

Legislative Bulletin.....July 29, 2009

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H.R. 2749 – The Food Safety Enhancement Act of 2009

Key Conservative Concerns

Take-Away Points

- **Questionable Effect:** The bill does little to enhance food safety and instead imposes significant regulatory burdens on small farms while doing little to hold the FDA accountable.
- **Duplicative:** H.R. 2749 provides the FDA with duplicative authority for a number of activities already being preformed by other agencies with greater expertise.
- **Bloated Bureaucracy:** The bill grants broad authority for the FDA to shut down or inspect business and determine what qualifies as a health concern.
- **User Fees:** Enacting “user fees” on inspections and licensing is the equivalent of placing a regressive tax on consumers by increasing the price of food.
- **Many Mandates:** Imposes performance standards, mandatory recall and quarantine authority, and county of original labeling requirements.

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

H.R. 2749—The Food Safety Enhancement Act of 2009
(Dingell, D-MI)

Order of Business: The bill is scheduled to be considered on Wednesday, July 29, 2009 under a motion to suspend the rules and pass the resolution.

Summary: Authorizing \$2.314 billion over the 2010 – 2014 period, H.R. 2749 grants the Food and Drug Administration (FDA) more authority and resources to regulate the nation's food supply. Specifically, the bill requires the creation of a tracing system that the FDA would use to track the source of food in order to identify where a contamination may have originated. The bill would also allow the FDA to impose mandatory recalls of

tainted foods. Additionally, the bill would require the FDA to inspect all food facilities, impose mandatory recalls of all compromised foods, and establish a quarantine of geographic regions that have tainted food supplies. Finally, the bill imposes a \$500 annual registration fee on facilities to carry out mandates imposed by the FDA. Some of the more notable provisions of the bill are as follows:

Exemptions: The amended version of the bill contains a number of exemptions limiting the scope of the FDA's jurisdiction so as to not apply to certain facilities already regulated by the U.S. Department of Agriculture (USDA), alcohol related facilities, and apply a standard definition for farm. However, many conservatives still view many of these exemptions to be inadequate and the bill still allows the FDA to regulate agricultural production practices

Food Facility Registration: H.R. 2749 mandates that all foods manufactured, processed, packed, or held in a facility for consumption be registered with the Secretary of Health and Human Services. The bill requires the Secretary to supply Congress a report each year assessing the number of registrations, and the level of risk, a facility may have for an outbreak. The legislation establishes three risk-schedules, mandating inspections between every 6 to 12 months, every 18 months to three years, or once every five years depending on the evaluation of each facility.

Some conservatives have expressed concern that the mandatory registration is effectively as a federal food license, making it illegal to sell food without the license and permitting the FDA to impose additional fees or suspend a company's registration.

Additionally, this section imposes an annual (adjusted for inflation) \$500 user fee on facilities to help pay for the mandates imposed by the law. For companies and individuals that own or operate multiple facilities, a maximum level for total fees per year is set at \$175,000.

Performance Standards: The bill grants the FDA the authority to establish performance standards in order to regulate agricultural production practices. 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.

Despite the fact the final version of the bill was modified to exclude row crop producers from FDA regulatory authority over growing and harvesting of crops and limits livestock producers from some certain aspects of the scope of the law, some conservatives believe the bill still leaves our nation's fruit and vegetable producers subject to objectionable regulatory burdens.

Recordkeeping & Traceability: The bill requires that within two years, every facility must provide records of activities they are doing to prevent an outbreak or contamination of the food supply. The bill requires officials from HHS to be provided with “reasonable” access to these records regardless of cause.

Additionally, the bill calls for the Secretary of HHS, after a feasibility and cost/benefit study and pilot project, to establish a system for tracing the food supply by maintaining data on interoperability and a “distribution history of the food.” The bill requires businesses to identify each person who grows, produces, manufactures, processes, packs, transports, stores or sells agricultural commodities, food, feed or feed ingredients for longer than two days. While the bill exempts restaurants and grocery stores from the registry that bought food directly from a farm, the bill does require them to keep their own records documenting the farm that was the source of the food. Additionally, farms must keep their own records for at least 6 months of restaurants and grocery stores to where the food was sold.

