

**Key Provisions in Select Food Safety Legislation (The Durbin and Waxman Bills; and Current Law)**  
**Prepared by Hogan & Hartson, LLP [last updated June 3, 2009]**

**Table of Contents**

	<b>Page</b>
<b>Facility Registration</b> .....	3
<b>Unique Facility Identification Number</b> .....	3
<b>Preventive Process Controls</b> .....	3
<b>Performance Standards</b> .....	6
<b>Produce Safety Standards</b> .....	6
<b>Protection Against Intentional Adulteration</b> .....	8
<b>Traceback</b> .....	8
<b>Inspection Frequency</b> .....	10
<b>Record Keeping and Records Access</b> .....	11
<b>Imports—Foreign Supplier Safety Assurance Program</b> .....	12
<b>Imports—Expedited Entry</b> .....	13
<b>Imports—Registration</b> .....	14
<b>Imports—Third Party Certification</b> .....	15
<b>Imports—Laboratory Testing</b> .....	18
<b>Imports—Prior Notice</b> .....	19
<b>Imports—Foreign Inspectorate</b> .....	19
<b>Imports—Building Capacity of Foreign Governments</b> .....	19
<b>Imports—Review of a Regulatory Authority of a Foreign Country</b> .....	20
<b>Imports—Entry Filings</b> .....	20
<b>Imports—Extraterritorial Jurisdiction</b> .....	21
<b>Suspension of Registration</b> .....	21
<b>Notification and Reporting</b> .....	22
<b>Mandatory Recall Authority</b> .....	23
<b>Administrative Detention</b> .....	24
<b>Civil Penalties</b> .....	25
<b>Criminal Penalties and False Statements</b> .....	25
<b>Subpoena Authority</b> .....	25
<b>Quarantine Authority</b> .....	26
<b>Seizure Procedures</b> .....	26

<b>Whistleblower Protections</b> .....	26
<b>Inspection Authority</b> .....	27
<b>Fees—Registration</b> .....	27
<b>Fees—Importers</b> .....	27
<b>Fees—Recalls</b> .....	27
<b>Fees—Reinspection</b> .....	28
<b>Fees—Voluntary Importer Program</b> .....	28
<b>Fees—Export Certificates</b> .....	28
<b>Authorization of Appropriations</b> .....	28
<b>Food Defense Strategy</b> .....	29
<b>Food and Agriculture Coordinating Councils</b> .....	29
<b>Domestic Capacity</b> .....	29
<b><i>Salmonella</i> Enteritidis in Shell Eggs</b> .....	30
<b>Sanitary Transportation of Food</b> .....	30
<b>Food Allergy and Anaphylaxis Management</b> .....	31
<b>Integrated Consortium of Laboratory Networks</b> .....	31
<b>Surveillance</b> .....	32
<b>Information Sharing</b> .....	32
<b>Decontamination and Disposal Standards and Plans</b> .....	33
<b>Jurisdiction</b> .....	33
<b>Carbon Monoxide Labeling</b> .....	33
<b>GRAS Substances</b> .....	34
<b>COOL</b> .....	34
<b>Infant Formula</b> .....	35
<b>Continued Operation of Field Labs and District Offices</b> .....	35
<b>Preemption</b> .....	36
<b>Education and Outreach</b> .....	36

## Key Provisions in Select Food Safety Legislation (The Durbin and Waxman Bills; and Current Law)

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Facility Registration</b>	<p>Food facilities, both domestic and foreign, would be required to register with FDA every two years. There would be an “abbreviated registration renewal” for those facilities reporting no changes. FDA would have the authority to adjust food registration categories.</p> <p>(Sec. 102)</p>	<p>Food facilities, both domestic and foreign, and importers would be required to register with FDA annually.</p> <p>The information required as part of registration would change. FDA could re-designate food categories required to be listed as part of registration.</p> <p>Food from a facility not duly registered would be misbranded.</p> <p>(Sec. 101)</p>	<p>FFDCA § 415. Requires initial registration of food facilities, both domestic and foreign; requires that registration be updated within 60 days of any change to any of the required information previously submitted; no required re-registration at designated interval.</p>
<b>Unique Facility Identification Number</b>	NONE	<p>The bill would require the submission of a unique facility identifier with the registration of a food facility. In the absence of FDA establishing a unique numerical identifier system, the bill would require use of the Dunn &amp; Bradstreet Universal Numbering System (DUNS).</p> <p>(Sec. 202)</p>	NONE
<b>Preventive Process Controls</b>	<p>Each registered facility would be required to conduct a hazard evaluation to identify known or reasonably foreseeable hazards,” including “biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color</p>	<p>Each registered facility would be required to conduct a hazard evaluation to identify hazards that are “reasonably likely to occur,” including “biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, filth,</p>	<p>FFDCA §§ 402(a)(4). Food is adulterated if it has been prepared, packed, or held under unsanitary conditions where it may have become contaminated by filth or rendered injurious to health.</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>additives,” as well as “hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced by acts of terrorism” and implement preventive controls (including at critical control points, if any) to provide assurances that the identified hazards would be significantly minimized and that the food would not be adulterated or contain an undeclared allergen.</p> <p>Preventive controls expressly include the following controls:</p> <ul style="list-style-type: none"> <li>• Sanitation</li> <li>• Training</li> <li>• Environmental controls</li> <li>• Allergen controls</li> <li>• Recall contingency plan</li> <li>• GMPs</li> <li>• Supplier verification activities</li> </ul> <p>Each facility would be required to monitor the controls; establish corrective actions; maintain records of monitoring, instances of nonconformance, and corrective actions taken; and verify that the plan is working.</p> <p>The results of the hazard evaluation and identification of preventive controls would be required to be reduced to writing and made available to FDA during an inspection (along with documentation that the plan is being implemented).</p>	<p>decomposition, parasites, and unapproved food and color additives,” and “hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced by acts of terrorism” and identify, implement, and validate preventive controls to prevent, eliminate, or reduce to acceptable levels the occurrence of those hazards.</p> <p>FDA may identify hazards that are reasonably likely to occur and may establish preventive controls for specific product types.</p> <p>Preventive controls must include the following controls:</p> <ul style="list-style-type: none"> <li>• Sanitation</li> <li>• Training</li> <li>• Process controls</li> <li>• Allergen controls</li> <li>• GMPs</li> <li>• Supplier verification activities</li> </ul> <p>Each facility would be required to monitor the controls, including through environmental and product testing as appropriate; establish corrective actions, including procedures to ensure no product enters commerce if controls are not fully implemented; verify that the plan is being implemented and the controls</p>	<p>FFDCA § 416. Sanitary Transportation Practices</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>A hazard re-evaluation would be required at least every three years or when a significant change is made in the activities conducted at a facility. The re-evaluation must be completed before the change in activities begins.</p> <p>FDA would promulgate regulations establishing minimum standards for the effective implementation of this section.</p> <p>Scope: Section excludes: (a) warehouses and pet food manufacturers at FDA’s discretion; (b) those facilities subject to the companion section on the safety of fruits and vegetables; (c) facilities subject to other FDA HACCP or analogous regulatory programs (seafood, juice and low acid canned foods).</p> <p>There would be no limitation on the agency to revise, issue, enforce product or category specific regulations such as existing HACCP programs.</p> <p>Failure to comply with this section would be a prohibited act.</p> <p>(Sec. 103)</p>	<p>have been validated; re-analyze and revise the plan every 2 years, when there is a change that could affect the hazard analysis, or if FDA determines it is appropriate to protect the public health; and maintain records of the above for 2 years.</p> <p>The results of the hazard evaluation and identification of preventive controls would be required to be reduced to writing (“food safety plan”). This plan would include the following: (1) the hazard analysis; (2) the preventive controls; (3) monitoring; (4) procedures for taking corrective action; (5) verification activities (6) record keeping procedures; (7) recall procedures; (8) traceback procedures; (9) supply chain management procedures; and (10) procedures to implement the performance standards.</p> <p>FDA would promulgate regulations or guidance establishing minimum standards for the effective implementation of this section.</p> <p>There would be no limitation on the agency to revise, issue, enforce product or category specific regulations such as existing HACCP programs.</p>	

