#### 109TH CONGRESS 1ST SESSION

# S. 1534

To reduce the risk to the food supply from intentional contamination, and for other purposes.

#### IN THE SENATE OF THE UNITED STATES

July 28, 2005

Mr. Durbin (for himself and Mr. Akaka) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

## A BILL

To reduce the risk to the food supply from intentional contamination, 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 "Safe and Secure Food Act of 2005".
- 6 (b) Table of Contents.—
  - Sec. 1. Short title; table of contents.

#### TITLE I—FOOD SECURITY

Subtitle A—Department of Agriculture

- Sec. 101. Food security for meat and meat food products.
- Sec. 102. Food security for poultry and poultry food products.
- Sec. 103. Food security for eggs and egg products.

Sec. 104. Confidentiality of information.

Subtitle B—Food and Drug Administration

Sec. 111. Food security for food products.

Subtitle C—Inspector Training

Sec. 121. Inspector training for food security.

#### TITLE II—RECALL AUTHORITY

#### Subtitle A—Department of Agriculture

- Sec. 201. Food safety enforcement for meat and meat food products.
- Sec. 202. Food safety enforcement for poultry and poultry food products.
- Sec. 203. Food safety enforcement for eggs and egg products.
- Sec. 204. Liability.

#### Subtitle B—Food and Drug Administration

Sec. 211. Food safety enforcement for food.

Sec. 212. Liability.

#### TITLE III—IMPORTED FOOD

Sec. 301. Imported food.

#### TITLE IV—RISK ASSESSMENT INFORMATION SHARING

Sec. 401. Risk assessment information sharing.

### 1 TITLE I—FOOD SECURITY

## 2 Subtitle A—Department of

## 3 **Agriculture**

- 4 SEC. 101. FOOD SECURITY FOR MEAT AND MEAT FOOD
- 5 PRODUCTS.
- 6 The Federal Meat Inspection Act (21 U.S.C. 601 et
- 7 seq.) is amended—
- 8 (1) by redesignating section 411 (21 U.S.C.
- 9 680) as section 415; and
- 10 (2) by inserting after section 410 (21 U.S.C.
- 11 679a) the following:

### 1 "SEC. 411. FOOD SECURITY.

2	"(a) In General.—The Secretary, in consultation
3	with the Secretary of Health and Human Services, shall
4	promulgate regulations that require persons to implement
5	procedures to prevent both unintentional and intentional
6	contamination of meat and meat food products at estab-
7	lishments covered by this Act.
8	"(b) Scope of Regulations.—The regulations
9	shall require a person responsible for an establishment
10	covered by this Act to implement security procedures for
11	the entire establishment, as determined by the Secretary,
12	including—
13	"(1) developing a security plan that addresses
14	the specific vulnerabilities of the establishment;
15	"(2) developing an emergency response plan for
16	the establishment;
17	"(3) securing establishment boundaries;
18	"(4) providing guards, alarms, and outside
19	lighting, as necessary;
20	"(5) performing background checks before hir-
21	ing new personnel;
22	"(6) limiting access to the establishment;
23	"(7) accounting for missing stock;
24	"(8) implementing mail-handling procedures;
25	and

1	"(9) such other security procedures as the Sec-
2	retary determines to be necessary to prevent unin-
3	tentional or intentional contamination of meat and
4	meat food products.
5	"(c) Training of Field Inspectors.—The Sec-
6	retary shall provide training for field inspectors of the
7	Food Safety and Inspection Service to monitor the imple-
8	mentation of the regulations described in subsection (a)."
9	SEC. 102. FOOD SECURITY FOR POULTRY AND POULTRY
10	FOOD PRODUCTS.
11	(a) In General.—The Poultry Products Inspection
12	Act (21 U.S.C. 451 et seq.) is amended—
13	(1) by redesignating sections 26 through 29 as
14	sections 31 through 34 and moving those sections to
15	the end of that Act;
16	(2) by redesignating section 30 as section 26
17	and
18	(3) by inserting after section 26 (as redesig-
19	nated by paragraph (2)) the following:
20	"SEC. 27. FOOD SECURITY.
21	"(a) In General.—The Secretary, in consultation
22	with the Secretary of Health and Human Services, shall
23	promulgate regulations that require persons to implement
24	procedures to prevent both unintentional and intentional

1	contamination of poultry and poultry food products at es-
2	tablishments covered by this Act.
3	"(b) Scope of Regulations.—The regulations
4	shall require a person that is responsible for an establish-
5	ment covered by this Act to implement security procedures
6	for the entire establishment, as determined by the Sec-
7	retary, including—
8	"(1) developing a security plan that addresses
9	the specific vulnerabilities of the establishment;
10	"(2) developing an emergency response plan for
11	the establishment;
12	"(3) securing establishment boundaries;
13	"(4) providing guards, alarms, and outside
14	lighting, as necessary;
15	"(5) performing background checks before hir-
16	ing new personnel;
17	"(6) limiting access to the establishment;
18	"(7) accounting for missing stock;
19	"(8) implementing mail-handling procedures;
20	and
21	"(9) such other security procedures as the Sec-
22	retary determines to be necessary to prevent unin-
23	tentional or intentional contamination of poultry and
24	poultry food products.

- 1 "(c) Training of Field Inspectors.—The Sec-
- 2 retary shall provide training for field inspectors of the
- 3 Food Safety and Inspection Service to monitor the imple-
- 4 mentation of the regulations described in subsection (a).".
- 5 (b) Conforming Amendments.—Section 5(c)(1) of
- 6 the Poultry Products Inspection Act (21 U.S.C.
- 7 454(c)(1) is amended in the first sentence—
- 8 (1) by striking ", by thirty days prior to the ex-
- 9 piration of two years after enactment of the Whole-
- some Poultry Products Act,"; and
- 11 (2) by striking "sections 1–4, 6–10, and 12–22
- of this Act" and inserting "sections 1 through 4, 6
- through 10, 12 through 22, and 27 through 30".
- 14 SEC. 103. FOOD SECURITY FOR EGGS AND EGG PRODUCTS.
- The Egg Products Inspection Act (21 U.S.C. 1031
- 16 et seq.) is amended—
- 17 (1) by redesignating sections 27 through 29 as
- sections 31 through 33, respectively;
- 19 (2) by inserting after section 26 (21 U.S.C.
- 20 1054) the following:
- 21 "SEC. 27. FOOD SECURITY.
- 22 "(a) In General.—The Secretary, in consultation
- 23 with the Secretary of Health and Human Services, shall
- 24 promulgate regulations that require persons to implement
- 25 procedures to prevent both unintentional and intentional

1	contamination of eggs and egg products at establishments
2	covered by this Act.
3	"(b) Scope of Regulations.—The regulations
4	shall require a person that is responsible for an establish-
5	ment covered by this Act to implement security procedures
6	for the entire establishment, as determined by the Sec-
7	retary, including—
8	"(1) developing a security plan that addresses
9	the specific vulnerabilities of the establishment;
10	"(2) developing an emergency response plan for
11	the establishment;
12	"(3) securing establishment boundaries;
13	"(4) providing guards, alarms, and outside
14	lighting, as necessary;
15	"(5) performing background checks before hir-
16	ing new personnel;
17	"(6) limiting access to the establishment;
18	"(7) accounting for missing stock;
19	"(8) implementing mail-handling procedures;
20	and
21	"(9) such other security procedures as the Sec-
22	retary determines to be necessary to prevent unin-
23	tentional or intentional contamination of eggs and
24	egg products.

