

106TH CONGRESS
1ST SESSION

S. 908

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

IN THE SENATE OF THE UNITED STATES

APRIL 28, 1999

Mr. DORGAN introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Consumer Food Safety Act of 1999”.

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 contamination of food products.
- Sec. 104. Tolerances for contaminants in food.
- Sec. 105. Inspections of processors and importers.
- 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 In this Act:

3 (1) **CONTAMINANT.**—The term “contaminant”
 4 includes a bacterium, a chemical contaminant, a nat-
 5 ural toxin, a virus, a parasite, and a physical hazard,
 6 that when found on or in food can cause human ill-
 7 ness or injury.

8 (2) **FACILITY.**—The term “facility” includes
 9 any factory, warehouse, or establishment (including
 10 a factory, warehouse, or establishment of an im-
 11 porter), that handles or processes food.

12 (3) **FOOD.**—The term “food” has the meaning
 13 given the term in section 201 of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 321).

1 (4) FOOD SAFETY LAW.—The term “food safety
2 law” means this Act and the provisions of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301
4 et seq.) that relate to food.

5 (5) PROCESS.—The term “process” means the
6 commercial harvesting, preparation, manufacture, or
7 transportation of a food product.

8 (6) SECRETARY.—The term “Secretary” means
9 the Secretary of Health and Human Services.

10 **TITLE I—NATIONAL FOOD** 11 **SAFETY PROGRAM**

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

13 (a) IN GENERAL.—

14 (1) FINDING.—Congress finds that persons who
15 produce or process food for human consumption
16 have the responsibility to prevent or minimize food
17 safety hazards related to their products.

18 (2) NATIONAL PROGRAM.—The Secretary shall
19 administer, in accordance with the provisions of this
20 Act, a national program for the purpose of pro-
21 tecting public health by ensuring that the food in-
22 dustry has effective programs in place to assure the
23 safety of food products consumed in the United
24 States.

1 (3) BASIS FOR PROGRAM.—The program
2 shall—

3 (A) be based on a comprehensive analysis
4 of the hazards associated with different food
5 products and with the processing (including
6 harvesting) and handling of different food prod-
7 ucts, including the identification and evaluation
8 of—

9 (i) the severity of the potential public
10 health hazards;

11 (ii) the sources and specific points of
12 potential contamination that may render
13 food products unsafe for human consump-
14 tion; and

15 (iii) the potential for persistence, mul-
16 tiplication, or concentration of naturally
17 occurring or added contaminants in foods,
18 including food products; and

19 (B) take into consideration the distinctive
20 characteristics of food processing and handling.

21 (b) PROGRAM ELEMENTS.—The program shall pro-
22 vide for—

23 (1) implementation of a national system for the
24 annual registration of facilities (including facilities
25 of importers) with the Secretary;

1 (2) development of a program to oversee the
2 implementation of process controls in facilities, in-
3 cluding the establishment and enforcement of health-
4 based standards for—

5 (A) substances that may contaminate food;
6 and

7 (B) safety and sanitation in the processing
8 and handling of food products;

9 (3) establishment of inspection and oversight
10 procedures to monitor that facilities are utilizing
11 preventive controls to minimize or eliminate identifi-
12 able hazards in food;

13 (4) implementation of a national system for
14 quarterly inspections of facilities (including facilities
15 of importers), except for facilities that meet the Sec-
16 retary's standards for exceptional or negligible-risk
17 facilities;

18 (5) implementation of procedures and require-
19 ments to ensure the safety of imported food prod-
20 ucts;

21 (6) coordination with other Federal agencies or
22 State governments in carrying out inspection, en-
23 forcement, and monitoring relating to the safety of
24 food products;

1 (7) implementation of a national surveillance
2 system to assess the public health hazards associated
3 with the human consumption of food products, in co-
4 operation with the Director of the Centers for Dis-
5 ease Control and Prevention;

6 (8) implementation of a sampling program to
7 ensure that industry programs to prevent food con-
8 tamination are effective and that food products meet
9 the standards established in paragraph (2);

10 (9) development of public education and advi-
11 sory programs relating to the safety of food prod-
12 ucts; and

13 (10) implementation of a research program to
14 further the objectives of this Act.

15 **SEC. 102. REGISTRATION OF PROCESSORS AND IMPORT-**
16 **ERS.**

17 (a) REGISTRATION.—

18 (1) IN GENERAL.—Any facility engaged in proc-
19 essing or handling food products for consumption in
20 the United States, including any facility of an im-
21 porter, shall be registered with the Secretary. To ob-
22 tain the registration—

23 (A) for a domestic facility not described in
24 subparagraph (B), the owner, operator, or

1 agent in charge of the facility shall submit an
2 application to the Secretary; and

3 (B) for a facility of an importer, or for a
4 foreign facility, the importer seeking to import
5 the food product processed or handled in the fa-
6 cility shall submit the application.

7 (2) APPLICATION.—

8 (A) IN GENERAL.—The applicant shall
9 submit the application to the Secretary in such
10 manner and containing such information as the
11 Secretary shall prescribe by regulation.

12 (B) SUBMISSION.—The applicant shall
13 submit the application not later than 24 months
14 after—

15 (i) the date of enactment of this Act;

16 or

17 (ii) the date the facility first processed
18 or handled food, if later than such date of
19 enactment.

20 (C) CONTENTS.—In the case of an applica-
21 tion submitted for a foreign facility, the appli-
22 cation shall contain, at a minimum, such infor-
23 mation as the Secretary may require dem-
24 onstrating that the facility, and the foreign na-

1 tion involved, will permit inspections described
2 in this title.

