

105TH CONGRESS
2D SESSION

H. R. 3676

To establish a comprehensive program to ensure the safety of food products intended for human consumption which are regulated by the Food and Drug Administration.

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1998

Mr. PALLONE (for himself, Mr. BONIOR, Mr. GREEN, Ms. DELAURO, Mr. WYNN, Mr. FROST, Mr. LEWIS of Georgia, Ms. FURSE, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Ms. MCCARTHY of Missouri, Mr. PASCRELL, Mr. MARTINEZ, Ms. JACKSON-LEE, Ms. CARSON, Mr. SERRANO, Mr. RUSH, Mr. ENGEL, Mr. ANDREWS, Mr. SAWYER, Ms. KAPTUR, Mr. CUMMINGS, Mr. WAXMAN, Mrs. LOWEY, Mr. MCGOVERN, Mr. MANTON, Ms. ESHOO, Mr. SANDERS, Mr. MARKEY, and Mr. MENENDEZ) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish a comprehensive program to ensure the safety of food products intended for human consumption which are regulated by the Food and Drug Administration.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Consumer Food Safety Act of 1998”.

6 (b) TABLE OF CONTENTS.—

- Sec. 1. Short title; table of contents.
 Sec. 2. Definitions.

TITLE I—NATIONAL FOOD SAFETY PROGRAM

- Sec. 101. Administration of national program.
 Sec. 102. Registration of processors and importers.
 Sec. 103. Process controls to reduce the adulteration of food products.
 Sec. 104. Inspections of processors and importers.
 Sec. 105. Tolerances for contaminants in food.
 Sec. 106. State and Federal cooperation.
 Sec. 107. Imports.

TITLE II—RESEARCH AND EDUCATION

- Sec. 201. Public health assessment system.
 Sec. 202. Public education and advisory system.
 Sec. 203. Research.

TITLE III—ENFORCEMENT

- Sec. 301. Amendments to the Federal Food, Drug, and Cosmetic Act.

TITLE IV—AUTHORIZATION

- Sec. 401. Authorization of appropriations.

1 **SEC. 2. DEFINITIONS.**

2 For purposes of this Act:

3 (1) The term “contaminants” includes bacteria,
 4 chemical contaminants, natural toxins, viruses, para-
 5 sites, and physical hazards that when found on or in
 6 food can cause human illness or injury.

7 (2) The term “facility” includes any factory,
 8 warehouse, establishment, or importer that handles
 9 or processes food.

10 (3) The term “process” means the commercial
 11 harvesting, preparation, manufacture, or transpor-
 12 tation of food products.

13 (4) The term “Secretary” means the Secretary
 14 of Health and Human Services.

1 **TITLE I—NATIONAL FOOD**
2 **SAFETY PROGRAM**

3 **SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.**

4 (a) IN GENERAL.—

5 (1) Persons who produce or process food for
6 human consumption have the responsibility to pre-
7 vent or minimize food safety hazards related to their
8 products. The Secretary shall administer a national
9 program for the purpose of protecting human health
10 by ensuring that the food industry has effective pro-
11 grams in place to assure the safety of food products
12 consumed in the United States.

13 (2) The program shall—

14 (A) be based on a comprehensive analysis
15 of the hazards associated with different food
16 products and with the harvesting, processing,
17 and handling of different food products, includ-
18 ing the identification and evaluation of—

19 (i) the severity of the potential health
20 risks;

21 (ii) the sources and specific points of
22 potential contamination that may render
23 food products unsafe for human consump-
24 tion; and

1 (iii) the potential for persistence, mul-
2 tiplication, or concentration of naturally
3 occurring or added contaminants in foods
4 and food products;

5 (B) take into consideration the distinctive
6 characteristics of food production and process-
7 ing;

8 (C) establish inspection and oversight pro-
9 cedures to monitor that facilities are utilizing
10 preventive controls to minimize or eliminate
11 identifiable hazards; and

12 (D) require each food processing facility to
13 annually register with the Secretary.

14 (b) PROGRAM ELEMENTS.—The program shall pro-
15 vide for—

16 (1) implementation of a national system for the
17 registration and quarterly inspection of facilities and
18 importers. Quarterly inspections can be waived by
19 plants that meet the Secretary’s standards for ex-
20 ceptional or negligible-risk facilities or importers;

21 (2) development of a program to oversee the
22 implementation of process controls in food process-
23 ing facilities;

24 (3) the establishment and enforcement of
25 health-based standards for (A) substances which

1 may contaminate food and (B) safety and sanitation
2 in the processing and handling of food products;

3 (4) implementation of a sampling program to
4 ensure that industry programs to prevent food con-
5 tamination are effective and that food products meet
6 the standards established in paragraph (1);

7 (5) implementation of procedures and require-
8 ments to ensure the safety of imported food prod-
9 ucts;

10 (6) coordination with other Federal agencies or
11 State governments in carrying out inspection, en-
12 forcement, and monitoring;

13 (7) implementation of a national surveillance
14 system to assess the health risks associated with the
15 human consumption of food products, in cooperation
16 with the Secretary of Agriculture and the Centers
17 for Disease Control and Prevention;

18 (8) development of public education and advi-
19 sory programs; and

20 (9) implementation of a research program in
21 furtherance of the purposes of this Act.

