

(3) Evaluation

The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall—

(A) develop metrics to measure progress for the evaluation process described in paragraph (1)(B); and

(B) report on the progress measured in subparagraph (A) as part of the National Agriculture and Food Defense strategy described in subsection (a)(1).

(c) Limited distribution

In the interest of national security, the Secretary of Health and Human Services and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, may determine the manner and format in which the National Agriculture and Food Defense strategy established under this section is made publicly available on the Internet Web sites of the Department of Health and Human Services, the Department of Homeland Security, and the Department of Agriculture, as described in subsection (a)(1).

(Pub. L. 111-353, title I, §108, Jan. 4, 2011, 124 Stat. 3910.)

Editorial Notes**REFERENCES IN TEXT**

The Secretary, referred to in subsec. (b)(3), probably means the Secretary of Health and Human Services.

§ 2203. Food and Agriculture Coordinating Councils

The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services and the Secretary of Agriculture, shall within 180 days of January 4, 2011, and annually thereafter, submit to the relevant committees of Congress, and make publicly available on the Internet Web site of the Department of Homeland Security, a report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council, including the progress of such Councils on—

(1) facilitating partnerships between public and private entities to help coordinate and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of—

(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).¹

(I) Specific efforts taken pursuant to the agreements authorized under section 350j(c) of this title (as added by section 201),² 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 Secretary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

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

¹ So in original. Probably should be “title).”

² See References in Text note below.

(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).²

(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 surveillance, 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 conduct³ 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

³ So in original. Probably should be "conducted".

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.)

Editorial Notes

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, 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.

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.

(b) Establishment of voluntary food allergy and anaphylaxis management guidelines

(1) Establishment

(A) In general

Not later than 1 year after January 4, 2011, the Secretary, in consultation with the Secretary of Education, shall—

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs; and

(ii) make such guidelines available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.

(B) Applicability of FERPA

Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of section 1232g of title 20 (commonly referred to as the “Family Educational Rights and Privacy Act of 1974”).

(2) Contents

The voluntary guidelines developed by the Secretary under paragraph (1) shall address each of the following and may be updated as the Secretary determines necessary:

(A) Parental obligation to provide the school or early childhood education program, prior to the start of every school year, with—

(i) documentation from their child’s physician or nurse—

(I) supporting a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

(II) identifying any food to which the child is allergic;

(III) describing, if appropriate, any prior history of anaphylaxis;

(IV) listing any medication prescribed for the child for the treatment of anaphylaxis;

(V) detailing emergency treatment procedures in the event of a reaction;

(VI) listing the signs and symptoms of a reaction; and

(VII) assessing the child’s readiness for self-administration of prescription medication; and

(ii) a list of substitute meals that may be offered to the child by school or early childhood education program food service personnel.

(B) The creation and maintenance of an individual plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any procedures for the self-administration of medication by such children in instances where—

(i) the children are capable of self-administering medication; and

(ii) such administration is not prohibited by State law.

(C) Communication strategies between individual schools or early childhood edu-