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**MEMORANDUM**

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FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: Food Safety Legislation in the 111<sup>th</sup> Congress

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Major food safety legislation is now pending in both the House and Senate. While several bills have been introduced, we continue to recommend focus on the following “lead bills” in each chamber:

- The “FDA Food Safety Modernization Act” (S. 510) introduced on March 3 by Senate Assistant Majority Leader Richard Durbin (D-IL) and a bipartisan group of Senators from the Committee with responsibility for amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (the “Durbin bill”).
- The “Food Safety Enhancement Act of 2009” (H.R. 2749) introduced on June 8, 2009 by Rep. Henry Waxman (D-CA), Chairman of the House Energy and Commerce Committee (the “Waxman bill”). The Waxman bill is a successor to the “Food and Drug Administration Globalization Act” (H.R. 759) introduced in January by Rep. John Dingell (D-MI).<sup>1</sup>

This memorandum compares the main provisions of the Durbin and Waxman bills, but is not intended to be a comprehensive analysis of either bill. It is based on the version of the Waxman bill that was marked up and ordered reported from the House Energy and Commerce Committee on June 17, 2009.<sup>2</sup>

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<sup>1</sup> See our memorandum dated March 3, 2009 comparing the Durbin and Dingell bills.

<sup>2</sup> This memorandum updates our previous memoranda dated May 18, 2009 (which relied on the May 5 discussion draft of the Waxman bill) and May 28, 2009 (which relied on the May 26, 2009 discussion draft of the Waxman bill).

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Several other food safety reform bills have been introduced in Congress, but are less likely to pass. These include the “Safe Food Enforcement, Assessment, Standards and Targeting Act” (or Safe FEAST Act) (H.R. 1332), introduced by Reps. Jim Costa (D-CA) and Adam Putnam (R-FL), and the “Food Safety Modernization Act” (H.R. 875) introduced by Rep. Rosa DeLauro (D-CT), Chair of the House Agricultural Appropriations Subcommittee, which would create a new food agency outside of the Food and Drug Administration (FDA) but within the Department of Health and Human Services (HHS). These other bills are not discussed in this memorandum.

Food safety legislation affecting meat and poultry products is also a possibility this year. At a listening session of the President’s Food Safety Working Group held on May 13, Secretary of Agriculture Tom Vilsack stated that the administration is reviewing the Federal Meat Inspection Act. This may indicate that whatever food safety reforms are adopted on the FDA side are also likely to be adopted on the U.S. Department of Agriculture (USDA) side.

While both President Obama and Congressional leaders have previously indicated that health care reform would be the first item on their health agenda, the recent nationwide recalls of peanut and pistachio products have elevated attention to food safety and increased dissatisfaction with FDA’s food safety program. Passage of food safety legislation in 2009 is a distinct possibility, especially if key members of Congress are willing to compromise on controversial provisions in these bills. Even if not passed during 2009, passage of a food safety bill in 2010 is likely.

**We recommend your prompt, careful consideration of the bills. Please contact us if you have comments that you would like us to relay to the sponsors.**

### **Summary**

Overall, the Durbin and Waxman bills include many similar provisions, including the following:

- Both would require food facilities to re-register with FDA on a regular basis, and both would prohibit unregistered facilities from introducing food into interstate commerce;
- Both would require registered food facilities to develop and implement written preventive controls plans;
- Both would establish new industry fees;
- Both would grant FDA sweeping new enforcement authorities, including mandatory recall authority, the authority to administratively detain food based only on a “reason to believe” the food is adulterated or misbranded, the authority to assess civil fines for specified violations, and the power to suspend the operations of any food facility if FDA determines that food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals;

- Both would establish substantial new regulatory requirements for importation of foods; and
- Both would provide that only tests conducted by Federal laboratories or accredited non-Federal laboratories may be used for regulatory purposes, and both would require that lab tests be sent directly to FDA.

The two bills differ from each other in many ways, including the following:

- The Waxman bill would require food facilities to re-register and pay a registration fee annually. The Durbin bill would require food facilities to re-register biennially but would not impose registration fees.
- The Waxman bill would require that FDA issue regulations creating a “tracing system for food” that would enable FDA to identify each person that grows, produces, manufactures, processes, packs, transports, holds, or sells an article of food within two business days. The Durbin bill has no comparable provision.
- The Waxman bill would require food importers and customs brokers and filers to register with FDA and would require food importers to pay an annual registration fee. The Durbin bill would not require importers, customs brokers, or filers to register, but it would require importers to pay fees sufficient to cover FDA’s administrative costs of operating the Voluntary Qualified Importer Program.
- The Waxman bill would authorize FDA to quarantine geographic areas within the United States if there is credible evidence an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals and FDA reasonably believes such article of food is located in or originated from that geographic area. The Durbin bill has no comparable provision.
- The Waxman bill would authorize FDA to assess civil fines for each prohibited act. For individuals, the bill authorizes fines up to \$50,000 per violation, with a cap of \$100,000 in any single proceeding. For corporations, it authorizes fines up to \$500,000 per violation, with a cap of \$7.5 million in any single proceeding. The Durbin bill would authorize FDA to assess civil fines only for failure to comply with a recall order.
- The Waxman bill would provide that a processed food is misbranded unless its labeling identifies the country where final processing occurred. The Durbin bill has no comparable provision.

