

AMENDMENT NO. _____ Calendar No. _____

Purpose: To ensure the safety of human and pet food.

IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.

S. 1082

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

1 At the end of the bill, insert the following:

2 **TITLE _____ —FOOD SAFETY**

3 **SEC. 01. FINDINGS.**

4 (a) FINDINGS.—Congress finds that—

5 (1) the safety and integrity of the United
6 States food supply is vital to the public health, to
7 public confidence in the food supply, and to the suc-
8 cess of the food sector of the Nation's economy;

9 (2) illnesses and deaths of individuals and com-
10 panion animals caused by contaminated food—

1 (A) have contributed to a loss of public
2 confidence in food safety; and

3 (B) have caused significant economic losses
4 to manufacturers and producers not responsible
5 for contaminated food items;

6 (3) the task of preserving the safety of the food
7 supply of the United States faces tremendous pres-
8 sures with regard to—

9 (A) emerging pathogens and other con-
10 taminants and the ability to detect all forms of
11 contamination; and

12 (B) an increasing volume of imported food
13 from a wide variety of countries; and

14 (C) a shortage of adequate resources for
15 monitoring and inspection;

16 (4) the United States is increasing the amount
17 of food that it imports such that —

18 (A) from 2003 to the present, the value of
19 food imports has increased from
20 \$45,600,000,000 to \$64,000,000,000; and

21 (B) imported food accounts for 13 percent
22 of the average Americans diet including 31 per-
23 cent of fruits, juices, and nuts, 9.5 percent of
24 red meat and 78.6 percent of fish and shellfish;
25 and

1 (5) the number of full time equivalent Food and
2 Drug Administration employees conducting inspec-
3 tions has decreased from 2003 to 2007.

4 **SEC. _02. ENSURING THE SAFETY OF PET FOOD.**

5 (a) PROCESSING AND INGREDIENT STANDARDS.—

6 Not later than 18 months after the date of enactment of
7 this Act, the Secretary of Health and Human Services (re-
8 ferred to in this title as the “Secretary”), in consultation
9 with the Association of American Feed Control Officials,
10 and other relevant stakeholder groups, including veteri-
11 nary medical associations, animal health organizations,
12 and pet food manufacturers, shall by regulation estab-
13 lish—

14 (1) processing and ingredient standards with
15 respect to pet food, animal waste, and ingredient
16 definitions; and

17 (2) updated standards for the labeling of pet
18 food that includes nutritional information and ingre-
19 dient information.

20 (b) EARLY WARNING SURVEILLANCE SYSTEMS AND

21 NOTIFICATION DURING PET FOOD RECALLS.—Not later
22 than 180 days after the date of enactment of this Act,
23 the Secretary shall by regulation establish an early warn-
24 ing and surveillance system to identify adulteration of the
25 pet food supply and outbreaks of illness associated with

1 pet food. In establishing such system, the Secretary
2 shall—

3 (1) use surveillance and monitoring mechanisms
4 similar to, or in coordination with, those mechanisms
5 used by the Centers for Disease Control and Preven-
6 tion to monitor human health, such as the
7 Foodborne Diseases Active Surveillance Network
8 (FoodNet) and PulseNet;

9 (2) consult with relevant professional associa-
10 tions and private sector veterinary hospitals; and

11 (3) work with the Health Alert Network and
12 other notification networks to inform veterinarians
13 and relevant stakeholders during any recall of pet
14 food.

15 **SEC. __03. ENSURING EFFICIENT AND EFFECTIVE COMMU-
16 NICATIONS DURING A RECALL.**

17 The Secretary shall, during an ongoing recall of
18 human or pet food—

19 (1) work with companies, relevant professional
20 associations, and other organizations to collect and
21 aggregate information pertaining to the recall;

22 (2) use existing networks of communication in-
23 cluding electronic forms of information dissemina-
24 tion to enhance the quality and speed of communica-
25 tion with the public; and

1 (3) post information regarding recalled prod-
2 ucts on the Internet website of the Food and Drug
3 Administration in a consolidated, searchable form
4 that is easily accessed and understood by the public.

