

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 350d of this title) 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 chapter.

**(g) Clarification**

This section shall not apply to produce that is produced by an individual for personal consumption.

**(h) Exception for activities of facilities subject to section 350g of this title**

This section shall not apply to activities of a facility that are subject to section 350g of this title.

(June 25, 1938, ch. 675, §419, as added Pub. L. 111-353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3899.)

**Editorial Notes**

REFERENCES IN TEXT

The Organic Foods Production Act of 1990, referred to in subsec. (a)(1)(A), (3)(E), is title XXI of Pub. L. 101-624, Nov. 28, 1990, 104 Stat. 3935, which is classified generally to chapter 94 (§6501 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 6501 of Title 7 and Tables.

The FDA Food Safety Modernization Act, referred to in subsec. (a)(3)(E), is Pub. L. 111-353, Jan. 4, 2011, 124 Stat. 3885, which enacted chapter 27 (§2201 et seq.) and sections 350g to 350l-1, 379j-31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture,

and section 280g-16 of Title 42, The Public Health and Welfare, amended sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b-20 of Title 42, and enacted provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2201 of this title and Tables.

**Statutory Notes and Related Subsidiaries**

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

SCIENTIFIC AND ECONOMIC ANALYSIS OF THE FDA FOOD SAFETY MODERNIZATION ACT

Pub. L. 113-79, title XII, §12311(a), Feb. 7, 2014, 128 Stat. 992, provided that: “When publishing a final rule with respect to ‘Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption’ published by the Department of Health and Human Services on January 16, 2013 (78 Fed. Reg. 3504), the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall ensure that the final rule (referred to in this section as the ‘final rule’) includes the following information:

“(1) An analysis of the scientific information used to promulgate the final rule, taking into consideration any information about farming and ranching operations of a variety of sizes, with regional differences, and that have a diversity of production practices and methods.

“(2) An analysis of the economic impact of the final rule.

“(3) A plan to systematically—

“(A) evaluate the impact of the final rule on farming and ranching operations; and

“(B) develop an ongoing process to evaluate and respond to business concerns.”

SMALL ENTITY COMPLIANCE POLICY GUIDE

Pub. L. 111-353, title I, §105(b), Jan. 4, 2011, 124 Stat. 3904, provided that: “Not later than 180 days after the issuance of regulations under section 419 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350h] (as added by subsection (a)), the Secretary of Health and Human Services shall issue a small entity compliance policy guide setting forth in plain language the requirements of such section 419 and to assist small entities in complying with standards for safe production and harvesting and other activities required under such section.”

NO EFFECT ON HACCP AUTHORITIES

Pub. L. 111-353, title I, §105(d), Jan. 4, 2011, 124 Stat. 3905, provided that: “Nothing in the amendments made by this section [enacting this section and amending section 331 of this title] limits the authority of the Secretary [of Health and Human Services] under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control [Points] Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.”

**§ 350i. Protection against intentional adulteration**

**(a) Determinations**

**(1) In general**

The Secretary shall—

(A) conduct a vulnerability assessment of the food system, including by consideration of the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessments;

(B) consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration of food at vulnerable points; and

(C) determine the types of science-based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food.

**(2) Limited distribution**

In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which determinations made under paragraph (1) are made publicly available.

**(b) Regulations**

Not later than 18 months after January 4, 2011, the Secretary, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, shall promulgate regulations to protect against the intentional adulteration of food subject to this chapter. Such regulations shall—

(1) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food; and

(2) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate.

**(c) Applicability**

Regulations promulgated under subsection (b) shall apply only to food for which there is a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (a), that could cause serious adverse health consequences or death to humans or animals and shall include those foods—

(1) for which the Secretary has identified clear vulnerabilities (including short shelf-life or susceptibility to intentional contamination at critical control points); and

(2) in bulk or batch form, prior to being packaged for the final consumer.

**(d) Exception**

This section shall not apply to farms, except for those that produce milk.

**(e) Definition**

For purposes of this section, the term “farm” has the meaning given that term in section 1.227 of title 21, Code of Federal Regulations (or any successor regulation).

(June 25, 1938, ch. 675, §420, as added Pub. L. 111-353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3905.)

**Statutory Notes and Related Subsidiaries**

**CONSTRUCTION**

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction

and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

**GUIDANCE DOCUMENTS**

Pub. L. 111-353, title I, §106(b), Jan. 4, 2011, 124 Stat. 3906, provided that:

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Jan. 4, 2011], the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies or measures to guard against such adulteration as required under section 420 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 450i], as added by subsection (a).

“(2) CONTENT.—The guidance documents issued under paragraph (1) shall—

“(A) include a model assessment for a person to use under subsection (b)(1) of section 420 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

“(B) include examples of mitigation strategies or measures described in subsection (b)(2) of such section; and

“(C) specify situations in which the examples of mitigation strategies or measures described in subsection (b)(2) of such section are appropriate.

“(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which the guidance documents issued under paragraph (1) are made public, including by releasing such documents to targeted audiences.”

**PERIODIC REVIEW**

Pub. L. 111-353, title I, §106(c), Jan. 4, 2011, 124 Stat. 3906, provided that: “The Secretary of Health and Human Services shall periodically review and, as appropriate, update the regulations under section 420(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 450i(b)], as added by subsection (a), and the guidance documents under subsection (b) [section 106(b) of Pub. L. 111-353, set out above].”

**§ 350j. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report**

**(a) Identification and inspection of facilities**

**(1) Identification**

The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:

(A) The known safety risks of the food manufactured, processed, packed, or held at the facility.

(B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

(C) The rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls.

(D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 381(h)(1) of this title.

(E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as de-