## **Comparison**

### 1. Jurisdiction

- Both bills state that they are not intended to alter the current division of jurisdiction between FDA and the U.S. Department of Agriculture (USDA).

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- The Waxman bill explicitly exempts: (a) food that is regulated by USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act (*i.e.*, meat food products, poultry products, and egg products); (b) official establishments regulated exclusively by USDA; and (c) farms “to the extent” they raise animals from which meat food products, poultry products, or egg products are derived. Thus, while the Waxman bill would extend FDA inspection authority and certain requirements to farms, it would exempt the portions of farms involved in livestock and poultry production. The Waxman bill also provides that it would not apply to alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) or facilities that exclusively manufacture, process, pack, or hold alcoholic beverages.
- The Durbin bill has no comparable provisions.

## 2. Registration of Food Facilities

### a. Covered Facilities

- The Waxman bill would require every facility that manufactures, processes, packs, or holds food for consumption in the United States “or for export from the United States” to register with FDA.
- The Durbin bill would not change the scope of the facility registration requirement under current law (*i.e.*, it would require registration of facilities that manufacture, process, pack, or hold food for consumption in the United States).

### b. Registration frequency

- The Waxman bill would require food facilities to register with FDA annually, on or before December 31 of each year.
- The Durbin bill would require food facilities to register with FDA biennially, between October 1 and December 31 of every even-numbered year.<sup>3</sup>

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<sup>3</sup> Under existing section 415(b) of the FD&C Act, a “facility” is defined as “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.” The definition includes both domestic and foreign facilities. It does not include farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared or served directly to consumers, or fishing vessels (except for vessels that engage in processing).

c. Registration information

- The Waxman bill would require the following new registration information: (a) the “primary purpose and business activity” of the facility; (b) the dates of operation if a facility is seasonal; (c) the name, address, and 24-hour emergency contact information for the U.S. “distribution agent” for each such facility;<sup>4</sup> (d) (with respect to the requirement to identify the product categories manufactured, processed, packed, or held at each facility) any other food categories (beyond those listed in 21 C.F.R. 170.3) required by FDA through guidance; and (e) a unique facility identifier.
- The Durbin bill would require the following new information: (a) a consent to permit FDA inspection of the registered facility; (b) 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 (c) 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.

d. Changes to registration information

- The Waxman bill would require the registrant to notify FDA of any change in the registration information within 30 days after such change. Under current law, facilities have 60 calendar days to update required registration information or cancel registration.
- The Durbin bill has no comparable provision.

e. Suspension/cancellation of registration

- Both bills 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 both bills require that FDA provide notice and an opportunity for an informal hearing before suspending registration.
- The Waxman bill also provides that registration may be cancelled if the facility fails to update its registration as required; if the registration contains false, incomplete, or inaccurate information; or if the facility’s registration fee is not paid within 30 days after the due date.
- The Durbin bill would require FDA to issue regulations describing the standards it will use in making a determination to suspend registration. The Durbin bill further provides

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<sup>4</sup> FDA regulations currently require that the registration of a foreign facility include the name, address, and phone number of a “U.S. agent,” but there is no requirement that the U.S. agent be involved in distribution of the facility’s products. The Waxman bill also requires that the U.S. “distribution agent” have access to detailed information to enable the traceability of food that has been manufactured, processed, packed or held at the registered facility.

that a suspended registration shall be reinstated if FDA determines that adequate grounds do not exist to continue the suspension.

f. Effect of suspension, cancellation, or non-registration

- Both bills would prohibit the introduction into interstate commerce of food from unregistered facilities.
- The Waxman bill provides that a food is deemed to be misbranded if it was manufactured, processed, packed, or held in a facility that is not duly registered or a facility whose registration has been suspended or cancelled.
- The Durbin bill would make it a prohibited act, subject to injunction and criminal prosecution, to introduce food from an unregistered facility into interstate commerce. In addition, a domestic facility whose registration is suspended would not be permitted to import food, and food from a foreign facility whose registration has been suspended would be refused admission into the United States.

