

AMENDMENT NO. _____ Calendar No. _____

Purpose: To limit the written plan and produce safety requirements for direct marketing farms and certain small facilities.

IN THE SENATE OF THE UNITED STATES—111th Cong., 2d Sess.

S. 510

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

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 Mr. TESTER

Viz:

1 On page 10, between lines 21 and 22, insert the following:
2

3 (c) CLARIFICATION OF INTENT.—

4 (1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of the term “retail food establishment” in section in 1.227(b)(11) of
5
6 title 21, Code of Federal Regulations to clarify that,
7
8 in determining the primary function of an establishment or a retail food establishment under such section,
9
10 the sale of food products directly to consumers
11
by such establishment and the sale of food directly

1 to consumers by such retail food establishment in-
2 clude—

3 (A) the sale of such food products or food
4 directly to consumers by such establishment at
5 a roadside stand or farmers' market where such
6 stand or market is located other than where the
7 food was manufactured or processed;

8 (B) the sale and distribution of such food
9 through a community supported agriculture
10 program; and

11 (C) the sale and distribution of such food
12 at any other such direct sales platform as deter-
13 mined by the Secretary.

14 (2) DEFINITIONS.—For purposes of paragraph
15 (1)—

16 (A) the term “community supported agri-
17 culture program” has the same meaning given
18 the term “community supported agriculture
19 (CSA) program” in section 249.2 of title 7,
20 Code of Federal Regulations (or any successor
21 regulation); and

22 (B) the term “consumer” does not include
23 a business.

24 On page 10, line 22, strike “(c)” and insert “(d)”.

1 On page 17, between lines 12 and 13, insert the fol-
2 lowing:

3 “(1) MODIFIED REQUIREMENTS FOR QUALIFIED FA-
4 CILITIES.—

5 “(1) QUALIFIED FACILITIES.—

6 “(A) IN GENERAL.—A facility is a quali-
7 fied facility for purposes of this subsection if
8 the facility meets the conditions under subpara-
9 graph (B) or (C).

10 “(B) VERY SMALL BUSINESS.—A facility is
11 a qualified facility under this subparagraph—

12 “(i) if the facility, including any sub-
13 sidiary or affiliate of the facility, is, collec-
14 tively, a very small business (as defined in
15 the regulations promulgated under sub-
16 section (n)); and

17 “(ii) in the case where the facility is
18 a subsidiary or affiliate of an entity, if
19 such subsidiaries or affiliates, are, collec-
20 tively, a very small business (as so de-
21 fined).

22 “(C) LIMITED ANNUAL MONETARY VALUE
23 OF SALES.—

1 “(i) IN GENERAL.—A facility is a
2 qualified facility under this subparagraph
3 if clause (ii) applies—

4 “(I) to the facility, including any
5 subsidiary or affiliate of the facility,
6 collectively; and

7 “(II) to the subsidiaries or affili-
8 ates, collectively, of any entity of
9 which the facility is a subsidiary or af-
10 filiate.

11 “(ii) AVERAGE ANNUAL MONETARY
12 VALUE.—This clause applies if—

13 “(I) during the 3-year period pre-
14 ceding the applicable calendar year,
15 the average annual monetary value of
16 the food manufactured, processed,
17 packed, or held at such facility (or the
18 collective average annual monetary
19 value of such food at any subsidiary
20 or affiliate, as described in clause (i))
21 that is sold directly to qualified end-
22 users during such period exceeded the
23 average annual monetary value of the
24 food manufactured, processed, packed,
25 or held at such facility (or the collec-

1 tive average annual monetary value of
2 such food at any subsidiary or affil-
3 iate, as so described) sold by such fa-
4 cility (or collectively by any such sub-
5 sidiary or affiliate) to all other pur-
6 chasers during such period; and

7 “(II) the average annual mone-
8 tary value of all food sold by such fa-
9 cility (or the collective average annual
10 monetary value of such food sold by
11 any subsidiary or affiliate, as de-
12 scribed in clause (i)) during such pe-
13 riod was less than \$500,000, adjusted
14 for inflation.