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		<p>Failure to comply with this section would render food adulterated.</p> <p>(Sec. 102)</p>	
<b>Performance Standards</b>	<p>FDA would be required every 2 years to review and evaluate “the most significant food-borne contaminants” and, when appropriate, FDA would then issue “science-based guidance documents, action levels, and regulations” to help prevent adulteration. The standards would be applicable to products and product classes and would not be facility specific.</p> <p>(Sec. 104)</p>	<p>FDA would be required to review and evaluate every 2 years “the most significant food-borne contaminants and the most significant resulting hazards” and issue, as appropriate, through guidance or regulation, science-based performance standards to minimize such hazards. The standards would be applicable to products and product classes and would not be specific to an individual facility.</p> <p>Food not in conformance with performance standards would be adulterated.</p> <p>(Sec. 103)</p>	<p>FFDCA § 406. FDA can establish tolerances for poisonous ingredients in food.</p> <p>FFDCA § 408. Tolerances and Exemptions for Pesticide Chemical Residues</p>
<b>Produce Safety Standards</b>	<p>Within a year of the bill’s enactment, FDA, in consultation with USDA and state departments of agriculture, would be required to publish a proposed rule establishing science-based standards for the safe production and harvesting of those types of fruits and vegetables for which FDA has determined that such standards would “minimize the risk of serious adverse health consequences or death.” FDA is instructed to prioritize regulations</p>	<p>Within 18 months of the bill’s enactment, FDA would be required to publish a proposed rule establishing standards for the safe production, harvesting, packing, sorting and storage of raw agricultural commodities that are from a plant or fungus and for which FDA has determined that such standards would “minimize the risk of serious adverse health consequences or death.”</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>for fruits and vegetables that have been associated with food-borne illness outbreaks.</p> <p>A final rule would be required within a year of the closing of the comment period on the proposal.</p> <p>The regulations must permit states and foreign governments to seek variances from the requirements and provide for coordination of education and enforcement activities with states and local governments. FDA may also coordinate with USDA.</p> <p>Also within a year of the bill's enactment, guidance would be published updating good agricultural practices.</p> <p>Violation of the regulations would be a prohibited act.</p> <p>Scope: This section does not apply to facilities subject to the companion section on preventive process controls.</p> <p>There would be no limitation on the agency to revise, issue, enforce product or category specific regulations such as existing HACCP programs.</p> <p>(Sec. 105)</p>	<p>A final rule would be required within three years.</p> <p>FDA could work with USDA and states to enforce the requirements.</p> <p>Also within a year of the bill's enactment, guidance would be published updating good agricultural practices.</p> <p>Foods that do not meet these standards would be considered adulterated.</p> <p>(Sec. 104)</p>	