3. Preventive Controls Plans

a. Requirement of preventive controls plan

- Both bills would require the owner, operator, or agent in charge of each registered food facility to develop and implement a written preventive controls plan.
- The Waxman bill would require the owner, operator, or agent of each registered facility to conduct a hazard analysis and implement a written food safety plan. The food safety plan would be required to include the following elements: a hazard analysis, preventive controls, validation, monitoring, verification activities, procedures for taking corrective actions, recordkeeping, 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, preventive controls for specific product types. When FDA does so, however, a facility generally may use alternative preventive controls different from the ones mandated by FDA for if they effectively address the relevant hazard. FDA would also be required to issue guidance regarding minimum standards for hazard analysis, preventive controls, and documentation.
- The Durbin bill would require 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 (at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping. FDA would be required to issue regulations setting minimum standards for hazard analysis, preventive controls, and documentation. FDA would also be required to issue a guidance document related to hazard analysis and preventive controls.

b. Exemptions

- The Waxman bill provides that FDA may exempt, or modify the requirements for preventive controls on the part of, facilities that are solely engaged in producing food for animals, storing packaged foods that are not exposed to the environment, or storing raw agricultural commodities for further processing. In addition, in implementing these requirements, FDA may take into account differences between human food and animal feed.
- The Durbin bill would exempt: (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) (*see* below). 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.

c. Requirement to reassess plan

- The Waxman bill would require a facility to perform a new hazard analysis and to reassess its preventive controls if there is a change in its product or process that could affect its hazard analysis or if FDA determines it is necessary, but in no case less frequently than every two years.
- The Durbin bill would require a facility to conduct a reanalysis 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.

d. FDA access to plan

- The Waxman bill provides that FDA may require the owner, operator, or agent of a registered facility to submit its food safety plan as well as the supporting information relied on by the facility to select its prevent controls and documentation of all corrective actions taken during the preceding 2 years.
- The Durbin bill would require each facility to make its plan, together with documentation showing that the plan is being implemented, available to FDA promptly upon oral or written request.

e. Failure to comply

- The Waxman bill provides that a food is deemed to be adulterated if it has been manufactured, processed, packed, or held in violation of this requirement.
- The Durbin bill would make it a prohibited act, subject to injunction and criminal prosecution, to operate a facility that manufactures, processes, packs, or holds foods for sale in the U.S. that does not comply with this requirement.

#### 4. Performance Standards

- Both bills would require FDA, not less frequently than every 2 years, to evaluate epidemiologic data and other appropriate information in order to identify the most significant foodborne contaminants. 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.
- The Waxman bill provides that food will be deemed to be adulterated if it has been manufactured, processed, packed, transported, or held under conditions that do not meet FDA performance standards. FDA would be required to publish in the *Federal Register* a list of the foodborne contaminants with the greatest adverse impact on public health.
- The Durbin bill has no comparable provision.

#### 5. Inspections

##### a. Inspection frequency

- Both bills would require FDA to inspect each registered facility no less frequently than once every 4 or 5 years. In addition, both bills would require FDA to target its inspection resources based on each facility's risk profile. The bills make no distinction, with regard to inspection frequency, between domestic facilities and foreign facilities.
- The Waxman bill would require 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. In addition, inspection frequency would depend upon a facility's category, as follows:
  - Category 1: High-risk facilities that manufacture or process food would be randomly inspected at least every 6 to 12 months;
  - Category 2: Low-risk facilities that manufacture or process food, and facilities to pack or label food, would be randomly inspected at least every 18 months to 3 years; and
  - Category 3: Facilities that hold food would be randomly inspected at least 5 years.

FDA may, by guidance, modify the types of facilities in each category, alter the inspection frequencies based on the need to respond to foodborne illness outbreaks and recalls, or inspect a facility more frequently than specified above.

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- The Durbin bill would require 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.

b. Inspections of farms and restaurants

- The Waxman bill would give FDA authority to inspect farms and restaurants.
- The Durbin bill has no comparable provision.

c. Foreign inspections

- The Waxman bill would 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 assist FDA in achieving the inspection frequency described in the bill.
- The Durbin bill provides that FDA may enter into agreements with foreign governments to facilitate inspection of foreign facilities registered with FDA. Although the Durbin bill does not include a provision explicitly requiring that foreign food facilities be inspected as frequently as domestic food facilities, this is implicit in section 201 of the bill.

d. Inspections of imports

- The Durbin bill would require 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 (*see* below); whether the importer participates in the Voluntary Qualified Importer Program (*see* below); 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.

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- The Waxman bill has no comparable provision prioritizing inspection of imported foods.

e. Finished product test results

- The Waxman bill would require FDA to conduct a feasibility study and 2 or more pilot projects to evaluate the feasibility of collecting positive finished product test results from category 1 food facilities. Following completion of the feasibility study and pilot projects, but not later than 2 years after the date of enactment, FDA would require submission of finished product test results from category 1 facilities, as FDA deems feasible and appropriate, that document the presence of contaminants in food that pose a risk of serious adverse health consequences or death.
- The Durbin bill has no comparable provision.

f. Delaying, limiting, or refusing inspection

- The Waxman bill provides that a food will be deemed to be adulterated if it has been produced, manufactured, processed, packed, or held in any farm, factory, warehouse, or establishment and the owner, operator, or agent of such farm, factory, warehouse, or establishment, or any agent of a government authority in the foreign country where such farm, factory, warehouse, or establishment is located, delays or limits an inspection or refuses to permit entry or inspection.
- The Durbin bill has no comparable provision.

