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U.S. House/Senate Food Safety Comparison

The two side-by-sides below describe the pending food safety bill in Congress that we believe impacts the pistachio industry. The debate surrounding food safety involves meat, program crops and speciality crops. Our summary focuses on the provisions we believe are important to the pistachio industry.

The House bill was voted out of the House and the Senate Bill is pending before the full Senate for Senate floor debate. Floor debate has not been scheduled nor is it known when the House/Senate conference will be held.

The first side-by-side is a review of the House bill and the pending Senate bill. The second side-by-side is a review of the House and Senate bills' foreign/import food safety requirements. As you may deduce from the bill's descriptions, the legislation was drafted for friendly and developed countries not for a country such as the Islamic Republic of Iran.

Important Food Safety Provisions Impacting the Specialty Crop Industry

Table of Contents

Registration of Facilities	pg. 2
Food Safety Plan, Hazard Analysis, Preventative Controls	pg. 3
Safety Standards for Produce	pg. 4
Inspections.....	pg. 5
Traceability of Food	pg. 7
Certification of Accredited Laboratories	pg. 9
Imports	pg. 10
Recall Authority	pg. 11
Quarantine Authority	pg. 12
Inspection and Access to Records	pg. 13
Fees Related to Inspection and Registration.....	pg. 14
Penalties.....	pg. 15
Relationship to State Law Preemption.....	pg. 16
Unique Facility Identifier	pg. 16
Dedicated Foreign Inspectorate	pg. 16
Export Certificate.....	pg. 16

	<p style="text-align: center;">H.R. 2749 The Food Safety Enhancement Act of 2009</p>	<p style="text-align: center;">S. 510 The Food Safety Modernization Act of 2009</p>
<p>Registration of Facilities</p>	<p>Section 101</p> <p>This section amends section 415 of the FFDCa to require annual facility registration. Registrants are required to provide additional information pertaining to the facility, including contact information, the primary purpose and business activity of the facility, all trade names under which the facility conducts business related to food, and for foreign facilities, the United States agent for the facility. The registrant is required to notify the Secretary of any change in the submitted information no later than 30 days after the date of such change.</p> <p>The Secretary is authorized to suspend the registration of a facility for a violation of the Act that could result in serious adverse health consequences or death. The Secretary is also granted authority to cancel a registration that the Secretary determines was not updated or otherwise contains false, incomplete, or inaccurate information, or if the required registration fee has not been paid within 30 days after the due date. However, an order to suspend or cancel a registration shall not be delegated to any officer or employee other than the Commissioner, the Principal Deputy Commissioner, the Associate Commissioner for Regulatory Affairs, or the Director for the Center for Food Safety and Applied Nutrition.</p> <p>The Secretary is required to provide a report to Congress annually detailing the number and type of facilities registered under this section.</p> <p>Section 101 requires the Secretary to assess and collect an annual fee of \$500 for the registration of a facility under section 415 of the FFDCa. The fee shall be collected and available to defray the costs of food safety activities (activities related to compliance by facilities registered under section 415 with the requirements of this Act relating to food). The registration fee shall not exceed \$175,000 for an individual company. The Secretary is required to hold a public meeting to allow stakeholders to provide input into how the fee revenue will be allocated.</p>	<p>Section 102</p> <p>This section requires the registration and re-registration of facilities on a biennial basis.</p> <p>The Secretary could suspend a facility’s registration if there is reasonable probability that food manufactured, packed, processed or held at the facility will cause adverse health effects to humans.</p>