1	"(c) Training of Field Inspectors.—The Sec-
2	retary shall provide training for field inspectors of the
3	Food Safety and Inspection Service to monitor the imple-
4	mentation of the regulations described in subsection (a).".
5	SEC. 104. CONFIDENTIALITY OF INFORMATION.
6	Section 1770(d) of the Food Security Act of 1985
7	(7 U.S.C. 2276(d)) is amended—
8	(1) in paragraph (11), by striking "or"; and
9	(2) by adding at the end the following:
10	"(13) section 411 of the Federal Meat Inspec-
11	tion Act;
12	"(14) section 31 of the Poultry Products In-
13	spection Act; or
14	"(15) section 27 of the Egg Products Inspec-
15	tion Act.".
16	Subtitle B—Food and Drug
17	Administration
18	SEC. 111. FOOD SECURITY FOR FOOD PRODUCTS.
19	(a) In General.—Chapter IV of the Federal Food,
20	Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
21	ed by adding at the end the following:
22	"SEC. 416. FOOD SECURITY.
23	"(a) In General.—The Secretary, in consultation
24	with the Secretary of Agriculture, shall promulgate regula-
25	tions that require persons to implement procedures to pre-

1	vent both unintentional and intentional contamination of
2	food at domestic facilities covered by this Act.
3	"(b) Scope of Regulations.—The regulations
4	shall—
5	"(1) direct food inspectors to check for the
6	safety and security of food during an inspection of
7	a domestic facility; and
8	"(2) require a person that is responsible for a
9	domestic facility to implement security procedures
10	for the entire domestic facility, as determined by the
11	Secretary, including—
12	"(A) developing a security plan that ad-
13	dresses the specific vulnerabilities of the facil-
14	ity;
15	"(B) developing an emergency response
16	plan for the facility;
17	"(C) securing establishment boundaries;
18	"(D) providing guards, alarms, and outside
19	lighting, as necessary;
20	"(E) performing background checks before
21	hiring new personnel;
22	"(F) limiting access to the facility;
23	"(G) accounting for missing stock;
24	"(H) implementing mail-handling proce-
25	dures; and

1	"(I) such other security procedures as the
2	Secretary determines to be necessary to prevent
3	unintentional or intentional contamination of
4	food.
5	"(c) Training of Field Inspectors.—The Sec-
6	retary shall provide training for field inspectors of the
7	Food and Drug Administration to monitor the implemen-
8	tation of the regulations described in subsection (a).
9	"(d) Protection of Information.—Information
10	furnished under the regulations described in subsection (a)
11	shall not be disclosed under section 552 of title 5, United
12	States Code (commonly known as the Freedom of Infor-
13	mation Act).
14	"(e) Definition.—In this section, the term 'domes-
15	tic facility' has the meaning given that term under section
16	415(b)(2).".
17	Subtitle C—Inspector Training
18	SEC. 121. INSPECTOR TRAINING FOR FOOD SECURITY.
19	(a) In General.—Not later than 180 days after the
20	date of enactment of this Act, the Secretary of Agri-
21	culture, in consultation with the Secretary of Health and
	Human Services, shall develop, publish, and initiate imple-

23 mentation of a joint training program for individuals who

24 perform inspections with respect to the food security regu-

1	lations promulgated pursuant to the amendments made by
2	this title.
3	(b) Continuing Training.—As part of the training
4	program implemented under subsection (a), the Secretary
5	of Agriculture and the Secretary of Health and Human
6	Services shall require individuals described in subsection
7	(a) to meet training and retraining requirements, as deter-
8	mined by the Secretaries, at least once every 2 years.
9	TITLE II—RECALL AUTHORITY
10	Subtitle A—Department of
11	Agriculture
12	SEC. 201. FOOD SAFETY ENFORCEMENT FOR MEAT AND
13	MEAT FOOD PRODUCTS.
14	(a) In General.—The Federal Meat Inspection Act
15	(21 U.S.C. 601 et seq.) is amended by adding after section
16	411 (as added by section 101) the following:
17	"SEC. 412. NOTIFICATION, NONDISTRIBUTION, AND RECALL
18	OF ADULTERATED OR MISBRANDED ARTI-
19	CLES.
20	"(a) Notification to Secretary of Violation.—
21	"(1) IN GENERAL.—A person (other than a
22	household consumer) that has reason to believe that
23	any carcass, part of a carcass, meat, or meat food
24	product of cattle, sheep, swine, goats, horses, mules,
25	or other equines (referred to in this section as an

'article') transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall, as soon as practicable, notify the Secretary of the identity and location of the article.

"(2) Manner of notification.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

### "(b) RECALL AND CONSUMER NOTIFICATION.—

"(1) Voluntary actions.—On receiving notification under subsection (a) or by other means, if the Secretary finds that an article is adulterated or misbranded and that there is a reasonable probability that human consumption of the article would present a threat to public health (as determined by the Secretary), the Secretary shall provide all appropriate persons (as determined by the Secretary), that transported, stored, distributed, or otherwise handled the article with an opportunity—

"(A) to cease distribution of the article;

"(B) to notify all persons that transport, store, distribute, or otherwise handle the article, or to which the article has been transported, sold, distributed, or otherwise handled, to cease immediately distribution of the article;

1	"(C) to recall the article; or
2	"(D) in consultation with the Secretary, to
3	provide notice of the finding of the Secretary to
4	all consumers to which the article was, or may
5	have been, distributed.
6	"(2) Mandatory actions.—If the appropriate
7	person referred to in paragraph (1) does not carry
8	out the actions described in that paragraph with re-
9	spect to an article within the time period and in the
10	manner prescribed by the Secretary, the Secretary
11	shall, by order, require, as the Secretary determines
12	to be necessary, the person—
13	"(A) to cease immediately distribution of
14	the article; and
15	"(B) to make immediately the notification
16	described in paragraph (1)(B).
17	"(3) Notice to consumers.—The Secretary
18	shall, as the Secretary determines to be necessary,
19	provide notice of the finding of the Secretary under
20	paragraph (1) to consumers to which the article was,
21	or may have been, distributed.
22	"(4) Nondistribution by notified per-
23	sons.—A person that transports, stores, distributes,
24	or otherwise handles the article, or to which the arti-
25	cle has been transported, sold, distributed, or other-

1	wise handled, and that is notified under paragraph
2	(1)(B) or (2)(B) shall cease immediately distribution
3	of the article.
4	"(5) Availability of records to sec-
5	RETARY.—Each appropriate person referred to in
6	paragraph (1) that transported, stored, distributed,
7	or otherwise handled an article shall make available
8	to the Secretary information necessary to carry out
9	this subsection, as determined by the Secretary, re-
10	garding—
11	"(A) persons that transport, store, dis-
12	tribute, or otherwise handle the article; and
13	"(B) persons to which the article has been
14	transported, sold, distributed, or otherwise han-
15	dled.
16	"(c) Informal Hearings on Orders.—
17	"(1) In general.—The Secretary shall provide
18	a person subject to an order under subsection (b)
19	with an opportunity for an informal hearing (in ac-
20	cordance with such rules or regulations as the Sec-
21	retary shall prescribe) on—
22	"(A) the actions required by the order; and
23	"(B) any reasons why the article that is
24	the subject of the order should not be recalled.

1	"(2) Timing of Hearings.—The Secretary
2	shall hold a hearing under paragraph (1) as soon as
3	practicable, but not later than 2 business days, after
4	the date of issuance of the order.
5	"(d) Post-Hearing Recall Orders.—
6	"(1) Amendment of orders.—If, after pro-
7	viding an opportunity for an informal hearing under
8	subsection (c), the Secretary determines that there is
9	a reasonable probability that human consumption of
10	the article that is the subject of an order under sub-
11	section (b) presents a threat to public health, the
12	Secretary may, as the Secretary determines to be
13	necessary—
14	"(A) amend the order under subsection
15	(b)—
16	"(i) to require recall of the article or
17	other appropriate action; and
18	"(ii) to specify a timetable during
19	which the recall shall occur;
20	"(B) require periodic reports to the Sec-
21	retary describing the progress of the recall; or
22	"(C) provide notice of the recall to con-
23	sumers to which the article was, or may have
24	been, distributed.

- 1 "(2) Vacation of orders.—If, after providing
- an opportunity for an informal hearing under sub-
- 3 section (c), the Secretary determines that adequate
- 4 grounds do not exist to continue the actions required
- 5 by the order, the Secretary shall vacate the order.
- 6 "(e) Remedies Not Exclusive.—The remedies au-
- 7 thorized by this section shall be in addition to any other
- 8 remedies that may be available.