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Protection Against Intentional Adulteration</b>	<p>FDA would be required to promulgate regulations to protect food against intentional adulteration within two years after enactment. These regulations would apply only to food in bulk or batch form prior to being packaged for the final consumer for which FDA has identified clear vulnerabilities and that there is a high risk that intentional adulteration could cause serious adverse health consequences or death. To make these determinations, FDA would be required to conduct vulnerability assessments of the food system, consider risks and costs, and determine the types of science-based strategies necessary for protection. Within a year of enactment, FDA would be required to issue guidance documents related to protection against intentional adulteration of food. Failure to comply with these regulations would be a prohibited act.</p> <p>Scope: This section would not apply to foods produced on farms, except for milk.</p> <p>(Sec. 106)</p>	NONE	FFDCA § 801(h). Requires FDA to give high priority to increasing the number of inspections for the purpose of enabling FDA to inspect food offered for import at ports of entry into the U.S., with the greatest priority given to inspections to detect the intentional adulteration of food.
<b>Traceability</b>	FDA, within nine months of enactment, would be required to establish a pilot project in coordination with the produce industry to test and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables.	FDA would be required to establish by regulation, a tracing system for all food, whether produced in the United States or imported. The regulations would require each person who produces, manufacturers, processes, packs, transports, or holds food to:	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>Within two years of enactment, the bill would require FDA to issue a notice of proposed rulemaking to establish standards for the type of information, format and timeframe for the submission of records to FDA to assist in FDA traceback activities in the event of a food-borne illness outbreak involving fruits and vegetables.</p> <p>(Sec. 204)</p>	<p>(1) maintain the full pedigree of the origin and previous distribution history of the food;</p> <p>(2) link that history with the subsequent distribution history of the food;</p> <p>(3) establish and maintain a system for tracing food that is interoperable with the systems maintained by other parties; and,</p> <p>(4) use a unique identifier for each facility.</p> <p>The bill also would require the use of lot numbers, a standardized format for pedigree information, and the use of a common nomenclature for food. FDA would have the authority to exempt certain foods from these requirements, although the “one-up, one-back” recordkeeping requirements from the Bioterrorism Act of 2002 would continue to apply.</p> <p>The bill would require FDA to take several procedural steps before issuing a proposed rule regarding the new tracing system: FDA would be required to hold at least two public meetings; conduct at least one pilot project with the food industry; and, identify and assess the feasibility and costs of tracing technologies. There is no mandated timeframe by which</p>	

