KENNEDY. Do all the canners use the same type of surveillance procedures?

Dr. SOMERS. They have to under this new regulation. We are very much involved at the present time with the Food and Drug Administration in giving schools, to which every canner has to send his processing supervisor and his can inspection supervisor. These schools are being conducted around the country.

We have just initiated what we have called our Food Processors Institute, which is an educational organization to further implement that training activity. The present training is being done jointly with the Bureau of Foods and Food and Drugs, so there is no confusion. What we do has their endorsement.

Senator KENNEDY. We had an earlier witness this morning that pointed out some of the problems in the Del Monte situation. You are probably not familiar in detail with those. Would you say those are rather unusual or exceptional?

Is there any comment you would like to make? Obviously we will let the Del Monte Corp., file a statement with us, make whatever statement they would like to, but is that atypical or typical? How could those things possibly happen with the kind of surveillance which you have outlined here, as you have indicated in your testimony is virtually industrywide?

Dr. SOMERS. I had no indication that this kind of information would be brought up. I would prefer to let the Del Monte Corp., answer the questions themselves.

Senator KENNEDY. Has there been any instance that you know about concerning any members of your association where the Food and Drug Administration has requested that information be made available to them and the canner refused?

Dr. SOMERS. I am sure there has, but not information we would consider critical to Food and Drug's control and surveillance of the industry.

Senator KENNEDY. Which you consider critical or which the Food and Drug Administration does?

Dr. SOMERS. We have worked out with them on the hazard analysis program what we think would be important and what we think would be just supplementary information. That which we feel is important to the revealing of critical control points and hazard within the industry, we have made available and have recommended our industry make available. In addition to that we have developed a communications system with the Food and Drug, that if anything develops in our industry which would have a potential health significance, day or night, we reveal this to Food and Drug on what we call our hotline. They have a similar requirement if anything turns up in their surveillance program, they communicate to our man, and we immediately pull out all stops and proceed to determine what has gone wrong. So we do not think we are operating in a vacuum nor do we think we are requiring them to do so.

Senator KENNEDY. What sort of things has the Food and Drug Administration requested of any of the members of your association that you felt were unreasonable?

Dr. SOMERS. I do not have any details on this, Senator. I would have to look at the specific cases.

Senator KENNEDY. Would I gather then from your testimony is that you do not really have any objection to establishing with the Food and Drug Administration these quality control or those surveillance procedures?

Dr. SOMERS. That is the direction we are moving. Of course we wholeheartedly endorse the registration requirements because this would give them a chance to see who the packers are and where they are.

Senator KENNEDY. Let us see what we can find out, what you are already doing and what we can possibly agree on. As I understand, you are already working out with the Food and Drug Administration on some quality controls and procedures. That is pretty much industrywide, that is what I gathered from your testimony.

Dr. SOMERS. It will be mandatory when the regulations are finalized and most of it is now finalized. The rest of it is still out for comment. It will be provided in three sections and the last section is out for comment, and when the date runs, it will become a final regulation.

Senator KENNEDY. You mean from the Food and Drug Administration?

Dr. SOMERS. Right.

Senator KENNEDY. So it is about being mandatory that you maintain records—

Dr. SOMERS. Records of processing and so on, and those records will be made available to the food and drug inspector upon request as he enters the plant.

Senator KENNEDY. It seems in our discussion (although I will reaffirm this with the Food and Drug Administration), at least it seemed a reasonably open question whether they could actually require that the companies make available to the Food and Drug Administration these studies. But as I understand, you are willing to do it. If that is the case, you would have no objection to us making sure that they are made available?

Dr. SOMERS. I can provide you with the documents, regulations published by Food and Drug, which do make specific reference to the requirement that these records be made available.

Senator KENNEDY. In the whole food processing industry?

Dr. SOMERS. In the canning industry, processing of low acid canned foods.

Senator KENNEDY. That relates only to low acid foods?

Dr. SOMERS. That is right.

Senator KENNEDY. That authority of control is limited to the emergencies, as I understand it. It seems to me from what you have said that your association, does not find that objectionable or particularly offensive or very burdensome as far as that aspect of the industry goes, am I correct?

Dr. SOMERS. It is in the processing of low acid foods where the greatest hazard comes.

Senator KENNEDY. What percent of the canning industry is processed low acid foods?

Dr. SOMERS. I cannot give you specific figures. I would guess it is over half of the industry. The other would be fruits, tomatoes. But we not only endorse that, we proposed it, took the proposed legislation, the regulation to Food and Drug, and they implemented it in a regulation.

Senator KENNEDY. So regarding a Food and Drug Administration requirement that quality control measures be taken within the canning industry, you have indicated that is already being done, as I understand it. Second, regarding a requirement that the procedures or the reports or the studies be available to Food and Drug Administration. You have indicated that is already being done pursuant to regulations with regard to low acid phase of the industry, and that is a majority of the industry.

Would you have any objection to establishing the same kind of procedures for the rest of the canning industry?

Dr. SOMERS. I would say we have not any position on that, Senator. This was not anticipated in the legislation that was proposed, so we have not obtained a consensus from our industry on that. I could not comment on that.

Senator KENNEDY. But you are living with the present regulations at the present time and you seem to have indicated to us in testimony that throughout the industry there is a rather extensive quality control procedure and that they are following rather strict standards and those things are already being done at the present time.

Dr. SOMERS. Right.

Senator KENNEDY. You do not have any objection to making available to the Food and Drug Administration the results of the quality control on the low acid phase of the industry. You indicated a willingness and cooperation. As a matter of fact, I think you said you initiated these kinds of efforts.

Dr. SOMERS. I might add, that is where the hazard is in our industry, and we are very anxious to do everything possible to eliminate it.

Senator KENNEDY. What about it, Dr. Bauman? What about in the grocery manufacturers? Do they have the same kind of quality control by the different manufacturers in the grocery field?

Dr. BAUMAN. I would say those that belong to GMA have relatively the same level of quality. There is a wide variation of quality control within the industry.

Senator KENNEDY. I suppose in many instances that the better ones do it and the poorer ones do not. Is that not a general rule of thumb?

Dr. BAUMAN. That is very true. As I have said a number of times in speeches and elsewhere, the food industry is probably the only one where someone could enter a business and start selling products without much in the way of any control, other than occasional inspection by Food and Drug.

Senator KENNEDY. At least if some do it, if they have assumed this responsibility, why would it not be in the interest of all in the industries to develop the kind of strict standards that some are doing in the industry today? Would that not be as far as the industry's own protection, would that not be worthwhile? Would that not be valuable?

Dr. BAUMAN. Yes, by all means. That is something many of us have been trying to promote and I personally take the position, and our corporation does, that the food manufacturer is responsible for the safety of his food, period.

Senator KENNEDY. But you have no way of doing it in your association—some do not want to join the association and some do not want to do it, and there is very little you can do about it unless there is going to be some regulation by the Food and Drug Administration?

Dr. BAUMAN. That is true. GMA has not taken a position, to my knowledge, in this area other than we believe in good safe food and good safe FDA enforcement with adequate resources.

Senator KENNEDY. Do you think that the association would object if they had some kind of uniform standards, requirements to live up in order to provide for adequate safety?

Dr. BAUMAN. Speaking as a member of the association, I do not see where they could object. I think in the area of the cooperative quality assurance program, this is exactly the kind of thing that is being done. Very strict standards are being established, and very strict quality assurance programs are being adhered to.

Senator KENNEDY. Is there any competitive disadvantage, if they were to make those quality standards available to the Food and Drug Administration, the procedures which they were following, to guarantee quality control, if they made those available to the Food and Drug Administration, would there be any competitive disadvantage that would affect some of the manufacturers and processors of food?

Dr. BAUMAN. I do not believe so.

Senator KENNEDY. Obviously, that would not be our intention. It would not seem to me to be necessary. I am not interested in trying to find out trade secrets, but I am interested in knowing what you were doing in trying to guarantee some health and safety factors in the processing of foods.

What if the Congress were to give the FDA more manpower or resources to help them meet their responsibilities under the congressional mandate for health and safety, what would be your reaction to this?

Dr. BAUMAN. My reaction to this is a personal one, in that after 20-some years in the food industry, just a mere increase in manpower is not really going to do that much good for FDA.

I think, first, the right approach is through the quality assurance program. Then the burden is on the manufacturer, and he has to set up critical control points and set up his own system, and in concurrence with FDA run his plan in appropriate fashion. FDA then becomes a monitoring agent. These records are available.

In this way, the burden is not on the taxpayer, but on the manufacturer.

Senator KENNEDY. Just in relationship to those records, I imagine your association, the majority, you would start off with the presumption to make available those records to the Food and Drug Administration?

Dr. BAUMAN. I think any records that are pertinent to the safety of the food that is being produced should be available.

Senator KENNEDY. Suppose the question comes down to who should interpret, whether it is the Food and Drug Administration or whether it is the association? I do not know of particular instances. That is why when I asked the question of Dr. Somers earlier whether there were instances where the Food and Drug Administration had requested information, that either the canners or your own group felt that they could not provide them, what that kind of information was?

Dr. BAUMAN. Corporations will have different policies on this, depending on their particular management. I can speak for our own corporation. If an FDA inspector comes in and makes a general statement that he would like to see our records, then he will not get them. But if he requests something specific that is pertinent to his inspection, then as far as I know, in all instances we have supplied him this information.

Senator KENNEDY. I want to thank you gentlemen for a very helpful testimony.

At this time, I order printed in the record an appendix including statements and other pertinent material submitted.

The subcommittee stands adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

[COMMITTEE PRINT NO. 3]

OCTOBER 8, 1973

93^d CONGRESS
1st SESSION

S. 2373

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 1973

Mr. MAGNUSON (for himself and Mr. HART) introduced the following bill; which was read twice and, by unanimous consent, referred to the Committee on Labor and Public Welfare until October 15, 1973, with instructions then to refer to the Committee on Commerce at the option of that committee

[Strike out all after the enacting clause and insert the part printed in italic]

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Federal Food Inspection
4 Act of 1973".

5 SEC. 2. Chapter IV of the Federal Food, Drug, and
6 Cosmetic Act is amended by adding the following new
7 section at the end thereof:

1 "SURVEILLANCE FOR ADULTERATED FOOD

2 "Regulations

3 "SEC. 410. (a) Not more than one hundred and eighty
4 days after the enactment date of this section, the Secretary
5 shall propose regulations which shall specify the surveillance
6 procedures that he will follow for the detection and preven-
7 tion of adulterated food. The Secretary may modify or
8 amend such regulations at any time after they have be-
9 come final on his own initiative or on the petition of any
10 interested person. Initial regulations promulgated under this
11 section shall become effective no later than one year from
12 such date of enactment.

13 "Minimum Requirements

14 (b) The procedures prescribed by the Secretary un-
15 der subsection (a) shall be such procedures for sur-
16 veillance as the Secretary determines are necessary to
17 carry out his responsibilities with respect to the detection and
18 prevention of adulterated food under this and other acts ad-
19 ministered by him, but such procedures shall require, at a
20 minimum, levels of surveillance sufficient to provide reason-
21 able assurance that the presence of adulterated food does not
22 constitute an unreasonable threat to the public health or wel-
23 fare. Where no practicable procedures are available to pro-
24 vide the assurance required by this section, the Secretary
25 shall include in regulations promulgated under this section

1 ~~(1)~~ a program for the development of such procedures
2 within the shortest feasible time, ~~(2)~~ specifications as to how
3 such program is to be carried out, and ~~(3)~~ a timetable for
4 the completion of such program.

5 "Hearings

6 "(c) Any person adversely affected by proposed regula-
7 tions, proposed modification, or amendment of such regula-
8 tions, or the denial of a petition for any such modification
9 or amendment may upon a showing of reasonable grounds,
10 file objections with the Secretary and request a hearing
11 which shall be granted by the Secretary. All hearings con-
12 ducted under this section shall consist of the oral and written
13 presentation of data, views, or arguments in accordance with
14 provisions of section 552 of title 5, United States Code.

15 "Increase in Surveillance Levels

16 "(d) If the Secretary finds a threat to the public
17 health or welfare which requires that there be an immedi-
18 ate increase in the level of surveillance with respect to any
19 food, he may direct an increase in the level of such surveil-
20 lance to the extent that he determines necessary. Such an
21 order may be entered without regard to any requirement for
22 previous notice or opportunity for a hearing, except that the
23 Secretary shall comply with any such notice or hearing re-
24 quirement as soon as practicable after such increase in the
25 level of surveillance has been initiated.

4

~~"Methodology~~

1

2 ~~"(c)~~ Analyses performed under this section to deter-
3 mine the presence and amount of adulteration in food shall
4 be performed through the use of the best instruments, tech-
5 nology, and trained personnel which are reasonably available.

6

~~"Public Access to Information~~

7

8 ~~"(f)~~ The Secretary shall make available to the public,
9 upon identifiable request and at cost, the results of any
analyses or research performed under this section.

10

~~"Relationship to Other Laws~~

11

12 ~~"(g)~~ This section shall not be construed to exempt the
13 Secretary or any other person from any obligation imposed
14 by any other provision of this Act or by the provisions of
15 any other Act. Nor shall this section be construed to permit
16 the use of any substance, practice, or conduct resulting in the
17 presence of adulterated food if such use, practice, or conduct
18 would not have been permitted in the absence of this
section."

19 That this Act may be cited as the "Food Amendments of
20 1973".

21

TITLE I—FOOD SURVEILLANCE

22

23 SEC. 101. Chapter IV of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 321) is amended by adding at the
end thereof the following new section:

1 "FOOD SURVEILLANCE PROCEDURES

2 "SEC. 410. (a) (1) Within six months after the date of
3 enactment of this Act the Secretary shall appoint and organize
4 a food surveillance advisory committee to study and report
5 to the Secretary existing and potential hazards to health and
6 safety resulting from food and recommend procedures to
7 reduce such hazards. To the maximum extent practical, the
8 committee shall provide an opportunity for any interested
9 person to submit data and views on all matters considered by
10 the committee. All meetings of the committee shall be open to
11 all members of the public.

12 "(2) Within one year after appointment and organiza-
13 tion of the committee (which time may be extended by the
14 Secretary by a notice published in the Federal Register
15 stating good cause therefor), the committee shall issue a re-
16 port to the Secretary which report shall specify (A) existing
17 and potential health hazards related to food for which surveil-
18 lance procedures can reduce or eliminate such hazards and
19 (B) rank such hazards by priority of public importance. The
20 report may also include recommendations regarding the sur-
21 veillance procedures to be established pursuant to paragraph
22 (1) of subsection (b). As soon as possible after receiving this
23 report, the Secretary shall publish it in the Federal Register
24 and provide interested persons an opportunity to comment
25 thereon. After reviewing such comments the Secretary shall

1 begin implementing subsection (b) as expeditiously as is
2 feasible.

3 “(3) The advisory committee shall constitute a perma-
4 nent advisory committee, which shall meet periodically, at
5 least twice each year, to review and if it so determines
6 revise its report and recommendations to the Secretary
7 and to monitor implementation of this section. Such
8 committee shall make such additional reports and recom-
9 mendations to the Secretary as it deems advisable, and such
10 reports shall be published by the Secretary in the Federal
11 Register with an opportunity for interested persons to com-
12 ment thereon.

13 “(4) The published reports and recommendations of the
14 committee shall constitute public notice that, as expeditiously
15 as is feasible, the Secretary will issue regulations under sub-
16 section (b) establishing specific surveillance procedures for
17 designated foods. The publication of such reports and recom-
18 mendations shall not relieve the Secretary of the obligation to
19 provide notice as required by paragraph (1) of subsection
20 (b) of this section. Any interested person will have an op-
21 portunity, pending promulgation of such specific procedures,
22 to undertake studies and other work appropriate to establish
23 such procedures or to assure compliance with them.

24 “(5) Committee members shall be qualified by training
25 and experience in the safety of food or in the use of statistical

1 sampling techniques, analytical methodology; or other tech-
2 nical disciplines relevant to food surveillance. In addition to
3 such technical experts, the committee shall include, as non-
4 voting members, a representative of consumer interests and a
5 representative of industry interests: Committee members may
6 be nominated by appropriate scientific, trade, and consumer
7 organizations. The Secretary shall designate one of the mem-
8 bers of the committee to serve as chairman. Committee
9 members shall, while attending meetings or confer-
10 ences of the committee or otherwise engaged on its busi-
11 ness, be compensated at per diem rates fixed by the Secretary
12 but not in excess of the rate for Grade GS-18 of the General
13 Schedule at the time of such service, including traveltime,
14 and while so serving away from their homes or regular places
15 of business they may be allowed travel expenses (including
16 per diem in lieu of subsistence) as authorized by title 5,
17 United States Code, section 5703, for persons in the Govern-
18 ment service employed intermittently. The Secretary shall
19 furnish the committee with adequate clerical and other neces-
20 sary assistance, and shall prescribe by regulation the proce-
21 dures to be followed by the committee.

22 “(b) (1) The Secretary shall, after notice and an oppor-
23 tunity for a hearing, promulgate regulations or modify
24 existing regulations to carry out the purposes of this section
25 as expeditiously as is feasible. In promulgating or

1 modifying such regulations the Secretary shall utilize the
2 reports and recommendations of the food surveillance advisory
3 committee and comments thereon. Such regulations, which
4 may be proposed on the Secretary's own initiative or on behalf
5 of any interested person who has submitted a petition, shall
6 designate—

7 “(A) a food or class of foods subject to the surveil-
8 lance procedures being established,

9 “(B) the persons required to conduct such surveil-
10 lance in accordance with such procedures,

11 “(C) the contaminants, properties, unsanitary prac-
12 tices, or other factors (including but not limited to micro-
13 organisms, heavy metals, toxins, drug residues, pesti-
14 cide residues, filth, and other potentially harmful consti-
15 tuents and practices) for which surveillance is required,

16 “(D) the sampling methods and methods of inspec-
17 tion of establishments by which such surveillance shall be
18 accomplished,

19 “(E) the methods of analysis by which such sur-
20 veillance shall be accomplished,

21 “(F) the circumstances under which reports of such
22 surveillance shall be submitted to the Secretary, and

23 “(G) the activities (including sampling, analysis,
24 and inspections) which the Secretary will undertake to

1 *assure compliance with the standard of paragraph (2)*
2 *of this subsection.*

3 “(2) The procedures established pursuant to paragraph
4 (1) of this subsection shall be sufficient to reduce or eliminate
5 existing or potential health hazards related to food and to
6 provide reasonable assurance that food does not present an
7 unreasonable risk to the public health and safety. Such pro-
8 cedures may vary among foods or classes of foods as appro-
9 priate. Where there is insufficient knowledge to establish such
10 a procedure for a food or class of foods, the Secretary shall
11 immediately initiate a program to develop such a procedure.

12 “(3) If the Secretary finds a threat or potential threat
13 to the public health which requires that there be an immediate
14 increase in the level of surveillance with respect to any food,
15 he may direct an increase in the level of such surveillance
16 (or otherwise modify the surveillance procedures) to the
17 extent that he determines necessary. Such an order may be
18 entered without regard to any requirement for an opportunity
19 for a hearing, except that the Secretary shall comply with any
20 hearing requirement as soon as practicable after the increase
21 in the level of surveillance has been required.

22 “(4) Chemical and other analyses performed under this
23 section to determine the presence and amount of contamina-
24 tion in food shall be performed through the use of the best

1 instruments, technology, and trained personnel which are
2 reasonably available.

3 “(5) Any person required to comply with the surveil-
4 lance procedures established under this section shall establish
5 and maintain such records as the Secretary may by regu-
6 lation require pertaining to such surveillance and make such
7 records available to the Secretary upon request.

8 “(6) The Secretary may require by general or specific
9 orders the submission of annual or special reports or answers
10 in writing to specific questions containing such data and
11 information relating to any surveillance procedures or the
12 implementation thereof or any matter relating to detection of
13 adulterated foods which may assist him in carrying out the
14 purposes of this section. The district courts of the United
15 States shall have jurisdiction to enforce such general or
16 specific orders and to require access to such information
17 upon application of the Attorney General or of the Secretary
18 with the consent of the Attorney General. An action for such
19 enforcement may be brought in any district court of the
20 United States where the person or establishment involved is
21 found or transacts business.

22 “(7) The Secretary shall make available to the public,
23 upon request and at cost of reproduction and mailing, any
24 and all information obtained or developed under this section
25 except to the extent that such information constitutes a trade

1 *secret or confidential commercial or financial information*
2 *which if disclosed would result in significant competitive*
3 *damage to its owner except that such information may*
4 *be disclosed by the Secretary—*

5 “(A) to other Federal Government departments,
6 agencies, and officials for official use, upon request, and
7 with reasonable need for such information;

8 “(B) to committees of Congress having jurisdiction
9 over the subject matter to which the information relates;

10 “(C) in any judicial proceeding relating to the pro-
11 visions of this section under a court order formulated to
12 preserve the confidentiality of such information without
13 impairing the proceeding;

14 “(D) if relevant in any proceeding under this sec-
15 tion, except that such disclosure shall preserve the confi-
16 dentiality to the extent possible without impairing the
17 proceeding;

18 “(E) to the public in order to provide reasonable
19 protection of the public health, after affording parties
20 who oppose disclosure notice and opportunity for com-
21 ment in writing or for discussion in closed session if the
22 delay resulting from such notice and opportunity for
23 comment would not be detrimental to the public health;
24 and

25 “(F) to a contractor in furtherance of the provi-

1 sions of this Act. Such contractor shall take such security
2 precautions as are prescribed in regulations promulgated
3 by the Secretary.

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

11 “(c)(1) Every person who owns or operates an estab-
12 lishment in which food is manufactured, processed, packed,
13 labeled, held, or otherwise handled, upon acquiring infor-
14 mation which supports the conclusion that such food is
15 adulterated in a manner which would create an unreason-
16 able risk to the public health, shall immediately notify
17 the Secretary of such adulteration if such food has left
18 the control of such person. Such person shall also
19 immediately notify the Secretary of any recall of food
20 which has left an establishment under his control. No
21 information or statements included in any notification re-
22 quired under this section (except for information contained
23 in records required to be maintained under any provision
24 of this Act) shall be used as evidence in any proceeding
25 brought against an individual pursuant to section 303 of this

1 Act with respect to a violation of law occurring prior to or
2 concurrently with such notification.

3 “(2) The notifications required by paragraph (1) of
4 this subsection shall contain a clear description of such adul-
5 teration or misbranding, an evaluation of the risk related
6 thereto, and a statement of the measures to be taken to effect
7 protection against the risk created by the adulteration or
8 misbranding.”

9 SEC. 102. Section 402 of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 342) is amended by adding:

11 “(f) If the methods use din, or facilities and controls
12 used for, its manufacture, processing, packing, labeling, hold-
13 ing, or other handling do not conform to, or are not oper-
14 ated or administered in conformity with, current good manu-
15 facturing practices, as determined by regulations of the
16 Secretary promulgated after consultation with all interested
17 persons and after an opportunity for a hearing, to assure
18 that such food is not adulterated.”

19 SEC. 103. (a) Section 301 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 331) is amended by adding
21 the following:

22 “(c) The failure to comply with surveillance procedures
23 or current good manufacturing practices required pursuant
24 to section 402(f) or section 410, the failure to maintain
25 or make available records or reports required pursuant to

14

1 section 410, or the failure or the refusal to furnish notification
2 or other information as required by section 410."

3 (b) Section 402 of such Act (21 U.S.C. 342) is
4 amended by adding:

5 "(g) If it is a food which was manufactured, processed,
6 packed, labeled, held, or otherwise handled other than in com-
7 pliance with surveillance procedures required pursuant to
8 section 410."

9 TITLE II—FOOD ESTABLISHMENT

10 REGISTRATION

11 FINDINGS

12 SEC. 201. The Congress finds and declares that in order
13 to make regulation of interstate commerce in food effective, it
14 is necessary to provide for registration and inspection of all
15 establishments in which foods are manufactured, processed,
16 packed, labeled, stored or otherwise handled; that the prod-
17 ucts of all such establishments are likely to enter the
18 channels of interstate commerce and directly affect such com-
19 merce; and that the regulation of interstate commerce in food,
20 without provision for registration and inspection of establish-
21 ments that may be engaged only in intrastate commerce in
22 such food, would discriminate against and depress interstate
23 commerce in such food and adversely burden, obstruct, and
24 affect such interstate commerce.

