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Key Conservative Concerns

Take-Away Points

- **Questionable Effect:** The bill does little to enhance food safety and instead imposes significant regulatory burdens on all farms while doing little to hold the Food & Drug Administration (FDA) accountable.
- **Overbearing Bureaucracy:** The bill grants broad authority for the FDA to shut down or inspect business and determine what qualifies as a health concern. When the FDA wrongly identified tomatoes (instead of Mexican Jalapeños) as the source of a salmonella outbreak in 2008, the tomato industry suffered \$100 million in losses.
- **User Fees:** Taxes are imposed on facilities involved in recalls by authorizing the FDA to collect up to \$25 million annually for costs associated with reinspection of facilities and up to \$20 million annually against companies that challenge recall orders. Some conservatives believe this is the equivalent of placing a regressive tax on consumers by increasing the price of food.
- **Democrat Inconsistency Alert:** The bill contains the Tester Amendment that is problematic for some conservatives for a variety of issues. Perhaps most ironic, the amendment undermines the ultimate goal of what Democrats seek to accomplish by creating exemptions for farms that do less than \$500,000 in sales a year, organic farms, and for farms engaging in sustainable production practices.
- **Potentially Duplicative:** The bill provides the FDA with duplicative authority for a number of activities already being performed by other agencies with greater expertise.
- **Many Mandates:** Imposes performance standards, mandatory recall requirements, and recordkeeping.

For more details on these and other concerns, see below.

Motion to Concur in the Senate Amendment to H.R. 2751—The Food Safety Enhancement Act (Waxman, D-CA)

Order of Business: The bill is scheduled to be considered on Tuesday, December 21, 2010, under a Martial Law Rule, which allows for the same-day consideration of any bill.

Summary: On July, 30, 2009, the House passed [H.R. 2749](#) the Food Safety Enhancement Act by a vote of [283 – 142](#). On November 30, 2010, the Senate passed their version of legislation (S. 510) involving the regulation of the U.S. food supply by a vote of 73-25. The two versions have a number of policy differences, however, it is reported that House Democratic leadership was willing to accept the Senate version. Since S. 510 contains provisions involving revenue-raising fees that violate the Constitution’s origination clause, the bill cannot be considered by the House. In order to rectify this issue, the House has added the text of S. 510 into part D of the Continuing Resolution to satisfy the Constitutional requirement. That provision is now be considered by the House as it has been removed from the Continuing Resolution.

Some of the key provisions of the Food Safety Bill the House will consider as part of the Continuing Resolution are as follows:

Food Inspection & Facility Registration: The bill permits the Secretary of Agriculture to have access to and review of all records relating a to a food product including information on distribution, packaging, transport, if he or she believes that there is a “reasonable probability” that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals. The bill requires the registration of all “food facilities” and gives the Secretary the authority to suspend the registration of a facility if he or she determines that food manufactured, processed, packed, received, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. The bill grants an appeals process. Some conservatives have expressed concern over these provisions because they grant the FDA the authority to conduct warrantless searches of businesses and it removes the limitation on records-access that the Secretary have a “reasonable belief that a product is adulterated and presents a threat of serious adverse health consequences.”

The bill requires owners and operators of registered facilities to evaluate reasonably foreseeable hazards,” including “biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color additives,” at risk for contamination. The bill requires the facility to provide to the Secretary with verification that the facility is in compliance and preventive measures are in place to prevent contamination. The bill requires the facility to keep at least two years of records.

Performance Standards: The bill requires the creation of “performance standards” established by the FDA in coordination with U.S. Department of Agriculture (USDA) to review and evaluate “the most significant food-borne contaminants” and issue regulations.

Produce Standards: The bill also creates a comprehensive produce safety standard to establish standards for the production and harvesting of certain fruits and vegetables in order to minimize the risk of serious adverse health consequences or death. While the FDA’s intention is to identify what causes outbreaks, many conservatives have expressed concern that the provision would allow the FDA to regulate how crops are raised, essentially dictating to farmers the best way to farm.

Tester Amendment: The so-called “Tester Amendment” exempts facilities that do less than \$500,000 in sales a year; that sell only within 275 miles of the farm, and sell only on the farm or to farmers markets, restaurants or grocery stores. Additionally, the bill exempts certain organic forms of production. Some conservatives argue that exemptions should be based on science and risk, not based on farms proximity to a selling point or income.

