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S.L.C.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 4974

To amend the Federal Food, Drug, and Cosmetic Act with respect to food safety.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Making America's Food Safer Act".

SEC. 2. EXPANSION OF THE ACCREDITED THIRD-PARTY CERTIFICATION PROGRAM.

(a) REVISED DEFINITIONS.—Section 808(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384d(a)) is amended—

(1) by striking paragraph (6) and inserting the following:

"(6) ELIGIBLE ENTITY.—The term 'eligible entity' means a foreign or domestic entity, including a foreign or domestic facility subject to registration under section 415, in the food supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor."; and

(2) in paragraph (7)(B)—

(A) in clause (i), by striking "; or" and inserting a semicolon;

(B) in clause (ii), by striking the period and inserting "; or"; and

(C) by adding at the end the following:

"(iii) whether a facility is eligible to receive a food or facility certification for other purposes described in subsection (c)(2)(B)(ii).".

(b) REMOVING LIMITATIONS ON THE USE OF CERTIFICATIONS.—Section 808(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384d(c)(2)) is amended—

(1) in subparagraph (A), by striking "food certification, described in section 801(q), or facility certification under section 806(a), as appropriate, to accompany each food shipment for import into the

United States from an eligible entity" and inserting "food certification or facility certification for purposes described in subparagraph (B), as appropriate,"; and

(2) by striking subparagraph (B) and inserting the following:

"(B) PURPOSE OF CERTIFICATION.—

"(i) IN GENERAL.—The Secretary shall use certification provided by accredited third-party auditors to—

"(I) determine, in conjunction with any other assurances the Secretary may require under section 801(q), whether a food satisfies the requirements of such section; and

"(II) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 806.

"(ii) OTHER CONSIDERATIONS.—The Secretary may consider the results of regulatory audits and food or facility certifications provided by accredited third-party auditors under this section in analyzing

risks and prioritizing inspections and other regulatory activities, as appropriate for the protection of public health.".

(c) TECHINICAL AND CONFORMING AMENDMENTS.—Section 808 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384d) is amended—

(1) in subsection (b)(1)(A)—

(A) by striking "ACCREDITATION BODIES" in the subparagraph heading and all that follows through "Not later than" in clause (i) and inserting the following: "ACCREDITATION BODIES—Not later than"; and

(B) by striking clause (ii);

(2) in subsection (c)—

(A) in paragraphs (1) and (2), by striking "(or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary)" each place it appears;

(B) in paragraph (2)(C)(i), by striking "food certification under section 801(q) or a facility certification described under this subparagraph (B)" and inserting "food certification or a facility certification described in this section";

(C) in paragraph (6)(A)(i), by striking "food certified under section 801(q) or from a

facility certified under paragraph (2)(B)" and inserting "food or facility certified under this section";

(D) in paragraph (6)(C), by striking "requirements under section 801(q), of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity" and inserting "requirements for certifying the food or facility under this section"; and

(E) in paragraph (7)(B)(i), by striking ", through direct accreditation under subsection (b)(1)(A)(ii) or"; and

(3) in subsection (d)—

(A) in paragraph (1), by striking "or"; and

(B) at the end of paragraph (2), by striking the period and inserting "; or"; and

(C) by adding at the end the following new paragraph:

"(3) otherwise seeks certification for purposes of subsection (c)(2)(B)(ii).".

SEC. 3. SHARING FOOD SAFETY INFORMATION WITH STATE, LOCAL, TRIBAL, AND TERRITORIAL AUTHORITIES.

(a) IN GENERAL.—Section 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) is amended by adding at the end the following:

"(d) SHARING FOOD SAFETY INFORMATION WITH STATE, LOCAL, TRIBAL, AND TERRITORIAL AUTHORITIES.—

"(1) AUTHORIZATION.—Notwithstanding section 301(j) and any other law, regulation, or policy, the Secretary may share, with a State, local, Tribal, or territorial authority with counterpart functions related to the protection of public health, unredacted information in the possession of the Food and Drug Administration relating to any of the following:

"(A) Foodborne illness surveillance data.

"(B) Laboratory sampling testing information.

"(C) Inspectional information and results.

"(D) Distribution lists for recalls and outbreaks.

"(E) Consumer complaints.

"(F) Any other information the Secretary determines will assist such authority in protecting the public.

"(2) TIMING.—The Secretary may share information pursuant to paragraph (1) as soon as is reasonably practicable.

"(3) LIMITATION ON FURTHER DISCLOSURE.—A State, local, Tribal, or Territorial authority in receipt of information provided by the Secretary under this subsection shall not further disclose such information without permission of the Food and Drug Administration unless such authority determines that disclosure of such information is necessary to contain a foodborne illness outbreak, carry out a recall, or carry out other State enforcement activities.

"(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the authority of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

"(e) INFORMATION DISCLOSURE DURING FOOD SAFETY INCIDENTS.—The Secretary is authorized to disclose commercial information obtained from a person that is protected under section 1905 of title 18, United States Code, when the disclosure of such information advances public health protection during a food safety incident, including a foodborne illness outbreak, an investigation related to contaminated food, or a food recall.".

(b) CONFORMING AMENDMENT.—The first sentence of section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) is amended—

(1) by inserting "to a State, local, Tribal, or territorial authority as specified in section 708(d)," after "of the Department,"; and

(2) by striking the second period at the end.

SEC. 4. DESTRUCTION OF CERTAIN REFUSED ARTICLES.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

"(v) ORDER TO DESTROY CERTAIN REFUSED ARTICLES.—

"(1) IN GENERAL.—For any article that has been refused admission and is in violation of this Act, the Secretary of Health and Human Services may issue to the owner or consignee an order that the article shall be destroyed, without the opportunity to export, if the Secretary of Health and Human Services finds that the article presents a significant public health concern. Before issuing an order to destroy an article under this subsection, the Secretary of Health and Human Services shall provide for notice and an opportunity to appear before the Secretary of Health and Human Services and in-

troduce testimony on the order to destroy. The Secretary of Health and Human Services may combine the opportunity to appear before the Secretary and the opportunity to introduce testimony into a single proceeding with respect to an article. The regulations under paragraph (2) shall provide that prior to the destruction of any such article, appropriate due process is available to the owner or consignee seeking to challenge the Secretary of Health and Human Service's decision to order destruction. Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony on the refusal as long as appropriate notice is provided to the owner or consignee about the potential order to destroy. The Secretary of the Treasury shall cause the owner or consignee to complete the destruction of any such article within 90 days of the order for destruction and the owner or consignee shall be responsible for the costs of such destruction.

"(2) REGULATIONS.—

"(A) PROPOSED.—Not later than 18 months after the date of enactment of the Making America's Food Safer Act, the Secretary of Health and Human Services shall issue proposed regulations to implement paragraph (1),

including a framework for due process, allowing for notice and comment on such proposed regulations.

"(B) FINAL.—Not later than 1 year after the issuance of the proposed regulations under subparagraph (A), the Secretary of Health and Human Services shall promulgate final regulations to implement paragraph (1).

"(3) EXCEPTIONS.—With respect to importation by an individual of a prescription drug that is not a controlled substance pursuant to section 804(j) and in a manner that is consistent with personal or household use, the authority provided under paragraph (1) shall not apply.

"(4) CLARIFICATION.—For purposes of this section, a prescription drug described in paragraph (3) that is imported as described in such paragraph shall not be considered a 'significant public health concern'.".