5 **SEC. 04. STATE AND FEDERAL COOPERATION.**

6 (a) IN GENERAL.—The Secretary shall work with the
7 States in undertaking activities and programs that assist
8 in improving the safety of fresh and processed produced
9 so that State food safety programs involving the safety
10 of fresh and processed produce and activities conducted
11 by the Secretaries function in a coordinated and cost-effec-
12 tive manner. With the assistance provided under sub-
13 section (b), the Secretary shall encourage States to—

14 (1) establish, continue, or strengthen State food
15 safety programs, especially with respect to the regu-
16 lation of retail commercial food establishments; and

17 (2) establish procedures and requirements for
18 ensuring that processed produce under the jurisdic-
19 tion of the State food safety programs is not unsafe
20 for human consumption.

21 (b) ASSISTANCE.—The Secretary may provide to a
22 State, for planning, developing, and implementing such a
23 food safety program—

24 (1) advisory assistance;

1 (2) technical assistance, training, and labora-
2 tory assistance (including necessary materials and
3 equipment); and

4 (3) financial and other assistance.

5 (c) SERVICE AGREEMENTS.—The Secretary may,
6 under an agreement entered into with a Federal, State,
7 or local agency, use, on a reimbursable basis or otherwise,
8 the personnel, services, and facilities of the agency to carry
9 out the responsibilities of the agency under this section.
10 An agreement entered into with a State agency under this
11 subsection may provide for training of State employees.

12 **SEC. 05. ADULTERATED FOOD REGISTRY.**

13 (a) FINDINGS.—Congress makes the following find-
14 ings:

15 (1) In 1994, Congress passed the Dietary Sup-
16 plement Health and Education Act (P.L. 103-417)
17 to provide the Food and Drug Administration with
18 the legal framework to ensure that dietary supple-
19 ments are safe and properly labeled foods.

20 (2) In 2006, Congress passed the Dietary Sup-
21 plement and Nonprescription Drug Consumer Pro-
22 tection Act (P.L. 109-462) to establish a mandatory
23 reporting system of serious adverse events for non-
24 prescription drugs and dietary supplements sold and
25 consumed in the United States.

1 (3) The adverse event reporting system created
2 under the Dietary Supplement and Nonprescription
3 Drug Consumer Protection Act will serve as the
4 early warning system for any potential public health
5 issues associated with the use of these food products.

6 (4) A reliable mechanism to track patterns of
7 adulteration in food would support efforts by the
8 Food and Drug Administration to effectively target
9 limited inspection resources to protect the public
10 health.

11 (b) IN GENERAL.—Chapter IV of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
13 ed by adding at the end the following:

14 **“SEC. 417. ADULTERATED FOOD REGISTRY.**

15 “(a) DEFINITIONS.—In this section:

16 “(1) IMPORTER.—The term ‘importer’, with re-
17 spect to an article of food, means the person who
18 submitted the notice with respect to such article of
19 food under section 801(m).

20 “(2) RESPONSIBLE PARTY.—The term ‘respon-
21 sible party’, with respect to an article of food, means
22 any registered food facility under section 415(a), in-
23 cluding those responsible for the manufacturing,
24 processing, packaging or holding of such food for
25 consumption in the United States.

1 “(3) REPORTABLE ADULTERATED FOOD.—The
2 term ‘reportable adulterated food’ for purposes of
3 this section means a food that is adulterated or—

4 “(A) presents a situation in which there is
5 a reasonable probability that the use of, or ex-
6 posure to, a violative product will cause serious
7 adverse health consequences or death as defined
8 in section 7.3(m)(1) of title, Code of Federal
9 Regulations (or any successor regulations); or

10 “(B) meets the threshold established in
11 section 304(h).

12 “(b) ESTABLISHMENT.—

13 “(1) IN GENERAL.—Not later than 180 days
14 after the date of enactment of this section, the Sec-
15 retary shall establish within the Food and Drug Ad-
16 ministration an Adulterated Food Registry to which
17 instances of reportable adulterated food may be sub-
18 mitted by the Food and Drug Administration after
19 receipt of reports of adulteration, via an electronic
20 portal, from—

21 “(A) Federal, State, and local public
22 health officials;

23 “(B) an importer;

24 “(C) a responsible party; or

25 “(D) a consumer or other individual.

1 “(2) REVIEW BY SECRETARY.—The Secretary
2 shall review and determine the validity of the infor-
3 mation submitted under paragraph (1) for the pur-
4 poses of identifying adulterated food, submitting en-
5 tries to the Adulterated Food Registry, acting under
6 subsection (c), and exercising other existing food
7 safety authorities under the Act to protect the public
8 health.