6. Requirement to Notify FDA of Hazardous Food

a. Reportable food registry

- Under existing section 417 of the FD&C Act, a “responsible party” is required to report to FDA if it determines that a food it has manufactured, processed, packed, or held is a “reportable food.” A “responsible party” is a person who submits the registration for the food facility where the article of food is manufactured, processed, packed, or held. A “reportable food” is a food (other than a dietary supplement or infant formula) for which there is a reasonable probability that use or exposure will cause serious adverse health consequences or death to humans or animals.
- The Waxman bill would amend the definition of “responsible party” to add the following: (a) “a person who owns, operates, is an agent of, or is otherwise responsible for such article of food on a farm”; (b) “a person who owns, operates, or is an agent of a restaurant or other retail food establishment”;<sup>5</sup> and (c) “a person that is required to

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<sup>5</sup> FDA would be required to make available “alternative means of reporting” for restaurants and other retail food establishments with limited ability for electronic reporting.

register under section 801(r) with respect to importation of such food” (*i.e.*, the importer). The Waxman bill also requires electronic submission to FDA of the results of any testing of the article of food and environmental testing of the facility where the article was manufactured, processed, packed, or held.

- The Durbin bill has no comparable provision.

b. New notification requirement

- The Waxman bill would require, in new section 420, that a “responsible party” or a food importer required to register under section 801(r) notify FDA as soon as practicable if such person has reason to believe that an article of food in interstate commerce is adulterated or misbranded in a manner that presents a reasonable probability that use or consumption of, or exposure to, the article will cause a threat of serious adverse health consequences or death to humans or animals. FDA may specify the manner and method of notification by regulation or guidance.
- The Durbin bill has no comparable provision.

7. Mandatory Recall Authority

- Both bills would give FDA mandatory recall authority.
- Under the Waxman bill, if FDA has reason to believe that use or consumption of, or exposure to, an article of food may cause serious adverse health consequences or death to humans or animals, FDA would have the authority to issue an order requiring any person who distributes such article to immediately cease distribution and notify any person to whom the food was distributed. If, after providing an opportunity for an informal hearing, FDA determines that the order should be amended to include a recall, FDA shall amend the order to require a recall. If FDA has a reasonable belief that the article of food presents an *imminent* threat of serious adverse health consequences or death to humans or animals, FDA may issue an emergency recall order, requiring an immediate recall and notification of affected persons. In the case of an emergency recall order, the informal hearing, if requested, would be held after initiation of the recall. A food offered for import would be refused admission if it is subject to an order to cease distribution or a recall order. Failure to comply with an order to cease distribution or recall a food would be a prohibited act, subject to injunction or criminal prosecution.
- Under the Durbin bill, 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, 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 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 require a recall. Failure to comply with the amended order would be a prohibited act, subject to injunction and criminal prosecution. In addition, the Durbin bill directs FDA to “consider” making public the names of retail consignees of recalled foods for Class I recalls, as the U.S. Department of Agriculture (USDA) does for meat and poultry recalls.

#### 8. Administrative Detention Authority

- Both bills would significantly expand FDA’s power to administratively detain foods. Under current law, FDA must have “credible evidence or information” that an article of food “presents a threat of serious adverse health consequences or death to humans or animals” to detain that article of food.
- The Waxman bill would give FDA the authority to administratively detain an article of food if FDA has “reason to believe” that the article is adulterated, misbranded, or otherwise in violation of the FD&C Act. It would also extend the maximum length of detention from 30 to 60 days, and it would extend the time for an informal hearing from 5 to 15 days.
- The Durbin bill would 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.

#### 9. Seizure

- The Waxman bill would amend the existing procedure for seizure actions against food to provide for expedited procedures. Specifically, it would provide that in seizure actions, “exigent circumstances shall be deemed to exist for all seizures brought under this section, and the summons and arrest warrant shall be issued by the clerk of the court without court review in any such case.”
- The Durbin bill has no comparable provision.

#### 10. Quarantine Authority

- The Waxman bill would give FDA the authority to quarantine any geographic area within the United States if: (a) FDA has credible evidence or information that an article of food presents an imminent threat of serious adverse health consequences or death to humans or animals; and (b) FDA reasonably believes the article of food is located in or originated from that geographic area. Quarantine authority includes the authority to prohibit or restrict the movement of food and vehicles being used to transport or hold food. FDA must first notify the appropriate official of the affected State and issue a public announcement. Violation of an FDA quarantine is a prohibited act, subject to injunction and criminal prosecution.

- The Durbin bill has no comparable provision.

## 11. Recordkeeping and Records Access/Traceability

### a. New recordkeeping requirements

- The Waxman bill would require FDA to issue regulations creating “a tracing system for food that is located in the United States or is for import into the United States.”<sup>6</sup> The tracing system would enable FDA “to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days.”<sup>7</sup> The records that would be required to be maintained under this “tracing system” appear to be in addition to the records of immediate previous sources and immediate subsequent recipients of food currently required under section 414(b) of the FD&C Act and 21 C.F.R. Part 1, Subpart J.
- The Durbin bill has no comparable provision.