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”. Additionally, 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.

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. H.R. 2749 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”.

Quarantine Authority: If the Secretary determines that there is credible evidence or information that an article of food presents an “imminent threat” of serious adverse health consequences or death to humans or animals, the Secretary may quarantine any geographic area within the United States in consultation with the state’s Governor.

Some conservative have expressed that this broad authority would allow the FDA to shut down extremely large areas of land and many businesses – even if they are not the cause of the contamination.

Penalties: The bill creates criminal and civil penalties for violators of this legislation, with fines totaling up to \$100,000 for individuals, up to \$7.5 million for a single incident, and up to 10 years in prison.

Country of Origin Labeling: The bill establishes a new country of origin labeling process by requiring a product to identify the country in which the final processing occurs.

Many conservatives have expressed concerns that this is unnecessary mandate that will do absolutely nothing to improve the safety of food.

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.

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.

Just last month, 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. In the 111th

Congress, House Democrat introduced a number of proposals the make major changes to the system. H.R. 2749 combines a number of these proposals.

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 increases the governments' involvement in the personal lives of Americans.

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 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.

Registration & Fees: Some conservatives have expressed concern that the mandatory registration is effectively a federal food license, making it illegal to sell food without the license and permitting the FDA to impose additional fees or suspend a company's registration.

Quarantine Authority: Some conservatives have expressed concern that the bill would grant the FDA too much authority to place entire geographic regions under quarantine. This new authority far exceeds the authority currently granted to the USDA.

By placing an undefined region under restriction, the food supply could be seriously disrupted or cause food prices to artificially rise. In rural areas many diverse farms produce many different products with close proximity of each other. Shutting down an entire region could result in economic disaster for many small businesses in areas already struggling financially. Additionally, the legislation does not provide indemnity for producers in the case of a false/erroneous recall or quarantine by FDA, unlike the USDA.

Use Fees: Some conservatives have expressed concern that imposing a user fee on any facility that hold or possesses food is the equivalent of an additional tax on food. While the legislation attempts to waive farms from the fee, the definition is narrow and could affect numerous small businesses. Many conservatives believe that the fees will be passed onto the consumer, and raise the price of food.

Process: Finally, some conservatives have expressed concern that H.R. 2749 has been brought up under suspension of the rules. Traditionally, the calendar is used for non-

controversial measures with negligible costs. This legislation costs over \$2 billion, creates countless new mandates on employers, and creates a new bureaucracy within the FDA. It is also important to note that the bill was drafted to ensure it would not face the jurisdiction of the Agriculture Committee, which currently has much of the jurisdiction of food safety and inspection.

Committee Action: On June 8, 2009, the bill was introduced and referred to the Energy and Commerce subcommittee on Health, which held a mark-up on June 10, 2009. On June 17, 2009, the full committee held a mark-up and ordered the bill to be reported by voice vote.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: According to CBO, H.R. 2749 would increase spending subject to appropriation, on net, by \$2.0 billion over the 2010-2014 period, assuming appropriation action consistent with the bill.” However, CBO estimates authorizations will amount to \$2.314 billion over the same period. In addition, CBO estimates “the gross costs for FDA to administer the new regulatory activities authorized under the legislation—about \$3.5 billion over the 2010-2014 period—would be partially *covered by fees* assessed on registered food facilities, importers, and exporters.”

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 requires companies that hold food for consumption to register with the Secretary of HHS and pay an annual fee. Currently, those companies are required to register with the Secretary except for facilities holding food for export, but the annual fee would be a new requirement.

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. Finally, the companies must conduct repeat hazard analyses at least every two years, and maintain records of these activities subject to FDA review at any time.

Does the Bill Comply with House Rules Regarding Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: Though the bill contains no earmarks, and there’s no accompanying committee report, the earmarks rule (House Rule XXI, Clause 9(a)) does not apply, by definition, to legislation considered under suspension of the rules.

Constitutional Authority: A committee report citing constitutional authority is unavailable for H.R. 2749.

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