9 “(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

10 “(1) IN GENERAL.—The Secretary shall issue
11 an alert with respect to an adulterated food if the
12 Adulterated Food Registry shows that the food—

13 “(A) has been associated with repeated
14 and separate outbreaks of illness or has been
15 repeatedly determined to be adulterated; or

16 “(B) is a reportable adulterated food.

17 “(2) SCOPE OF ALERT.—An alert under para-
18 graph (1) may apply to a particular food or to food
19 from a particular producer, manufacturer, shipper,
20 growing area, or country, to the extent that elements
21 in subparagraph (A) or (B) of paragraph (1) are as-
22 sociated with the particular food, producer, manu-
23 facturer, shipper, growing area, or country.

24 “(d) SUBMISSION BY A CONSUMER OR OTHER INDI-
25 VIDUAL.—A consumer or other individual may submit a

1 report to the Food and Drug Administration using the
2 electronic portal data elements described in subsection (e).
3 Such reports shall be evaluated by the Secretary as speci-
4 fied in subsection (b)(2).

5 “(e) NOTIFICATION AND REPORTING OF ADULTERA-
6 TION.—

7 “(1) DETERMINATION BY RESPONSIBLE PARTY
8 OR IMPORTER.—If a responsible party or importer
9 determines that an article of food it produced, proc-
10 essed, manufactured, distributed, or otherwise han-
11 dled is a reportable adulterated food, the responsible
12 party shall provide the notifications described under
13 paragraph (2).

14 “(2) NOTIFICATION OF ADULTERATION.—

15 “(A) IN GENERAL.—Not later than 5 days
16 after a responsible party or importer receives a
17 notification, the responsible party or importer,
18 as applicable, shall review whether the food ref-
19 erenced in the report described in paragraph
20 (1) is a reportable adulterated food.

21 “(B) NOTIFICATION.—If a determination
22 is made by such responsible party or importer
23 that the food is a reportable adulterated food,
24 such responsible party or importer shall, no
25 later than 5 days after such determination is

1 made, notify other responsible parties directly
2 linked in the supply chain to which and from
3 which the article of reportable adulterated food
4 was transferred.

5 “(3) SUBMISSION OF REPORTS TO THE FOOD
6 AND DRUG ADMINISTRATION BY A RESPONSIBLE
7 PARTY OR IMPORTER.—The responsible party or im-
8 porter, as applicable, shall submit a report to the
9 Food and Drug Administration through the elec-
10 tronic portal using the data elements described in
11 subsection (f) not later than 2 days after a respon-
12 sible party or importer—

13 “(A) makes a notification under paragraph
14 (2)(B); or

15 “(B) determines that an article of food it
16 produced, processed, manufactured, distributed,
17 imported, or otherwise handled is a reportable
18 adulterated food, except that if such adultera-
19 tion was initiated with such responsible party or
20 importer, was detected prior to any transfer of
21 such article of food, and was destroyed, no re-
22 port is necessary.

23 “(f) DATA ELEMENTS IN THE REGISTRY.—A report
24 submitted to the Food and Drug Administration electronic

1 portal under subsection (e) shall include the following data
2 elements:

3 “(1) Contact information for the individual or
4 entity submitting the report.

5 “(2) The date on which an article of food was
6 determined to be adulterated or suspected of being
7 adulterated.

8 “(3) A description of the article of food includ-
9 ing the quantity or amount.

10 “(4) The extent and nature of the adulteration.

11 “(5) The disposition of the article.

12 “(6) Product information typically found on
13 packaging including product codes, use by dates,
14 and names of manufactures or distributors.

15 “(7) Information about the place of purchase or
16 process by which the consumer or other individual
17 acquired the article of adulterated food.

18 “(8) In the case of a responsible party or an
19 importer, the elements required for the registration
20 of food facilities under section 415(a).

21 “(9) The contact information for parties di-
22 rectly linked in the supply chain and notified under
23 subsection (e)(2).

1 “(10) In the case of an importer, the elements
2 required for the prior notice of imported food ship-
3 ments under section 801(m).

4 “(g) MAINTENANCE AND INSPECTION OF
5 RECORDS.—The responsible person or importer shall
6 maintain records related to each report received, notifica-
7 tion made, and report submitted to the Food and Drug
8 Administration under this section and permit inspection
9 of such records as provided for in section 414. Such
10 records shall also be made available during an inspection
11 under section 704.

