

Topic	Sen. Durbin	Rep. Dingell
Registration of Food Facilities Registration Frequency	- Requires food facilities to register with FDA biennially, between Oct. 1 and Dec. 31 of every even-numbered year.	Requires food facilities to register with FDA annually.
- Registration information	Requires the following new information: <i>(a)</i> a consent to permit FDA inspection of the registered facility; <i>(b)</i> the email address for the facility's contact person (or, in the case of a foreign facility, the email address of the facility's U.S. agent); and <i>(c)</i> any other food categories (beyond the food categories listed in 21 C.F.R. 170.3) determined by FDA to be appropriate, including by guidance document.	Requires the following new registration information: <i>(a)</i> the name, address, and emergency contact information for each facility operated by the registrant engaged in manufacturing, processing, packing, or holding food for consumption in the U.S.; <i>(b)</i> the "primary purpose and business activity" of each such facility; <i>(c)</i> the dates of operation if a facility is seasonal; <i>(d)</i> the name, address, and 24-hour emergency contact information for the U.S. "distribution agent" for each such facility; <i>(e)</i> any other food categories (beyond those listed in 21 C.F.R. 170.3) determined by FDA to be appropriate.
- Changes in registration information	No change comparable to the Dingell bill	Changes the period from 60 days to 30 days in which a registrant must notify FDA of any change in the products, function, or legal status of a facility (including cessation of business)
- Suspension of registration	Both provide that FDA may suspend a facility's registration if food from the facility could result in serious adverse health consequences or death to humans or animals, and also require that FDA provide notice and an opportunity for an informal hearing before suspending registration.	

Requires FDA to issue regulations describing the standards it will use in making a determination to suspend registration, and provides that a suspended registration shall be reinstated if FDA determines that adequate grounds do not exist to continue the suspension.

Provides that registration may be suspended if the facility fails to re-register each year or if the facility or one of its employees refuses, delays, or limits an FDA inspection, and also provides that a suspended registration may be reinstated pursuant to criteria published by FDA in the *Federal Register* and posted on a public FDA website.

- Effect of suspension, non-registration

Both prohibit the introduction into interstate commerce of food from unregistered facilities.

Introducing food from an unregistered facility into interstate commerce would become a prohibited act, subject to injunction and criminal prosecution. In addition, a domestic facility with a suspended registration would not be permitted to import food, and food from a foreign facility with a suspended registration would be refused admission into the U.S.

Provides that a food is deemed to be misbranded if it was manufactured, processed, packed or held in a facility that is not registered or has not paid its registration fee.

Preventive Controls Plans

- Requirement of preventive controls plans

Both require the owner, operator or agent in charge of each registered food facility to develop and implement a written preventive controls plan.

Requires the owner, operator or agent in charge of each registered facility to conduct a hazard analysis and develop and implement a preventive controls plan. Each covered facility would be required to implement a written plan that includes the following elements: a hazard analysis, preventive controls, monitoring, verification, corrective actions and record keeping. FDA would be required to issue regulations setting minimum standards for hazard analysis, preventive controls and documentation, and issue a guidance document related to hazard analysis and preventive controls.

Requires the owner, operator or agent in charge of each registered facility to conduct a hazard analysis and implement a written Hazard Analysis and Critical Control Points (HACCP) plan. The written HACCP plan would be required to include the same elements as the Durbin bill, including: recall procedures, traceback procedures, procedures for ensuring a safe and secure supply chain and science-based performance standards. FDA may establish, by regulation or guidance, additional preventive controls for specific product types and would also be required to issue guidance regarding minimum standards for hazard analysis, preventive controls and documentation.

- Exemptions

(a) Facilities subject to FDA's seafood or juice HACCP regulations or FDA's low-acid canned foods regulations; and
(b) Facilities subject to section 419 (fresh produce standards). In addition, FDA may, by regulation, exempt (or modify the requirements for) facilities solely engaged in the production of animal feed or in the storage of packaged foods that are not exposed to the environment.

Does not provide for any exemptions from this requirement.

