

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 “retail food establishment” in section 1.227 of title 21, Code of
5 Federal Regulations to clarify that, for purposes of
6 applying such definition established under section
7 415(b)(1) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 350d(b)(1)), the term “retail food
9 establishment” includes an establishment whose pri-
10
11

1 mary function is to sell food manufactured, proc-
2 essed, packed, or held by such establishment directly
3 to consumers, including in the case that an estab-
4 lishment makes such sales at locations other than
5 the location where the food was manufactured, proc-
6 essed, packed, or held by such establishment.

7 (2) CONSUMER.—For purposes of paragraph
8 (1), the term “consumer” does not include a busi-
9 ness.

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

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

13 “(1) MODIFIED REQUIREMENTS FOR QUALIFIED FA-
14 CILITIES.—

15 “(1) QUALIFIED FACILITIES.—

16 “(A) IN GENERAL.—A facility is a quali-
17 fied facility for purposes of this subsection if
18 the facility meets the conditions under subpara-
19 graph (B) or (C).

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

22 “(i) if the facility, including any sub-
23 sidiary or affiliate of the facility, is, collec-

1 tively, a very small business (as defined in
2 the regulations promulgated under sub-
3 section (n)); and

4 “(ii) in the case where the facility is
5 a subsidiary or affiliate of an entity, if
6 such subsidiaries or affiliates, are, collec-
7 tively, a very small business (as so de-
8 fined).

9 “(C) LIMITED ANNUAL MONETARY VALUE
10 OF SALES.—

11 “(i) IN GENERAL.—A facility is a
12 qualified facility under this subparagraph
13 if clause (ii) applies—

14 “(I) to the facility, including any
15 subsidiary or affiliate of the facility,
16 collectively; and

17 “(II) to the subsidiaries or affili-
18 ates, collectively, of any entity of
19 which the facility is a subsidiary or af-
20 filiate.

21 “(ii) AVERAGE ANNUAL MONETARY
22 VALUE.—This clause applies if—

23 “(I) during the 3-year period pre-
24 ceding the applicable calendar year,
25 the average annual monetary value of

1 the food manufactured, processed,
2 packed, or held at such facility (or the
3 collective average annual monetary
4 value of such food at any subsidiary
5 or affiliate, as described in clause (i))
6 that is sold directly to qualified end-
7 users during such period exceeded the
8 average annual monetary value of the
9 food manufactured, processed, packed,
10 or held at such facility (or the collec-
11 tive average annual monetary value of
12 such food at any subsidiary or affil-
13 iate, as so described) sold by such fa-
14 cility (or collectively by any such sub-
15 sidiary or affiliate) to all other pur-
16 chasers during such period; and

17 “(II) the average annual mone-
18 tary value of all food sold by such fa-
19 cility (or the collective average annual
20 monetary value of such food sold by
21 any subsidiary or affiliate, as de-
22 scribed in clause (i)) during such pe-
23 riod was less than \$500,000, adjusted
24 for inflation.

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

1 “(A) shall not be subject to the require-
2 ments under subsections (a) through (i) and
3 subsection (n) in an applicable calendar year;
4 and

5 “(B) shall submit to the Secretary—

6 “(i)(I) documentation that dem-
7 onstrates that the owner, operator, or
8 agent in charge of the facility has identi-
9 fied potential hazards associated with the
10 food being produced, is implementing pre-
11 ventive controls to address the hazards,
12 and is monitoring the preventive controls
13 to ensure that such controls are effective;
14 or

15 “(II) documentation (which may in-
16 clude licenses, inspection reports, certifi-
17 cates, permits, credentials, certification by
18 an appropriate agency (such as a State de-
19 partment of agriculture), or other evidence
20 of oversight), as specified by the Secretary,
21 that the facility is in compliance with
22 State, local, county, or other applicable
23 non-Federal food safety law; and

24 “(ii) documentation, as specified by
25 the Secretary in a guidance document

1 issued not later than 1 year after the date
2 of enactment of this section, that the facil-
3 ity is a qualified facility under paragraph
4 (1)(B) or (1)(C).

5 “(3) DEFINITIONS.—In this subsection:

6 “(A) AFFILIATE.—The term ‘affiliate’
7 means any facility that controls, is controlled
8 by, or is under common control with another fa-
9 cility.

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

13 “(i) the consumer of the food; or

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

18 “(I) is located—

19 “(aa) in the same State as
20 the qualified facility that sold the
21 food to such restaurant or estab-
22 lishment; or

23 “(bb) not more than 400
24 miles from such facility; and

1 “(iv) the incidence of foodborne illness
2 originating from each size and type of op-
3 eration and the type of food facilities for
4 which no reported or known hazard exists;
5 and

6 “(v) the effect on foodborne illness
7 risk associated with commingling, proc-
8 essing, transporting, and storing food and
9 raw agricultural commodities, including
10 differences in risk based on the scale and
11 duration of such activities.

12 “(B) SIZE.—The results of the study con-
13 ducted under subparagraph (A) shall include
14 the information necessary to enable the Sec-
15 retary to define the terms ‘small business’ and
16 ‘very small business’, for purposes of promul-
17 gating the regulation under subsection (n). In
18 defining such terms, the Secretary shall include
19 consideration of harvestable acres, income, the
20 number of employees, and the volume of food
21 harvested.

