

108TH CONGRESS  
1ST SESSION

# H. R. 1496

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

MARCH 27, 2003

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and 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 2003”.

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. Process controls to reduce the adulteration of food products.

Sec. 103. Inspections of processors and importers.  
 Sec. 104. Tolerances for contaminants in food.  
 Sec. 104. State and Federal cooperation.  
 Sec. 106. 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,  
 5 parasites, and physical hazards that when found on  
 6 or in 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 proc-  
7 essing;

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 proc-  
23 essing 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.

1 **SEC. 102. PROCESS CONTROLS TO REDUCE THE ADULTERA-**  
2 **TION OF FOOD PRODUCTS.**

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

6 (1) limit the presence of human pathogens and  
7 other potentially harmful substances in food prod-  
8 ucts;

9 (2) ensure that all registered facilities imple-  
10 ment appropriate measures to control and reduce  
11 the presence and growth of human pathogens and  
12 other potentially harmful substances on food prod-  
13 ucts;

14 (3) ensure that all fully processed or ready-to-  
15 eat food products are processed in a sanitary man-  
16 ner, using reasonably available techniques and tech-  
17 nologies to eliminate any human pathogens or other  
18 potentially harmful substances likely to cause  
19 foodborne illness; and

20 (4) ensure that food products intended for final  
21 processing outside commercial establishments are la-  
22 beled with instructions for handling and preparation  
23 for consumption which, when adhered to, will de-  
24 stroy any human pathogens or other potentially  
25 harmful substance likely to cause foodborne illness.

1 (b) REGULATIONS.—The Secretary shall, within one  
2 year of the enactment of this Act, issue regulations that  
3 require all registered facilities to adopt processing controls  
4 adequate to protect public health and to limit the presence  
5 and growth of human pathogens and other potentially  
6 harmful substances in food products prepared in any reg-  
7 istered facility. Such regulations shall—

8 (1) set standards for sanitation;

9 (2) set tolerances for biological, chemical, and  
10 physical hazards as appropriate;

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

14 (4) require recordkeeping to monitor compli-  
15 ance;

16 (5) require sampling to assure that processing  
17 controls are effective and that regulatory standards  
18 are being met; and

19 (6) provide for agency access to records kept by  
20 official establishments and submission of copies of  
21 such records to the Secretary as the Secretary  
22 deems appropriate.

23 Public access to records that relate to the adequacy of  
24 measures taken by official establishments to protect the  
25 public health and to limit the presence and growth of

1 human pathogens and other potentially harmful sub-  
2 stances shall be governed by 5 U.S.C. 552 et seq. The  
3 Secretary may, as the Secretary deems necessary, require  
4 any person, firm, or corporation with responsibility for or  
5 control over food ingredients to adopt processing controls,  
6 where such processing controls are needed to assure the  
7 protection of public health.

8 **SEC. 103. INSPECTIONS OF PROCESSORS AND IMPORTERS.**

9 (a) NATURE OF INSPECTIONS.—

10 (1) The inspection system shall provide for fre-  
11 quent unannounced inspections of food processing  
12 and importing facilities to determine if such facilities  
13 are operated in a sanitary manner and if food prod-  
14 ucts are unsafe for human consumption, or adulter-  
15 ated or misbranded under the Federal Food, Drug,  
16 and Cosmetic Act (21 U.S.C. 301 et seq.). Inspec-  
17 tions shall include review of processing records and  
18 sampling of food products.

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

23 (3) Standards for exceptional or negligible-risk  
24 facilities shall consider the hazards associated with  
25 the type of product being produced; and the facility's



1 history of compliance, food safety problems and such  
2 other factors as the Secretary may deem appro-  
3 priate. The Secretary shall specify an alternative in-  
4 spection frequency for each facility which is deemed  
5 exceptional or negligible-risk. Each inspection shall  
6 include an examination of whether the facility con-  
7 tinues to meet the standards for exceptional or neg-  
8 ligible-risk facilities.

