

Summary of Tester Amendment

Senator Jon Tester (D-MT) has sponsored an amendment to the food safety bill (S. 510) to further protect small, local food processors and producers.

Retail Food Establishments:

In the 2002 Bioterrorism Act, Congress required that all facilities that manufacture, process, pack, or hold food must register with FDA, but it exempted from that requirement “retail food establishments.” FDA defined the term at 21 CFR 1.227(b)(11). For purposes of the definition, the Tester amendment would require FDA to clarify that “direct sales” of food to consumers includes sales that occur other than where the food was manufactured, such as at a roadside stand or farmers’ market.

Qualified Exemptions:

-Facilities:

- Food facilities would qualify for an exemption from the preventive control/HACCP provisions in section 103 of S. 510 under certain conditions:
 - (1) they are either a “very small business” as defined by FDA in rulemaking; or (2) the average annual monetary value of all food sold by the facility during the previous 3 year period was less than \$500,000, but only so long as the majority of the food sold by that facility was sold directly to consumers, restaurants, or grocery stores (as opposed to 3rd party food brokers) and were in the same state where the facility sold the food or within 275 miles of the facility.
- Facilities that qualify would be exempt from the preventive control/HACCP provisions in S. 510, but would still have to comply with one of the following:
 - (1) They would have to demonstrate that they have identified potential hazards and are implementing preventive controls to address the hazards, or
 - (2) they would have to demonstrate to FDA that they are in compliance with state or local food safety laws.
- Disclosure: Any food sold by a facility that opts for compliance option (2), above, would have to prominently and conspicuously provide the name and address of the facility that produced it on a food packaging label, or at the point of purchase, as appropriate.
- Study: FDA would have to conduct a study of the food processing sector to help inform the definition of what it means to be a “very small” facility for purposes of the exemption above.

-Farms:

- Farms would qualify for an exemption from the produce safety standards in section 105 of S. 510 if, during the previous 3 year period, the average monetary value of the food they sold was less than \$500,000, but only so long as the majority of sales were to consumers, restaurants, or grocery stores (as opposed to 3rd party food brokers) and were in the same state where the farm harvested or produced the food or within 275 miles of the farm.
- Any food sold under the exemption would have to have the same disclosure set forth above.

-Limitation:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to a facility or farm exempted under this 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 facility or farm that are material to the safety of food, the Secretary may withdraw the exemption provided to such facility under this section. No activities under this limitation expand existing FDA authorities to inspect farms.