- Requirement to reassess plan	Requires a facility to conduct a re-analysis at least once every 3 years and whenever a significant change is made in the activities conducted at the facility if such change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard.	Requires a facility to perform a new hazard analysis and reassess its preventive controls whenever there is a reasonable potential for a new hazard or a significant increase in a previously identified hazard, but never less frequently than every two years.
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- FDA access to plan	Requires each facility to make its preventive controls plan and documentation showing that the plan is being implemented available to FDA promptly upon oral or written request.	Requires FDA to review a facility's HACCP plan during inspections.
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- Prohibited acts	i. Both would make operating a facility that manufactures, processes, packs, or holds foods for sale in the U.S. but does not comply with this requirement a prohibited act, subject to injunction and criminal prosecution.	
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<u>Performance Standards</u>	- Both require FDA to evaluate epidemiologic data and other appropriate information in order to identify the most significant foodborne contaminants not less frequently than every 2 years. Based on this evaluation, FDA would be required to issue, by regulation or guidance, science-based performance standards (which may include action levels) to significantly minimize, prevent, or eliminate such hazards.	
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<u>Inspections</u>	- Both require FDA to inspect each registered facility no less frequently than once every 4 years for both domestic facilities and foreign facilities. In addition, both would require FDA to target its inspection resources based on each facility's risk profile.	
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Requires FDA to allocate resources to inspect registered facilities according to their risk profile, based on the following factors: the risk profile of the food manufactured, processed, packed or held at the facility; the facility's history of recalls, outbreaks and violations; the rigor of the facility's hazard analysis and preventive controls; whether the facility has been certified by an accredited third-party auditor; whether the food manufactured, processed, packed, handled, prepared, treated, distributed or stored at the facility meets the criteria for priority under FD&C Act section 801(h)(1) (i.e., possible intentional adulteration); and any other criteria deemed appropriate by FDA. FDA would be required to inspect high-risk facilities at least once every 2 years during the first 2 years after the date of enactment, and at least once each year thereafter. FDA would be required to inspect non-high-risk facilities at least once every 4 years.

Requires FDA to inspect facilities "at a frequency determined according to a risk-based schedule." FDA would be required to establish the risk-based schedule no later than 18 months after the date of enactment. Frequency of inspection would be based on the following factors: the type of food, the facility's compliance history, whether the facility is certified by an accredited certifying agent and such other factors as FDA determines by guidance to be relevant. However, in no case may inspections occur less frequently than once every 4 years.

- Foreign inspections

Bill provides that FDA may enter into agreements with foreign governments to facilitate inspection of foreign facilities registered with FDA. Although a provision explicitly requiring that foreign food facilities be inspected as frequently as domestic food facilities is not included, this is implicit in section 201 of the bill.

Require FDA to establish and maintain a "corps of inspectors dedicated to inspections of foreign food.... facilities and establishments." This foreign inspectorate must be staffed and funded sufficiently to enable it to inspect foreign food facilities at least as frequently as domestic food facilities.

- Inspections of imports

Requires FDA to allocate resources to inspect imported foods according to their risk profile, based on the following factors: the risk profile of the imported food; the risk profile of the countries of origin and transport of the imported food; the importer's history of recalls, outbreaks, and violations; the rigor of the importer's Foreign Supplier Verification Program; whether the importer participates in the Voluntary Qualified Importer Program; whether the food meets the criteria for priority under FD&C Act section 801(h)(1) (i.e., possible intentional adulteration); whether the food is from a facility that has been certified by an accredited certifying agent and any other criteria deemed appropriate by FDA.

No comparable provision prioritizing inspection of imported foods.

- Prohibited acts

No comparable provision.

Refusing, limiting or delaying inspection (including any such refusal, limitation, or delay by an agent of a foreign government) would become a prohibited act, subject to injunction and criminal prosecution.

Mandatory Recall Authority

- Both give FDA mandatory recall authority. If FDA determines that an article of food should be recalled, FDA would be required to give the responsible person the opportunity to cease distribution, recall the product and notify certain other parties. If the responsible person does not take action within the time and in the manner prescribed by FDA, FDA would be required to (or, in the Durbin bill, would be authorized to) issue an order requiring the responsible person to cease distribution and notify other parties. Failure to obey such an order would be a prohibited act, subject to injunction and criminal prosecution. If, after an opportunity for a hearing, the responsible party fails to comply with the order, FDA may amend the order to mandate a recall. Failure to comply with the amended order would be a prohibited act, subject to injunction and criminal prosecution.