3 (3) PROCEDURE.—Upon receipt and review of a
4 completed application described in paragraph (1),
5 the Secretary shall issue to the applicant a certifi-
6 cate of registration unless the Secretary finds that
7 there is good cause for denial of the application. The
8 Secretary shall promptly notify the applicant of the
9 denial, include in the notification a written expla-
10 nation of the reasons for such denial, and provide an
11 opportunity for a hearing or reapplication upon re-
12 quest.

13 (b) SUSPENSION OF REGISTRATION.—

14 (1) BASIS.—The registration of a facility, in-
15 cluding the facility of an importer, may be sus-
16 pended immediately by the Secretary for—

17 (A) failure to permit access to the facility
18 for inspection under this Act;

19 (B) violation of a food safety law, includ-
20 ing a regulation issued under a food safety law,
21 concerning the facility, in a case in which the
22 Secretary determines that such suspension is
23 likely to prevent a significant risk of adverse
24 health consequences; or

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

3 (i) any felony relating to food, wheth-
4 er or not the felony is based upon the ac-
5 quisition, handling, or distribution of adul-
6 terated or misbranded food; or

7 (ii) more than 1 violation of any law
8 relating to food, whether or not the viola-
9 tion involves any fraud in connection with
10 transactions in food.

11 (2) IMPACT.—No person may introduce a food
12 product into interstate commerce, or offer a food
13 product for import into the United States, from a
14 facility with a suspended registration.

15 (3) REINSTATEMENT.—Any registration sus-
16 pended under paragraph (1) may be reinstated
17 whenever the Secretary determines that the suspen-
18 sion is no longer necessary.

19 (c) EXEMPTION AUTHORITY.—The Secretary may by
20 regulation exempt classes of facilities from the require-
21 ments of subsection (a) if the Secretary determines that
22 the registration of such facilities is not needed for effective
23 enforcement of a food safety law.

1 **SEC. 103. PROCESS CONTROLS TO REDUCE THE CONTAMI-**
2 **NATION OF FOOD PRODUCTS.**

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

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

9 (2) ensure that all facilities registered under
10 section 102 implement appropriate process controls
11 to control and reduce the presence and growth of
12 contaminants and other potentially harmful sub-
13 stances in food products;

14 (3) ensure that all processed or ready-to-eat
15 food products are processed and handled in a sani-
16 tary manner, using reasonably available techniques
17 and technologies to minimize any contaminants or
18 other 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 that, when adhered to, will destroy
24 any contaminant or other potentially harmful sub-
25 stance likely to cause foodborne illness.

26 (b) REGULATIONS.—

1 (1) IN GENERAL.—In implementing subsection
2 (a), the Secretary shall, not later than 1 year after
3 the date of enactment of this Act, issue regulations
4 that require each facility registered under section
5 102 to adopt process controls adequate to protect
6 public health by controlling and reducing the pres-
7 ence and growth of contaminants and other poten-
8 tially harmful substances in food products prepared
9 in the facility.

10 (2) ELEMENTS.—Such regulations shall—

11 (A) set standards for sanitation in food
12 products;

13 (B) set tolerances for biological, chemical,
14 and physical contaminants in food products, as
15 appropriate;

16 (C) require process controls to assure that
17 food products are safe and that relevant regu-
18 latory and other safety standards, including the
19 standards and tolerances described in subpara-
20 graphs (A) and (B), are met;

21 (D) require recordkeeping to monitor com-
22 pliance with the process controls;

23 (E) require sampling (in accordance with
24 the sampling guidelines described in section
25 201(b)) to assure that the process controls are

1 effective and that regulatory and other safety
2 standards are being met; and

3 (F) provide for agency access to records
4 kept under subparagraph (D) and submission
5 of copies of such records to the Secretary as the
6 Secretary determines to be appropriate.

7 (c) RECORDS.—Public access to records kept under
8 subsection (b)(2)(D) that relate to the adequacy of meas-
9 ures taken by facilities to protect public health by control-
10 ling and reducing the presence and growth of contami-
11 nants and other potentially harmful substances in food
12 products shall be governed by section 552 of title 5,
13 United States Code.

14 (d) PROCESS CONTROLS FOR USE OF FOOD INGRE-
15 DIENTS.—The Secretary may require any person, firm, or
16 corporation that has responsibility for or control over food
17 ingredients and that is registered under section 102 to
18 adopt process controls, to the extent the Secretary deter-
19 mines that such process controls are needed to assure the
20 protection of public health.

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

22 (a) TOLERANCES.—In adopting, under section
23 103(b)(2), tolerances for facilities registered under section
24 102, the Secretary shall establish tolerances limiting the
25 quantity, in food products, of contaminants, except for

1 pesticide chemical residues regulated under section 408,
2 or food additives regulated under section 409, of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 346a or
4 348), that, when found in food products, may render such
5 products unsafe for human consumption. Such tolerances
6 may include indicators (including indicator organisms)
7 from which the presence of a contaminant in a food prod-
8 uct may reasonably be inferred. In developing a tolerance
9 for a contaminant, the Secretary shall take into account
10 the extent to which consumers may be exposed to such
11 contaminant from sources other than food, and the extent
12 to which such contaminant can be avoided or minimized
13 in the commercial processing and handling of such food.

14 (b) REGULATIONS.—

15 (1) IN GENERAL.—The Secretary, after notice
16 and an opportunity for comment, shall promulgate
17 regulations to implement subsection (a) not later
18 than 48 months after the date of enactment of this
19 Act. In promulgating such regulations, the Secretary
20 shall establish tolerances for the contaminants that
21 the Secretary determines have the greatest public
22 health impact, as early as feasible after the date of
23 enactment of this Act.

