

107TH CONGRESS  
1ST SESSION

# H. R. 3184

To amend the Federal Food, Drug, and Cosmetic Act to add provisions regarding protecting the United States food supply.

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IN THE HOUSE OF REPRESENTATIVES

OCTOBER 30, 2001

Ms. DELAURO introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to add provisions regarding protecting the United States food supply.

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.**

4 This Act may be cited as the “Protecting the Food  
5 Supply from Bioterrorism Act”.

6 **SEC. 2. REGISTRATION OF PROCESSORS AND IMPORTERS.**

7 (a) REGISTRATION.—

8 (1) IN GENERAL.—Any facility engaged in proc-  
9 essing or handling food products for consumption in  
10 the United States, including any facility of an im-

1 porter, shall be registered with the Secretary. To ob-  
2 tain the registration—

3 (A) for a domestic facility not described in  
4 subparagraph (B), the owner, operator, or  
5 agent in charge of the facility shall submit an  
6 application to the Secretary; and

7 (B) for a facility of an importer, or for a  
8 foreign facility, the importer seeking to import  
9 the food product processed or handled in the fa-  
10 cility shall submit the application.

11 (2) APPLICATION.—

12 (A) IN GENERAL.—The applicant shall  
13 submit the application to the Secretary in such  
14 manner and containing such information as the  
15 Secretary shall prescribe.

16 (B) SUBMISSION.—The applicant shall  
17 submit the application as provided for by the  
18 Secretary.

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

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

11          (4) LIST.—The Secretary shall compile and  
12          maintain an up-to-date list of facilities that are reg-  
13          istered under this section.

14          (b) SUSPENSION OF REGISTRATION.—

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

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

20           (B) violation of a food safety law, includ-  
21           ing a regulation issued under a food safety law,  
22           concerning the facility, in a case in which the  
23           Secretary determines that such suspension is  
24           likely to prevent a significant risk of adverse  
25           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.

24 (d) DEFINITIONS.—In this section:

1           (1) FACILITY.—The term “facility” includes  
2           any factory, warehouse, or establishment (including  
3           a factory, warehouse, or establishment of an im-  
4           porter), that handles or processes food.

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

7 **SEC. 3. ENFORCEMENT AUTHORITIES.**

8           (a) DETENTION.—Chapter III of the Federal Food,  
9           Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is amend-  
10          ed by inserting after section 304 the following:

11 **“SEC. 304A. ADMINISTRATIVE DETENTION.**

12          “Any food that the Secretary reasonably believes may  
13          be adulterated or misbranded when introduced into or  
14          while in interstate commerce, or while held for sale  
15          (whether or not the first sale) after shipment in interstate  
16          commerce, may be detained and held by the Secretary for  
17          not more than 20 days, pending action regarding such  
18          food under sections 302 or 304. During such 20-day pe-  
19          riod, such food shall not be moved by any person (other  
20          than the Secretary) from the place at which such food was  
21          seized until the Secretary authorizes a release.”.

22          (b) RECORDS.—Chapter IV of the Federal Food,  
23          Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-  
24          ed by inserting after section 404 the following:

1 **“SEC. 404A. RECORDS.**

2       “(a) IN GENERAL.—The Secretary shall promulgate  
3 regulations requiring each factory, warehouse, or estab-  
4 lishment in which food is manufactured, processed,  
5 packed, or held for introduction into interstate commerce  
6 to retain records to effect and monitor any recall author-  
7 ized under this Act and to retain any other records reason-  
8 ably bearing on food that is manufactured or held in the  
9 facility that may be in violation of a Federal or State food  
10 safety law. Such regulations shall require that the Sec-  
11 retary have access to and be allowed to copy such records  
12 at all times. It shall be unlawful for any person to fail  
13 to retain such records or to fail to permit the Secretary  
14 to inspect or copy such records.

15       “(b) CONTENT.—The records retained under sub-  
16 section (a) shall be maintained for a reasonable period of  
17 time as determined by the Secretary. The records shall  
18 include information concerning—

19               “(1)(A) the origin, receipt, delivery, sale, move-  
20 ment, holding, and disposition of food products, or  
21 ingredients for food products, processed or handled  
22 at the facility;

23               “(B) the identity and amount of ingredients  
24 used in the food involved;

25               “(C) the processing or handling of food;

1           “(D) the results of laboratory, sanitation, or  
2           other quality control tests performed on the food or  
3           in the facility; and

4           “(E) consumer complaints concerning food or  
5           the packaging of the food; and

6           “(2) other matters reasonably related to wheth-  
7           er food products processed or handled at the facility  
8           may be in violation of a food safety law under this  
9           Act.