	<p align="center">H.R. 2749 The Food Safety Enhancement Act of 2009</p>	<p align="center">S. 510 The Food Safety Modernization Act of 2009</p>
<p>Food Safety Plan, Hazard Analysis, Preventative Controls</p>	<p>Section 102 This section requires the owner, operator, or agent of a facility to develop and implement a written food safety plan. As part of this food safety plan, the owner, operator, or agent shall conduct a hazard analysis; identify and implement effective preventive controls; monitor preventive controls; institute corrective actions when monitoring shows that preventive controls have not been properly implemented or were ineffective; conduct verification activities; maintain records of monitoring, corrective action, and verification; and reanalyze for hazards. The food safety plan shall also include a description of the facility’s procedures for recordkeeping; recall; trace back; supply chain safety; and science-based performance standards. When developing food safety plans under Section 102, facilities should evaluate whether there are hazards that could affect the safety, sanitation, or wholesomeness of the food manufactured, processed, packed, transported, or held by the facility. This analysis should include consideration of biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives, and should include consideration of such contamination on surfaces or in the air or from other possible vectors.</p> <p>The requirements of this section shall take effect 18 months after the date of enactment. Small businesses and very small businesses will have 2 years and 3 years, respectively, to comply.</p> <p>Section 102 also requires certain high-risk facilities to submit finished product test results documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death. Before requiring the reporting of such test results, the Secretary must conduct two or more pilot projects and a study to evaluate the feasibility of such a reporting system.</p>	<p>Section 103 This section requires each owner, operator or agent of a facility to identify potential hazards and establish preventative measures to ensure that food manufactured, processed, packed or held at the facility is not adulterated.</p> <p>Each facility must prepare and keep a written food safety plan that identifies each known hazard along with the preventative measures that are being taken to prevent adulteration of food.</p> <p>Records must be kept for not less than 2 years documenting the preventative measures and the steps taken to mitigate hazards.</p> <p>This section excludes: warehouses, the storage of raw agricultural commodities other than fruits and vegetables intended for other processing.</p>

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<p>Safety Standards for Produce</p>	<p>Section 104 This section requires the Secretary to establish by regulation science-based standards for the safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death to humans or animals. The Secretary shall provide a reasonable period of time for compliance, taking into account the needs of small business for additional time to comply.</p> <p>Section 104 requires the Secretary, in issuing the regulations under this section, to take into consideration, consistent with ensuring enforceable public health protection, the impact of any regulations issued under this section on small-scale and diversified farms, and on wildlife habitat, conservation practices, water-shed protection efforts, and organic production methods. The Secretary is permitted to provide for coordination with other entities and provide for recognition through guidance of other existing publicly available procedures, processes, and practices that the Secretary determines to be equivalent to the goals established under this section.</p> <p>Section 104 requires the Secretary to update the guidance document entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."</p>	<p>Section 105 This section gives the Secretary in conjunction with the Secretary of Agriculture and state departments of agriculture to establish regulations for science based minimum standards for the production and harvesting of fruits and vegetables that the Secretary deems high risk to microbial contamination.</p> <p>These regulations will provide flexibility to various entities engaged in the production and harvesting of fruits and vegetables and will include standards on growing, harvesting, packing, sorting, storage, soil amendments, hygiene, packaging, temperature controls, animal encroachment and water.</p> <p>The Secretary will make foods that have been involved in food borne illness outbreaks a priority.</p> <p>States and foreign governments may apply for a variance from the regulations if they can prove that their growing practices and other items meet food safety standards and will not cause adulteration.</p> <p>This section is not applicable to those facilities that are regulated under the section in this language on preventative controls and hazard analysis.</p>