### b. Changes to existing recordkeeping requirements

- The Waxman bill would amend section 414(b) to extend that the maximum retention period for records of immediate previous sources and immediate subsequent recipients of food from 2 years to 3 years. It would also remove the exemption for farms and restaurants. However, restaurants would only be required to maintain records showing their suppliers and “subsequent distribution other than to consumers.” It would require FDA to promulgate revised regulations implementing these changes.<sup>8</sup>

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<sup>6</sup> Food would be exempt from the tracing system if it is produced on a farm or fishery and sold directly to consumers, restaurants, or grocery stores. However, the farm or fishery would be required to keep records identifying the restaurant or grocery stores to which the food was sold for at least 6 months, and the restaurant or grocery store also would be required to keep records identifying the farm that was the source of the food. FDA may, by *Federal Register* notice, exempt or modify the traceability requirements with respect to other foods or with respect to a type of facility, farm, or restaurant.

<sup>7</sup> Before publishing a proposed rule, FDA would be required to identify technologies for tracing the distribution history of food and assess their costs and benefits. FDA would also be required to hold public meetings and conduct one or more pilot projects.

<sup>8</sup> The Waxman bill would also amend section 414(b) to authorize FDA to issue regulations requiring recordkeeping by persons who produce, manufacture, process, pack, transport, distribute, receive, or hold food in the United States “or for import into the United States.” This language appears to authorize recordkeeping requirements for overseas persons.

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- The Durbin bill has no comparable provisions.

c. Records access

- Both bills would 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.
- The Waxman bill would: (a) remove 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 in order to access such records; (b) remove the requirement that FDA provide a written notice in order to invoke this records access authority; (c) remove the exemption for farms and restaurants; and (d) give 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. In addition, the Waxman bill includes the following additional records access provisions:
  - FDA may require the owner, operator, or agent of a registered facility to submit to FDA its food safety plan, as well as the supporting information relied on by the facility to select its preventive controls and documentation of all corrective actions taken during the preceding 2 years.
  - If FDA sends a letter identifying specific records it wishes to see immediately upon commencing an inspection, such records must be made available immediately upon commencement of the inspection.
  - If FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death to humans or animals, FDA may require each person who manufactures, processes, packs, transports, distributes, receives, holds, or imports such food, or any article of food FDA determines may be affected in a similar manner, to submit to FDA all records reasonably related to such article of food. The request for submission may be made by notice served personally and outside normal business hours to the distribution agent or U.S. agent named in a facility's registration.
  - Every person engaged in the importing, brokering for import, or filing for import of any food shall permit FDA to inspect its facilities and to inspect and copy "any related records."
- The Durbin bill would only make one minor change in current law. 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.”

d. Failure to comply

- The Waxman bill provides that violation of “any requirement of the food tracing system” would be prohibited act, subject to injunction and criminal prosecution. In addition, an article of food offered for import would be refused admission if “the requirements of section 414 have not been complied with regarding such article.”
- The Durbin bill has no comparable provision.

12. Third-Party Certification

a. Accreditation of third-party certifying agents

- The Waxman bill would require certification by a “qualified certifying entity” only for certain imported foods. FDA would require certification, as an additional condition of granting admission to an article of food offered for import, if (a) such certification would assist FDA in making an admissibility determination with respect to food imported from a particular country or region, based on the adequacy of government controls or other information; (b) the food is a type of food that could pose a significant risk to health, and certification would assist FDA in determining whether the food poses such a risk; or (c) there is an agreement between FDA and the government of the exporting country providing for such certification. A qualified certifying entity may be a foreign government agency or an entity or individual determined by FDA to be qualified.
- The Durbin bill would require that FDA, no later than 2 years after the date of enactment, establish a system in which FDA would recognize accreditation bodies, and these accreditation bodies would accredit third-party auditors and audit agents to certify “eligible entities.”<sup>9</sup> 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. Thus, 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. In addition, only foreign facilities would be able to seek third-party certification.

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<sup>9</sup> The Durbin bill uses the terms “third-party auditor” and “audit agent” instead of the term “certifying agent.” The Durbin bill defines “third-party auditor” as a foreign government, foreign cooperative, or other qualified third party, as FDA determines appropriate, that conducts audits of eligible entities. It defines “audit agent” as an individual who is qualified to conduct food safety audits and who may be an employee or agent of a third-party auditor.

b. FDA use of third-party certification

- The Waxman bill provides that FDA would require third-party certifications only for certain imported foods. An article of food offered for import that is required to have such a certification and does not would be refused admission, and any food that is part of that shipment would be deemed to be misbranded.
- The Durbin bill 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.<sup>10</sup> 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.

c. Certifying agent's obligation to notify FDA

- The Durbin bill would require 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.
- The Waxman bill has no comparable provision. However, it would require a qualified certifying entity to notify FDA whenever it suspends or cancels a facility's certification.

d. Certification and re-certification

- The Durbin bill 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 Waxman bill has no comparable provision.