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		<p>FDA must propose or issue regulations creating the tracing system.</p> <p>Direct sales from farms to consumers or restaurants would be exempt from these requirements.</p> <p>Failure to comply with the traceability system would be a prohibited act.</p> <p>(Sec. 107)</p>	
<b>Inspection Frequency</b>	<p>FDA would be required to adopt a risk-based approach to inspections of facilities taking into account the risk profile of the food, the history of recalls at the facility, the rigor of the facility’s preventive controls plan, whether the food may be subject to intentional adulteration and thus receive high priority for inspection at importation and whether the facility is certified. (Same for imports, including the rigor of the foreign supplier verification of the importer and whether the importer participates in the Voluntary Qualified Importer Program).</p> <p>High risk facilities would be subject to inspection once in the first two years after enactment and then at least once annually. Low risk facilities would be subject to inspection at least once every four years.</p> <p>FDA would be required to submit an annual report to Congress regarding</p>	<p>The bill would establish a risk-based inspection frequency schedule using three categories of food establishments.</p> <p>Category 1 establishments would be “high-risk” facilities, including facilities that manufacture or process raw products of animal origin (including seafood) and other types of food as FDA would designate. FDA would be required to inspect such establishments at least once every 6 to 18 months.</p> <p>Category 2 establishments would be “low-risk” facilities that manufacture, process, pack, or label any other type of food. Such establishments would be inspected at least once every 18 months to 3 years.</p>	<p>FFDCA §704. FDA has the authority to conduct inspections, but the frequency of inspection is not established.</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>inspection frequency.</p> <p>(Sec. 201)</p>	<p>Category 3 establishments would be those facilities that hold food (warehouses) and would be inspected at least once every 3 to 4 years.</p> <p>FDA would have the authority to alter the types of facilities within each category and the inspection frequency specified. The inspection frequency must be based on the type of food at the facility, the compliance history of the facility, and other factors. (Sec. 105)</p> <p>FDA would be required to submit an annual report regarding the frequency and cost of inspections.</p> <p>It would be a prohibited act to delay, limit, or refuse to permit an inspection. (Sec. 203)</p>	
<b>Record Keeping and Records Access</b>	<p>If FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death, FDA would have access to and be able to copy all records relating to such article of food and would have access to records for any “other article of food” that “the Secretary reasonably believes is likely to be affected in a similar manner.” These related articles would likely include food produced on the same manufacturing line. (Sec. 101)</p>	<p>FDA would have access to and the ability to copy all records relating to the production, manufacture, processing, packing, distribution, receipt, holding or importation of an article of food needed to determine whether such article of food is adulterated or misbranded, or in violation of the Act, including all records relating to preventive controls and food safety plans and product and environmental testing. A written request for records would not be</p>	<p>FFDCA § 414.</p> <p>If FDA has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death, FDA can have access to all records relating to such article needed to determine if it is adulterated or presents a threat of serious adverse health consequences or death. Additionally, under this same standard FDA can request records relating to the reportable food registry.</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>FDA would be required to issue a notice of proposed rulemaking to establish standards for the type of information, format and timeframe for the submission of records to FDA to assist in FDA traceback activities in the event of a food-borne illness outbreak involving fruits and vegetables. (Sec. 204)</p> <p>FDA would have access to preventive control plans and associated documentation of implementation in order to verify compliance. (Sec. 103)</p> <p>FDA would have access to records relating to the Foreign Supplier Verification Program and FDA would have access to inspection reports and other documentation gathered by third party auditors during the auditing process. (Sec. 301)</p>	<p>required. (Sec. 106)</p> <p>FDA would have the authority to require the establishment and maintenance of records and have the discretion to require that such records be maintained in a standardized electronic format.</p> <p>FDA’s records access and recordkeeping authority would apply to any person who produces, manufactures, processes, packs, transports, distributes, receives, or holds food. The bill’s amendments to FFDCA 414 and 704 would remove the current exemption for farms and restaurants.</p> <p>FDA would have the authority to review accredited laboratory records and would have access to testing results when testing must be conducted by an accredited laboratory. (Sec. 109)</p> <p>FDA would have access to any related records of an importer, customs broker, or filer. (Sec. 201)</p>	<p>FDA is authorized to enact regulations requiring records of immediate previous sources and subsequent recipients of articles of food (and their packaging).</p> <p>FFDCA § 703. (FDA can inspect records relating to the interstate transport of foods.)</p> <p>FFDCA § 704. (FDA can inspect records regarding infant formula.)</p>
<b>Imports—Foreign Supplier Safety Assurance Program</b>	Each importer of food (defined as the owner of the food at the time of entry into the United States) would be required to have in place a program to verify that its imported food is produced in accordance	NONE	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>with U.S. requirements (including the new preventive controls and produce standards), is not adulterated and does not contain an undeclared allergen. FDA would be required to issue guidance on the development of foreign supplier verification programs and promulgate regulations regarding the content of these programs. Regulations would establish the process for verification by a United States importer for each relevant foreign supplier. Related records would be required to be maintained for two years and made available upon request. FDA would be required to publish a list on the Internet of the name and location of importers participating in this program. An exemption would be provided for importers of seafood, juice, and low-acid canned foods required to comply with HACCP based regulations.</p> <p>The importation of food without a foreign supplier safety assurance program would be a prohibited act.</p> <p>(Sec. 301)</p>		
<b>Imports— Expedited Entry</b>	FDA would be required to establish, in consultation with DHS, a program for expedited review and importation of products from importers voluntarily participating in a qualified importer program. Eligibility for the program would require third party certification and	FDA would be authorized to establish, by regulation or guidance, a program to facilitate the importation of food if the importer meets certain requirements, including supplier verification activities.	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>consideration of the nature of the food, risk of intentional adulteration of the food, compliance history of the foreign supplier, exporting country's capability for ensuring compliance with U.S. standards, compliance with the foreign supplier verification program, and recordkeeping, testing, facility inspections and audits, traceability, temperature controls, and sourcing practices of the importer. FDA would be permitted to allow the expedited review and importation by importers of certain foods or from certain countries based on these criteria. FDA would be required to reevaluate importers qualified under this program every three years. To qualify under the program, importer must be importing food from certified facilities. (Sec. 302)</p> <p>The bill would establish a user fee for this program. (Sec. 107)</p>	<p>FDA would establish guidelines for food safety and security and would take into account personnel, the physical and procedural safety of the supply chain, the sufficiency of preventive controls for food and ingredients, and vendor and supplier information.</p> <p>(Sec. 113)</p>	
<b>Imports— Registration</b>	NONE	<p>Importers, customs brokers, and filers would be required to register with FDA to import food into the U.S. Food imported by an importer, customs broker, or filer not registered would be misbranded. With registration, importers, custom brokers and filers would be required to submit a unique facility identifier. Importers would be required to comply with good importer practices including the verification of good manufacturing</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		<p>practices and preventive controls of their foreign suppliers. FDA would have the authority to suspend registration for a violation of the Act or an incomplete or inaccurate import submission filing. Suspension of registration would be preceded by notice and an opportunity for a hearing. An importer could request that a suspended registration be vacated. FDA would be required to vacate the suspension if it determines that adequate reasons to continue it do not exist. FDA also would be authorized to cancel a registration with 10 days notice if it is not updated accordingly or is false or incomplete. The importer would have 7 days to correct the registration.</p> <p>FDA would be required to issue regulations to carry out this section.</p> <p>(Sec. 201)</p>	
<b>Imports— Third Party Certification</b>	<p>Certification may be required, based on public health considerations, including risks associated with the type of food or its place of origin. These certifications or assurances could be provided in the form of shipment-specific certificates, a listing of certified entities, or in other form specified by FDA. FDA could require that certifications be renewed as deemed appropriate and refuse to accept</p>	<p>FDA could require certification from a qualified certifying entity if FDA determines that such certification is necessary based on (a) the adequacy of controls in the country or region of origin; (b) whether the type of food could pose a significant health risk; or, (c) if FDA has an agreement with the exporting country to provide such certification. FDA would have</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>certifications it deems no longer valid. Such certification would be required for designated food from countries with which FDA has an agreement to establish a certification program and imported food would be refused admission unless accompanied by a certification. The requirement for such certification would not prevent the FDA from conducting random checks of the covered imports. (Sec. 303)</p> <p>FDA would implement a system whereby (a) it would recognize accrediting bodies that operate in accordance with established standards, rather than carrying out that function itself; (b) the accreditation bodies would then evaluate and accredit third party auditors and auditing agents; and, (c) these auditing bodies would certify that foreign facilities meet the requirements of the Act. FDA would issue model standards that accrediting bodies should ensure auditors meet. The program would apply to imported foods only.</p> <p>As a condition of accreditation, an auditor would be required to agree to issue a written and electronic certification to accompany each food shipment made for import from a facility certified. Such certificates would be considered by FDA when targeting inspection resources. Certification would be required to</p>	<p>flexibility to determine the appropriate certification form.</p> <p>Certifying entities could be agencies or representatives of foreign governments, or private parties as designated by the FDA. FDA would have complete discretion to determine which private entities are qualified to provide certification. There is no reference to professional organizations performing that task, but also no prohibition from FDA designating them to do so.</p> <p>If FDA establishes a certification requirement, certification would be required as a condition of entry and food would be misbranded if not accompanied by certification.</p> <p>Certifying entities would be required to notify FDA whenever the certifying entity cancels or suspends the certification of a facility.</p> <p>FDA would be required to promulgate regulations to prevent conflicts-of-interest. The regulations would include a prohibition on a certifying entity providing consultative services to any facility that it certifies.</p> <p>FDA would continue to be allowed to</p>	

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>participate in the Voluntary Qualified Importer Program.</p> <p>FDA would be authorized to monitor auditors, conduct its own inspections, and review inspection reports generated by auditors. The bill draws a distinction between consultative audits and regulatory audits, with this provision directed to regulatory audits. However, reports from the consultative audits would be accessible under Section 414 of the Act.</p> <p>The agency would also publish a public list on the Internet of accreditation bodies and accredited third party auditors.</p> <p>FDA would be required to issue regulations regarding conflicts of interest, including a requirement that audits be unannounced. In addition, false statements to auditors would be considered a criminal act. Auditors would be required to immediately notify FDA upon discovering “a condition that could cause or contribute to a serious risk to the public health.”</p> <p>FDA could withdraw accreditation from an auditor if food from a facility it certifies is linked to an illness outbreak, if the auditor no longer meets requirements, or following a refusal to allow U.S. officials to conduct necessary audits.</p>	<p>conduct random inspections of imports, issue import alerts, and take other steps regarding the admissibility of imports.</p> <p>(Sec. 109)</p>	

