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# Food & Drug

## E-ALERT

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## Bipartisan Food Safety Bill Introduced in the Senate

On March 3, 2009, Senators Dick Durbin (D-IL), Judd Gregg (R-NH), Ted Kennedy (D-MA), and Richard Burr (R-NC) introduced a bipartisan food safety bill entitled the "FDA Food Safety Modernization Act" ("the bill" or "the Durbin bill").[1] The bill would amend the Federal Food, Drug and Cosmetic Act ("FDCA") and is intended to enhance the safety of the food supply.

This alert summarizes the bill's provisions, all of which relate to food safety. The current version of the bill is nearly identical to the one Senator Durbin introduced last year in the wake of a salmonella outbreak linked to fresh peppers. A key change is that Senator Ted Kennedy (D-MA) has since joined as a co-sponsor. This version of the bill has been introduced in the aftermath of the largest food recall in history, involving salmonella-tainted peanut butter products. If enacted as drafted, the bill would impose substantial new obligations on FDA and the food industry, both domestically and overseas. The bill would also significantly expand FDA's authority in the field of food safety regulation. Notably, the bill follows just weeks after Representative John Dingell (D-MI) introduced his food and drug safety import bill, the "Food and Drug Administration Globalization Act of 2009" ("the Dingell bill").[2] This alert will also note key differences between the provisions of the Durbin bill and the food safety-related provisions of the Dingell bill.

### Summary of Provisions of the Durbin Bill

The Durbin bill addresses food safety regulation under three broad headings: prevention of food safety problems, detection and response to such problems, and improving the safety of imported food.

#### A. Provisions Aimed at Preventing Food Safety Problems

The key provisions of the bill aimed at *improving capacity to prevent food safety problems* would have the following effects:

*1. Enhanced FDA Access to Records*

The Durbin bill would enhance FDA authority to access food-related records – including laboratory test results – in multiple contexts:

- FDA would have access not only to records related to food that the agency believes may be adulterated or may pose health risks, but also to records related to any other article of food that FDA believes *could be affected in a similar manner.*
- Food facility operators would be required to provide to FDA, upon request, the written plans they develop to comply with the provisions of the bill relating to hazard analysis (discussed further below in A3).

[1] S. 510, 111th Cong. (2009).
[2] *See* Covington & Burling LLP's E-Alert on the Dingell bill, available by clicking here.

- Food importers would be required to provide to FDA, upon request, records related to the foreign supplier verification program (discussed further below in C1).

*2. Expanded Registration Requirements for Food Facilities*

The bill would expand existing registration requirements for food facilities to require that each domestic and foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered and *subsequently re-registered on a biennial basis.* Under current law, no facility re-registration requirement exists. The bill would also empower FDA to suspend a facility's registration if there is a reasonable probability that food from the facility could cause serious adverse health consequences or death. The Dingell bill provisions are stricter, requiring *annual* re-registration of facilities, and requiring FDA to suspend the registration of any facility that fails to comply with re-registration requirements. Additionally, the Dingell bill would impose registration fees on food facilities (with an exemption for small businesses), while the Durbin bill proposes no such fee.

*3. Hazard Analysis and Risk-Based Preventive Controls*

The bill would mandate that all owners, operators, or agents in charge of a food facility take four basic steps to ensure the safety of the food supply:

> (i) identify and evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility;
>
> (ii) implement preventive controls to minimize such hazards and protect the food supply from adulteration or misbranding;
>
> (iii) monitor the effectiveness of preventive controls implemented; and
>
> (iv) establish corrective action procedures that the facility will implement if the preventive controls are found to be ineffective.

In conjunction with these responsibilities, facility owners would need to verify the adequacy of their efforts, maintain records documenting monitoring and preventive control efforts, and prepare a written plan – *which would be available to FDA on request* – documenting procedures to ensure compliance with all such requirements. A facility owner would be required to re-analyze the procedures upon the occurrence of any significant change at the facility that could increase food-related hazards, and even if no changes occur, the procedures would need to be reviewed at least once every three years. The bill would require FDA to issue regulations and guidance to establish science-based minimum standards for implementing a hazard analysis program. A facility's failure to comply with these requirements would constitute a prohibited act under section 301 of the FDCA. These provisions are similar to the Dingell bill's requirement that food facilities develop and implement a written food safety plan.