9 (b) CONDUCT OF INSPECTIONS.—

10 (1) An inspection under subsection (a) of any  
11 domestic, foreign, or importing facility shall extend  
12 to all things therein (including records required to  
13 be maintained under subsection (e), processes, con-  
14 trols, and premises) that bear on whether food prod-  
15 ucts are in compliance with this Act or the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
17 seq.). Access to records may include the copying of  
18 such records.

19 (2) In conducting such inspections, officers or  
20 employees duly designated by the Secretary, upon  
21 presenting appropriate credentials to the owner, op-  
22 erator, or agent in charge, are authorized—

23 (A) to enter at reasonable times any facil-  
24 ity in which persons are engaged in the food  
25 processing or importing of food products, or to

1 enter any vehicle being used to transport or  
2 hold such food products;

3 (B) to inspect in a reasonable manner such  
4 facility or vehicle and all pertinent equipment,  
5 finished and unfinished materials, containers,  
6 labeling, processes, controls, and premises; and

7 (C) to collect and retain samples of food  
8 products or ingredients or of any other items  
9 found during an inspection that may contribute  
10 to a finding of whether such food products are  
11 unsafe for human consumption or adulterated  
12 or misbranded under the Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 301 et seq.).

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

24 (c) PRODUCT DETENTION AND CONDEMNATION.—

1           (1) If, during an inspection conducted under  
2           this section, an officer or employee making the in-  
3           spection has reason to believe that a food product is  
4           unsafe for human consumption, or adulterated or  
5           misbranded under the Federal Food, Drug, and Cos-  
6           metic Act (21 U.S.C. 301 et seq.), such officer or  
7           employee may order the food product segregated,  
8           impounded, and if objection is not made within 48  
9           hours, condemned. If objection is made, such food  
10          products that are in perishable form may be proc-  
11          essed to the extent necessary to prevent spoilage,  
12          and a hearing shall be commenced expeditiously.

13          (2) If the Secretary determines that, through  
14          relabeling or other action, such food products can be  
15          brought into compliance with this Act and the Fed-  
16          eral Food, Drug, and Cosmetic Act (21 U.S.C. 301  
17          et seq.), the food may be released following a deter-  
18          mination by the Secretary that such relabeling or  
19          other action as specified by the Secretary has been  
20          performed.

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

24          (d) OFFICIAL MARK.—The Secretary shall prescribe  
25          by regulation the conditions under which any food product

1 shall display an official mark, when needed to facilitate  
2 exports, that signifies that the food product has been proc-  
3 essed in accordance with standards approved by the Sec-  
4 retary. Such a mark may be subject to a fee.

5 (e) MAINTENANCE OF RECORDS.—Each facility or  
6 person registered under this section shall maintain and  
7 make available for inspection by the Secretary such  
8 records as the Secretary may prescribe. Such records shall  
9 be maintained for a reasonable period of time as deter-  
10 mined by the Secretary. The records shall include, but are  
11 not limited to, information concerning—

12 (1) the origin, receipt, delivery, sale, movement,  
13 holding, and disposition of food products or ingredi-  
14 ents; the identity and amount of ingredients used in  
15 the food; the processing of the food; the results of  
16 laboratory, sanitation, or other quality control tests  
17 performed on the food or in the facility; consumer  
18 complaints concerning the food or its packaging; and

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

24 (f) OTHER INSPECTION RIGHTS AND DUTIES.—Sec-  
25 tion 704 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 374) is amended by adding at the end the fol-  
2 lowing new subsection:

3 “(f) The rights and duties under this section of duly  
4 designated officers and employees and of other persons  
5 shall apply to enforcement of the Consumer Food Safety  
6 Act of 2003 to the same extent and in the same manner  
7 as they apply to enforcement of this Act.”.

8 **SEC. 104. TOLERANCES FOR CONTAMINANTS IN FOOD.**

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

1 avoided or minimized in the commercial handling and  
2 processing of such food.