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<sup>10</sup> As explained later in this memorandum, the Durbin bill would authorize FDA to require an import certificate or "other assurances" for designated imported foods. Such import certificates may be issued by the government of the country from which the food originated or by an accredited third-party auditor or audit agent.

e. Certification required to accompany shipment of imported food

- The Waxman bill provides that, when required, certifications must be submitted electronically to FDA.
- The Durbin bill 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.

f. Renewal of accreditation

- The Waxman bill provides that FDA will require renewal of accreditation at such times as FDA determines appropriate.
- The Durbin bill 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.”

g. Withdrawal of accreditation

- The Durbin bill 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 found not to be in compliance with the bill’s requirements.
- The Waxman bill has no comparable provision.

h. FDA access to certifying agent records

- The Durbin bill would give 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.<sup>11</sup>
- The Waxman bill has no comparable provision.

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<sup>11</sup> The Durbin bill distinguishes between “regulatory audits” and “consultative audits.” A “consultative audit” is an audit the results of which are for internal facility purposes only.

13. Laboratory Accreditation; Direct Submission of Lab Tests to FDA

a. Laboratory accreditation

- Both bills would require FDA to establish a program for the recognition of laboratory accreditation bodies.
- The Waxman bill would require FDA to establish, by regulations or guidance, a program for the recognition of lab accreditation bodies based on standards FDA deems appropriate. FDA would be required to post on its website a current list of lab accreditation bodies recognized by FDA. Recognized lab accreditation bodies would be required to promptly notify FDA whenever they accredit a new laboratory or withdraw or suspend accreditation. The violation of any requirement of this section would be a prohibited act, subject to injunction and criminal prosecution.
- The Durbin bill would require FDA 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 be required to periodically, at least every 5 years, reevaluate recognized accreditation bodies.

b. Requirement to use accredited labs for regulatory tests

- The Waxman bill provides that, whenever analytical testing of an article of food is conducted as part of testimony for purposes of determining admissibility or for other purposes as FDA deems appropriate, such testing must be conducted by a lab that has been accredited for the analytical method used by a recognized lab accreditation body. In exigent circumstances, FDA may waive the requirement that the lab only use analytical methods for which it has been accredited. The lab must be independent of the person on whose behalf the testing is conducted, and the samples must be collected by the lab or an independent third party. FDA may observe an accreditation body's onsite audit of a lab or may conduct its own onsite audit of a lab accredited by a recognized accreditation body (including inspection and copying of "any related records").
- The Durbin bill 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.

c. Prior notification to FDA

- The Waxman bill would require the person on whose behalf the testing is conducted to notify FDA before any samples are collected. Such notice shall identify the article of food, the location of the article, and each lab that will analyze samples.
- The Durbin bill has no comparable provision.

d. Requirement to report lab results to FDA

- The Waxman bill would require the accredited lab to submit test results directly to FDA the results of all tests conducted on each sample, as well as information FDA deems appropriate to determine whether the lab is accredited, identify the article of food, evaluate the test results, and determine whether all requirements have been met.
- The Durbin bill would require that lab tests be sent directly to FDA in order to be used in the making of regulatory decisions.

14. Imports

a. Registration

- The Waxman bill would require food importers to register with FDA and pay an annual fee of \$500. If a person is subject to registration fees for both registered food facilities and because such person is a registered food importer, FDA would waive one of the two fees. Customs brokers and filers would also be required to register with FDA, but would not be required to pay a registration fee. The registration of an importer or customs broker or filer would be subject to suspension and cancellation, following notice and an informal hearing, for violations of the FD&C Act or for knowing or repeated submission or inaccurate or incomplete information to FDA. In the case of importers, FDA may also condition maintenance of registration on an importer's compliance with good importer practices. It would be a prohibited act, subject to injunction and criminal prosecution, for an importer or customs broker or filer to fail to register, and food imported or offered for import by an importer or customs broker or filer that is not duly registered would be deemed to be misbranded.
- The Durbin bill has no comparable provision.

b. Voluntary program to expedite imports

- The Waxman bill provides that FDA may establish, by regulation or guidance, a program to facilitate movement of food through the import process if each facility involved in the production, manufacture, processing, packaging, and holding of the food has agreed to

abide by, and has been determined by FDA to be in compliance with, a set of food safety and security guidelines to be developed by FDA.

- The Durbin bill would require 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 for import food from a facility that has been certified by an accredited third-party auditor.<sup>12</sup> 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.

c. Foreign supplier verification program

- The Durbin bill would require every U.S. importer to have a Foreign Supplier Verification Program.<sup>13</sup> 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, 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). 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

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<sup>12</sup> For purposes of the Voluntary Qualified Importer Program, the Durbin bill defines "importer" to mean "the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States."