#### 9 "SEC. 413. REFUSAL OR WITHDRAWAL OF INSPECTION OF

- 10 ESTABLISHMENTS.
- 11 "(a) IN GENERAL.—The Secretary may, for such pe-
- 12 riod, or indefinitely, as the Secretary considers necessary
- 13 to carry out this Act, refuse to provide or withdraw inspec-
- 14 tion under title I with respect to an establishment if the
- 15 Secretary determines, after opportunity for a hearing on
- 16 the record is provided to the applicant for, or recipient
- 17 of, inspection, that the applicant or recipient, or any per-
- 18 son responsibly connected with the applicant or recipient
- 19 (within the meaning of section 401), has committed a will-
- 20 ful violation or repeated violations of this Act (including
- 21 a regulation promulgated under this Act).
- 22 "(b) Denial or Suspension of Inspection Pend-
- 23 ING HEARING.—The Secretary may deny or suspend in-
- 24 spection under title I, pending opportunity for an expe-
- 25 dited hearing, with respect to an action under subsection

1	(a), if the Secretary determines that the denial or suspen-
2	sion is in the public interest to protect the health or wel-
3	fare of consumers or to ensure the effective performance
4	of an official duty under this Act.
5	"(c) Judicial Review.—
6	"(1) IN GENERAL.—A determination and order
7	of the Secretary with respect to the refusal or with-
8	drawal of inspection under this section shall be final
9	unless, not later than 30 days after the effective
10	date of the order, the affected applicant for, or re-
11	cipient of, inspection—
12	"(A) files a petition for judicial review of
13	the order; and
14	"(B) simultaneously sends a copy of the
15	petition by certified mail to the Secretary.
16	"(2) Refusal or withdrawal of inspec-
17	TION PENDING REVIEW.—Inspection shall be refused
18	or withdrawn as of the effective date of the order
19	pending any judicial review of the order unless the
20	Secretary directs otherwise.
21	"(3) Venue; record.—Judicial review of the
22	order shall be—
23	"(A) in—
24	"(i) the United States court of ap-
25	peals for the circuit in which the applicant

1	for, or recipient of, inspection resides or
2	has its principal place of business; or
3	"(ii) the United States Court of Ap-
4	peals for the District of Columbia Circuit;
5	and
6	"(B) on the record on which the deter-
7	mination and order are based.
8	"(d) Remedies Not Exclusive.—The remedies au-
9	thorized by this section shall be in addition to any other
10	remedies that may be available.
11	"SEC. 414. CIVIL PENALTIES.
12	"(a) In General.—
13	"(1) Assessment.—The Secretary may assess
14	against a person that commits a serious violation (as
15	defined by the Secretary by regulation) of this Act
16	(including a regulation promulgated or order issued
17	under this Act) a civil penalty for each violation of
18	not more than \$100,000.
19	"(2) Separate offenses.—Each violation
20	and each day during which the violation continues
21	shall be considered to be a separate offense.
22	"(3) Notice and opportunity for hear-
23	ING.—The Secretary shall not assess a civil penalty
24	under this section against a person unless the person
25	is given notice and opportunity for a hearing on the

1	record before the Secretary in accordance with sec-
2	tions 554 and 556 of title 5, United States Code.
3	"(4) Determination of civil penalty
4	AMOUNT.—The amount of a civil penalty under this
5	section—
6	"(A) shall be assessed by the Secretary by
7	written order, taking into account—
8	"(i) the gravity of the violation;
9	"(ii) the degree of culpability of the
10	person;
11	"(iii) the size and type of the business
12	of the person; and
13	"(iv) any history of prior offenses by
14	the person under this Act; and
15	"(B) shall be reviewed only in accordance
16	with subsection (b).
17	"(b) Judicial Review.—
18	"(1) In general.—An order assessing a civil
19	penalty against a person under subsection (a) shall
20	be final unless the person—
21	"(A) not later than 30 days after the effec-
22	tive date of the order, files a petition for judi-
23	cial review of the order in—
24	"(i) the United States court of ap-
25	peals for the circuit in which the person re-

1	sides or has its principal place of business;
2	$\operatorname{or}$
3	"(ii) the United States Court of Ap-
4	peals for the District of Columbia Circuit;
5	and
6	"(B) simultaneously sends a copy of the
7	petition by certified mail to the Secretary.
8	"(2) FILING OF COPY OF RECORD.—The Sec-
9	retary shall promptly file in the court a certified
10	copy of the record on which the order was issued.
11	"(c) Collection Actions for Failure To Pay
12	Assessment.—
13	"(1) Referral to attorney general.—If a
14	person fails to pay a civil penalty assessed under
15	subsection (a) after the order assessing the civil pen-
16	alty has become a final order, or after the court of
17	appeals has entered final judgment in favor of the
18	Secretary, the Secretary shall refer the matter to the
19	Attorney General.
20	"(2) Action by attorney general.—Upon
21	referral of a matter under paragraph (1), the Attor-
22	ney General shall bring a civil action to recover the
23	amount of the civil penalty in United States district
24	court.

1	"(3) Scope of Review.—In a civil action
2	under paragraph (2), the validity and appropriate-
3	ness of the order of the Secretary assessing the civil
4	penalty shall not be subject to review.
5	"(d) Refusal or Withdrawal of Inspection
6	PENDING PAYMENT.—If a person fails to pay the amount
7	of a civil penalty after the order assessing the civil penalty
8	has become a final order, the Secretary may refuse to pro-
9	vide or withdraw inspection under title I of the person
10	until the civil penalty is paid or until the Secretary directs
11	otherwise.
12	"(e) Penalties in Lieu of Other Actions.—
13	Nothing in this Act requires the Secretary to report for
14	prosecution, or for the commencement of an action, any
15	violation of this Act in any case in which the Secretary
16	believes that the public interest will be adequately served
17	by the assessment of a civil penalty under this section.
18	"(f) Remedies Not Exclusive.—The remedies au-
19	thorized by this section shall be in addition to any other
20	remedies that may be available.".
21	(b) Criminal Penalties.—
22	(1) Assaulting, resisting, or impeding
23	CERTAIN PERSONS.—Section 405 of the Federal
24	Meat Inspection Act (21 U.S.C. 675) is amended—

1	(A) in the first sentence, by striking "not
2	more than \$5,000" and inserting "under title
3	18, United States Code,"; and
4	(B) in the second sentence, by striking
5	"not more than \$10,000" and inserting "under
6	title 18, United States Code,".
7	(2) Violations.—Section 406 of the Federal
8	Meat Inspection Act (21 U.S.C. 676) is amended—
9	(A) by striking "of not more than \$1,000,"
10	and inserting "under title 18, United States
11	Code,"; and
12	(B) by striking "of not more than
13	\$10,000," and inserting "under title 18, United
14	States Code,".
15	(c) Conforming Amendments.—
16	(1) Section 1 of the Federal Meat Inspection
17	Act (21 U.S.C. 601) is amended by adding at the
18	end the following:
19	"(w) Person.—The term 'person' means any indi-
20	vidual, partnership, corporation, association, or other busi-
21	ness unit.".
22	(2) The Federal Meat Inspection Act (21
23	U.S.C. 601 et seq.) is amended—

1	(A) by striking "person, firm, or corpora-
2	tion" each place it appears and inserting "per-
3	son'';
4	(B) by striking "persons, firms, and cor-
5	porations" each place it appears and inserting
6	"persons"; and
7	(C) by striking "persons, firms, or corpora-
8	tions" each place it appears and inserting "per-
9	sons''.
10	SEC. 202. FOOD SAFETY ENFORCEMENT FOR POULTRY AND
11	POULTRY FOOD PRODUCTS.
12	(a) In General.—The Poultry Products Inspection
13	Act (21 U.S.C. 451 et seq.) (as amended by section 102)
14	is amended by inserting after section 27 (as added by sec-
15	tion $102(a)(3)$ ) the following:
16	"SEC. 28. NOTIFICATION, NONDISTRIBUTION, AND RECALL
17	OF ADULTERATED OR MISBRANDED ARTI-
18	CLES.
19	"(a) Notification to Secretary of Violation.—
20	"(1) IN GENERAL.—A person (other than a
21	household consumer) that has reason to believe that
22	any poultry or poultry product (referred to in this
23	section as an 'article') transported, stored, distrib-
24	uted, or otherwise handled by the person is adulter-
25	ated or misbranded shall, as soon as practicable, no-

1	tify the Secretary of the identity and location of the
2	article.
3	"(2) Manner of Notification.—Notification
4	under paragraph (1) shall be made in such manner
5	and by such means as the Secretary may require by
6	regulation.
7	"(b) Recall and Consumer Notification.—
8	"(1) Voluntary actions.—On receiving noti-
9	fication under subsection (a) or by other means, it
10	the Secretary finds that an article is adulterated or
11	misbranded and that there is a reasonable prob-
12	ability that human consumption of the article would
13	present a threat to public health (as determined by
14	the Secretary), the Secretary shall provide all appro-
15	priate persons (as determined by the Secretary),
16	that transported, stored, distributed, or otherwise
17	handled the article with an opportunity—
18	"(A) to cease distribution of the article;
19	"(B) to notify all persons that transport
20	store, distribute, or otherwise handle the article
21	or to which the article has been transported
22	sold, distributed, or otherwise handled, to cease
23	immediately distribution of the article;
24	"(C) to recall the article; or