22 **SEC. 102. REGISTRATION OF PROCESSORS AND IMPORT-**
23 **ERS.**

24 (a) IN GENERAL.—Any facility engaged in processing
25 of food products and any person who imports food prod-

1 icts shall register with the Secretary. Application for reg-
2 istration shall be made to the Secretary using such forms
3 and containing such information as the Secretary shall
4 prescribe by regulation within 24 months after the date
5 of enactment of this Act. Upon receipt and review of a
6 completed application, the Secretary shall issue to the ap-
7 plicant a certificate of registration unless good cause is
8 shown why such application should be denied. The Sec-
9 retary shall promptly notify any applicant of such denial,
10 include a written explanation of the reasons for such de-
11 nial, and provide an opportunity for a hearing or re-
12 application upon request.

13 (b) SUSPENSION OF REGISTRATION.—

14 (1) The registration may be suspended imme-
15 diately by the Secretary for—

16 (A) failure to permit access for inspection
17 under this Act;

18 (B) violation of this Act or regulation
19 issued under this Act, where the Secretary de-
20 termines that such suspension is likely to pre-
21 vent a significant risk of adverse health con-
22 sequences; or

23 (C) conviction of the applicant or reg-
24 istrant in any Federal or State court of—

1 (i) any felony other than a felony
2 based upon the acquiring, handling, or dis-
3 tribution of adulterated or misbranded
4 food; or

5 (ii) more than one violation of any law
6 other than a violation involving any fraud
7 in connection with transactions in food.

8 (2) Any registration suspended under para-
9 graph (1) may be reinstated whenever the Secretary
10 determines that suspension is no longer necessary.

11 (c) EXEMPTION AUTHORITY.—The Secretary may by
12 regulation exempt classes of facilities from the require-
13 ments of subsection (a) if the Secretary determines that
14 the registration of such facilities or persons is not needed
15 for effective enforcement of this Act.

16 **SEC. 103. PROCESS CONTROLS TO REDUCE THE ADULTERA-**
17 **TION OF FOOD PRODUCTS.**

18 (a) IN GENERAL.—The Secretary shall, upon the
19 basis of the best available scientific and technological data,
20 prescribe regulations to—

21 (1) limit the presence of human pathogens and
22 other potentially harmful substances in food prod-
23 ucts;

24 (2) ensure that all registered facilities imple-
25 ment appropriate measures to control and reduce

1 the presence and growth of human pathogens and
2 other potentially harmful substances on food prod-
3 ucts;

4 (3) ensure that all fully processed or ready-to-
5 eat food products are processed in a sanitary man-
6 ner, using reasonably available techniques and tech-
7 nologies to eliminate any human pathogens or other
8 potentially harmful substances likely to cause
9 foodborne illness; and

10 (4) ensure that food products intended for final
11 processing outside commercial establishments are la-
12 beled with instructions for handling and preparation
13 for consumption which, when adhered to, will de-
14 stroy any human pathogens or other potentially
15 harmful substance likely to cause foodborne illness.

16 (b) REGULATIONS.—The Secretary shall, within one
17 year of the enactment of this Act, issue regulations that
18 require all registered facilities to adopt processing controls
19 adequate to protect public health and to limit the presence
20 and growth of human pathogens and other potentially
21 harmful substances in food products prepared in any reg-
22 istered facility. Such regulations shall—

23 (1) set standards for sanitation;

24 (2) set tolerances for biological, chemical, and
25 physical hazards as appropriate;

1 (3) require process controls to assure that food
2 is safe and that relevant regulatory and safety
3 standards are met;

4 (4) require recordkeeping to monitor compli-
5 ance;

6 (5) require sampling to assure that processing
7 controls are effective and that regulatory standards
8 are being met; and

9 (6) provide for agency access to records kept by
10 official establishments and submission of copies of
11 such records to the Secretary as the Secretary
12 deems appropriate.

13 Public access to records that relate to the adequacy of
14 measures taken by official establishments to protect the
15 public health and to limit the presence and growth of
16 human pathogens and other potentially harmful sub-
17 stances shall be governed by (5 U.S.C. 552 et seq.). The
18 Secretary may, as the Secretary deems necessary, require
19 any person, firm, or corporation with responsibility for or
20 control over food ingredients to adopt processing controls,
21 where such processing controls are needed to assure the
22 protection of public health.

23 **SEC. 104. INSPECTIONS OF PROCESSORS AND IMPORTERS.**

24 (a) NATURE OF INSPECTIONS.—

1 (1) The inspection system shall provide for fre-
2 quent unannounced inspections of food processing
3 and importing facilities to determine if such facilities
4 are operated in a sanitary manner and if food prod-
5 ucts are unsafe for human consumption, or adulter-
6 ated or misbranded under the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 301 et seq.). Inspec-
8 tions shall include review of processing records and
9 sampling of food products.

10 (2) Inspections shall be conducted at least quar-
11 terly, unless the Secretary determines that the facil-
12 ity, is an exceptional or negligible-risk facility under
13 standards established by the Secretary.