10          “(c) RULE OF CONSTRUCTION.—Nothing in this sec-  
11          tion shall be construed to alter or amend in any way sec-  
12          tion 301(j) of this Act or section 552 of title 5 or section  
13          1995 of title 18, United States Code.”.

14          (c) PENALTIES.—Section 303(g)(2)(A) of the Fed-  
15          eral Food, Drug, and Cosmetic Act (21 U.S.C.  
16          333(g)(2)(A)) is amended by striking “402(a)(2)(B)” and  
17          inserting “402”.

18          (d) CROSS-UTILIZATION OF INSPECTORS.—Section  
19          702 of the Federal Food, Drug, and Cosmetic Act is  
20          amended by inserting after the first sentence: “In the case  
21          of food, the Secretary is additionally authorized to conduct  
22          examinations and investigations for the purposes of this  
23          Act through the officers and employees of the Department  
24          of Agriculture, duly commissioned by the Secretary as an

1 officer of the Department of Health and Human Serv-  
2 ices.”.

3 (e) CLARIFICATION OF AUTHORITIES BASED ON EPI-  
4 DEMIOLOGICAL EVIDENCE.—Section 402 of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 342) is  
6 amended—

7 (1) in subsection (a)—

8 (A) by striking “; or (7)” and inserting “;  
9 (7)”; and

10 (B) by striking “to section 409.” and in-  
11 serting “to section 409; or (8) if the Secretary  
12 declares such food to pose an immediate risk of  
13 significant harm to public health or safety  
14 based on epidemiological evidence, except that  
15 the authority to make such declaration shall not  
16 be delegated and the Secretary shall promptly  
17 after such a declaration initiate a proceeding in  
18 accordance with sections 554 and 556 of title 5,  
19 United States Code, to affirm or withdraw the  
20 declaration.”.

21 **SEC. 4. NOTIFICATION AND RECALL.**

22 Chapter IV of the Federal Food, Drug, and Cosmetic  
23 Act (21 U.S.C. 341 et seq.) is amended by adding after  
24 section 409 the following:

1 **“SEC. 409A. NOTIFICATION AND RECALL OF UNSAFE FOOD.**

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

12       “(b) RECALL AND CONSUMER NOTIFICATION.—

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

25                       “(A) cease distribution of such article;

26                       “(B) notify all persons—

1           “(i) producing, manufacturing, pack-  
2           ing, processing, preparing, treating, pack-  
3           aging, distributing, or holding such article  
4           to immediately cease such activities with  
5           respect to such article; or

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

9           “(C) recall such article;

10          “(D) provide, in consultation with the Sec-  
11          retary, notice of the finding of the Secretary to  
12          consumers to whom such article was, or may  
13          have been, distributed; or

14          “(E) take any combination of the above  
15          measures, as determined by the Secretary to be  
16          appropriate in the circumstances.

17          “(2) PREHEARING ORDER TO CEASE DISTRIBU-  
18          TION AND GIVE NOTICE.—If such appropriate person  
19          refuses to or does not voluntarily cease distribution,  
20          make notification, recall such article, or provide no-  
21          tice to consumers, as applicable, within the time and  
22          in the manner prescribed by the Secretary, the Sec-  
23          retary shall, by order, require, as the Secretary de-  
24          termines to be necessary, such person to—

1           “(A) immediately cease distribution of  
2 such article;

3           “(B) immediately notify all persons—

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

9                 “(ii) to which such article has been  
10 distributed, transported, or sold, to imme-  
11 diately cease distribution of such article; or

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

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

20           “(c) HEARING ON ORDER.—The Secretary shall pro-  
21 vide any person subject to an order under subsection (b)  
22 with an opportunity for a hearing, to be held as soon as  
23 practicable but not later than 2 days after the issuance  
24 of the order, on the actions required by the order and on

1 whether the article that is the subject of the order should  
2 be recalled.