Gives FDA mandatory recall authority only if FDA determines there is a reasonable probability that an article of food (other than infant formula) is adulterated or misbranded under FD&C Act 403(w) (allergen labeling) and that use of or exposure to such article will cause serious adverse health consequences or death to humans or animals. In addition the bill directs FDA to “consider” making public the names of retail consignees of recalled foods for Class I recalls, as USDA does for meat and poultry recalls.

Gives FDA mandatory recall authority if FDA determines that an article of food is adulterated or misbranded in a manner that may result in injury or illness

Administrative Detention Authority

- Both give FDA the authority to administratively detain an article of food if FDA has “reason to believe” that the article of food is adulterated or misbranded. This would significantly expand FDA’s power to administratively detain foods. Under current law, FDA must have “credible evidence or information” that the article of food “presents a threat of serious adverse health consequences or death to humans or animals.” Both bills would require FDA to issue an interim final rule implementing this change no later than 120 days after the date of enactment.

Recordkeeping & Record Access

- Recordkeeping

- No comparable provision.

Requires that records of immediate previous sources and immediate subsequent recipients of food (required under section 414(b) of the FD&C Act and 21 C.F.R. Part 1, Subpart J) must be maintained in a standardized electronic form. Currently, such records may be kept in paper or electronic form. The Dingell bill would also extend this recordkeeping requirement to farms and restaurants.

- Records access

Both expand FDA's records access authority under section 414 of the FD&C Act. Currently, section 414 gives FDA authority to inspect and copy certain records pertaining to an article of food if FDA has a reasonable belief that a particular article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA may, upon presenting credentials and a written notice, inspect and copy all records relating to that particular article of food that are needed to determine whether the food is adulterated and presents a risk of serious adverse health consequences or death to humans or animals.

If FDA has a reasonable belief that a particular article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA would have access to all records relating to that article of food and "any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner."

Removes the requirement that FDA have a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, removes the requirement that FDA provide a written notice in order to invoke this records access authority, and gives FDA access to all records needed to determine whether the article of food is adulterated, misbranded, or otherwise in violation of the FD&C Act.

Third-Party Certification

- Accreditation of third-party certifying agents

- Both require FDA to establish a system in which accredited third-party certifying agents would certify food facilities' compliance with the FD&C Act.

Requires that FDA establish a system, no later than 2 years after the date of enactment, in which FDA would recognize accreditation bodies, and these accreditation bodies would accredit third-party auditors and audit agents to certify "eligible entities." Importantly, the Durbin bill defines "eligible entities" as foreign entities, including foreign facilities registered with FDA, in the food import supply chain that wish to be certified by accredited third-party auditors or audit agents. FDA's role would be to recognize other entities as accreditation bodies, and those recognized accreditation bodies would accredit the third-party auditors and audit agents. Additionally, only foreign facilities would be able to seek third-party certification.

Requires that FDA establish a system, no later than 2 years after the date of enactment, in which any foreign government, State or regional food authority, foreign or domestic cooperative that aggregates the products of growers or processors, or other third party may apply to FDA to be accredited as a certifying agent to certify food facilities. Thus, FDA would accredit third-party certifying agents, and both domestic and foreign food facilities would be able to seek third-party certification.

- FDA Use of Third-Party Certification

Provides that FDA shall consider whether a foreign facility is certified in targeting inspection resources. In addition, FDA shall consider third-party certification in determining an importer's eligibility to participate in the Voluntary Qualified Importer Program and in determining whether an article of food is eligible for an export certificate. The Durbin bill would require FDA to establish a publicly available registry of all accreditation bodies and all accredited third-party auditors and audit agents.

Does not explicitly state how FDA is to use third-party certification in regulatory decisions. It does require that FDA post on its website a current list of all accredited certifying agents.