14 (3) Standards for exceptional or negligible-risk
15 facilities shall consider the hazards associated with
16 the type of product being produced; and the facility's
17 history of compliance, food safety problems and such
18 other factors as the Secretary may deem appro-
19 priate. The Secretary shall specify an alternative in-
20 spection frequency for each facility which is deemed
21 exceptional or negligible-risk. Each inspection shall
22 include an examination of whether the facility con-
23 tinues to meet the standards for exceptional or neg-
24 ligible-risk facilities.

25 (b) CONDUCT OF INSPECTIONS.—

1 (1) An inspection under subsection (a) of any
2 domestic, foreign, or importing facility shall extend
3 to all things therein (including records required to
4 be maintained under subsection (e), processes, con-
5 trols, and premises) that bear on whether food prod-
6 ucts are in compliance with this Act or the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
8 seq.). Access to records may include the copying of
9 such records.

10 (2) In conducting such inspections, officers or
11 employees duly designated by the Secretary, upon
12 presenting appropriate credentials to the owner, op-
13 erator, or agent in charge, are authorized—

14 (A) to enter at reasonable times any facil-
15 ity in which persons are engaged in the food
16 processing or importing of food products, or to
17 enter any vehicle being used to transport or
18 hold such food products;

19 (B) to inspect in a reasonable manner such
20 facility or vehicle and all pertinent equipment,
21 finished and unfinished materials, containers,
22 labeling, processes, controls, and premises; and

23 (C) to collect and retain samples of food
24 products or ingredients or of any other items
25 found during an inspection that may contribute

1 to a finding of whether such food products are
2 unsafe for human consumption or adulterated
3 or misbranded under the Food, Drug, and Cos-
4 metic Act (21 U.S.C. 301 et seq.).

5 (3) Immediately after completion of inspection,
6 the officer or employee making the inspection shall
7 give to the owner, operator, or agent in charge a re-
8 port in writing setting forth any conditions or prac-
9 tices observed which indicate that either processing
10 controls are inadequate to prevent or minimize food
11 safety hazards or that any food from such facility is
12 unsafe for human consumption, or adulterated or
13 misbranded under the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 301 et seq.).

15 (c) PRODUCT DETENTION AND CONDEMNATION.—

16 (1) If, during an inspection conducted under
17 this section, an officer or employee making the in-
18 spection has reason to believe that a food product is
19 unsafe for human consumption, or adulterated or
20 misbranded under the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 301 et seq.), such officer or
22 employee may order the food product segregated,
23 impounded, and if objection is not made within 48
24 hours, condemned. If objection is made, such food
25 products that are in perishable form may be proc-

1 essed to the extent necessary to prevent spoilage,
2 and a hearing shall be commenced expeditiously.

3 (2) If the Secretary determines that, through
4 relabeling or other action, such food products can be
5 brought into compliance with this Act and the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
7 et seq.), the food may be released following a deter-
8 mination by the Secretary that such relabeling or
9 other action as specified by the Secretary has been
10 performed.

11 (3) Any food product condemned without objec-
12 tion, or after hearing and judicial review, shall be
13 destroyed under supervision of the Secretary.

14 (d) OFFICIAL MARK.—The Secretary shall prescribe
15 by regulation the conditions under which any food product
16 shall display an official mark, when needed to facilitate
17 exports, that signifies that the food product has been proc-
18 essed in accordance with standards approved by the Sec-
19 retary. Such a mark may be subject to a fee.

20 (e) MAINTENANCE OF RECORDS.—Each facility or
21 person registered under this section shall maintain and
22 make available for inspection by the Secretary such
23 records as the Secretary may prescribe. Such records shall
24 be maintained for a reasonable period of time as deter-

1 mined by the Secretary. The records shall include, but are
2 not limited to, information concerning—

3 (1) the origin, receipt, delivery, sale, movement,
4 holding, and disposition of food products or ingredi-
5 ents; the identity and amount of ingredients used in
6 the food; the processing of the food; the results of
7 laboratory, sanitation, or other quality control tests
8 performed on the food or in the facility; consumer
9 complaints concerning the food or its packaging; and

10 (2) other matters reasonably related to whether
11 food products may be unsafe for human consump-
12 tion, or adulterated or misbranded under the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
14 et seq.).

15 (f) OTHER INSPECTION RIGHTS AND DUTIES.—Sec-
16 tion 704 of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 374) is amended by adding at the end the fol-
18 lowing new subsection:

19 “(f) The rights and duties under this section of duly
20 designated officers and employees and of other persons
21 shall apply to enforcement of the Consumer Food Safety
22 Act of 1998 to the same extent and in the same manner
23 as they apply to enforcement of this Act.”.

1 **SEC. 105. TOLERANCES FOR CONTAMINANTS IN FOOD.**

2 (a) TOLERANCES.—The Secretary shall establish tol-
3 erances limiting the quantity of contaminants, except for
4 pesticide residues regulated under section 408 or food ad-
5 ditives regulated under section 409 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), that,
7 when found in food products, may render such products
8 unsafe for human consumption. Contaminants include but
9 are not limited to bacteria, chemical contaminants, natural
10 toxins, viruses and parasites that when found on or in food
11 can cause human illness. Such tolerances may include in-
12 dicators (including indicator organisms) from which it
13 may reasonably be inferred that a contaminant is present
14 in a food product. In developing a tolerance, the Secretary
15 shall take into account the extent to which consumers may
16 be exposed to such contaminant from sources other than
17 food, and the extent to which such contaminant can be
18 avoided or minimized in the commercial handling and
19 processing of such food.