25 SEC. 202. Chapter IV of the Federal Food, Drug, and

1 *Cosmetic Act*, as amended by this Act, is further amended
2 by adding after section 410 the following new section:

3 "REGISTRATION OF FOOD ESTABLISHMENTS

4 "SEC. 411. (a) As used in this section, (1) the term
5 'name' includes in the case of a partnership the name of
6 each partner and in the case of a corporation the name of
7 each principal corporate officer and the State of incorpora-
8 tion and (2) the terms 'processing' and 'processed' include
9 manufacturing, processing, packing, labeling, storing, im-
10 porting, or otherwise handling food.

11 "(b) On or before December 31 of each year, every
12 person who owns or operates an establishment in any State
13 engaged in the processing of food shall register with the Secre-
14 tary his name, principal place of business, the location of
15 each such establishment, and for each such establishment, a
16 complete list, in such form as the Secretary's regulations shall
17 prescribe, of all foods or classes of foods processed at that
18 establishment. Such list shall define the types of processing for
19 each food or class of food. To achieve uniformity in the
20 registration of classes of foods and types of processing, the
21 Secretary shall promulgate regulations defining food classes
22 and types of processing for purposes of the registration re-
23 quired by this section.

24 "(c) Any person upon first engaging in the processing
25 of food in any establishment which he owns or operates in

1 any State shall immediately register with the Secretary the
2 information required by subsection (b).

3 “(d) Every person registered in accordance with sub-
4 section (b) or (c) of this section shall immediately regis-
5 ter with the Secretary any additional establishment which
6 he owns or operates in any State and in which he begins the
7 processing of food. Such registration shall include the infor-
8 mation required by subsection (b).

9 “(e) The Secretary may assign a registration number
10 to any person or any establishment registered in accordance
11 with this section.

12 “(f) The Secretary shall make available for inspection
13 to any person so requesting, any registration statement filed
14 pursuant to this section.

15 “(g) This section shall not apply to such classes of
16 persons as the Secretary may by regulation exempt from the
17 application of this section upon a finding that registration by
18 such classes of persons in accordance with this section is not
19 necessary for the protection of the public health.

20 “(h) Every establishment in any State registered with
21 the Secretary pursuant to this section shall be subject to
22 inspection pursuant to section 704.

23 “(i) The Secretary may by regulation provide for the
24 registration of foreign establishments engaged in the process-

1 ing of food intended to be offered for importation into the
2 United States."

3 SEC. 203. Section 301 of the Federal Food, Drug, and
4 Cosmetic Act, as amended by this Act, is further amended
5 by adding after paragraph (p) the following:

6 "(q) The failure to register as required by section
7 411."

8 SEC. 204. Section 403 of the Federal Food, Drug, and
9 Cosmetic Act is amended by adding after paragraph (n)
10 the following:

11 "(o) If it is a food and it was processed in an establish-
12 ment required to be registered under section 411 of this Act
13 and not so registered."

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

17 "(2) The Secretary may refuse entry of any food
18 offered for importation into the United States which has
19 been processed in any establishment other than an estab-
20 lishment registered pursuant to section 411."

21 SEC. 206. (a) The amendments made by sections 203
22 and 204 of this Act shall take effect on the first day of the
23 seventh calendar month which begins after the month in which
24 this title is enacted.

1 (b) Any person who, on the day immediately preceding
2 the date of enactment of this title, owned or operated any
3 establishment in any State engaged in the processing of food,
4 may register his name, principal place of business, and loca-
5 tion of each such establishment, prior to the effective date of
6 this title. Such registration shall be deemed to have complied
7 with section 411 of the Federal Food, Drug, and Cosmetic
8 Act for the calendar year during which this title becomes
9 effective.

10 TITLE III—FOOD INGREDIENT LABELING

11 DISCLOSURE OF INGREDIENTS IN FOODS

12 SEC. 301. (a) Section 401 of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 341) is amended by striking
14 out the fourth sentence.

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

17 “(g) If it purports to be or is represented as a food
18 for which a definition and standard of identity has been
19 prescribed by regulations as provided by section 401, unless
20 (1) it conforms to such definition and standard, and (2)
21 its label bears the name of the food specified in the definition
22 and standard.”

23 (c)(1) Section 403(i) of such Act (21 U.S.C. 343
24 (i)) is amended by striking out “If it is not subject to the
25 provisions of paragraph (g) of this section unless its label

1 bears" and inserting in lieu thereof "If its label fails to
2 bear".

3 (2) Section 403(i) of such Act (21 U.S.C. 343(i))
4 is further amended by inserting "(in the order of their
5 predominance)" immediately after "each such ingredient".

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

9 EFFECTIVE DATE

10 SEC. 302. The amendments made by this title shall take
11 effect on the first day of the thirteenth month beginning
12 after the date of their enactment, except that such effective
13 date shall be postponed, if the Secretary of Health, Educa-
14 tion, and Welfare determines that there is good cause there-
15 for, for a period not to exceed an additional twelve months
16 with respect to any specific food product not in compliance
17 with such amendments, other than a product bearing a label
18 printed after the first day of the fourth month beginning
19 after the date of such enactment.

STATEMENT OF TERRANCE HANOLD
ON BEHALF OF THE
GROCERY MANUFACTURERS OF AMERICA, INC.*

We thank you very much for affording us your valuable time to listen to our views on this most important proposed legislation.

I am Terrance Hanold, Chairman of the Executive Committee of The Pillsbury Company. Accompanying me are Howard E. Bauman, Ph.D., Vice President, Science and Technology, The Pillsbury Company; Walter H. Meyer; and Murray D. Sayer, Assistant General Counsel, General Foods Corporation.

We are appearing before you today on behalf of our trade association, the Grocery Manufacturers of America, the trade association of many of the nation's leading processors of food and related products found in virtually all American homes.

We apologize if our request for this meeting has caused you any inconvenience. We wish to discuss with you, however, a matter of transcending importance in the food industry and to consumers--the issue of food safety, a vital and complex subject that forms the heart of Committee Print No. 3 of S.2373.

The food surveillance provisions of this bill were not present in the original S.2373 upon which a hearing was held. We feel that these new provisions overshadow in importance everything else in the bill, and that they deserve to be openly and fully considered before the bill is reported.

Our comments today, therefore, will concentrate on the food surveillance provisions of the new S.2373, and to a much more limited extent on the ingredient labeling provisions of the new bill which also did not appear until after the hearings on the original proposal.

*Prepared for the Subcommittee on Health, Committee on Labor and Public Welfare, The United States Senate, October 30, 1973.

- 2 -

We hope that you will consider our views as constructive suggestions pertaining to a mutual goal.

Food Safety: A Common Goal

The major goal of S.2373 is to increase the safety of the United States food supply. GMA and its approximately 160 members, who manufacture a major percentage of the total volume of processed foods in this country, as well as the entire food industry, share that goal.

While the United States food industry remains the safest and most productive in the world, we recognize that there is still a need for improvement in our efforts to assure that safe and wholesome foods are being offered to consumers. Any instance of risk to consumers, no matter how statistically insignificant it might appear, is a matter of critical concern to us.

The food industry takes seriously its responsibility to identify, reduce, and eliminate, if possible, all safety risks that may be associated with the foods we eat.

To that end, GMA has continuously supported such concepts as registration of all food plants. We have also testified in support of the provision of additional resources and upgrading of current resources in the federal Food and Drug Administration, publicly favoring such proposals as the addition of 500 new inspectors and better training of all inspectors.

I might add that many member companies have undertaken individual efforts to assist in the job of assuring food safety. For example, my company, Pillsbury, has assisted the FDA in training its inspectors and in developing new safety control techniques which are multiplying the effectiveness and efficiency of the standard setting and standard monitoring program of the plant inspection service. The value of these techniques is shown by their extensive use at

- 3 -

NASA and the recent development of a like program by the Consumer Product Safety Commission.

GMA's Basic Concern: Don't Shift the Safety Burden

The primary responsibility for food safety, however, must rest on the food manufacturer. It is the food manufacturer who has the expertise and direct interest in producing safe and wholesome foods. Without the manufacturer's affirmative discharge of this obligation, no amount of regulatory authority can assure safe foods to the consumer. And it is clear that this responsibility is being willingly taken by virtually all food manufacturers and processors.

But in that regard the new S.2373 appears to shift that burden of responsibility for the safety of the food supply from the manufacturer to the Government. In ordinary usage "food surveillance" means the supervision, management, and control of food. By vesting the power of food surveillance in the Secretary, the bill appears to impose on the Secretary the duty to supervise, manage, and control the food supply so as "to provide reasonable assurance that food does not present an unreasonable risk to the public health and safety." [Sec. 410(b)(2).]

This apparent power to supervise and duty to manage the food supply is fortified by the subsequent provision giving the Secretary authority to "direct an immediate increase in the level of such surveillance [whenever] he determines necessary . . . without regard to any requirement for an opportunity for a hearing...." [Sec. 410(b)(3).] The detail in which the Secretary is expected to control and direct food manufacturing, processing, packing, labeling, and handling is indicated by Sec. 410(b)(1).

Implicit in the bill is the idea that FDA can assure food safety by issuing and enforcing regulations that purport to control and direct day-to-day operations at many hundreds of thousands of individual plants, warehouses,

- 4 -

stores, restaurants, and institutions handling and producing hundreds of thousands of different items.

If such a shift is intended to be a result of this bill, we ask for your most serious reconsideration. We firmly believe that the primary obligation of assuring food safety must remain at the operating site and must not be relocated to Washington. This is not to say that FDA's authority in this area should not be increased to assure improved food safety. On the contrary, GMA agrees that the FDA authority should be broadened consistent with the need to reduce or eliminate those instances where food safety is a present or potential problem. As a means to that end, general regulations setting policy are appropriate. Adequate procedures for monitoring and auditing manufacturing performance to assure compliance with such policies are essential to their implementation and, indeed, are considered the primary function and statutory responsibility of FDA.

But compliance with public policy by a manufacturer in the discharge of his own obligation for the safety of his own product is quite a different matter from obedience to an operating directive of an agency to which the manufacturer's duty to the public and responsibility for the product have been transferred.

In the past 50 years, the food industry has developed remarkably in its technical competence, economic efficiency, distributive capability, adaptive character, and in the variety, suitability, and safety of its output. We gladly concede in advance of the claim that the incentives for these gains began in good part outside the industry. We are always under the scrutiny of the public and the government, and frequently in the eye of many other critical groups and institutions as well. But the point is that we do listen, we do communicate, and we do respond.

Without straining the bounds of either modesty or credibility, I can say that these gains also originated in good part from impulses generated within the industry. This is said not to invite your applause but to make the point that we are also perceptive of new needs and we do initiate measures to meet them.

This disposition of the food industry toward positive efforts to advance the public interest is the direct result of its established responsibility to the public for the character of the products it offers in the market. We fear that the dilution of this responsibility, if effected by the diffused language of S.2373, would discourage initiative in the field of food safety, and in the future, unlike the past, the maximum effort in this area would be the minimum level required by the FDA.

Merely giving carte blanche power to FDA to issue detailed regulations governing practices and procedures by industry classes will not accomplish our mutual goal of continuously improving product safety. In fact we fear the opposite would occur. Any such regulations will demand much labor and more time for their formation, as the terms of the bill admit. It seems to conceive knowledge and capability as static elements capable of definitive statement.

In fact research and technology in this field are extremely dynamic and demand constant restatement. It seems inevitable that the regulations contemplated will embalm practices already outmoded at the time of their promulgation, and the regulations will compel their continuance long after they should be superseded. Hence the transfer of responsibility implicit in the bill is more likely to obstruct than advance progress in the field of food safety.

- 6 -

The great range in manufacturing circumstances and practices and the wide variations in food products make it impossible for a government agency to bear the entire burden of the safety of our food supply or even in major part. Thus the challenge of assuring food safety must begin and end with each food processor. Strengthening the design of the enforcement pattern and sharpening the consequences of a default in performance can contribute to the processor's resolve to meet his safety obligation. But penalties and enforcement should not be considered as a substitute for affirmative safety assurance efforts by the processor based on his own expertise and his intimate involvement with his products, plant, and manufacturing practices.

We cannot rely solely on the police power of the Government in this area. Any proposal which may eventually be construed by processors and the public as shifting food safety initiative and responsibility is a dangerous step.

Progress in all parts of the food industry depends on the self-regard and self-respect of its members. This is eminently the case in matters of food safety. These attitudes are rooted in the fact that we are directly and finally responsible for the products we market. To guide us in their manufacture, we should have clear statements of the objectives which public policy would have us attain, plain definitions of the standards which the public interest requires us to meet.

And as our competence grows, so should the reach of the objectives we are told to attain and the standards we are required to meet. But if we are to be responsible, we must have discretion as to the means to be employed in the discharge of these obligations.

Public needs will be met over either the short or long term only by a progressive food industry. The essential quality of a progressive industry is resourcefulness. At the end we are resourceful only so long as we are responsible.

Elements of Food Safety Control

There are certain basic elements of an effective food safety program regardless of the size of the manufacturer or the number of products or nature of the products involved. Governmental responsibility in these areas, as you will see, is, and always will be, secondary to processor responsibility. The basic elements of a food safety program are:

- (1) dedication of those in control of the processing, both in management and on the production line;
- (2) adequate physical facilities and equipment to produce the food product safely;
- (3) adequate competence on site to operate the physical facilities and equipment;
- (4) identification of areas of risk related to food safety in the processing operation through a systems analysis of critical control points;
- (5) establishment of programs and specifications to eliminate or reduce such risks;
- (6) monitoring, constant reevaluation and improvement of risk and safety control measures;
- (7) adequate recordkeeping in support of the internal monitoring, identification and investigation procedures; and,
- (8) proper reaction and corrective procedure to isolate and recover potentially harmful products.

When applied to the infinite number of variables in the food manufacturing industry, it is clear that these basic elements affecting food safety can only be managed and controlled at the local level by the manufacturer. We believe therefore that safety assurance is an inseparable part of the manufacturing process which the FDA can neither assume nor discharge.

But leaving the responsibility for food safety with the manufacturer where it necessarily belongs does not prevent the grant of a larger function in the area to FDA. There is no doubt that Government may more effectively exercise its proper powers in the area of safety assurance than it does now.

- 8 -

At present FDA polices processor performance of the food safety assurance function largely by field examination of the manufactured product. FDA's point of emphasis should be on the process which produces the product. We suggest that food safety is better tested by an examination of the process and that field tests of the product should be treated as checks to determine whether the safety assurance program approved is working.

It is the manufacturer's job to incorporate into the manufacturing process procedures "sufficient to reduce or eliminate existing or potential health hazards related to food and to provide reasonable assurance that food does not present an unreasonable risk to the public health and safety." It should be FDA's job to review the adequacy of the procedures installed and to obtain assurance by examination of appropriate records or otherwise of the continuing compliance by the manufacturer with these procedures. Since the installation and observance of adequate procedures by the manufacturer should condition his right to introduce his goods into interstate commerce there can be no doubt of FDA's power of effective enforcement of the manufacturer's obligation.

Areas Needing Improvement In S. 2373

GMA endorses giving the FDA additional regulatory power so that the agency is better able to police and encourage food safety. We endorse the concept of plant registration and the requirement that all processors establish an adequate safety assurance system. We also endorse granting the FDA access to confidential records relating to such a system where unreasonable risk to public health or safety requires this.

It is essential, however, that any new grant of powers be reasonably related and carefully restricted to recognizing and dealing with the problem at issue -- the problem of assuring greater food safety.

We can acknowledge that the new S. 2373 could be interpreted to provide for procedures that encompass the needed basic elements of food safety control. But the bill also can easily be interpreted as providing for much more and different regulatory schemes that diffuse the safety provisions and would be counterproductive if implemented.

A food safety proposal of the scope of S. 2373 should define the subject matter with a fair degree of precision and outline the expected duties and responsibilities of the FDA and those whom it would regulate. This is particularly so where, as here, strict liability criminal sanctions against individuals are available to enforce the new requirements.

S. 2373 does not yet meet these tests. It does not yet provide sufficient guidance or limitations on the responsibilities and actions of the FDA or industry in pursuit of the bill's clear goal of food safety.

The problem begins with the terminology adopted -- "food surveillance" -- which is a meaningless term in the context of food regulation. It could suggest some kind of FDA undercover work, without describing or defining any specific type of action to meet food safety goals. It is not even clear to whom the term applies, FDA or industry.

Nowhere in the bill is food surveillance defined, yet it is used to describe the types of activities that are to be required by regulations, after study by an advisory committee.

S. 2373 tries to accomplish its laudable goals by imposing upon FDA and the industry complex procedures, without precise guidelines for determining crucial issues.

The mechanism established begins with an advisory committee whose mission is to study and report existing and potential food hazards and recommend surveillance procedures to reduce those hazards. The unknown committee is

- 10 -

insinuated into this process with, essentially, a free hand to explore the food industry and to invent any new procedures it pleases. Those familiar with the current safety practices of the industry will, by and large, be excluded from voting membership on this committee because of their affiliations; those eligible for voting membership will first have to educate themselves before exercising their mandate. This is an unnecessary step which will delay and possibly confuse considerably decisionmaking on issues which, by definition, should be expedited.

The FDA then is required (it cannot refuse) to issue regulations establishing surveillance procedures, based on the committee report. The failure to define or limit the concept of surveillance appears to leave the FDA free to devise any procedures it desires, possibly including licensing of processors of foods, premarket clearance, or even round-the-clock resident inspection, as practiced by the Department of Agriculture. Although such results may now seem unlikely, they nevertheless may be permitted under the bill as drafted. For example, the bill now clearly would grant FDA authority to oversee the Department of Agriculture's inspection actions, and it is conceivable that this was intended. No

Most importantly, S. 2373 now places initial responsibility for food safety control on FDA, rather than the manufacturer, and then leaves FDA with overall responsibility for assuring food safety.

No express responsibility is placed on the manufacturer until after the FDA has promulgated final regulations covering his operations. Once such regulations are issued, the manufacturer's responsibility is to comply with those regulations.

FDA's broad powers to regulate and control food safety operations under S. 2373 are supplemented by equally broad record and reporting requirements

- 11 -

that are subject to the same vagaries surrounding the term, "surveillance." Fishing expeditions are not guarded against by limiting new record access powers to food safety; required records and reports may be used for self-incrimination in criminal prosecutions involving stringent penalties, and even trade secrets may be publicly disclosed. Such overextensions of power beyond the safety area are unnecessary, will diffuse the bill's potential effectiveness and will inhibit the industry from collecting and recording data relevant to the safety of food.

General Suggestions For Revising S. 2373

GMA comments keyed to specific sections of the present bill have been provided already, and we have available for you, if you wish, specific legislative language consistent with our views. Let me just conclude our remarks on this critical area of food safety with some general suggestions in summary form.

The goal of S. 2373 can be met if the legislation is revised to focus clearly on food safety and to eliminate vague generalities which tend to detract from that subject.

The keystone of the bill should be plant registration, FDA access to critical control point records, and a mechanism for mandatory development by the manufacturer of critical control point systems. FDA should attempt regulatory action only where necessary to reduce specific food safety risks that have not been adequately dealt with by a substantial number of manufacturers. The concept of a food surveillance advisory committee should be abandoned.

- 12 -

Comments on Title III

Let me conclude my remarks with a brief comment on Title III of S. 2373, a title which did not appear in the bill when it underwent hearings before the Subcommittee.

This title requires that ingredients of standardized food products be listed on labels in the same manner as ingredients for nonstandardized foods.

We heartily endorse this requirement. In fact, on September 20, 1972, the GMA Board adopted the following position to formalize a voluntary effort of long standing by the Association:

GMA supports a requirement that the ingredients of standardized food products be listed on the label in a manner consistent with current FDA regulations for nonstandardized products to the extent that the packaging, labeling and manufacturing characteristics of the product permit.

GMA has worked with its membership to promote the concept of ingredient labeling on standardized food products, even though there was no federal requirement that these products disclose the complete ingredient composition. This effort has resulted in the voluntary practice by many manufacturers of fully disclosing the ingredient composition of their standardized foods. Similar positions were subsequently taken by other food-oriented trade associations.

Again, let me thank you for this opportunity to show our concern and support. We shall be happy to attempt to answer any questions you may have.

TITLE I--FOOD SURVEILLANCE

Section 101. Chapter IV of the Federal Food, Drug, and Cosmetic Act (21. U. S. C. 341 et. seq.) is amended by adding at the end thereof the following new section:

"Critical Control Points Procedures

"Section 410. (a) (1) Within six months after the date of enactment any person who owns or operates any establishment engaged in manufacturing or processing any food intended for distribution in interstate commerce, shall establish and conform to a critical control points system for each such establishment, which shall be set forth in a written document. A critical control points system shall extend to all points in the establishment's operations at which safety controls must be maintained in order to reduce or eliminate any existing or potential hazard to health or safety resulting from food, and shall specify with respect to each such point--

"(A) the existing or potential hazard to health or safety associated therewith;

"(B) the controls necessary to reduce or eliminate such hazard;

"(C) the monitoring methods and procedures to be utilized, including sampling, analytic and inspection methods; and

"(D) the records to be maintained relating to critical control points at each establishment.

"(2) The critical control points system at each establishment shall be reviewed at least annually by the owner or operator and, where appropriate,

shall be revised to reflect new information or changes in methods of processing food.

"(b) (1) Whenever the Secretary finds that a food intended for distribution in interstate commerce is being manufactured or processed in a significant number of establishments in such a manner as to present an unreasonable risk to the public health, he shall promulgate regulations establishing critical control points procedures for such manufacturing or processing of such food to reduce or eliminate such risk. Such regulations shall be promulgated in conformance with the requirements of §701 (e) of this Act, and shall be subject to judicial review in accordance with §§701 (f) and (g) of this Act.

"(2) Such critical control points procedures may be proposed on the Secretary's own initiative or on petition of any interested person, and shall specify--

"(A) the food or class of food subject to the critical control points procedures being established;

"(B) the critical control points in a particular food process where the hazard to health or safety may arise;

"(C) the nature of the hazard to health or safety, identifying 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) which give rise to such hazard;

"(D) the sampling methods and methods of inspection of establishments necessary to assure the effectiveness of the critical control points system;

"(E) the methods of analysis necessary to assure the effectiveness of the critical control points system; and

"(F) the circumstances under which reports relating to the critical control points system shall be submitted to the Secretary.

"(3) If the Secretary finds a threat or potential threat to the public health which requires that there be an immediate modification in any critical control points system with respect to any food, he may provide for such modification to the extent that he determines necessary. Such an order may be entered without regard to any requirement for an opportunity for a hearing, except that the Secretary shall comply with any hearing requirement as soon as practicable after such modification has been required.

"(4) Chemical and other analyses performed under this section to determine the presence and amount of contamination in food shall be performed through the use of the best instruments, technology, and trained personnel which are reasonably available.

"(5) Any person required to comply with the critical control points procedures established under this section shall establish and maintain such records as the Secretary may by regulation require pertaining to such critical control points system and make such records available to the Secretary upon request.

"(6) 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 critical control points procedures or the implementation thereof or any matter relating to detection of adulterated foods which would create an unreasonable risk to the public health which may assist him in carrying out the purpose of this section. 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 the Secretary with the consent of the Attorney General. 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.

"(7) This section shall not be construed to exempt the Secretary or any other person from any obligation imposed by any other provisions 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.

"(c)(1) Every person who owns or operates an establishment in which food is manufactured or processed, upon acquiring information which reasonably demonstrates that such food is adulterated in a manner which would create an unreasonable risk to the public

health, shall immediately notify the Secretary of such adulteration if such food has left the control of such person. Such person shall also immediately notify the Secretary of any recall of food which has left an establishment under his control, where such a recall was based, in whole or in part, on a risk to the public health.