*4. Safety Standards for Fresh Produce*

The Durbin bill would direct FDA to issue regulations establishing safety standards for fresh produce. The bill would require FDA to prioritize regulations for fruit and vegetables that constitute raw agricultural commodities and that have been associated with foodborne illness outbreaks. The bill provides that a failure to comply with these standards is a prohibited act under section 301 of the FDCA. These provisions are similar to those in the Dingell bill.

*5. Protection Against Intentional Adulteration*

Within two years of the enactment of the bill, FDA would be required to promulgate regulations to protect against the intentional adulteration of food. These regulations would only apply to food: (i) with clear vulnerabilities, such as a short shelf-life, or susceptibility to intentional contamination at critical control points, (ii) in bulk or batch form, prior to being packaged for the final consumer, and (iii) for which there is a high risk of intentional contamination that may cause serious adverse health consequences or death.

*6. Authority to Collect Fees*

The bill would authorize FDA to collect fees from domestic facilities and importers of food solely to cover: (i) the cost of reinspection (for those facilities that do not pass muster on the first FDA inspection), (ii) the costs associated with food recalls (for those facilities subject to a recall in that fiscal year), and (iii) the administrative costs associated with the voluntary qualified importer program. While these fees are few and narrowly targeted, the Dingell bill proposes a host of industry fees – including registration fees – the revenue from which would be used to fund increased FDA inspections. In contrast, the Durbin bill would fund increased inspections entirely through appropriations.

*7. National Agriculture and Food Defense Strategy*

The Durbin bill would require a collaborative effort from the Departments of Health and Human Services, Agriculture, and Homeland Security to implement a national strategy focused on preparedness, detection, emergency response, and recovery in the context of potential crises in the food supply system.

## B. Provisions Aimed at Detecting and Responding to Food Safety Problems

The key provisions of the Durbin bill aimed at *improving capacity to detect and respond to food safety problems* would have the following effects:

*1. Increased Inspections*

Beginning on the date of enactment of the Durbin bill, FDA would increase the frequency of inspection of all food facilities. It would need to conduct annual inspections of high-risk facilities, and it would need to ensure that other facilities were inspected at least once every four years. FDA would also allocate resources to inspect imported food, prioritizing the review of higher-risk food items based on factors such as the country of origin, the particular type of food, the compliance history of the foreign supplier, and whether the foreign facility is certified by an FDA-accredited party. The Dingell bill also provides for a similar, enhanced, risk-based inspection schedule.

*2. Recognition of Lab Accreditation for Analyses of Foods*

Within two years of the enactment of the bill, FDA would be required to recognize accreditation bodies to accredit laboratories with a demonstrated capability to conduct analytical testing of food products. Accredited laboratories may be domestic or foreign, provided that all meet the standards applicable to domestic accredited laboratories. FDA would also need to develop model accreditation standards. Once accredited laboratories have been recognized, all required food testing, including testing of foods offered for import, would need to be done by one of these entities. The results of testing *would be provided directly to FDA.* These provisions are similar to those under the Dingell bill, but the Dingell bill provisions would take effect three years after enactment.

*3. Enhanced Traceback and Recordkeeping*

The bill would require enhancement of the ability to track and trace fruits and vegetables in the event of a foodborne illness outbreak. The bill specifies that FDA should establish a pilot project to explore and evaluate potential methods for rapidly and effectively tracking such raw produce. The agency would then report its findings to Congress, recommend traceback and trace forward procedures, and then subsequently engage in rulemaking to effectuate such recommendations. The Dingell bill also contains provisions pertaining to the traceability of food, but they are more definitive and expansive when compared to the Durbin bill's exploratory approach.

*4. Mandatory Recall Authority*

Under the Durbin bill, if FDA finds a reasonable probability that an article of food is adulterated or misbranded, and that exposure to such article will cause serious adverse health consequences or death to humans or animals, it would provide the responsible party with an opportunity to voluntarily recall such article from distribution. If, however, the party does not voluntarily recall the food, FDA may, by order, immediately cease distribution of the article and notify the public. The Dingell bill also proposes to give FDA mandatory recall authority.

*5. Enhanced Administrative Detention Authority*

The bill amends and strengthens currently effective statutory provisions by altering the standards FDA would use to determine that a particular article of food should be detained. While current law requires "credible evidence or information," the Durbin bill requires only a "reason to believe" that food meets detention criteria. Similarly, while current law requires that an article of food present "a threat of serious adverse health consequences or death to humans and animals," the Durbin bill simply requires that the food be "adulterated or misbranded."