<p>- Certifying agent's obligation to notify FDA</p>	<p>Requires an accredited audit agent to immediately notify FDA if the audit agent discovers a condition that could cause or contribute to a serious risk to public health.</p>	<p>Requires a certifying agent to immediately notify FDA if, during a facility audit, it discovers a condition that could cause or contribute to illness or injury to an individual consuming food manufactured, processed, packed or held by the facility.</p>
<p>- Certification, Re-certification, and De-certification</p>	<p>Provides that FDA shall develop model accreditation standards for third-party auditors and audit agents, and recognized accreditation bodies must ensure that accredited third-party auditors and audit agents meet such standards. Audits of all eligible entities would be required to be unannounced. Each eligible entity must be re-certified annually if it intends to participate in the Voluntary Qualified Importer Program or if it is required to provide an export certificate for any of its products. The Durbin bill does not address de-certification of eligible entities.</p>	<p>Provides that certifying agents may not certify a facility unless they have conducted an onsite audit, reviewed the facility's written HACCP plan, prepared an audit report and conducted such other review, analysis or testing as FDA determines to be appropriate. Audits of domestic facilities would be required to be unannounced. The Dingell bill does not specify any frequency for re-certification of facilities. Certifying agents would be required to decertify a facility if, after providing a reasonable opportunity for corrective action, it determines that the facility no longer meets the applicable requirements of the FD&C Act.</p>
<p>- Certification required to accompany shipment of imported food</p>	<p>Provides that an accreditation body may not accredit a third-party auditor or audit agent unless the latter agrees to issue a written and electronic certificate to accompany each shipment of food offered for import.</p>	<p>Provides that, for each shipment of food offered for import that was manufactured, processed, packed or held by a certified facility, the certifying agent must issue a written and electronic certification to accompany the shipment. Beginning 3 years after the date of enactment, any food that is part of a shipment that violates this requirement would be deemed to be misbranded.</p>

- Renewal of accreditation	Requires that FDA reevaluate recognized accreditation bodies at least once every 4 years, and audit each accredited third-party auditor and audit agent at least once every 4 years. In addition, FDA may conduct an onsite audit of an eligible entity certified by an accredited third-party auditor or audit agent "at any time."	Requires that FDA audit accredited certifying agents for the purpose of renewing their accreditation at least once every 4 years.
- Withdrawal of accreditation	Provides that FDA shall withdraw accreditation from a third-party auditor or audit agent if food from a facility certified by the third-party auditor or audit agent is linked to an outbreak of human or animal illness, if FDA determines the third-party auditor or audit agent no longer meets accreditation requirements or if the third-party auditor or audit agent refuses to allow U.S. officials to conduct such audits or investigations as may be necessary to ensure its continued compliance. In addition, FDA shall revoke its recognition of an accreditation body if it finds it not to be in compliance with the bill's requirements.	Provides that FDA may withdraw accreditation of a certifying agent if a facility certified by it is linked to an outbreak of human or animal illness, or if FDA determines the certifying agent no longer meets its accreditation requirements. FDA must withdraw accreditation if the certifying agent refuses to allow FDA to conduct such audits and investigations as may be necessary to ensure its continued compliance with accreditation standards.
- FDA access to certifying agent records	Gives FDA access to onsite audit reports or other documents required as part of the audit process, but not to documents resulting from a consultative audit.	Requires certifying agents to provide to FDA, upon request, copies of audit reports, records relating to corrective actions by audited facilities and any other records related to certification or de-certification of a facility, a facility's compliance with regulatory requirements or accreditation of the certifying agent.

Laboratory Accreditation: Direct Submission of Lab Tests to FDA

- Laboratory certification/accreditation

- Requires FDA to provide for the recognition of laboratory accreditation bodies and to establish a publicly available registry of recognized lab accreditation bodies. FDA would be required to develop model standards that accreditation bodies could use to accredit laboratories. FDA would also be required to reevaluate recognized accreditation bodies at least every 5 years.

Requires FDA to establish a program for certification of laboratories, no later than 2 years after the date of enactment. FDA would also be required to develop standards for certifying labs no later than 18 months after the date of enactment. The bill also provides that FDA may establish an accreditation system under which third parties may request FDA accreditation as lab certifying agents. FDA would be required to post on its website a current list of accredited lab certifying agents as well as a current list of certified labs. Many of the provisions applicable to accredited certifying agents that certify facilities (e.g., conflict of interest provisions) would also apply to accredited certifying agents that certify laboratories. The submission of a false or misleading statement by an employee or agent of a lab to a lab certifying agent would be a prohibited act, subject to injunction and criminal prosecution.

- Requirement to use certified/accredited labs for regulatory tests

Provides that testing of food by or on behalf of its owner or consignee for the purposes listed below would have to be conducted by either a Federal laboratory or a non-Federal laboratory that has been accredited by a recognized accreditation body and the results sent directly to FDA: to support the admission of an imported food; to ensure compliance with a specific requirement of the FD&C Act or its implementing regulations; to support removal from an Import Alert and such other purposes as FDA deems appropriate.