3 (b) REGULATIONS.—

4 (1) The Secretary, after notice and an oppor-  
5 tunity for comment, shall promulgate regulations to  
6 implement subsection (a) within 48 months after the  
7 date of enactment of this Act. In promulgating such  
8 regulations, the Secretary shall establish tolerances  
9 for the contaminants that the Secretary determines  
10 are having the greatest public health impact as early  
11 as feasible after implementation of this Act.

12 (2) A tolerance established under this section  
13 shall be based on—

14 (A) a scientific analysis of the health risks  
15 attributable to the contaminant for which the  
16 tolerance is established; and

17 (B) analysis of the risks for sensitive  
18 groups, such as children, elderly, pregnant  
19 women and the immune compromised.

20 (3) The Secretary shall, in a timely manner,  
21 issue revisions to the regulations under paragraph  
22 (1) which take into account new information. The  
23 Secretary may contract with the National Academy  
24 of Sciences to provide such data or assistance as the  
25 Secretary deems necessary.

1       (c) REPORT.—The Secretary shall report to the Con-  
2 gress on the progress of the Secretary in establishing tol-  
3 erances under this section. The report shall include a de-  
4 scription of the research that has been conducted with re-  
5 spect to such tolerances and the research that must be  
6 conducted before additional tolerances may be established,  
7 the health significance of the lack of such additional toler-  
8 ances, a timetable for the establishment of such toler-  
9 ances, and the estimated costs, including costs of research,  
10 associated with the establishment of such tolerances. The  
11 report shall be transmitted on or about the end of the 18th  
12 month after the date of enactment of this Act, and bienni-  
13 ally thereafter during the 6-year period that begins on  
14 such date of enactment.

15 **SEC. 105. STATE AND FEDERAL COOPERATION.**

16       (a) IN GENERAL.—The Secretary shall work with the  
17 States in undertaking activities and programs that con-  
18 tribute to the national food safety program so that State  
19 and Federal programs function in a coordinated and cost-  
20 effective manner. With the assistance provided in sub-  
21 section (b), the Secretary shall encourage States to—

22               (1) continue, strengthen, or establish State food  
23 safety programs, especially with respect to the regu-  
24 lation of retail commercial food establishments,  
25 transportation, harvesting, and fresh markets; and

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

4       (b) ASSISTANCE.—

5           (1) The Secretary may provide to a State, for  
6       planning, developing, and implementing a food safe-  
7       ty program—

8           (A) advisory assistance;

9           (B) technical and laboratory assistance  
10       and training (including necessary materials and  
11       equipment); and

12          (C) financial and other aid.

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



1 **SEC. 106. IMPORTS.**

2 (a) **ROLE OF SECRETARY.**—Within 24 months after  
3 the date of enactment of this Act, the Secretary shall es-  
4 tablish and administer a comprehensive and efficient sys-  
5 tem to ensure the safety of food imported into the United  
6 States. The Secretary shall routinely inspect processing  
7 facilities in exporting nations and imports at ports of entry  
8 into the United States. The Secretary shall assure the ef-  
9 fective operation through verification and other activities  
10 as the Secretary considers necessary.

11 (b) **IMPORT REQUIREMENTS.**—

12 (1) No food product may enter the United  
13 States, or be withdrawn from a warehouse, for con-  
14 sumption in the United States if such food prod-  
15 uct—

16 (A) appears unsafe for human consump-  
17 tion, or adulterated or misbranded under the  
18 Federal Food, Drug, and Cosmetic Act (21  
19 U.S.C. 301 et seq.);

20 (B) is not marked or labeled as required  
21 by regulations for domestic or imported articles;  
22 or

23 (C) does not comply with the requirements  
24 of this section.

25 (2) Upon entry for consumption in the United  
26 States, food products that are not prohibited from

1 entry or from withdrawal from a warehouse under  
2 paragraph (1) shall be deemed to be and treated as  
3 domestic food products, except that all labeling of  
4 such products shall clearly identify the country of  
5 origin to facilitate the identification of products  
6 linked to outbreaks of illness.