	<p style="text-align: center;">H.R. 2749 The Food Safety Enhancement Act of 2009</p>	<p style="text-align: center;">S. 510 The Food Safety Modernization Act of 2009</p>
<p>Inspections</p>	<p>Section 105</p> <p>This section requires that each facility registered under section 415 be inspected by the Secretary, by a federal, state, or local official in the case of a domestic facility, or by an agency or representative of a country in the case of a foreign facility, according to a risk-based schedule. The risk-based schedule shall be implemented not later than 18 months after enactment and shall provide for a frequency of inspections commensurate with the risk presented by the facility and shall be based on the following categories and inspection frequencies:</p> <p>Category 1 (high-risk)—the Secretary shall randomly inspect a category 1 food facility at least every 6 to 12 months.</p> <p>Category 2 (low-risk)—the Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.</p> <p>Category 3 (facility that holds food)—the Secretary shall randomly inspect a category 3 facility at least every 5 years.</p> <p>Section 105 requires the Secretary to provide an annual report to Congress on the number of facilities inspected and the costs of implementing the risk-based inspection schedule for the preceding 12 months. In the third year after enactment, the Secretary is also required to submit to Congress a report describing recommendations on the risk-based inspection schedule, including recommendations for adjustments to the timing of the schedule. In making recommendations to change the inspection schedule, the Secretary shall consider the nature of the food products being processed, stored, or transported; the manner in which food products are processed, stored, or transported; the inherent likelihood that the products will contribute to the risk of food-borne illness; the best available evidence concerning reported illnesses associated with the foods processed, stored, held, or transported in the category of facilities; and the overall record of compliance with food safety law among facilities in the category, including compliance with applicable performance standards and the frequency of recalls.</p> <p>Six months after submitting the Third-Year Report, the Secretary may implement the adjustments to the inspection schedule</p>	<p>Section 201</p> <p>The Secretary will allocate resources to inspect facilities according to the risk profile of the facility which includes the following:</p> <ul style="list-style-type: none"> - risk profile of the food manufactured, processed, packed or held at the facility; - the compliance history of the facility <ul style="list-style-type: none"> - the rigor and effectiveness of the hazard analysis and preventative controls - any other criteria that the Secretary deems necessary. <p>Frequency of inspections -</p> <ul style="list-style-type: none"> - High Risk facilities - in the first two years after enactment of the Act, high risk facilities will be inspected not less than once every two years. In the following years, each facility will be inspected not less than once a year in each consecutive year. - Non High Risk Facilities - Facilities will be inspected not less than once every four years. <p>Imports will be inspected at the port of entry under the same criteria for the risk profile of the importing facility.</p> <p>Section 307</p> <p>Inspection of foreign facilities - The Secretary is authorized to enter into agreements with foreign governments to facilitate inspections of facilities that ship to the U.S. Shipments will be refused entry into the U.S. if facilities refuse U.S. inspectors access to a facility for inspection.</p>

	<p>recommended in the Third-Year Report with respect to category 2 and category 3 facilities only. The new inspection schedule and a justification for the changes must be published in the Federal Register.</p>	
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<p>Traceability of Food</p>	<p>Section 107</p> <p>This section requires the Secretary to establish, by regulation, a tracing system for food that is located in the United States or is for import into the United States. Before issuing a proposed regulation, the Secretary shall conduct information gathering to (1) identify technologies and methodologies for tracing to enable each person who produces, manufactures, processes, packs, transports, or holds a food to maintain the full pedigree of the origin and previous distribution history of the food, link that history with the subsequent distribution of the food, establish and maintain a system for tracing the food that is interoperable with the systems established and maintained by other such persons, and to use a unique identifier; and (2) to the extent practicable, assess the costs and benefits associated with the adoption of such technologies, the feasibility of such technologies for different sectors for the food industry, and whether such technologies are compatible with the requirements of this subsection.</p> <p>Section 107 requires the Secretary to take into account information obtained through the information gathering process, and to conduct at least two public meetings and one or more pilot projects.</p> <p>After completing this public input process, the Secretary shall issue proposed regulations establishing a tracing system that enables the Secretary to identify each person who grows, produces, manufacturers, processes, packs, transports, holds or sells such food in as short a timeframe as practicable, but in no longer than two business days. The Secretary may include in such regulation: the establishment and maintenance of lot numbers; a standardized format for pedigree information; and the use of a common nomenclature for food.</p> <p>Food produced on a farm or a fishery and sold directly to a</p>	<p>Section 204</p> <p>The Secretary in coordination with the Secretary of Agriculture and State Departments of Health and Agriculture are authorized to create a national traceback program for fruit and vegetables.</p> <p>The Secretary will have three pilot projects in coordination with the produce industry to evaluate traceback methods, technology, etc. A public rulemaking process is required - industry, business and public can make comment on the proposed regulation.</p> <p>Section 205</p> <p>The Secretary is authorized to create a traceback program for the processed food industry. This will be done through a pilot project in consultation with the processed food industry and other relevant business.</p>