## C. Provisions Aimed at Improving the Safety of Imported Food

The key provisions of the Durbin bill aimed at improving the safety of imported food would have the following effects:

*1. Foreign Supplier Verification Program*

Importers would need to perform a risk-based verification that imported food is not adulterated or misbranded, and that it is produced in compliance with the bill's provisions relating to hazard analysis and produce safety. Importers would also be required to maintain any records related to the foreign supplier verification program for at least two years, and provide these records, upon request, to FDA. Importation of food by an importer without a foreign supplier verification program in place would be a prohibited act under section 301 of the FDCA.

*2. Voluntary Qualified Importer Program*

Within one year of enactment of the bill, FDA would need to establish a voluntary program to provide for the *expedited* review and importation of food. In order to be eligible for participation in this program, importers would need to be obtaining food from foreign suppliers who have been specifically certified after undergoing an audit by FDA-accredited third-party auditors. While the Durbin bill proposes voluntary certification for foreign suppliers, the Dingell bill would *require* foreign suppliers to undergo the certification process. Uncertified imports would not be allowed into the United States under that bill.

*3. Authority to Require Import Certifications for Food*

The Durbin bill would give FDA the authority to require import certification from foreign suppliers, providing assurances that imported food complies with all applicable requirements of the FDCA. FDA's determination of the need for certification would be based on public health considerations, including risks associated with the food type or place of origin.

*4. Inspection of Foreign Food Facilities*

The Durbin bill would give FDA power to enter into agreements with foreign governments to facilitate inspection of foreign facilities registered as food suppliers. If a foreign government or a registered foreign facility refuses to allow FDA to enter and inspect the facility, food from that source would be refused admission into the United States.

*5. Review of Regulatory Authority of a Foreign Country*

FDA would be authorized to review information from a foreign country detailing its regulatory regime, and conduct on-site audits in such foreign country in order to determine whether the country can provide reasonable assurances that its food supply is equivalent in safety to that of the United States. The Dingell bill contains similar provisions.

*6. Establishment of Foreign FDA Offices*

Under the Durbin bill, by October 1, 2010, FDA would be required to establish offices in at least five foreign countries to facilitate efforts to ensure the safety of food exported by those countries into the United States.

## Other Provisions

Aside from the major provisions discussed thus far, the Durbin bill would have several other effects on FDA and the food industry, some of which are highlighted briefly below:

- *Surveillance System* – The Department of Health and Human Services, acting through the Centers for Disease Control and Prevention, would be required to enhance surveillance systems to monitor food-borne illnesses. This effort would also involve implementing strategies to improve the food safety and defense capacities of state and local agencies. The Dingell bill contains similar surveillance-based provisions.
- *Salmonella in Shell Eggs* – Within one year of enactment, FDA would need to issue a final rule addressing the prevention of salmonella enteritidis in shell eggs during production.
- *Sanitary Food Transportation* – Within one year of enactment, FDA would need to promulgate regulations addressing the sanitary transportation of food.
- *Food Allergies and Anaphylaxis* – The Department of Health and Human Services and the Department of Education would need to cooperate to develop guidelines and protocols to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs.
- *Increased FDA Resources* – The bill appropriates $825 million to fund food-related activities in FY 2010, and "such sums as may be necessary" for subsequent fiscal years.
- *Increased FDA Staff* – The bill proposes yearly increases in personnel goals.

## Conclusion

If enacted, the Durbin bill would impose significant new obligations on FDA and the food industry, with respect to both imported and domestically-manufactured food. In the aftermath of the peanut butter recall crisis, it is likely that Congress will consider such a bill more seriously than it would have in the past. The Durbin bill is the first food safety legislation proposal to be introduced in the Senate this term. Compared with the Dingell proposal – the leading House bill – the Durbin bill's most notable distinction is that it does not include substantial user fees. Durbin has stated that this difference in approach is based on the controversy surrounding Dingell's proposal and the desire to ensure bipartisan support in the Senate. Thus far, the Durbin bill, with its smaller number of fees and mandatory programs, appears to be more palatable to some industry groups.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:


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Ms. Jijon is not yet a member of the District of Columbia bar. She is supervised by principals of the firm.