

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.

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## 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

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## 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 ucts 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 fection 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 same 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 DISTRIBUTION AND GIVE NOTICE.—If such person refuses to  
15 or does not voluntarily cease distribution, make noti-  
16 fication, recall such article, or provide notice to con-  
17 sumers, as applicable, within the time and in the  
18 manner prescribed by the Secretary, the Secretary  
19 shall, by order, require, as the Secretary deems nec-  
20 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 administering 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.