24 (2) BASIS.—A tolerance established under this
25 section shall be based on—

1 (A) a scientific analysis of the public
2 health risks attributable to the contaminant for
3 which the tolerance is established; and

4 (B) analysis of the public health risks at-
5 tributable to the contaminant for sensitive
6 groups, such as children, elderly individuals,
7 pregnant women, and individuals with com-
8 promised immune systems.

9 (3) REVISIONS.—The Secretary shall, in a time-
10 ly manner, issue revisions to the regulations under
11 paragraph (1) that take into account new informa-
12 tion relating to the contaminants involved.

13 (4) DATA OR ASSISTANCE.—The Secretary may
14 enter into a contract with the National Academy of
15 Sciences to provide such data or assistance as the
16 Secretary of Health and Human Services determines
17 to be necessary to carry out this subsection.

18 (c) REPORT.—The Secretary shall prepare and sub-
19 mit to Congress a report on the progress of the Secretary
20 in establishing tolerances under this section. The report
21 shall include a description of the research that has been
22 conducted with respect to such tolerances and the research
23 that needs to be conducted before additional tolerances
24 may be established under this section, the health signifi-
25 cance of the lack of such additional tolerances, a timetable

1 for the establishment of such tolerances, and the estimated
2 costs, including costs of research, associated with the es-
3 tablishment of such tolerances. The report shall be sub-
4 mitted not later than 18 months after the date of enact-
5 ment of this Act, and biennially thereafter during the 6-
6 year period that begins on such date of enactment.

7 **SEC. 105. INSPECTIONS OF PROCESSORS AND IMPORTERS.**

8 (a) NATURE OF INSPECTIONS.—

9 (1) IN GENERAL.—The inspection system re-
10 ferred to in section 101(b)(4) shall provide for reg-
11 ular and unannounced inspections of facilities (in-
12 cluding facilities of importers) registered under sec-
13 tion 102 to determine if such facilities are operated
14 in a sanitary manner and if food products processed
15 or handled in the facilities is in violation of a food
16 safety law.

17 (2) SCHEDULE.—The Secretary shall inspect
18 each facility described in paragraph (1) at least
19 quarterly, except that the Secretary shall specify an
20 alternative inspection frequency for a facility that
21 the Secretary determines to be an exceptional or
22 negligible-risk facility, under standards issued under
23 paragraph (3).

24 (3) STANDARDS.—The Secretary shall issue
25 standards for determining whether a facility is an

1 exceptional or negligible-risk facility. In issuing the
2 standards, the Secretary shall classify facilities by
3 considering the hazards associated with the type of
4 product being produced at a facility, the facility's
5 history of compliance and food safety problems, and
6 such other factors as the Secretary may determine
7 to be appropriate.

8 (4) EXAMINATION OF CLASSIFICATIONS.—Each
9 inspection of a facility classified as an exceptional or
10 negligible-risk facility shall include an examination
11 of whether the facility is appropriately classified
12 under the standards issued under paragraph (3).

13 (b) CONDUCT OF INSPECTIONS.—

14 (1) SCOPE.—An inspection under subsection (a)
15 of any domestic or foreign facility (including a facil-
16 ity of an importer) shall extend to all things in the
17 facility (including records required to be maintained
18 under subsection (e), processes, controls, and prem-
19 ises) that bear on whether food products are in com-
20 pliance with a food safety law. The inspection shall
21 include a review of processing or handling records
22 and sampling of food products. Access to records
23 may include the copying of such records.

24 (2) AUTHORITIES.—In conducting such inspec-
25 tions, officers or employees duly designated by the

1 Secretary, on presenting appropriate credentials to
2 the owner, operator, or agent in charge of a facility,
3 are authorized—

4 (A) to enter at reasonable times any facil-
5 ity described in subsection (a) in which persons
6 are engaged in the processing or handling of
7 food products (including a facility of an im-
8 porter), which may include entering any vehicle
9 being used to transport or hold food products
10 for processing or handling;

11 (B) to inspect in a reasonable manner such
12 facility (which may include inspecting a vehicle
13 described in subparagraph (A)), including all
14 pertinent equipment, finished and unfinished
15 materials, containers, labeling, processes, con-
16 trols, and premises; and

17 (C) to collect and retain samples of food
18 products or ingredients or of any other items
19 found during an inspection that may contribute
20 to a finding of whether such food products are
21 in violation of a food safety law.

22 (3) REPORT.—Immediately after completion of
23 the inspection, the officer or employee making the
24 inspection shall give to the owner, operator, or agent
25 in charge a report, in writing, setting forth any con-

1 ditions or practices observed that indicate that either
2 process controls are inadequate to prevent or mini-
3 mize food safety hazards or that any food product
4 from such facility is in violation of a food safety law.

5 (c) PRODUCT DETENTION AND CONDEMNATION.—

6 (1) IN GENERAL.—If, during an inspection con-
7 ducted under this section of a domestic facility, an
8 officer or employee making the inspection deter-
9 mines that a food product is in violation of a food
10 safety law, such officer or employee may order the
11 food product segregated, impounded, and if objection
12 is not made within 48 hours after the issuance of
13 the impoundment order, condemned. If objection is
14 made within such 48 hours, food products that are
15 in perishable form may be processed to the extent
16 necessary to prevent spoilage, and the Secretary
17 shall expeditiously commence a hearing regarding
18 the determination and any action required for com-
19 pliance with the food safety laws.