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>To make the program revenue-neutral, FDA would establish a method by which auditors reimburse FDA for the work performed to establish and administer the accreditation system; no revenue surplus should be generated.</p> <p>(Sec. 308)</p>		
<b>Imports— Laboratory Testing</b>	<p>FDA would be required to provide for the recognition of accreditation bodies that accredit laboratories and to establish a publicly available registry of recognized accreditation bodies. As a condition of inclusion on this registry, accreditation bodies would have to require laboratories meet certain model standards developed by FDA. Foreign laboratories that meet these standards are also eligible for accreditation. FDA would be required to periodically reevaluate all recognized accreditation bodies every five years and to revoke recognition if warranted.</p> <p>Either federal labs or labs accredited by an accreditation body on FDA’s registry would be required to be used for all food testing in support of admission of an imported food, as required by specific regulations (but only when applied to address an identified or suspected food safety problem), as required by an Import Alert, or as otherwise deemed appropriate by FDA (also to meet an identified or suspected food safety problem) and the test</p>	<p>FDA would be required to provide for the recognition of accreditation bodies that accredit laboratories and to establish a publicly available registry of recognized accreditation bodies. FDA would be required to issue regulations or guidance to implement this program.</p> <p>Testing would be required to be conducted at accredited laboratories for import admissions under Section 801(a). Laboratories would have to transmit all results from such testing directly to FDA. In addition, the person on whose behalf the testing is conducted would be required to notify FDA before the testing is performed</p> <p>FDA would have the authority to observe and/or conduct onsite audits of laboratories and have access to any related records.</p> <p>The accreditation body would be required to notify FDA when it grants,</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>results would be provided directly to FDA. If the testing of food by a state-run lab results in a state recall of a particular food, FDA would be required to review the sampling and testing results to determine the need for a national recall.</p> <p>(Sec. 202)</p>	<p>withdraws, or suspends accreditation of a laboratory.</p> <p>Violation of this section would be a prohibited act.</p> <p>(Sec. 110)</p>	
<b>Imports—Prior Notice</b>	<p>Prior notice of an imported food would be required to include the name of any country that refused entry to the food.</p> <p>(Sec. 304)</p>	NONE	<p>FFDCA § 801(m). Requires FDA, in consultation with the Secretary of the Treasury, to require prior notice to FDA for all imported food.</p>
<b>Imports—Foreign Inspectorate</b>	<p>FDA would be authorized to enter into agreements with foreign countries to facilitate the inspection of registered foreign facilities and require that inspection resources be directed to those facilities that present the highest risk.</p> <p>(Sec. 307)</p> <p>By October 1, 2010, the bill would require FDA to establish an office in no fewer than 5 foreign countries to provide assistance to those countries with respect to safety of food exported to the United States, including by directly conducting risk-based inspections. (Sec. 309)</p>	<p>FDA would establish a foreign inspection force at a level sufficient to assist FDA in achieving inspections of foreign facilities at the same frequency as domestic facilities.</p> <p>(Sec. 204)</p>	NONE
<b>Imports—Building Capacity of Foreign Governments</b>	<p>The bill would require FDA, within two years of enactment, to develop a plan to expand the technical, scientific, and regulatory capacity of foreign countries exporting food to the United States. Reflecting consultation with other</p>	NONE	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>government agencies, the plan would include recommendations for bilateral or multilateral agreements, provisions for electronic data sharing, provisions for mutual recognition of inspection reports, training of foreign governments and producers, recommendations for harmonization with Code Alimentarius, and provisions for multilateral acceptance of laboratory methods and detection techniques.</p> <p>(Sec. 306)</p>		
<b>Imports—Review of a Regulatory Authority of a Foreign Country</b>	<p>FDA would have the authority to review the food safety systems of other countries and, based on that review, determine whether those countries can provide reasonable assurances that the food supply of the country is equivalent in safety to that of the United States.</p> <p>(Sec. 307)</p>	NONE	NONE
<b>Imports—Entry Filings</b>	NONE	<p>The bill would prohibit import entry filings that contain inaccurate or incomplete information and would allow FDA to require, by regulation or guidance, the submission of any documentation for an imported article of food.</p> <p>(Sec. 136)</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Imports— Extraterritorial Jurisdiction</b>	NONE	The bill states that FDA jurisdiction extends to products that are intended for import into the U.S. The bill also would make it a prohibited act to manufacture, prepare, produce, hold or distribute an adulterated or misbranded article of food with the knowledge or intent that the article will be imported into the U.S.  (Sec. 209)	NONE
<b>Suspension of Registration</b>	FDA would have the authority to suspend the registration of any facility if FDA determines that food manufactured, processed, packed or held by that facility “has a reasonable probability of causing serious adverse health consequences or death.” Informal hearings to challenge a suspension determination would be permitted. Issuance of an order to suspend registration and authority to hold an informal hearing would be assigned to the FDA Commissioner and could not be further delegated. Following such hearings, the Commissioner could either vacate the order or require the submission of a corrective action plan before lifting the suspension. Any facility with a suspended registration would be prohibited from importing or otherwise introducing food into interstate commerce.  (Sec. 102)	FDA would have the authority to suspend a facility’s registration for any violation of the Act that could result in serious adverse health consequences or death; must be preceded by notice and an opportunity for an informal hearing; and there would be process for reinstatement. There is no limitation on what level of official within FDA could be delegated the authority to suspend or reinstate a facility’s registration.  FDA also would have the authority to cancel a facility’s registration if it is not updated appropriately or contains, false, inaccurate, or incomplete information. Cancellation would be preceded by 10 days notice and an opportunity to correct the registration information.  (Sec. 101)	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Notification and Reporting</b>	NONE	<p>The bill would mandate that any “responsible party” (as defined in Section 417, as amended) that has reason to believe that an article of food is adulterated or misbranded in manner that presents a reasonable probability of causing a threat of serious adverse health consequences or death, notify FDA as soon as practicable. Failure to notify FDA would be a prohibited act. (Sec. 111)</p> <p>In addition, the bill would amend the requirements of the reportable food registry to include farms, restaurants, retailers, and importers as responsible parties.</p> <p>The bill also would amend the reporting standard to “no later than 24 hours after information <u>reasonably available to a responsible party indicates</u>” that an article of food is reportable.</p> <p>Finally, the bill would require the submission of testing results for any article, component, or environmental testing conducted by or on behalf of the responsible party. (Sec. 112)</p>	<p>FFDCA § 417. Reportable Food Registry (applies to the person submitting the registration for a registered food facility and when there is a reasonable probability that an article of food will cause serious adverse health consequences or death).[Note: Just added in 2007.]</p> <p>The 2007 enacted Reportable Food Registry established a reporting standard of “no later than 24 hours after the <u>responsible party determines</u>” that a food is reportable.</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Mandatory Recall Authority</b>	<p>FDA would be granted mandatory recall authority if a company refuses to voluntarily recall a product for which “there is a reasonable probability” that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause “serious adverse health consequences or death.” Procedures would be established for informal hearings on mandatory recall orders and the authority to issue a mandatory recall order would not be delegated beyond the FDA Commissioner.</p> <p>FDA would also be required to consult USDA policies in determining whether to publish a public list of retail consignees involved in a Class I recall.</p> <p>Failure to comply with a recall order would trigger a civil money penalty. It would also constitute a prohibited act for which criminal penalties are provided under existing law.</p> <p>(Sec. 206)</p>	<p>FDA would be granted mandatory recall authority under a two-tiered system.</p> <p><u>Tier 1, or Regular Recall:</u> FDA would be able ask any person to voluntarily recall an article of food that the agency believes is adulterated, misbranded, or in violation of the Act. If FDA has reason to believe that an article of food may cause any type of adverse health consequences or death (without regard to seriousness), the agency would have the authority to issue an order to any person to cease distributing the article and to notify each person to whom the article was distributed of the order. Any person subject to such an order would be required to comply immediately and would have the opportunity to appeal the order and request an informal hearing. FDA’s granting of a hearing would be discretionary, and, if granted, an informal hearing must be held within ten days. After the hearing, FDA would determine whether the order should be amended to require a recall or vacated.</p> <p><u>Tier 2, or Emergency Recall:</u> If FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death,</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		<p>FDA would be authorized issue an emergency recall order before a hearing. Any person subject to an emergency recall order would be required to comply immediately and would have the opportunity to appeal the order and request an informal hearing <u>afterwards</u>, which, if granted, would be held within ten days.</p> <p>There is no limitation on what level of official within FDA could be delegated the authority to order a recall.</p> <p>Failure to comply with a recall order would be a prohibited act.</p> <p>(Sec. 111)</p>	