"(2) The notifications required by paragraph (1) of this subsection shall contain a clear description of such adulteration, an evaluation of the risk related thereto, and a statement of the measures to be taken to effect protection against the risk created by the adulteration.

"(d) No information or statement included in, or derived from, any notification, record, or response to an information demand under this section shall be used as evidence against a person in any proceeding brought pursuant to section 303 of this Act."

"(e) This section shall not apply to any processing subject to the exclusive jurisdiction of the Secretary of Agriculture or to any food or class of food which the Secretary may by regulation exempt from the application of this section upon a finding that such action is consistent with the protection of the public health."

Section 102. (a) Section 301 of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 331) is amended by adding the following:

"(q) The failure to comply with critical control points procedures, the failure to maintain or make available records or reports, or the failure or the refusal to furnish notification or other information, as required by Section 410."

(b) Section 402 of such Act (21 U. S. C. 342) is amended by adding:

(f) If it is a food which was manufactured or processed other than in compliance with a critical control points system required pursuant to section 410 (a) or critical control points procedures required pursuant to section 410 (b)."

Section 103. (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 sentences:

"In the case of any establishment manufacturing or processing food, inspection shall extend to critical control point records bearing upon whether a food may be adulterated within the meaning of section 402(a), if the Secretary has reason to believe that any such food may be so adulterated and that the public health and safety requires access to such records. Critical control point records shall be limited to process flow diagrams, any analytical procedure or method used and the results obtained to ascertain compliance with critical control point practices or requirements, any quality assurance instruction or manual, any complaint, any record which relates to a breakdown in or demonstrates a pattern or possible weakness in critical control point practices or requirements, food ingredient usage records, process validation and control records, coding information and shipping information, related to adulteration within the meaning of section 402(a). Such records shall be deemed to be trade secrets and confidential and shall not be made available to the public unless the person from whom the records are obtained expressly waives his right to such status for specific records."

(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 "fifth sentence."

NATIONAL CANNERS ASSOCIATION

1133 20TH STREET, N.W. • WASHINGTON, D. C. 20036 • AREA CODE 202/331-7070

ROBERTS E. SNIVELY, CHAIRMAN
 ARTHUR H. HEISER, VICE CHAIRMAN
 CHARLES J. CAREY, PRESIDENT
 IRA I. SOMERS, EXECUTIVE VICE PRESIDENT



October 27, 1973

Supplemental Submission
 of the
 National Canners Association
 on S. 2373, Committee Print No. 3 --
 Food Amendments of 1973

The National Canners Association presented testimony at the hearings chaired by Senator Kennedy on S. 2373 on September 11 before the Health Subcommittee, expressing the views of the Association and the canning industry on the text of the bill as introduced, with the proposed food registration amendment of Senator Kennedy. On the basis of the testimony at the hearings before the Health Subcommittee S. 2373 has been substantially revised and redrafted, and the Association has been given the opportunity to consider this revision, in the form of Committee Print No. 3, and to submit any further views or comments it may wish to express.

Because Committee Print No. 3 varies so substantially in many respects from the original bill, and because of the brief time available, it has been impossible for the Association to canvass the issue with all members of the Association and all segments of the canning industry. In the time available, the Association has reviewed Committee Print No. 3 and

-2-

prepared a series of suggested modifications and further revisions that are believed to be consistent with the basic purpose and approach of the new bill. These revisions were discussed informally with the staffs of the Subcommittee and the members of the Subcommittee, and the Association was provided an opportunity to submit a supplemental statement containing the precise wording of proposed amendments and revisions.

This memorandum will attempt to set forth in a concise and summary form the proposed amendments, with a brief justification for them. In the interest of brevity and because of the lack of time, no attempt will be made to elaborate fully on all of the issues raised by Committee Print No. 3. If the members of the Subcommittee or the staff have any questions concerning the submission, the Association will of course do its best to respond in timely fashion.

I.

In his testimony before the Health Subcommittee, Dr. Ira I. Somers, Executive Vice President of the Association, made clear the Association's support for FDA authority for access to food plant records where questions of a hazard to public health are involved. He pointed out that the Better Process Control Plan, developed on a cooperative basis by the Federal Food and Drug Administration and the National Canners Association, calls for the maintenance and disclosure of records relating to the processing of low-acid canned foods. In

-3-

the same spirit, the Association generally supports and endorses the approach of Committee Print No. 3 to provide for the maintenance of and FDA access to food plant processing records directly related to identified public health hazards.

On the other hand, the Association is convinced that there are few, if any, health hazards associated with foods that are not now adequately dealt with under existing law and regulations. It would be extremely unfortunate, we believe, if the consideration and enactment of this legislation would create the false impression that the United States food supply is in any sense one of questionable safety. The fact is that the food supply is wholesome, healthful, and safe. Under these circumstances, the legislation, if it is to be enacted, must be recognized as purely preventive in nature, rather than as a response to an emergent identified existing problem or series of problems. If each aspect of the lives of American consumers were as safe and reliable as their food supply, their health and safety would be immeasurably greater than it is today.

II.

The suggested revisions to Committee Print No. 3 outlined below reflect the best thinking of the Association in the time available. In each case it is believed that the proposed revisions are consistent with the approach and intent of the bill, and in fact would improve its effectiveness or eliminate unneeded ambiguities.

-4-

1. Provide for consideration of food surveillance issues by the Food Protection Committee of the National Academy of Sciences-National Research Council rather than by a totally new committee to be appointed by the Secretary. The appointment and establishment of a new committee is unnecessary and would create undue uncertainty and apprehension. The Food Protection Committee is an established, recognized body with acknowledged expertise and objectivity, and has previously acted in an advisory capacity for FDA.

Proposed Revision. [See amendment 2 below.]

2. Revise the language of Section 410(a)(1) to eliminate the virtual assumption that hazards do exist, and instead charge the Committee to determine whether hazards exist that are not adequately dealt with under existing regulations and procedures.

Proposed Revision. Revise the first sentence of Section 410(a)(1) to read as follows:

"Within three months after the date of enactment of this Act the Secretary shall request the Food Protection Committee of the National Academy of Sciences-National Research Council to study and report to the Secretary whether there are existing or potential hazards to public health and safety resulting from food that are

-5-

or may not be adequately dealt with under existing regulations and by existing industry practices, and to recommend procedures to reduce such hazards when they are found to exist."

Revise Section 410(a)(2)(A) to read as follows:

"(A) whether there are existing and potential health hazards related to foods that are not adequately dealt with by existing regulations and existing industry practices for which surveillance procedures can reduce or eliminate such hazards and . . ."

Revise the first sentence of Section 410(a)(3) to read in relevant part as follows:

"The Food Protection Committee shall meet periodically to review, and if it so determines, revise its report and recommendations to the Secretary and to monitor implementation of this section."

Strike Section 410(a)(5).

3. The wording should make clear that the Secretary could not circumvent operations of the Committee and that regulations under Section 410(b) can be adopted only after the procedures of Section 410(a) have been followed.

-6-

Proposed Revision. Revise the first sentence of Section 410(b)(1) to read as follows:

"The Secretary shall, after appropriate action by the Committee pursuant to subsection 410(a), and after notice and opportunity for a hearing, promulgate regulations or modify existing regulations to carry out the purposes of this section as expeditiously as is feasible."

4. The bill should make clear that it is not the intention to freeze technology by rigidly requiring adherence to methods of inspection, analysis or sampling where better or equivalent results can be obtained through alternative methods. It is entirely likely that companies with their own research and laboratory capability may develop more refined and efficient methods of analysis, alternate methods of sampling or inspection, and explicit provision should be made for such companies to obtain approvals of such methods as a substitute for methods specified in the regulations.

Proposed Revision. Add an additional sentence between the second and third sentences of Section 410(b)(2) to read as follows:

"In accordance with procedures established by the Secretary, any person or group of persons may petition for an amendment of or exception to the regulations so as to permit the

use of methods other than those specified in the regulations, upon a showing that such alternative method is equal to or more effective than the method specified in the regulations, and in those instances where the requested amendment or exception is not approved by the Secretary, the Secretary shall, upon the request of the person or group of persons affected, refer the question to the Food Protection Committee for its consideration and recommendation."

5. Depending upon the recommendations of the Committee and the action of the Secretary, it is possible that the adoption of regulations specifying methods of sampling, inspection, and analysis will impose a substantial and costly burden upon small businesses. It may well adversely affect the capability of those businesses to operate properly. Whether or not loans to small business, such as those authorized in Section 8 of the Federal Water Pollution Control Act Amendments of 1972, would become necessary is by no means clear at this time. Nevertheless, the Committee may wish to consider some appropriate approach to this problem in view of increasing regulatory burdens upon small businesses in the food industry. It has become increasingly clear that compliance with

the Occupational Safety and Health Act, the Federal Water Pollution Control Act, and new food sanitation and safety regulations will accelerate the disappearance of small firms from the industry.

6. The language of Section 410(b)(6) relating to the submission of annual or special reports or answers to specific questions creates an unnecessary ambiguity and uncertainty by its reference to "any matter relating to the detection of adulterated foods." Because this clause is followed by the limitation "which may assist him [the Secretary] in carrying out the purposes of this section," it appears clear that it is the intent and effect of this provision to require reports and answers relating solely to data and information relating to the surveillance procedures provided in regulations adopted under Section 410(b). In this context the reference to "any matter relating to detection of adulterated foods" might conceivably be read to broaden the scope of the legislation beyond issues relating to existing and potential hazards to health. Adulteration of food under Section 402 of the basic Food and Drug Act embraces many issues of economic or aesthetic inferiority that are wholly unrelated to potential injury to public health. The elimination of this language would make it clear beyond question that the Secretary could request information or reports with reference to compliance with the regulations, but at the same time would eliminate any ambiguity or uncertainty.

Proposed Revision. Revise line 13 on page 10, in Section 410(b)(6), to read "adulterated foods that may present an unreasonable risk to the public health and safety that may assist him in carrying out the."

7. There has been inadequate time to consider the full potential effect of the trade secret provisions of Section 410(b)(7). There remains considerable concern as to the adequacy of protection for genuine trade secrets and confidential information, and particularly in view of the list of exceptions for the disclosure of such information. Of particular concern is the question as to the finality of any administrative determination as to what confidential or trade secret data is of competitive significance, and the absence of any review procedure of that determination. The Association will give continued consideration to these provisions and as soon as conveniently possible make further recommendations in this regard.

8. In Section 410(c) there is a provision for notification to the Secretary by a person who acquires information that a food in distribution is adulterated in a manner which would create an unreasonable risk to the public health. The subsequent provisions of Section 410(c) provide for the notification of recalls, but not just those recalls involving an unreasonable risk to public health. It is entirely possible

that an across-the-board requirement of notification of recalls may in fact discourage companies from making recalls in questionable situations in order to avoid the consequent adverse publicity. In any number of instances companies may wish to make recalls for purposes totally unrelated to public health. It would thus seem to be wholly appropriate and consistent with the purposes of the bill to limit notification of recalls to the few circumstances that will apply to the notification of adulterated food already in distribution as to which there is an unreasonable risk to the public health.

Proposed Revision. Revise the second sentence of Section 410(c)(1) to read as follows:

"Such person shall also immediately notify the Secretary of any recall of such food which is adulterated in a manner which would create an unreasonable risk to the public health and which has left an establishment under his control."

Revise Section 410(c)(2) by striking the words "or misbranding" in both instances where they occur, on page 13, lines 5 and 7-8.

9. The provision for the adoption of substantive Good Manufacturing Practice regulations would create vast new authority in FDA, and should properly be subject to reasonable provisions for administrative procedure and judicial review.

Section 102 of the bill would amend Section 402 of the FD&C Act to add a new subsection (f) which would render a food adulterated if it were not manufactured in accordance with current good manufacturing practices "as determined by regulations of the Secretary promulgated after consultation with all interested persons and after an opportunity for a hearing." Ideally, these substantive regulations should be adopted according to the formal rulemaking procedures of Section 701(e), (f), and (g), which are generally applicable to the adoption of other FDA substantive regulations (e.g., food standards under Section 401, dietary regulations under Section 403(j), emergency permit control regulations under Section 404, etc.). The GMP regulations will in effect specify new areas of responsibility for all food manufacturers and should provide for a full opportunity for public participation, factual and legal justification by FDA, establishment of a record, and provision for cross-examination. If the Subcommittee determines that application of Section 701(e), (f), and (g) procedures is not appropriate, then there should at least be provision for additional procedural safeguards. The Association wishes to emphasize that although it provides alternative forms of revision in this regard, its members feel most strongly that any new substantive rulemaking authority of FDA should be covered by the Section 701(e), (f), and (g) procedures. (It should be noted that the alternative revision does not provide for the

full invocation of the Section 701 administrative procedures, but does provide for judicial review as provided in Section 701(f). Regardless of the administrative procedures followed, such substantive regulations should be subject to statutory judicial review.)

Proposed Revision. Amend Section 701(e)(1) of the FD&C Act to add "402(f)" following "section 401," and preceding "403(j)".

Alternative Proposed Revision. Revise Section 402(f), as proposed in Section 102 of the bill, to add the following proviso:

"PROVIDED THAT in promulgating regulations pursuant to this provision the Secretary shall publish findings and an adequate statement of reasons underlying the provisions adopted, including responses to objections and comments of interested parties, AND PROVIDED FURTHER that an order promulgating regulations or amendments thereto pursuant to this section shall be deemed to be an order for purposes of judicial review under section 701(f)."

10. Section 410(c)(1) provides that information obtained pursuant to a notification of adulterated food in

distribution or notification of a recall shall not be used as evidence in a criminal proceeding brought against individuals, except for information obtained from records required to be maintained under the Act. It is submitted that the same justification for the exclusionary provision with respect to notification should apply with respect to the new statutory requirement of maintaining specified records and making them available for inspection. Whatever may be said with regard to the absolute criminal liability approach of the FD&C Act, that approach becomes particularly troublesome and inequitable in the context of compulsory access to documents and records in the hands of the potential individual defendant, where the failure or the refusal to furnish such records is made a criminal violation under the proposed Section 301(q). The use of documents compulsorily obtained from an individual in his criminal prosecution raises grave questions of self-incrimination and constitutional fairness. Since a constitutional issue is created, it would not seem to be appropriate for Congress to expand the FDA's authority in this way and in doing so to expand greatly the potential impact of the absolute criminal liability provisions upon individuals.

Proposed Revision. In Section 410(c)(1) strike the words "(except for information contained in records required to be maintained under any provision of this Act)". In Section 410(b) add a new paragraph following paragraph (6) to read as follows:

"No information or statements included in any record referred to in paragraph (5) or in any report or answer referred to in paragraph (6) shall be used as evidence in any proceeding brought against an individual pursuant to section 303 of this Act."

11. Section 103 of the bill would amend Section 402 of the FD&C Act to provide that a food shall be deemed to be adulterated if it is manufactured or handled other than in compliance with the surveillance procedures required pursuant to Section 410. The effect of this provision would be to render such foods subject to seizure and condemnation solely on the grounds that particular aspects of the surveillance procedure regulations were not adhered to, and regardless of whether the food in question was in fact otherwise adulterated or harmful to health. It should be made clear that such foods would be subject to condemnation only upon a finding that the food is in fact adulterated. Section 304 of the basic Act provides for the seizure of any adulterated food. In view of the amendment to Section 301 that would make failure to comply with surveillance procedures a prohibited act, it would seem to be unnecessary to provide that foods produced other than in compliance, but not in fact adulterated, would be deemed to be adulterated. Accordingly, this provision should be eliminated.

Proposed Revision. Strike Section 103(b) in its entirety.

12. From the standpoint of the effectiveness of the regulations and the equitable treatment of the consumer and those regulated, it is necessary that food surveillance procedures adopted for domestic companies be equally applied to companies whose products are imported into the United States for sale to American consumers. If any situation exists in the production of any food or class of foods as a result of which the public health may be potentially injured, it is equally important that the consumer be safeguarded from any imports that may equivalently hazard the public health.

Proposed Revision. Add to the bill an additional section specifying that

"Sec. 104(a). Whenever the Secretary pursuant to section 410 shall issue a regulation specifying food surveillance procedures for any food or class of foods, every person offering any such food or class of foods for importation into the United States, its territories, and possessions, shall file with the Secretary, at least thirty (30) days prior to such importation, a certificate, on such forms as the Secretary shall specify, demonstrating that the

-16-

particular imported food or class of foods has been produced in compliance with the food surveillance procedures specified in such regulation.

"(b) The Secretary shall request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of this Act, of any such food or class of foods which the Secretary determines has not been manufactured in compliance with the food surveillance procedures promulgated in any applicable regulation under section 410, or where the importer has failed to file the certification required in this section.

"(c) Any such food refused admission shall not be admitted until such time as the Secretary may determine that the food offered for import 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 of the Food and Drug Administration be permitted to inspect the manufacturing, processing, and packing

- 17 -

procedures employed in the production of the food or class of food offered for import."

13. In Title II, some additional language may preclude unnecessary duplication. In Section 411(c) provision should be made for seasonal food production and for the discontinuance of food manufacture at any particular establishment.

Proposed Revision. Add to Section 411(c), on line 2 on page 16, the following:

"Any person duly registered in accordance with this section shall notify the Food and Drug Administration not later than ninety (90) days after he ceases or discontinues the manufacture of any food or class of food in any establishment, but such notification shall not be required in the case of the temporary cessation of manufacture necessitated by the seasonal character of operations at the particular establishment or caused by temporary conditions beyond the control of such person."

SHELLFISH INSTITUTE OF NORTH AMERICA

SUITE 9 - 212 WASHINGTON AVENUE
BALTIMORE, MARYLAND 21204
301-821-7860

*President*

CLIFFORD V. VARIN
FIRE ISLAND SEA CLAM CO., INC.
P. O. BOX 85
WEST SAYVILLE, NEW YORK 11796

Executive Vice-President

RICHARD H. LORING
CULTURED CLAM CORPORATION
DIV. OF AQUACULTURAL RESEARCH CORP.
P. O. BOX 597
DENNIS, MASSACHUSETTS 02638

Vice-President

RALPH V. PAUSINA
PAUSINA OYSTER CORPORATION
8651 LOUISVILLE STREET
NEW ORLEANS, LOUISIANA 70124

Vice-President

BOB O. BOWER
ELLISON BROTHERS OYSTER CO.
ROUTE 14, BOX 127
OLYMPIA, WASHINGTON 98501

Vice-President

WILLIAM H. RIGGIN
RIGGIN & ROBBINS
DIV. OF THE GORTON CORPORATION
PORT NORRIS, NEW JERSEY 08349

Secretary-Treasurer

EVERETT A. TOLLEY
SUITE 9
212 WASHINGTON AVENUE
BALTIMORE, MARYLAND 21204

DIRECTORS

Alabama

JOHN R. NELSON

California

DORI HALLDORSON

WILLIAM W. BUDGE

Connecticut

NORMAN R. BLOOM

J. RICHARDS NELSON

Florida

CLYDE RICHBOURG

Georgia

L. PAUL MAGGIONI

Illinois

J. N. AUSLENDER

Louisiana

A. J. BUQUET

LUKE PETROVICH

Maine

HAROLD F. SNOW

Maryland

CHARLES W. DENTON

WILLIAM H. HARRIS

CALVERT B. TOLLEY

Massachusetts

W. F. O'CONNOR

GEORGE J. PAPPAS

RICHARD C. NELSON

Michigan

R. W. BROWN

Mississippi

REGINALD H. SEWELL

New Jersey

LUTHER R. JEFFRIES, JR.

CARL W. REED

LEON ROBBINS, JR.

New York

ROBERT L. DOXSEE

EMIL USINGER

G. H. VANDERBORGH, JR.

North Carolina

ELMER D. WILLIS

Oregon

SAM M. HAYES

Pennsylvania

EUGENE B. GOLDENBERG

Rhode Island

F. H. RICHARDSON

South Carolina

T. P. DUKE III

WALTER F. LUBKIN, JR.

Virginia

LEONARD L. BURTON

DILLER HARDING

W. CALVIN HAYWOOD

Washington

EDWARD J. GRUBLE

EARL P. MORGAN

Statement by
Everett A. Tolley
Executive Director
Shellfish Institute of North America
212 Washington Avenue
Baltimore, Maryland 21204

to the
Health Subcommittee
of the
Committee on Labor and Public Welfare
of the
United States Senate

on

S.2373
"Food Amendments of 1973"

October 30, 1973

Thank you for giving the Shellfish Institute of North America
an opportunity to make a statement concerning S.2373.

My name is Everett A. Tolley, Executive Director of the Shellfish
Institute of North America, an organization which represents the
shellfish industry in the United States, as well as in Canada,
Japan and Korea. Present with me are Richard H. Loring, Executive
Vice President, and Calvert B. Tolley, a member of the Board of
Directors of our Association.

Page two

We have - for 65 years - been a strong proponent of safe and wholesome food, and for the past 47 years have worked and lived successfully under the auspices of The National Shellfish Sanitation Program. This tripartite program has been protecting the health and well-being of the consumer. It is a joint effort between the Food and Drug Administration, States and industry.

Commencing early in 1974, The National Shellfish Sanitation Program will be functioning under the Good Manufacturing Practices Regulations. We would like to show how the Good Manufacturing Practices Regulations will work more effectively to strengthen further the National Shellfish Sanitation Program. Since the issuance of the General Accounting Office Report on the National Shellfish Sanitation Program improvements have been made, other improvements are in progress, and we continue to work for further improvements.

While reference has been made concerning foods imported from foreign countries, we believe that there still is not enough protection for the consumer. As the General Accounting Office report states, and the recent resolution of The Northeast Shellfish Sanitation Association stated, "all countries exporting shellfish, fresh or frozen, to the United States, must be certified by the Food and Drug Administration." At present, the domestic shellfish industry lives under a program certifying the growing waters, while imports, except from Canada, Japan and Korea (which operates by treaty under the provision of the National Shellfish Sanitation Program) can come into the United States with no control. Such legislation would thus insure that only safe, pure, and wholesome shellfish are imported and would eliminate the inequity to our domestic shellfishermen. Furthermore, the word may has been used in connection with imports, and this should be changed to shall.

We recommend having civil penalties instead of the severe criminal penalties now in the bill.

Industry input has not been adequately provided for. The food surveillance advisory committee should be made up of members of each major segment of the food industry. There should be voting rights for the technical experts, consumer interests, and industry interests.

We will be happy to work with the staff concerning any changes we have recommended, and any others which may be under consideration.

Thank you.