	<p>consumer, restaurant, or grocery store is exempt from the tracing system requirements, although restaurants and grocery stores must keep records documenting the farm that was the source of the food.</p> <p>The Secretary is also granted authority to exempt a food or type of facility from the tracing system requirements if the Secretary determines application of these requirements is not necessary to protect the public health. For a food so exempted, each person who produces, manufactures, processes, packs, transports, or holds such food is required to maintain records to identify the immediate previous sources of such food and its ingredients and the immediate subsequent recipients of such food.</p>	
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	H.R. 2749 The Food Safety Enhancement Act of 2009	S. 510 The Food Safety Modernization Act of 2009
Certification of Accredited Laboratories	<p>Section 110</p> <p>This section requires that whenever analytical testing of an article of food is conducted as part of testimony in a food import detention hearing or for other purposes as the Secretary deems appropriate, such testing shall be conducted by a laboratory that is accredited for the analytical method used, by a laboratory accreditation body that has been recognized by the Secretary; and samples such article with adequate controls for ensuring the integrity of the samples analyzed. When testing is required for purposes of a food import detention hearing, in response to a finding of non-compliance by the Secretary, or for certain products designated by the Secretary, the test must be conducted by an accredited, independent laboratory that is independent of the person on whose behalf such testing is being conducted.</p> <p>The Secretary shall establish and implement a program for the recognition of laboratory accreditation bodies that accredit laboratories to perform analytical testing for the purposes of this section. Whenever such analytical testing is conducted, the laboratory conducting such testing shall submit, directly to the Secretary the results of all analyses conducted by the laboratory on each sample of such article; and all information the Secretary deems appropriate to determine whether the laboratory is accredited by a recognized laboratory accreditation body, identify the article tested, evaluate the analytical results, and determine whether the requirements of this section have been met.</p>	<p>Section 202</p> <p>The Secretary shall provide recognition of accreditation bodies that certify laboratories to sample and test food and to establish a public registry of the accreditation bodies for public use.</p> <p>Accreditation bodies may certify laboratories outside of the United States if they meet the proper criteria.</p>

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Imports	<p>Section 109, Certification and Accreditation</p> <p>Section 109 establishes that certain imported foods be accompanied by a certification that the food complies with specified requirements of the Federal Food, Drug, and Cosmetic Act. The Secretary shall require certification for food imported from a particular country or region if certification would assist the Secretary in determining whether to refuse to admit such article; for a type of food that could pose a significant risk to health, certification would assist the Secretary in determining whether such article poses such risk; or for an article imported from a particular country, there is an agreement between the Secretary and the government of such country providing for such certification.</p> <p>Certifications under this section must be provided by a “qualified certifying entity.” A qualified certifying entity may be an agency or a representative of the government of the country from which the article originated, an individual or entity determined by the Secretary, or an accredited body recognized by the Secretary. The Secretary is required to issue regulations to ensure that any qualified certifying entity and its auditors are free from conflicts of interest.</p> <p>Section 113, Safe and Secure Food Importation Program</p> <p>Section 113 permits the Secretary to establish by regulation or guidance a program to facilitate the movement of food through the importation process if the importer of such food verifies that each facility involved in the production, manufacture, processing, packaging, and holding of the food has been determined to be in compliance with food safety and security guidelines developed by the Secretary.</p>	<p>Section 302, Voluntary Qualified Importer Program</p> <p>The Secretary is authorized to create a program to provide an expedited review and importation of food offered for import by importers who voluntarily participate in this program. Guidance will be written about participation and compliance for the program.</p> <p>Section 303, Authority to Require Import Certifications for Food</p> <p>The Secretary is authorized to require a certification of food being imported based on the risk of the food product or the country of import. The certificate would be a verification of safe food practices according to standards set by the U.S. law.</p> <p>Section 308, Accreditation of Third party Auditors and Audit Agents</p> <p>The Secretary will establish a system for recognizing accreditation bodies that accredit third party auditors and audit agents. Foreign governments would be considered an accreditation body.</p>