20 (b) REGULATIONS.—

21 (1) The Secretary, after notice and an oppor-
22 tunity for comment, shall promulgate regulations to
23 implement subsection (a) within 48 months after the
24 date of enactment of this Act. In promulgating such
25 regulations, the Secretary shall establish tolerances
26 for the contaminants that the Secretary determines

1 are having the greatest public health impact as early
2 as feasible after implementation of this Act.

3 (2) A tolerance established under this section
4 shall be based on—

5 (A) a scientific analysis of the health risks
6 attributable to the contaminant for which the
7 tolerance is established; and

8 (B) analysis of the risks for sensitive
9 groups, such as children, elderly, pregnant
10 women and the immune compromised.

11 (3) The Secretary shall, in a timely manner,
12 issue revisions to the regulations under paragraph
13 (1) which take into account new information. The
14 Secretary may contract with the National Academy
15 of Sciences to provide such data or assistance as the
16 Secretary deems necessary.

17 (c) REPORT.—The Secretary shall report to the Con-
18 gress on the progress of the Secretary in establishing tol-
19 erances under this section. The report shall include a de-
20 scription of the research that has been conducted with re-
21 spect to such tolerances and the research that must be
22 conducted before additional tolerances may be established,
23 the health significance of the lack of such additional toler-
24 ances, a timetable for the establishment of such toler-
25 ances, and the estimated costs, including costs of research,

1 associated with the establishment of such tolerances. The
2 report shall be transmitted on or about the end of the 18th
3 month after the date of enactment of this Act, and bienni-
4 ally thereafter during the 6-year period that begins on
5 such date of enactment.

6 **SEC. 106. STATE AND FEDERAL COOPERATION.**

7 (a) IN GENERAL.—The Secretary shall work with the
8 States in undertaking activities and programs that con-
9 tribute to the national food safety program so that State
10 and Federal programs function in a coordinated and cost-
11 effective manner. With the assistance provided in sub-
12 section (b), the Secretary shall encourage States to—

13 (1) continue, strengthen, or establish State food
14 safety programs, especially with respect to the regu-
15 lation of retail commercial food establishments,
16 transportation, harvesting, and fresh markets; and

17 (2) establish procedures and requirements for
18 ensuring that food products under the jurisdiction of
19 the State are not unsafe for human consumption.

20 (b) ASSISTANCE.—

21 (1) The Secretary may provide to a State, for
22 planning, developing, and implementing a food safe-
23 ty program—

24 (A) advisory assistance;

1 (B) technical and laboratory assistance
2 and training (including necessary materials and
3 equipment); and

4 (C) financial and other aid.

5 (c) SERVICE AGREEMENTS.—The Secretary may,
6 under agreements entered into with Federal, State, or
7 local agencies, use on a reimbursable basis or otherwise
8 the personnel, services, and facilities of such agencies in
9 carrying out their responsibilities under this Act. Such an
10 agreement shall provide that any compliance records, no-
11 tices, or reports issued in connection with activities under
12 the agreement and in the possession of the agency or gov-
13 ernment which entered into the agreement shall be made
14 available in accordance with section 552 of title 5, United
15 States Code. Agreements with a State under this sub-
16 section may provide for training of State employees.

17 **SEC. 107. IMPORTS.**

18 (a) ROLE OF SECRETARY.—Within 24 months after
19 the date of enactment of this Act, the Secretary shall es-
20 tablish and administer a comprehensive and efficient sys-
21 tem to ensure the safety of food imported into the United
22 States. The Secretary shall routinely inspect processing
23 facilities in exporting nations and imports at ports of entry
24 into the United States. The Secretary shall assure the ef-

1 fective operation through verification and other activities
2 as the Secretary considers necessary.

3 (b) IMPORT REQUIREMENTS.—

4 (1) No food product may enter the United
5 States, or be withdrawn from a warehouse, for con-
6 sumption in the United States if such food prod-
7 uct—

8 (A) appears unsafe for human consump-
9 tion, or adulterated or misbranded under the
10 Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 301 et seq.);

12 (B) is not marked or labeled as required
13 by regulations for domestic or imported articles;
14 or

15 (C) does not comply with the requirements
16 of this section.

17 (2) Upon entry for consumption in the United
18 States, food products that are not prohibited from
19 entry or from withdrawal from a warehouse under
20 paragraph (1) shall be deemed to be and treated as
21 domestic food products, except that all labeling of
22 such products shall clearly identify the country of
23 origin to facilitate the identification of products
24 linked to outbreaks of illness.

25 (c) INSPECTION OF IMPORTS.—

1 (1) Food products that are offered for importa-
2 tion, or withdrawn from a warehouse, for consump-
3 tion in the United States, shall be subject to exami-
4 nations inspections, sampling, and such other proce-
5 dures at the port of entry or in the exporting nation
6 by officers or employees duly designated by the Sec-
7 retary. Such procedures shall be conducted with
8 such frequency and in such manner as the Secretary
9 may prescribe by regulation.

