Food & Drug

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Putnam & Costa Introduce Comprehensive Food Safety Bill

On March 5, 2009, Representatives Adam Putnam (R-FL) and Jim Costa (D-CA) introduced a comprehensive food safety bill entitled the "Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009" or the "Safe FEAST Act of 2009" ("the bill" or "the Putnam-Costa 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.

Representatives Putnam and Costa introduced a similar bill in April 2008 in the wake of an E.coli bacteria outbreak linked to spinach from California. This year, they re-introduce the bill in the wake of the salmonella outbreak linked to peanut products. This bill also follows closely on the heels of the introduction of other, similar food safety reform legislation, such as the House bill introduced by Representative John Dingell (D-MI) in late January,[2] and the bipartisan Senate bill introduced by Senators Dick Durbin (D-IL), Judd Gregg (R-NH), Ted Kennedy (D-MA), and Richard Burr (R-NC) on March 3.[3] This alert summarizes the key provisions of the Putnam-Costa bill, and notes similarities and differences between this bill and the Dingell and Durbin bills.

Summary of Provisions of the Putnam-Costa Bill

The Putnam-Costa bill addresses food safety regulation under three broad headings: general food provisions, detection and surveillance, and specific provisions for imported food.

A. General Food Provisions

The key provisions of the bill aimed at addressing general food safety issues would have the following effects:

1. Enhanced FDA Access to Records During Food-Related Emergencies

The Putnam-Costa bill would grant FDA expanded access to food facility records in the following 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 A4).

[1] H.R. 1332, 111th Cong. (2009).
[2] *See* Covington & Burling LLP's E-Alert on the Dingell bill, available by clicking here.
[3] *See* Covington & Burling LLP's E-Alert on the Durbin 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).

These provisions are similar to those proposed in the Durbin bill.

2. Expanded Registration Requirements for Food Facilities

The bill would expand current registration requirements for food facilities to require all food facilities and importers to register and *subsequently re-register on a biennial basis*. Under current law, no 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. These provisions are similar to those proposed in the Durbin bill. 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 and Putnam-Costa bills propose no such fees.

3. Mandatory Recall Authority

Under the bill, if FDA determines that food is adulterated or misbranded (such that it contains undeclared allergens), and that exposure to such food "will cause" serious adverse health consequences or death to humans or animals, the agency would provide the responsible party with an opportunity to voluntarily recall the food from distribution. If, however, the party does not voluntarily recall the food, FDA may order the party to immediately cease distribution of the article and notify the public. Although all three bills propose to give FDA mandatory recall authority, the language in the Dingell bill is significantly different than that in the Durbin and Putnam-Costa bills. In the Dingell bill, the Secretary, when notified of a "suspected" adulteration or misbranding of food, may, in essence, mandate a recall on a finding that the food "may result in illness or injury." The Durbin and Putnam-Costa bills identically provide that the Secretary can, in essence, mandate a recall upon a finding that there is a "reasonable probability" that a food is adulterated or misbranded and that its use "will cause serious adverse health consequences or death to humans or animals." Thus, the Dingell bill would allow the Secretary to mandate recalls following a less serious triggering event ("suspected" versus "reasonable probability of" adulteration or misbranding) and a lower level of potential harm ("may result in illness or injury" versus "will cause serious adverse health consequences or death to humans or animals) than would the Durbin or Putnam-Costa bills.

4. Hazard Analysis and Risk-Based Prevention 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;
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> (ii) implement preventive controls to minimize such hazards and protect the food supply from adulteration or misbranding;
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> (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. High-risk facilities would be required to submit their plans to FDA's Center for Food Safety and Applied Nutrition ("CFSAN"). 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 would provide flexible compliance timeframes for small and very small businesses, and would deem facilities in compliance with existing seafood, juice, and low-acid canned foods regulations to be in compliance with this section. These provisions are similar to the Dingell and Durbin bill requirements that food facilities develop and implement a written food safety plan.

5. Performance Standards

The bill would require FDA – not less than every two years – to determine the most significant food-borne contaminants and where appropriate, issue science-based guidance documents, action levels, and regulations to prevent adulteration. This requirement is similar to those proposed by both the Dingell and Durbin bills.

6. *Standards for the Safety of Fruits and Vegetables*

The bill would give FDA authority to set commodity-specific standards for the safe production, harvesting, handling, and packing of fruits and vegetables. FDA would also have authority to establish mandatory standards for produce considered to be high-risk, as well as guidance for Good Agricultural Practices ("GAPS") for all produce. These provisions are similar to those in the Dingell and Durbin bills.

7. Increased, Targeted Inspections

Under the Putnam-Costa bill, FDA would be required to allocate food inspection resources according to the risk profile of food facilities, as well as other important criteria. FDA would be required to increase the frequency of inspection of all facilities. High-risk facilities would need to be inspected at least every two years, and all other facilities would need to be 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 and Durbin bills also provide for similar, enhanced, risk-based inspection schedules.

8. Enhanced Administrative Detention Authority

The bill would amend and strengthen 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 Putnam-Costa 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 Putnam-Costa bill simply requires that the food be "adulterated or misbranded." These provisions are similar to those in the Durbin bill.

9. National Agriculture and Food Defense Strategy

The Putnam-Costa bill would require the Department of Health and Human Services to coordinate with the Department of Agriculture and the Department of Homeland Security to develop a national agricultural and food defense strategy focused on specific emergency preparedness, detection, response, and recovery goals in the context of food-related emergencies. The Durbin bill contains similar provisions.

10. Authority to Collect Fees

The bill would authorize FDA to assess fees to cover the costs of compliance failures (recalls and reinspections), as well as for services rendered, such as the issuance of export certificates, and participation in the voluntary qualified importer program (discussed further below in C2). Like those in the Durbin bill, these fees are few and narrowly targeted. The Dingell bill, in comparison, proposes numerous industry fees, such as registration fees, which are intended to fund FDA's increased inspections.