	<p style="text-align: center;">H.R. 2749 The Food Safety Enhancement Act of 2009</p>	<p style="text-align: center;">S. 510 The Food Safety Modernization Act of 2009</p>
<p>Recall Authority</p>	<p>Section 111</p> <p>This section requires food facilities, importers, customs brokers, and filers that have reason to believe that an article of food is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article will cause a threat of serious adverse health consequences or death to humans or animals to notify the Secretary of the identity and location of the article as soon as practicable.</p> <p>The Secretary may request that any person who distributes an article of food that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily recall such article.</p> <p>The Secretary shall have the authority to issue an order requiring any person who distributes an article of food to immediately cease distribution of such article if the Secretary has reason to believe that the use or consumption of, or exposure to, the article of food may cause serious adverse health consequences or death to humans or animals. The person subject to the order may appeal the order and request an informal hearing. If after providing an opportunity for an informal hearing under subsection (d), the Secretary determines that the order should be amended to include a recall of the article with respect to which the order was issued, the Secretary shall amend the order to require a recall. Only the Secretary or an official designated by the Secretary may order the recall.</p>	<p>Section 207</p> <p>If the Secretary finds reason to believe that a food is adulterated, they can require the facility to voluntarily recall the product. If they find that the facility does not recall the product, the Secretary can use the mandatory recall authority and can order the person to immediately cease distribution of the product.</p> <p>The effected party(s) will be afforded an informal hearing after the order is made to make known the reasons for the order.</p> <p>A formal public hearing will be called later for any amendments of the order or to cease the recall order.</p>

	H.R. 2749 The Food Safety Enhancement Act of 2009	S. 510 The Food Safety Modernization Act of 2009
Quarantine Authority	<p>Section 133, Authority to Prohibit or Restrict the Movement of Food</p> <p>Section 133 permits the Secretary authority to prohibit or restrict the movement of food within a State or any portion of the State within the United States if the Secretary determines that there is reasonable evidence or information that an article of food that is located in such area presents an imminent threat of serious adverse health consequences or death to humans or animals.</p> <p>Before exercising authority to restrict or prohibit the movement of food, the Secretary is required to notify an appropriate official of the state effected and to issue a public announcement of the Secretary’s findings that support the action; the area affected by the intended restriction; the reasons; and where practicable, an estimate of the anticipated duration of the restriction.</p> <p>Section 133 requires that any restriction or prohibition of the movement of food must come from the FDA Commissioner or Principal Deputy Commissioner.</p>	Not in Senate Bill.

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<p>Inspection and Access to Records</p>	<p>Section 106</p> <p>This section requires each person who produces, manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States to permit an officer or employee duly designated by the Secretary to have access to and copy all records relating to such article bearing on whether the food may be adulterated, misbranded, or otherwise in violation of this Act during an inspection.</p> <p>If the Secretary has a reasonable belief that an article of food presents a threat of serious adverse health consequences of death to human or animals, the Secretary is authorized to remotely access records reasonably related to that food. The Secretary may also remotely access records related to the food safety plan, supporting information relied on by the facility to select the preventive controls to include in its food safety plan, and documentation of corrective actions, if any, taken within the preceding two years.</p> <p>Section 106 allows the Secretary to establish requirements regarding the establishment and maintenance, for not longer than three years, of records by persons who produce, manufacture, process, pack, transport, distribute, receive, or hold food in the United States or for import into the United States. The Secretary shall take into account the size of a business in promulgating regulations under this section. The Secretary is only authorized to require restaurants to maintain distribution records showing their suppliers, and subsequent distribution other than to consumers.</p>	<p>Section 101</p> <p>If the Secretary has reasonable probability that an article of food will cause adverse health consequences or death, each person (excluding farms and restaurants) who manufactures, processes, packs, holds or imports the food shall permit the appropriate official to inspect and copy the records.</p>

	H.R. 2749 The Food Safety Enhancement Act of 2009	S. 510 The Food Safety Modernization Act of 2009
Fees Related to Inspection and Registration	<p>Section 108</p> <p>This section requires the Secretary to assess and collect fees from each facility in a fiscal year that undergoes additional inspection by the FDA due to a violation of any requirement of the Federal Food, Drug, and Cosmetic Act or is subject to a recall.</p> <p>Section 108 establishes that there will be an exemption from the fees for a recall that FDA inappropriately ordered.</p>	<p>Section 107</p> <p>This section gives the Secretary the authority to assess and collect fees from facilities that undergo any re-inspection due to adulterated food or recalls.</p>