12 “(h) REQUEST FOR INFORMATION.—Section 552 of
13 title 5, United States Code, shall apply to any request for
14 information regarding a record in the Adulterated Food
15 Registry.

16 “(i) HOMELAND SECURITY NOTIFICATION.—If, after
17 receiving a report under subsection (e), the Secretary sus-
18 pects such food may have been deliberately adulterated,
19 the Secretary shall immediately notify the Secretary of
20 Homeland Security. The Secretary shall make the data in
21 the Adulterated Imported Food Registry available to the
22 Secretary of Homeland Security.”.

23 “(e) DEFINITION.—Section 201(ff) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is

1 amended by striking “section 201(g)” and inserting “sec-
2 tions 201(g) and 417”.

3 (d) PROHIBITED ACTS.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
5 amended by this Act, is further amended by adding at the
6 end the following:

7 “(kk) The failure to provide a report as required
8 under section 417(e)(3).

9 “(ll) The falsification a report as required under sec-
10 tion 417(e)(3).”.

11 (e) SUSPECTED FOOD ADULTERATION REGULA-
12 TIONS.—The Secretary shall, within 180 days of enact-
13 ment of this Act, promulgate regulations that establish
14 standards and thresholds by which importers and respon-
15 sible parties shall be required and consumers may be able
16 to, under section 417 of the Federal Food, Drug, and Cos-
17 metic Act (as added by this section)—

18 (1) report instances of suspected reportable
19 adulteration of food to the Food and Drug Adminis-
20 tration for possible inclusion in the Adulterated
21 Food Registry after evaluation of such report; and

22 (2) notify, in keeping with subsection (e)(2) of
23 such section 417, other responsible parties directly
24 linked in the supply chain, including establishments
25 as defined in section 415(b) of such Act.

1 (f) EFFECTIVE DATE.—The requirements of section
2 417(e) of the Federal Food, Drug, and Cosmetic Act, as
3 added by subsection (a), shall become effective 180 days
4 after the date of enactment of this Act.

5 **SEC. _06. SENSE OF THE SENATE.**

6 It is the sense of the Senate that—

7 (1) it is vital for Congress to provide the Food
8 and Drug Administration with additional resources,
9 authorities, and direction with respect to ensuring
10 the safety of the food supply of the United States;

11 (2) additional inspectors are required to im-
12 prove the Food and Drug Administration’s ability to
13 safeguard the food supply of the United States;

14 (3) because of the increasing volume of inter-
15 national trade in food products the Secretary of
16 Health and Human Services should make it a pri-
17 ority to enter into agreements with the trading part-
18 ners of the United States with respect to food safe-
19 ty; and

20 (4) the Senate should work to develop a com-
21 prehensive response to the issue of food safety.

22 **SEC. _07. ANNUAL REPORT TO CONGRESS.**

23 The Secretary shall, on an annual basis, submit to
24 the Committee on Health, Education, Labor, and Pen-
25 sions and the Committee on Appropriations of the Senate

1 and the Committee on Energy and Commerce and the
2 Committee on Appropriations of the House of Representa-
3 tives a report that includes, with respect to the preceding
4 1-year period—

5 (1) the number and amount of food products
6 regulated by the Food and Drug Administration im-
7 ported into the United States, aggregated by country
8 and type of food;

9 (2) a listing of the number of Food and Drug
10 Administration inspectors of imported food products
11 referenced in paragraph (1) and the number of Food
12 and Drug Administration inspections performed on
13 such products; and

14 (3) aggregated data on the findings of such in-
15 spections, including data related to violations of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 201 et seq.), and enforcement actions used to follow-
18 up on such findings and violations.

19 **SEC. _08. RULE OF CONSTRUCTION.**

20 Nothing in this title (or an amendment made by this
21 title) shall be construed to affect—

22 (1) the regulation of dietary supplements under
23 the Dietary Supplement Health and Education Act;
24 or

1 (2) the adverse event reporting system for die-
2 tary supplements created under the Dietary Supple-
3 ment and Nonprescription Drug Consumer Protec-
4 tion Act.

5 **SEC. 09. AUTHORIZATION OF APPROPRIATIONS.**

6 There are authorized to be appropriated to carry out
7 this title (and the amendments made by this title) such
8 sums as may be necessary.