20 (2) RELEASE.—If the Secretary determines
21 that, through relabeling or other action, such food
22 product can be brought into compliance with the
23 food safety laws, the food product may be released
24 following a determination by the Secretary that such

1 relabeling or other action as specified by the Sec-
2 retary has been performed.

3 (3) DESTRUCTION.—Any food product con-
4 demned under paragraph (1)—

5 (A) in a case in which no objection is made
6 under paragraph (1);

7 (B) after the hearing and any judicial re-
8 view; or

9 (C) after failure of the owner, operator, or
10 agent to perform relabeling or other action de-
11 scribed in paragraph (2);

12 shall be destroyed under supervision of the Sec-
13 retary.

14 (d) OFFICIAL MARK.—The Secretary shall prescribe
15 by regulation 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 and handled in accordance with standards approved
19 by the Secretary. The Secretary may assess a fee for the
20 use of such a mark. The Secretary shall deposit fees re-
21 ceived under this subsection in an account, and may use
22 the funds in the account to carry out enforcement activi-
23 ties under the food safety laws, or to carry out section
24 106.

1 (e) MAINTENANCE OF RECORDS.—The registrant for
2 each facility registered under section 102 shall maintain
3 and make available for inspection by the Secretary such
4 records as the Secretary may prescribe. Such records shall
5 be maintained for a reasonable period of time as deter-
6 mined by the Secretary. The records shall include informa-
7 tion concerning—

8 (1)(A) the origin, receipt, delivery, sale, move-
9 ment, holding, and disposition of food products, or
10 ingredients for food products, processed or handled
11 at the facility;

12 (B) the identity and amount of ingredients used
13 in the food involved;

14 (C) the processing or handling of the food;

15 (D) the results of laboratory, sanitation, or
16 other quality control tests performed on the food or
17 in the facility; and

18 (E) consumer complaints concerning the food or
19 the packaging of the food; and

20 (2) other matters reasonably related to whether
21 food products processed or handled at the facility
22 may be in violation of a food safety law.

23 (f) OTHER INSPECTION RIGHTS AND DUTIES.—Sec-
24 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 “(g) Except as otherwise provided in section 106(b)
 4 of the Consumer Food Safety Act of 1999, the provisions
 5 of the last 2 sentences of subsection (a)(1), and sub-
 6 sections (c) and (d), relating to the powers and duties of
 7 officers and employees to enforce this Act, and to the
 8 rights and duties of persons with respect to whom such
 9 powers are exercised, apply to the powers and duties of
 10 officers and employees designated by the Secretary to en-
 11 force the Consumer Food Safety Act of 1999, and to the
 12 rights and duties of persons with respect to whom such
 13 powers are exercised, respectively.”.

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

15 (a) IN GENERAL.—The Secretary shall work with the
 16 States in undertaking activities and programs that con-
 17 tribute to the national program established under section
 18 101 so that State food safety programs and the national
 19 program function in a coordinated and cost-effective man-
 20 ner. With the assistance provided under subsection (b),
 21 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 food safety programs are not unsafe for
4 human consumption.

5 (b) ASSISTANCE.—The Secretary may provide to a
6 State, for planning, developing, and implementing a food
7 safety program—

8 (1) advisory assistance;

9 (2) technical assistance, training, and labora-
10 tory assistance (including necessary materials and
11 equipment); and

12 (3) financial and other assistance.

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 that are recorded or issued in connection
20 with activities under the agreement and are in the posses-
21 sion of the agency that entered into the agreement shall
22 be made available in accordance with section 552 of title
23 5, United States Code. An agreement entered into with
24 a State agency under this subsection may provide for
25 training of State employees.

1 **SEC. 107. IMPORTS.**

2 (a) **ROLE OF SECRETARY.**—Not later than 24
3 months after the date of enactment of this Act, the Sec-
4 retary shall establish and administer a comprehensive and
5 efficient system to ensure the safety of food products im-
6 ported into the United States. In administering the sys-
7 tem, the Secretary shall routinely inspect facilities reg-
8 istered under section 102 in exporting nations and imports
9 at ports of entry into the United States, in accordance
10 with this section and section 105. The Secretary shall as-
11 sure that the facilities are operating in compliance with
12 the food safety laws, through such verification and other
13 activities as the Secretary considers to be necessary.

14 (b) **IMPORT REQUIREMENTS.**—

15 (1) **SAFETY STANDARDS.**—No food product
16 may enter the United States, or be withdrawn from
17 a facility for consumption in the United States if
18 such food product appears to be in violation of a
19 food safety law.

20 (2) **TREATMENT.**—Upon entry for consumption
21 in the United States, food products that are not pro-
22 hibited from entry or from withdrawal from a facil-
23 ity under paragraph (1) shall be considered to be
24 and treated as domestic food products for purposes
25 of the Federal Food, Drug, and Cosmetic Act (21
26 U.S.C. 301 et seq.), except that all labeling of such

1 products shall clearly identify the country of origin
2 to facilitate the identification of products linked to
3 outbreaks of illness.

4 (c) INSPECTION OF IMPORTS.—

5 (1) EXAMINATIONS, INSPECTIONS, SAMPLING
6 AND OTHER PROCEDURES.—Food products that are
7 offered for importation, or withdrawn from a facil-
8 ity, for consumption in the United States, shall be
9 subject to examinations, inspections, sampling, and
10 such other procedures as the Secretary may deter-
11 mine to be appropriate at the port of entry or at the
12 facility registered under section 102 in the exporting
13 nation by officers or employees duly designated by
14 the Secretary. Such procedures shall be conducted
15 with such frequency and in such manner as the Sec-
16 retary may prescribe by regulation.