	<p style="text-align: center;">H.R. 2749 The Food Safety Enhancement Act of 2009</p>	<p style="text-align: center;">S. 510 The Food Safety Modernization Act of 2009</p>
<p>Penalties</p>	<p>Section 134</p> <p>This section amends section 303 of the Federal Food, Drug, and Cosmetic Act to require that any person who knowingly violates section 301 of the FFDCA with respect to any food that is misbranded or adulterated shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.</p> <p>Section 135 amends section 303 of the FFDCA to require that any person who violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than \$20,000 in the case of an individual, not to exceed \$50,000 in a single proceeding; \$250,000 in the case of any other person, not to exceed \$1,000,000 in a single proceeding. Any person who knowingly violates a provision of section 301 relating to food shall be subject to a civil penalty for each such violation of not more than \$50,000 in the case of an individual, not to exceed \$100,000 in a single proceeding; and \$500,000 in the case of any other person, not to exceed \$7,500,000 in a single proceeding.</p>	<p>There is no comparable section in the Senate bill to Section 134 - no criminal penalties.</p> <p>There is no comparable section in the Senate bill to Section 135 - no civil penalties without first a hearing opportunity.</p>

	H.R. 2749 The Food Safety Enhancement Act of 2009	S. 510 The Food Safety Modernization Act of 2009
Relationship to State Law Preemption	<p>Section 4</p> <p>This section establishes that the Food Safety Enhancement Act of 2009 shall not be construed as modifying or otherwise affecting any action or the liability of any person under the law of any State.</p>	Not in Senate Bill.
Unique Facility Identifier	<p>Section 206</p> <p>Each facility, custom broker and importer of food that is required to register will also be required to submit or be assigned a unique identification number. These identifiers will be determined by the Secretary and guidance will be written as to the specific requirements.</p>	Not in Senate Bill.
Dedicated Foreign Inspectorate	<p>Section 208</p> <p>This section requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign food facilities.</p>	<p>Section 309</p> <p>This section requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign food facilities.</p>
Export Certificate	<p>Section 203</p> <p>This section authorizes the Secretary to impose a fee for the issuance of export certificates for foods and animal feeds. Such fee shall not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates with respect to the export of food and animal feed.</p>	<p>Section 107</p> <p>This section would authorize the Secretary to certify food exports and impose a fee for the export certification.</p>

IMPORT REQUIREMENTS IN THE HOUSE AND SENATE FOOD SAFETY LEGISLATION

Table of Contents

Registration Fees	p.2
Risk-based inspection schedule/Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry	p.3
Certification and accreditation/Authority to require import certification for food	p.5
Safe and secure food importation program	p.5
Improper import entry fillings	p.6
Country of origin labeling; disclosure of source of ingredients	p.6
Registration for customs brokers and filers	p.7
Unique identification number for food facilities, importers, custom brokers, and filers	p.7
Voluntary qualified importer program	p.8
Foreign supplier verification program	p.9
Prior notice of imported food shipments	p.9
Review of a regulatory authority of a foreign country	p.10
Accreditation of third parties auditors and audit agents	p.10
Foreign offices of the FDA	p.11
Building capacity of foreign governments with respect to food	p.11
Smuggled food	p.12

IMPORT REQUIREMENTS IN THE HOUSE AND SENATE FOOD SAFETY LEGISLATION

PROVISION	H.R. 2749	S-510
<p>Registration Fees</p>	<p>Section 204</p> <p>Annual Registration fee: \$500</p> <ul style="list-style-type: none"> • “An importer that is also a facility (according to section 101) is subject to only one fee” • The Secretary through regulation would establish good importer practices • If an importer violates the FFDCFA, or gives inaccurate or incomplete information, the registration may be canceled by the Secretary • Also, if the registration is not updated or contains incomplete, inaccurate, or false information, the Secretary may cancel the registration. However, if the information is corrected before 7 days, the registration will not be canceled 	<p>Section 102</p> <p>Renewal of registration is required on a biennial bases (each even-numbered year).</p> <ul style="list-style-type: none"> • A registration may be suspended if the Secretary believes there is a probability that a food manufactured, processed, packed, or held in a registered facility causes adverse consequences to human or animal health or death. • There is an opportunity for an informal hearing in order to reinstate the suspended registration if there is not reason to continue the suspension. • If after the hearing the Secretary considers there are reasons to hold the suspension, then a corrective action plan is required to be submitted • If the registration is suspended, the food can not be imported to the U.S. or enter U.S. commerce.