7 (c) INSPECTION OF IMPORTS.—

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

17 (2) Food products from a nation that is cer-  
18 tified for such food products under subsection (e)(3)  
19 shall be subject to random examinations, inspections,  
20 sampling, and other procedures. Food products from  
21 a nation that is not certified for such food products  
22 under subsection (e)(3) shall be subject to such in-  
23 tensified examinations, inspections, sampling, and  
24 other verification procedures, including inspection in

1 the country of origin, as the Secretary determines  
2 are necessary to ensure compliance with this Act.

3 (d) DETENTION OF IMPORTED FOOD PRODUCT.—If  
4 during an inspection or other verification procedure car-  
5 ried out under this section, an officer or employee con-  
6 ducting the procedure has reason to believe that a food  
7 product is unsafe for human consumption, or adulterated  
8 or misbranded under the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 301 et seq.), such officer or employee  
10 may order the food product segregated, impounded, and  
11 if objection is not made within 48 hours, condemned. If  
12 objection is made, such food products that are in perish-  
13 able form may be processed to the extent necessary to pre-  
14 vent spoilage, and a hearing shall be commenced expedi-  
15 tiously. The final condemnation or other disposition of  
16 such food product shall be subject to the provisions of sec-  
17 tion 103(c).

18 (e) AGREEMENTS WITH FOREIGN NATIONS.—

19 (1) The Secretary may enter into an agreement  
20 with any nation desiring to export food products to  
21 the United States. Prior to concluding such an  
22 agreement, the Secretary shall evaluate the food  
23 safety program of the foreign nation to determine if  
24 such program provides at least the same level of pro-  
25 tection, with respect to food products intended for

1 export to the United States, as domestic laws that  
2 affect the safety of the food supply. In such evalua-  
3 tion, the Secretary shall consider—

4 (A) the potential for health, sanitary, envi-  
5 ronmental, or other conditions within the for-  
6 eign nation to adversely affect the safety of  
7 food products exported from such nation; and

8 (B) how well the food safety programs of  
9 the foreign nation functions to minimize any  
10 adverse effects on such safety.

11 (2) Any agreement under this subsection with a  
12 nation desiring to export food products to the  
13 United States shall—

14 (A) require that the exporting nation  
15 shall—

16 (i) establish and maintain a food safe-  
17 ty system that is adequate to ensure that  
18 the food products intended for export to  
19 the United States are safe for human con-  
20 sumption, and not adulterated or mis-  
21 branded under the Federal Food, Drug,  
22 and Cosmetic Act (21 U.S.C. 301 et seq.);  
23 and

24 (ii) promptly notify the Secretary of  
25 any violations affecting the safety of food

1 products exported or intended for export to  
2 the United States;

3 (B) provide for such activities (whether in  
4 the exporting nation or at the port of entry dur-  
5 ing importation) by the Secretary, including ex-  
6 aminations, inspections, sampling, and testing,  
7 at such stages in the growth or harvest of food,  
8 or in the processing or handling of food prod-  
9 ucts, as the Secretary considers appropriate to  
10 ensure that the food safety program of the ex-  
11 porting nation continues to provide at least the  
12 same level of protection, with respect to food  
13 products intended for export to the United  
14 States, as domestic laws that affect the safety  
15 of the food supply; and

16 (C) provide for reciprocity with respect to  
17 the treatment of food imports and exports be-  
18 tween the United States and the exporting na-  
19 tion.

20 (3) If the Secretary determines that a nation  
21 desiring to export food products to the United States  
22 has a program that provides at least the same level  
23 of protection, with respect to food products intended  
24 for export to the United States, as domestic laws  
25 that affect the safety of the food supply, the Sec-

1       retary shall, upon entry into force of an agreement  
 2       under subsection (e)(1), certify the types of food  
 3       products for which the nation maintains such a pro-  
 4       gram.