17 (2) RANDOM OR INTENSIFIED PROCEDURES.—
18 Food products from a nation that is certified for
19 such food products under subsection (e)(3) shall be
20 subject to random examinations, inspections, sam-
21 pling, and other procedures under paragraph (1).
22 Food products from a nation that is not certified for
23 such food products under subsection (e)(3) shall be
24 subject to such intensified examinations, inspections,
25 sampling, and other verification procedures, includ-

1 ing inspection in the exporting nation, under para-
2 graph (1), as the Secretary determines are necessary
3 to ensure compliance with the food safety laws.

4 (d) DETENTION OF IMPORTED FOOD PRODUCT.—If,
5 during an inspection or other verification procedure car-
6 ried out under this section at a port of entry, an officer
7 or employee conducting the procedure determines that a
8 food product is in violation of a food safety law, such offi-
9 cer or employee may order the food product segregated,
10 impounded, and if objection is not made within such 48
11 hours, condemned. If objection is made, within such 48
12 hours such food products that are in perishable form may
13 be processed to the extent necessary to prevent spoilage,
14 and the Secretary shall expeditiously commence a hearing
15 regarding the determination and any action required for
16 compliance with the food safety laws. The final condemna-
17 tion or other disposition of such food product shall be sub-
18 ject to the provisions of paragraphs (2) and (3) of section
19 105(c).

20 (e) AGREEMENTS WITH FOREIGN NATIONS.—

21 (1) EVALUATION.—The Secretary may enter
22 into an agreement described in paragraph (2) with
23 any nation desiring to export food products to the
24 United States. Prior to concluding such an agree-
25 ment, the Secretary shall evaluate the food safety

1 program of the foreign nation to determine if such
2 program provides at least the same level of protec-
3 tion, with respect to food products intended for ex-
4 port to the United States, as domestic laws that af-
5 fect the safety of the food supply. In such evalua-
6 tion, the Secretary shall consider—

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

11 (B) how well the food safety programs of
12 the foreign nation function to minimize any ad-
13 verse effects on such safety.

14 (2) REQUIREMENTS.—Any agreement under
15 this subsection with a nation desiring to export food
16 products to the United States shall—

17 (A) require that the exporting nation
18 shall—

19 (i) establish and maintain a food safe-
20 ty system that is adequate to ensure that
21 the food products intended for export to
22 the United States are not in violation of
23 the food safety laws; 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 other
7 procedures, at such stages in the growth or har-
8 vest of food, or in the processing or handling of
9 food products, as the Secretary considers to be
10 appropriate to ensure that the food safety pro-
11 gram of the exporting nation continues to pro-
12 vide at least the same level of protection, with
13 respect to food products intended for export to
14 the United States, as domestic laws that affect
15 the safety 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) CERTIFICATION.—If the Secretary deter-
21 mines that a nation desiring to export food products
22 to the United States has a program that provides at
23 least the same level of protection, with respect to
24 food products intended for export to the United
25 States, as domestic laws that affect the safety of the

1 food supply, the Secretary shall, upon entry into
2 force of an agreement under paragraph (1), certify
3 the types of food products for which the nation
4 maintains such a program.

5 (4) REVIEWS OF CERTIFICATIONS.—

6 (A) IN GENERAL.—The Secretary shall pe-
7 riodically or for good cause, and not less than
8 once every 3 years, review certifications made
9 under paragraph (3), and shall revoke the cer-
10 tification of any nation that the Secretary de-
11 termines is not maintaining a food safety pro-
12 gram that provides at least the same level of
13 protection, with respect to food products in-
14 tended for export to the United States, as do-
15 mestic laws that affect the safety of the food
16 supply.

17 (B) IMPACT ON AGREEMENTS.—The Sec-
18 retary shall review and modify, as needed, an
19 agreement made under paragraph (1) with any
20 nation whose certification has been revoked
21 under subparagraph (A).

1 **TITLE II—RESEARCH AND**
2 **EDUCATION**

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

4 (a) COOPERATION WITH THE CENTERS FOR DISEASE
5 CONTROL AND PREVENTION.—The Secretary, acting
6 through the Director of the Centers for Disease Control
7 and Prevention, shall maintain an active surveillance sys-
8 tem for food, to include on a representative proportion of
9 the population of the United States, to assess more accu-
10 rately the frequency and sources of human illness in the
11 United States associated with the consumption of food.

12 (b) PUBLIC HEALTH SAMPLING.—

13 (1) GUIDELINES.—Not later than 12 months
14 after the date of enactment of this Act, the Sec-
15 retary, in cooperation with the Secretary of Agri-
16 culture, shall establish guidelines for a sampling sys-
17 tem under which the Secretary and the Secretary of
18 Agriculture shall collect and analyze samples of food
19 products to assist the Secretary in carrying out the
20 food safety laws, and to assess more accurately the
21 nature, frequency of occurrence, and amounts of
22 contaminants in food products.

23 (2) MONITORING AND OTHER INFORMATION.—

24 In carrying out the sampling system, the Secretary
25 and the Secretary of Agriculture shall provide for—

1 (A) statistically valid monitoring, including
 2 the conduct of market-basket studies, on the
 3 nature, frequency of occurrence, and amounts
 4 of contaminants in food products available to
 5 consumers; and

6 (B) at the request of the Secretary of
 7 Health and Human Services, the collection and
 8 analysis of such other information, including
 9 analysis of information from monitoring and
 10 verification samples, as the Secretary deter-
 11 mines may be useful in assessing the occurrence
 12 of contaminants in food products.