Provides that, effective 3 years after the date of enactment, only Federal laboratories and certified non-Federal laboratories would be allowed to conduct testing of food for the following regulatory purposes: to determine admissibility of imported food, to support removal from an Import Alert, to show compliance with an order, to support an appeal of an order, and such other purposes as FDA deems appropriate.

- Requirement to report lab results to FDA	Requires that lab tests be sent directly to FDA in order to used in the making of regulatory decisions.	Requires certified labs to promptly transmit test results to FDA in electronic format.
<u>Imports</u> - Registration	- No comparable provision.	Requires food importers to register with FDA if not already registered under the food facility registration requirement (FD&C Act section 415). It would make it a prohibited act to import food (other than for personal use) by an importer that is not registered with FDA.
- Voluntary program to expedite imports	Requires FDA to establish, by guidance, a Voluntary Qualified Importer Program to expedite movement of food through the import process. To be eligible for the program, a U.S. importer must be offering food from a facility that has been certified by an accredited third-party auditor for import. Under the program, the importer would submit to FDA a notice of intent to participate in the program for the coming fiscal year, and FDA would consider the risk of the food to be imported based on such factors as the nature of the food, the compliance history of the foreign supplier, the regulatory system of the country of export, the importer's Foreign Supplier Verification Program, and the potential risk of intentional adulteration. A participating importer would need to be reevaluated by FDA at least once every 3 years.	Requires FDA to establish, by regulation, a program to expedite movement of food through the import process if each facility involved in the production, manufacture, processing, packaging and holding of the food is certified by an accredited certifying agent and agrees to comply with food safety and security guidelines to be developed by FDA.

- Foreign supplier verification program

Requires every U.S. importer to have a Foreign Supplier Verification Program. FDA would be required to issue regulations specifying the content of importers' Foreign Supplier Verification Programs no later than 1 year after the date of enactment. FDA would also be required to issue guidance to assist importers in developing their Foreign Supplier Verification Programs. Each importer would be required to perform risk-based foreign supplier verification activities (e.g., monitoring records of shipments, lot-by-lot certification, annual on-site inspections of foreign suppliers, checking the hazard analysis and preventive control plans of foreign suppliers and periodic sampling and testing of shipments) to ensure that: (a) imported food is not adulterated under FD&C Act section 402 or misbranded under FD&C Act section 403(w) (allergen labeling); and (b) imported food was produced in compliance with FD&C Act sections 418 (hazard analysis and preventive controls) and 419 (fresh produce standards).

No comparable provision.

Every U.S. importer would be required to maintain records related to its Foreign Supplier Verification Program for at least 2 years and to make them available to FDA upon request. FDA would be required to post on its website a list of importers required to have Foreign Supplier Verification Programs. Importing food, or offering food for import, if the importer does not have a Foreign Supplier Verification Program in place would be a prohibited act, subject to injunction and criminal prosecution. In addition, imported food would be refused admission if it appears that the importer does not have a Foreign Supplier Verification Program.

- Import certificates

Authorizes FDA to require import certificates for designated imported foods. Based on public health considerations including risks associated with a food or its place of origin, FDA may require, as a condition of granting admission into the U.S., a certification or other assurance from the government of the country in which the food originated or from an accredited third-party auditor or audit agent. Such certification would be required only in the case of designated foods imported from countries with which FDA has an agreement to establish a certification requirement.

No comparable provision.

- Refusal of admission

Both provide that a food offered for import shall be refused admission if it comes from a foreign facility that refuses to permit FDA inspection.

Provides that a food offered for import shall be refused admission if the owner, operator, or agent in charge of a foreign facility registered with FDA, or the government of a foreign country, refuses to permit entry of U.S. inspectors into the facility for more than 48 hours.

Provides that a food offered for import shall be refused admission if it has been processed, packed, or held at a facility that has refused, limited or delayed inspection. In addition, if a foreign facility or a foreign government does not timely consent to an FDA investigation when food from that facility or country is found to be adulterated or misbranded or is linked to a foodborne illness outbreak, FDA may refuse admission.

- Other import provisions

Requires that the prior notice submitted to FDA for imported foods must include "any country to which the article has been refused entry." FDA would be required to issue an interim final rule amending its prior notice regulation no later than 120 days after the date of enactment. The bill also provides that FDA may review a foreign country's food safety system and make a determination whether that country can provide reasonable assurances that its food safety system is equivalent to that of the U.S.

