AMENDMENT NO. ________        Calendar No. ________

Purpose: To limit the written plan and produce safety re-
quirements 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 fol-
   lowing:

   (c) CLARIFICATION OF INTENT.—

   (1) RETAIL FOOD ESTABLISHMENT.—The Sec-
   retary shall amend the definition of the term “retail
   food establishment” in section in 1.227(b)(11) of
title 21, Code of Federal Regulations to clarify that,
in determining the primary function of an establish-
ment or a retail food establishment under such sec-
tion, the sale of food products directly to consumers
by such establishment and the sale of food directly
to consumers by such retail food establishment include—

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

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

(C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

(2) Definitions.—For purposes of paragraph (1)—

(A) the term “community supported agriculture program” has the same meaning given the term “community supported agriculture (CSA) program” in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation); and

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

On page 10, line 22, strike “(c)” and insert “(d)”. 
On page 17, between lines 12 and 13, insert the following:

“(l) MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES.—

“(1) QUALIFIED FACILITIES.—

“(A) In general.—A facility is a qualified facility for purposes of this subsection if the facility meets the conditions under subparagraph (B) or (C).

“(B) Very small business.—A facility is a qualified facility under this subparagraph—

“(i) if the facility, including any subsidiary or affiliate of the facility, is, collectively, a very small business (as defined in the regulations promulgated under subsection (n)); and

“(ii) in the case where the facility is a subsidiary or affiliate of an entity, if such subsidiaries or affiliates, are, collectively, a very small business (as so defined).

“(C) Limited annual monetary value of sales.—
“(i) IN GENERAL.—A facility is a qualified facility under this subparagraph if clause (ii) applies—

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

“(II) to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

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

“(I) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as described in clause (i)) that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collec-
tive average annual monetary value of such food at any subsidiary or affiliate, as so described) sold by such facility (or collectively by any such subsidiary or affiliate) to all other purchasers during such period; and

“(II) the average annual monetary value of all food sold by such facility (or the collective average annual monetary value of such food sold by any subsidiary or affiliate, as described in clause (i)) during such period was less than $500,000, adjusted for inflation.

“(2) EXEMPTION.—A qualified facility—

“(A) shall not be subject to the requirements under subsections (a) through (i) and subsection (n) in an applicable calendar year; and

“(B) shall submit to the Secretary—

“(i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing pre-
ventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective; or

“(II) documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and

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

“(3) Withdrawal; rule of construction.—

“(A) In general.—In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under this sub-
section, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under this subsection.

“(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

“(4) DEFINITIONS.—In this subsection:

“(A) AFFILIATE.—The term ‘affiliate’ means any facility that controls, is controlled by, or is under common control with another facility.

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

“(i) the consumer of the food; or

“(ii) a restaurant or retail food establishment (as those terms are defined by the
Secretary for purposes of section 415)

that—

“(I) is located—

“(aa) in the same State as

the qualified facility that sold the

food to such restaurant or estab-

ishment; or

“(bb) not more than 275

miles from such facility; and

“(II) is purchasing the food for

sale directly to consumers at such res-

taurant or retail food establishment.

“(C) CONSUMER.—For purposes of sub-

paragraph (B), the term ‘consumer’ does not

include a business.

“(D) SUBSIDIARY.—The term ‘subsidiary’

means any company which is owned or con-

trolled directly or indirectly by another com-

pany.

“(5) STUDY.—

“(A) IN GENERAL.—The Secretary, in con-

sultation with the Secretary of Agriculture,

shall conduct a study of the food processing

sector regulated by the Secretary to deter-

mine—
“(i) the distribution of food production by type and size of operation, including monetary value of food sold;

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

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

“(iv) the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists; and

“(v) the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.

“(B) SIZE.—The results of the study conducted under subparagraph (A) shall include the information necessary to enable the Secretary to define the terms ‘small business’ and ‘very small business’, for purposes of promul-
gating the regulation under subsection (n). In defining such terms, the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

“(C) Submission of report.—Not later than 18 months after the date of enactment the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that describes the results of the study conducted under subparagraph (A).

“(6) No preemption.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

“(7) Notification to consumers.—

“(A) In general.—A qualified facility that is exempt from the requirements under subsections (a) through (i) and subsection (n) and does not prepare documentation under paragraph (2)(B)(i)(I) shall—

“(i) with respect to a food for which a food packaging label is required by the
Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed; or

“(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provisions of this Act, prominently and conspicuously display, at the point of purchase, the name and business address of facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

“(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

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

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

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

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

“(B) to define, for purposes of this section, the terms ‘small business’ and ‘very small business’, taking into consideration the study described in subsection (l)(5).

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

On page 18, line 13, strike “paragraph (1)” and insert “paragraph (1)(A)”.

On page 19, line 17, strike “paragraph (1)” and insert “paragraph (1)(A)”.

Beginning on page 24, strike line 13 and all that follows through line 6 on page 25 and insert the following:

(ii) LIMITATION.—The exemptions or modifications under clause (i) shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added under subsection (a)).

On page 26, line 6, strike “subsection (m)” and insert “subsection (n)”.

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

(i) EFFECTIVE DATES.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of enactment of this Act.
(2) FLEXIBILITY FOR SMALL BUSINESSES.—

Notwithstanding paragraph (1)—

(A) the amendments made by this section
shall apply to a small business (as defined in
the regulations promulgated under section
418(n) of the Federal Food, Drug, and Cos-

metic Act (as added by this section)) beginning
on the date that is 6 months after the effective
date of such regulations; and

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

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

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

On page 32, line 24, strike the period and insert “; and”.
On page 32, after line 24, insert the following:

“(F) define, for purposes of this section, the terms ‘small business’ and ‘very small business’.

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

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

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

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

On page 36, line 8, strike “facility” and insert “business”.

On page 40, between lines 5 and 6, insert the following:

“(f) EXEMPTION FOR DIRECT FARM MARKETING.—
“(1) IN GENERAL.—A farm shall be exempt from the requirements under this section in a calendar year if—

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

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

“(2) NOTIFICATION TO CONSUMERS.—

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

“(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the farm where the produce was grown; or

“(ii) with respect to a food for which a food packaging label is not required by
the Secretary under any other provision of this Act, prominently and conspicuously display, at the point of purchase, the name and business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

“(B) No additional label.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

“(3) Withdrawal; rule of construction.—

“(A) In general.—In the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm that are material to the safety of the food produced or
harvested at such farm, the Secretary may withdraw the exemption provided to such farm under this subsection.

“(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

“(4) DEFINITIONS.—

“(A) QUALIFIED END-USER.—In this subsection, the term ‘qualified end-user’, with respect to a food means—

“(i) the consumer of the food; or

“(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 415) that is located—

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

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

“(B) CONSUMER.—For purposes of subparagraph (A), the term ‘consumer’ does not include a business.

“(5) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-
Federal law regarding the safe production, harvesting, holding, transportation, and sale of fresh fruits and vegetables. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

“(6) LIMITATION OF EFFECT.—Nothing in this subsection shall prevent the Secretary from exercising any authority granted in the other sections of this Act.

On page 40, between lines 5 and 6, insert the following:

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

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

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