13 (c) ASSESSMENT OF PUBLIC HEALTH HAZARDS.—
 14 Using information obtained through the surveillance sys-
 15 tem referred to in subsection (a) and the sampling system
 16 described in subsection (b), the Secretary shall rank food
 17 categories based on their hazard to public health and iden-
 18 tify appropriate industry and regulatory approaches to
 19 minimize hazards in the food supply. In conducting the
 20 ranking and identification, the Secretary may determine—

21 (1) the public health hazards associated with
 22 food products that are commercially harvested and
 23 prepared, as compared with the public health haz-
 24 ards associated with food products that are har-

1 vested for recreational or subsistence purposes and
2 prepared noncommercially;

3 (2) the public health hazards associated with
4 food products that are domestically harvested and
5 processed, as compared with the public health haz-
6 ards associated with food products that are har-
7 vested or processed outside the United States; and
8 (3) the extent of contamination originating
9 from handling practices that occur prior to or after
10 sale of food products to consumers.

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

12 (a) PUBLIC EDUCATION.—The Secretary, in coopera-
13 tion with private and public organizations, including the
14 State cooperative extension services and appropriate State
15 entities, shall design and implement a national public edu-
16 cation program on food safety. In carrying out the pro-
17 gram, the Secretary shall—

18 (1) provide information to the public regarding
19 Federal standards and good practice requirements
20 relating to food safety, and promote public aware-
21 ness, understanding, and acceptance of such stand-
22 ards and requirements;

23 (2) provide information to health professionals
24 so that the health professionals may improve diag-
25 nosis and treatment of food-related illness and ad-

1 vise individuals whose health conditions place the in-
 2 dividuals at particular risk for that illness; and

3 (3) provide such other information or advice to
 4 consumers and other persons as the Secretary deter-
 5 mines will promote the objectives of this Act.

6 (b) **HEALTH ADVISORIES.**—The Secretary, in con-
 7 sultation with the Secretary of Agriculture and the Admin-
 8 istrator of the Environmental Protection Agency, and in
 9 cooperation with States and other appropriate entities,
 10 shall—

11 (1) develop and distribute regional and national
 12 advisories concerning food safety;

13 (2) develop standardized formats for written
 14 and broadcast advisories concerning food safety; and

15 (3) incorporate State and local advisories, con-
 16 cerning food safety into the national public edu-
 17 cation program required under subsection (a).

18 **SEC. 203. RESEARCH.**

19 (a) **IN GENERAL.**—The Secretary shall conduct re-
 20 search to assist in the implementation of this Act, includ-
 21 ing studies relating to—

22 (1) improving sanitation and food safety prac-
 23 tices in the processing and handling of food prod-
 24 ucts;

- 1 (2) developing improved techniques for the
- 2 monitoring of food and inspection of food products;
- 3 (3) developing efficient, rapid, and sensitive
- 4 methods for determining and detecting the presence
- 5 of contaminants in food products;
- 6 (4) determining the sources of contamination of
- 7 food (including food products); and
- 8 (5) developing consumption data with respect to
- 9 food products.

10 (b) CONTRACT AUTHORITY.—The Secretary is au-
 11 thorized to enter into contracts and agreements with any
 12 State, institution of higher education, other government
 13 agency, or other person to carry out the activities de-
 14 scribed in this section.

15 **TITLE III—ENFORCEMENT**

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

18 (a) IN GENERAL.—The Federal Food, Drug, and
 19 Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

20 (1) by inserting after the chapter heading for
 21 chapter IV the following:

22 “SUBCHAPTER A—FOOD STANDARDS”; and

23 (2) by adding at the end the following:

1 “SUBCHAPTER B—REMEDIES

2 **“SEC. 421. DEFINITIONS.**

3 “In this subchapter, the term ‘food safety law’ means
4 the Consumer Food Safety Act of 1999 and the provisions
5 of this Act that relate to food.

6 **“SEC. 422. NOTIFICATION AND RECALL.**

7 “(a) NOTICE TO SECRETARY OF VIOLATION.—Any
8 person (other than a household consumer or other indi-
9 vidual who is the intended consumer of an article of food)
10 that has a reasonable basis for believing that any article
11 of food introduced into or in interstate commerce, or held
12 for sale (whether or not the first sale) after shipment in
13 interstate commerce, may be in violation of a food safety
14 law shall immediately notify the Secretary, in such manner
15 and by such means as the Secretary may by regulation
16 prescribe, of the identity and location of such article.

17 “(b) RECALL AND CONSUMER NOTIFICATION.—

18 “(1) VOLUNTARY PROCEDURES.—If the Sec-
19 retary finds, on notification under subsection (a) or
20 otherwise, that any article of food is in violation of
21 a food safety law when introduced into or while in
22 interstate commerce or while held for sale (whether
23 or not the first sale) after shipment in interstate
24 commerce and there is a reasonable probability that
25 such article, if consumed, would present a threat to

1 public health, as determined by the Secretary, the
2 Secretary shall provide the appropriate persons (in-
3 cluding the manufacturers, importers, distributors,
4 or retailers of the article) with an opportunity to—

5 “(A) cease distribution of such article;

6 “(B) notify all persons—

7 “(i) producing, manufacturing, pack-
8 ing, processing, preparing, treating, pack-
9 aging, distributing, or holding such article
10 to immediately cease such activities with
11 respect to such article; or

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

15 “(C) recall such article;

16 “(D) provide, in consultation with the Sec-
17 retary, notice of the finding of the Secretary to
18 consumers to whom such article was, or may
19 have been, distributed; or

20 “(E) take any combination of the above
21 measures, as determined by the Secretary to be
22 appropriate in the circumstances.