AREA

Associated RETAIL BAKERS



WILLIAM A. QUINLAN
GENERAL COUNSEL
AND
WASHINGTON
REPRESENTATIVE

of AMERICA

OFFICERS

O. W. ASTON
PRESIDENT
DALLAS, TEXAS
THOMAS J. GRACE
1st VICE PRESIDENT
FENTON, MISSOURI
HENRY A. FISCHER
2nd VICE PRESIDENT
CALOWELL, NEW JERSEY
EUGENE W. WILSON
3rd VICE PRESIDENT
VALDOSTA, GEORGIA
CLYDE A. MYTH
TREASURER
MINNEAPOLIS, MINNESOTA
RICHARD C. COOK
EXECUTIVE VICE PRESIDENT
AND SECRETARY
CHICAGO, ILLINOIS

DIRECTORS

A. J. SAUM, JR.
BATON ROUGE, LOUISIANA
JOSEPH A. BECKER
SIOUX FALLS, SOUTH DAKOTA
BERNARD BOWLING
LOUISVILLE, KENTUCKY
ROBERT E. BRIDGE
PENNSAULTON, NEW JERSEY
A. H. FERTI
PORT HOPE, ONTARIO, CANADA
ROBERT A. CHANEY
PESQUERA, CALIFORNIA
E. C. "JOHN" CLARK
FT. WAYNE, INDIANA
BUDY DANIEL
SILVER SPRING, MARYLAND
HARRY E. DOLCH
AZUSA, CALIFORNIA
CHARLES E. EGERTER
BRADDOCK, PENNSYLVANIA
DONALD FAVORAT
MALDEN, MASSACHUSETTS
HELMUT GERST
SEABOARD, ILL. NEW YORK
HERMAN GUTEN
DENVER, COLORADO
FRED HEIMBURGER
ST. LOUIS, MISSOURI
JOHN JURET
MT. OLIVE, ILLINOIS
EDWARD J. KLEIN
LINCOLN, NEBRASKA
BERNARD F. KOWASARA
BUFFALO, NEW YORK
JOSEPH KURAS
MILWAUKEE, WISCONSIN
JOHN J. LARSON
WATSFIELD, MASSACHUSETTS
JACK W. MCLAIN
KANSAS CITY, MISSOURI
JOHN J. HAZUE
LYNDHURST, NEW JERSEY
STEVENS W. MULLER
HAYESBORO, PENNSYLVANIA
GENE J. NOWAK
CHICAGO, ILLINOIS
PAUL A. PERRY
DENVER, COLORADO
ARTHUR E. PILE
CLEVELAND, OHIO
JERRY L. POTTER
TRAYBURN CITY, MICHIGAN
TERRAN REED
PASADENA, TEXAS
WILLIAM H. "BILL" SEBOLD
GRANITE CITY, ILLINOIS
ROBERT SROGHESTER
BALTIMORE, MARYLAND
ROBERT J. STATHAN
ATLANTA, GEORGIA
ARTHUR L. WILE
BELLEVUE, WASHINGTON

ROUTE 8, BOX 238 • ANNAPOLIS, MARYLAND 21401

PHONE IN WASHINGTON, D.C.: AREA 261-6294
FROM OTHER POINTS ADD AREA CODE 301

November 2, 1973

To the Members of the Senate Committee on
Labor and Public Welfare:

Re: S. 2373

This is the further statement promised in our Western
Union Mailgram of October 31, 1973, reading as follows:

"S. 2373, providing for registration of all food establishments and listing and defining of all products, would interfere with the ability of retail bakers to provide the unlimited and changing variety of bakery foods desired by consumers, in addition to creating another enormous bureaucracy and more paperwork for these already overburdened small businessmen and craftsmen. Will submit further statement soon as possible."

The Associated Retail Bakers of America, on behalf of over 20,000 neighborhood retail bakeries and pursuant to action by its Board of Directors, respectfully requests that you exempt such bakeries from the provisions of Title II of S. 2373 requiring registration of every food establishment with the Federal Food and Drug Administration, including listing of all foods or classes of foods and types of processing according to definitions to be issued by the Secretary of Health, Education, and Welfare for the purpose of uniformity of registration.

The bill as written would apply to every food establishment, regardless of size or whether it is engaged in interstate commerce. Even the smallest retail bakery would be required to register and list its products annually.

HONORARY DIRECTORS

WILLIAM A. QUINLAN
GENERAL COUNSEL AND
WASHINGTON REPRESENTATIVE
ANNAPOLIS, MARYLAND
HENRY A. FISCHER, JR.
ASSOCIATE GENERAL COUNSEL AND
WASHINGTON REPRESENTATIVE
WASHINGTON, D.C.
BARNEY L. SCHMITZ
DIRECTOR OF PROMOTIONS
PITTSBURGH, PENNSYLVANIA

HUGO BOMBERG
West Allis, Wisconsin

WALTER W. DOLCH
Muskego, Iowa
PETER REIDER
Fond du Lac, Wisconsin

BERNARD E. GOODE
Belle Creek, Michigan
WALTER SCHUCKARDT
Bellefleur, Missouri

CHARLES W. KOCH
St. Louis, Missouri
CHARLES J. SCHUPP
Kensington, Maryland

JACK W. KOENIG
San City, Arizona
GUSTAV A. WILDE
Pittsburgh, Pennsylvania

CHARLES O. PETTY
Covington, Kentucky

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 food classes and types of processing for purposes of the registration" 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.

The proposal for annual, unnecessary registration of hundreds of thousands of small food processors and stores is a very bad one. We urge you to reject it, or at least to exempt retail bakeries, in respect to which the registration and classification probably would do the greatest injury to the public interest.

The provision in Title I of the bill for regulations to make mandatory what the Administration considers "good manufacturing practices" also is a serious threat to every legitimate, clean, well-operated retail bakery.

The "good manufacturing practices" which the Food and Drug Administration has so far considered for bakeries are to a considerable extent suitable for large, mechanized wholesale bread plants but are inappropriate and impracticable, indeed would in many respects be absurd, for retail bakeries.

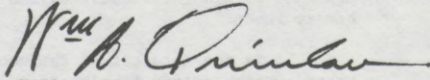
- 3 -

A retail bakery bears more resemblance to a housewife's kitchen than to a food factory, and the proposed provisions, for example, for separating a bakery into as many as seven compartments, for adopting sanitation standards of questionable validity prescribed by non-governmental organizations and for microbiological analyses of ingredients are totally unsuitable for retail bakeries.

We urge that retail bakeries also be exempted from that provision of the bill, or that it be deleted from the bill pending a complete study and further public hearings on its implications.

Respectfully submitted,

ASSOCIATED RETAIL BAKERS OF AMERICA
By:

A handwritten signature in dark ink, appearing to read "Wm. A. Quinlan", with a long horizontal flourish extending to the right.

William A. Quinlan, General Counsel

Copies to:

Robert E. Nagle, Esq.
Eugene Mittelman, Esq.
✓ Ms. Jessica Silver
Jay Cutler, Esq.

APPENDIX APARTIAL LIST OF PRODUCTS PRODUCED BY RETAIL BAKERSBREADS

Black Forest Rye Bread	Home-Made Bread
Bran Bread	Honey Rye Bread
Brioche Bread	Italian Bread
Boston Brown Bread	Jewish Twist Bread
Bun Bread	Nut Bread
Buttermilk Rye Bread	Oatmeal Bread
Butter N'Honey Bread	Oatmeal Honey Bread
Cheese Bread	Old Fashioned White Bread
Cheese Rye Bread	Orange Bread
Cherry Nut Bread	Pantry Bread
Christmas Holiday Bread	Peanut Butter White Bread
Cinnamon Bread	Pizza-Brown 'N Serve Bread
Cinnamon Twirl Bread	Potato Bread
Corn Bread	Potato Rye Bread
Corn Top Honey Bread	Pumpnickel Bread
Cracked Wheat Bread	Prune Bread
Cracked Wheat Hearth Bread	Quick Bread
Cuban Bread	Raisin Bread
Date Nut Bread	Roman Meal Bread
English Cottage Loaf Bread	Round Raisin Rye Bread
English Muffin Bread	Rye Bread
French Bread	Rye Cheese Bread
Garlic Bread	Salt Free Bread
Gluten Bread	Salt Rising Bread
Hearth Bread	Sesame Egg Bread
Holland Dutch Bread	Sesame Seed Twist Bread
Holland Raisin Bread	Snack Rye Bread

- 2 -

Sour Rye Bread
 Swedish Rye Limpa Bread
 Tomato Juice Bread
 Vienna Bread
 Vienna Salt Rye Bread
 White Bread, Old Fashioned
 Whole Milk Bread
 Whole Wheat Bread
 Whole Wheat Bread (100%)

MUFFINS

Almond Muffins
 Apple Nut Muffins
 Applesauce Muffins
 Banana Muffins
 Blueberry Muffins
 Boston Brown Bread Muffin
 Bran Muffin
 Corn Muffins
 Corn Sticks
 Crisp Butter Muffins
 Date Muffins
 French Cinnamon Muffins
 French Orange Muffins
 Fruit Nut Muffins
 Honey Muffins
 Honey Rye Muffins
 Oatmeal Prune Muffins
 Orange Coconut Muffins
 Pecan Muffins

Potato Muffins
 Raisin Spice Muffins
 Rhubarb Muffins

ROLLS - YEAST

Apple Cheese Rolls
 Bialy Rolls
 Butter Fluff Rolls
 Caraway Seed Rolls
 Cheese Butter Bits
 Cloverleaf Rolls
 Crisp Crusted Rolls
 Dinner Rolls
 Egg Rolls
 Egg Shell Rolls
 Frankfurter Buns
 French Butter Crescents
 French Dinner Rolls
 French Pastry Dinner Rolls
 Hamburger Buns
 Hard Rolls
 Kaiser Rolls
 Onion Rolls
 Orange Cream Rolls
 Pan Rolls
 Paradise Rolls
 Parker House Rolls
 Potato Soft Rolls
 Rye Rolls
 Rye Onion Rolls

Soft Crust Rolls

Soft Dinner Rolls

Sour Cream Rolls

Tenderflake Rolls

Water Rolls

Whole Wheat Rolls

QUICK BREADS

Apricot Quick Bread

Banana Quick Bread

Chopped Apple Quick Bread

Cranberry Quick Bread

Date Nut Quick Bread

Fresh Orange Quick Bread

Fruited Orange Quick Bread

Rhubarb Quick Bread

SWEET YEAST UNITS - COFFEE CAKES

Almond Cream Coffee Cake

Almond Rings

Apple Butterscotch Coffee Cake

Apple Coffee Cake

Apricot Coffee Cake

Braided Ring

Cheese Ring

Cream Rings

Danish Butternut Coffee Cake

Danish Caramel Braid

Deep Butter Cake

Easter Rabbit

Fruit Coffee Cake

Harlequin Fruit Filled Coffee Cake

Heart Coffee Cake

Honey Nut Coffee Cake

Horse Shoe Coffee Cake

Lace Coffee Cake

Orange Butter Coffee Cake

Orange Butter Pull-Apart Coffee Cake

Plantation Nut Ring

Raisin Rings

Rich Butter Round Danish

Ring Coffee Cake

Round Ring Rooster Comb

Sunflower Coffee Cake

Tutti Fruitti Coffee Cake

Vienna Coffee Cake

SWEET YEAST UNITS - FRIED

Bismarcks

Doughnuts

Jelly Delights

Long Johns

Pershings

Potato Doughnuts

Skookum Doughnuts

SWEET YEAST UNITS - ROLLS

Almond Crescents

Apricot Logs

Battle Ship Rolls

Bear Claws

Bunker Hill Rolls

Butterfly Rolls

Celestial Rolls

Cinnamon Rolls

Coconut Squares

Danish Twists

Diamonds

Figure 8 Rolls

Filled Flakies

Filled Pockets

Finger Twist Rolls

Horse Shoes

Knot Rolls

Kolackys

Lenten Butternut Rolls

Palm Leaf Rolls

Pecan Caramel Rolls

Pin Wheels

Pretzel Rolls

Orange Rolls

Schnecken

Rose Buds

Snail Rolls

Tea Tasties

Twist Rolls

Wagon Wheels

FILLINGS, GLAZES, TOPPINGS - for
COFFEE CAKES AND ROLLS

Almond Butter Crunch Topping

Almond Fillings

Almond Nut Fillings

Almond Nut Streussel

Brittle for Pizza Coffee Cake

Bunker Hill Roll Spreads

Butter Filling

Buttercream Filling

Butternut Topping

Butterscotch Filling, Cooked

Butterscotch Filling or Topping

Butterscotch Icing

Butterscotch Mix

Butterscotch Paste

Butterscotch Syrup

Caramel Cream Coconut Topping

Caramel Dressing

Caramel Spreads for Bunker Hill Rolls

Cheese Fillings

Cherry Nut Filling

Chewy Butter Topping

Chocolate Streussel

Cinnamon Filling

Cinnamon Streussel

Cinnamon Sugar Mixture

Coconut Macaroon Filling
 Coconut Mixture for Tubing
 Coconut Topping
 Cottage Cheese Fillings
 Cream Filling (Buttercream)
 Danish Butter Filling
 Date Pecan Filling
 Deep Butter Cake Dressing
 Edelweiss Filling
 Filbert Filling
 Glaze, Doughnut
 Glaze, Fruit
 Graham Cracker Filling
 Heart Coffee Cake Filling
 Honey Coffee Cake Topping
 Honey Nut Filling
 Honey Pecan Topping
 Hungarian Coffee Cake Sugar Mix
 Lemon Streussel
 Nut Crisp Topping
 Old Fashioned Stollen Filling
 Orange Butter Topping
 Orange Coconut Sunkist Topping
 Orange Filling
 Orange Sugar
 Paradise Topping, Filling
 Peanut Butter Filling
 Pecan Topping

Raisin Nut Filling
 Sour Cream Filling
 Sour Cream Topping
 Southern Pecan Filling
 Streussel
 Streussel, Almond Nut
 Streussel, Chocolate
 Streussel, Cinnamon
 Streussel, Lemon
 Streussel, White

DOUGHNUTS - CRULLERS - MISCELLANEOUS FRIED

Angel Wings
 Crullers, Honey
 Doughnuts, plain yeast
 Doughnuts, Old Fashioned Coconut
 Honey Crullers
 Italian Pastries
 Old Fashioned Coconut Doughnuts

PASTRIES

Almond Pecan Slices
 Angel Wings
 Apple Slices
 Cream Cheese Pastries
 Date Squares
 Italian Pastries
 Puff Pastry Dough #1
 Puff Pastry Dough #2

PUFF PASTRY

Apple Turnovers

Cheese Twists

Cream Rolls

Filled Squares

Fruit Slices

Glazed Bars

Horse Shoes

Palm Leaves

Patty Shells

Napoleons

Pretzels

Salt Bars

Windmills

PIES

Angel Fluff Pie

Apple Blossom Pie

Boston Cream Pie

Cream Pie Filling, Lemon, with milk

Cream Pie Filling, Lemon, with water

Cream Pie Fillings - Chocolate, Coconut,
Fruit, Nut, Vanilla

Crust, Tender, Crispy

Pecan Tart or Pie Filling

Pumpkin Chiffon Pie

Sack Apple Pie

Stock for Fruit Pies

Strawberry Pie with Whole Berries

Taffy Apple Pie

MUFFINS - POPOVERS

Aunt Myrt's Blueberry Muffins

Harvest Spice Muffins

Pineapple Bran Muffins

Popovers

CAKES

Banana Praline Cake

Banana Roll

Boston Cream Pie

Butter Pound Cake

Butter Sponge Cake

Charlotte Russe

Chocolate Spice Banana Cake

Dobasch Torte

Double Fruit Torte

Four Seasons Fruit Ring

French Strawberry Roll

German Chocolate Cake

Golden Chiffon Layers

Lady Fingers

Maysville Fudge Cake

Old Fashioned Brownie Cake

Orange Nut Loaf Cake

Pineapple Orange Delight

Shortcake, Batter (Biscuit Type)

Shortcake, Biscuit

Spumoni Cake

Toasted Coconut Chocolate Cake

Tutti Fruitti Angel Puffs

White Chocolate Cake

CAKE ICINGS, FILLINGS, TOPPINGS

Banana Icing

Bavarian Cream

Bavarian Cream Icing

Boiled Icing

Butter Cream, Fondant

Butter Cream, French

Butter Cream, Rich, Light

Butterscotch Fudge Icing

Butterscotch Syrup for Icing

Chocolate Fillings

Chocolate Fudge Icing

Chocolate Icing

Chocolate Malted Milk Icing

Custard Fillings

Decorating Icing

Fondant Icing, Cherry

French Cream

French Custard

Fudge Icings

German Chocolate Cake Icing

Homogenized Cream #1

Homogenized Cream #2

Praline Topping

Strawberry Filling

Toasted Coconut Chocolate Icing

Vanilla Fudge Icing

Whipped Cream, Chocolate

Whipped Cream, Chocolate Rum

Whipped Cream, Malted

Whipped Cream, Mocha

Whipped Cream Toppings

COOKIES - SNACKS

Almond Butter Spritz

Arizona Date Bars

Brandy Snaps

Butter Slices

Butter Spritz

Butterscotch Oatmeal Cookies

Cheese Bits

Cheese Crisps

Chewy Nut Delights

Chinese Almond Cookies, Famous

Chocolate Chip Butterscotchies

Chocolate Pecan Rocks

Coconut Chocolate Bars

Ice-Box or Cut-Out Cookies

Lady Fingers

Lemon Crisp Cookies

Mediterranean Macaroons

Nut Horn Cookies

Oatmeal Ice-Box Wafers

Praline Cookies

Raisin Filled Cookies

Rum Wafers

Southern Nut Drops

Swedish Dreams

Toasted Oatmeal Ice-Box Cookies

Walnut Clusters

CHEESE CAKES

California Type Cheese Cake

Chicago Cheese Slices

Crumb Mix

Rich Party Cheese Cake

Whipped Cream Cheese Torte

COMMENTS ON

COMMITTEE PRINT NO. 3
October 3, 1973

S. 2373
Food Surveillance

Submitted to

Committee on Labor and Public Welfare
Subcommittee on Health

November 5, 1973

National Association of Margarine Manufacturers
1725 K Street N.W.
Suite 1202
Washington, D.C. 20006
Tel: (202) 785-3232

NATIONAL ASSOCIATION OF MARGARINE MANUFACTURERS
COMMENTS ON COMMITTEE PRINT NO. 3
SENATE BILL S 2373, FOOD SURVEILLANCE

INTRODUCTION

The National Association of Margarine Manufacturers respectfully submits its comments herewith on Committee Print No. 3 of S 2373, 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.

The members of our industry have and will continue to participate in the common effort of all U.S. food processors to assure the continuing safety and quality of their products. The outstanding record of safety and health in U.S. food processing and packaging is a record which speaks for itself. Improvement in safety and quality techniques is and will continue to be a primary goal of our industry.

COMMENTS

1. In general, we believe that safety and health hazards associated with foods are, for the most part, adequately covered and dealt with under existing laws and regulations and thus, while we concur in the spirit of the proposed legislation, we believe the goal of the proposed legislation could best be achieved by the Food & Drug Administration under its existing rule-making procedures.

2. The "advisory committee" approach to the food surveillance regulations enumerated in the Bill has the effect of injecting a new "preliminary" agency over an already existing regulator, the Food & Drug Administration. While this unknown committee, to be sure, will have technical experts and a consumer and industry representative, the latter two will be non-voting members. Thus, industry, which might well have the best input into safety practices and techniques will not even have a vote and this could substantially affect the contents of the committee's report and recommendations. Since under the Bill, the FDA must issue regulations establishing surveillance procedures based upon this committee's report, industry's vote would appear to be essential. The mandate for issuance of regulations by FDA based upon the committee report in effect imposes a preliminary regulation over FDA.

The Association firmly believes this preliminary committee procedure to be unnecessary and that it would lend itself to uncertainty and confusion in the rule-making process.

3. Even assuming arguendo, the Committee approach to food surveillance rule-making to be appropriate or necessary, the Association would respectfully submit that the Bill as written assumes the "existence" of safety hazards which the subsequent regulations will cure. The initial question for the Committee should be whether such hazards do exist, not what hazards are to be cured. The assumption of the existence of hazards does not lend itself to objective review and appears to compel the finding of hazards.

4. To the extent that the proposed legislation would freeze rules promulgated thereunder by requiring strict adherence to inspection methods, sampling, or analysis, where equivalent, or improved alternative methods could be obtained, the Association believes the Bill to be unreasonable. We strongly recommend provision for the FDA approval of acceptable substitutes or alternatives upon appropriate application.

5. The trade secret provisions of Section 410(b)(7) of the proposed legislation appear to create so many exceptions to non-disclosure of such information as to amount to no real or adequate protection for authentic trade secrets and/or confidential information at all. In addition, the section, as written, is too broad and provides no criterion for, or review of the Secretary's determination of "significant competitive disadvantage".

6. Section 102 of the Bill would amend Section 402 of the Food & Drug Act to add a new subsection (f) which would render a food adulterated if it were not manufactured in accordance with current good manufacturing practices as determined by "regulations promulgated after consultation with all interested persons and after opportunity for hearing." Since the Bill thus contemplates the issuance of substantive regulations by FDA on good marketing practices, our Association strongly believes that it should be made clear that the promulgation of these regulations be subject to the formal rule-making procedure

of Section 701(e), (f), and (g) of the Act which are applicable to other FDA substantive regulations. In a word, there should be full opportunity for public participation in creation of a sufficient record subject to judicial review and a full legal basis and factual basis for the regulations evidenced in that record.

7. Section 103(b) of the Bill would amend Section 402 of the Food & Drug Act (21 U.S.C. 342) by rendering a food adulterated if it is manufactured, processed, etc., in non-compliance with surveillance procedures required pursuant to Section 410. Section 304 of the present Food & Drug Act provides for seizure of adulterated food. The Association strongly believes any food which can be subject to seizure should be so subject, only if it in fact is adulterated. The net effect of the proposed Bill would render foods subject to seizure solely on the basis that the "surveillance procedure" regulations were not adhered to and regardless of whether the food in question was in fact adulterated or harmful to public safety or health. Foods not in compliance with the surveillance "procedural" regulations should not be deemed adulterated when in fact they are not adulterated (i.e., when they are not a threat to public safety and health). This sanction is inappropriate.

8. Section 410(c) of the Bill provides in part for notification to the Secretary of "any recall of food which has left an

establishment" under the control of any person. While the Association believes that recalls which involve a reasonable risk to public health and safety might be appropriately subject to the notice provisions, recalls for other purposes not related to public health and safety should not be subject to these provisions. Accordingly, the Section should be revised to limit notification only to those situations in which recall is related to a risk to public health and safety.

This same provision provides that information obtained pursuant to notification of a recall should not be used as evidence in criminal proceedings except for information obtained from records required to be maintained under the Act. The Association believes evidence obtained because of the proposed new requirements for maintaining records under the proposed Bill should be afforded the same protection as evidence related in notification of recall especially since under proposed Section 301(q) failure to furnish such records is made a criminal violation. To couple criminal penalties for failure to furnish such records with the possibility of criminal action for information contained in those records so furnished, prompts an immediate question of 5th Amendment constitutionality.

9. In general, the Association interposes no objection to Title II, Food Establishment Registration or Title III, Food Ingredient Labeling.

We hope that our comments will be seriously considered and weighed and will serve as an aid in the review of the proposed legislation.

CONSUMER COMMENTS, S.2373

Committee Print number 3 of the Federal Food Inspection Act, S. 2373, is a great improvement over the original version of the Bill. In general, the consumer panel supports it enthusiastically, and believes it will contribute to food sanitation and consumer awareness. We think the Bill has two defects.

A. We strongly support the new Bill in general outline for the following reasons:

1. Comprehensive report on food hazards. The Bill requires appointment of an advisory committee which would assess potential health hazards from the food supply, make recommendations for prevention of hazards, and monitor the food surveillance performance of the FDA. The idea of creating an advisory committee with duties of initiating studies and actions is a novel one, and may well produce excellent results at FDA. It will provide both a support and a challenge for regular FDA employees. FDA Advisory committees have usually provided the more passive function of objecting or consenting to FDA official decisions, on the basis of information spoon-fed them by FDA officials. Given strong members and independent investigatory resources, there is no reason why advisory committee could not fulfill the initiator functions required by this Bill.

2. Public participation The Bill instructs the advisory committee to provide opportunities for public input to its work to the maximum extent practical. All meetings are open. Interested persons have an opportunity to comment on the final report of the advisory committee, and on subsequent additions to the

report, and the SEcretary is instructed to review the comments. Opportunity to comment on the general outlines of the committee's work, and on food hazards in general, is an indispensable part of fertilization of FDA work by the public interest and academic communities. This is a major advance over the earlier bill, in which public comment was reserved for the technicalities of specific surveillance methods.

3. Open Information. The Bill has excellent freedom of information~~ation~~ provisions. In addition to completely public meetings, all information obtained or developed is available for public inspection, (with the usual limitations of trade secret and confidential commercial and financial information.)
4. Flexible policy making. The Bill requires a hearing on changes in surveillance procedures, but makes it clear that if such changes involve an increase in surveillance for hazards, the hearings shall occur after the surveillance procedures have been changed. This provision eliminates the danger that hearings, or the threat of hearings, will be used by the industry to block stronger regulations, and cement FDA into bad habits (This was a major source of objection in the original Bill). If changes in the surveillance procedures involve a decrease in the level of surveillance, a public hearing prior to enactment would be necessary.
5. Accessibility of food plant records. The Bill has added aprovision asking_for accessibility of plant records to inspectors

- 3 -

This is an urgent need, for the reasons cited in our original testimony.