5           (4)(A) The Secretary shall periodically or for  
 6       good cause, and not less than once every 3 years, re-  
 7       view certifications made under paragraph (3), and  
 8       shall revoke the certification of any nation that the  
 9       Secretary determines is not maintaining a food safe-  
 10      ty program that provides at least the same level of  
 11      protection, with respect to food products intended  
 12      for export to the United States, as domestic laws  
 13      that affect the safety of the food supply.

14          (B) The Secretary shall review and modify, as  
 15      needed, an agreement made under paragraph (1)  
 16      with any nation whose certification has been revoked  
 17      under subparagraph (A) of this paragraph.

## 18       **TITLE II—RESEARCH AND** 19       **EDUCATION**

### 20      **SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.**

21          (a) COOPERATION WITH THE CENTERS FOR DISEASE  
 22      CONTROL AND PREVENTION.—The Secretary shall work,  
 23      through the Centers for Disease Control and Prevention,  
 24      to include food in an active surveillance system, based on  
 25      a representative proportion of the population of the United

1 States, and to assess more accurately the frequency and  
2 sources of human illness in the United States associated  
3 with the consumption of food.

4 (b) PUBLIC HEALTH SAMPLING.—

5 (1) Within 12 months after the date of enact-  
6 ment of this Act, the Secretary in cooperation with  
7 the Secretary of Agriculture shall establish guide-  
8 lines for a sampling system under which the Sec-  
9 retary and the Secretary of Agriculture shall take  
10 and analyze samples of food products to assist the  
11 Secretary in carrying out this Act and the Federal  
12 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
13 seq.), and to more accurately assess the nature, fre-  
14 quency of occurrence, and amounts of contaminants  
15 in food products.

16 (2) Such sampling system shall provide—

17 (A) statistically valid monitoring, including  
18 market-basket studies, on the nature, frequency  
19 of occurrence, and amounts of contaminants in  
20 food products available to consumers; and

21 (B) at the request of the Secretary, such  
22 other information, including analysis of moni-  
23 toring and verification samples, as the Sec-  
24 retary determines may be useful in assessing

1           the occurrence of contaminants in food prod-  
2           ucts.

3           (c) ASSESSMENT OF HEALTH HAZARDS.—Through  
4 the surveillance system referred to in subsection (a) and  
5 the sampling system described in subsection (b), the Sec-  
6 retary shall rank food categories based on their hazard  
7 to human health and identify appropriate industry and  
8 regulatory approaches to minimize hazards in the food  
9 supply. Such analysis could include—

10           (1) the safety of commercial harvesting and  
11           processing, as compared with the health hazards as-  
12           sociated with food products that are harvested for  
13           recreational or subsistence purposes and prepared  
14           noncommercially;

15           (2) the safety of food products that are domes-  
16           tically harvested and processed, as compared with  
17           the health hazards associated with food products  
18           that are harvested or processed outside the United  
19           States; and

20           (3) contamination originating from handling  
21           practices that occur prior to or after sale of food  
22           products to consumers.

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

24           (a) PUBLIC EDUCATION.—The Secretary, in coopera-  
25           tion with private and public organizations, including the



1 cooperative extension services and appropriate State enti-  
2 ties, shall design and implement a national public edu-  
3 cation program on food safety. The program shall pro-  
4 vide—

5           (1) information to the public regarding Federal  
6 standards and good practice requirements and pro-  
7 motion of public awareness understanding and ac-  
8 ceptance of such standards and requirements;

9           (2) information to health professionals so that  
10 they may improve diagnosis and treatment of food-  
11 related illness and advise individuals whose health  
12 conditions place them in particular risk; and

13           (3) such other information or advice to con-  
14 sumers and other persons as the Secretary deter-  
15 mines will promote the purposes of this Act.