1	"(D) in consultation with the Secretary, to
2	provide notice of the finding of the Secretary to
3	all consumers to which the article was, or may
4	have been, distributed.
5	"(2) Mandatory actions.—If the appropriate
6	person referred to in paragraph (1) does not carry
7	out the actions described in that paragraph with re-
8	spect to an article within the time period and in the
9	manner prescribed by the Secretary, the Secretary
10	shall, by order, require, as the Secretary determines
11	to be necessary, the person—
12	"(A) to cease immediately distribution of
13	the article; and
14	"(B) to make immediately the notification
15	described in paragraph (1)(B).
16	"(3) Notice to consumers.—The Secretary
17	shall, as the Secretary determines to be necessary,
18	provide notice of the finding of the Secretary under
19	paragraph (1) to consumers to which the article was
20	or may have been, distributed.
21	"(4) Nondistribution by notified per-
22	sons.—A person that transports, stores, distributes,
23	or otherwise handles the article, or to which the arti-
24	cle has been transported, sold, distributed, or other-

wise handled, and that is notified under paragraph

25

1	(1)(B) or $(2)(B)$ shall cease immediately distribution
2	of the article.
3	"(5) Availability of records to sec-
4	RETARY.—Each appropriate person referred to in
5	paragraph (1) that transported, stored, distributed,
6	or otherwise handled an article shall make available
7	to the Secretary information necessary to carry out
8	this subsection, as determined by the Secretary, re-
9	garding—
10	"(A) persons that transport, store, dis-
11	tribute, or otherwise handle the article; and
12	"(B) persons to which the article has been
13	transported, sold, distributed, or otherwise han-
14	dled.
15	"(c) Informal Hearings on Orders.—
16	"(1) In general.—The Secretary shall provide
17	a person subject to an order under subsection (b)
18	with an opportunity for an informal hearing (in ac-
19	cordance with such rules or regulations as the Sec-
20	retary shall prescribe) on—
21	"(A) the actions required by the order; and
22	"(B) any reasons why the article that is
23	the subject of the order should not be recalled.
24	"(2) Timing of Hearings.—The Secretary
25	shall hold a hearing under paragraph (1) as soon as

1	practicable, but not later than 2 business days, after
2	the date of issuance of the order.
3	"(d) Post-Hearing Recall Orders.—
4	"(1) Amendment of orders.—If, after pro-
5	viding an opportunity for an informal hearing under
6	subsection (c), the Secretary determines that there is
7	a reasonable probability that human consumption of
8	the article that is the subject of an order under sub-
9	section (b) presents a threat to public health, the
10	Secretary may, as the Secretary determines to be
11	necessary—
12	"(A) amend the order under subsection
13	(b)—
14	"(i) to require recall of the article or
15	other appropriate action; and
16	"(ii) to specify a timetable during
17	which the recall shall occur;
18	"(B) require periodic reports to the Sec-
19	retary describing the progress of the recall; or
20	"(C) provide notice of the recall to con-
21	sumers to which the article was, or may have
22	been, distributed.
23	"(2) Vacation of orders.—If, after providing
24	an opportunity for an informal hearing under sub-
25	section (c), the Secretary determines that adequate

- 1 grounds do not exist to continue the actions required
- 2 by the order, the Secretary shall vacate the order.
- 3 "(e) Remedies Not Exclusive.—The remedies au-
- 4 thorized by this section shall be in addition to any other
- 5 remedies that may be available.
- 6 "SEC. 29. REFUSAL OR WITHDRAWAL OF INSPECTION OF
- 7 ESTABLISHMENTS.
- 8 "(a) IN GENERAL.—The Secretary may, for such pe-
- 9 riod, or indefinitely, as the Secretary considers necessary
- 10 to carry out this Act, refuse to provide or withdraw inspec-
- 11 tion under this Act with respect to an establishment if the
- 12 Secretary determines, after opportunity for a hearing on
- 13 the record is provided to the applicant for, or recipient
- 14 of, inspection, that the applicant or recipient, or any per-
- 15 son responsibly connected with the applicant or recipient
- 16 (within the meaning of section 18(a)), has committed a
- 17 willful violation or repeated violations of this Act (includ-
- 18 ing a regulation promulgated under this Act).
- 19 "(b) Denial or Suspension of Inspection Pend-
- 20 ING HEARING.—The Secretary may deny or suspend in-
- 21 spection under this Act, pending opportunity for an expe-
- 22 dited hearing, with respect to an action under subsection
- 23 (a), if the Secretary determines that the denial or suspen-
- 24 sion is in the public interest to protect the health or wel-

1	fare of consumers or to ensure the effective performance
2	of an official duty under this Act.
3	"(c) Judicial Review.—
4	"(1) In general.—A determination and order
5	of the Secretary with respect to the refusal or with-
6	drawal of inspection under this section shall be final
7	unless, not later than 30 days after the effective
8	date of the order, the affected applicant for, or re-
9	cipient of, inspection—
10	"(A) files a petition for judicial review of
11	the order; and
12	"(B) simultaneously sends a copy of the
13	petition by certified mail to the Secretary.
14	"(2) Refusal or withdrawal of inspec-
15	TION PENDING REVIEW.—Inspection shall be refused
16	or withdrawn as of the effective date of the order
17	pending any judicial review of the order unless the
18	Secretary directs otherwise.
19	"(3) Venue; record.—Judicial review of the
20	order shall be—
21	"(A) in—
22	"(i) the United States court of ap-
23	peals for the circuit in which the applicant
24	for, or recipient of, inspection resides or
25	has its principal place of business; or

1	"(ii) the United States Court of Ap-
2	peals for the District of Columbia Circuit;
3	and
4	"(B) on the record on which the deter-
5	mination and order are based.
6	"(d) Remedies Not Exclusive.—The remedies au-
7	thorized by this section shall be in addition to any other
8	remedies that may be available.
9	"SEC. 30. CIVIL PENALTIES.
10	"(a) In General.—
11	"(1) Assessment.—The Secretary may assess
12	against a person that commits a serious violation (as
13	defined by the Secretary by regulation) of this Act
14	(including a regulation promulgated or order issued
15	under this Act) a civil penalty for each violation of
16	not more than \$100,000.
17	"(2) Separate offenses.—Each violation
18	and each day during which the violation continues
19	shall be considered to be a separate offense.
20	"(3) Notice and opportunity for hear-
21	ING.—The Secretary shall not assess a civil penalty
22	under this section against a person unless the person
23	is given notice and opportunity for a hearing on the
24	record before the Secretary in accordance with sec-
25	tions 554 and 556 of title 5, United States Code.

1	"(4) Determination of civil penalty
2	AMOUNT.—The amount of a civil penalty under this
3	section—
4	"(A) shall be assessed by the Secretary by
5	written order, taking into account—
6	"(i) the gravity of the violation;
7	"(ii) the degree of culpability of the
8	person;
9	"(iii) the size and type of the business
10	of the person; and
11	"(iv) any history of prior offenses by
12	the person under this Act; and
13	"(B) shall be reviewed only in accordance
14	with subsection (b).
15	"(b) Judicial Review.—
16	"(1) In general.—An order assessing a civil
17	penalty against a person under subsection (a) shall
18	be final unless the person—
19	"(A) not later than 30 days after the effec-
20	tive date of the order, files a petition for judi-
21	cial review of the order in—
22	"(i) the United States court of ap-
23	peals for the circuit in which the person re-
24	sides or has its principal place of business;
25	or

1	"(ii) the United States Court of Ap-
2	peals for the District of Columbia Circuit;
3	and
4	"(B) simultaneously sends a copy of the
5	petition by certified mail to the Secretary.
6	"(2) FILING OF COPY OF RECORD.—The Sec-
7	retary shall promptly file in the court a certified
8	copy of the record on which the order was issued.
9	"(c) Collection Actions for Failure To Pay
10	Assessment.—
11	"(1) Referral to attorney general.—If a
12	person fails to pay a civil penalty assessed under
13	subsection (a) after the order assessing the civil pen-
14	alty has become a final order, or after the court of
15	appeals has entered final judgment in favor of the
16	Secretary, the Secretary shall refer the matter to the
17	Attorney General.
18	"(2) ACTION BY ATTORNEY GENERAL.—Upon
19	referral of a matter under paragraph (1), the Attor-
20	ney General shall bring a civil action to recover the
21	amount of the civil penalty in United States district
22	court.
23	"(3) Scope of Review.—In a civil action
24	under paragraph (2), the validity and appropriate-