B. Detection, Surveillance, and Response

The key provisions of the bill aimed at addressing detection, surveillance, and response to food safety problems would have the following effects:

1. Recognition of Laboratory Accreditation

Within two years of enactment, the bill would require FDA to review laboratory accreditation bodies and to establish a publicly available registry of FDA-recognized accrediting bodies that would accredit food testing laboratories, including state and locally-run and operated laboratories. Once accredited laboratories have been recognized, all laboratory testing of food for FDA regulatory purposes would have to be conducted by an FDA-accredited laboratory (or one accredited by an accrediting body recognized by FDA). The results of such testing would be *provided directly to FDA.* These provisions are similar to those in the Durbin bill and the Dingell bill, but the Dingell bill provisions would take effect three years after enactment.

2. Enhanced Traceback and Recordkeeping

The bill would require enhancement of the ability to track and trace fruits, vegetables, and other raw commodities in the event of an emergency. FDA would be required to establish a pilot project to test and evaluate methods for rapidly and effectively tracking and tracing raw produce. Upon completion of the pilot project, FDA would need to report its findings to Congress, recommend traceback and trace forward procedures, and subsequently engage in rulemaking to implement its recommendations. These provisions are similar to those in the Durbin bill. The Dingell bill contains traceability provisions, but these are more concrete and expansive when compared with the approach taken by either the Durbin bill or the Putnam-Costa bill.

3. Surveillance System

The bill would require the Department of Health and Human Services to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on such illnesses. The development of the surveillance system would be a collaborative effort involving stakeholders in federal, state, and local food safety and health agencies, as well as the food industry, consumer organizations, and academia. The food safety and defense capabilities of state and local agencies would also need to be enhanced. Both the Durbin bill and the Dingell bill contain similar provisions pertaining to

surveillance.

C. Specific Provisions for Imported Food

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

1. Foreign Supplier Verification Program

The bill would require importers to perform risk-based food safety supplier verification activities in order to mitigate risks posed by imported foods. Such activities would implicate processes such as sanitation, storage, handling, training, and recordkeeping. FDA would be required to issue guidance to assist importers in developing foreign supplier verification programs. Importers would 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. Importers required to comply with existing seafood, juice, and low-acid canned foods regulations would be deemed to be in compliance with this section. 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. The Durbin bill contains similar requirements.

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. To be eligible for participation in this program, importers would need to obtain food from foreign suppliers who have been specifically certified by FDA-accredited third party auditors. The Durbin bill proposes similar voluntary certification procedures. The Dingell bill provisions are stricter, and would *require* foreign suppliers to undergo certification. Under the Dingell bill, uncertified imports would not be allowed into the United States.

3. Authority to Require Certification of Certain Imports

The Putnam-Costa bill would give FDA the authority to require export certificates for high-risk foods from certifying entities in the exporting countries. Shipments lacking the required certificates would not be permitted to enter the United States. FDA's determination of the need for certification would be based on public health considerations, such as risks associated with a particular food type or the country of export. These provisions are similar to those in the Durbin bill.

4. Prior Notice of Imported Food Shipment

The Putnam-Costa bill would amend the FDCA to require prior notice for an imported food to include the name of any country that refused entry of the food. The Durbin bill proposes a similar requirement.

5. Review of Regulatory Authority of a Foreign Government

FDA would be authorized to review the statutes, regulations, and standards of foreign countries, and conduct on-site audits to verify regulatory compliance in order to determine if exporting countries can provide reasonable assurances that their food supply is equivalent in safety to that of the United States. The Durbin and Dingell bills contain similar provisions.

6. Building Capacity of Foreign Governments

Within two years of enactment, FDA would be required to develop a comprehensive plan to help expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries. The Durbin bill contains similar provisions.

7. Inspection of Foreign Food Facilities

The Putnam-Costa bill would give FDA authority to enter into agreements and arrangements 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 not be permitted to enter the United States. The Durbin bill contains a similar provision.

8. Accreditation of Qualified Third Party Auditors

The bill would direct FDA to establish an accreditation system by which qualified third parties and trained auditing agents would be able to certify that food facilities are in compliance with United States food safety standards. Qualified third party auditors could include foreign governments, states, and foreign or other eligible third parties. FDA would be required to establish adequate protections against conflicts of interest between facilities and certifying agents. Applicants would pay for the costs of the accreditation program. The Durbin bill contains similar provisions.

Conclusion

The Putnam-Costa bill is very similar in its policies and provisions to the recently-introduced Durbin bill, which is under consideration in the Senate. One major difference between the two bills is that the Putnam-Costa bill does not directly provide any additional funding or staff for FDA, while the Durbin bill explicitly authorizes appropriations and staffing increases for the agency. If enacted, the Putnam-Costa bill would impose significant new obligations on FDA and the food industry, both domestically and abroad. The proliferation of food safety bills in the aftermath of the peanut recall crisis suggests that Congress may be willing to consider such bills more seriously than it would have in the past. Although the Dingell bill has been the leading House bill thus far, the Putnam-Costa bill – with its smaller number of proposed user fees and mandatory programs – may be more palatable to 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:

Peter Barton Hutt	202.662.5522	phutt@cov.com
Eugene Lambert	202.662.5422	elambert@cov.com
Clausen Ely	202.662.5152	cely@cov.com
Jeannie Perron	202.662.5687	jperron@cov.com
Miriam Guggenheim	202.662.5235	mguggenheim@cov.com
Carrie Harney	202.662.5417	charney@cov.com
Alissa Jijon*	202.662.5341	ajijon@cov.com

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