6. Food Plant Registration. The Bill provides for food plant registratinn, a substantial aid to FDA regulatory activities.

7. Full ingredient labeling. The Bill abolishes the hidden ingredients of standardized foods. Present law allows mandatory ingredients in food standards to go unlabeled, so consumers cannot tell what is in the product. We strongly endorse full labeling requirements (and the additional requirement-- now required by FDA, 21C.F.R. §1.10 for non-standard foods--that ingredients be listed in decreasing order of predominance).

B. We have two major objections to the bill (both can be easily corrected).

1. The food surveillance advisory committee. The success of the food surveillance sections of the Bill depends on a aggressive and vigilant advisory committee which is willing to excel in inquisitiveness and independent information gathering on food pollution. The committee would be ^afordoomed to inertia if it had members with financial conflicts of interest or potential conflicts of interest. While we are not opposed to a non-voting industry representative (together with a consumer representative), in view of the key position of the advisory committee, there should be no voting members from the regulated industry or its trade associations or research or promotion organizations. At section 410(a)(5), we recommend adding:

- 4 -

All voting members should be free of proprietary interest in companies regulated by the Food and Drug Administration.

2. The reporting requirement. The Bill requires "Every person who owns or operates [a food establishment]" to report to the FDA information "which supports the conclusion that such food is adulterated in a manner which would create an unreasonable risk to the public health," and grants immunity from criminal prosecution to persons making such reports.

a. This provision will not provide information for FDA. Even with immunity, no person, for reasons of public relations and private and self-relations, would conclude and declare that his product was adulterated and created unreasonable risk to the public health. A reporting provision which might get information to FDA is:

Every person who owns or operates [a food establishment]...upon acquiring information about such food which is alarming or which may affect adversely the quality of the food or the descriptiveness of its label, shall immediately notify the Secretary.

b. The immunity provision is deeply offensive. White collar offenders should be held as fully responsible for their acts as other kinds of law breakers. The immunity provision will provide food manufacturers substantial ammunition to ward off criminal prosecutions following any reports they make to FDA. A manufacturer with a potentially hazardous product on hand, fearing regulatory action, would merely

- 5 -

report such fact with the magic wording and thereby secure immunity. Even without the magic words, he will have strong arguments at FDA and Justice, that he is immune for any reports he makes. (The industry has interpreted similar provision in the pending Medical Devices bill, to cover all reports to FDA. It has been described with near-euphoria by the trade press.).

The dangers of this immunity provision, and the precedent it would set, far outweigh the (probably non-existent) benefits of the present reporting provision. We strongly disagree with the Health Subcommittee staffer's contention that immunity is constitutionally required, and believe that this contention is damaging because it summarily removes immunities from the province of policy discussion.

--Anita Johnson, Health Research
Group

--Susan Sechler, Agribusiness Accounta-
bility Research Group
concurs.

--Michael Jacobson, Center for Science in
the Public Interest
concurs.

October 19, 1973

93D CONGRESS }
1st Session }

SENATE

{ REPORT
No. 93-605

FOOD AMENDMENTS OF 1973

DECEMBER 7, 1973.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Public Welfare,
submitted the following

REPORT

together with

SUPPLEMENTAL VIEWS

[To accompany S. 2373]

The Committee on Labor and Public Welfare, to which was referred the bill (S. 2373) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

The amendment strikes out all after the enacting clause and inserts a substitute text which appears in *italic* in the reported bill.

I. NEED FOR THE LEGISLATION

TITLE I—FOOD SURVEILLANCE

Contamination of food can result from a number of sources: chemical substances which pollute the environment, toxic industrial chemicals used in packaging, heating systems and machinery, and chemical substances of natural origin can enter the food supply and constitute a potential health hazard. Improper processing conditions can also lead to the adulteration of food.

One has only to read the daily newspaper to understand the need for legislation to better ensure that action is taken to reduce and eliminate risks and potential risks to health from food. The Food and Drug Administration (FDA), the agency through which the Secretary of Health, Education, and Welfare enforces the Food, Drug, and Cosmetic Act, has uncovered widespread deviations from good manufacturing practices in sectors of the canning industry which result in

risk of development of botulinum toxin. Over two years ago the Nation was shocked to learn of the risk of botulism poisoning from improperly processed vichyssoise soup. We now know that this was not an isolated occurrence but a problem shared by a large portion of the canning industry on the basis of which FDA has issued emergency permit control regulation. FDA has only recently learned that improper processing in the mushroom canning industry has exposed the Nation to similar risks to health.

Every year people die from botulism poisoning. Outbreaks of foodborne disease number in the thousands year after year and each outbreak represents illness affecting at least two individuals and often many more. The Center for Disease Control projects that there were about 3,100 outbreaks in 1971. The Center acknowledges that food poisoning in the United States is grossly underreported. Moreover, it is often difficult to diagnose food poisoning and distinguish its symptoms from those associated with other illnesses. The FDA Task Force on Salmonella, convened to consider problems associated with one type of foodborne disease, recommended regulatory initiatives to lessen the risks of salmonella contamination in the preparation and distribution of food.

Mankind's exposure to chemicals from all sources has taken a quantum leap in recent decades. Heavy metals, primarily mercury, lead, and cadmium have been a source of great concern in the area of food safety. All of these metals are found naturally in the environment and many metals are indeed essential to life. However, because of increased exposure to industrial and agricultural sources, it is now possible that these metals can become hazardous when ingested in quantities greater than the body can safely accommodate. Many of these metals accumulate in the body, thereby posing additional chronic hazards. The long term ingestion of small amounts may have deleterious effects on human health. Unfortunately, there is little scientific evidence concerning the chronic effect of these substances. The potential for serious, acute health problems is amply demonstrated by the 1953 episodes in the Minamata Bay area in Japan and later in Niigata, Japan. In these incidents, 111 persons were affected after eating fish or shellfish, contaminated with mercury, including 19 congenital cases of brain damaged children of mothers who ate large amounts of shellfish. In this country, further evidence of the danger of organic mercury is provided by the experience of a New Mexico family whose three children suffered serious illness after eating mercury-contaminated meat. The excessive mercury content found in swordfish resulted in the virtual ban of that seafood and has required large-scale surveillance with respect to tuna.

The serious effect of lead contamination is well-documented in cases of children ingesting lead-based paint, a problem which gave rise to the Lead Based Paint Poisoning Prevention Act. The leachable lead from improperly processed ceramic dinnerware has been found to exceed permissible levels. The FDA is now engaged in a cooperative program with the evaporated milk industry to assure that the possibility of lead contamination from cans of evaporated milk does not pose a health hazard. This is a matter of particular concern since babies and small children are frequently the consumers of evaporated milk.

The discovery of polychlorinated biphenyls (PCB's) in foods demonstrate that toxic, industrial chemicals not intended for food use can nevertheless be incorporated in food during processing. Studies are now underway to determine the rate of body buildup, the potential effect on the liver, and whether deposits of PCB's can cause genital changes. FDA has established regulations providing tolerances for certain products including poultry, infant food, dairy products, fish, and paper packaging products.

Chemical toxins of bacterial origin and toxic chemicals derived from certain fungi can also contaminate food. Probably the most dangerous contaminant in this class is the highly toxic and carcinogenic mycotoxin known as aflatoxin which can contaminate such foods as corn, peanuts, cottonseed, and tree nuts. Serious aflatoxin contamination of imported pistachio nuts resulted in a large cooperative program between the United States and the importing country. Food additives and pesticides intentionally added to food can also create significant health hazards if improperly applied.

In addition, insanitary conditions and inadequate controls in the food processing and warehousing industry can lead to potential hazards from rodent, bird and animal filth, and insect infestation. The extent of such insanitary conditions was highlighted by a recent study of the General Accounting Office which found that 23 percent of the establishments inspected had significant insanitary conditions.

The problem of adulterated food in this country is *not* insignificant. In fiscal year 1973, the Food and Drug Administration instituted 3,020 regulatory actions (including recalls, seizures, and import detentions) against adulterated food. It is recognized that these figures represent only the surface of the problem. There are approximately 60,000 companies in the food industry, 32,000 are manufacturers and processors. Through inspections, samplings, and retail surveys, FDA can hope to discover only a fraction of the adulterated food which is sold to consumers. More importantly, action is usually taken after the food is sold and often after someone has been injured. Presently, since FDA must itself perform all of surveillance for adulterated food, little can be done to prevent adulteration or detect it prior to sale.

Limitations in FDA authority prevent it from providing the comprehensive protection to which the American consumer is entitled. Conscientious members of industry recognize that they have the primary responsibility for assuring the safety of the food they produce. And it is clear that the most effective means of controlling adulteration is by daily adherence to procedures by those engaged in the production process. Yet, FDA lacks the general authority to require industry to do its own sampling and testing. The agency must rely upon emergency powers and voluntary cooperation. Indeed, in testimony before this committee, Dr. Howard Bauman, of the Grocery Manufacturers of America stated:

... the food industry is probably the only one where someone could enter a business and start selling products without much in the way of any control, other than occasional inspection by Food and Drug.

The lack of authority to gather information needed to assess the magnitude of a risk to health from food also presents a significant obstacle to FDA effectiveness. If a food manufacturer conducts a

study showing that a particular substance is hazardous, FDA is not empowered to obtain the results of that study nor is FDA authorized to examine plant records to determine the amount of an additive being used in a particular food or to require reporting by industry to ascertain the total amount of a potentially harmful substance being put into the food supply. Other weaknesses in statutory authority have inhibited FDA activities. The agency cannot now require records to be kept or order tests performed, and FDA's authority to require compliance with regulations setting out current good manufacturing practices has been disputed.

Essential to an effective food control program is a means of detecting emerging problems. FDA conducts market basket surveys on the retail level to determine the presence of contaminants. Yet this early warning system has not been sufficient to detect a number of problems which have arisen, notably the levels of mercury in fish. Although it is probable that much of the information needed to detect patterns suggesting the need for more regulatory attention already exists in the food industry, FDA lacks a mechanism for gathering the existing information. Even when a manufacturer discovers that food which he produced and sold is adulterated he is not required to report that information to FDA.

At the same time, there is no standard to govern FDA action. Nor is there a mechanism for establishing priorities in a fashion which involves broad participation, and provides guidance to FDA in approaching the unknowns and in assigning its resources. There are, of course, a number of other practical difficulties facing any attempt to design a truly full protection system to ensure food safety. Appropriate analytical methods may not exist for the detection of chemicals, and the potential hazards of a particular compound may be totally unknown. But we must begin to deal with these unresolved matters in a purposeful and orderly fashion.

Provisions similar to Title I were included in the fish inspection bill proposed by Senator Hart (S. 1528, 92d Congress). This legislation would have required the Secretary of HEW to establish regulations specifying dangerous materials which might reach toxic levels in fish and fishery products, and set out the intensive screening procedures which would be followed to detect such dangerous materials. A clean bill (S. 2824) was reported by the Committee on Commerce which expanded the intensive screening provision so as to apply to all foods, not just fishery products. The bill was also amended to allow the Secretary more time to develop a list of dangerous materials (180 days rather than 90 days), and to provide that when analytical methods do not exist for a particular substance the duty to screen would be satisfied by research to develop such methods. The bill passed the Senate on December 2, 1971 but did not pass the House during the 92d Congress.

In this Congress, the legislation was first introduced as Amdt. No. 1 to S. 426, the Toxic Substances Control Act. Hearings were held on Amdt. No. 1 before the Subcommittee on the Environment, Senate Commerce Committee, on March 21, 1973. The Commerce Committee did not include Amdt. No. 1 in the Toxic Substances Act as reported on June 26, 1973 (Rept. No. 93-254). A revised version of the amendment was subsequently introduced as S. 2373 and referred to

this Committee with instructions that it be referred to the Committee on Commerce at the option of that Committee.

TITLE II—REGISTRATION OF FOOD ESTABLISHMENTS

The Food and Drug Administration is charged with regulation and inspection of all food establishments which are engaged in interstate commerce or which receives food in interstate commerce. However, that agency does not have available a ready means of locating the establishments it is charged with regulating. It is obvious that if FDA is to do its job, it must have a complete inventory of those food establishments subject to its jurisdiction. FDA's present methods of obtaining this information consist of review of its own files of previous inspections and information from state and local officials; at times FDA has resorted to the use of telephone directories to determine the location of establishments for which it has regulatory responsibility. Recently, in the effort to improve its present inventory, FDA contracted with a private credit institution to obtain data on establishments producing food which may be subject to its jurisdiction. A 1972 GAO study, "Dimensions of Insanitary Conditions in the Food Manufacturing Industry," concluded that the present means of obtaining an inventory of food establishments were inaccurate and inadequate. The GAO report described the need as follows:

FDA needs a complete and accurate inventory to (1) know which plants it is responsible for inspecting, particularly those which may not have been included in the inventory, (2) better plan its selection of plants to be inspected, and (3) provide appropriate congressional committees with meaningful statistics to relate to the need for resources to carry out the FDA mission. We believe that, even if the current efforts to improve the inventory are fully implemented, FDA periodically should verify the accuracy of the inventory.

The recent scare with regard to botulism from mushrooms is ample evidence of the need for and utility of food establishment registration. Although the very real threat to health made recalls necessary FDA did not know precisely who was processing mushrooms. While it is clear that such information would in no way correct the deficient processing procedures causing the problem faced by mushroom canneries, it would facilitate the quick action in surveying the mushroom industry and searching for potentially hazardous products.

TITLE III—INGREDIENT LABELING

FDA's lack of authority to require that all food labels fully disclose their ingredients is a deficiency which has been criticized by government, industry and consumers. Foods which are subject to a standard of identity under section 401 of the Federal Food, Drug, and Cosmetic Act do not have to list mandatory ingredients on the label (*i.e.*, those ingredients which must be included in the food for it to comply with the standard). Optional ingredients must be disclosed only if the Secretary of Health, Education, and Welfare specifically requires that such ingredients appear on the label. Although the distinction between

standardized and nonstandardized foods may have made more sense in the 1930's when consumers were more likely to be familiar with the basic ingredients of such food staples as mayonnaise, catsup, and salad dressing, it is surely anomalous today.

FDA's failure to require full ingredient labeling of standardized foods came under attack in a petition filed with FDA to require disclosure of all ingredients: mandatory and optional. The petition argued that the intent of Congress, as evidenced by the legislative history of the Federal Food, Drug, and Cosmetic Act was being contravened since food standards were intended to promote honesty and fair dealing in the interest of consumers. The FDA published the proposal, and requested comments on its legal authority to require the labeling of mandatory ingredients on standardized foods. The Commissioner of FDA did, however, agree that food labels should be as complete as possible. To this end, he issued a statement of policy expressing FDA's intention to amend the definitions and standards to require the label disclosure of all optional ingredients. The statement of policy also attempted to foster the voluntary listing of mandatory ingredients by providing that the requirement in some standards that optional ingredients be designated in a specific manner, would be waived if the food label included a complete list of ingredients, including mandatory ingredients. FDA concluded that it was without authority to *require* such label disclosures and its position was upheld by the United States Court of Appeals for the District of Columbia Circuit.

After the petition was denied the Administration sent a proposal to Congress (introduced in the 93rd Congress as S. 1451) designed to require the listing of all ingredients on labels of standardized foods. Hearings on an identical bill sponsored by the Administration (H.R. 14641, 92d Congress) were held on May 12, 1972, before the Subcommittee on Public Health and the Environment. Former FDA Commissioner Edwards, testifying on behalf of the Department of Health, Education, and Welfare, endorsed the legislation stating:

A more informed consumer is an important step. As you know, Mr. Chairman, mandatory ingredients in a food for which a standard of identity has been established need not be declared on the label. The rationale for the exemption for mandatory ingredients from the labeling provisions of the Act was that consumers would be familiar with the mandatory ingredients of a standardized product. This legislative assumption, which was made in 1938 when the Federal Food, Drug, and Cosmetic Act became law, has since proven invalid, especially as a result of the many new and complex variations of standardized foods which have been introduced into the market.

II. HEARINGS

The Committee conducted public hearings on S. 2373, as introduced, on September 11, 1973. That bill would have required the Secretary to publish all of his surveillance activities as regulations subject to a minimum standard. The bill was substantially revised in Subcommittee to provide the Secretary with the authority to require processors to conduct surveillance, to register, and to label standardized foods with all ingredients. After the revised S. 2373 was reported out of the

Subcommittee staff, upon the Committee's instructions, held numerous meetings with industry and consumer representatives. The hearing record was reopened to receive supplemental statements regarding the revised bill.

Witnesses at the hearing included Lloyd B. Tepper, M.D., Associate Commissioner for Science, Food and Drug Administration; Robert Wetherell, Acting Director, Office of Legislative Services, FDA; Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare; Michael Jacobson, Ph.D., Center for Science in the Public Interest; Susan Sechler, Agribusiness Accountability Project; Anita Johnson, Health Research Group; Ira Somers, Ph.D., Executive Vice President, National Canners Association; Howard Bauman, Grocery Manufacturers of America.

Supplemental statements were submitted by Michael Jacobson, Ph.D., Center for Science in the Public Interest; Susan Sechler, Agribusiness Accountability Project; Anita Johnson, Health Research Group; Terrance Hanold, Howard Bauman, Ph.D., Walter H. Meyer, and Murray D. Sayer, Grocery Manufacturers of America; the National Canners Association; Everett A. Tolley, Richard H. Loring, and Calvert B. Tolley, Shellfish Institute of North America; William A. Quinlan, Associated Retail Bakers of America; and the National Association of Margarine Manufacturers.

A. TITLE I—FOOD SURVEILLANCE

Comments on Bill as Introduced

The need for food safety legislation was emphasized by testimony of FDA witnesses that during fiscal year 1973, FDA instituted a total of 3,020 regulatory actions (including recalls, seizures and import detentions) against adulterated foods. Mr. Jacobson and Ms. Sechler provided recent examples of contamination of food products. Moreover, it was noted that regulatory actions represent only a small fraction of contaminated products. Since FDA cannot inspect each lot of food, much adulteration goes undetected.

The FDA witnesses described that agency's current efforts in assuring the safety of food and pointed out that the bill, as introduced, gave FDA no additional authority which could be used to improve the effectiveness of its program. They raised objections to any requirement that FDA publish its entire food control program as regulations, citing cost, administrative burden, and reduced regulatory flexibility. FDA should be permitted to increase its surveillance activities whenever necessitated by a potential threat to health, without first amending its regulations to permit such action. In general, the FDA witnesses were fearful that the bill, as introduced, would restrict FDA's present authority. Several witnesses suggested that the focus of legislation in the food safety area should be on increasing FDA's authority and on recognizing the responsibility of the food industry to assure the safety of food.

All of the witnesses testified that the responsibility for assuring the safety of food lies, in the first instance, with the food industry. Food adulteration can be controlled most effectively at the processing plant by processors who can conduct surveillance on a continuing

basis by building safeguards into the processing procedures themselves. Such a program, monitored and enforced by FDA, would be far more effective than the activities currently undertaken by FDA alone. However, FDA witnesses pointed out that FDA has no general authority to require industry to conduct surveillance and acknowledged that without such authority a safety assurance system which relies heavily on industry participation would be meaningless. Ms. Sechler, Mr. Jacobson and Ms. Johnson emphasized the inadequacies of a voluntary program. Mr. Jacobson testified that surveillance should include inspection and analytical methods.

Drs. Bauman and Somers indicated that many members of industry have instituted surveillance programs. Dr. Bauman noted that the degree of surveillance varies among manufacturers and stated that industry should not object to uniform standards established for all manufacturers. FDA witnesses added that for those responsible manufacturers who already provide for surveillance, legislation requiring surveillance would require no additional expenditures.

The need to give FDA access to food plant records was emphasized by Mr. Jacobson, Ms. Sechler and Ms. Johnson. Such records can be used by FDA to identify problems arising from particular processes. Dr. Somers testified that such records are kept and often made available to FDA. However, it was acknowledged that FDA cannot compel a manufacturer to make his records available. Dr. Bauman stated that there would be no competitive disadvantage in making records of surveillance efforts available to FDA.

Mr. Jacobson testified that manufacturers should be required to notify FDA whenever they institute voluntary recalls so that FDA can examine the extent of the problem. FDA witnesses noted that there is no authority to require manufacturers to report to FDA even when they learn that food they have sold is adulterated.

On the issue of public participation, Ms. Johnson and Mr. Jacobson suggested that FDA should be required to publish a broad outline of food safety hazards and the actions to be taken to deal with those hazards and permit public comment, with FDA responding to those comments prior to taking action. In addition, Mr. Jacobson stated that summaries of inspection records should be made available to the public to the extent that they do not contain trade secrets. Ms. Johnson noted that formal rulemaking procedures should not be required prior to issuance of regulations since such procedures are often utilized by industry to delay adoption of necessary regulations.

Supplemental Statements

The Grocery Manufacturers of America submitted a statement recognizing the need to improve efforts to assure the safety of food and emphasizing that the primary responsibility for food safety must rest with industry and should not be shifted to the government. The great range of manufacturing circumstances and practices and the wide variation in food products make it impossible for FDA to bear the entire or even a major part of the burden of assuring the safety of food. The statement endorsed giving FDA additional regulatory authority regarding food safety, including requiring manufacturers to establish their own safety assurance systems and providing FDA access to confidential records relating to that system when such authority

is exercised to assure greater food safety. Where there exists a present or potential problem of food safety FDA should promulgate general policy-setting regulations and establish adequate procedures for monitoring and auditing manufacturer performance to assure compliance with those policies. Compliance should be determined by field tests, examination of records and other procedures. The statement emphasized that manufacturers should be permitted discretion in the choice of methods for assuring food safety. Research and technology are dynamic and regulations should not embalm practices which may become outmoded.

More specifically, the statement of the Grocery Manufacturers of America suggested that the provisions of the bill dealing with surveillance and good manufacturing practices regulations be replaced with a provision authorizing the Secretary to issue critical control point regulations when there is a problem in a significant number of establishments and that manufacturers be required to establish their own "critical control point" system to assure food safety. The statement urged that individuals and corporations be given immunity from criminal prosecution on the basis of any information included in or derived from any notification, record or response to an information demand required by the bill. It was further suggested that critical control point records should be deemed to be trade secrets or other confidential information and available for inspection only if there is prior evidence of adulteration and that critical control point regulations be promulgated only after a full adjudicatory hearing. Finally, the statement expressed opposition to provisions establishing an advisory committee.

The statement of the National Canners Association expressed its support for giving FDA the authority to obtain access to food plant records where questions of public health hazard are involved. The statement outlined suggested revisions which the Association considered consistent with the approach and intent of the bill, including: (1) charge the advisory committee to determine whether hazards exist which are not adequately dealt with under existing regulations; (2) require that surveillance regulations be issued only after the advisory committee has reported and recommended such action; (3) permit the use of alternate methods of sampling, analysis and inspection which achieve better or equivalent results as those specified in surveillance regulations, to avoid freezing the technology; (4) require notifications of recalls which involve an unreasonable risk to public health; (5) utilize the services of the Food Protection Committee of the National Academy of Sciences in place of an advisory committee; (6) provide additional procedural safeguards in issuing regulations by requiring an adjudicatory hearing or by requiring that the Secretary publish his findings and an adequate statement of the underlying reasons, including responses to comments; (7) place judicial review of regulations in the courts of appeals; (8) provide individuals with immunity from criminal prosecution on the basis of information included in any record or report required to be submitted to the Secretary since failure to do so raises questions of constitutional fairness; (9) delete provision which would deem food to be adulterated if it is not manufactured in accordance with applicable regulations; (10) apply food surveillance requirements to imported foods so that the system is equitable

and the public is adequately protected. The statement also expressed concern about the cost to small manufacturers of adhering to surveillance regulations, about the scope of the public information provision and the protection of genuine trade secrets, and about limiting the use of surveillance regulations to deal with potential injury to health.

The Shellfish Institute of North America submitted a statement advocating increased protection against imported food which is adulterated. The statement also urged deletion of criminal penalties under the Food, Drug and Cosmetic Act and voting industry representation in the advisory committee.

