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Proposed 2009 Food Safety Enhancement Act Changes 70-Year Old Food Safety Law

By Luann C. Battersby and Mark A. Kinzie

The Food Safety Enhancement Act of 2009 (H.R. 2749) (the "Food Safety Bill" or "Bill") proposes to amend the long-standing Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish new provisions governing food safety. (Existing law: 21 USC §341 *et seq*) The new proposed legislation is in response to some of the recent food scares including tainted milk from China as well as multiple *E. coli* and *Salmonella* poisoning cases and to the accusations that the Food and Drug Administration (FDA) is reactive rather than proactive to matters of food protection. The Food Safety Bill is designed to close some of the gaps in our food safety net. The Bill focuses on keeping contaminants out of the food supply by locating the source of food-borne contamination through regulation and inspection. This legislation proposes expansion of FDA power, including the power to require food recalls, increased inspection, improved quality systems in the food supply and of course, more fees.

Key provisions of the Food Safety Enhancement Act

Proposed New Requirements for Food Facilities. The Bill requires a food facility to: 1) perform a hazard analysis; 2) implement preventive controls; and 3) implement a food safety plan. (Sec. 102) The hazard analysis will evaluate whether there are any hazards in the food, including hazards due to the source of the ingredient, and any hazards that may affect the safety, wholesomeness or sanitation of the food

manufactured, processed, packed, transported, or held by the facility. Such hazards include *inter alia*, biological, chemical, physical, radiological, natural toxins, pesticides, drug residues, filth, decomposition, parasites, allergens, and unapproved food and color additives.

Preventative controls as currently pending, would require identification and implementation of controls to prevent, eliminate, or reduce to acceptable levels the occurrence of any hazards identified in the hazard analysis. These controls are risk-based procedures, practices, and processes that a knowledgeable person would employ including sanitation procedures, hygiene training, process controls, allergen controls, good manufacturing practices and verification procedures.

The food safety plan is a written plan that must be in place prior to placing food in commerce. The content of the plan includes the hazard analysis as well as descriptions for monitoring, corrective actions, verification activities, recordkeeping, recall procedures and tracing procedures.

The Bioterrorism Act of 2002 requires domestic and foreign facilities that manufacture, process, pack or hold food in the US to register with the FDA. The Food Safety Bill would require such registration with fee payment annually. The Bill clarifies which entities are exempt facilities including farms, restaurants, nonprofit food establishments, grocery stores and convenience



stores. (Sec. 101) Importers and Customs Brokers will also be subject to registration and fees. (Sections 204, 205)

Proposed New Requirements for FDA. The Bill will require FDA to: 1) issue science-based performance standards to minimize the hazards from foodborne contaminants imposed on farms and manufacturers (Sec. 103); 2) establish science-based standards for raw agricultural commodities (Sec. 104); 3) inspect facilities at a frequency compatible with a risk-based schedule (Sec. 105); 4) enhance FDA access to records (Sec. 106); 5) establish a food tracing system by identifying new technology to be used by food growers, manufacturers, and distributors to determine the origin of food and its movement through the supply chain (Sec. 107); 6) assess fees relating to food facility reinspection and food recall (Sec. 108); and 7) establish an accreditation program for laboratories that perform analytical testing of food for import or export (Sec. 110).

Of these new requirements, the traceability and accreditation programs seem to be sparking the most interest. There are a myriad of questions about how these systems will be set up, how they will function, and the like. While we watch these topics develop, there is the more mundane question of how FDA will hire, train and oversee enough inspectors to visit every registered food facility in the world on a routine basis.

Proposed New Authority for FDA. The Food Safety Bill is designed to produce risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting and holding of foods, including raw fruits and vegetables. (Sec. 104) Under the Bill, the FDA would gain authority to require a recall of adulterated food. (Sec. 111) Until now, recalls have been voluntary. (21 CFR §7.40) The FDA has operated by threatening or producing press releases to pressure manufacturers to recall their product. Most

manufacturers have responded to this incentive and have recalled their products when necessary. If the Food Safety Bill passes as written, the FDA may issue mandatory recalls forcing foreign or domestic recalcitrant manufacturers into action. (Sec. 111 and Sec. 213)

Other powers granted to the FDA under the Bill include providing the Commissioner with subpoena authority with respect to food proceedings (Sec. 211, 311) and the ability to quarantine food in any geographic area within the U.S. (Sec. 133). The Bill further grants authority to the FDA to set up an importer verification program to establish that each facility involved in the food supply is in compliance with food safety and security guidelines. (Sec. 113) Whistleblower protections have also been added. (Sec. 212)

Impact to industry

Inspection, inspection, inspection. More inspections will be required under the Bill. Facilities will be inspected annually to every three years depending on the risk assessment. More sites will be inspected including foreign sites and importer sites, and more inspectors will be available to the FDA.