10 (2) Food products from a nation that is cer-
11 tified for such food products under subsection (e)(3)
12 shall be subject to random examinations, inspections,
13 sampling, and other procedures. Food products from
14 a nation that is not certified for such food products
15 under subsection (e)(3) shall be subject to such in-
16 tensified examinations, inspections, sampling, and
17 other verification procedures, including inspection in
18 the country of origin, as the Secretary determines
19 are necessary to ensure compliance with this Act.

20 (d) DETENTION OF IMPORTED FOOD PRODUCT.—If
21 during an inspection or other verification procedure car-
22 ried out under this section, an officer or employee conduct-
23 ing the procedure has reason to believe that a food product
24 is unsafe for human consumption, or adulterated or mis-
25 branded under the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 301 et seq.), such officer or employee may
2 order the food product segregated, impounded, and if ob-
3 jection is not made within 48 hours, condemned. If objec-
4 tion is made, such food products that are in perishable
5 form may be processed to the extent necessary to prevent
6 spoilage, and a hearing shall be commenced expeditiously.
7 The final condemnation or other disposition of such food
8 product shall be subject to the provisions of section 104(c).

9 (e) AGREEMENTS WITH FOREIGN NATIONS.—

10 (1) The Secretary may enter into an agreement
11 with any nation desiring to export food products to
12 the United States. Prior to concluding such an
13 agreement, the Secretary shall evaluate the food
14 safety program of the foreign nation to determine if
15 such program provides at least the same level of pro-
16 tection, with respect to food products intended for
17 export to the United States, as domestic laws that
18 affect the safety of the food supply. In such evalua-
19 tion, the Secretary shall consider—

20 (A) the potential for health, sanitary, envi-
21 ronmental, or other conditions within the for-
22 eign nation to adversely affect the safety of
23 food products exported from such nation; and

1 (B) how well the food safety programs of
2 the foreign nation functions to minimize any
3 adverse effects on such safety.

4 (2) Any agreement under this subsection with a
5 nation desiring to export food products to the
6 United States shall—

7 (A) require that the exporting nation
8 shall—

9 (i) establish and maintain a food safe-
10 ty system that is adequate to ensure that
11 the food products intended for export to
12 the United States are safe for human con-
13 sumption, and not adulterated or mis-
14 branded under the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 301 et seq.);
16 and

17 (ii) promptly notify the Secretary of
18 any violations affecting the safety of food
19 products exported or intended for export to
20 the United States;

21 (B) provide for such activities (whether in
22 the exporting nation or at the port of entry dur-
23 ing importation) by the Secretary, including ex-
24 aminations, inspections, sampling, and testing,
25 at such stages in the growth or harvest of food,

1 or in the processing or handling of food prod-
2 ucts, as the Secretary considers appropriate to
3 ensure that the food safety program of the ex-
4 porting nation continues to provide at least the
5 same level of protection, with respect to food
6 products intended for export to the United
7 States, as domestic laws that affect the safety
8 of the food supply; and

9 (C) provide for reciprocity with respect to
10 the treatment of food imports and exports be-
11 tween the United States and the exporting na-
12 tion.

13 (3) If the Secretary determines that a nation
14 desiring to export food products to the United States
15 has a program that provides at least the saline level
16 of protection, with respect to food products intended
17 for export to the United States, as domestic laws
18 that affect the safety of the food supply, the Sec-
19 retary shall, upon entry into force of an agreement
20 under subsection (e)(1), certify the types of food
21 products for which the nation maintains such a pro-
22 gram.

23 (4)(A) The Secretary shall periodically or for
24 good cause, and not less than once every 3 years, re-
25 view certifications made under paragraph (3), and

1 shall revoke the certification of any nation that the
2 Secretary determines is not maintaining a food safe-
3 ty program that provides at least the same level of
4 protection, with respect to food products intended
5 for export to the United States, as domestic laws
6 that affect the safety of the food supply.

7 (B) The Secretary shall review and modify, as
8 needed, an agreement made under paragraph (1)
9 with any nation whose certification has been revoked
10 under subparagraph (A) of this paragraph.

11 **TITLE II—RESEARCH AND** 12 **EDUCATION**

13 **SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.**

14 (a) COOPERATION WITH THE CENTERS FOR DISEASE
15 CONTROL AND PREVENTION.—The Secretary shall work,
16 through the Centers for Disease Control and Prevention,
17 to include food in an active surveillance system, based on
18 a representative proportion of the population of the United
19 States, and to assess more accurately the frequency and
20 sources of human illness in the United States associated
21 with the consumption of food.

22 (b) PUBLIC HEALTH SAMPLING.—

23 (1) Within 12 months after the date of enact-
24 ment of this Act, the Secretary in cooperation with
25 the Secretary of Agriculture shall establish guide-

1 lines for a sampling system under which the Sec-
2 retary and the Secretary of Agriculture shall take
3 and analyze samples of food products to assist the
4 Secretary in carrying out this Act and the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
6 seq.), and to more accurately assess the nature, fre-
7 quency of occurrence, and amounts of contaminants
8 in food products.

9 (2) Such sampling system shall provide—

10 (A) statistically valid monitoring, including
11 market-basket studies, on the nature, frequency
12 of occurrence, and amounts of contaminants in
13 food products available to consumers; and

14 (B) at the request of the Secretary, such
15 other information, including analysis of mon-
16 itoring and verification samples, as the Sec-
17 retary determines may be useful in assessing
18 the occurrence of contaminants in food prod-
19 ucts.