1	ness of the order of the Secretary assessing the civil
2	penalty shall not be subject to review.
3	"(d) Refusal or Withdrawal of Inspection
4	PENDING PAYMENT.—If a person fails to pay the amount
5	of a civil penalty after the order assessing the civil penalty
6	has become a final order, the Secretary may refuse to pro-
7	vide or withdraw inspection under this Act of the person
8	until the civil penalty is paid or until the Secretary directs
9	otherwise.
10	"(e) Penalties in Lieu of Other Actions.—
11	Nothing in this Act requires the Secretary to report for
12	prosecution, or for the commencement of an action, any
13	violation of this Act in any case in which the Secretary
14	believes that the public interest will be adequately served
15	by the assessment of a civil penalty under this section.
16	"(f) Remedies Not Exclusive.—The remedies au-
17	thorized by this section shall be in addition to any other
18	remedies that may be available.".
19	(b) Criminal Penalties.—Section 12 of the Poul-
20	try Products Inspection Act (21 U.S.C. 461) is amend-
21	ed—
22	(1) in the first sentence of subsection (a)—
23	(A) by striking "not more than \$1,000"
24	and inserting "under title 18, United States
25	Code,"; and

1	(B) by striking "not more than \$10,000"
2	and inserting "under title 18, United States
3	Code,"; and
4	(2) in subsection (c)—
5	(A) in the first sentence, by striking "not
6	more than \$5,000" and inserting "under title
7	18, United States Code,"; and
8	(B) in the second sentence, by striking
9	"not more than \$10,000" and inserting "under
10	title 18, United States Code,".
11	SEC. 203. FOOD SAFETY ENFORCEMENT FOR EGGS AND
12	EGG PRODUCTS.
13	(a) In General.—The Egg Products Inspection Act
14	(21 U.S.C. 1031 et seq.) is amended by inserting after
15	section 27 (as added by section 103) the following:
16	"SEC. 28. NOTIFICATION, NONDISTRIBUTION, AND RECALL
17	OF ADULTERATED OR MISBRANDED ARTI-
18	CLES.
19	"(a) Notification to Secretary of Violation.—
20	"(1) IN GENERAL.—A person (other than a
21	household consumer) that has reason to believe that
22	any egg or egg product (referred to in this section
23	as an 'article') transported, stored, distributed, or
24	otherwise handled by the person is adulterated or

1 misbranded shall, as soon as practicable, notify the 2 Secretary of the identity and location of the article. "(2) Manner of Notification.—Notification 3 4 under paragraph (1) shall be made in such manner 5 and by such means as the Secretary may require by 6 regulation. 7 "(b) RECALL AND CONSUMER NOTIFICATION.— "(1) Voluntary actions.—On receiving noti-8 9 fication under subsection (a) or by other means, if 10 the Secretary finds that an article is adulterated or 11 misbranded and that there is a reasonable prob-12 ability that human consumption of the article would 13 present a threat to public health (as determined by 14 the Secretary), the Secretary shall provide all appro-15 priate persons (as determined by the Secretary), 16 that transported, stored, distributed, or otherwise 17 handled the article with an opportunity— 18 "(A) to cease distribution of the article; 19 "(B) to notify all persons that transport, 20 store, distribute, or otherwise handle the article, 21 or to which the article has been transported, 22 sold, distributed, or otherwise handled, to cease 23 immediately distribution of the article; "(C) to recall the article; or 24

1	"(D) in consultation with the Secretary, to
2	provide notice of the finding of the Secretary to
3	all consumers to which the article was, or may
4	have been, distributed.
5	"(2) Mandatory actions.—If the appropriate
6	person referred to in paragraph (1) does not carry
7	out the actions described in that paragraph with re-
8	spect to an article within the time period and in the
9	manner prescribed by the Secretary, the Secretary
10	shall, by order, require, as the Secretary determines
11	to be necessary, the person—
12	"(A) to cease immediately distribution of
13	the article; and
14	"(B) to make immediately the notification
15	described in paragraph (1)(B).
16	"(3) Notice to consumers.—The Secretary
17	shall, as the Secretary determines to be necessary,
18	provide notice of the finding of the Secretary under
19	paragraph (1) to consumers to which the article was,
20	or may have been, distributed.
21	"(4) Nondistribution by notified per-
22	SONS.—A person that transports, stores, distributes,
23	or otherwise handles the article, or to which the arti-
24	cle has been transported, sold, distributed, or other-

wise handled, and that is notified under paragraph

25

1	(1)(B) or (2)(B) shall cease immediately distribution
2	of the article.
3	"(5) Availability of records to sec-
4	RETARY.—Each appropriate person referred to in
5	paragraph (1) that transported, stored, distributed,
6	or otherwise handled an article shall make available
7	to the Secretary information necessary to carry out
8	this subsection, as determined by the Secretary, re-
9	garding—
10	"(A) persons that transport, store, dis-
11	tribute, or otherwise handle the article; and
12	"(B) persons to which the article has been
13	transported, sold, distributed, or otherwise han-
14	dled.
15	"(c) Informal Hearings on Orders.—
16	"(1) IN GENERAL.—The Secretary shall provide
17	a person subject to an order under subsection (b)
18	with an opportunity for an informal hearing (in ac-
19	cordance with such rules or regulations as the Sec-
20	retary shall prescribe) on—
21	"(A) the actions required by the order; and
22	"(B) any reasons why the article that is
23	the subject of the order should not be recalled.
24	"(2) Timing of Hearings.—The Secretary
25	shall hold a hearing under paragraph (1) as soon as

1	practicable, but not later than 2 business days, after
2	the date of issuance of the order.
3	"(d) Post-Hearing Recall Orders.—
4	"(1) Amendment of orders.—If, after pro-
5	viding an opportunity for an informal hearing under
6	subsection (c), the Secretary determines that there is
7	a reasonable probability that human consumption of
8	the article that is the subject of an order under sub-
9	section (b) presents a threat to public health, the
10	Secretary may, as the Secretary determines to be
11	necessary—
12	"(A) amend the order under subsection
13	(b)—
14	"(i) to require recall of the article or
15	other appropriate action; and
16	"(ii) to specify a timetable during
17	which the recall shall occur;
18	"(B) require periodic reports to the Sec-
19	retary describing the progress of the recall; or
20	"(C) provide notice of the recall to con-
21	sumers to which the article was, or may have
22	been, distributed.
23	"(2) Vacation of orders.—If, after providing
24	an opportunity for an informal hearing under sub-
25	section (c), the Secretary determines that adequate

- 1 grounds do not exist to continue the actions required
- 2 by the order, the Secretary shall vacate the order.
- 3 "(e) Remedies Not Exclusive.—The remedies au-
- 4 thorized by this section shall be in addition to any other
- 5 remedies that may be available.
- 6 "SEC. 29. REFUSAL OR WITHDRAWAL OF INSPECTION OF
- 7 ESTABLISHMENTS.
- 8 "(a) IN GENERAL.—The Secretary may, for such pe-
- 9 riod, or indefinitely, as the Secretary considers necessary
- 10 to carry out this Act, refuse to provide or withdraw inspec-
- 11 tion under this Act with respect to an establishment if the
- 12 Secretary determines, after opportunity for a hearing on
- 13 the record is provided to the applicant for, or recipient
- 14 of, inspection, that the applicant or recipient, or any per-
- 15 son responsibly connected with the applicant or recipient
- 16 (within the meaning of section 18), has committed a will-
- 17 ful violation or repeated violations of this Act (including
- 18 a regulation promulgated under this Act).
- 19 "(b) Denial or Suspension of Inspection Pend-
- 20 ING HEARING.—The Secretary may deny or suspend in-
- 21 spection under this Act, pending opportunity for an expe-
- 22 dited hearing, with respect to an action under subsection
- 23 (a), if the Secretary determines that the denial or suspen-
- 24 sion is in the public interest to protect the health or wel-

1	fare of consumers or to ensure the effective performance
2	of an official duty under this Act.
3	"(c) Judicial Review.—
4	"(1) In general.—A determination and order
5	of the Secretary with respect to the refusal or with-
6	drawal of inspection under this section shall be final
7	unless, not later than 30 days after the effective
8	date of the order, the affected applicant for, or re-
9	cipient of, inspection—
10	"(A) files a petition for judicial review of
11	the order; and
12	"(B) simultaneously sends a copy of the
13	petition by certified mail to the Secretary.
14	"(2) Refusal or withdrawal of inspec-
15	TION PENDING REVIEW.—Inspection shall be refused
16	or withdrawn as of the effective date of the order
17	pending any judicial review of the order unless the
18	Secretary directs otherwise.
19	"(3) Venue; record.—Judicial review of the
20	order shall be—
21	"(A) in—
22	"(i) the United States court of ap-
23	peals for the circuit in which the applicant
24	for, or recipient of, inspection resides or
25	has its principal place of business; or

1	"(ii) the United States Court of Ap-
2	peals for the District of Columbia Circuit;
3	and
4	"(B) on the record on which the deter-
5	mination and order are based.
6	"(d) Remedies Not Exclusive.—The remedies au-
7	thorized by this section shall be in addition to any other
8	remedies that may be available.
9	"SEC. 30. CIVIL PENALTIES.
10	"(a) In General.—
11	"(1) Assessment.—The Secretary may assess
12	against a person that commits a serious violation (as
13	defined by the Secretary by regulation) of this Act
14	(including a regulation promulgated or order issued
15	under this Act) a civil penalty for each violation of
16	not more than \$100,000.
17	"(2) Separate offenses.—Each violation
18	and each day during which the violation continues
19	shall be considered to be a separate offense.
20	"(3) Notice and opportunity for hear-
21	ING.—The Secretary shall not assess a civil penalty
22	under this section against a person unless the person
23	is given notice and opportunity for a hearing on the
24	record before the Secretary in accordance with sec-
25	tions 554 and 556 of title 5, United States Code.

