The Food Safety Enhancement Act: Adjusting Food Safety Procedures for the 21st Century

(July 24, 2009)

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Prepared for original publication in the September/October 2009 edition of the Food and Drug Law Institute Update Magazine

Spinach, peanuts, pistachios, cookie dough … the list of food products that have been contaminated in recent months continues to grow. Consumer concerns have prompted the federal legislature to consider several food safety bills in an attempt to alleviate those worries. The modernization of food safety depends on enhanced and up-to-date legislation.

Today, due to the complexity of food distribution systems, the line of production from farm to fork is longer than ever, which increases the risk of contamination that a food product possesses. Changes in “demographics and consumption patterns”\(^1\) also are believed to contribute to the increased susceptibility of contamination in food products.

The Food Safety Enhancement Act of 2009\(^2\) may be the answer to these problems.

The Food Safety Enhancement Act (FSEA), if passed, will be the most comprehensive food safety act the United States has seen since the enactment of the

\(^2\) Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (as reported by the House Comm. on Energy and Commerce on June 17, 2009).
Federal Food, Drug, and Cosmetic Act (FFDCA).³ Traditionally, food safety has been incorporated as part of more comprehensive legislation. For example, food safety is only one aspect of the FFDCA, which also covers drugs and cosmetics. The FSEA is revolutionary in that its sole function is to address food safety issues.

The FSEA combines provisions of several other food safety legislative proposals of the 111th Congress.⁴ Most notably, the FSEA borrows from the Food Safety Modernization Act⁵ and the Food and Drug Administration Globalization Act.⁶ The FSEA assumed several provisions from those two bills, including the annual registration of food facilities, civil fines for violations, and the detainment of unsafe food. The FSEA, like the Food and Drug Administration Globalization Act, includes a registration fee as well as traceability via electronic records. Similar to a provision in the Food Safety Modernization Act, the FSEA increases criminal sanctions for individuals who violate the act.

The sponsors of the FSEA believe it to be the right blend of industry responsibility and government power, highlighting the best aspects of previously introduced legislation. That may explain why the House of Representatives Energy and Commerce Committee

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⁶ H.R. 759, 111th Cong. (2009). Rep. John Dingell (D-MI) introduced the bill on January 28, 2009 as an amendment to the FFDCA. It was referred to the House Committee on Energy and Commerce. The bill required oversight from both the Department of Health and Human Services (HHS) and the FDA. Besides addressing food safety, the bill also had provisions governing drug and device and cosmetic safety.
passed the FSEA unanimously on June 17, 2009. Although Rep. John Dingell (D-MI) introduced the FSEA, a powerful force behind the bill has been Rep. Henry Waxman (D-CA), Chairman of the committee, who is also a co-sponsor of the bill. In his opening statement to the committee, Rep. Waxman said, “We stand on the verge of passing a comprehensive, broadly supported and bipartisan reform of our nation’s food safety laws.”

**Provisions of the FSEA**

The current version of the FSEA would considerably alter how food facilities and the Food and Drug Administration (FDA) operate. An amendment to the FFDCA, the FSEA will impact nearly every facet of the food industry, including areas such as production, packing, and shipping. The bill’s broad provisions range from imposing registration fees and criminal sanctions to requiring science-based production methods.

- **Annual Registration Fees**: Food facilities that handle food for consumption in the United States or for export from the United States would be required to pay an annual registration fee. The fee would need to be submitted electronically. Originally, the fee was set at $1000, but it was reduced to $500 when the bill was in the House Energy and Commerce Committee. The fee would be adjusted annually and include a yearly cap of $175,000 per person for those who own or operate multiple facilities.

- **Unique facility identifiers**: Each facility would be required to submit a unique identifier for itself upon registration. The absence of an identifier would indicate the facility is unregistered, and thus, all products from that location would be considered misbranded.

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7 Representatives Diana DeGette (D-CO), Frank Pallone Jr. (D-NJ), Bart Stupak (D-MI), and Betty Sutton (D-CA) also co-sponsored H.R. 2749.
9 See id. § 101(c).
10 See id. § 206.
• **Risk-based Inspection Schedule**: Each facility would be assessed to establish its level of risk. Three categories would exist: category 1 would require inspection at least every 6-18 months, category 2 would require inspection at least every 18–36 months, and category 3 would require inspection at least every 36-48 months.\(^\text{11}\)

• **Quarantines**: The FDA would have the authority to impose mandatory quarantines on specific geographic areas from which it believes dangerous food articles originated.\(^\text{12}\)

• **Access to records**: The FDA would have the authorization to access the records of any food facility without having to present a cause or reason. The records would need to be made immediately available to the FDA upon notice.\(^\text{13}\)

• **Traceability**: The full pedigree of any food that is located within or imported into the United States would need to be maintained. The FDA would establish a tracing system after new technologies were explored. Once the tracing system was implemented, all facilities would be required to comply with its mandates. Food that is produced on a farm and directly sold by the farm would be exempted from the requirement.\(^\text{14}\)

• **Country of Origin Labeling**: A processed item would be considered misbranded if the label did not identify the country where the final processing took place. The labels of non-processed foods also would need to indicate the country of origin.\(^\text{15}\)

• **Science-based Safety Standards**: Produce and certain other raw agricultural commodities would need to be grown, harvested, processed, packed, sorted, transported, and held according to the scientific and risk-based standards outlined in the legislation in order to avoid being considered adulterated.\(^\text{16}\)

• **Hazard Analysis**: The bill would require that all facilities conduct at least one hazard analysis to identify preventive controls. Facilities would be required to present the records to the FDA upon request.\(^\text{17}\)

• **Foreign Inspectors**: In order to make the increase in facility inspections outside the United States possible, the bill would establish a dedicated foreign inspectorate, maintained by the FDA.\(^\text{18}\)

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\(^{11}\) See id. § 105.