PROVISION	H.R. 2749	S-510
<p>Risk-based inspection schedule/ Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry</p>	<p>Section 105</p> <p>Foreign facilities should be inspected by an agency or country representative according to a risk-based schedule.</p> <ul style="list-style-type: none"> • Category 1. High risk facility: Inspection should take place every 6 to 12 months • Category 2. Low-risk facility: Inspection should take place every 18 months to 3 years • Category 3. Facility that holds food: Inspection should take place every 5 years <p>Section 208</p> <p>The Secretary would establish inspectors dedicated to foreign facilities</p>	<p>Section 201</p> <ul style="list-style-type: none"> • Foreign and domestic facilities will be inspected based on their risk profile: <ul style="list-style-type: none"> ▶ Risk of facility: <ul style="list-style-type: none"> - High-risk facility: Not less than two years (for the first two years after the enactment). In subsequent years at least once a year - Non-high-risk facilities: At least once every four years ▶ History of compliance(food recalls, outbreak, and violation of food standards) ▶ Hazard Analysis and preventive actions ▶ Any other criteria considered appropriate by the Secretary

PROVISION	H.R. 2749	S-510
<p>Risk-based inspection schedule/ Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry</p>		<p>Identification and inspection at ports of entry based on:</p> <ul style="list-style-type: none"> ▶ The risk profile of the food ▶ The risk of the country/region of origin ▶ Compliance history of the importer ▶ Effectiveness of the foreign supplier verification program under section 806 ▶ If the food meets the criteria for priority (Section 801 (h)(1)) ▶ If the facility where the food is coming from has been certified ▶ Any other criteria considered pertinent by the Secretary <p>Section 307</p> <ul style="list-style-type: none"> ▶ Agreements between governments ▶ Give permission to U.S. inspectors to inspect the facilities

PROVISION	H.R. 2749	S-510
<p>Certification and accreditation/ Authority to require import certification for food</p>	<p>Section 109</p> <p>Some imported foods need to be certified so that it complies with the FFDCA. An agency or government where the product is originated or an entity determined by the Secretary or an accredited entity recognized by the Secretary may issue a certification.</p>	<p>Section 303</p> <p>The Secretary will grant admission to an imported food if the food complies with the requirements of this Act. Also, foods that have originated in countries in which the FDA has agreements with may be granted certification. Certifications may be provided as:</p> <ul style="list-style-type: none"> ▶ Shipment-specific certificates ▶ Certified entities ▶ Other forms <p>Certificates may be given by:</p> <ul style="list-style-type: none"> ▶ Agency of representative of the government of the country where the food is originated ▶ Entities accredited (Section 809) <p>The certifications need to be renewed.</p>
<p>Safe and secure food importation program</p>	<p>Section 113</p> <p>The movement of import foods may be expedited if the facility where the production, manufacture, processing, packaging, and holding of the food is in compliance with the food safety guidelines determined by the Secretary</p>	

PROVISION	H.R. 2749	S-510
Improper import entry fillings	<p>Section 136</p> <p>The Secretary may require the submission of complete information and documents related to the imported food</p>	
Country of origin labeling; disclosure of source of ingredients	<p>Section 202</p> <ul style="list-style-type: none"> • For processed foods, the label should include the final country where the food was processed • For non-processed foods, the label should indicate the country of origin of the food. 	