3 “(d) POST-HEARING RECALL ORDER.—

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

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

13 “(B) specify a timetable in which the recall  
14 shall occur;

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

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

20 “(2) VACATION OF ORDER.—If, after such a  
21 hearing, the Secretary determines that adequate  
22 grounds do not exist to continue the actions required  
23 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. 5. DEFINITIONS AND STANDARDS FOR FOOD.**

5       Section 401 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 341 et seq.) is amended—

7           (1) by striking “Whenever in the judgment”  
8       and inserting “(a) Whenever in the judgment”; and

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

10       “(b) The Secretary shall issue regulations that estab-  
11 lish standards for process controls and tolerances for con-  
12 taminants in food products as appropriate to assure that  
13 food from both domestic and imported facilities are in  
14 compliance with the requirements of food safety laws  
15 under this Act.”.

16 **SEC. 6. STRENGTHENING IMPORT INSPECTIONS.**

17       (a) ASSURING EQUIVALENT STANDARDS FOR IM-  
18 PORTS.—Section 402 of the Federal Food, Drug, and Cos-  
19 metic Act is amended by adding at the end the following:

20       “(h) If it is food that is offered for import into the  
21 United States and has not been manufactured, processed,  
22 packed or held under a system or conditions, or subject  
23 to measures that meet the requirements of this Act, or  
24 that otherwise achieve the level of protection required, as  
25 determined by the Secretary, for such food manufactured,

1 processed, packed or held in the United States. In deter-  
2 mining whether a system, conditions, or measures meet  
3 the requirements of this Act or otherwise achieve the level  
4 of protection required, the Secretary may consider whether  
5 an officer or employee, duly designated by the Secretary  
6 has requested, and has been refused, access to the estab-  
7 lishment or location where such food was manufactured,  
8 processed, packed or held for the purpose of inspection  
9 (including sample collection), testing, or other relevant  
10 procedures, at a reasonable time and in a reasonable man-  
11 ner, and may deny the importation of such food from such  
12 establishment or location on the basis of such refusal and  
13 other relevant factors.”.

14 (b) ADVANCE NOTICE REGARDING IMPORTED  
15 FOOD.—Chapter VIII of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 381 et seq.) is amended by add-  
17 ing at the end the following:

18 **“SEC. 805. NOTICE REGARDING IMPORTED FOOD.**

19 “The Secretary of Health and Human Services, in  
20 consultation with the Secretary of the Treasury, may re-  
21 quire a manufacturer or importer of food imported or of-  
22 fered for import into the United States to provide the Sec-  
23 retary of Health and Human Services with advance notice  
24 of such importation before such importation.”.

1 **SEC. 7. RESEARCH AND TRAINING AMENDMENTS TO THE**  
2 **PUBLIC HEALTH SERVICE ACT.**

3 Subpart 6 of title IV of the Public Health Service  
4 Act (42 U.S.C. 285f et seq.) is amended by adding at the  
5 end the following:

6 **“SEC. 447C. FOOD SECURITY RESEARCH INITIATIVE**  
7 **THROUGH DIRECTOR OF NATIONAL INSTI-**  
8 **TUTES OF HEALTH.**

9 “(a) EXPANSION, INTENSIFICATION, AND COORDINA-  
10 TION OF ACTIVITIES.—

11 “(1) IN GENERAL.—The Director of NIH, in  
12 consultation with the Joint Institute for Food Safety  
13 Research, and other agencies as appropriate, shall  
14 coordinate, expand, and intensify their programs  
15 concerning food-borne illness, including food-borne  
16 illnesses potentially associated with terrorism.

17 “(b) CENTERS OF EXCELLENCE.—

18 “(1) IN GENERAL.—The Director of NIH shall  
19 award grants and contracts to public or nonprofit  
20 private entities to pay all or part of the costs of  
21 planning, establishing, improving, and providing  
22 basic operating support for centers of excellence for  
23 research into and training in food-borne illness, in-  
24 cluding food-borne illnesses potentially associated  
25 with terrorism.

1           “(2) POLICIES.—A grant or contract awarded  
2           under paragraph (1) shall be entered into an accord-  
3           ance with policies established by the Director of  
4           NIH.