\(^{12}\) H.R. 2749 § 133.

\(^{13}\) See id. § 106(a)(1).

\(^{14}\) See id. § 107.

\(^{15}\) See id. § 202.

\(^{16}\) See id. § 104(b).

\(^{17}\) H.R. 2749 § 102(a)(2).
• **Food Safety Plan:** Before a facility could introduce or deliver food for interstate commerce, it would need to develop and implement a written food safety plan.\textsuperscript{19}

• **Recalls:** The FDA would be able to request that a distributor voluntarily recall an item that the FDA believes to be misbranded or adulterated. The distributor would need to provide notice to any affected persons. In addition, the FDA would be able to issue a “cease to distribute” order if the FDA believed that the article could cause serious health consequences or death to humans or animals. If there was an imminent threat, the FDA could issue an emergency recall order, which would require the article to be immediately recalled.\textsuperscript{20}

• **Educational Programs:** The FDA would design and implement a national public education program on food safety with private and public organizations, as well as state governments. This would include the development of an advisory system to quickly distribute critical food safety information to the public.\textsuperscript{21}

• **Further Research:** The bill would charge the FDA with conducting further research in a number of areas including, but not limited to, sanitation, food safety practices, food-borne illness detection, and pathogens.\textsuperscript{22}

• **Criminal Penalties:** The bill would allow imprisonment for up to ten years for an individual who knowingly violated the bill.\textsuperscript{23}

• **Civil Penalties:** An unintentional violation of the provisions of the bill would incur a maximum penalty of up to $50,000 for individuals and $1,000,000 for partnerships, corporations, and associations. A knowing violation would result in up to $100,000 in fines for an individual and $7,500,000 in fines for a partnership, corporation, or association.\textsuperscript{24}

In addition, the bill would increase the funding and staffing of the FDA in order to implement the provisions. This would be possible through the facility registration fee that

\textsuperscript{18} See id. § 208.
\textsuperscript{19} See id. § 102(a)(2).
\textsuperscript{20} H.R. 2749 § 111(b).
\textsuperscript{21} See id. § 122.
\textsuperscript{22} See id. § 123.
\textsuperscript{23} See id. § 134.
\textsuperscript{24} See id. § 135.
is projected to raise $189 million a year. President Obama stressed the importance of such increases in his March 14, 2009; weekly address entitled “Reversing a Troubling Trend in Food Safety.” It is an issue that has been negatively impacting the workings of the FDA for quite some time and one that must be rectified in order for the FSEA to be successful.

There would be two important exemptions within the FSEA. The first affects the meat, poultry and egg industries. Any product or facility regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act would be exempted from the FSEA provisions because they are regulated by the United States Department of Agriculture. Farms that sell directly to consumers would be exempted for the same reason.

Reactions to the FSEA

As is expected with such a sweeping bill, there is intense controversy surrounding the FSEA. Several interest groups are urging their supporters to oppose, stop, and denounce the bill. Some of those opposed to the bill accuse it of being a “one-size-fits-all regulatory scheme” that will negatively impact smaller members of the industry. They are concerned that the bill’s science-based production standards would allow the government

25 According to Dr. Margaret Hamburg, Commissioner of the FDA, there are approximately 378,000 registered food facilities. Testimony of Margaret A. Hamburg, M.D. before the Subcommittee on Health, Committee on Energy and Commerce (June 3, 2009).
26 http://www.whitehouse.gov/blog/09/03/14/Food-Safety/ (last visited July 24, 2009).
30 H.R. 2749 § 5.
to regulate farms too closely and that the legislation does not address the real causes of unsafe food. Support for the bill is just as emphatic. Many supporters are pleased that the bill’s main focus is food safety. Some believe it is a good starting point for additional food safety legislation in the future. Proponents of the bill are comfortable with the power the bill allocates to the FDA and the increased responsibility placed on the industry.

There are two provisions that many parties on both sides feel are missing from the FSEA. The first is the proposal to transfer responsibility for food safety to a new agency within the Department of Health and Human Services. That proposal, from the Food Safety Modernization Act, did not make it into the FSEA. The second missing provision is the regulation of bisphenol A (BPA). The bill authorizes research to determine if “the available scientific data support[s] a determination that there is a reasonable certainty of no harm, for infants, young children, pregnant women, and adults, for approved uses of polycarbonate plastic and epoxy resin made with bisphenol A in food and beverage containers” by December 31, 2009. Some interest groups want to see stronger legislation regulating BPA and not just a promise to look into it further.

Conclusion

The FSEA shifts a lot of responsibility onto the food industry. The future will bring more costs, more paperwork, more inspections and more accountability. Will the consumer feel the burden of the new requirements? The strain on small operations from the

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31 H.R. 875 § 101. The Food Safety Modernization Act proposed creating the Food Safety Administration and changing the name of the current Food and Drug Administration to the Federal Drug and Device Administration.

32 H.R. 2749 § 215.
registration fee may cause consumers to feel the pinch. Even larger outfits may need to increase costs by employing more staff in order to keep in compliance with the increased number of inspections and enhanced traceability requirements. At a press conference for President Obama’s Food Safety Working Group on February 7, 2009, Secretary of Agriculture Thomas Vilsack, co-chair of the Group, said that the government’s top priority was to prevent any harm to consumers.\(^{33}\) It is uncertain if he considered the impact of increased food costs on consumers when he made that statement.

The time is certainly ripe to modernize food safety procedures, but it is still unclear if the enactment of the FSEA is the best approach. The FSEA will make consumers feel safer but not without sacrifice by the food industry and likely by consumers. As the Food Safety Enhancement Act continues to move through the legislative process, the next step is for Congress to decide if its benefits outweigh its costs.