1	"(4) Determination of civil penalty
2	AMOUNT.—The amount of a civil penalty under this
3	section—
4	"(A) shall be assessed by the Secretary by
5	written order, taking into account—
6	"(i) the gravity of the violation;
7	"(ii) the degree of culpability of the
8	person;
9	"(iii) the size and type of the business
10	of the person; and
11	"(iv) any history of prior offenses by
12	the person under this Act; and
13	"(B) shall be reviewed only in accordance
14	with subsection (b).
15	"(b) Judicial Review.—
16	"(1) In general.—An order assessing a civil
17	penalty against a person under subsection (a) shall
18	be final unless the person—
19	"(A) not later than 30 days after the effec-
20	tive date of the order, files a petition for judi-
21	cial review of the order in—
22	"(i) the United States court of ap-
23	peals for the circuit in which the person re-
24	sides or has its principal place of business;
25	or

1	"(ii) the United States Court of Ap-
2	peals for the District of Columbia Circuit;
3	and
4	"(B) simultaneously sends a copy of the
5	petition by certified mail to the Secretary.
6	"(2) FILING OF COPY OF RECORD.—The Sec-
7	retary shall promptly file in the court a certified
8	copy of the record on which the order was issued.
9	"(c) Collection Actions for Failure to Pay
10	Assessment.—
11	"(1) Referral to attorney general.—If a
12	person fails to pay a civil penalty assessed under
13	subsection (a) after the order assessing the civil pen-
14	alty has become a final order, or after the court of
15	appeals has entered final judgment in favor of the
16	Secretary, the Secretary shall refer the matter to the
17	Attorney General.
18	"(2) Action by attorney general.—Upon
19	referral of a matter under paragraph (1), the Attor-
20	ney General shall bring a civil action to recover the
21	amount of the civil penalty in United States district
22	court.
23	"(3) Scope of Review.—In a civil action
24	under paragraph (2), the validity and appropriate-

1	ness of the order of the Secretary assessing the civil
2	penalty shall not be subject to review.
3	"(d) Refusal or Withdrawal of Inspection
4	PENDING PAYMENT.—If a person fails to pay the amount
5	of a civil penalty after the order assessing the civil penalty
6	has become a final order, the Secretary may refuse to pro-
7	vide or withdraw inspection under this Act of the person
8	until the civil penalty is paid or until the Secretary directs
9	otherwise.
10	"(e) Penalties in Lieu of Other Actions.—
11	Nothing in this Act requires the Secretary to report for
12	prosecution, or for the commencement of an action, any
13	violation of this Act in any case in which the Secretary
14	believes that the public interest will be adequately served
15	by the assessment of a civil penalty under this section.
16	"(f) Remedies Not Exclusive.—The remedies au-
17	thorized by this section shall be in addition to any other
18	remedies that may be available.".
19	(b) Criminal Penalties.—Section 12 of the Egg
20	Products Inspection Act (21 U.S.C. 1041) is amended—
21	(1) in subsection (a)—
22	(A) by striking "of not more than \$5,000"
23	and inserting "under title 18, United States
24	Code'': and

1	(B) by striking "of not more than
2	\$10,000" and inserting "under title 18, United
3	States Code";
4	(2) in subsection (b)—
5	(A) by striking "not more than \$5,000"
6	and inserting "under title 18, United States
7	Code''; and
8	(B) by striking "not more than \$10,000"
9	and inserting "under title 18, United States
10	Code'';
11	(3) by striking subsection (e);
12	(4) in subsection (e), by striking "paragraph (c)
13	of this section 12" and inserting "section 30"; and
14	(5) by redesignating subsections (d) and (e) as
15	subsections (c) and (d), respectively.
16	SEC. 204. LIABILITY.
17	This subtitle and the amendments made by this sub-
18	title shall not affect the liability of any person under any
19	provision of law as in effect before the application of this
20	subtitle and the amendments made by this subtitle.
21	Subtitle B—Food and Drug
22	Administration
23	SEC. 211. FOOD SAFETY ENFORCEMENT FOR FOOD.
24	(a) IN GENERAL.—Chapter IV of the Federal Food,
25	Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) (as

1	amended by section 111) is amended by adding at the end
2	the following:
3	"SEC. 417. NOTIFICATION, NONDISTRIBUTION, AND RECALL
4	OF ADULTERATED OR MISBRANDED FOOD.
5	"(a) Notice to Secretary of Violation.—
6	"(1) IN GENERAL.—A person (other than a
7	household consumer or other individual who is the
8	intended consumer of a food) that has reason to be-
9	lieve that any food introduced into or in interstate
10	commerce, or held for sale (whether or not the first
11	sale) after shipment in interstate commerce, may be
12	in violation of this Act shall immediately notify the
13	Secretary of the identity and location of the food.
14	"(2) Manner of notification.—Notification
15	under paragraph (1) shall be made in such manner
16	and by such means as the Secretary may require by
17	regulation.
18	"(b) RECALL AND CONSUMER NOTIFICATION.—
19	"(1) Voluntary actions.—If the Secretary
20	determines that food is in violation of the food safe-
21	ty law when introduced into or while in interstate
22	commerce or while held for sale (whether or not the
23	first sale) after shipment in interstate commerce and
24	that there is a reasonable probability that the food.

if consumed, would present a threat to public health,

1	as determined by the Secretary, the Secretary shall
2	give the appropriate persons (including the manufac-
3	turers, importers, distributors, or retailers of the
4	food) an opportunity to—
5	"(A) cease distribution of the food;
6	"(B) notify all persons—
7	"(i) processing, distributing, or other-
8	wise handling the food to immediately
9	cease such activities with respect to the
10	food; or
11	"(ii) to which the food has been dis-
12	tributed, transported, or sold, to imme-
13	diately cease distribution of the food;
14	"(C) recall the food;
15	"(D) in conjunction with the Secretary,
16	provide notice of the finding of the Secretary—
17	"(i) to consumers to whom the food
18	was, or may have been, distributed; and
19	"(ii) to State and local public health
20	officials; or
21	"(E) carry out any combination of the
22	measures described in this paragraph, as deter-
23	mined by the Secretary to be appropriate in the
24	circumstances.

1	"(2) Mandatory actions.—If a person re-
2	ferred to in paragraph (1) refuses to or does not
3	adequately carry out the actions described in that
4	paragraph within the time period and in the manner
5	prescribed by the Secretary, the Secretary shall—
6	"(A) have authority to control and possess
7	the food, including ordering the shipment of the
8	food from the food establishment to the Sec-
9	retary—
10	"(i) at the expense of the food estab-
11	lishment; or
12	"(ii) in an emergency (as determined
13	by the Secretary), at the expense of the
14	Administration; and
15	"(B) by order, require, as the Secretary
16	determines to be necessary, the person to imme-
17	diately—
18	"(i) cease distribution of the food; and
19	"(ii) notify all persons—
20	"(I) processing, distributing, or
21	otherwise handling the food to imme-
22	diately cease such activities with re-
23	spect to the food; or

1	"(II) if the food has been distrib-
2	uted, transported, or sold, to imme-
3	diately cease distribution of the food.
4	"(3) Notification to consumers by sec-
5	RETARY.—The Secretary shall, as the Secretary de-
6	termines to be necessary, provide notice of the find-
7	ing of the Secretary under paragraph (1)—
8	"(A) to consumers to whom the food was,
9	or may have been, distributed; and
10	"(B) to State and local public health offi-
11	cials.
12	"(4) Nondistribution by notified per-
13	sons.—A person that processes, distributes, or oth-
14	erwise handles the food, or to which the food has
15	been distributed, transported, or sold, and that is
16	notified under paragraph (1)(B) or (2)(B) shall im-
17	mediately cease distribution of the food.
18	"(5) Availability of records to sec-
19	RETARY.—Each person referred to in paragraph (1)
20	that processed, distributed, or otherwise handled
21	food shall make available to the Secretary informa-
22	tion necessary to carry out this subsection, as deter-
23	mined by the Secretary, regarding—
24	"(A) persons that processed, distributed,
25	or otherwise handled the food; and