<b>Administrative Detention</b>	<p>FDA would be provided with administrative detention authority when the agency “has reason to believe” that a food “is adulterated or misbranded.”</p> <p>FDA would be required to issue an interim final rule implementing this provision.</p> <p>(Sec. 207)</p>	<p>FDA would be provided with administrative detention authority when the agency “has reason to believe” that a food “is adulterated or misbranded.” FDA could detain food for up to 60 days would have 15 days to confirm or terminate a detention order.</p> <p>FDA would be required to issue regulations or guidance implementing this provision.</p> <p>(Sec. 132)</p>	<p>FFDCA § 334(h) FDA may order the administrative detention of an article of food if an officer or qualified employee has “credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death.”</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Civil Penalties</b>	<p>Failure to comply with a mandatory recall order would trigger a civil money penalty of no more than \$50,000 per individual and \$250,000 per other entities, not to exceed \$500,000 for all related violations.</p> <p>(Sec. 206)</p>	<p>The bill would authorize civil money penalties for any prohibited act up to \$100,000 per individual and \$500,000 for company for each such act. Each day would be considered a separate offense. There is no maximum amount of a penalty in a single proceeding.</p> <p>(Sec. 135)</p>	<p>FFDCA § 303(f)(2). In the one situation where persons who introduce adulterated food due the presence of <u>pesticides</u> into interstate commerce are liable to civil penalties of \$50,000 for an individual, \$250,000 for any other person, not to exceed \$500,000 in a single proceeding. Farmers are not subject to this penalty.</p> <p>If FDA assesses a civil penalty, it may not use its criminal authorities or seizure/injunction authorities.</p>
<b>Criminal Penalties and False Statements</b>	<p>False statements by or to third party auditors, would be subject to criminal liability under 18 USC § 1001 of the Federal Criminal Code. (Sec. 308)</p> <p>Any false statement or representation by an importer would be subject to criminal liability under the Federal Criminal Code. (Sec. 302)</p>	<p>The bill would increase the criminal penalties available to up to 10 years in prison for anyone who knowingly violates designated prohibited acts. The bill would conform the available fine in accordance with Title 18 of the Federal Criminal Code. (Sec. 134)</p> <p>False or misleading reports to FDA would be a prohibited Act. (Sec. 206)</p>	<p>FFDCA § 303. Violations of the prohibited acts section result in one year imprisonment, a fine of \$1000, or both. Repeated violations or violations with the intent to defraud or mislead result in up to 3 years imprisonment or a fine of \$10,000, or both.</p>
<b>Subpoena Authority</b>	NONE	FDA would have subpoena authority to compel the production of documents and the testimony of witnesses. The bill would also require immediate compliance with a subpoena, if FDA deems it necessary to address a threat of serious adverse health consequences or death. FDA could also request a court order barring the disclosure of the existence of a subpoena.	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		<p>There is no limitation on what level of official within FDA could be delegated the authority to issue a subpoena.</p> <p>(Sec. 207)</p>	
<b>Quarantine Authority</b>	NONE	<p>If FDA determines there is credible evidence or information that an article of food presents a threat of serious adverse health consequences or death, FDA would be authorized to quarantine any geographic area within the United States where FDA reasonably believes such food is located or from which it originated.</p> <p>Violation of a quarantine order would be a prohibited act.</p> <p>(Sec. 133)</p>	NONE
<b>Seizure Procedures</b>	NONE	<p>The bill would add language to the Act that would streamline the process for seizures sought in Federal court.</p> <p>(Sec. 131)</p>	FFDCA § 304. This section sets forth the rules and procedures for seizure.
<b>Whistleblower Protections</b>	NONE	<p>Whistleblowers would receive protection against retaliation or discrimination.</p> <p>(Sec. 208)</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Inspection Authority</b>	<p>The importation of food from foreign facilities that refuse to permit, limit, or unduly delay United States inspections would be prohibited.</p> <p>(Sec. 307)</p>	<p>Delaying, limiting, or refusing to permit an inspection of any farm, factory, or warehouse would render food from such facility adulterated.</p> <p>The bill would also amend section 704 to clearly state that FDA would have access to inspect foreign facilities.</p> <p>(Sec. 203)</p>	FFDCA § 704. This section sets forth FDA's inspection authority.
<b>Fees—Registration</b>	NONE	<p>Each registered facility would be required to pay a registration fee of \$1000, subject to inflationary adjustments in subsequent years.</p> <p>(Sec. 101)</p>	NONE
<b>Fees—Importers</b>	NONE	<p>Importers, customs brokers, and filer would be required to pay an annual registration fee, as determined by FDA.</p> <p>(Sec. 201)</p>	NONE
<b>Fees—Recalls</b>	<p>The bill would authorize fees to cover recall related activities performed by FDA, capped at \$20 million annually. Fees would be assessed against those companies subject to the recall.</p> <p>(Sec. 107)</p>	<p>FDA would have authority to collect fees to fully defray the costs of recall activities. Fees would be assessed against those companies subject to the recall.</p> <p>(Sec. 108)</p>	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Fees— Reinspection</b>	<p>FDA would have authority to collect fees to fully defray the costs of reinspections. Fees would be assessed against those companies subject to the reinspection.</p> <p>Reinspection related fees would be capped at \$25 million.</p> <p>(Sec. 107)</p>	<p>FDA would have authority to collect fees to fully defray the costs of reinspections. Fees would be assessed against those companies subject to the reinspection.</p> <p>(Sec. 108)</p>	NONE
<b>Fees—Voluntary Importer Program</b>	<p>The bill would authorize user fees for participation in the Qualified Importer Program equivalent to the cost of the activity.</p> <p>(Sec. 107)</p>	NONE	NONE
<b>Fees—Export Certificates</b>	<p>The bill would authorize FDA to certify food and animal feed for export and charge a fee not to exceed \$175 for each certification.</p> <p>(Sec. 107)</p>	<p>The bill provides for user fees for export certificates to cover FDA’s costs in providing the certificates. FDA would be able to determine the fee.</p> <p>(Sec. 144)</p>	NONE
<b>Authorization of Appropriations</b>	<p>The bill would authorize appropriations for FDA’s Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and related activities in the Office of Regulatory Affairs for \$825 million for fiscal year 2009. The bill also sets a goal that the field inspection staff for FDA’s food safety programs should increase by over 1,000 persons over a 5 year period.</p> <p>(Sec. 401)</p>	NONE	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Food Defense Strategy</b>	<p>HHS and USDA, in consultation with DHS, would be required to submit to Congress a National Agriculture and Food Defense Strategy, which would include a coordinated research agenda and a description of the process for meeting the following goals: (1) enhancing the preparedness of the agriculture and food system, (2) improving agriculture and food system detection capabilities, (3) ensuring an efficient response to agriculture and food emergencies, and (4) securing agriculture and food production after an emergency. Every four years, a revised plan would be submitted to Congress.</p> <p>(Sec. 108)</p>	NONE	NONE
<b>Food and Agriculture Coordinating Councils</b>	<p>USDA, FDA, and DHS would be required to submit a report to Congress on the activities of the Food and Agriculture Sector Coordinating Council and the Government Coordinating Council.</p> <p>(Sec. 109)</p>	NONE	NONE
<b>Domestic Capacity</b>	<p>FDA would be required to submit a report to Congress identifying its food safety programs and practices. This would include descriptions of the following: analysis of the need for additional regulations or guidance, outreach to food industry sectors, systems for distributing information and technical assistance to industry, communication systems to disseminate information concerning</p>	NONE	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	<p>specific threats, surveillance systems to detect foodborne illness outbreaks, and resources needed to implement the plan. This report also should include information on risk-based activities, the capacity for laboratory analyses, information technology, and recommendations for enhanced surveillance, outbreak response and traceability involving fruits and vegetables. Thereafter, FDA would be required to submit a report on a biennial basis reviewing previous food safety programs and practices and identifying future ones. In addition, on a biennial basis, FDA would be required to submit a food safety and food defense research plan to Congress.</p> <p>(Sec. 110)</p>		
<b><i>Salmonella</i> Enteritidis in Shell Eggs</b>	<p>Within a year of enactment, FDA would be required to issue a final rule based on the 2004 proposal concerning prevention of <i>salmonella</i> enteritidis in shell eggs.</p> <p>(Sec. 111)</p>	NONE	NONE
<b>Sanitary Transportation of Food</b>	<p>Within one year of enactment, the bill would require FDA to promulgate regulations regarding the sanitary transportation of food.</p> <p>(Sec. 112)</p>	NONE	FFDCA § 416. Requires FDA to establish regulations that require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
			food adulterated.
<b>Food Allergy and Anaphylaxis Management</b>	<p>Secretary of Health and Human Services, in consultation with the Secretary of Education, would be directed to develop voluntary, food allergy management guidance to manage the risk of food allergy and anaphylaxis in schools or early childhood education programs. In addition, the bill would provide for non-renewable food allergy management incentive grants for up to two years to assist local education agencies with adoption and implementation of the voluntary food allergy management guidelines.</p> <p>(Sec. 113)</p>	NONE	NONE
<b>Integrated Consortium of Laboratory Networks</b>	<p>Department of Homeland Security (DHS), in consultation with HHS, USDA, and EPA, would be required to maintain an agreement through which laboratory network members could do the following: (1) agree on common lab methods for the sharing of information, (2) identify the means by which the members could work cooperatively, and (3) engage in ongoing dialog and build relationships to support integrated responses during emergencies.</p> <p>(Sec. 203)</p> <p>FDA, in coordination with USDA and DHS would have to submit periodic reports to Congress on the implementation of the food emergency response network</p>	NONE	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
	of laboratories. (Sec. 202)		
<b>Surveillance</b>	<p>The CDC would be required to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting and usefulness of data on food-borne illness by, among other activities, coordinating with federal, state, and local surveillance systems; increasing participation in national networks of public health; facilitating the sharing of findings among governmental agencies on a timely basis; and, developing improved epidemiological tools. This section would also require FDA to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies. In addition, the bill would establish a working group of experts and stakeholders to make recommendations on improving food-borne illness surveillance.</p> <p>(Sec. 205)</p>	<p>HHS would be required to build upon existing surveillance systems to assess the frequency and sources of food-borne illness and conduct sampling to monitor for contamination. The Secretary would be authorized to rank food categories based on their hazard to human health and make the results of its survey publicly available. (Sec. 121)</p> <p>HHS would be directed to conduct food safety related research including rapid test methods. (Sec. 123)</p>	NONE
<b>Information Sharing</b>	NONE	<p>FDA would be able to share trade secrets and commercial or financial information and its list of registered facilities with other federal, state, local, and foreign agencies, provided those agencies can assure confidentiality of the information. FDA also would be allowed to share confidential information with the public, if necessary to protect the</p>	<p>FFDCA § 708. This section authorizes FDA to provide confidential information to other persons in connection with an activity that is undertaken under contract with the agency and which relates to administration of the FFDCA, if FDA is not prohibited from using the information and the person receiving the information takes security</p>