20 (c) ASSESSMENT OF HEALTH HAZARDS.—Through
21 the surveillance system referred to in subsection (a) and
22 the sampling system described in subsection (b), the Sec-
23 retary shall rank food categories based on their hazard
24 to human health and identify appropriate industry and

1 regulatory approaches to minimize hazards in the food
2 supply. Such analysis could include—

3 (1) the safety of commercial harvesting and
4 processing, as compared with the health hazards as-
5 sociated with food products that are harvested for
6 recreational or subsistence purposes and prepared
7 noncommercially;

8 (2) the safety of food products that are domes-
9 tically harvested and processed, as compared with
10 the health hazards associated with food products
11 that are harvested or processed outside the United
12 States; and

13 (3) contamination originating from handling
14 practices that occur prior to or after sale of food
15 products to consumers.

16 **SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

17 (a) PUBLIC EDUCATION.—The Secretary, in coopera-
18 tion with private and public organizations, including the
19 cooperative extension services and appropriate State enti-
20 ties, shall design and implement a national public edu-
21 cation program on food safety. The program shall pro-
22 vide—

23 (1) information to the public regarding Federal
24 standards and good practice requirements and pro-

1 motion of public awareness understanding, and ac-
2 ceptance of such standards and requirements;

3 (2) information to health professionals so that
4 they may improve diagnosis and treatment of food-
5 related illness and advise individuals whose health
6 conditions place them in particular risk; and

7 (3) such other information or advice to consum-
8 ers and other persons as the Secretary determines
9 will promote the purposes of this Act.

10 (b) HEALTH ADVISORIES.—The Secretary, in con-
11 sultation with the Secretary of Agriculture and the Admin-
12 istrator of the Environmental Protection Agency, shall
13 work with the States and other appropriate entities to—

14 (1) develop and distribute regional and national
15 advisories concerning food safety;

16 (2) develop standardized formats for written
17 and broadcast advisories; and

18 (3) incorporate State and local advisories into
19 the national public education program required
20 under subsection (a).

21 **SEC. 203. RESEARCH.**

22 (a) IN GENERAL.—The Secretary shall conduct re-
23 search to assist in the implementation of this Act, includ-
24 ing studies to—

1 (1) improve sanitation and food safety practices
2 in the processing of food products;

3 (2) develop improved techniques for the mon-
4 itoring of food and inspection of food products;

5 (3) develop efficient, rapid, and sensitive meth-
6 ods for determining and detecting the presence of
7 contaminants in food products;

8 (4) determine the sources of contamination of
9 food and food products with contaminants; and

10 (5) develop consumption data with respect to
11 food products.

12 (b) CONTRACT AUTHORITY.—The Secretary is au-
13 thorized to enter into contracts and agreements with any
14 State, university, other government agencies or other per-
15 sons to carry out the activities under this section.

16 **TITLE III—ENFORCEMENT**

17 **SEC. 301. AMENDMENTS TO THE FEDERAL FOOD, DRUG,** 18 **AND COSMETIC ACT.**

19 (a) IN GENERAL.—The Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 301 et seq.) is amended by add-
21 ing after section 413 the following new sections:

22 **“SEC. 414. NOTIFICATION AND RECALL.**

23 “(a) NOTICE TO SECRETARY OF ADULTERATION OR
24 MISBRANDING.—Any person (other than a household con-
25 sumer or other individual who is the intended consumer

1 of an article of food) that has a reasonable basis for believ-
2 ing that any article of food introduced into or in interstate
3 commerce, or held for sale (whether or not the first sale)
4 after shipment in interstate commerce, may be adulterated
5 or misbranded or otherwise in violation of the Consumer
6 Food Safety Act of 1998 shall immediately notify the Sec-
7 retary, in such manner and by such means as the Sec-
8 retary may by regulation prescribe, of the identity and lo-
9 cation of such article.

10 “(b) RECALL AND CONSUMER NOTIFICATION.—

11 “(1) VOLUNTARY PROCEDURES.—If the Sec-
12 retary finds, upon notification under subsection (a)
13 or otherwise, that any article of food is adulterated
14 or misbranded when introduced into or while in
15 interstate commerce or while held for sale (whether
16 or not the first sale) after shipment in interstate
17 commerce and there is a reasonable probability that
18 such article, if consumed, would present a threat to
19 public health, as determined by the Secretary, the
20 Secretary shall provide the appropriate persons (in-
21 cluding the manufacturers, importers, distributors,
22 or retailers) with an opportunity to—

23 “(A) cease distribution of such article;

24 “(B) notify all persons—

1 “(i) producing, manufacturing, pack-
2 ing, processing, preparing, treating, pack-
3 aging, distributing, or holding such article;
4 or

5 “(ii) to which such article has been
6 distributed, transported, or sold, to imme-
7 diately cease distribution of such article;

8 “(C) recall such article;

9 “(D) provide, in consultation with the Sec-
10 retary, notice to consumers to whom such arti-
11 cle was, or may have been, distributed; or

12 “(E) take any combination of the above
13 measures, as appropriate in the circumstances.