1	"(B) persons to which the food has been
2	transported, sold, distributed, or otherwise han-
3	dled.
4	"(c) Informal Hearings on Orders.—
5	"(1) In general.—The Secretary shall provide
6	any person subject to an order under subsection (b)
7	with an opportunity for an informal hearing, to be
8	held as soon as practicable but not later than 2 busi-
9	ness days after the issuance of the order.
10	"(2) Scope of the hearing.—In a hearing
11	under paragraph (1), the Secretary shall consider
12	the actions required by the order and any reasons
13	why the food that is the subject of the order should
14	not be recalled.
15	"(d) Post Hearing Recall Orders.—
16	"(1) Amendment of order.—If, after pro-
17	viding an opportunity for an informal hearing under
18	subsection (c), the Secretary determines that there is
19	a reasonable probability that the food that is the
20	subject of an order under subsection (b), if con-
21	sumed, would present a threat to the public health,
22	the Secretary, as the Secretary determines to be nec-
23	essary, may—
24	"(A) amend the order to require recall of
25	the food or other appropriate action.

1	"(B) specify a timetable in which the recall
2	shall occur;
3	"(C) require periodic reports to the Sec-
4	retary describing the progress of the recall; and
5	"(D) provide notice of the recall to con-
6	sumers to whom the food was, or may have
7	been, distributed.
8	"(2) Vacation of orders.—If, after providing
9	an opportunity for an informal hearing under sub-
10	section (c), the Secretary determines that adequate
11	grounds do not exist to continue the actions required
12	by the order, the Secretary shall vacate the order.
13	"(e) Remedies Not Exclusive.—The remedies
14	provided for in this section shall be in addition to, and
15	not exclusive of, other remedies that may be available.
16	"SEC. 418. REFUSAL OR WITHDRAWAL OF INSPECTION OF
17	ESTABLISHMENTS.
18	"(a) In General.—The Secretary may, for such pe-
19	riod, or indefinitely, as the Secretary considers necessary
20	to carry out this chapter, refuse to provide or withdraw
21	inspection under this chapter with respect to an establish-
22	ment if the Secretary determines, after opportunity for a
23	hearing on the record is provided to the applicant for, or
24	recipient of, inspection, that the applicant or recipient, or
25	any person responsibly connected (within the meaning

1	under section 18 of the Egg Products Inspection Act (21
2	U.S.C. 1047)) with the applicant or recipient, has com-
3	mitted a willful violation or repeated violations of this
4	chapter (including a regulation promulgated under this
5	chapter).
6	"(b) Denial or Suspension of Inspection Pend-
7	ING HEARING.—The Secretary may deny or suspend in-
8	spection under this chapter, pending the opportunity for
9	an expedited hearing, with respect to an action under sub-
10	section (a), if the Secretary determines that the denial or
11	suspension is in the public interest to protect the health
12	or welfare of consumers or to ensure the effective perform-
13	ance of an official duty under this Act.
14	"(c) Judicial Review.—
15	"(1) In general.—A determination and order
16	of the Secretary with respect to the refusal or with-
17	drawal of inspection under this section shall be final
18	unless, not later than 30 days after the effective
19	date of the order, the affected applicant for, or re-
20	cipient of, inspection—
21	"(A) files a petition for judicial review of
22	the order; and
23	"(B) simultaneously sends a copy of the
24	petition by certified mail to the Secretary.

1	"(2) Refusal or withdrawal of inspec-
2	TION PENDING REVIEW.—Inspection shall be refused
3	or withdrawn as of the effective date of the order
4	pending any judicial review of the order unless the
5	Secretary directs otherwise.
6	"(3) Venue; record.—Judicial review of the
7	order shall be—
8	"(A) in—
9	"(i) the United States court of ap-
10	peals for the circuit in which the applicant
11	for, or recipient of, inspection resides or
12	has its principal place of business; or
13	"(ii) the United States Court of Ap-
14	peals for the District of Columbia Circuit;
15	and
16	"(B) on the record on which the deter-
17	mination and order are based.
18	"(d) Remedies Not Exclusive.—The remedies au-
19	thorized by this section shall be in addition to any other
20	remedies that may be available.
21	"SEC. 419. CIVIL PENALTIES.
22	"(a) In General.—
23	"(1) Assessment.—The Secretary may assess
24	against a person that commits a serious violation (as
25	defined by the Secretary by regulation) of section

1	417 (including a regulation promulgated or order
2	issued under such section) a civil penalty for each
3	violation of not more than \$100,000.
4	"(2) Separate offenses.—Each violation
5	and each day during which the violation continues
6	shall be considered to be a separate offense.
7	"(3) Notice and opportunity for hear-
8	ING.—The Secretary shall not assess a civil penalty
9	under this section against a person unless the person
10	is given notice and opportunity for a hearing on the
11	record before the Secretary in accordance with sec-
12	tions 554 and 556 of title 5, United States Code.
13	"(4) Determination of civil penalty
14	AMOUNT.—The amount of a civil penalty under this
15	section—
16	"(A) shall be assessed by the Secretary by
17	written order, taking into account—
18	"(i) the gravity of the violation;
19	"(ii) the degree of culpability of the
20	person;
21	"(iii) the size and type of the business
22	of the person; and
23	"(iv) any history of prior offenses by
24	the person under this Act; and

1	"(B) shall be reviewed only in accordance
2	with subsection (b).
3	"(b) Judicial Review.—
4	"(1) In general.—An order assessing a civil
5	penalty against a person under subsection (a) shall
6	be final unless the person—
7	"(A) not later than 30 days after the effec-
8	tive date of the order, files a petition for judi-
9	cial review of the order in—
10	"(i) the United States court of ap-
11	peals for the circuit in which the person re-
12	sides or has its principal place of business;
13	or
14	"(ii) the United States Court of Ap-
15	peals for the District of Columbia Circuit;
16	and
17	"(B) simultaneously sends a copy of the
18	petition by certified mail to the Secretary.
19	"(2) FILING OF COPY OF RECORD.—The Sec-
20	retary shall promptly file in the court a certified
21	copy of the record on which the order was issued.
22	"(c) Collection Actions for Failure to Pay
23	Assessment.—
24	"(1) Referral to attorney general.—If a
25	person fails to pay a civil penalty assessed under

- 1 subsection (a) after the order assessing the civil pen-
- 2 alty has become a final order, or after the court of
- 3 appeals has entered final judgment in favor of the
- 4 Secretary, the Secretary shall refer the matter to the
- 5 Attorney General.
- 6 "(2) ACTION BY ATTORNEY GENERAL.—Upon
- 7 referral of a matter under paragraph (1), the Attor-
- 8 ney General shall bring a civil action to recover the
- 9 amount of the civil penalty in United States district
- 10 court.
- 11 "(3) Scope of Review.—In a civil action
- under paragraph (2), the validity and appropriate-
- 13 ness of the order of the Secretary assessing the civil
- penalty shall not be subject to review.
- 15 "(d) Refusal or Withdrawal of Inspection
- 16 Pending Payment.—If a person fails to pay the amount
- 17 of a civil penalty after the order assessing the civil penalty
- 18 has become a final order, the Secretary may refuse to pro-
- 19 vide or withdraw inspection under this chapter of the per-
- 20 son until the civil penalty is paid or until the Secretary
- 21 directs otherwise.
- 22 "(e) Penalties in Lieu of Other Actions.—
- 23 Nothing in this Act requires the Secretary to report for
- 24 prosecution, or for the commencement of an action, any
- 25 violation of this chapter in any case in which the Secretary

- 1 believes that the public interest will be adequately served
- 2 by the assessment of a civil penalty under this section.
- 3 "(f) Remedies Not Exclusive.—The remedies au-
- 4 thorized by this section shall be in addition to any other
- 5 remedies that may be available.".
- 6 (b) Prohibited Acts.—Section 301 of the Federal
- 7 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
- 8 ed by adding at the end the following:
- 9 "(hh)(1) The failure to notify the Secretary in viola-
- 10 tion of section 417(a).
- 11 "(2) The failure to comply with—
- "(A) an order under section 417(b); or
- 13 "(B) an amended order issued under section
- 14 417(d)(1).".
- 15 SEC. 212. LIABILITY.
- 16 This subtitle and the amendments made by this sub-
- 17 title shall not affect the liability of any person under any
- 18 provision of law as in effect before the application of this
- 19 subtitle and the amendments made by this subtitle.

