

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 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, 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:

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

**(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 education programs and providers of emergency medical services, including appropriate instructions for emergency medical response.

(D) Strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas such as cafeterias.

(E) The dissemination of general information on life-threatening food allergies to school or early childhood education program staff, parents, and children.

(F) Food allergy management training of school or early childhood education program personnel who regularly come into contact with children with life-threatening food allergies.

(G) The authorization and training of school or early childhood education program personnel to administer epinephrine when the nurse is not immediately available.

(H) The timely accessibility of epinephrine by school or early childhood education program personnel when the nurse is not immediately available.

(I) The creation of a plan contained in each individual plan for food allergy management that addresses the appropriate response to an incident of anaphylaxis of a child while such child is engaged in extracurricular programs of a school or early childhood education program, such as non-academic outings and field trips, before- and after-school programs or before- and after-early child education program programs,<sup>1</sup> and school-sponsored or early childhood education program-sponsored programs held on weekends.

(J) Maintenance of information for each administration of epinephrine to a child at risk for anaphylaxis and prompt notification to parents.

<sup>1</sup> So in original.

(K) Other elements the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early childhood education programs.

**(3) Relation to State law**

Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding whether students at risk for anaphylaxis may self-administer medication.

**(c) School-based food allergy management grants**

**(1) In general**

The Secretary may award grants to local educational agencies to assist such agencies with implementing voluntary food allergy and anaphylaxis management guidelines described in subsection (b).

**(2) Application**

**(A) In general**

To be eligible to receive a grant under this subsection, a local educational agency shall submit an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

**(B) Contents**

Each application submitted under subparagraph (A) shall include—

(i) an assurance that the local educational agency has developed plans in accordance with the food allergy and anaphylaxis management guidelines described in subsection (b);

(ii) a description of the activities to be funded by the grant in carrying out the food allergy and anaphylaxis management guidelines, including—

(I) how the guidelines will be carried out at individual schools served by the local educational agency;

(II) how the local educational agency will inform parents and students of the guidelines in place;

(III) how school nurses, teachers, administrators, and other school-based staff will be made aware of, and given training on, when applicable, the guidelines in place; and

(IV) any other activities that the Secretary determines appropriate;

(iii) an itemization of how grant funds received under this subsection will be expended;

(iv) a description of how adoption of the guidelines and implementation of grant activities will be monitored; and

(v) an agreement by the local educational agency to report information required by the Secretary to conduct evaluations under this subsection.

**(3) Use of funds**

Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

(A) Purchase of materials and supplies, including limited medical supplies such as epi-

nephrine and disposable wet wipes, to support carrying out the food allergy and anaphylaxis management guidelines described in subsection (b).

(B) In partnership with local health departments, school nurse, teacher, and personnel training for food allergy management.

(C) Programs that educate students as to the presence of, and policies and procedures in place related to, food allergies and anaphylactic shock.

(D) Outreach to parents.

(E) Any other activities consistent with the guidelines described in subsection (b).

**(4) Duration of awards**

The Secretary may award grants under this subsection for a period of not more than 2 years. In the event the Secretary conducts a program evaluation under this subsection, funding in the second year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

**(5) Limitation on grant funding**

The Secretary may not provide grant funding to a local educational agency under this subsection after such local educational agency has received 2 years of grant funding under this subsection.

**(6) Maximum amount of annual awards**

A grant awarded under this subsection may not be made in an amount that is more than \$50,000 annually.

**(7) Priority**

In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 6333(c) of title 20.

**(8) Matching funds**

**(A) In general**

The Secretary may not award a grant under this subsection unless the local educational agency agrees that, with respect to the costs to be incurred by such local educational agency in carrying out the grant activities, the local educational agency shall make available (directly or through donations from public or private entities) non-Federal funds toward such costs in an amount equal to not less than 25 percent of the amount of the grant.

**(B) Determination of amount of non-Federal contribution**

Non-Federal funds required under subparagraph (A) may be cash or in kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal funds.

**(9) Administrative funds**

A local educational agency that receives a grant under this subsection may use not more

than 2 percent of the grant amount for administrative costs related to carrying out this subsection.

**(10) Progress and evaluations**

At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide the Secretary with information on how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines described in subsection (b).

**(11) Supplement, not supplant**

Grant funds received under this subsection shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this subsection.

**(12) Authorization of appropriations**

There is authorized to be appropriated to carry out this subsection \$30,000,000 for fiscal year 2011 and such sums as may be necessary for each of the 4 succeeding fiscal years.

**(d) Voluntary nature of guidelines**

**(1) In general**

The food allergy and anaphylaxis management guidelines developed by the Secretary under subsection (b) are voluntary. Nothing in this section or the guidelines developed by the Secretary under subsection (b) shall be construed to require a local educational agency to implement such guidelines.

**(2) Exception**

Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis management guidelines as a condition of the receipt of a grant under subsection (c).

(Pub. L. 111-353, title I, §112, Jan. 4, 2011, 124 Stat. 3916.)

REFERENCES IN TEXT

The Head Start Act, referred to in subsec. (a)(1)(A), is subchapter B (§635 et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97-35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of Title 42 and Tables.

**§ 2206. Alcohol-related facilities**

**(a) In general**

Except as provided by sections 102, 206, 207, 302, 304, 402, 403, and 404 of this Act, and the amendments made by such sections, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that—

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and

(2) under section 350d of this title is required to register as a facility because such facility is

engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.

**(b) Limited receipt and distribution of non-alcohol food**

Subsection (a) shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that such paragraph shall apply to a facility described in such paragraph that receives and distributes non-alcohol food, provided such food is received and distributed—

(1) in a prepackaged form that prevents any direct human contact with such food; and

(2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.

**(c) Rule of construction**

Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214<sup>1</sup> of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act).

(Pub. L. 111-353, title I, §116, Jan. 4, 2011, 124 Stat. 3922.)

REFERENCES IN TEXT

This Act, referred to in subsecs. (a) and (c), 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. Sections 102, 206, 207, 302, 304, 402, 403, and 404 of the Act enacted sections 350l, 350l-1, 384b, 399d, 2251, and 2252 of this title, amended sections 331, 333, 334, 350d, and 381 of this title, and enacted provisions set out as notes under sections 334, 350d, 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.

The Federal Alcohol Administration Act, referred to in subsecs. (a)(1) and (c), is act Aug. 29, 1935, ch. 814, 49 Stat. 977, which is classified generally to subchapter I (§201 et seq.) of chapter 8 of Title 27, Intoxicating Liquors. Section 214 of the Act probably means section 203 of the Act, which is classified to section 214 of Title 27 and defines “alcoholic beverage”. For complete classification of this Act to the Code, see section 201 of Title 27 and Tables.

The Internal Revenue Code of 1986, referred to in subsec. (a)(1), is classified generally to Title 26, Internal Revenue Code.

SUBCHAPTER II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

**§ 2221. Food emergency response network**

The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal gov-

<sup>1</sup> See References in Text note below.