14 “(2) PRE-HEARING ORDER TO CEASE DISTRIBU-
15 TION AND GIVE NOTICE.—If such person refuses to
16 or does not voluntarily cease distribution, make noti-
17 fication, recall such article, or provide notice to con-
18 sumers, as applicable, within the time and in the
19 manner prescribed by the Secretary, the Secretary
20 shall, by order, require, as the Secretary deems nec-
21 essary, such person to—

22 “(A) immediately cease distribution of
23 such article;

24 “(B) immediately notify all persons—

1 “(i) producing, manufacturing, pack-
2 ing, processing, preparing, treating, pack-
3 aging, distributing, or holding such article;
4 or

5 “(ii) to which such article has been
6 distributed, transported, or sold, to imme-
7 diately cease distribution of such article; or

8 “(C) immediately take the actions specified
9 in both subparagraphs (A) and (B).

10 “(3) NOTIFICATION OF CONSUMERS BY SEC-
11 RETARY.—The Secretary shall, as the Secretary
12 deems necessary, provide notice to consumers to
13 whom such article was, or may have been, distrib-
14 uted.

15 “(c) HEARING ON ORDER.—The Secretary shall pro-
16 vide any person subject to an order under subsection (b)
17 with an opportunity for a hearing, to be held as soon as
18 possible but not later than 2 days after the issuance of
19 the order, on the actions required by the order and on
20 why the article that is the subject of the order should not
21 be recalled.

22 “(d) POST-HEARING RECALL ORDER.—

23 “(1) AMENDMENT OF ORDER.—If, after provid-
24 ing opportunity for a hearing under subsection (c),
25 the Secretary determines that there is a reasonable

1 probability that the article that is the subject of an
2 order under subsection (b), if consumed, presents a
3 threat to public health, the Secretary, as the Sec-
4 retary deems necessary, may—

5 “(A) amend the order to require recall of
6 such article or other appropriate action;

7 “(B) specify a timetable in which the recall
8 shall occur;

9 “(C) require periodic reports to the Sec-
10 retary describing the progress of the recall; and

11 “(D) provide notice to consumers to whom
12 such article was, or may have been, distributed.

13 “(2) VACATION OF ORDER.—If, after such a
14 hearing, the Secretary determines that adequate
15 grounds do not exist to continue the actions required
16 by the order, the Secretary shall vacate the order.

17 “(e) REMEDIES NOT EXCLUSIVE.—The remedies
18 provided in this section shall be in addition to and not
19 exclusive of other remedies that may be available.

20 **“SEC. 415. CIVIL PENALTIES.**

21 “(a) IN GENERAL.—

22 “(1) ACTS SUBJECT TO PENALTY; PENALTY
23 AMOUNT.—Any person that commits an act that vio-
24 lates this Act with respect to food or the Consumer
25 Food Safety Act of 1998 may be assessed a civil

1 penalty by the Secretary of not more than \$100,000
2 for each such act. Each such act and each day dur-
3 ing which such act continues shall be a separate of-
4 fense.

5 “(2) NOTICE AND HEARING.—No penalty shall
6 be assessed by the Secretary under this section un-
7 less such person is given notice and opportunity for
8 a hearing on the record before the Secretary in ac-
9 cordance with sections 554 and 556 of title 5,
10 United States Code.

11 “(3) OTHER REQUIREMENTS.—The amount of
12 such civil penalty shall be assessed by the Secretary
13 by written order, taking into account the gravity of
14 the violation, degree of culpability, size and type of
15 business, and any history of prior offenses; and may
16 be reviewed only as provided in subsection (b).

17 “(b) JUDICIAL REVIEW.—An order assessing a civil
18 penalty under subsection (a) shall be final and conclusive
19 unless the person files, within 30 days from the effective
20 date of the order, an application for judicial review in the
21 Court of Appeals of the United States for the circuit in
22 which such person resides or has its principal place of
23 business or in the United States Court of Appeals for the
24 District of Columbia Circuit by filing a notice of appeal
25 in such court and by simultaneously sending a copy of

1 such notice by certified mail to the Secretary. The Sec-
2 retary shall promptly file in such court a certified copy
3 of the record upon which such penalty was assessed. The
4 findings of the Secretary shall be set aside only if found
5 to be unsupported by substantial evidence on the record
6 as a whole.

7 “(c) COLLECTION ACTIONS.—If any person fails to
8 pay an assessment of a civil penalty after it has become
9 a final and unappealable order, or after the appropriate
10 court of appeals has entered final judgment in favor of
11 the Secretary, the Secretary shall refer the matter to the
12 Attorney General, who shall institute a civil action to re-
13 cover the amount assessed in an appropriate district court
14 of the United States. In such collection action, the validity
15 and appropriateness of the Secretary’s order imposing the
16 civil penalty shall not be subject to review.

17 “(d) PENALTIES PAID INTO TREASURY.—All pen-
18 alties collected under authority of this section shall be paid
19 into the Treasury of the United States.

20 “(e) SECRETARY’S DISCRETION TO PROSECUTE.—
21 Nothing in this Act shall be construed as requiring the
22 Secretary to report for prosecution, or for the institution
23 of libel or injunction proceedings, violations of this Act
24 whenever the Secretary believes that the public interest
25 will be adequately served by assessment of civil penalties.

1 “(f) REMEDIES NOT EXCLUSIVE.—The remedies
2 provided in this section shall be in addition to and not
3 exclusive of other remedies that may be available.

