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**MEMORANDUM**

May 2, 2008

FROM: Olsson Frank Weeda Terman Bode Matz PC  
RE: Rep. Costa (D-CA) Introduced Food Safety Legislation

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Rep. Jim Costa (D-CA), a member of the House Agriculture Committee, introduced food safety legislation, the *Safe Food Enforcement, Assessment, Standards and Targeting Act of 2008*, or the Safe FEAST Act, H.R. 5904, on April 24, 2008. The draft bill would amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish new procedures and requirements to improve food safety. The bill currently has four co-sponsors: Rep. Adam Putnam (R-FL), Rep. Dennis Cardoza (D-CA), Rep. Sam Farr (D-CA), and Rep. Devin Nunes (R-CA).

This memorandum briefly summarizes the main provisions of the bill:

1. FDA Inspection Authority

- FDA would have access to all records related to an article of food that it reasonably believes presents a threat of serious adverse health consequences or death to humans or animals.<sup>1</sup>
- FDA would be required to allocate its resources to inspect facilities according to the risk profile of the facility. FDA would be required to inspect high-risk domestic facilities at least once a year. FDA would be required to inspect shipments of food imported into the United States according to the risk profile of the shipment.

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<sup>1</sup> This provision is intended to expand somewhat the records access authority given to FDA under the Bioterrorism Act for food-related emergencies.

2. Hazard Analysis and Preventive Controls Plans

- Facilities would be required to identify and evaluate known or reasonably foreseeable hazards associated with their facility and implement “reasonably appropriate science-based preventive controls,” such as sanitation procedures, employee training, good manufacturing practices, allergen control procedures, an environmental monitoring program to verify the effectiveness of pathogen controls, and a recall contingency plan. The hazard analysis and preventive controls would have to be documented in a written plan.
- Facilities would be required to validate the effectiveness of the plan, monitor the effectiveness of preventive controls, establish corrective actions to be taken when preventive controls are ineffective, verify that the plan is operating as intended, and maintain records of the monitoring.
- The written plan and documentation of its operation would have to be made available to FDA upon oral or written request.
- Facilities would be required to conduct a reanalysis of the plan biennially or whenever a significant change is made in the facility’s activities such that there is a reasonable potential for a new hazard or significant increase in a previously identified hazard.
- This requirement would not apply to facilities subject to HACCP (Hazard Analysis and Critical Control Points) programs “or other regulatory program” of FDA.<sup>2</sup> This requirement also would not apply to facilities subject to new FD&C Act section 419 related to raw fruits and vegetables (see below).
- Operating a facility that processes or packs food for sale in the United States without such a written plan, without conducting a hazard analysis, without implementing reasonably appropriate science-based preventive controls, or without reanalysis of the plan as required would be a prohibited act, subject to injunction or criminal prosecution.
- FDA would be required to issue a guidance document related to the preparation of a hazard analysis and preventive control plan, not later than one year after the date enactment. FDA would also be required to promulgate regulations to establish minimum standards for hazard analysis and preventive control plans.

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<sup>2</sup> Juice products and fishery products would be exempt from this new requirement, since they are subject to existing FDA HACCP regulations. It is not clear whether this provision is intended to also exempt foods subject to “other regulatory programs” such as low-acid canned foods.

- “Facility” is defined as “a domestic or foreign facility that is required to register under section 415, but does [sic]<sup>3</sup> include a warehouse that – (A) holds food packaged for sale to consumers or packed in cases for commercial distribution; and (B) does not process food or otherwise expose food to the environment in a way as to dramatically increase the likelihood for contamination, not including processing incidental to the handling of fruits and vegetables that may be held in the warehouse and regulated under section 419.”

3. Imports – Foreign Supplier Safety Assurance Program

- U.S. importers of record would be required to adopt and document a foreign supplier safety assurance program. An “importer of record” would not include a person holding a valid license as a customs broker, if the customs broker has a written agreement with another person who has agreed to comply with the requirements of the bill with respect to the imported food.
- The foreign supplier safety assurance program would include procedures needed to reasonably ensure that imported food complies with U.S. food safety requirements and is not adulterated.
- The U.S. importer of records would be required to verify that each foreign supplier from which it obtains food has its own effective safety assurance program (i.e., its own hazard analysis and preventive control plan). The importer of record may rely on a recognized third party certification to verify that its suppliers are in compliance.
- FDA would be required to issue guidance, within 270 days after the date of enactment, to assist U.S. importers of record in developing foreign supplier safety assurance programs.
- FDA would have access to the records of importers of record related to their foreign supplier safety assurance program for a period of not less than 2 years.
- Importing food, or offering food for import, if the importer of record does not have a foreign supplier safety assurance program would be a prohibited act, subject to injunction and criminal prosecution.