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		public health.  (Sec. 112)	precautions.  FFDCA § 301(j). This section prohibits the sharing of trade secret information, except to other HHS employees, the courts, or Congress.
<b>Decontamination and Disposal Standards and Plans</b>	EPA would be required to provide support for and technical assistance to state and local governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency. To do this, the EPA would develop and disseminate specific standards, including model plans, concerning clean up, clearance, and recovery activities following the decontamination and disposal of specific threat agents and foreign animal diseases. Exercises to identify weaknesses in the plans would be conducted at least annually, with modifications to the plan made at least every two years.  (Sec. 208)	NONE	NONE
<b>Jurisdiction</b>	Jurisdiction between FDA and USDA would not be changed.  (Sec. 402)	NONE	NONE
<b>Carbon Monoxide Labeling</b>	NONE	The bill would treat the use of carbon monoxide in meat, poultry, or seafood as color additive and would require FDA to either promulgate a regulation regarding its use or publish in the Federal Register a decision against	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		promulgating such a regulation.  (Sec. 141)	
<b>GRAS Substances</b>	NONE	The bill would require FDA to post notice of a GRAS submission and the supporting scientific information on its website.  The bill also changes the characterization of a GRAS submission to the FDA from a “notification” to a “request for a substance <u>to be determined by the Secretary</u> to be a GRAS food substance.”  (Sec. 142)	NONE
<b>COOL</b>	NONE	The bill would create a two-tier system of Country-of-Origin Labeling for processed food: (1) labeling for where final processing was conducted; and (2) website for each ingredient.  For non-processed food this would be: (1) labeling; and (2) website for the original packer.  Note: Because existing Customs regulations already require country of origin labeling of imported products, the new labeling requirement for finished products would, in effect, only apply to U.S.-made product.	Customs Law (19 U.S.C. § 1304(a)(3)(J); 19 C.F.R. § 134.33) Nearly every item imported into the U.S. must indicate to the ultimate purchaser its country of origin, except agricultural products, including produce, nuts, meat, and fish, that are offered for sale to the ultimate purchaser in their natural state (not processed) and in bulk (not in retail packages).  USDA Law (7 U.S.C. § 1638 (Agricultural Marketing Act § 281)) Requires retailers to notify their consumers of the country of origin of certain covered commodities: fruits