4 **“SEC. 416. WHISTLEBLOWER PROTECTION.**

5 “(a) IN GENERAL.—No employee or other person
6 may be harassed, prosecuted, held liable, or discriminated
7 against in any way because that person—

8 “(1) has commenced, caused to be commenced,
9 or is about to commence a proceeding, testified or is
10 about to testify at a proceeding, or assisted or par-
11 ticipated or is about to assist or participate in any
12 manner in such a proceeding or in any other action
13 to carry out the purposes, functions, or responsibil-
14 ities of the Consumer Food Safety Act of 1998, the
15 Federal Food, Drug, and Cosmetic Act, the Meat
16 Inspection Act, or the Poultry Products Inspection
17 Act; or

18 “(2) is refusing to violate or assist in violation
19 of law, rule, or regulation.

20 “(b) PROCEDURES.—The process and procedures
21 with respect to prohibited discrimination under subsection
22 (a) shall be governed by the applicable provisions of sec-
23 tion 31105 of title 49, United States Code, unless the
24 party bringing an action under this subsection chooses al-

1 ternative dispute resolution procedures such as mediation
2 or arbitration.

3 “(c) BURDENS OF PROOF.—The legal burdens of
4 proof with respect to prohibited discrimination under sub-
5 section (a) shall be governed by the applicable provisions
6 of sections 1214 and 1221 of title 5, United States Code.

7 **“SEC. 417. ADMINISTRATION AND ENFORCEMENT; APPLICA-**
8 **BILITY OF PENALTY PROVISIONS; CONDUCT**
9 **OF INQUIRIES; POWER AND JURISDICTION OF**
10 **COURTS.**

11 “For the efficient administration and enforcement of
12 this chapter, the provision (including penalties) of sections
13 46, 48, 49, and 50 of title 15 (except subsections (c)
14 through (h) of section 46 and section 49 of title 15), are
15 made applicable to the jurisdiction, powers, and duties of
16 the Secretary in administrating and enforcing the provi-
17 sions of this chapter and to any person with respect to
18 whom such authority is exercised. The Secretary, in per-
19 son or by such agents as he may designate, may prosecute
20 any inquiry necessary to his duties under this chapter in
21 any part of the United States, and the powers conferred
22 by said sections 49 and 50 of title 15 on the district courts
23 of the United States may be exercised for the purposes
24 of this chapter by any appropriate court.

1 **“SEC. 418. TRACEBACK.**

2 “The Secretary may impose on a food product re-
3 quirements for the traceability of such type or class of food
4 product whenever such requirements are necessary to as-
5 sure the protection of the public health. Traceability re-
6 quirements shall be established in accordance with regula-
7 tions and guidelines issued by the Secretary.

8 **“SEC. 419. CITIZEN’S CIVIL ACTIONS.**

9 “Any person may commence a civil action against—

10 “(1) any person who violated any rule, toler-
11 ance, order, or other action of the Secretary to en-
12 sure the safety of food products; or

13 “(2) the Secretary where there is alleged a fail-
14 ure of the Secretary to perform any act or duty to
15 ensure the safety of food products, which is not dis-
16 cretionary.

17 The district courts shall have jurisdiction, without regard
18 for the amount in controversy, or the citizenship of the
19 parties, to enforce such rule, tolerance, order, or other ac-
20 tion of the Secretary, or to order the Secretary to perform
21 such act or duty. The suit shall be commenced in the dis-
22 trict in which the defendant resides or is found or has
23 an agent. The court may award damages sustained and
24 if the court determines it to be in the interest of justice,
25 may award the plaintiff the costs of suit, including reason-
26 able attorney’s fees, reasonable expert witness fees, and

1 penalties. The remedies provided for in this section shall
 2 be in addition to and not in lieu of any other remedies
 3 provided by common law or under Federal or State law.”.

4 (b) CONFORMING AMENDMENT; PROHIBITED ACT.—
 5 Section 301 of the Federal Food, Drug, and Cosmetic Act
 6 (21 U.S.C. 331) is amended by adding at the end the fol-
 7 lowing new subsections:

8 “(x) The failure or refusal to comply with an order
 9 issued under section 414(b)(2) or 414(d).

10 “(y) The failure to comply with the Consumer Food
 11 Safety Act of 1998.”.

12 **TITLE IV—AUTHORIZATION**

13 **SEC. 401. AUTHORIZATION OF APPROPRIATIONS.**

14 (a) IN GENERAL.—There are authorized to be appro-
 15 priated, to carry out this Act, such sums as may be nec-
 16 essary for fiscal year 1999 and for fiscal year 2000.

17 (b) ASSISTANCE TO STATES.—Of the funds author-
 18 ized to be appropriated under subsection (a), there are au-
 19 thorized to be appropriated such sums as may be nec-
 20 essary for fiscal year 1999 and for fiscal year 2000, for
 21 carrying out State program assistance activities under sec-
 22 tion 106.

23 (c) RESEARCH PROGRAM AUTHORIZATION.—Of the
 24 funds authorized to be appropriated under subsection (a),
 25 there are authorized to be appropriated such sums as may

1 be necessary for fiscal year 1999 and for fiscal year 2000,
2 for carrying out the research program authorized by sec-
3 tion 203.

○