The statement of the Associated Retail Bakers of America suggested that good manufacturing practices should not apply to retail bakeries since the procedures would be impracticable and inappropriate.

The National Association of Margarine Manufacturers submitted a statement expressing its concurrence in the spirit of the revised bill but indicating that the goals can be accomplished under existing authority. The statement outlined suggested revisions, including: (1) delete provisions establishing the advisory committee; (2) provide additional protection for trade secrets; (3) provide for FDA approval of acceptable alternative methods of surveillance; (4) require adjudicatory hearing prior to issuance of regulations; (5) place judicial review of regulations in the courts of appeals; (6) delete provision which would deem food to be adulterated if it is not manufactured in accordance with applicable regulations; (7) require notification of recalls involving risk to the public health; (8) provide immunity from criminal prosecution on the basis of information included in records made available to FDA because failure to so provide would present constitutional problems.

A joint statement was submitted on behalf of Anita Johnson, Health Research Group, Susan Sechler, Agribusiness Accountability Project, and Michael Jacobson, Center for Science in the Public Interest. The statement of the consumer representatives supported the revised bill as a substantial improvement of the original version, as introduced. More particularly, it advocated those sections of the revised bill which provided: (1) establishment of an independent advisory committee which can prompt action on food safety hazards; (2) an opportunity for public participation through input in the advisory committee, open meetings of the committee and comment on final reports of the committee; (3) broad public access to information with protection for trade secrets, confidential commercial and financial information; (4) where an immediate increase in surveillance is necessary such increase may be ordered without first holding a hearing, so that industry cannot use the hearing procedure or threat of hearing to block stronger regulations; and (5) accessibility of plant records to FDA. In addition, the statement suggested two changes: (1) provide that voting members of the advisory committee shall be free of conflicts of interest, so that the committee would be independent in performing its responsibilities, and (2) broaden the notification provisions to require notification upon acquiring information about food which is alarming or which may affect adversely the quality of the food or the descriptiveness of its label and delete the immunity provision regarding notifications because it is not constitutionally required.

B. TITLES II AND III—REGISTRATION AND INGREDIENT LABELING

The FDA witnesses endorsed mandatory registration of food processing establishments. They stated that the lack of authority to require registration seriously inhibits that agency's ability to properly regulate the food supply. The food supply system cannot be adequately monitored without information on the location of processors.

All of the witnesses at the hearings supported registration of food establishments including Ms. Sechler, Agribusiness Accountability Project, Ms. Johnson, Health Research Group, and Mr. Jacobson, Center for Science in the Public Interest. Dr. Somers, National Canners Association, testified that registration would benefit consumers, FDA and industry. Canners of low acid foods are presently required to register. The results have been beneficial and registration should be extended to the whole industry. Dr. Bauman, Grocery Manufacturers of America, noted that registration is a necessary step in improving FDA's monitoring of food production and distribution. He suggested that each registrant should provide information regarding the products he produces, so that education and enforcement programs can be tailored to product classes or to manufacturers engaged in similar types of processing. Identification of types of processing should relate to general categories, such as baking, canning or freezing without requiring the processor to reveal the details of his processing procedures.

In a supplemental statement, registration was supported by the National Association of Margarine Manufacturers. The Associated Retail Bakers of America voiced opposition to the registration requirement and requested an exemption for bakeries on the grounds that registration of small food processors is unnecessary and that requiring them to submit a list of the foods which they process would limit their freedom to provide unlimited, unclassified varieties of bakery food. The National Canners Association suggested that a processor be required to notify the Secretary if he discontinues the processing of any food except where such cessation is temporary and is necessitated by the seasonal character of the operations or temporary conditions beyond the control of the processor.

Supplemental statements from the Grocery Manufacturers of America, the National Association of Margarine Manufacturers, Ms. Johnson, Health Research Group, Ms. Sechler, Agribusiness Accountability Project, and Mr. Jacobson, Center for Science in the Public Interest supported ingredient labeling of standardized food and labeling of ingredients of all foods in order of decreasing predominance.

III. COMMITTEE VIEWS

TITLE I—FOOD SURVEILLANCE

A. SURVEILLANCE PROCEDURES AND GOOD MANUFACTURING PRACTICES

The Committee has considered the testimony presented at the hearings and the supplemental statements submitted by interested persons. The Committee agrees with those witnesses who stated that the food industry must exercise a greater role in assuring the safety of the food it produces. To achieve that goal, the Committee believes that the Sec-

retary must be given additional authority to require that food processors employ procedures in the processing of food designed to detect and prevent adulterated food. It is to that end, that the Committee provided that the Secretary shall have the authority to promulgate regulations designating surveillance procedures and good manufacturing practices.

The Committee believes that the Secretary's efforts cannot be truly effective unless his regulations are given the force and effect of law. Consequently, failure to comply with either surveillance or good manufacturing practices regulations is made a violation of the Federal Food, Drug, and Cosmetic Act.

The Committee intends that the promulgation of such regulations should be surrounded with adequate procedural safeguards and has provided accordingly. Prior to the issuance of regulations an opportunity for a hearing must be afforded interested persons. The hearing requirement is intended to invoke the informal rulemaking procedures of section 553 of title 5 of the United States Code. It is the view of the Committee that neither the formal hearing procedures found elsewhere in title 5 nor the adjudicatory hearing procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act are necessary to develop adequate regulations and that, in fact, the use of such procedures is likely to result in unnecessary delay, and, accordingly, those procedures are not required.

It is the intention of the Committee that the term "surveillance procedures" shall encompass all procedures which may reasonably be utilized to assure that food is safe within the meaning of the Federal Food, Drug, and Cosmetic Act. The term is meant to include, but is not limited to, samplings, analyses and inspections designed to determine the presence of harmful contaminants. However, surveillance would not include such far-reaching measures as licensing of food processors, premarket clearance of finished foods, or round-the-clock resident inspection by the Secretary.

The Committee believes that by adhering to procedures designated in surveillance and good manufacturing practices regulations food processors make a significant contribution to the safety of the nation's food supply. At the same time, the Committee wishes to emphasize that by giving industry added responsibility it has in no way reduced the efforts to be made by the Secretary. It is intended that the Secretary will not reduce his food safety activities because of increased industry activities. The Committee intends that the Secretary continue to audit the safety assurance procedures and monitor the food supply and not permit this Act should not be considered a vehicle for instituting a program of self-regulation by industry without government enforcement.

The Committee feels that in promulgating surveillance regulations, the Secretary should include the surveillance activities which he will undertake to assure that processors are complying with the surveillance procedures and to detect adulterated food. The Committee intends that such activities shall include the monitoring of food through retail surveys and other means and the inspection of plants and shipments.

This Committee received testimony concerning the vast amount of material and guidelines the Secretary has established regarding these

areas of regulation. It is not the purpose of the Committee by the inclusion of this provision to require the publication of a burdensome amount of material. Rather, this provision should be read as providing for a succinct statement concerning the manner in which the Secretary will carry out his responsibilities under section 410 and other specific information which the Secretary determines is pertinent and should in the interest of public health protection be published.

In promulgating surveillance regulations, the bill provides that the Secretary will utilize the reports of the advisory committee. The Committee does not intend that provision to be construed to require the Secretary to obtain a report from the committee before he issues surveillance regulations. If the Secretary determines that a food safety problem requires the issuance of regulations he may proceed even absent a committee report on that problem. At the same time, the Committee believes the Secretary should not circumvent the committee and may request that the committee prepare a report on the problem, if there is sufficient time to do so.

The Committee was impressed with the "critical control points" philosophy expressed in the supplemental statements submitted by the Grocery Manufacturers of America. The Committee rejected setting the critical points into law at this time but expects the Secretary to give this concept the consideration it deserves as a method of food surveillance.

B. AMENDMENTS AND EXCEPTIONS TO PERMIT USE OF ALTERNATIVE METHODS

Although the Committee believes that the Secretary should have the authority to specify the methods to be utilized as surveillance procedures, it recognizes that there may be more than one method which is appropriate. Consequently, it has provided that any person may petition for an amendment of or exception to a surveillance regulation to permit the use of an alternative method, upon a showing that the alternative method is equal to or more effective than the method specified in the regulation. A processor who wishes to develop his own surveillance procedures will be permitted to do so, but he has the burden of demonstrating that his method is at least equivalent to that required by the Secretary.

C. MINIMUM STANDARD

The Committee believes that a minimum standard should be established for the issuance of surveillance regulations by the Secretary. The Secretary must establish surveillance procedures which are "sufficient to reduce or eliminate existing or potential health hazards" and "to provide reasonable assurance that food does not present an unreasonable risk to the public health." The Committee intends this standard to represent the minimum activity which the Secretary must undertake in issuing regulations and performing his own surveillance. The language of this requirement should not be construed to prevent the Secretary from applying a more stringent test and issuing regulations which might not be required by the minimum standard.

The Committee intends that surveillance regulations at least comply with the standard. If food is not processed in accordance with an

applicable regulation that food will be considered adulterated under the Federal Food, Drug, and Cosmetic Act. The standard is not intended to have any other effect on the definition of adulteration in section 402 of the Act. Thus, while the regulations must be designed to provide assurance that food does not present an unreasonable risk to health and safety, that should not be construed to suggest that the absence of such risk would mean that food was not adulterated within the meaning of section 402. The Committee intends the addition of this standard to expand, rather than limit the definition of adulteration.

By the "unreasonable risk" criterion, the Committee intends to institute an interest-balancing test for determining the appropriate level of surveillance by the food industry and the Secretary. With respect to each risk to health and safety posed by a food contaminant or an unsanitary practice, the Secretary would be expected to weigh the extent of the risk against the cost of eliminating it and to require its elimination wherever the former exceeded the latter. The Committee most definitely does not intend that the amount of funds available to the Secretary at a given time should be taken into account in this process. The Secretary (and any court reviewing the Secretary's action) should decide whether money spent to eliminate threats and risks would be profitably spent irrespective of whether the Secretary has that money available to spend. In the case where funds on hand are insufficient to comply with regulations required of the Secretary under this Act, it is the Committee's intention that the Secretary request the needed funds that must be appropriated to enable him to comply with the law.

D. IMMEDIATE INCREASE IN LEVEL OF SURVEILLANCE

The Committee believes that the Secretary must be given the authority to act immediately to order processors to increase the level of surveillance where the Secretary finds that a threat or potential threat to the public health makes such immediate increase necessary. Where prompt action is needed the Secretary should not be required to delay implementation of increased surveillance while a hearing is held. However, an opportunity for a hearing must be afforded interested persons as soon as practicable after the increased level of surveillance has been required. It is anticipated that the original order would be modified to the extent appropriate, in accordance with information produced at the hearing.

The Committee does not intend that the provision regarding immediate increase should be viewed in the same fashion as the traditional "imminent hazard" sections in many consumer protection statutes. This provision should not be interpreted as being so restrictive that it cannot be used. Frequent use of the provision is certainly not expected but is anticipated that it will be used and should be readily available to the Secretary when situations such as the recent mushroom problem arise. The Committee anticipates that the Secretary will define the conditions under which he would use this section by issuing section 701(a) regulations which will be accorded proper recognition within the industry and the courts.

E. SECRETARY'S AUTHORITY

The Committee believes that its bill provides the Secretary with additional authority to deal with the problem of unsafe food. It is the Committee's intention to add to the Secretary's authority, not to limit his existing statutory authority. Accordingly, the Committee has provided that nothing in this bill shall be construed to relieve the Secretary or any other person from an obligation under other provisions of the Federal Food, Drug, and Cosmetic Act or other laws or to permit the adulteration of a product which would not otherwise have been permitted. This provision is intended to insure that the Secretary is free to regulate foods under other sections of the Act as well as section 410. This legislation is not in any way intended to diminish his present authority. If a conflict arises, the Secretary is free to choose the provision of law best suited for the particular circumstance. By including this provision there is no intent to render section 410 meaningless and permit the Secretary to ignore section 410. On the contrary, the Secretary is to use section 410 to the extent possible. For example, the Secretary presently has the authority to increase his own surveillance activities without first issuing regulations. That authority is not intended to be disturbed by the Committee's legislation.

F. ADVISORY COMMITTEE

The Committee believes that establishment of an advisory committee to study and report health problems associated with food is necessary to any effort to deal with the question of food safety and, accordingly, it has provided for such a committee. The Committee is charged with monitoring implementation of the food surveillance program. As new problems arise or as issues take on added importance it is anticipated that the committee will revise its reports and make additional reports and recommendations. The primary purpose of the advisory committee is to serve as a means of broad participation in the policy determinations of the Secretary with respect to food safety regulation. To insure that there is broad representation the committee should be as well balanced as possible and the administrator should seek nominations from as many recognized groups as practicable. The voting members are to be qualified by training and experience in the safety of food or in technical disciplines relevant to food surveillance. The Committee intends that such experts shall include scientists with broad environmental and public health training skills which are applicable to food safety. The Committee intends that in order to assure independence and objectivity voting members of the advisory committee be considered "special employees" within the meaning of chapter 11 of title 18 of the United States Code, and, as such, be governed by the conflicts of interest provisions of that chapter.

Although the committee is intended to represent the public interest, it is not intended to be a substitute for full participation on the part of any person. The Committee has required that the advisory committee shall provide an opportunity for any interested persons to submit data and views on all matters pending before the committee. The Committee anticipates that the advisory committee will seek assistance from industry groups in regard to the technical aspects of assuring

safety of food. In addition, all meetings of the committee shall be open to the public.

The advisory committee, which it is anticipated will be composed of up to fifteen voting members, is intended to advise the Secretary. Advice and recommendations of the Committee must be carefully weighed by the Secretary and any differences the Secretary may have with respect to any recommendations should be substantiated and the reasons for such differences must be made public. If the Secretary finds the action recommended in the advisory committee's report or part thereof to be inappropriate he is required to publish his findings in the *Federal Register* and provide an adequate statement of his reasons for failure to act. Thus, although the recommendations of the committee are not binding, they must be taken seriously by the Secretary and adequately and fully considered. If the Secretary chooses to act on the committee's recommendations, he must do so expeditiously. Although the Committee has not designated a deadline for issuance of regulations, it intends that the Secretary shall begin action as soon as the problems are identified, that he shall act simultaneously on all identified problems and that he shall issue regulations within a reasonable period of time.

Support for the advisory committee is to be provided by the Secretary through the Food and Drug Administration. (The FDA will be the agency exercising the functions of the Secretary with respect to appointment of the members, organization and staffing of the Committee, and other administrative responsibilities.) Since the committee's acquisition of information within and without the agency is crucial to the quality of its assessment of food hazards, and the quality of its ongoing evaluation of FDA food surveillance performance, the Committee expects that it shall have funds to support a staff and aggressive investigatory work. Although it is expected that the Secretary will provide the committee with the full range of needed administrative support, it is not thereby intended that the committee will be unable, on its own initiative, to request and receive support or information from any other agency bearing on matters within its jurisdiction.

The advisory committee is directed to rank food hazards in order of "public importance." The Committee intends that the term "public importance" should relate to the hazards posed and the public health consequences of any such hazards and should not encompass economic considerations.

G. RECORDS

The Committee agrees with those witnesses who testified that the authority to require that processors maintain records and make them available for inspection is essential if the Secretary is to obtain the information he needs to implement an effective food control program. The Committee intends that processors be required to maintain those records relating to surveillance and make them available to the Secretary during routine inspections or upon request. Since access to records will aid the Secretary in uncovering problem areas as well as in formulating action once a problem area has been uncovered, the Committee does not believe that it is appropriate to require that the Secretary make some initial finding in order to obtain access to such records,

and accordingly, no such provision was adopted. It is anticipated that the Secretary will issue regulations designating those records which will be required to be maintained.

H. GENERAL AND SPECIFIC ORDERS FOR REPORTS OR ANSWERS TO SPECIFIC QUESTIONS

The Committee believes that the Secretary must have access to information relating to surveillance procedures and to the detection of adulterated foods in order to properly assess risks to health associated with food and take appropriate action. Accordingly, the Committee has provided that the Secretary may require from processors the submission of reports or answers in writing to specific questions which seek information which will enable him to implement an effective food surveillance program. The Secretary is authorized to obtain information essential both to the development and later amendment of surveillance procedures, and to the enforcement of such procedures once they have been adopted. It is important that a general investigative tool such as this be available to permit the Secretary to determine problem areas in order fully to enforce the intent of the new provisions. The Secretary should also utilize this tool to secure information needed by the advisory committee to enable it to evaluate real and potential health risks.

I. NOTIFICATIONS

The Committee believes that a food processor should be under an obligation to notify the Secretary when he learns that food which has left his control is adulterated in a manner which would create an unreasonable risk to the public health or when he initiates a recall of such food. The requirement of immediate notification is not intended to mean notification six months after he learns of the adulteration nor in most cases does it mean the day the person learns this information (since he should have a chance to make reasonable inquiries to verify the information depending on the circumstances). The Committee anticipates that the Secretary will establish guidelines, under section 701(a), to outline what is meant by immediate notification and when notification is required.

J. PUBLIC INFORMATION

The Committee believes that the Freedom of Information Act (5 U.S.C. section 522 et seq.) provides adequate protection both to the rights of the public to information obtained by the government and to the concerns of industry for protection of trade secrets and confidential information and intends that the provisions of that statute shall govern information obtained under section 410. The Committee believes that classification of information as confidential or as a trade secret should be rendered on a case-by-case basis according to regulations of the Secretary and with the right of appeal to the courts. These are relative concepts and their definition should be left to those with expertise and experience in rendering such classifications. Accord-

ingly, the Committee has rejected industry proposals which would deem records to be trade secrets and confidential information.

K. IMMUNITY FROM CRIMINAL PROSECUTION

The notification provision of this bill requires that a processor notify the Secretary when he obtains information which supports the conclusion that food which has left his control is adulterated in a manner which would create an unreasonable risk to public health or when he initiates a recall of such food. Since the notification amounts to an admission that the processor has violated the Federal Food, Drug, and Cosmetic Act, the Committee believes that if information exclusively derived from such notification were used in a criminal prosecution of an individual for violation of the Act, that individual's constitutional privilege against self-incrimination might be violated. Accordingly, the Committee has provided that individuals shall have immunity from criminal prosecution under the Federal Food, Drug, and Cosmetic Act based on evidence derived exclusively from required notifications. The Committee intends that this provision be construed narrowly since it is intended to provide protection coextensive with the scope of the constitutional privilege and immunity is intended to be no broader than is required to protect that privilege.

The Committee believes that it is not necessary to extend immunity to information contained in records which are required to be maintained and made available to the Secretary, since recent decisions of the Supreme Court indicate that the use of such records is not protected by the privilege against self-incrimination. Accordingly, these records are excepted from the immunity provision. Similarly, the Committee does not believe that it is necessary to grant immunity in connection with reports and answers to specific questions in order to avoid conflict with the constitutional privilege. Consequently, the Committee has specifically rejected proposals to include such an immunity provision.

The Committee rejects any contention that immunity from criminal prosecution should be given to processors to encourage their cooperation and free disclosure of information. Processors of food which is consumed by the American people have an obligation to obey the law and to cooperate with the government. The Committee believes that the Federal Food, Drug, and Cosmetic Act can be effectively enforced only if those whose action it governs are subject to criminal penalties for failure to comply with its provisions. The Committee rejects any provision which would strip away any of the enforcement provisions of the Act.

L. IMPORTED FOODS

The Committee agrees with those persons who submitted supplemental statements urging the application of surveillance procedures equally to food offered for importation. The Committee is persuaded that consumers can best be protected from the hazards associated with unsafe food if such procedures are followed by processors of imported food and there appears to be no reason to apply a lower standard of food safety control to imported food. Accordingly, the Committee's

bill provides for the application of surveillance procedures to food offered for importation.

M. EXEMPTION FOR MEAT, POULTRY AND EGG PRODUCTS

Titles I and II do not alter the present exemptions for meat and meat food products set forth in section 902(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. S392(c)) and section 409 of the Federal Meat Inspection Act (21 U.S.C. S679); the exemption for poultry and poultry products set forth in section 24(a) of the Poultry Products Inspection Act (21 U.S.C. S467f); or the exemption set forth in section 23(c) of the Egg Products Inspection Act (21 U.S.C. S1052(c)).

Existing law requires the Secretary of Agriculture to conduct continuing inspection in all establishments slaughtering or processing meat or poultry for sale in interstate commerce; to maintain surveillance over meat and poultry slaughter and processing in intrastate commerce; and to inspect the processing of all egg products. The present legislation does not create additional surveillance procedures or registration requirements for meat and poultry establishments inspected pursuant to federal standards or standards at least equal thereto, nor does it create such surveillance procedures or registration requirements for egg processing establishments. However, the Committee recognizes that exclusive jurisdiction of the Secretary of Agriculture exists only until the regulated product leaves the meat or poultry establishment.

TITLE II—FOOD ESTABLISHMENT REGISTRATION

The Committee believes that legislation to provide the Secretary with a complete and accurate inventory of all food processors is long overdue. The purpose of registration is simply to provide the Secretary with information on establishments which are processing food and are thereby subject to its inspection and other regulatory powers. The registration provision is in no way a licensing provision and registration cannot be refused by the Secretary.

In addition to a requirement that each food processor file his name and address with the Secretary, the registration provision also calls for the submission of information with respect to the type of food being processed, and the type of processing being conducted in each establishment. It is anticipated that the Secretary will establish guidelines defining classes of foods and types of processing with a view towards uniformity in reporting. The purpose of this provision is to give the Secretary information which he may utilize to establish priorities with regard to inspection and regulation of food establishments and to secure enforcement when a problem has been discovered regarding a particular class of foods or type of processing.

It is not the purpose of this Committee to impose unnecessary burdens on either the Secretary or the food industry. It believes the exemption provision is sufficiently broad to authorize the Secretary to devise a reregistration mechanism to lessen the impact and burden of annual registration if he finds that such action is necessary, and that

the public health would in no way be adversely affected. The Committee anticipates that the exemption provision will be employed by the Secretary to exempt such groups as farmers who are not engaged in processing, truckers who do not handle food on a regular basis and retail establishments whose registration is not required to protect the public health.

In designating classes of food and types of processing it is anticipated that the Secretary shall establish broad categories which are meaningful from a regulatory standpoint including any reasonable categorization of food by its type of processing, manner of handling, ingredients, where it is stored or sold or other factors permitting reasonable distinction of one class from another. The Committee does not intend that processors should be required to submit a list of all foods which they process or detailed descriptions of their processing procedures.

Since food additives are foods, processors of food additives will be required to register.

TITLE III—FOOD INGREDIENT LABELING

The Committee believes that the public will be served by extending the ingredient labeling requirement to standardized foods. The Committee is persuaded that there is no justification for distinguishing between standardized and nonstandardized foods for purposes of ingredient labeling and that in each case consumers are entitled to information regarding the ingredients present and the order of their predominance in the food.

IV. SECTION-BY-SECTION ANALYSIS

TITLE I—FOOD SURVEILLANCE

Section 101. Adds a new section 410 to the Federal Food, Drug, and Cosmetic Act as follows:

Sec. 410(a) (1) Provides for the establishment by the Secretary of a food advisory committee within six months after enactment. The committee shall provide interested persons with an opportunity to submit data or views on matters considered by the committee, and all committee meetings shall be open to the public.

(2) (A) Within one year after appointment of the committee (which time may be extended for good cause and notice published in the *Federal Register*) the committee shall issue a report which determines whether there are health hazards and potential health hazards related to food and which may be reduced by surveillance procedures, specifies such hazards and establishes priorities of public importance relative thereto. The report may also include proposals for the establishment of surveillance regulations.

(B) As soon as possible after receiving the report, the Secretary shall publish it in the *Federal Register* and provide a period for comments. After reviewing such comments and evaluating the report, and within six months after the issuance of such report, the Secretary shall determine whether it is appropriate to act under subsection (b). Where he deems it appropriate to act he shall do so as expeditiously

as is feasible. If he determines that such action is inappropriate he shall publish in the *Federal Register* his reasons for failure to take action and provide interested persons an opportunity to comment thereon.