16       (b) HEALTH ADVISORIES.—The Secretary, in con-  
17 sultation with the Secretary of Agriculture and the Admin-  
18 istrator of the Environmental Protection Agency, shall  
19 work with the States and other appropriate entities to—

20           (1) develop and distribute regional and national  
21 advisories concerning food safety;

22           (2) develop standardized formats for written  
23 and broadcast advisories; and

1           (3) incorporate State and local advisories into  
2       the national public education program required  
3       under subsection (a).

4   **SEC. 203. RESEARCH.**

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

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

10          (2) develop improved techniques for the moni-  
11       toring of food and inspection of food products;

12          (3) develop efficient, rapid, and sensitive meth-  
13       ods for determining and detecting the presence of  
14       contaminants in food products;

15          (4) determine the sources of contamination of  
16       food and food products with contaminants; and

17          (5) develop consumption data with respect to  
18       food products.

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

1           **TITLE III—ENFORCEMENT**

2   **SEC. 301. AMENDMENTS TO THE FEDERAL FOOD, DRUG,**  
3                   **AND COSMETIC ACT.**

4           (a) IN GENERAL.—The Federal Food, Drug, and  
5   Cosmetic Act (21 U.S.C. 301 et seq.) is amended by add-  
6   ing after section 415 the following new sections:

7   **“SEC. 416. NOTIFICATION AND RECALL.**

8           “(a) NOTICE TO SECRETARY OF ADULTERATION OR  
9   MISBRANDING.—Any person (other than a household con-  
10   sumer or other individual who is the intended consumer  
11   of an article of food) that has a reasonable basis for believ-  
12   ing that any article of food introduced into or in interstate  
13   commerce, or held for sale (whether or not the first sale)  
14   after shipment in interstate commerce, may be adulterated  
15   or misbranded or otherwise in violation of the Consumer  
16   Food Safety Act of 2003 shall immediately notify the Sec-  
17   retary, in such manner and by such means as the Sec-  
18   retary may by regulation prescribe, of the identity and lo-  
19   cation of such article.

20          “(b) RECALL AND CONSUMER NOTIFICATION.—

21               “(1) VOLUNTARY PROCEDURES.—If the Sec-  
22   retary finds, upon notification under subsection (a)  
23   or otherwise, that any article of food is adulterated  
24   or misbranded when introduced into or while in  
25   interstate commerce or while held for sale (whether

or not the first sale) after shipment in interstate commerce and there is a reasonable probability that such article, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall provide the appropriate persons (including the manufacturers, importers, distributors, or retailers) with an opportunity to—

“(A) cease distribution of such article;

“(B) notify all persons—

“(i) producing, manufacturing, packing, processing, preparing, treating, packaging, distributing, or holding such article; or

“(ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article;

“(C) recall such article;

“(D) provide, in consultation with the Secretary, notice to consumers to whom such article was, or may have been, distributed; or

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

“(2) PRE-HEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.—If such person refuses to or does not voluntarily cease distribution, make noti-

1       fication, recall such article, or provide notice to con-  
2       sumers, as applicable, within the time and in the  
3       manner prescribed by the Secretary, the Secretary  
4       shall, by order, require, as the Secretary deems nec-  
5       essary, such person to—

6               “(A) immediately cease distribution of  
7       such article;

8               “(B) immediately notify all persons—

9                       “(i) producing, manufacturing, pack-  
10                   ing, processing, preparing, treating, pack-  
11                   aging, distributing, or holding such article;  
12                   or

13                       “(ii) to which such article has been  
14                   distributed, transported, or sold, to imme-  
15                   diately cease distribution of such article; or

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

18               “(3) NOTIFICATION OF CONSUMERS BY SEC-  
19       RETARY.—The Secretary shall, as the Secretary  
20       deems necessary, provide notice to consumers to  
21       whom such article was, or may have been, distrib-  
22       uted.

23               “(c) HEARING ON ORDER.—The Secretary shall pro-  
24       vide any person subject to an order under subsection (b)  
25       with an opportunity for a hearing, to be held as soon as

1 possible but not later than 2 days after the issuance of  
2 the order, on the actions required by the order and on  
3 why the article that is the subject of the order should not  
4 be recalled.