23 “(2) PRE-HEARING ORDER TO CEASE DISTRIBU-
24 TION AND GIVE NOTICE.—If such appropriate person
25 refuses to or does not voluntarily cease distribution,

1 make notification, recall such article, or provide no-
 2 tice to consumers, as applicable, within the time and
 3 in the manner prescribed by the Secretary, the Sec-
 4 retary shall, by order, require, as the Secretary de-
 5 termines to be necessary, 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 to immediately cease such activities with
 13 respect to such article; or

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

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

19 “(3) NOTIFICATION OF CONSUMERS BY SEC-
 20 RETARY.—The Secretary shall, as the Secretary de-
 21 termines to be necessary, provide notice of the find-
 22 ing of the Secretary under paragraph (1) to con-
 23 sumers to whom such article was, or may have been,
 24 distributed.

1 “(c) HEARING ON ORDER.—The Secretary shall pro-
2 vide any person subject to an order under subsection (b)
3 with an opportunity for a hearing, to be held as soon as
4 practicable but not later than 2 days after the issuance
5 of the order, on the actions required by the order and on
6 whether the article that is the subject of the order should
7 be recalled.

8 “(d) POST-HEARING RECALL ORDER.—

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

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

18 “(B) specify a timetable in which the recall
19 shall occur;

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

22 “(D) provide notice of the recall to con-
23 sumers to whom such article was, or may have
24 been, distributed.

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

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

8 **“SEC. 423. CIVIL PENALTIES.**

9 “(a) IN GENERAL.—

10 “(1) ACTS SUBJECT TO PENALTY; PENALTY
11 AMOUNT.—Any person that commits an act that vio-
12 lates a food safety law may be assessed a civil pen-
13 alty by the Secretary of not more than \$100,000 for
14 each such act. Each such act and each day during
15 which such act continues shall be a separate offense.

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

22 “(3) OTHER REQUIREMENTS.—Such civil pen-
23 alty shall be assessed by the Secretary by written
24 order. The amount of the civil penalty shall be deter-
25 mined by the Secretary, taking into account the

1 gravity of the violation, degree of culpability of the
2 person, size and type of business of the person, and
3 any history of prior offenses by the person, and shall
4 be specified in the order. The order may be reviewed
5 only as provided in subsection (b).

6 “(b) JUDICIAL REVIEW.—An order assessing a civil
7 penalty under subsection (a) shall be final and conclusive
8 unless the person files, within 30 days after the effective
9 date of the order, an application for judicial review of the
10 order in the United States Court of Appeals for the circuit
11 in which such person resides or has its principal place of
12 business, or in the United States Court of Appeals for the
13 District of Columbia Circuit. The person shall file the ap-
14 plication by filing a notice of appeal in such court and
15 by simultaneously sending a copy of such notice by cer-
16 tified mail to the Secretary. The Secretary shall promptly
17 file in such court a certified copy of the record upon which
18 such order was issued. The findings of the Secretary relat-
19 ing to the order shall be set aside only if found to be un-
20 supported by substantial evidence on the record as a
21 whole.

22 “(c) COLLECTION ACTIONS.—If any person fails to
23 pay a civil penalty assessed under subsection (a) after the
24 order assessing the penalty has become a final and conclu-
25 sive order, or after the court of appeals described in sub-

1 section (b) has entered final judgment in favor of the Sec-
2 retary, the Secretary shall refer the matter to the Attorney
3 General, who shall institute a civil action to recover the
4 amount assessed in a United States district court of com-
5 petent jurisdiction. In such action, the validity and appro-
6 priateness of the Secretary's order assessing the civil pen-
7 alty shall not be subject to review.

8 “(d) PENALTIES PAID INTO ACCOUNT.—The Sec-
9 retary shall deposit penalties collected under this section
10 in an account, and may use the funds in the account to
11 carry out enforcement activities under the food safety
12 laws, or to carry out section 106 of the Consumer Food
13 Safety Act of 1999.

14 “(e) SECRETARY'S DISCRETION TO PROSECUTE.—
15 Nothing in this Act shall be construed as requiring the
16 Secretary to report for prosecution, or for the institution
17 of libel or injunction proceedings, violations of a food safe-
18 ty law whenever the Secretary believes that the public in-
19 terest will be adequately served by assessment of civil pen-
20 alties under this section.

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

1 **“SEC. 424. WHISTLEBLOWER PROTECTION.**

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

5 “(1) has commenced, caused to be commenced,
6 or is about to commence a proceeding, has testified
7 or is about to testify at a proceeding, or has assisted
8 or participated or is about to assist or participate in
9 any manner in a proceeding or other action, to carry
10 out the objectives, functions, or responsibilities spec-
11 ified in the Consumer Food Safety Act of 1999, the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 301 et seq.), the Federal Meat Inspection Act (21
14 U.S.C. 601 et seq.), or the Poultry Products Inspec-
15 tion Act (21 U.S.C. 451 et seq.); or

16 “(2) is refusing to violate or assist in violation
17 of a law described in paragraph (1), including a reg-
18 ulation issued under that law.

19 “(b) PROCEDURES.—

20 “(1) IN GENERAL.—A person alleging a viola-
21 tion of subsection (a) may file a complaint as de-
22 scribed in subsection (b) of section 31105 of title 49,
23 United States Code.

24 “(2) ADMINISTRATION.—The process, proce-
25 dures, and remedies that apply under subsections
26 (b), (c), and (d) of that section 31105 with respect

1 to allegations of violations of subsection (a) of that
 2 section shall be the process, procedures, and rem-
 3 edies that apply with respect to allegations of viola-
 4 tions of subsection (a), except as provided in para-
 5 graphs (3) and (4).