## 20 TITLE III—IMPORTED FOOD

- 21 SEC. 301. IMPORTED FOOD.
- 22 (a) Certification of Foreign Food Facili-
- 23 TIES.—Section 415 of the Federal Food, Drug, and Cos-
- 24 metic Act (21 U.S.C. 350d) is amended by—

1	(1) striking paragraphs (3) and (4) of sub-
2	section (a);
3	(2) redesignating subsections (b) as subsection
4	(d);
5	(3) striking subsection (c);
6	(4) inserting after subsection (a) the following:
7	"(b) CERTIFICATION OF FOREIGN FACILITIES AND
8	GOVERNMENTS.—
9	"(1) IN GENERAL.—Not later than 1 year after
10	the date of enactment of the Safe and Secure Food
11	Act of 2005, a foreign facility or foreign government
12	that submits a registration to import food to the
13	United States under this section shall request certifi-
14	cation from the Secretary by demonstrating, in a
15	manner determined appropriate by the Secretary,
16	that food produced under the supervision of the for-
17	eign facility or foreign government has met stand-
18	ards for food safety, inspection, labeling, and con-
19	sumer protection that are at least equivalent to the
20	standards applicable to food produced in the United
21	States.
22	"(2) Certification approval.—
23	"(A) REQUEST BY FOREIGN GOVERN-
24	MENT.—Prior to granting the certification re-
25	quest of a foreign government, the Secretary

shall review, audit, and certify the food safety
program of a requesting foreign government
(including all statutes, regulations, and inspection authority) as at least equivalent to the food
safety program in the United States, as demonstrated by the foreign government.

- "(B) REQUEST BY FOREIGN FACILITY.—
  Prior to granting the certification request of a foreign facility, the Secretary shall certify, based on an onsite inspection, the food safety programs and procedures of a requesting foreign facility as at least equivalent to the food safety programs and procedures of the United States.
- "(3) LIMITATION.—A foreign government or foreign facility approved by the Secretary to import food to the United States under this section shall be certified to export only the approved food products to the United States for a period not to exceed 5 years.
- "(4) WITHDRAWAL OF CERTIFICATION.—The Secretary may withdraw certification of any food from a foreign government or foreign facility—
- 24 "(A) if such food is linked to an outbreak 25 of human illness;

1	"(B) following an investigation by the Sec-
2	retary that finds that the foreign government
3	programs and procedures or foreign facility is
4	no longer equivalent to the food safety pro-
5	grams and procedures in the United States; or
6	"(C) following a refusal to allow United
7	States officials to conduct such audits and in-
8	vestigations as may be necessary to fulfill the
9	requirements under this section.
10	"(5) Renewal of Certification.—The Sec-
11	retary shall audit a foreign government or a foreign
12	facility that imports food to the United States every
13	5 years to ensure the continued compliance with the
14	standards set forth in this section.
15	"(6) REQUIRED ROUTINE INSPECTION.—The
16	Secretary shall routinely inspect food before it enters
17	the United States to ensure that it is—
18	"(A) safe for human consumption;
19	"(B) labeled as required for food produced
20	in the United States; and
21	"(C) otherwise meets requirements under
22	the food safety law.
23	"(7) Enforcement.—The Secretary—
24	"(A) may deny importation of food from
25	any foreign government that does not permit

1	United States officials to enter the foreign
2	country to conduct such audits and inspections
3	as may be necessary to fulfill the requirements
4	under this section;
5	"(B) may deny importation of food from
6	any foreign government or foreign firm that
7	does not consent to an investigation by the Ad-
8	ministration when food from that foreign coun-
9	try or foreign firm is linked to a food-borne ill-
10	ness outbreak or is otherwise found to be adul-
11	terated or mislabeled; and
12	"(C) is authorized to promulgate rules and
13	regulations to carry out the purposes of this
14	section, including setting terms and conditions
15	for the destruction of products that fail to meet
16	the standards of this Act.
17	"(c) Administrative Requirements.—
18	"(1) Procedure.—
19	"(A) Domestic facilities.—Upon the
20	receipt of a completed registration described in
21	subsection (a)(1), the Secretary shall notify the
22	domestic facility of the receipt of such registra-

tion and assign a registration number to each

registered domestic facility.

23

"(B) Foreign facilities.—Upon the re-ceipt of a completed registration described in subsection (a)(1) and a certification under sub-section (b), the Secretary shall notify the for-eign facility of the receipt of such registration and certification and assign a registration num-ber to each registered and certified foreign fa-cility.

"(2) LIST.—The Secretary shall maintain an up-to-date list of domestic facilities that are registered and of foreign facilities that are registered and certified under this section. Such list and any registration or certification documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration or certification documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered or certified person."; and

- (5) by adding at the end the following:
- "(e) EFFECT ON CERTAIN FOREIGN FACILITIES.—
  Foreign facilities maintaining a registration under this

1	Safe and Secure Food Act of 2005 shall submit a request
2	for certification under subsection (b)(1) not later than $3$
3	years after the date of enactment of such Act.".
4	(b) In General.—Section 801 of the Federal Food,
5	Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6	adding at the end the following:
7	"(p)(1) The Secretary shall—
8	"(A) conduct an evaluation comparing the laws
9	of the United States with other countries with re-
10	spect to the inspection and security of food; and
11	"(B) promulgate regulations to—
12	"(i) develop new methods of detecting con-
13	taminated imported food;
14	"(ii) increase coordination between Fed-
15	eral, State, and local food safety officials with
16	regard to food safety and security;
17	"(iii) direct food inspectors to check for
18	the safety and security of food during an in-
19	spection of a foreign facility; and
20	"(iv) require persons to implement proce-
21	dures to prevent the unintentional and inten-
22	tional contamination of food at foreign facilities
23	covered by this Act.
24	"(2) The regulations promulgated under paragraph
25	(1) shall require a person to implement security proce-

dures for the entire foreign facility, as determined by the 1 2 Secretary, including— 3 "(A) developing a security plan that addresses 4 the specific vulnerabilities of the facility; 5 "(B) developing an emergency response plan for 6 the facility; 7 "(C) securing establishment boundaries: "(D) providing guards, alarms, and outside 8 9 lighting, as necessary; "(E) performing background checks before hir-10 11 ing new personnel; 12 "(F) limiting access to the facility; "(G) accounting for missing stock; 13 14 "(H) implementing mail-handling procedures; 15 and "(I) such other security procedures as the Sec-16 17 retary determines to be necessary to prevent unin-18 tentional or intentional contamination of food. "(3) In this subsection, the term 'foreign facility' has 19 the meaning given that term in section 415(b)(3).". 20 21 (c) Adulteration.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amend-23 ed by adding at the end the following: 24 "(i) If it is food from a domestic or foreign facility (as those terms are defined in section 415(b)) that fails

1	to comply with the regulations promulgated under section
2	416 or 801(p).".
3	(d) Conforming Amendment.—Section 801(l)(1)
4	of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5	381(l)(1)) is amended by inserting "or that has not re-
6	ceived a certification from the Secretary" after "for which
7	a registration has not been submitted to the Secretary".
8	TITLE IV—RISK ASSESSMENT
9	INFORMATION SHARING
10	SEC. 401. RISK ASSESSMENT INFORMATION SHARING.
11	(a) Coordination of Agencies.—The Secretary of
12	Health and Human Services shall coordinate with the Sec-
13	retary of Agriculture, the Secretary of Homeland Security,
14	and the Director of the Centers for Disease Control and
15	Prevention to—
16	(1) assess the security risks to the food supply
17	of the United States; and
18	(2) not later than 1 year after the date of en-
19	actment of this Act, submit to Congress a report
20	that—
21	(A) describes the assessment under para-
22	graph (1);
23	(B) outlines measures to address any secu-
24	rity risks described in such assessment; and

1	(C) describes the costs of addressing such
2	security risks.
3	(b) Coordination With Undersecretary for
4	SCIENCE AND TECHNOLOGY.—
5	(1) IN GENERAL.—The Secretary of Health and
6	Human Services shall coordinate with the Undersec-
7	retary of Science and Technology of the Department
8	of Homeland Security with respect to entities award-
9	ed grants relating to food safety under section
10	307(b) of the Homeland Security Act of 2002 (6
11	U.S.C. 187(b)).
12	(2) Information sharing.—The Undersecre-
13	tary of Science and Technology shall grant access to
14	the Secretary of Health and Human Services with
15	respect to information and data gathered at entities
16	awarded grants relating to food safety under section
17	307(b) of the Homeland Security Act of 2002 (6
۱۵	USC 187(b))

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