Most major food and agricultural organizations opposed the inclusion of this amendment in the Senate version of the bill.

Fees: The bill allows the collection of user fees to for the purpose of covering the cost of recall activities and reinspections. Recall fees would be capped at \$20 million and applied to companies that do not comply with recall. Reinspection fees would be applied to companies and importers, and capped at \$25 million annually. The bill also authorizes appropriations in the amount determined by fees on export certification on food and animal feed.

Dietary Guidelines: The bill gives the authority to the FDA to determine the safety of dietary supplements if it believes it contains anabolic steroids, and is required to notify the Drug Enforcement Agency if a product is believed to contain a steroid. Within 180 days of enactment the FDA is required to publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, the evidence needed to document the safety of new dietary ingredients, and the appropriate methods for establishing the identify of a new dietary ingredient.

Exemptions: The bill contains a small number of exemptions limiting the scope of the FDA’s jurisdiction so as to not apply to certain facilities already regulated by the USDA, and alcohol related facilities, among other facilities. However, many conservatives still view many of these exemptions to be inadequate and the bill still allows the FDA to regulate agricultural production practices.

Inspection Frequency: The bill requires the Secretary to increase the number of inspection on domestic facilities, foreign facilities (minimum 600 a year), and ports of entry to evaluate risk for contamination, the affect of rigor on foods, and the overall packaging process. The bill requires the Secretary to establish a new program for the testing of food by accredited laboratories to address or identify suspected food safety problems. Additionally, the bill requires the Secretary, in coordination with other federal agencies, to submit a report on the progress in implementing a national food emergency response laboratory network that provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply, develops and implements a methods repository for use by Federal, State, and local officials, and responds to food-related emergencies.

Recordkeeping & Traceability: Within 270 days, the bill requires the FDA to conduct several pilot projects to explore methods to improve the tracking and tracing of food. At the conclusion of the projects, the FDA would be required to assess the cost and benefits associated with adoption of product tracing technologies and feasibility of implementing a nation system.

Within two years of enactment, the bill requires the Secretary to publish a notice of proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as “high-risk foods.” Some conservatives may argue that the traceability requirements only add enormous regulatory burdens on businesses with little reason to believe it will prevent outbreaks within the food supply.

Surveillance: The bill authorizes \$24 million per year between FY 2011 and FY 2015 for foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses.

Mandatory Recall Provisions: The bill allows the Secretary to issue a recall order if he or she has *any reason to believe* a product has been adulterated or misbranded. The bill strikes the current requirement that the FDA must have “credible evidence or information indicating that such article presents a threat of serious adverse health consequences” and allows the agency to act upon merely a “reasonable belief.”

Grant Programs: The bill authorizes “such sums” to create several grant programs eligible to a wide variety of entities, including farms, state agencies, local governments, non-profit food distributors, among others, for improve educational outreach on tactics to increase food safety. The bill also authorizes “such sums” to create “Food Safety Integrated Centers of Excellence” to provide resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations, among other duties.

Imported Foods: The bill requires the FDA, within one year of enactment, to promulgate regulations that require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier processes and procedures, including reasonably appropriate risk-based preventive controls, which provide the same level of public health protection as those required under current law.

The bill creates a new program to allow the FDA to provide expedited review for importers who voluntarily participate in a qualified inspection program and are certified by a third party. The program requires records of an importer related to a foreign supplier to be maintained for at least two years and be made available promptly to a duly authorized representative of the Secretary, upon request.

Federal Employees: The bill authorizes the appropriations of funds for the FDA to hire 17,800 additional employees through 2014 to carry out the requirements enacted under the Food Safety Enhancement.

Additional Background: While the food supply of the United States is considered one of the safest in the world, health officials within the administration estimate that millions of individuals become sick each year directly as a cause of contaminants that enter the food supply despite stringent regulatory measures already in place. Over the past few years, several widely reported food-related contamination incidents have raised public concern over food safety. The Democrat Congress has introduced a number of measures to increase regulations on the industry.

According to the Congressional Research Service, between April and July of 2008 “more than 1,300 persons in 43 states, the District of Columbia, and Canada were found to be infected with the same unusual strain of bacteria” (a type of Salmonella). Public health officials originally believed the strain came from domestically grown tomatoes, however, it was later determined through genetic testing the strain originated from samples of Serrano pepper and irrigation waters in Mexico. It is estimated this error cost the tomato industry close to \$100 million in lost revenues.