5 “(d) POST-HEARING RECALL ORDER.—

6 “(1) AMENDMENT OF ORDER.—If, after pro-  
7 viding opportunity for a hearing under subsection  
8 (c), the Secretary determines that there is a reason-  
9 able probability that the article that is the subject  
10 of an order under subsection (b), if consumed, pre-  
11 sents a threat to public health, the Secretary, as the  
12 Secretary deems necessary, may—

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

15 “(B) specify a timetable in which the recall  
16 shall occur;

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

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

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

1       “(e) 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. 417. CIVIL PENALTIES.**

5       “(a) IN GENERAL.—

6               “(1) ACTS SUBJECT TO PENALTY; PENALTY  
7 AMOUNT.—Any person that commits an act that vio-  
8 lates this Act with respect to food or the Consumer  
9 Food Safety Act of 2003 may be assessed a civil  
10 penalty by the Secretary of not more than \$100,000  
11 for each such act. Each such act and each day dur-  
12 ing which such act continues shall be a separate of-  
13 fense.

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

20              “(3) OTHER REQUIREMENTS.—The amount of  
21 such civil penalty shall be assessed by the Secretary  
22 by written order, taking into account the gravity of  
23 the violation, degree of culpability, size and type of  
24 business, and any history of prior offenses; and may  
25 be reviewed only as provided in subsection (b).

1       “(b) JUDICIAL REVIEW.—An order assessing a civil  
2 penalty under subsection (a) shall be final and conclusive  
3 unless the person files, within 30 days from the effective  
4 date of the order, an application for judicial review in the  
5 Court of Appeals of the United States for the circuit in  
6 which such person resides or has its principal place of  
7 business or in the United States Court of Appeals for the  
8 District of Columbia Circuit by filing a notice of appeal  
9 in such court and by simultaneously sending a copy of  
10 such notice by certified mail to the Secretary. The Sec-  
11 retary shall promptly file in such court a certified copy  
12 of the record upon which such penalty was assessed. The  
13 findings of the Secretary shall be set aside only if found  
14 to be unsupported by substantial evidence on the record  
15 as a whole.

16       “(c) COLLECTION ACTIONS.—If any person fails to  
17 pay an assessment of a civil penalty after it has become  
18 a final and unappealable order, or after the appropriate  
19 court of appeals has entered final judgment in favor of  
20 the Secretary, the Secretary shall refer the matter to the  
21 Attorney General, who shall institute a civil action to re-  
22 cover the amount assessed in an appropriate district court  
23 of the United States. In such collection action, the validity  
24 and appropriateness of the Secretary’s order imposing the  
25 civil penalty shall not be subject to review.



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

4       “(e) SECRETARY’S DISCRETION TO PROSECUTE.—  
 5 Nothing in this Act shall be construed as requiring the  
 6 Secretary to report for prosecution, or for the institution  
 7 of libel or injunction proceedings, violations of this Act  
 8 whenever the Secretary believes that the public interest  
 9 will be adequately served by assessment of civil penalties.

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

13       **“SEC. 418. WHISTLEBLOWER PROTECTION.**

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

17               “(1) has commenced, caused to be commenced,  
 18 or is about to commence a proceeding, testified or is  
 19 about to testify at a proceeding, or assisted or par-  
 20 ticipated or is about to assist or participate in any  
 21 manner in such a proceeding or in any other action  
 22 to carry out the purposes, functions, or responsibil-  
 23 ities of the Consumer Food Safety Act of 2003, the  
 24 Federal Food, Drug, and Cosmetic Act, the Meat

1 Inspection Act, or the Poultry Products Inspection  
 2 Act; or

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

5 “(b) PROCEDURES.—The process and procedures  
 6 with respect to prohibited discrimination under subsection  
 7 (a) shall be governed by the applicable provisions of sec-  
 8 tion 31105 of title 49, United States Code, unless the  
 9 party bringing an action under this subsection chooses al-  
 10 ternative dispute resolution procedures such as mediation  
 11 or arbitration.