22 “(C) SUBMISSION OF REPORT.—Not later
23 than 18 months after the date of enactment the
24 FDA Food Safety Modernization Act, the Sec-
25 retary shall submit to Congress a report that

1 describes the results of the study conducted
2 under subparagraph (A).

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

9 “(6) NOTIFICATION TO CONSUMERS.—

10 “(A) IN GENERAL.—A qualified facility
11 that is exempt from the requirements under
12 subsections (a) through (i) and subsection (n)
13 and does not prepare documentation under
14 paragraph (2)(B)(i)(I) shall—

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

22 “(ii) with respect to a food for which
23 a food packaging label is not required by
24 the Secretary under any other provisions of
25 this Act, prominently and conspicuously

1 display, at the point of purchase, the name
2 and business address of facility where the
3 food was manufactured or processed, on a
4 label, poster, sign, placard, or documents
5 delivered contemporaneously with the food
6 in the normal course of business, or, in the
7 case of Internet sales, in an electronic no-
8 tice.

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

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

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

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

18 “(A) to establish science-based minimum
19 standards for conducting a hazard analysis,
20 documenting hazards, implementing preventive
21 controls, and documenting the implementation

1 of the preventive controls under this section;
2 and

3 “(B) to define, for purposes of this section,
4 the terms ‘small business’ and ‘very small busi-
5 ness’, taking into consideration the study de-
6 scribed in subsection (l)(4).

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

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

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

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

15 (ii) LIMITATION.—The exemptions or
16 modifications under clause (i) shall not in-
17 clude an exemption from the requirement
18 to register under section 415 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21
20 U.S.C. 350d), as amended by this Act, if
21 applicable, and shall apply only to small

1 businesses and very small businesses, as
2 defined in the regulation promulgated
3 under section 418(n) of the Federal Food,
4 Drug, and Cosmetic Act (as added under
5 subsection (a)).

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

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

10 (i) EFFECTIVE DATES.—

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

14 (2) FLEXIBILITY FOR SMALL BUSINESSES.—
15 Notwithstanding paragraph (1)—

16 (A) the amendments made by this section
17 shall apply to a small business (as defined in
18 the regulations promulgated under section
19 418(n) of the Federal Food, Drug, and Cos-
20 metic Act (as added by this section)) beginning
21 on the date that is 6 months after the effective
22 date of such regulations; and

1 (B) the amendments made by this section
2 shall apply to a very small business (as defined
3 in such regulations) beginning on the date that
4 is 18 months after the effective date of such
5 regulations.

6 On page 30, line 23, strike “small and very small
7 businesses” and insert “small businesses and very small
8 businesses (as such terms are defined in the regulation
9 promulgated under subparagraph (A))”.

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

12 On page 32, line 24, strike the period and insert “;
13 and”.

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

15 (F) define, for purposes of this section,
16 the terms ‘small business’ and ‘very small busi-
17 ness’.

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

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

4 On page 35, line 18, strike “facilities” and insert
5 “businesses”.

6 On page 35, line 25, strike “facility” and insert
7 “business”.

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

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

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

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

16 “(A) during the previous 3-year period, the
17 average annual monetary value of the food sold
18 by such farm directly to qualified end-users
19 during such period exceeded the average annual
20 monetary value of the food sold by such farm
21 to all other buyers during such period; and

1 “(B) the average annual monetary value of
2 all food sold during such period was less than
3 \$500,000, adjusted for inflation.

4 “(2) NOTIFICATION TO CONSUMERS.—

5 “(A) IN GENERAL.—A farm that is exempt
6 from the requirements under this section
7 shall—

8 “(i) with respect to a food for which
9 a food packaging label is required by the
10 Secretary under any other provision of this
11 Act, include prominently and conspicuously
12 on such label the name and business ad-
13 dress of the farm where the produce was
14 grown; or

15 “(ii) with respect to a food for which
16 a food packaging label is not required by
17 the Secretary under any other provision of
18 this Act, prominently and conspicuously
19 display, at the point of purchase, the name
20 and business address of the farm where
21 the produce was grown, on a label, poster,
22 sign, placard, or documents delivered con-
23 temporaneously with the food in the nor-
24 mal course of business, or, in the case of
25 Internet sales, in an electronic notice.

1 “(B) NO ADDITIONAL LABEL.—Subpara-
2 graph (A) does not provide authority to the
3 Secretary to require a label that is in addition
4 to any label required under any other provision
5 of this Act.

6 “(3) DEFINITIONS.—

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

10 “(i) the consumer of the food; or

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

15 “(I) in the same State as the
16 farm that produced the food; or

17 “(II) not more than 400 miles
18 from such farm.

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

22 “(4) NO PREEMPTION.—Nothing in this sub-
23 section preempts State, local, county, or other non-
24 Federal law regarding the safe production, har-
25 vesting, holding, transportation, and sale of fresh

1 fruits and vegetables. Compliance with this sub-
2 section shall not relieve any person from liability at
3 common law or under State statutory law.

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

8 On page 40, between lines 5 and 6, insert the fol-
9 lowing:

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

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

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