

- (A) animal or plant disease outbreaks;
- (B) food contamination; and
- (C) natural disasters affecting agriculture and food.

(Pub. L. 111-353, title I, §109, Jan. 4, 2011, 124 Stat. 3912.)

#### § 2204. Building domestic capacity

##### (a) In general

###### (1) Initial report

The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall, not later than 2 years after January 4, 2011, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities. Such report shall include a description of the following:

(A) Analysis of the need for further regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 2203 of this title, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

(C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.

(D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.

(E) Surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards, including how such systems and networks are integrated.

(F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress implementing strategies developed under sections 2202 and 2224 of this title.

(G) The estimated resources needed to effectively implement the programs and practices identified in the report developed in this section over a 5-year period.

(H) The impact of requirements under this Act (including amendments made by this Act) on certified organic farms and facilities (as defined in section 350d of this title).<sup>1</sup>

(I) Specific efforts taken pursuant to the agreements authorized under section 350j(c) of this title (as added by section 201),<sup>2</sup> together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

###### (2) Biennial reports

On a biennial basis following the submission of the report under paragraph (1), the Sec-

retary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

(B) outlines the success of those programs and practices;

(C) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (H) of paragraph (1), as necessary.

###### (b) Risk-based activities

The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources available to the Secretary for food safety-related activities are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources. The Secretary shall promptly undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

###### (c) Capability for laboratory analyses; research

The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including commercially-available techniques that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities and progress toward laboratory accreditation under section 350k of this title (as added by section 202).<sup>2</sup>

###### (d) Information technology

The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility registration system under section 350d of this title, and the prior notice system under section 381(m) of this title with other information technology systems that are used by the Federal Government for the processing of food offered for import into the United States.

###### (e) Automated risk assessment

The report developed under subsection (a)(1) shall include a description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

###### (f) Traceback and surveillance report

The Secretary shall include in the report developed under subsection (a)(1) an analysis of the Food and Drug Administration's performance in foodborne illness outbreaks during the 5-year period preceding January 4, 2011, involving fruits and vegetables that are raw agricultural commodities (as defined in section 321(r) of this title) and recommendations for enhanced sur-

<sup>1</sup> So in original. Probably should be "title."

<sup>2</sup> See References in Text note below.

veillance, outbreak response, and traceability. Such findings and recommendations shall address communication and coordination with the public, industry, and State and local governments, as such communication and coordination relates to outbreak identification and traceback.

**(g) Biennial food safety and food defense research plan**

The Secretary, the Secretary of Agriculture, and the Secretary of Homeland Security shall, on a biennial basis, submit to Congress a joint food safety and food defense research plan which may include studying the long-term health effects of foodborne illness. Such biennial plan shall include a list and description of projects conducted during the previous 2-year period and the plan for projects to be conducted during the subsequent 2-year period.

**(h) Effectiveness of programs administered by the Department of Health and Human Services**

**(1) In general**

To determine whether existing Federal programs administered by the Department of Health and Human Services are effective in achieving the stated goals of such programs, the Secretary shall, beginning not later than 1 year after January 4, 2011—

(A) conduct an annual evaluation of each program of such Department to determine the effectiveness of each such program in achieving legislated intent, purposes, and objectives; and

(B) submit to Congress a report concerning such evaluation.

**(2) Content**

The report described under paragraph (1)(B) shall—

(A) include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions;

(B) include recommendations for consolidation and elimination to reduce duplication and inefficiencies in such programs at such Department as identified during the evaluation conduct<sup>3</sup> under this subsection; and

(C) be made publicly available in a publication entitled “Guide to the U.S. Department of Health and Human Services Programs”.

**(i) Unique identification numbers**

**(1) In general**

Not later than 1 year after January 4, 2011, the Secretary, acting through the Commissioner of Food and Drugs, shall conduct a study regarding the need for, and challenges associated with, development and implementation of a program that requires a unique identification number for each food facility registered with the Secretary and, as appropriate, each broker that imports food into the United States. Such study shall include an evaluation of the costs associated with development and implementation of such a system, and make

recommendations about what new authorities, if any, would be necessary to develop and implement such a system.

**(2) Report**

Not later than 15 months after January 4, 2011, the Secretary shall submit to Congress a report that describes the findings of the study conducted under paragraph (1) and that includes any recommendations determined appropriate by the Secretary.

(Pub. L. 111-353, title I, §110, Jan. 4, 2011, 124 Stat. 3913.)

REFERENCES IN TEXT

The Secretary, referred to in subsecs. (a), (b), (d), (f), (g), (h)(1), and (i), probably means the Secretary of Health and Human Services.

This Act, referred to in subsec. (a)(1)(H), is Pub. L. 111-353, Jan. 4, 2011, 124 Stat. 3885, known as the FDA Food Safety Modernization Act, which enacted this chapter 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, 350j 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.

Section 350d of this title, referred to in subsec. (a)(1)(H), and section 321(r) of this title, referred to in subsec. (f), were in the original “section 415 (21 U.S.C. 350d)” and “section 201(r) (21 U.S.C. 321(r))”, respectively, and were translated as meaning sections 415 and 201(r) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, to reflect the probable intent of Congress.

Section 201, referred to in subsec. (a)(1)(I), and section 202, referred to in subsec. (c), mean sections 201 and 202, respectively, of Pub. L. 111-353.

**§ 2205. Food allergy and anaphylaxis management**

**(a) Definitions**

In this section:

**(1) Early childhood education program**

The term “early childhood education program” means—

(A) a Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 et seq.);

(B) a State licensed or regulated child care program or school; or

(C) a State prekindergarten program that serves children from birth through kindergarten.

**(2) ESEA definitions**

The terms “local educational agency”, “secondary school”, “elementary school”, and “parent” have the meanings given the terms in section 7801 of title 20.

**(3) School**

The term “school” includes public—

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

**(4) Secretary**

The term “Secretary” means the Secretary of Health and Human Services.

<sup>3</sup>So in original. Probably should be “conducted”.