Annual registration, new user fees, and mandatory recalls are the main impacts to larger facilities. Smaller players in the industry may find the hazard analysis and safety plan burdensome. Under the Food Safety Bill, the FDA will be required and authorized to establish a corps of inspectors dedicated to inspections of foreign food facilities, as well as food importers. Once passed, the Department of Health and Human Services, the agency in which FDA resides, has three years to write precise standards for inspection, regulation, and recalls. (Sec. 103-110)

New definitions of food adulteration. The Food Safety Bill expands the definition of adulteration



to include foods from food facilities or importers whose management has caused an inspection to be delayed, limited, or refused. (Sec. 207) The term “color additive” will be defined to include carbon monoxide that may affect the color of fresh meat, poultry products, or seafood.

Importers must comply. Inspection of food importers’ businesses also will increase. The country of origin labeling will be required on food. Annual registration of importers and payment of fees will be required. Unique identifiers that allow product tracking and traceability will be required for each importer. Importers would be required to use only accredited testing laboratories. A requirement for third party certification of imports will be included. Safety and security guidelines for food imports will be instituted. (Sections 206-208)

Food manufacturing requirements. Planning and documentation of planning will expand. Manufacturers must conduct a hazard analysis and implement risk-based preventive controls, as well as develop and implement a written food safety plan, and these regulations will apply to foreign processors as well. Unique facility identifiers are required for food facilities, importers and custom brokers. (Sec. 206)

Prospects for passing the Bill are murky.

According to the Center for Disease Control, foodborne disease affects 76 million US residents who are sickened, 325,000 U.S. residents who are hospitalized and some 5,000 people who die each year. (CDC, Frequently Asked Questions, Foodborne Illness, published January 10, 2005.) In the past, food products, with a few notable exceptions, were the product of US farmers and the products of small to medium US food processors. Currently the food industry, like everything else, is global and multi-national and our laws have not kept pace. While the US has

enjoyed the lower food costs that global markets provide the need to act to safeguard US consumers is strong. The current food safety laws were enacted about 70 years ago. Recognizing this are consumer groups, industry organizations, and Congress, who are all in the process of hammering out legislation that will affect every food grower, processor and importer.

The Congressional Budget Office estimates that the Food Safety Bill would increase spending, on net, by \$2.0 billion over the 2010-2014 time period. It is estimated that little more than half of that would be generated by industry inspection fees. (CBO Report on HR2749 issued June 17, 2009)

Among the criticisms to the Bill are that the FDA does not have the experience or manpower to inspect and regulate grain and livestock properly, that the new user fees the Bill would impose would be too expensive, that the paperwork may be too confusing, and that the mandatory recalls the Bill envisions may be unnecessary.

This causes concern among agricultural groups who fear their individually compliant businesses may be threatened because of a rogue operator in their geographic area. The quarantine and additional recordkeeping and regulations have caused most farm groups to oppose the proposed act.

To date, FDA Commissioner Dr. Margaret A. Hamburg is in favor of the Bill (Discussion of Legislation before the Subcommittee on Health, House Committee on Energy and Commerce, June 3, 2009) along with such industry groups as Grocery Manufacturers of America, which favors food safety plans and risk-based inspection while emphasizing the need for foreign processors to build the capacity to be in compliance with these requirements as well. Mainstream consumer



advocacy groups such as Consumers Union seem ecstatic about the proposed Act.

However, some industry groups, including the National Farmers Union (NFU) recognizes the importance of food safety and believes that one fully-funded regulatory agency is wise, rather than the patchwork of FDA, USDA and various state agencies. However, the NFU regards the current proposed Food Safety Enhancement Act as a punitive approach, unlikely to achieve its goals.

Because of consumer concern over foods from spinach to eggs, it seems that food safety would be a bipartisan issue and that some form of the Food Safety Enhancement Act would pass the Congress this fall. The Bill passed the House by a vote of 283-142 and awaits a Senate vote. There is also a companion bill in the Senate, S.510 the Food Safety Modernization Act which is sitting in committee.

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