No comparable provision.

Fees

- Both impose new fees on the food industry. In addition, both bills would authorize FDA to assess a fee for issuing export certificates.
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The Durbin bill would impose the following new fees for fiscal year 2010 and each subsequent fiscal year:

- o An annual fee from each domestic facility that is subject to a re-inspection in that fiscal year in an amount sufficient to cover 100% of FDA's total "reinspection- related costs" (up to a total of no more than \$25 million for any fiscal year);
- o An annual fee from each domestic facility and importer that is subject to a food recall in that fiscal year sufficient to cover 100% of FDA's food recall activities (up to a total of no more than \$20 million for any fiscal year);
- o An annual fee from each importer participating in the Voluntary Qualified Importer Program in that fiscal year sufficient to cover 100% of FDA's administrative costs of operating the Voluntary Qualified Importer Program; and
- o An annual fee from each importer that is subject to a re-inspection in that fiscal year sufficient to cover 100% of FDA's "reinspection-related costs" at ports of entry (up to a total of no more than \$25 million for any fiscal year).

The Dingell bill would impose the following new fees on industry:

- o An annual facility registration fee "to defray increases...in the costs of inspecting" registered establishments and "related activities" for each of fiscal years 2010 through 2014. The registration fee would be waived for any facility that is a small business as defined by FDA, and the registration fee would sunset after fiscal year 2014;
- o An annual registration fee for food importers, which would be set at \$10,000;
- o A re-inspection fee to be assessed if FDA re-inspects a facility because of any violations of the FD&C Act by that facility. The amount of the re-inspection fee would be set so as to fully defray the costs of conducting re-inspections;
- o A fee for accrediting third-party facility certifying agents; and
- o An annual fee for accrediting laboratory certifying agents.

The amount of the fees for the upcoming fiscal year would be published in the Federal Register no later than 60 days before the start of each fiscal year.

Civil Fines

- Authorizes FDA to assess civil fines for failure to comply with a recall order. Any person who fails to comply with a recall order would be liable for a civil penalty not to exceed \$50,000 for an individual, \$250,000 for a corporation.

Authorizes FDA to assess civil fines of against any person who commits a prohibited act with respect to an article of food. The bill authorizes fines of up to \$100,000 for individuals and up to \$500,000 for other persons. Each prohibited act, and each day it continues, would be considered a separate offense. Civil fines must be assessed by written order after providing notice and an opportunity for a hearing.

Fresh Produce

- GAPs and regulations

- Both require FDA to publish updated Good Agricultural Practices (GAPs) and guidance for the safe production and harvesting of (unspecified) specific types of fresh produce no later than 1 year after the date of enactment. Both bills require FDA to issue regulations establishing minimum standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death. Both would require that FDA publish a proposed rule no later than 1 year after the date of enactment, and a final rule no later than 1 year after the close of the comment period for the proposed rule. Both provide that producing or harvesting fresh produce not in accordance with FDA minimum standards or a variance would be a prohibited act, subject to injunction and criminal prosecution.

Provides that the FDA regulations on produce safety must include standards addressing soil amendments, hygiene, packaging, temperature control, animal encroachment and water. Implementation would prioritize specific fruits and vegetables that have been associated with foodborne illness outbreaks.

Provides that the FDA regulations on produce safety must include standards addressing use of manure, water quality, employee hygiene, animal control, temperature control, and nutrients. It also states that the regulations would apply to growing, harvesting, packing, sorting, and storage operations. Implementation would prioritize specific fruits and vegetables that have been associated with foodborne illness outbreaks.

- Traceability

Requires FDA, in consultation with USDA and State government agencies, to improve its capacity to effectively and rapidly track and trace fruits and vegetables that are raw agricultural commodities. FDA, in coordination with the produce industry, would be required to establish, no later than 9 months after the date of enactment, a pilot project to explore and evaluate new methods for rapid and effective tracking and tracing of fruits and vegetables that are raw agricultural commodities. FDA would be required to report to Congress the findings of the pilot project and make recommendations for improving traceback and trace forward procedures for fresh produce, no later than 18 months after the date of enactment. FDA would be required to publish, no later than 2 years after the date of enactment, a proposed rule to establish standards for the type of information, format, and timeframe for submitting records to aid FDA in tracking and tracing fresh produce.