5           “(3) USE OF FUNDS.—Funds awarded under  
6           this subsection may be used for—

7                   “(A) the development of diagnostic tech-  
8                   niques that are capable of rapidly detecting and  
9                   identifying agents of food-borne illness, includ-  
10                  ing food-borne illnesses that are potentially as-  
11                  sociated with terrorism; and

12                   “(B) clinical training, including training  
13                   for allied health professionals, continuing edu-  
14                   cation for health professionals and allied health  
15                   professions personnel, and information pro-  
16                   grams for the public with respect to food-borne  
17                   illness, including food-borne illness potentially  
18                   associated with terrorism.

19           “(c) COORDINATION WITH OTHER INSTITUTES.—  
20           The Director of NIH shall coordinate the activities under  
21           this section with similar activities conducted by other na-  
22           tional research institutes, centers, and agencies of the Na-  
23           tional Institutes of Health, the Food and Drug Adminis-  
24           tration, and other agencies to the extent that such insti-  
25           tutes, centers, and agencies have responsibilities that are

1 related to food-borne illness, including food-borne illness  
2 potentially associated with terrorism.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
4 is authorized to be appropriated to carry out this section,  
5 \$50,000,000 for fiscal year 2002, and such sums as may  
6 be necessary for subsequent fiscal years.”.

7 **SEC. 8. SURVEILLANCE AND INFORMATION GRANTS AND**  
8 **AUTHORITIES.**

9 Title III of the Public Health Service Act (42 U.S.C.  
10 241 et seq.) is amended by inserting after section 317P  
11 the following:

12 **“SEC. 317Q. FOOD SAFETY GRANTS.**

13 “(a) IN GENERAL.—The Secretary may award food  
14 safety grants to States to expand the number of States  
15 participating in Pulsenet, the Foodborne Diseases Active  
16 Surveillance Network, and other networks to enhance Fed-  
17 eral, State, and local food safety efforts.

18 “(b) USE OF FUNDS.—Funds awarded under this  
19 section shall be used by States to assist such States in  
20 meeting the costs of establishing and maintaining the food  
21 safety surveillance, technical and laboratory capacity need-  
22 ed to participate in Pulsenet, Foodborne Diseases Active  
23 Surveillance Network, and other networks to enhance Fed-  
24 eral, State, and local food safety efforts.

1       “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
2 is authorized to be appropriated to carry out this section,  
3 \$40,000,000 for fiscal year 2002, and such sums as may  
4 be necessary for subsequent fiscal years.

5       **“SEC. 317R. SURVEILLANCE OF ANIMAL AND HUMAN**  
6                                   **HEALTH.**

7       “(a) IN GENERAL.—The Secretary, through the  
8 Commissioner of the Food and Drug Administration, the  
9 Director of the Centers for Disease Control and Preven-  
10 tion, and the Secretary of Agriculture, shall develop and  
11 implement a plan for coordinating the surveillance for  
12 zoonotic disease and human disease.

13       “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
14 is authorized to be appropriated to carry out this section,  
15 such sums as may be necessary.

16       **“SEC. 317S. INFORMATION RESOURCES FOR HEALTH PRO-**  
17                                   **FESSIONALS.**

18       “(a) IN GENERAL.—The Secretary, through the Di-  
19 rector of the Centers for Disease Control may establish,  
20 or, may enter into contracts to establish hotlines, informa-  
21 tion technology systems, or other information resources to  
22 assist and educate health professionals in the diagnosis  
23 and detection of illnesses caused by bioterrorism, including  
24 food-borne bioterrorism.

1       “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
2 is authorized to be appropriated to carry out this section,  
3 \$10,000,000 for fiscal year 2002, and such sums as may  
4 be necessary for subsequent fiscal years.”.

5 **SEC. 9. DEFINITIONS.**

6       Chapter II of the Federal Food, Drug, and Cosmetic  
7 Act (21 U.S.C. 321 et seq.) is amended by adding at the  
8 end the following:

9       “(kk) The term ‘contaminant’ includes a bacterium,  
10 a chemical contaminant, a natural toxin, a virus, a para-  
11 site, and a physical hazard, that when found on or in food  
12 can cause human illness or injury.

13       “(ll) The term ‘process’ means the commercial har-  
14 vesting, preparation, manufacture, or transportation of a  
15 food product.”.

○