15 “(2) EXEMPTION.—A qualified facility—

16 “(A) shall not be subject to the require-
17 ments under subsections (a) through (i) and
18 subsection (n) in an applicable calendar year;
19 and

20 “(B) shall submit to the Secretary—

21 “(i)(I) documentation that dem-
22 onstrates that the owner, operator, or
23 agent in charge of the facility has identi-
24 fied potential hazards associated with the
25 food being produced, is implementing pre-

1 ventive controls to address the hazards,
2 and is monitoring the preventive controls
3 to ensure that such controls are effective;
4 or

5 “(II) documentation (which may in-
6 clude licenses, inspection reports, certifi-
7 cates, permits, credentials, certification by
8 an appropriate agency (such as a State de-
9 partment of agriculture), or other evidence
10 of oversight), as specified by the Secretary,
11 that the facility is in compliance with
12 State, local, county, or other applicable
13 non-Federal food safety law; and

14 “(ii) documentation, as specified by
15 the Secretary in a guidance document
16 issued not later than 1 year after the date
17 of enactment of this section, that the facil-
18 ity is a qualified facility under paragraph
19 (1)(B) or (1)(C).

20 “(3) WITHDRAWAL; RULE OF CONSTRUC-
21 TION.—

22 “(A) IN GENERAL.—In the event of an ac-
23 tive investigation of a foodborne illness out-
24 break that is directly linked to a qualified facil-
25 ity subject to an exemption under this sub-

1 section, or if the Secretary determines that it is
2 necessary to protect the public health and pre-
3 vent or mitigate a foodborne illness outbreak
4 based on conduct or conditions associated with
5 a qualified facility that are material to the safe-
6 ty of the food manufactured, processed, packed,
7 or held at such facility, the Secretary may with-
8 draw the exemption provided to such facility
9 under this subsection.

10 “(B) RULE OF CONSTRUCTION.—Nothing
11 in this subsection shall be construed to expand
12 or limit the inspection authority of the Sec-
13 retary.

14 “(4) DEFINITIONS.—In this subsection:

15 “(A) AFFILIATE.—The term ‘affiliate’
16 means any facility that controls, is controlled
17 by, or is under common control with another fa-
18 cility.

19 “(B) QUALIFIED END-USER.—The term
20 ‘qualified end-user’, with respect to a food,
21 means—

22 “(i) the consumer of the food; or

23 “(ii) a restaurant or retail food estab-
24 lishment (as those terms are defined by the

1 Secretary for purposes of section 415)
2 that—

3 “(I) is located—

4 “(aa) in the same State as
5 the qualified facility that sold the
6 food to such restaurant or estab-
7 lishment; or

8 “(bb) not more than 275
9 miles from such facility; and

10 “(II) is purchasing the food for
11 sale directly to consumers at such res-
12 taurant or retail food establishment.

13 “(C) CONSUMER.—For purposes of sub-
14 paragraph (B), the term ‘consumer’ does not
15 include a business.

16 “(D) SUBSIDIARY.—The term ‘subsidiary’
17 means any company which is owned or con-
18 trolled directly or indirectly by another com-
19 pany.

20 “(5) STUDY.—

21 “(A) IN GENERAL.—The Secretary, in con-
22 sultation with the Secretary of Agriculture,
23 shall conduct a study of the food processing
24 sector regulated by the Secretary to deter-
25 mine—

1 “(i) the distribution of food produc-
2 tion by type and size of operation, includ-
3 ing monetary value of food sold;

4 “(ii) the proportion of food produced
5 by each type and size of operation;

6 “(iii) the number and types of food
7 facilities co-located on farms, including the
8 number and proportion by commodity and
9 by manufacturing or processing activity;

10 “(iv) the incidence of foodborne illness
11 originating from each size and type of op-
12 eration and the type of food facilities for
13 which no reported or known hazard exists;
14 and

15 “(v) the effect on foodborne illness
16 risk associated with commingling, proc-
17 essing, transporting, and storing food and
18 raw agricultural commodities, including
19 differences in risk based on the scale and
20 duration of such activities.

21 “(B) SIZE.—The results of the study con-
22 ducted under subparagraph (A) shall include
23 the information necessary to enable the Sec-
24 retary to define the terms ‘small business’ and
25 ‘very small business’, for purposes of promul-

1 gating the regulation under subsection (n). In
2 defining such terms, the Secretary shall include
3 consideration of harvestable acres, income, the
4 number of employees, and the volume of food
5 harvested.

6 “(C) SUBMISSION OF REPORT.—Not later
7 than 18 months after the date of enactment the
8 FDA Food Safety Modernization Act, the Sec-
9 retary shall submit to Congress a report that
10 describes the results of the study conducted
11 under subparagraph (A).