<sup>13</sup> For purposes of this requirement, the Durbin bill defines "importer" to mean, with respect to an article of food, either: (a) the U.S. owner or consignee of the article of food at the time of entry into the United States; or (b) if there is no U.S. owner or consignee, the U.S. agent or representative of a foreign owner or consignee of the article of food at the time of entry into the United States. The owner, operator, or agent in charge of a facility subject to FDA's seafood HACCP, juice HACCP, or low acid canned foods regulations would be deemed to be in compliance with this requirement with respect to such facility.

required to have Foreign Supplier Verification Programs. Importing food, or offering food for import, if the importer does not have in place a Foreign Supplier Verification Program 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.

- The Waxman bill has no comparable provision.

d. Import certificates

- The Waxman bill would require certification by a “qualified certifying entity,” as an additional condition of granting admission to an article of food offered for import, if FDA determines that (a) such certification is needed to ensure the safety of food imported from a particular country or region, or (b) such certification is needed to ensure that effective preventive controls have been properly implemented for a type of food that could pose a significant risk to health in the absence of such controls. A qualified certifying entity may be a foreign government agency or an entity or individual determined by FDA to be qualified.
- The Durbin bill would authorize 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.

e. Import filings

- The Waxman bill provides that submission of a unique facility identifier is a “condition of importation.” An article of food offered for import shall be refused admission unless the importer, customs broker, or filer submits the unique facility identifier for the facility used for the importation of such article. The Waxman bill also provides that failure to submit required import information, or failure to submit accurate and complete information in any import filing, is a prohibited act, subject to injunction and criminal prosecution.
- The Durbin bill has no comparable provision.

f. Delaying, limiting, or refusing inspection

- The Waxman bill provides that a food will be deemed to be adulterated if it has been produced, manufactured, processed, packed, or held in any farm, factory, warehouse, or establishment and the owner, operator, or agent of such farm, factory, warehouse, or establishment, or any agent of a government authority in the foreign country where such

farm, factory, warehouse, or establishment is located, delays or limits an inspection or refuses to permit entry or inspection.

- The Durbin bill 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.

g. Other import provisions

- The Durbin bill would require 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 Durbin bill 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.
- The Waxman bill provides that any person engaged in the importing, brokering for import, or filing for import of food shall permit FDA to inspect its facilities and to inspect and copy “any related records.”

15. Fees

- Both bills would impose new fees on the food industry. In addition, both bills would authorize FDA to assess a fee for issuing export certificates.
- The Waxman bill would impose the following new fees on industry:
  - An annual registration fee of \$500 for food facilities required to register with FDA (beginning in fiscal year 2010 and which would sunset after fiscal year 2014);
  - An annual registration fee for food importers, which would be set at \$500; and
  - A reinspection fee to be assessed if FDA reinspects a facility because of any violations of the FD&C Act by that facility or because of a recall. The amount of the reinspection fee would be set so as to fully defray the costs of conducting reinspections.
- The Durbin bill would impose the following new fees for fiscal year 2010 and each subsequent fiscal year:
  - An annual fee from each domestic facility that is subject to a reinspection 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);

- 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);
- 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
- An annual fee from each importer that is subject to a reinspection 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).

#### 16. Civil Fines

- The Waxman bill would authorize 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 \$20,000 for individuals (with a cap of \$50,000 in a single proceeding) and up to \$250,000 for other persons (with a cap of \$1 million in a single proceeding). For violations committed "knowingly," the bill authorizes fines of up to \$50,000 for individuals (with a cap of \$100,000 in a single proceeding) and \$500,000 for other persons (with a cap of \$7.5 million in a single proceeding). Each prohibited act, and each day it continues, would be considered a separate offense.
- The Durbin bill would authorize FDA to assess civil fines for failure to comply with a recall order (*see* "Mandatory Recall Authority" above). 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.

#### 17. Criminal Penalties

- The Waxman bill would increase the criminal penalties for certain specified prohibited acts (*e.g.*, the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded food or an unsafe dietary supplement) from a maximum of one year imprisonment and a \$1,000 fine to 10 years imprisonment and a fine authorized under Title 18 of the United States Code.
- The Durbin bill has no comparable provision.

18. Fresh Produce and Other Raw Agricultural Commodities

a. GAPs and regulations

- The Waxman bill would require FDA to publish updated Good Agricultural Practices (GAPs) no later than 1 year after the date of enactment.<sup>14</sup> In addition, the Waxman bill would require FDA to establish, by regulation, science-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of “raw agricultural commodities<sup>15</sup> (1) that are from a plant or a fungus; and (2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.” Food grown, harvested, processed, packed, sorted, transported, or held under conditions that do not meet such standards would be deemed to be adulterated.
- The Durbin bill would 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. It would also 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. Such regulations 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. FDA would be required to 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. Producing or harvesting fresh produce not in accordance with FDA minimum standards, or a variance,<sup>16</sup> would be a prohibited act, subject to injunction and criminal prosecution.

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<sup>14</sup> The formal name for this guidance document is “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (Oct. 26, 1998).

<sup>15</sup> The FD&C Act defines “raw agricultural commodity” as “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.” 21 U.S.C. 321(r).

