(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

(k) Construction

Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 381(d)(1) of this title as provided in this section.

***(l)* Effectiveness of section**

(1) Commencement of program

This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) Termination of program

(A) In general

If, after the date that is 1 year after the effective date of the regulations under subsection (b) of this section and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

(B) Procedure

The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, the Secretary—

(i)(I) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

(II) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

(III) identifies specifically the causes of the increased risk; and

(IV)(aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

(II) determines that the benefits do not outweigh the detriment.

(m) Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, §804, as added Pub. L. 108–173, title XI, §1121(a), Dec. 8, 2003, 117 Stat. 2464.)

PRIOR PROVISIONS

A prior section 384, act June 25, 1938, ch. 675, §804, as added Pub. L. 106–387, §1(a) [title VII, §745(c)(2)], Oct. 28, 2000, 114 Stat. 1549, 1549A–36, related to importation of covered products, prior to repeal by Pub. L. 108–173, title XI, §1121(a), Dec. 8, 2003, 117 Stat. 2464.

TRANSFER OF FUNCTIONS

For transfer of functions, personnel, assets, and liabilities of the United States Customs Service of the Department of the Treasury, including functions of the Secretary of the Treasury relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see sections 203(1), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

STUDY AND REPORT ON IMPORTATION OF DRUGS

Pub. L. 108–173, title XI, §1122, Dec. 8, 2003, 117 Stat. 2469, directed the Secretary of Health and Human Services to conduct a study on the importation of drugs into the United States pursuant to this section and to submit to Congress, not later than 12 months after Dec. 8, 2003, a report providing the findings of such study.

§ 384a. Foreign supplier verification program

(a) In general

(1) Verification requirement

Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is—

(A) produced in compliance with the requirements of section 350g of this title or section 350h of this title, as appropriate; and

(B) is not adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(2) Importer defined

For purposes of this section, the term ''importer'' means, with respect to an article of food—

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

(b) Guidance

Not later than 1 year after January 4, 2011, the Secretary shall issue guidance to assist importers in developing foreign supplier verification programs.

(c) Regulations

(1) In general

Not later than 1 year after January 4, 2011, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

(2) Requirements

The regulations promulgated under paragraph (1)—

(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 350g of this title or section 350h of this title (taking into consideration variances granted under section 350h of this title), as appropriate; and

(ii) section 342 of this title and section 343(w) of this title.[1]

(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

(3) Considerations

In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

(4) Activities

Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

(d) Record maintenance and access

Records of an importer related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and shall be made available promptly to a duly authorized representative of the Secretary upon request.

(e) Exemption of seafood, juice, and low-acid canned food facilities in compliance with HACCP

This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

The exemption under paragraph (3) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter[2] 21, Code of Federal Regulations (or any successor regulations).

(f) Additional exemptions

The Secretary, by notice published in the Federal Register, shall establish an exemption from the requirements of this section for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public.

(g) Publication of list of participants

The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.

(June 25, 1938, ch. 675, § 805, as added Pub. L. 111–353, title III, § 301(a), Jan. 4, 2011, 124 Stat. 3953.)

EFFECTIVE DATE

Section effective 2 years after Jan. 4, 2011, see section 301(d) of Pub. L. 111–353, set out as an Effective Date of 2011 Amendment note under section 331 of this title.

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.

§ 384b. Voluntary qualified importer program

(a) In general

Beginning not later than 18 months after January 4, 2011, the Secretary shall—

(1) establish a program, in consultation with the Secretary of Homeland Security—

(A) to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program; and

(B) consistent with section 384d of this title, establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such program; and

(2) issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program.

[1] So in original.

[2] So in original. Probably should be ''title''.