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
		Food not in compliance with this requirement would be misbranded.  (Sec. 143)	and vegetables, peanuts, fish and shellfish, and beef, lamb, and pork. Covered commodities that are ingredients in “processed food items” are exempt.
<b>Infant Formula</b>	NONE	The bill would prohibit the marketing and distribution of a new infant formula without a letter from the Secretary confirming that the registration and submission requirements have been satisfied. Infant formula manufacturers would be required to submit scientific evidence demonstrating that the infant formula meets certain requirements. FDA would be authorized to require clinical studies demonstrating that an infant formula supports normal physical growth.  Infant formula not in compliance with these requirements would be misbranded.  (Sec. 114)	FFDCA § 412. Infant formula must meet certain nutritional and other quality factors; must be manufactured according to good manufacturing procedures; is subject to specific recordkeeping and access provisions; and must not be sold without meeting certain registration and premarket submission requirements.
<b>Continued Operation of Field Labs and District Offices</b>	NONE	FDA would be prevented from closing any of the field laboratories or district offices without prior congressional review of the reorganization plan.  (Sec. 205)	NONE

	<b>FDA Food Safety Modernization Act (S. 510) (Durbin)</b>	<b>Food Safety Enhancement Act of 2009 (Waxman)</b>	<b>Current Law (FFDCA)</b>
<b>Preemption</b>	NONE	The bill would have no effect on actions or liability under state law, thereby voiding claims of federal preemption. The bill, however, would expressly not prohibit the introduction of evidence of compliance with federal law into any such state law proceeding.  (Sec. 4)	§ 403A contains express preemption provisions added by NLEA
<b>Education and Outreach</b>	NONE	HHS, in cooperation with private and public organizations would implement a national public education program on food safety. The program would provide information to both the public and health professionals. HHS would be required to work with states and other entities to develop and distribute advisories regarding food safety.  (Sec. 122)	NONE

Last updated June 3, 2009