Removes the exception for farms and restaurants from Section 414 of the FD&C Act. This means that farms and restaurants would be required to maintain records of immediate previous sources and immediate subsequent recipients of food (see 21 C.F.R. Part 1, Subpart J). In addition, such records would be required to be maintained in a standardized electronic form. A food would be deemed to be misbranded if it is a raw agricultural product unless each commercial shipment contains information enabling FDA to identify the grower, the lot on which it was produced, the harvesting and packing dates and any other information FDA determines is appropriate.

Country of Origin Labeling

- No provision on country of origin labeling.

Makes country of origin labeling a requirement of the FD&C Act for the first time. Also provides that a processed food is misbranded unless its labeling identifies the country in which final processing occurred, and the manufacturer's website identifies the country (or countries) of origin for each ingredient in the food. It would provide that a non-processed food is misbranded unless its labeling and the original packer's website both identify the country of origin of the food. The bill would require FDA to issue final regulations implementing this requirement no later than 180 days after the date of enactment, and the requirement would become effective 2 years after the date of enactment.

Miscellaneous Provisions

- The Durbin bill includes the following miscellaneous provisions that have no counterpart in Dingell's bill:
 - o Requires FDA to issue a final rule on measures to prevent Salmonella enteritidis in shell eggs during production no later than 1 year after the date of enactment. NB: The proposed rule was published in 2004. 69 Fed. Reg. 56824 (Sept. 22, 2004).
 - o Requires FDA to issue regulations governing the sanitary transportation of food no later than 1 year after the date of enactment.
 - o Requires that FDA, in consultation with the Department of Education, develop voluntary guidelines for managing the risk of food allergy and anaphylaxis in schools and early childhood education programs no later than 1 year after the date of enactment. The guidelines shall address, among other issues, strategies to reduce the risk of exposure to allergens in classrooms and cafeterias.

The Dingell bill includes the following miscellaneous provisions that have no counterpart in the Durbin bill:

- o Gives FDA the power to issue subpoenas requiring the attendance and testimony of witnesses and production of documents for the purpose of any hearing, investigation or other proceeding regarding violations of the FD&C Act. Failure to obey such a subpoena would be a prohibited act, subject to injunction and criminal prosecution.
- o Requires FDA to revive its former GRAS (generally recognized as safe) affirmation procedure. FDA would be required to publish a notice in the Federal Register no later than 60 days after receiving a request for a GRAS determination, and to make its determination no later than 90 days after publishing the notice.
- o Makes it a prohibited act, subject to injunction and criminal prosecution, to submit any report required by or under the FD&C Act that is false or misleading in any material respect.

o Requires FDA to issue regulations, no later than 2 years after the date of enactment, to protect against intentional adulteration of food. These regulations would apply only to the following types of food: (a) food for which FDA has identified clear vulnerabilities; (b) food in bulk or batch form, prior to being packaged for the consumer; and (c) food for which there is a high risk of intentional contamination, as determined by FDA, that could cause serious adverse health consequences of death to humans or animals. The regulations will not apply to food on farms, except for milk. Failure to comply with the regulations would be a prohibited act, subject to injunction and criminal prosecution. FDA would also be required to issue guidance documents related to protection against intentional adulteration of food no later than 1 year after the date of enactment.¹² Finally, FDA and USDA, in coordination with the Department of Homeland Security, would be required to develop, submit to Congress, and make available on the Internet a National Agriculture and Food Defense Strategy.

o Prohibits FDA from terminating or consolidating any of its 13 field laboratories or 20 District Offices (or transferring inspection or compliance functions among District Offices) without first submitting a reorganization plan to Congress and the Comptroller General of the United States and consulting with personnel and unions.

o Grants “whistleblower protections” to any employee of a person required to submit a food facility registration to FDA.

o Require a warning notice on meat, poultry, and seafood products that have been treated with carbon monoxide.

o Provides that, if any person (other than a household consumer or other individual who is the intended consumer of the food) has reason to believe that an article of food is adulterated or misbranded in a manner that may result in injury or illness, such person is required to notify FDA of the identity and location of the food as soon as practicable. Failure to notify FDA would be a prohibited act, subject to injunction and criminal prosecution.