(3) The Committee shall be a permanent advisory committee which shall meet at least twice a year and may review or revise its reports and may monitor implementation of this section. The committee may make additional reports and upon the issuance of such reports the Secretary shall comply with the requirements of (2)(B).

(4) Reports and recommendations of the committee shall serve as public notice that regulations will be issued expeditiously except where the Secretary has determined that action under subsection (b) is inappropriate. Interested persons will thereby be notified that they may begin appropriate studies regarding the establishment of such procedures or compliance with them. Such notice will not constitute notice as required by subsection (b).

(5) The Committee members shall have expertise with respect to food safety, sampling techniques, analytical methodology, or related disciplines. The committee shall also include nonvoting representatives of consumer and industry interests. The committee may be nominated by appropriate scientific, trade, and consumer organizations. The Secretary shall appoint the chairman of the committee and members will be entitled to compensation (not to exceed GS-18) and per diem as authorized for persons in the service of the Government who are employed intermittently. The Secretary shall provide administrative support to the committee. Conflict of interest provisions of current law shall apply to voting members of the committee.

(b)(1) After notice and opportunity for a hearing in accordance with 5 U.S.C. section 553, the Secretary shall promulgate regulations utilizing the report and recommendations of the food advisory committee and the comments received thereon. The Secretary shall publish his findings and statement of reasons underlying the provisions adopted, including responses to comments. The regulations shall be subject to judicial review in accordance with section 701(f) of the Act. Regulations may be proposed by the Secretary or on the petition of any interested persons. The regulations shall designate:

- (A) the foods subject to surveillance;
- (B) persons required to conduct surveillance;
- (C) the contaminants, insanitary practices, or other factors (including chemical residues and filth) for which surveillance is required;
- (D) sampling and inspection methods to be used;
- (E) methods of analysis to be used;
- (F) the circumstances under which reports of surveillance will be required to be submitted;
- (G) activities the Secretary shall take to assure compliance with such surveillance procedures.

(2) Any persons may petition for an exception to the regulations permitting the use of an alternative method which is equal to or more effective than a method specified in the regulations. If the Secretary rejects a proposed exception any interested person may have it referred to the advisory committee for its recommendations.

(3) Procedures established under this section shall be sufficient to reduce or eliminate hazards and provide reasonable assurance that food does not present a risk to the public. Such procedures may vary among foods. Where insufficient knowledge is available to establish such procedures, the Secretary shall initiate a program to develop such procedures.

(4) The Secretary may immediately increase the level of surveillance specified in the regulations when he finds a threat or potential threat to the public health requiring such action and shall afford interested persons an opportunity for a hearing as soon as practicable after such increase.

(5) Analyses performed under this section shall use the best instruments, technology, and personnel reasonably available.

(6) The Secretary may require maintenance of records relating to such surveillance and make them available to the Secretary upon request.

(7) The Secretary may require by general or specific orders the submission of annual or special reports or answers to specific questions regarding the establishment or implementation of the surveillance procedures. The District Courts shall have the authority to enforce such orders on the application of the Attorney General or the Secretary (with the consent of the Attorney General).

(8) This section will not exempt the Secretary or any other persons from any obligation imposed under the Federal Food, Drug, and Cosmetic Act or other Acts nor shall it be construed to permit the use of substances which could render a food adulterated.

(c) (1) Persons who own or operate food establishments shall notify the Secretary when they receive information that foods which they produced may be adulterated in a manner which would create a health hazard if such food has left their control. Such persons shall also immediately notify the Secretary of any recall that they undertake of food which is adulterated in a manner which would create a health hazard. Information exclusively derived from such notification shall not be used as evidence in criminal proceedings against individuals under the Act except with respect to records required under the Act to be kept.

(2) The notification required above shall include a clear description of the adulteration, evaluation of the risk present, and a statement of the measures taken to correct the problem.

(d) Processing subject to the exclusive jurisdiction of the Secretary of Agriculture is exempt from the provisions of this section.

Section 102. Amends section 402 of the Federal Food, Drug, and Cosmetic Act to provide that a food is adulterated if the methods, facilities, or controls used in the processing of the food do not conform with regulations of the Secretary (promulgated in accordance with 5 U.S.C. section 553 after consultation with interested persons and after an opportunity for a hearing) setting forth current good manufacturing practices. The Secretary shall publish his findings and statement of reasons underlying the provisions adopted, including responses to comments.

Section 103(a). Amends section 301 of the Federal Food, Drug and Cosmetic Act to make failure to comply with surveillance procedures

or current good manufacturing practices, failure to maintain or make available required records or reports and failure or refusal to furnish required notification prohibited acts.

(b) Amends section 402 of the Federal Food, Drug, and Cosmetic Act to provide that a food is adulterated if it was processed other than in compliance with applicable surveillance procedures.

Section 104. Amends 801 of the Federal Food, Drug, and Cosmetic Act as follows:

Section 801(e)(1). Importers of food for which the Secretary has issued a surveillance regulation shall file with the Secretary, at least 30 days prior to importation of such food, a certificate demonstrating that the food has been produced in compliance with the applicable surveillance procedures.

(2) The Secretary shall request the Secretary of the Treasury to refuse admission into the United States of any food which has not been produced in compliance with applicable surveillance procedures or where the importer has failed to file a certification.

(3) Any food refused admission shall not be admitted until the Secretary determines that it is not injurious to health.

Section 105. Amends section 201 of the Federal Food, Drug, and Cosmetic Act to provide that the term "food" as used in sections 402 (f), 410, and 411 shall not include articles used for food or drink for animals.

TITLE II—FOOD ESTABLISHMENT REGISTRATION

Section 201. Findings and declaration of policy providing that firms engaged wholly in intrastate commerce shall be subject to registration and inspection under this section.

Section 202. Amends the Federal Food, Drug, and Cosmetic Act by adding a new section 411 as follows:

Section 411(a) defines: (1) the term "name" to include the name of partners in the case of a partnership and the names of principal corporate officers and the state of incorporation with respect to corporations; and

(2) The terms "processing" and "processed" to include manufacturing, processing, packing, labeling, storing, importing, or otherwise handling food.

(b) On or before December 31 of every year each person who processes food shall register his name, places of business, and a complete list (in such form as the Secretary may prescribe by regulation) of all classes of foods processed in such establishments and the type of processing being carried out with respect to each such food. For the purpose of uniformity, the Secretary may define by regulation food classes and types of processing.

(c) Persons upon first beginning the processing of foods shall immediately register with the Secretary. Persons who are registered shall notify the Secretary within 90 days after they cease the processing of any food, except where the cessation is temporary and necessitated by the seasonal character of operations or temporary conditions beyond their control.

(d) Persons registered under this section shall immediately register additional establishments in which they begin processing food.

(e) The Secretary may assign a registration number to any person or establishment.

(f) The Secretary shall make available for inspection by the public any registration filed under this section.

(g) The Secretary may by regulation exempt classes of persons if registration is not necessary for protection of the public health. Establishments subject to the exclusive jurisdiction of the Secretary of Agriculture are exempt.

(h) Establishments registered under this section shall be subject to inspection.

(i) The Secretary may by regulation provide for the registration of foreign establishments processing food for importation.

Section 203. Sec. 301 of the Federal Food, Drug, and Cosmetic Act is amended to make failure to register a prohibited act.

Section 204. Sec. 403 of the Federal Food, Drug, and Cosmetic Act is amended to provide that food from an establishment not properly registered is misbranded.

Section 205. Section 801(a) of the Federal Food, Drug, and Cosmetic Act is amended as follows:

Section 801(a) (2). The Secretary may refuse entry of any food offered for importation which was processed in an establishment which was not registered.

Section 206(a). The amendments made by sections 203 and 204 shall take effect seven months after enactment.

(b) Any person engaged in food processing prior to the date of enactment may register his name, principal place of business and location of each establishment prior to the effective date and such registration shall be deemed to have complied with the registration requirement for the year during which the title becomes effective.

TITLE III—FOOD INGREDIENT LABELING

Section 301(a). This section strikes the sentence in section 401 of the Federal Food, Drug, and Cosmetic Act which requires that the Secretary shall designate those optional ingredients which would appear on the label of foods subject to a standard.

(b) Amends section 403 of the Federal Food, Drug, and Cosmetic Act to provide that a food is misbranded if it purports to be or is labeled as a food for which a standard of identity has been established unless it conforms to such standard and its label bears the name of the food specified in the standard.

(c) (1) Amends section 403(i) of the Federal Food, Drug, and Cosmetic Act to provide that labels of all foods whether or not subject to a standard shall bear the common or usual name of the food, and if it is fabricated from two or more ingredients, the common or usual name of each ingredient except that spices, flavorings, and colorings may be designated as such. To the extent that compliance with this provision is impracticable or results in deception, the Secretary may issue exemptions.

(2) Further amends section 403 to provide that the list of ingredients shall be in the order of their predominance.

(d) Conforming amendment.

Section 302. This Title shall take effect in one year with an additional year authorized if the Secretary finds it necessary except such extension may not apply to food bearing labels printed more than four months after enactment.

V. COST ESTIMATES PURSUANT TO SECTION 252 OF THE LEGISLATIVE REORGANIZATION ACT OF 1970

No additional authorizations of appropriations are included in the bill as reported by the Committee.

VI. TABULATION OF VOTES CAST IN COMMITTEE

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabulation of votes in Committee: Motion to report the bill to the Senate carried unanimously.

VII. CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by titles I through III of the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets; new matter printed in italic):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, *except that in sections 402(f), 410, and 411 such term shall not include articles used for food or drink for animals*, (2) chewing gum, and (3) articles used for components of any such article.

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * *

(g) *The failure to comply with surveillance procedures or current good manufacturing practices required pursuant to section 402(f) or section 410 of this Act, the failure to maintain or make available records or reports required pursuant to section 410 of this Act, or the failure or the refusal to furnish notification or other information as required by section 410 of this Act.*

(r) *The failure to register as required by section 411 of this Act.*

* * * * *

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. [In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.] Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) * * *

* * * * *

(f) *If the methods used in, or facilities and controls used for its processing do not conform to, or are not operated or administered in conformity with, current good manufacturing practices, as determined by regulations of the Secretary promulgated in accordance with title 5, United States Code, section 553, after consultation with all interested persons and after an opportunity for a hearing, to assure that such food is not adulterated: Provided, that in promulgating regulations pursuant to this provision the Secretary shall publish his findings and an adequate statement of reasons underlying the provision adopted, including responses to objections and comments of interested persons: And provided further, That an order promulgating regulations or amendments thereto pursuant to this section shall be subject to judicial review in accordance with section 701(f) of this Act.*

(g) *If it is a food which was processed other than in compliance with surveillance procedures required pursuant to section 410.*

* * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) * * *

* * * * *

(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, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard [.] [and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.]

* * * * *

(i) [If it is not subject to the provisions of paragraph (g) of this section unless its label bears] *If its label fails to bear* (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient (*in the order of their predominance*); except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

* * * * *

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and [paragraphs (g) and (i)] *paragraph (i)* with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

* * * * *

(o) *If it is a food and it was processed in an establishment required to be registered under section 411 of this Act and not so registered.*

FOOD SURVEILLANCE PROCEDURES

SEC. 410. (a) (1) *Within six months after the date of enactment of this Act the Secretary shall appoint and organize a food surveillance advisory committee to study and report to the Secretary existing and potential hazards to health and safety related to food and recommend procedures to reduce such hazards. To the maximum extent practical, the committee shall provide an opportunity for any interested person to submit data and views on all matters considered by the committee. All meetings of the committee shall be open to all members of the public.*

(2) (A) Within one year after appointment and organization of the committee (which time may be extended by the Secretary by a notice published in the Federal Register stating good cause therefor), the committee shall issue a report to the Secretary which report shall (i) determine whether there are existing and potential health hazards related to food for which surveillance procedures can reduce or eliminate such hazards, (ii) specify such hazards, and (iii) rank such hazards by priority of public importance. The report may also include recommendations regarding the surveillance procedures to be established pursuant to paragraph (1) of subsection (b). (B) As soon as possible after receiving this report, the Secretary shall publish it in the Federal Register and provide interested persons an opportunity to comment thereon. After reviewing such comments and evaluating the report, the Secretary shall determine whether it is appropriate to act under subsection (b). Where the Secretary deems such action appropriate he shall begin implementing subsection (b) as expeditiously as is feasible.

If the Secretary determines that such action is inappropriate he shall publish in the Federal Register his findings and an adequate statement of reasons for failure to take action under subsection (b) and provide interested persons an opportunity to comment thereon. The Secretary shall determine the appropriateness of action under subsection (b) on the advisory committee report within six months after the issuance of such report.

(3) The advisory committee shall constitute a permanent advisory committee, which shall meet periodically, at least twice each year, to review and if it so determines revise its report and recommendations to the Secretary and to monitor implementation of this section. Such committee shall make such additional reports and recommendations to the Secretary as it deems advisable. Upon the issuance of such reports the Secretary shall comply with the requirements of subparagraph (B) of paragraph (2) of this subsection.

(4) The published reports and recommendations of the committee shall constitute public notice that, as expeditiously as is feasible, the Secretary will issue regulations under subsection (b) establishing specific surveillance procedures for designated foods, except that such reports and recommendations shall not constitute notice when the Secretary has determined, pursuant to subparagraph (3) of paragraph 2 of this subsection, that it is inappropriate to act under subsection (b). The publication of such reports and recommendations shall not relieve the Secretary of the obligation to provide notice as required by paragraph (1) of subsection (b) of this section. Any interested person will have an opportunity, pending promulgation of such specific procedures, to undertake studies and other work appropriate to establish such procedures or to assure compliance with them.

(5) Committee members shall be qualified by training and experience in the safety of food or in the use of statistical sampling techniques, analytical methodology, or other technical disciplines relevant to food surveillance. The provisions of title 18, United States Code, chapter 11, shall apply to voting members of the committee. In addition to such technical experts, the committee shall include, as non-voting members, a representative of consumer interests and a repre-

sentative of industry interests. Committee members may be nominated by appropriate scientific, trade, and consumer organization. The Secretary shall designate one of the members of the committee to serve as chairman. Committee members shall, while attending meetings or conferences of the committee or otherwise engaged on its business, be compensated at per diem rates fixed by the Secretary but not in excess of the rate for Grade GS-18 of the General Schedule at the time of such service, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by title 5, United States Code, section 5703, for persons in the Government service employed intermittently. The Secretary shall furnish the committee with adequate clerical and other necessary assistance, and shall prescribe by regulation the procedures to be followed by the committee.

(b) (1) The Secretary shall promulgate regulations or modify existing regulations to carry out the purposes of this section as expeditiously as is feasible. Such regulations shall be promulgated in accordance with title 5, United States Code, section 553, after notice and an opportunity for a hearing: Provided, That the Secretary shall publish his findings and an adequate statement of reasons underlying the provisions adopted, including responses to objections and comments of interested persons: And provided further, That an order promulgating regulations or amendments thereto pursuant to this section shall be subject to judicial review in accordance with section 701(f) of this Act. In promulgating or modifying such regulations the Secretary shall utilize the reports and recommendations of the food surveillance advisory committee and comments thereon. Such regulations, which may be proposed on the Secretary's own initiative or on behalf of any interested person who has submitted a petition, shall designate—

(A) a food or class of foods subject to the surveillance procedures being established,

(B) the persons required to conduct such surveillance in accordance with such procedures,

(C) the contaminants, properties, unsanitary practices, or other factors (including but not limited to microorganisms, 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 of establishments by which such surveillance shall be accomplished,

(E) the methods of analysis by which such surveillance shall be accomplished,

(F) the circumstances under which reports of such surveillance shall be submitted to the Secretary, and

(G) the activities (including sampling, analysis, and inspections) which the Secretary will undertake to assure compliance with the standard of paragraph (3) of this section.

(2) In accordance with procedures established by the Secretary, any person or group of persons may petition for an amendment of or exception to the regulations so as to permit the use of methods other than those specified in the regulations, upon a showing that such alternative method is equal to or more effective than the method specified

in the regulations, and in those instances where the requested amendment or exception is not approved by the Secretary, the Secretary shall, upon the request of any interested person, refer the amendment or exception to the food advisory committee for its consideration and recommendation.

(3) The procedures established pursuant to paragraph (1) of this subsection shall be sufficient to reduce or eliminate existing or potential health hazards related to food and to provide reasonable assurance that food does not present an unreasonable risk to the public health and safety. Such procedures may vary among foods or classes of foods as appropriate. Where there is insufficient knowledge to establish such a procedure for a food or class of foods, the Secretary shall immediately initiate a program to develop such a procedure.

(4) 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 with respect to any food, he may direct an increase in the level of such surveillance (or otherwise modify the surveillance procedures) to the extent that he determines necessary. Such an order may be entered without regard to any requirement for an opportunity for a hearing, except that the Secretary shall comply with any hearing requirement as soon as practicable after the increase in the level of surveillance has been required.

(5) Chemical and other analyses performed under this section to determine the presence and amount of contamination in food shall be performed through the use of the best instruments, technology, and trained personnel which are reasonably available.

(6) Any person required to comply with the surveillance procedures established under this section shall establish and maintain such records as the Secretary may by regulation require pertaining to such surveillance and make such records available to the Secretary upon request.

(7) The Secretary may require by general or specific orders the submission of annual or special reports or answers in writing to specific questions containing such data and information relating to any surveillance procedures or the implementation thereof or any matter relating to detection of adulterated foods which may assist him in carrying out the purposes of this section. 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 with the consent of the Attorney General. 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.

(8) 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.

(c)(1) Every person who owns or operates an establishment in which food is processed upon acquiring information which supports the conclusion that such food is adulterated in a manner which would create an unreasonable risk to the public health, shall immediately

notify the Secretary of such adulteration if such food has left the control of such person. Such person shall also immediately notify the Secretary of any recall of such food which has left an establishment under his control. Nor which is adulterated in a manner which would create an unreasonable risk to the public health if such food has left an establishment under his control. No information or statements exclusively derived 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 a 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 of such adulteration, an evaluation of the risk related thereto, and a statement of the measures to be taken to effect protection against the risk created by the adulteration." (d) This section shall not apply to any processing subject to the exclusive jurisdiction of the Secretary of Agriculture.

REGISTRATION OF FOOD ESTABLISHMENTS¹

SEC. 411. (a) As used in this section and sections 402(f), 402(g), 403(o), 410, 801(a), and 801(e) of this Act, (1) the term "name" includes in the case of a partnership the name of each partner and in the case of a corporation the name of each principal corporate officer and the State of incorporation and (2) the terms "processing" and "processed" include manufacturing, processing, packing, labeling, storing, importing, or otherwise handling food.

(b) On or before December 31 of each year, every person who owns or operates an establishment in any State engaged in the processing of food shall register with the Secretary his name, principal place of business, the location of each such establishment, and for each such establishment, a complete list, in such form as the Secretary's regulations shall prescribe, of all foods or classes of foods processed at that establishment. Such list shall define the types of processing for each food or class of food. To achieve uniformity in the registration of classes of foods and types of processing, the Secretary shall promulgate regulations defining food classes and types of processing for purposes of the registration required by this section.

(c) Any person upon first engaging in the processing of food in any establishment which he owns or operates in any State shall immediately register with the Secretary the information required by subsection (b) of this section. Any person duly registered in accordance with this section shall notify the Secretary not later than ninety days after he ceases or discontinues the processing of any food or class of food in any establishment, but such notification shall not be required in the case of the temporary cessation of processing necessitated by the

¹ The Congress finds and declares that 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 foods are manufactured, processed, packed, labeled, stored or otherwise handled; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that 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 adversely burden, obstruct, and affect such interstate commerce.

seasonal character of operations at the particular establishment or caused by temporary conditions beyond the control of such person.

(d) Every person registered in accordance with subsection (b) or (c) of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the processing of food. Such registration shall include the information required by subsection (b).

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

(f) The Secretary shall make available for inspection to any person so requesting any registration statement filed pursuant to this section.

(g) This section shall not apply to such classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health. This section shall not apply to any establishment subject to the exclusive jurisdiction of the Secretary of Agriculture.

(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 of this Act.

(i) 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.

* * * * *

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) (1) The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs be delivered to the Secretary of Health, Education, and Welfare, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may

be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(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 411 of this Act.*

* * * * *

(e) (1) *Whenever the Secretary pursuant to section 410 of this Act issues a regulation specifying surveillance procedures of any food or class of foods, every person importing or offering for importation into the United States any such food or class of food shall file with the Secretary, at least thirty 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 compliance with the surveillance procedures specified in such regulation.*

(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 manufactured in compliance with the surveillance procedures promulgated in any applicable regulation under 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 import 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 import.*

* * * * *

SUPPLEMENTAL VIEWS OF MR. TAFT, MR. BEALL, AND MR. DOMINICK

Unfortunately, the press of time and business upon our Committee prevented giving this bill, S. 2373, the formal attention its potential deserves. A hearing was held in subcommittee on September 11, 1973 on a vastly different bill than what has now been reported. Six witnesses appeared at that September hearing, representing the Administration, three consumer groups and two industry associations. The entire transcript of the hearings covers less than 100 pages, and the limited comments on the original food surveillance provisions shared one commonality among the witnesses—all of them were critical of the food surveillance provisions as drafted.

A rewriting of the bill was accomplished by the Subcommittee and, as reported to the full Committee, contained greatly revised food surveillance provisions. As a result, we received many requests from members of the food industry for another hearing on the revised provisions. They pointed out that the new provisions in the reported bill had never undergone hearings, and requested an opportunity to suggest changes that they considered essential. To this end, we requested the Committee to hold an additional hearing. It was considered undesirable to remand the bill to subcommittee. Therefore, a compromise was struck under which the Committee staff and staff of Committee members met at various times with industry groups to receive statements and discuss the issues.

On November 5, a new Committee print was published. This contained changes which combined some of the major recommendations of some food industry representatives with some of the concepts in the bill as originally reported by the Subcommittee. As such compromises go, there was still much dissatisfaction with the provisions. Industry proponents suggested a series of revisions necessary for their support, and some industry representatives suggested that we go back to the reported bill with several revisions. In short, the most vocal industry groups on this issue could not agree at that time upon what type of legislation was appropriate.

The Committee reverted to the bill as reported by Subcommittee with several modifications, and reported it with my support. In the meantime, however, the various industry groups interested in this bill managed to reconcile their differences and come up with a number of major revisions which we believe deserves consideration. Unfortunately, these suggestions could not be made available to the Committee members in enough time to allow for adequate consideration before voting on S. 2373.

Basically, the concept of the industry groups is to impose upon *all* food processors the responsibility for adopting a safety assurance system to prevent adulteration which may be injurious to the public

health, and to grant the Food and Drug Administration the power to review these systems and to mandate safety practices where a significant number of establishments are processing food in such a manner as to present an unreasonable risk of such adulteration. In other words, if there was such a risk in a segment of the food industry, the FDA could promulgate safety practice requirements for the entire segment. Problems with individual plants or companies would be handled by FDA through seizure of products, injunctions and criminal prosecutions on an individual basis.

The industry approach appears to be far more comprehensive than the approach taken in the bill reported here. S. 2373 as reported would place all of the responsibility upon the FDA and still another advisory committee to search out problem areas and come up with regulations to solve these problems on an ad hoc basis. The industry approach would require an immediate response from all of industry, and still allow for FDA regulations.

This is an approach that deserves serious consideration at a further hearing. The industry group has come up with suggested language, some of which may not be entirely satisfactory, but it should be thoroughly reviewed before we send this bill to the floor. A hearing is possible, because the Commerce Committee still has jurisdiction over the bill, and a hearing is suggested because we must get some consumer and public viewpoints on this, as well as industry views.

All of the witnesses before our Committee testified that the responsibility for assuring the safety of food lies in the first instance with the food industry. Therefore, we hope that the Commerce Committee will exercise its jurisdiction and hold a hearing on this bill and take into consideration the suggested language of the food industry.