Within the past year, another Salmonella outbreak was traced to the Peanut Corporation of America that produces industrial peanut butter and other products containing peanut ingredients. The Centers for Disease Control (CDC) has identified this outbreak as causing more than 700 cases of Salmonella poisoning and possibly contributing to nine deaths. This outbreak comes on the heels of another outbreak detected by Peter Pan and Great Value brand of peanut butter produced by ConAgra, that caused hundreds of individuals illness beginning in August of 2006.

In June of 2009, the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention issued a public warning that consumers not eat any variety of prepackaged Nestle Toll House refrigerated cookie dough due to the risk of contamination with E. coli. The CDC estimates that the breakout caused the hospitalization of at least two dozen people as a result of eating raw cookie dough.

The Government Accountability Office cites approximately 30 different laws related to food safety that are administered by 15 federal agencies. However, the vast majority of oversight is conducted by the Food Safety and Inspection Service (FSIS) under the Department of Agriculture, which inspects mostly meat and poultry. The FSIS had a budget of more than \$1 billion in FY 2009. The FDA also conducts oversight for many other food products.

In 2007, the Bush Administration called for a major overhaul of the system after the Salmonella outbreaks first appeared. President Obama has continued to call for reform and announced the creation of a “Food Safety Working Group” in March of 2009. In the 111th Congress, House Democrats introduced a number of proposals the make major changes to the system.

Conservative Concerns: Some conservatives have expressed concern that the legislation only imposes significant regulatory burdens on small businesses and does little to enhance food safety. In the same spirit of cap and tax or nationalizing health care, this is another example of Congress expanding the scope of bureaucracy and increasing the government’s involvement in the personal lives of Americans. As Sen. Tom Coburn, R-OK, stated: the bill will “grow the government, increase food prices, and drive small producers out of business without making our food any safer.” As the Wall Street Journal [editorializes](#) that under the bill, “the Food and Drug Administration will gain new powers over the 2.2 million farms and 28,000 food producers in America—including federal standards for agricultural practices and food processing, transportation and storage—as well as the authority to mandate nationwide recalls.”

Duplication: Specifically, some conservatives have expressed concerns over the duplicative nature of the bill in which the FDA would be tasked with many responsibilities already administered by the USDA and other federal agencies. Additionally, conservatives have expressed concerned the over extremely high number of mandates.

Some conservatives have expressed concerns over the bill’s provisions to grant the FDA the authority to inspect the records of grain farmers and ranchers because they believe the FDA lacks the expertise to adequately review the conditions of a facility. Additionally many conservatives

have expressed concern that because this provision allows the FDA to conduct random audits, without needing reasonable cause, this regulation is obtrusive and overly burdensome for many small businesses.

User Fees: Some conservatives have expressed concern that imposing fees on production facilities that hold or possesses food is the equivalent of an additional tax on food. Many conservatives believe that the fees will be passed onto the consumer, and raise the price of food. Additionally, the bill does not permit the government the ability to indemnify companies or commodities it wrongfully implicates in a food borne illness outbreak.

Committee Action: None.

Administration Position: No Statement of Administration Policy is available; however, the President has indicated to the press he will support it.

Cost to Taxpayers: A CBO score for this provision of the Continuing Resolution is unavailable. However, a CBO score for a similar legislation considered in the Senate would increase spending subject to appropriation, on net, by about \$1.4 billion over the 2011-2015 period, assuming annual appropriation action consistent with the bill. However, CBO also estimated the bill would have no net increase on the deficit.

Does the Bill Expand the Size and Scope of the Federal Government?: Yes, the bill dramatically expands the number regulations and jurisdiction of several federal agencies involving the inspection of the food supply.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: Yes, the bill contains a number of mandates, on individuals and entities involved in producing, manufacturing, processing, packing, transporting, distributing, receiving, holding, importing, or exporting articles of food. The bill also imposes additional mandates because it requires the Secretary of Health and Human Services to establish a tracing system for food located in the United States (or for import into the country) and to develop safety and security guidelines for the importation of food. Additionally, the bill requires operators of facilities to implement and monitor preventive controls and institute corrective actions.

Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: A committee report regarding compliance for house rules on earmarks is not available.

Constitutional Authority: A committee report citing constitutional authority is unavailable for the bill.

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