6 “(3) ALTERNATIVE PROCESS.—The person fil-
 7 ing a complaint under paragraph (1) may elect to
 8 use an alternative dispute resolution procedure, such
 9 as mediation or arbitration, in lieu of the hearing
 10 described in subsection (b) of that section 31105.

11 “(4) SECRETARY.—The powers and duties that
 12 apply to the Secretary of Labor under that section
 13 31105 shall apply to the Secretary of Health and
 14 Human Services.

15 “(c) BURDENS OF PROOF.—The legal burdens of
 16 proof with respect to a violation of subsection (a) shall
 17 be governed by the applicable provisions of sections 1214
 18 and 1221 of title 5, United States Code.

19 **“SEC. 425. ADMINISTRATION AND ENFORCEMENT; APPLICA-**
 20 **BILITY OF PENALTY PROVISIONS; CONDUCT**
 21 **OF INQUIRIES; POWER AND JURISDICTION OF**
 22 **COURTS.**

23 “(a) IN GENERAL.—For the efficient administration
 24 and enforcement of the food safety laws, the provisions
 25 (including provisions relating to penalties) of sections 6,

1 8, 9, and 10 of the Federal Trade Commission Act (15
 2 U.S.C. 46, 48, 49, and 50) (except subsections (c) through
 3 (h) of such section 6), relating to the jurisdiction, powers,
 4 and duties of the Federal Trade Commission and the At-
 5 torney General to administer and enforce that Act, and
 6 to the rights and duties of persons with respect to whom
 7 such powers are exercised, apply to the jurisdiction, pow-
 8 ers, and duties of the Secretary and the Attorney General
 9 in administering and enforcing the provisions of this chap-
 10 ter and the Consumer Food Safety Act of 1999 and to
 11 the rights and duties of persons with respect to whom such
 12 powers are exercised, respectively.

13 “(b) INQUIRIES AND ACTIONS.—The Secretary, in
 14 person or by such agents as the Secretary may designate,
 15 may prosecute any inquiry necessary to carry out the du-
 16 ties of the Secretary under this chapter and the Consumer
 17 Food Safety Act of 1999 in any part of the United States,
 18 and the powers conferred by sections 9 and 10 of the Fed-
 19 eral Trade Commission Act (15 U.S.C. 49 and 50) on the
 20 United States district courts may be exercised for the pur-
 21 poses of this chapter by any United States district court
 22 of competent jurisdiction.

23 **“SEC. 426. TRACEBACK.**

24 “The Secretary may impose on a food product re-
 25 quirements for the traceability of such type or class of food

1 product whenever such requirements are necessary to as-
2 sure the protection of public health. Traceability require-
3 ments shall be established in accordance with regulations
4 and guidelines issued by the Secretary and shall apply to
5 persons registered under section 102 of the Consumer
6 Food Safety Act of 1999.

7 **“SEC. 427. CITIZEN’S CIVIL ACTIONS.**

8 “(a) CIVIL ACTIONS.—Any person may commence a
9 civil action against—

10 “(1) any person who violates any rule (includ-
11 ing a rule establishing a tolerance), order, or other
12 action of the Secretary to ensure the safety of food
13 products; or

14 “(2) the Secretary, if the Secretary fails to per-
15 form any act or duty to ensure the safety of food
16 products that is not discretionary under a food safe-
17 ty law.

18 “(b) COURT.—The action shall be commenced in the
19 United States district court for the district in which the
20 defendant resides or is found or has an agent. The court
21 shall have jurisdiction, without regard to the amount in
22 controversy, or the citizenship of the parties, to enforce
23 such rule (including a rule establishing a tolerance), order,
24 or other action of the Secretary, or to order the Secretary
25 to perform such act or duty. The court may award dam-

1 ages, in the amount of damages actually sustained, and,
 2 if the court determines it to be in the interest of justice,
 3 may award the plaintiff the costs of suit, including reason-
 4 able attorney’s fees, reasonable expert witness fees, and
 5 penalties.

6 “(c) REMEDIES NOT EXCLUSIVE.—The remedies
 7 provided for in this section shall be in addition to and not
 8 exclusive of other remedies that may be available.”.

9 **“SEC. 428. ADMINISTRATION.**

10 “Notwithstanding any other provision of this Act, the
 11 remedy for any foreign facility that violates a food safety
 12 law shall be suspension of registration under section 102
 13 of the Consumer Food Safety Act of 1999.”.

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 “(aa) The failure or refusal to comply with an order
 19 issued under section 422(b)(2) or 422(d).

20 “(bb) The failure to comply with the Consumer Food
 21 Safety Act of 1999.”.

22 **TITLE IV—AUTHORIZATION**

23 **SEC. 401. AUTHORIZATION OF APPROPRIATIONS.**

24 (a) IN GENERAL.—There are authorized to be appro-
 25 priated to carry out this Act, other than sections 106 and

1 203, such sums as may be necessary for each of fiscal
2 years 2000 and 2001.

3 (b) ASSISTANCE TO STATES.—There are authorized
4 to be appropriated such sums as may be necessary for
5 each of fiscal years 2000 and 2001, for carrying out sec-
6 tion 106 (relating to State program assistance).

7 (c) RESEARCH PROGRAM AUTHORIZATION.—There
8 are authorized to be appropriated such sums as may be
9 necessary for each of fiscal years 2000 and 2001, for car-
10 rying out section 203 (relating to research).

○