12 “(6) NO PREEMPTION.—Nothing in this sub-
13 section preempts State, local, county, or other non-
14 Federal law regarding the safe production of food.
15 Compliance with this subsection shall not relieve any
16 person from liability at common law or under State
17 statutory law.

18 “(7) NOTIFICATION TO CONSUMERS.—

19 “(A) IN GENERAL.—A qualified facility
20 that is exempt from the requirements under
21 subsections (a) through (i) and subsection (n)
22 and does not prepare documentation under
23 paragraph (2)(B)(i)(I) shall—

24 “(i) with respect to a food for which
25 a food packaging label is required by the

1 Secretary under any other provision of this
2 Act, include prominently and conspicuously
3 on such label the name and business ad-
4 dress of the facility where the food was
5 manufactured or processed; or

6 “(ii) with respect to a food for which
7 a food packaging label is not required by
8 the Secretary under any other provisions of
9 this Act, prominently and conspicuously
10 display, at the point of purchase, the name
11 and business address of facility where the
12 food was manufactured or processed, on a
13 label, poster, sign, placard, or documents
14 delivered contemporaneously with the food
15 in the normal course of business, or, in the
16 case of Internet sales, in an electronic no-
17 tice.

18 “(B) NO ADDITIONAL LABEL.—Subpara-
19 graph (A) does not provide authority to the
20 Secretary to require a label that is in addition
21 to any label required under any other provision
22 of this Act.

23 On page 17, line 13, strike “(l)” and insert “(m)”.

1 On page 17, line 22, strike“(m)” and insert “(n)”.

2 On page 18, strike line 1 through line 5 and insert
3 the following: “regulations—

4 “(A) to establish science-based minimum
5 standards for conducting a hazard analysis,
6 documenting hazards, implementing preventive
7 controls, and documenting the implementation
8 of the preventive controls under this section;
9 and

10 “(B) to define, for purposes of this section,
11 the terms ‘small business’ and ‘very small busi-
12 ness’, taking into consideration the study de-
13 scribed in subsection (l)(5).

14 On page 18, line 7, strike “paragraph (1)” and insert
15 “paragraph (1)(A)”.

16 On page 18, line 13, strike “paragraph (1)” and in-
17 sert “paragraph (1)(A)”.

18 On page 19, line 17, strike “paragraph (1)” and in-
19 sert “paragraph (1)(A)”.

1 Beginning on page 24, strike line 13 and all that fol-
2 lows through line 6 on page 25 and insert the following:

3 (ii) LIMITATION.—The exemptions or
4 modifications under clause (i) shall not in-
5 clude an exemption from the requirement
6 to register under section 415 of the Fed-
7 eral Food, Drug, and Cosmetic Act (21
8 U.S.C. 350d), as amended by this Act, if
9 applicable, and shall apply only to small
10 businesses and very small businesses, as
11 defined in the regulation promulgated
12 under section 418(n) of the Federal Food,
13 Drug, and Cosmetic Act (as added under
14 subsection (a)).

15 On page 26, line 6, strike “subsection (m)” and in-
16 sert “subsection (n)”.

17 Beginning on page 27, strike line 17 through line 9
18 on page 28 and insert the following:

19 (i) EFFECTIVE DATES.—

20 (1) GENERAL RULE.—The amendments made
21 by this section shall take effect 18 months after the
22 date of enactment of this Act.

1 (2) FLEXIBILITY FOR SMALL BUSINESSES.—

2 Notwithstanding paragraph (1)—

3 (A) the amendments made by this section
4 shall apply to a small business (as defined in
5 the regulations promulgated under section
6 418(n) of the Federal Food, Drug, and Cos-
7 metic Act (as added by this section)) beginning
8 on the date that is 6 months after the effective
9 date of such regulations; and

10 (B) the amendments made by this section
11 shall apply to a very small business (as defined
12 in such regulations) beginning on the date that
13 is 18 months after the effective date of such
14 regulations.

15 On page 30, line 23, strike “small and very small
16 businesses” and insert “small businesses and very small
17 businesses (as such terms are defined in the regulation
18 promulgated under subparagraph (A))”.

19 On page 32, line 14, strike “; and” and insert a semi-
20 colon.

21 On page 32, line 24, strike the period and insert “;
22 and”.

1 On page 32, after line 24, insert the following:

2 “(F) define, for purposes of this section,
3 the terms ‘small business’ and ‘very small busi-
4 ness’.