4. Imports – Memoranda of Understanding with Foreign Regulatory Authorities

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<sup>3</sup> It appears that this is a typo and should read, “but does not include a warehouse...” Since warehouses are included in the definition of a facility under FD&C Act section 415, the purpose of this amendment seems to be to exclude certain warehouses from the requirement to have a food safety plan.

- Whenever the Secretary of Health and Human Services (the Secretary) enters into a memorandum of understanding or similar agreement with a foreign food regulatory authority, the Secretary shall include in such agreement a provision to provide for certification of certain foods offered for import into the U.S by a competent regulatory authority in the country of export.
- Whenever the Secretary enters into an agreement that includes such a certification requirement, the Secretary shall notify the Secretary of Homeland Security. The Secretary of Homeland Security shall deny entry to any food for which a required certification is not provided in a timely manner.
- The Secretary would be required to maintain a registry of facilities whose food shipments have been so certified.

5. Imports – Voluntary Qualified Importer Program

- FDA would be required to establish a voluntary qualified importer program, a voluntary program under which participating U.S. importers of record would receive expedited review and importation of foods they offer for import.
- FDA would assess fees from each importer required to register with FDA under FD&C Act section 415 for participation in the program.
- FDA may also establish a list of foods for which expedited review and importation is authorized.

6. Exports – Export Certification Fee

- FDA would be authorized to charge a fee, not to exceed \$175 per certification, for issuance of export certificates for food and animal feed.

7. Third-Party Certification Programs

- FDA would be required to establish a process for recognition of third party certification programs and maintain a registry of recognized third party certification programs.
- Recognition of a third party certification program may be terminated if it is found to be out of compliance or if it refuses to allow audits of its program.
- “Third party certification program” is defined as an independent auditing and certification program that evaluates food safety practices of food producers and processors using recognized standards.

8. Laboratories

- FDA would be required to provide for recognition of laboratories that have a demonstrated capability to conduct analytical testing of food products through programs administered by other government agencies or qualified non-governmental organizations. FDA would be required to establish a registry of recognized labs.
- The agency or organization running the lab recognition program would be required to periodically reassess the labs it recognizes and revoke the recognition of any lab found not to be in compliance with its standards. The agency or organization would be required to promptly notify FDA of any change in status of a previously recognized lab.
- The bill would not prohibit any person from using a non-recognized lab, provided such person submits to FDA evidence establishing the lab's qualifications and use of a validated testing method as well as all test results.

9. Fruit and Vegetable Safety

- FDA would be required to establish regulations for the safe production, harvesting, and packaging of those types of fruits and vegetables for which FDA has determined such regulations are necessary to minimize the risk of serious adverse health consequences.
- FDA would be required to coordinate enforcement activities with the U.S. Department of Agriculture, appropriate State and local agencies, and appropriate agencies of foreign governments.
- State and foreign governments would be permitted to seek variances from the requirements of the regulations, in order to meet local growing conditions.
- Producing, harvesting, or packaging of raw fruits and vegetables not in accordance with the FDA regulations or a variance would be a prohibited act, subject to injunction and criminal prosecution.
- FDA would be required to publish updated guidance on Good Agricultural Practices no later than one year after the date of enactment.
- For purposes of the bill, "fruits and vegetables" would mean "raw agricultural products as defined in section 201(r)."<sup>4</sup>

10. Biennial Registration of Facilities

- Facilities would be required to renew their FDA registration biennially.

11. Mandatory Recall Authority

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<sup>4</sup> Presumably, the bill is referring to the definition of "raw agricultural commodity" in FD&C Act section 201(r), and the definition does not include raw agricultural commodities other than raw fruits and vegetables.

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- If FDA determines that there is a reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences, FDA would be required to give the responsible party (i.e., the person who produced, processed, packed, or held the food) an opportunity to cease distribution, recall the food, and notify appropriate parties.
- If the responsible party does not carry out the above actions, FDA may, as it deems necessary, order such person to immediately cease distribution of the product and notify other parties.
- After an opportunity for a hearing, FDA may amend the order to mandate a recall or other appropriate action.
- Failure to comply with a recall order would be a prohibited act, subject to injunction and criminal prosecution. Any person who fails to comply with a recall order would also be liable to a fine of up to \$10,000 for each day of non-compliance, imprisonment for up to six months, or both.