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

16 **“SEC. 419. ADMINISTRATION AND ENFORCEMENT; APPLICA-**  
 17 **BILITY OF PENALTY PROVISIONS; CONDUCT**  
 18 **OF INQUIRIES; POWER AND JURISDICTION OF**  
 19 **COURTS.**

20 “For the efficient administration and enforcement of  
 21 this chapter, the provision (including penalties) of sections  
 22 46, 48, 49, and 50 of title 15 (except subsections (c)  
 23 through (h) of section 46 and section 49 of title 15), are  
 24 made applicable to the jurisdiction, powers, and duties of  
 25 the Secretary in administering and enforcing the provi-

1 sions of this chapter and to any person with respect to  
2 whom such authority is exercised. The Secretary, in per-  
3 son or by such agents as he may designate, may prosecute  
4 any inquiry necessary to his duties under this chapter in  
5 any part of the United States, and the powers conferred  
6 by said sections 49 and 50 of title 15 on the district courts  
7 of the United States may be exercised for the purposes  
8 of this chapter by any appropriate court.

9 **“SEC. 420. TRACEBACK.**

10       “The Secretary may impose on a food product re-  
11 quirements for the traceability of such type or class of food  
12 product whenever such requirements are necessary to as-  
13 sure the protection of the public health. Traceability re-  
14 quirements shall be established in accordance with regula-  
15 tions and guidelines issued by the Secretary.

16 **“SEC. 421. CITIZEN’S CIVIL ACTIONS.**

17       “Any person may commence a civil action against—

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

21               “(2) the Secretary where there is alleged a fail-  
22 ure of the Secretary to perform any act or duty to  
23 ensure the safety of food products, which is not dis-  
24 cretionary.

1 The district courts shall have jurisdiction, without regard  
2 for the amount in controversy, or the citizenship of the  
3 parties, to enforce such rule, tolerance, order, or other ac-  
4 tion of the Secretary, or to order the Secretary to perform  
5 such act or duty. The suit shall be commenced in the dis-  
6 trict in which the defendant resides or is found or has  
7 an agent. The court may award damages sustained and  
8 if the court determines it to be in the interest of justice,  
9 may award the plaintiff the costs of suit, including reason-  
10 able attorney's fees, reasonable expert witness fees, and  
11 penalties. The remedies provided for in this section shall  
12 be in addition to and not in lieu of any other remedies  
13 provided by common law or under Federal or State law.”.

14 (b) CONFORMING AMENDMENT; PROHIBITED ACT.—  
15 Section 301 of the Federal Food, Drug, and Cosmetic Act  
16 (21 U.S.C. 331) is amended by adding at the end the fol-  
17 lowing:

18 “(hh) The failure or refusal to comply with an order  
19 issued under section 416(b)(2) or 416(d).

20 “(ii) The failure to comply with the Consumer Food  
21 Safety Act of 2003.”.

1       **TITLE IV—AUTHORIZATION**

2       **SEC. 401. AUTHORIZATION OF APPROPRIATIONS.**

3           (a) IN GENERAL.—There are authorized to be appro-  
4       priated, to carry out this Act, such sums as may be nec-  
5       essary for fiscal year 2004 and for fiscal year 2005.

6           (b) ASSISTANCE TO STATES.—Of the funds author-  
7       ized to be appropriated under subsection (a), there are au-  
8       thorized to be appropriated such sums as may be nec-  
9       essary for fiscal year 2004 and for fiscal year 2005, for  
10      carrying out State program assistance activities under sec-  
11      tion 105.

12          (c) RESEARCH PROGRAM AUTHORIZATION.—Of the  
13      funds authorized to be appropriated under subsection (a),  
14      there are authorized to be appropriated such sums as may  
15      be necessary for fiscal year 2004 and for fiscal year 2005,  
16      for carrying out the research program authorized by sec-  
17      tion 203.

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