5 On page 34, strike lines 8 through 11 and insert “de-
6 fined in the regulation promulgated under subsection
7 (a)(1)) after the date that is 1 year after the”.

8 On page 34, strike lines 16 through 19 and insert
9 “(as defined in the regulation promulgated under sub-
10 section (a)(1)) after the date that is 2”.

11 On page 35, line 18, strike “facilities” and insert
12 “businesses”.

13 On page 35, line 25, strike “facility” and insert
14 “business”.

15 On page 36, line 8, strike “facility” and insert “busi-
16 ness”.

17 On page 40, between lines 5 and 6, insert the fol-
18 lowing:

19 “(f) EXEMPTION FOR DIRECT FARM MARKETING.—

1 “(1) IN GENERAL.—A farm shall be exempt
2 from the requirements under this section in a cal-
3 endar year if—

4 “(A) during the previous 3-year period, the
5 average annual monetary value of the food sold
6 by such farm directly to qualified end-users
7 during such period exceeded the average annual
8 monetary value of the food sold by such farm
9 to all other buyers during such period; and

10 “(B) the average annual monetary value of
11 all food sold during such period was less than
12 \$500,000, adjusted for inflation.

13 “(2) NOTIFICATION TO CONSUMERS.—

14 “(A) IN GENERAL.—A farm that is exempt
15 from the requirements under this section
16 shall—

17 “(i) with respect to a food for which
18 a food packaging label is required by the
19 Secretary under any other provision of this
20 Act, include prominently and conspicuously
21 on such label the name and business ad-
22 dress of the farm where the produce was
23 grown; or

24 “(ii) with respect to a food for which
25 a food packaging label is not required by

1 the Secretary under any other provision of
2 this Act, prominently and conspicuously
3 display, at the point of purchase, the name
4 and business address of the farm where
5 the produce was grown, on a label, poster,
6 sign, placard, or documents delivered con-
7 temporaneously with the food in the nor-
8 mal course of business, or, in the case of
9 Internet sales, in an electronic notice.

10 “(B) NO ADDITIONAL LABEL.—Subpara-
11 graph (A) does not provide authority to the
12 Secretary to require a label that is in addition
13 to any label required under any other provision
14 of this Act.

15 “(3) WITHDRAWAL; RULE OF CONSTRUC-
16 TION.—

17 “(A) IN GENERAL.—In the event of an ac-
18 tive investigation of a foodborne illness out-
19 break that is directly linked to a farm subject
20 to an exemption under this subsection, or if the
21 Secretary determines that it is necessary to pro-
22 tect the public health and prevent or mitigate
23 a foodborne illness outbreak based on conduct
24 or conditions associated with a farm that are
25 material to the safety of the food produced or

1 harvested at such farm, the Secretary may
2 withdraw the exemption provided to such farm
3 under this subsection.

4 “(B) RULE OF CONSTRUCTION.—Nothing
5 in this subsection shall be construed to expand
6 or limit the inspection authority of the Sec-
7 retary.

8 “(4) DEFINITIONS.—

9 “(A) QUALIFIED END-USER.—In this sub-
10 section, the term ‘qualified end-user’, with re-
11 spect to a food means—

12 “(i) the consumer of the food; or

13 “(ii) a restaurant or retail food estab-
14 lishment (as those terms are defined by the
15 Secretary for purposes of section 415) that
16 is located—

17 “(I) in the same State as the
18 farm that produced the food; or

19 “(II) not more than 275 miles
20 from such farm.

21 “(B) CONSUMER.—For purposes of sub-
22 paragraph (A), the term ‘consumer’ does not
23 include a business.

24 “(5) NO PREEMPTION.—Nothing in this sub-
25 section preempts State, local, county, or other non-

1 Federal law regarding the safe production, har-
2 vesting, holding, transportation, and sale of fresh
3 fruits and vegetables. Compliance with this sub-
4 section shall not relieve any person from liability at
5 common law or under State statutory law.

6 “(6) LIMITATION OF EFFECT.—Nothing in this
7 subsection shall prevent the Secretary from exer-
8 cising any authority granted in the other sections of
9 this Act.

10 On page 40, between lines 5 and 6, insert the fol-
11 lowing:

12 “(g) CLARIFICATION.—This section shall not apply to
13 produce that is produced by an individual for personal
14 consumption.

15 On page 40, line 6, strike “(f)” and insert “(h)”.

16 On page 211, line 18, strike “310” and insert “309”.