PROVISION	H.R. 2749	S-510
<p>Registration for customs brokers and filers</p>	<p>Section 205</p> <p>Must be registered with the FDA</p> <ul style="list-style-type: none"> • The registration may be suspended by the Secretary after notice and with opportunity for an informal hearing <ul style="list-style-type: none"> ▶ If the custom broker or filer violates the FFDCA ▶ If the custom broker or filer have given inaccurate, incomplete information related to the importation of foods • Also, the registration may be canceled after notice if the registration has not updated information as well as false, incomplete or inaccurate statements. 	
<p>Unique identification number for food facilities, importers, custom brokers, and filers</p>	<p>Section 206</p> <p>Each facility, custom broker and importer of food that is required to register will also be required to submit or be assigned a unique identification number. These identifiers will be determined by the Secretary and guidance will be written as to the specific requirements.</p>	

PROVISION	H.R. 2749	S-510
<p>Voluntary qualified importer program</p>		<p>Section 302</p> <ul style="list-style-type: none"> • Importers that import food from facilities that have been certified are eligible. • Factors for eligibility: <ul style="list-style-type: none"> ▶ Nature of food ▶ Compliance history ▶ Recordkeeping, testing, inspections, audits, traceability, temperature controls, sourcing practices of the importer. ▶ Potential risk for adulteration ▶ Any other aspect the Secretary considers pertinent • Revision will be made at least once every three years

PROVISION	H.R. 2749	S-510
<p>Foreign supplier verification program</p>		<p>Each importer shall perform risk-based foreign supplier verification activities:</p> <ul style="list-style-type: none"> ▶ Monitor records for shipment ▶ Lot-by-lot certification compliance ▶ Annual on-site inspections ▶ Hazard analysis and risk-based preventive controls should be checked ▶ Periodic testing and sampling of shipments <ul style="list-style-type: none"> • The Secretary shall issue guidance to importers in developing foreign supplier verification programs not later than a year after the promulgation of this Act • Records should be maintained for not less than two years. • The Secretary shall publish a list of importers on the FDA website
<p>Prior notice of imported food shipments</p>		<p>Section 304</p> <p>The Prior imports regulation is amended to add “any country to which the article has been refused entry” to the list of information that is needed to import food into the U.S. per the prior notice interface through FDA and U.S. Customs.</p>

PROVISION	H.R. 2749	S-510
<p>Review of a regulatory authority of a foreign country</p>		<p>Section 305 The Secretary may review the:</p> <ul style="list-style-type: none"> • Statutes • Regulations • Standards • Controls • Conduct audits <p>Based on the analysis of the previous points the Secretary will determine if the country meets the standards of food safety in manufacturing, processing, packing, and holding as in the U.S.</p>
<p>Accreditation of third parties auditors and audit agents</p>		<p>Section 308</p> <p>To check the entity is in compliance with this Act, meeting the pertinent standards</p> <ul style="list-style-type: none"> • Results will be used to decide if the entity is eligible for certification and for the voluntary qualifies importer program • If the accreditation body is not in compliance with the requirements of this section the accreditation may be revoked • <u>Limitation</u>: An accredited agent may not perform a regulatory audit on an entity if the agent has performed a consultative or regulatory audit of the entity in the last 24 months. • The Secretary shall publish the registry of accredited agents and third parties auditors.

PROVISION	H.R. 2749	S-510
Foreign offices of the FDA		<p>Section 309</p> <p>The Secretary shall establish offices in foreign countries in order to provide assistance to the foreign government about meeting food safety standards, as well as conduct inspections.</p>
Building capacity of foreign governments with respect to food		<p>Section 306</p> <p>The Secretary not later than 2 years after the enactment of this Act will expand the technical, scientific, and regulatory capacity of the governments of countries from which food is being exported to the U.S. Also,</p> <ul style="list-style-type: none"> • Bilateral and multilateral agreements • Provisions to ensure food safety • Provisions to secure electronic data sharing • Provisions for mutual recognition of inspection reports, laboratory methods and detection techniques • Harmonization under Codex Alimentarius

PROVISION	H.R. 2749	S-510
Smuggled food		<p>Section 310</p> <p>If the Secretary identifies smuggled food and has reasons to believe that the food may be a hazard for human and animal health or cause death, the Secretary shall issue a press release to warn consumers.</p>