<sup>16</sup> The Durbin bill provides that the FDA regulations on produce safety shall include a process whereby States and foreign countries may request a variance necessary in light of local growing conditions, provided the practices to be followed under the variance are reasonably likely to ensure the produce is not adulterated. The Dingell bill refers to a subsection 419A(e) dealing with variances, but there is no subsection (e) in 419A.

b. Traceability

- The Waxman bill would remove 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). The Waxman bill also would require FDA to issue regulations creating “a tracing system for food that is located in the United States or is for import into the United States” (*see* Recordkeeping and Records Access/Traceability above). However, the tracing system regulations would exempt food that is produced on a farm or fishery and sold directly to consumers, restaurants, or grocery stores, except that the farm or fishery would be required to keep records identifying the restaurant or grocery store to which the food was sold for at least 6 months.
- The Durbin bill would require 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.

19. Country of Origin Labeling

- The Waxman bill would, for the first time, make country of origin labeling a requirement of the FD&C Act. It would provide that a processed food is misbranded unless its labeling identifies the country in which final processing of the food occurred. It would provide that a non-processed food is misbranded unless its labeling identifies 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. The implementing regulations would be required to provide that food is in compliance if:

- (a) in the case of a processed food, the label informs the consumer where final processing occurred in accordance with U.S. Customs and Border Protection (CBP) requirements;<sup>17</sup> or (b) in the case of a non-processed food, the label informs the consumer of the country of origin in accordance with U.S. Department of Agriculture requirements.
- The Durbin bill has no provision on country of origin labeling.

## 20. Miscellaneous Provisions

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

- The Waxman bill would give FDA the power to issue subpoenas requiring the attendance and testimony of witnesses and production of documents and “other things” for the purpose of any hearing, investigation, or other proceeding regarding violations of the FD&C Act, the Public Health Service Act, or the Federal Anti-Tampering Act. Failure to obey such a subpoena would be a prohibited act, subject to injunction and criminal prosecution. [In addition, food offered for import would be refused admission if any person who manufacture, processed, packed, held, or shipped such food has failed or refused to obey a subpoena that was issued, in whole or in part, for the purpose of determining whether food is adulterated or misbranded.]
- The Waxman bill would require FDA to post on its website, within 60 days after receipt, all GRAS (generally recognized as safe) notifications it receives along with their supporting scientific justifications. Currently, FDA posts agency response letters to GRAS notifications, but not the notifications themselves. The bill would also require FDA to acknowledge receipt of a GRAS notification within 60 days by informing the notifier in writing.
  - The Waxman bill would make 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.
  - The Waxman bill would prohibit 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.

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<sup>17</sup> In this regard, it should be noted that many processed foods currently are not required to bear this information. CBP regulations do not require country of origin information on labels of domestically produced foods. In addition, CBP regulations require labeling to identify the country of origin, which may not be the same as the country in which final processing occurs. Therefore, if this provision becomes law, some processed foods may be required to identify on their labels both a country of origin and a country of final processing.

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- The Waxman bill would grant “whistleblower protections” to any employee of a person required to submit “any information related to a food” to FDA.
- The Waxman bill explicitly provides that it does not modify or otherwise affect any action or the liability of any person under State law.
- The Waxman bill would require a unique facility identifier for each registered food facility and each facility at which a person required to register under section 801(r) or (s) (*i.e.*, an importer or customs broker or filer) conducts business.
- The Waxman bill provides that a new infant formula is deemed to be misbranded if FDA has not issued a letter confirming that the product has satisfied certain registration requirements. In addition, it would: (a) provide that the quality factor requirements for infant formula may include “one or more clinical studies to demonstrate that the new infant formula supports normal physical growth of infants”; (b) authorize FDA to inspect and copy records of regularly scheduled audits of infant formula manufacturers; and (c) require submission of scientific and other evidence (rather than merely assurances) that the infant formula complies with FDA-established quality factors, good manufacturing practices, and nutrient requirements.<sup>18</sup>
- The Waxman bill would require FDA to notify Congress, no later than December 31, 2009, whether the available scientific data support a determination that there is a reasonable certainty of no harm from approved uses of bisphenol A in polycarbonate plastic and epoxy resin. If such a determination cannot be made, FDA would be required to notify Congress what actions it intends to take to restrict use of bisphenol A.<sup>19</sup>

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

- The Durbin bill would require 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).
- The Durbin bill would require FDA to issue regulations governing the sanitary transportation of food no later than 1 year after the date of enactment.
- The Durbin bill would require 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

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<sup>18</sup> Majority staff have indicated that further amendments to this provision may be made before the bill goes to the House floor.

<sup>19</sup> The new FDA Commissioner, Dr. Margaret Hamburg, has already announced a review of the safety of approved uses of bisphenol A in food and beverage containers.

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- 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 Durbin bill would require 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.<sup>20</sup> 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.

OFWTBM:mhh

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<sup>20</sup> FDA has already issued several guidance documents on food security preventive measures, which are available at <http://www.cfsan.fda.gov/~dms/defguids.html>.