J. GLENN BEALL, Jr.
ROBERT TAFT, Jr.
PETER H. DOMINICK.

93D CONGRESS
1ST SESSION

S. 2373

[Report No. 93-605]

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 1973

Mr. MAGNUSON (for himself, Mr. HART, Mr. KENNEDY, Mr. JAVITS, and Mr. HUGHES) introduced the following bill; which was read twice, and by unanimous consent, referred to the Committee on Labor and Public Welfare until October 15, 1973, with instructions then to refer to the Committee on Commerce at the option of that committee

DECEMBER 7, 1973

Reported by Mr. KENNEDY, with an amendment

DECEMBER 7, 1973

Referred to the Committee on Commerce

[Strike out all after the enacting clause and insert the part printed in italic]

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Federal Food Inspection
4 Act of 1973".

5 SEC. 2. Chapter IV of the Federal Food, Drug, and
6 Cosmetic Act is amended by adding the following new
7 section at the end thereof:

1 ~~"SURVEILLANCE FOR ADULTERATED FOOD~~

2 ~~"Regulations~~

3 ~~"SEC. 410. (a) Not more than one hundred and eighty~~
4 ~~days after the enactment date of this section, the Secretary~~
5 ~~shall propose regulations which shall specify the surveillance~~
6 ~~procedures that he will follow for the detection and preven-~~
7 ~~tion of adulterated food. The Secretary may modify or~~
8 ~~amend such regulations at any time after they have be-~~
9 ~~come final on his own initiative or on the petition of any~~
10 ~~interested person. Initial regulations promulgated under this~~
11 ~~section shall become effective no later than one year from~~
12 ~~such date of enactment.~~

13 ~~"Minimum Requirements~~

14 ~~(b) The procedures prescribed by the Secretary un-~~
15 ~~der subsection (a) shall be such procedures for sur-~~
16 ~~veillance as the Secretary determines are necessary to~~
17 ~~carry out his responsibilities with respect to the detection and~~
18 ~~prevention of adulterated food under this and other acts ad-~~
19 ~~ministered by him, but such procedures shall require, at a~~
20 ~~minimum, levels of surveillance sufficient to provide reason-~~
21 ~~able assurance that the presence of adulterated food does not~~
22 ~~constitute an unreasonable threat to the public health or wel-~~
23 ~~fare. Where no practicable procedures are available to pro-~~
24 ~~vide the assurance required by this section, the Secretary~~
25 ~~shall include in regulations promulgated under this section~~

1 ~~(1)~~ a program for the development of such procedures
2 within the shortest feasible time; ~~(2)~~ specifications as to how
3 such program is to be carried out; and ~~(3)~~ a timetable for
4 the completion of such program.

5 "Hearings

6 "(c) Any person adversely affected by proposed regu-
7 lations, proposed modification, or amendment of such regula-
8 tions; or the denial of a petition for any such modification
9 or amendment may upon a showing of reasonable grounds,
10 file objections with the Secretary and request a hearing
11 which shall be granted by the Secretary. All hearings con-
12 ducted under this section shall consist of the oral and written
13 presentation of data, views, or arguments in accordance with
14 provisions of section 552 of title 5, United States Code.

15 "Increase in Surveillance Levels

16 "(d) If the Secretary finds a threat to the public
17 health or welfare which requires that there be an immedi-
18 ate increase in the level of surveillance with respect to any
19 food, he may direct an increase in the level of such surveil-
20 lance to the extent that he determines necessary. Such an
21 order may be entered without regard to any requirement for
22 previous notice or opportunity for a hearing, except that the
23 Secretary shall comply with any such notice or hearing re-
24 quirement as soon as practicable after such increase in the
25 level of surveillance has been initiated.

1 “Methodology

2 “(e) Analyses performed under this section to deter-
3 mine the presence and amount of adulteration in food shall
4 be performed through the use of the best instruments, tech-
5 nology, and trained personnel which are reasonably available.

6 “Public Access to Information

7 “(f) The Secretary shall make available to the public,
8 upon identifiable request and at cost, the results of any
9 analyses or research performed under this section.

10 “Relationship to Other Laws

11 “(g) This section shall not be construed to exempt the
12 Secretary or any other person from any obligation imposed
13 by any other provision of this Act or by the provisions of
14 any other Act. Nor shall this section be construed to permit
15 the use of any substance, practice, or conduct resulting in the
16 presence of adulterated food if such use, practice, or conduct
17 would not have been permitted in the absence of this
18 section.”.

19 *That this Act may be cited as the “Food Amendments of*
20 *1973”.*

21 TITLE I—FOOD SURVEILLANCE

22 *SEC. 101. Chapter IV of the Federal Food, Drug, and*
23 *Cosmetic Act (21 U.S.C. 321) is amended by adding at the*
24 *end thereof the following new section:*

1 "FOOD SURVEILLANCE PROCEDURES

2 "SEC. 410. (a)(1) Within six months after the date of
3 enactment of this Act the Secretary shall appoint and organize
4 a food surveillance advisory committee to study and report
5 to the Secretary existing and potential hazards to health and
6 safety related to food and recommend procedures to re-
7 duce such hazards. To the maximum extent practical, the
8 committee shall provide an opportunity for any interested
9 person to submit data and views on all matters considered by
10 the committee. All meetings of the committee shall be open to
11 all members of the public.

12 "(2)(A) Within one year after appointment and or-
13 ganization of the committee (which time may be extended by
14 the Secretary by a notice published in the Federal Register
15 stating good cause therefor), the committee shall issue a
16 report to the Secretary which report shall (i) determine
17 whether there are existing and potential health hazards re-
18 lated to food for which surveillance procedures can reduce
19 or eliminate such hazards, (ii) specify such hazards, and
20 (iii) rank such hazards by priority of public importance.
21 The report may also include recommendations regarding the
22 surveillance procedures to be established pursuant to para-
23 graph (1) of subsection (b). (B) As soon as possible after
24 receiving this report, the Secretary shall publish it in the
25 Federal Register and provide interested persons an oppor-

1 tunity to comment thereon. After reviewing such comments
2 and evaluating the report the Secretary shall determine
3 whether it is appropriate to act under subsection (b). Where
4 the Secretary deems such action appropriate he shall begin
5 implementing subsection (b) as expeditiously as is feasible.
6 If the Secretary determines that such action is inappropriate
7 he shall publish in the Federal Register his findings and an
8 adequate statement of reasons for failure to take action under
9 subsection (b) and provide interested persons an opportunity
10 to comment thereon. The Secretary shall determine the appro-
11 priateness of action under subsection (b) on the advisory
12 committee report within six months after the issuance of such
13 report.

14 “(3) The advisory committee shall constitute a perma-
15 nent advisory committee, which shall meet periodically, at
16 least twice each year, to review and if it so determines revise
17 its report and recommendations to the Secretary and to
18 monitor implementation of this section. Such committee shall
19 make such additional reports and recommendations to the
20 Secretary as it deems advisable. Upon the issuance of such
21 reports the Secretary shall comply with the requirements of
22 subparagraph (B) of paragraph (2) of this subsection.

23 “(4) The published reports and recommendations of the
24 committee shall constitute public notice that, as expeditiously
25 as is feasible, the Secretary will issue regulations under sub-

1 section (b) establishing specific surveillance procedures for
2 designated foods, except that such reports and recommenda-
3 tions shall not constitute notice when the Secretary has deter-
4 mined, pursuant to subparagraph (B) of paragraph 2 of
5 this subsection, that it is inappropriate to act under sub-
6 section (b). The publication of such reports and recom-
7 mendations shall not relieve the Secretary of the obligation to
8 provide notice as required by paragraph (1) of subsection
9 (b) of this section. Any interested person will have an op-
10 portunity, pending promulgation of such specific procedures,
11 to undertake studies and other work appropriate to establish
12 such procedures or to assure compliance with them.

13 “(5) Committee members shall be qualified by training
14 and experience in the safety of food or in the use of statistical
15 sampling techniques, analytical methodology, or other tech-
16 nical disciplines relevant to food surveillance. The pro-
17 visions of title 18, United States Code, chapter 11, shall
18 apply to voting members of the committee. In addition to
19 such technical experts, the committee shall include, as non-
20 voting members, a representative of consumer interests and a
21 representative of industry interests. Committee members may
22 be nominated by appropriate scientific, trade, and consumer
23 organizations. The Secretary shall designate one of the mem-
24 bers of the committee to serve as chairman. Committee
25 members shall, while attending meetings or confer-

1 *ences of the committee or otherwise engaged on its busi-*
2 *ness, be compensated at per diem rates fixed by the Secretary*
3 *but not in excess of the rate for Grade GS-18 of the General*
4 *Schedule at the time of such service, including traveltime,*
5 *and while so serving away from their homes or regular places*
6 *of business they may be allowed travel expenses (including*
7 *per diem in lieu of subsistence) as authorized by title 5,*
8 *United States Code, section 5703, for persons in the Govern-*
9 *ment service employed intermittently. The Secretary shall*
10 *furnish the committee with adequate clerical and other neces-*
11 *sary assistance, and shall prescribe by regulation the proce-*
12 *dures to be followed by the committee.*

13 “(b)(1) *The Secretary shall promulgate regulations or*
14 *modify existing regulations to carry out the purposes of this*
15 *section as expeditiously as is feasible. Such regulations*
16 *shall be promulgated in accordance with title 5, United States*
17 *Code, section 553, after notice and an opportunity for a hear-*
18 *ing: Provided, That the Secretary shall publish in the Federal*
19 *Register his findings and an adequate statement of reasons un-*
20 *derlying the provisions adopted, including responses to objec-*
21 *tions and comments of interested persons: And provided fur-*
22 *ther, That an order promulgating regulations or amendments*
23 *thereto pursuant to this section shall be subject to judicial re-*
24 *view in accordance with section 701 (f) of this Act. In promul-*
25 *gating or modifying such regulations the Secretary shall*

1 utilize the reports and recommendations of the food advisory
2 committee and comments thereon. Such regulations, which
3 may be proposed on the Secretary's own initiative or on behalf
4 of any interested person who has submitted a petition, shall
5 designate—

6 “(A) a food or class of foods subject to the surveil-
7 lance procedures being established,

8 “(B) the persons required to conduct such surveil-
9 lance in accordance with such procedures,

10 “(C) the contaminants, properties, unsanitary prac-
11 tices, or other factors (including but not limited to micro-
12 organisms, heavy metals, toxins, drug residues, pesti-
13 cide residues, filth, and other potentially harmful consti-
14 tuents and practices) for which surveillance is required,

15 “(D) the sampling methods and methods of inspec-
16 tion of establishments by which such surveillance shall be
17 accomplished,

18 “(E) the methods of analysis by which such sur-
19 veillance shall be accomplished,

20 “(F) the circumstances under which reports of such
21 surveillance shall be submitted to the Secretary, and

22 “(G) the activities (including sampling, analysis,
23 and inspections) which the Secretary will undertake to
24 assure compliance with the standard of paragraph (3)
25 of this section.

1 “(2) In accordance with procedures established by
2 the Secretary, any person or group of persons may petition
3 for an amendment of or exception to the regulations so as
4 to permit the use of methods other than those specified in the
5 regulations, upon a showing that such alternative method is
6 equal to or more effective than the method specified in the
7 regulations, and in those instances where the requested amend-
8 ment or exception is not approved by the Secretary, the Sec-
9 retary shall, upon the request of any interested person, refer
10 the amendment or exception to the food advisory committee
11 for its consideration and recommendation.

12 “(3) The procedures established pursuant to paragraph
13 (1) of this subsection shall be sufficient to reduce or eliminate
14 existing or potential health hazards related to food and to
15 provide reasonable assurance that food does not present an
16 unreasonable risk to the public health and safety. Such pro-
17 cedures may vary among foods or classes of foods as appro-
18 priate. Where there is insufficient knowledge to establish such
19 a procedure for a food or class of foods, the Secretary shall
20 immediately initiate a program to develop such a procedure.

21 “(4) If the Secretary finds a threat or potential threat
22 to the public health which requires that there be an immediate
23 increase in the level of surveillance with respect to any food,
24 he may direct an increase in the level of such surveillance
25 (or otherwise modify the surveillance procedures) to the

1 *extent that he determines necessary. Such an order may be*
2 *entered without regard to any requirement for an opportunity*
3 *for a hearing, except that the Secretary shall comply with any*
4 *hearing requirement as soon as practicable after the increase*
5 *in the level of surveillance has been required.*

6 “(5) Chemical and other analyses performed under this
7 section to determine the presence and amount of contamina-
8 tion in food shall be performed through the use of the best
9 instruments, technology, and trained personnel which are
10 reasonably available.

11 “(6) Any person required to comply with the surveil-
12 lance procedures established under this section shall establish
13 and maintain such records as the Secretary may by regu-
14 lation require pertaining to such surveillance and make such
15 records available to the Secretary upon request.

16 “(7) The Secretary may require by general or specific
17 orders the submission of annual or special reports or answers
18 in writing to specific questions containing such data and
19 information relating to any surveillance procedures or the
20 implementation thereof or any matter relating to detection of
21 adulterated foods which may assist him in carrying out the
22 purposes of this section. The district courts of the United
23 States shall have jurisdiction to enforce such general or
24 specific orders and to require access to such information
25 upon application of the Attorney General or of the Secretary

1 with the consent of the Attorney General. An action for such
2 enforcement may be brought in any district court of the
3 United States where the person or establishment involved is
4 found or transacts business.

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

12 “(c)(1) Every person who owns or operates an estab-
13 lishment in which food is processed upon acquiring infor-
14 mation which supports the conclusion that such food is
15 adulterated in a manner which would create an unreason-
16 able risk to the public health, shall immediately notify
17 the Secretary of such adulteration if such food has left
18 the control of such person. Such person shall also
19 immediately notify the Secretary of any recall of such food
20 which is adulterated in a manner which would create an
21 unreasonable risk to the public health if such food has left
22 an establishment under his control. No information or state-
23 ments exclusively derived from any notification required
24 under this section (except for information contained in records
25 required to be maintained under any provision of this Act)

1 shall be used as evidence in any proceeding brought against
2 an individual pursuant to section 303 of this Act with respect
3 to a violation of law occurring prior to or concurrently with
4 such notification.

5 “(2) The notifications required by paragraph (1) of
6 this subsection shall contain a clear description of such adul-
7 teration, an evaluation of the risk related thereto, and a
8 statement of the measures to be taken to effect protection
9 against the risk created by the adulteration.

10 “(d) This section shall not apply to any processing
11 subject to the exclusive jurisdiction of the Secretary of
12 Agriculture.”

13 SEC. 102. Section 402 of the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 342) is amended by adding:

15 “(f) If the methods used in, or facilities and controls
16 used for its processing do not conform to, or are not oper-
17 ated or administered in conformity with, current good manu-
18 facturing practices, as determined by regulations of the
19 Secretary promulgated in accordance with title 5, United
20 States Code, section 553, after consultation with all inter-
21 ested persons and after an opportunity for a hearing, to
22 assure that such food is not adulterated: Provided, That in
23 promulgating regulations pursuant to this provision the
24 Secretary shall publish in the Federal Register his findings
25 and an adequate statement of reasons underlying the provi-

1 sion adopted, including responses to objections and comments
2 of interested persons: And provided further, That an order
3 promulgating regulations or amendments thereto pursuant to
4 this section shall be subject to judicial review in accordance
5 with section 701(f) of this Act."

6 SEC. 103. (a) Section 301 of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 331) is amended by adding
8 the following:

9 "(q) The failure to comply with surveillance procedures
10 or current good manufacturing practices required pursuant
11 to section 402(f) or section 410 of this Act, the failure to
12 maintain or make available records or reports required
13 pursuant to section 410 of this Act, or the failure or the
14 refusal to furnish notification or other information as re-
15 quired by section 410 of this Act."

16 (b) Section 402 of such Act (21 U.S.C. 342) is
17 amended by adding:

18 "(g) If it is a food which was processed other than in
19 compliance with surveillance procedures required pursuant
20 to section 410."

21 SEC. 104. Section 801 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 381) is amended by adding
23 the following:

24 "(e)(1) Whenever the Secretary pursuant to section
25 410 of this Act issues a regulation specifying surveillance

1 procedures for any food or class of foods, every person im-
2 porting or offering for importation into the United States any
3 such food or class of food shall file with the Secretary, at least
4 thirty days prior to such importation, a certificate, in such
5 manner as the Secretary shall specify, demonstrating that
6 the particular imported food or class of foods has been pro-
7 duced in compliance with the surveillance procedures speci-
8 fied in such regulation.

9 “(2) The Secretary shall request the Secretary of
10 the Treasury to refuse admission into the United States, pur-
11 suant to this section, of any such food or class of food which
12 the Secretary determines has not been manufactured in
13 compliance with the surveillance procedures promulgated
14 in any applicable regulation under section 410 of this Act,
15 or where the importer has failed to file the certification
16 required in this subsection.

17 “(3) Any such food refused admission shall not be
18 admitted until such time as the Secretary may determine
19 that the food offered for import is not injurious to the public
20 health. For the purpose of making such determination, the
21 Secretary reserves the right to request that a duly authorized
22 employee or agent of the Secretary be permitted to inspect
23 the processing procedures employed in the production of
24 the food or class of food offered for import.”

25 SEC. 105. Section 201(f) of the Federal Food, Drug

1 *and Cosmetic Act (21 U.S.C. 321) is amended by inserting*
2 *the following immediately after the word "animals,": "except*
3 *that in sections 402(f), 410, and 411 such term shall not*
4 *include articles used for food or drink for animals,".*

5 TITLE II—FOOD ESTABLISHMENT

6 REGISTRATION

7 FINDINGS

8 *SEC. 201. The Congress finds and declares that in order*
9 *to make regulation of interstate commerce in food effective, it is*
10 *necessary to provide for registration and inspection of all es-*
11 *tablishments in which foods used for human consumption are*
12 *manufactured, processed, packed, labeled, stored or otherwise*
13 *handled; that the products of all such establishments are likely*
14 *to enter the channels of interstate commerce and directly affect*
15 *such commerce; and that the regulation of interstate commerce*
16 *in food, without provision for registration and inspection of*
17 *establishments that may be engaged only in intrastate com-*
18 *merce in such food, would discriminate against and depress*
19 *interstate commerce in such food and adversely burden,*
20 *obstruct, and affect such interstate commerce.*

21 *SEC. 202. Chapter IV of the Federal Food, Drug, and*
22 *Cosmetic Act, as amended by this Act, is further amended*
23 *by adding after section 410 the following new section:*

1 "REGISTRATION OF FOOD ESTABLISHMENTS

2 "SEC. 411. (a) As used in this section and sections
3 402(f), 402(g), 403(o), 410, 801(a), and 801(e) of this
4 Act, (1) the term 'name' includes in the case of a partnership
5 the name of each partner and in the case of a corporation the
6 name of each principal corporate officer and the State of in-
7 corporation and (2) the terms 'processing' and 'processed'
8 include manufacturing, processing, packing, labeling, storing,
9 importing, or otherwise handling food.

10 "(b) On or before December 31 of each year, every
11 person who owns or operates an establishment in any State
12 engaged in the processing of food shall register with the Secre-
13 tary his name, principal place of business, the location of
14 each such establishment, and for each such establishment, a
15 complete list, in such form as the Secretary's regulations shall
16 prescribe, of all classes of foods processed at that establish-
17 ment. Such list shall define the types of processing for each
18 food or class of food. To achieve uniformity in the registra-
19 tion of classes of foods and types of processing, the Secretary
20 shall promulgate regulations defining food classes and types
21 of processing for purposes of the registration required by
22 this section.

23 "(c) Any person upon first engaging in the processing

1 of food in any establishment which he owns or operates in
2 any State shall immediately register with the Secretary the
3 information required by subsection (b) of this section. Any
4 person duly registered in accordance with this section shall
5 notify the Secretary not later than ninety days after he
6 ceases or discontinues the processing of any food or class of
7 food in any establishment, but such notification shall not
8 be required in the case of the temporary cessation of process-
9 ing necessitated by the seasonal character of operations at
10 the particular establishment or caused by temporary condi-
11 tions beyond the control of such person.

12 “(d) Every person registered in accordance with sub-
13 section (b) or (c) of this section shall immediately regis-
14 ter with the Secretary any additional establishment which
15 he owns or operates in any State and in which he begins the
16 processing of food. Such registration shall include the infor-
17 mation required by subsection (b).

18 “(e) The Secretary may assign a registration number
19 to any person or any establishment registered in accordance
20 with this section.

21 “(f) The Secretary shall make available for inspection
22 to any person so requesting, any registration statement filed
23 pursuant to this section.

24 “(g) This section shall not apply to such classes of
25 persons as the Secretary may by regulation exempt from the

1 application of this section upon a finding that registration by
2 such classes of persons in accordance with this section is not
3 necessary for the protection of the public health. This section
4 shall not apply to any establishment subject to the exclusive
5 jurisdiction of the Secretary of Agriculture.

6 “(h) Every establishment in any State registered with
7 the Secretary pursuant to this section shall be subject to
8 inspection pursuant to section 704 of this Act.

9 “(i) The Secretary may by regulation provide for the
10 registration of foreign establishments engaged in the process-
11 ing of food intended to be offered for importation into the
12 United States.”

13 SEC. 203. Section 301 of the Federal Food, Drug, and
14 Cosmetic Act, as amended by this Act, is further amended
15 by adding after paragraph (q) the following:

16 “(r) The failure to register as required by section 411
17 of this Act.”.

18 SEC. 204. Section 403 of the Federal Food, Drug, and
19 Cosmetic Act is amended by adding after subsection (n)
20 thereof the following:

21 “(o) If it is a food and it was processed in an establish-
22 ment required to be registered under section 411 of this Act
23 and not so registered.”.

24 SEC. 205. Section 801(a) of such Act (21 U.S.C. 381
25 (a)) is amended by inserting “(1)” immediately after “(a)”
26 and adding at the end thereof:

1 “(2) The Secretary may refuse entry of any food
2 offered for importation into the United States which has
3 been processed in any establishment other than an estab-
4 lishment registered pursuant to section 411 of this Act.”

5 SEC. 206. (a) The amendments made by sections 203
6 and 204 of this Act shall take effect on the first day of the
7 seventh calendar month which begins after the month in which
8 this title is enacted.

9 (b) Any person who, on the day immediately preceding
10 the date of enactment of this title, owned or operated any
11 establishment in any State engaged in the processing of food,
12 may register his name, principal place of business, and loca-
13 tion of each such establishment, prior to the effective date of
14 this title. Such registration shall be deemed to have complied
15 with section 411 of the Federal Food, Drug, and Cosmetic
16 Act for the calendar year during which this title becomes
17 effective.

18 TITLE III—FOOD INGREDIENT LABELING

19 DISCLOSURE OF INGREDIENTS IN FOODS

20 SEC. 301. (a) Section 401 of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 341) is amended by striking
22 out the fourth sentence.

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

25 “(g) If it purports to be or is represented as a food
26 for which a definition and standard of identity has been

1 *prescribed by regulations as provided by section 401, unless*
2 *(1) it conforms to such definition and standard, and (2)*
3 *its label bears the name of the food specified in the definition*
4 *and standard."*

5 *(c)(1) Section 403(i) of such Act (21 U.S.C. 343*
6 *(i)) is amended by striking out "If it is not subject to the*
7 *provisions of paragraph (g) of this section unless its label*
8 *bears" and inserting in lieu thereof "If its label fails to*
9 *bear".*

10 *(2) Section 403(i) of such Act (21 U.S.C. 343(i))*
11 *is further amended by inserting "(in the order of their*
12 *predominance)" immediately after "each such ingredient".*

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

16 *EFFECTIVE DATE*

17 *SEC. 302. The amendments made by this title shall take*
18 *effect on the first day of the thirteenth month beginning*
19 *after the date of their enactment, except that such effective*
20 *date shall be postponed, if the Secretary of Health, Educa-*
21 *tion, and Welfare determines that there is good cause there-*
22 *for, for a period not to exceed an additional twelve months*
23 *with respect to any specific food product not in compliance*
24 *with such amendments, other than a product bearing a label*
25 *printed after the first day of the fourth month beginning*
26 *after the date of such enactment.*

