

LEGAL ALERT

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FOOD SAFETY ENHANCEMENT ACT 2009: CONGRESS PROPOSES CHANGES TO H.R. 2759

By Todd W. Millar, Attorney

The Food Safety Enhancement Act of 2009 (FSEA), which is currently being considered in Congress, is designed to give the FDA the funding and power it will need to better ensure the safety of the American food supply. However, if passed by Congress, the new stipulations included in the bill may cause consequences for your current business practices.

Background

On May 26, 2009, the members of the Committee of Energy and Commerce released a draft and discussion points of the FSEA. On June 3, 2009, the Subcommittee of Health held a legislative hearing for discussion of the Act. The purpose of the hearing was to elicit views from the FDA and other parties of interest. On June 17, 2009, the House Commerce and Energy Committee held a markup session and later released the Bill to the House floor for consideration. The Bill contains many important changes that will greatly affect the business practices of producing food.

Additional Registration Requirements

Under the current law, all food facilities are required to register with the Secretary of the Department of Health and Human Services. Currently, registration is only required once and there is no fee. The FSEA would amend the current law to require facilities to register annually and require an annual fee of \$1000. Furthermore, it would require that all registration forms be submitted in electronic format only. Failure to do so would constitute misbranding and would be a violation of the proposed law.

Quality Control Standards

The proposed Bill would also require additional paperwork. In hopes of ensuring the best quality of all food products, the FSEA would require each facility to do a hazard analysis, have effective preventive controls, implement corrective action plans, record and monitor those corrective actions, and verify the success of each of these programs. In addition,

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The agribusiness team of attorneys at Smith Haughey has a long history of representing individuals and businesses engaged in all manner of agricultural operations in Michigan. We serve a wide variety of clients, including local farmers, international distributors, food processors, supermarkets, dairies, vineyards, agricultural trade associations, agricultural research institutions, and more.

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a food safety plan must be developed in order to ship foods interstate. It must include the above plans and preventative programs, but the FDA has the authority to mandate minimum requirements for each food safety plan. Finally, all registered facilities would be subject to federal inspection. Inspections of high-risk food facilities would occur at least every six to eighteen months. Current law only allows inspection of a factory, warehouse, or establishment of a firm engaged in interstate commerce. Refusing an inspection would constitute a violation of the FSEA.

Record Keeping Requirements

Under the FSEA, all food producers would have to make their records available to FDA inspectors. This would include records of where supplies are bought, how crops are raised, and a list of customers. Under the current law, the FDA can only examine the records of those in the food business, which does not include farms or restaurants, if there is a reasonable belief that the food is contaminated and presents a serious health threat. The FSEA, however, would require that all those in the food business, including farms and restaurants, turn over all records to the FDA. This requirement would apply to any records relating to the production, manufacture, processing, packing, transporting, and distribution, of food that is maintained at any location.

Improved Traceability

The FSEA would also establish a tracing system. All persons who produce, manufacture, process, pack, or transport food would be required to maintain records of the origin and previous distribution history of the food, along with where the food is transported. There is an exemption from the traceability requirement if the food is produced on a farm and sold by the owner to a consumer, restaurant, or grocery store. The Bill would also require that all processed food have labels to indicate the country in which the processing occurred.

Mandated Growing Standards

The Bill would mandate standards for safe growing, harvesting, packing, sorting, transporting, and holding of raw agricultural produce that originated from a plant or a fungus. The FDA would also have the power to set performance standards for the pasteurization of raw milk and infant formulas, and the irradiation of meat. Finally, if the Secretary determines that food standards for any product would minimize the risk of serious health consequences then that too may be regulated. It also directs the FDA to assess the use of carbon monoxide in certain foods. If the food conditions do not meet these standards it will be considered adulterated under the FSEA.

Increased Enforcement Authority

The FSEA would greatly increase the FDA’s power to regulate and enforce the proposed standards.

Currently, the FDA can only detain food if there is credible evidence or information indicating that the article of food presents a serious health threat to humans or animals. The FSEA would lower the standard for confinement, permitting the government to detain food if there is any reason to believe that the article of food is contaminated or otherwise in violation of the act. The FSEA further grants the power to the Secretary to order the distribution of food to cease if there is a reason to believe that an article of food poses a health concern. Finally, the bill would give the FDA the power to order a quarantine of a geographic location. This would allow the agency to halt the movement of all food in any given location if it deems necessary. The agency could take this action without any court order. The only requirements are that the Secretary notify the appropriate official of the state affected and issue a public announcement.

Greater Criminal and Civil Penalties

Under current law, anyone in violation of the Federal Food, Drug and Cosmetic Act (FFDCA) can be imprisoned for up to three years if the violation is committed with the intent to defraud or mislead. The FSEA, allows for up to ten years in prison if anyone knowingly violates certain prohibitions contained in the FFDCA. The proposed Bill also provides for fines of up to \$100,000 for each violation by an individual. A corporation or other entity can be fined up to \$500,000 for each violation. Compared to the current law, where civil fines are half as high and only incurred if someone has introduced or delivered contaminated food into interstate commerce.

Conclusion

The FSEA gives the Food and Drug Administration tremendous power, specifically granting it the authority to regulate how crops are raised and harvested, to quarantine a geographic area, to make searches of business records, and to establish a national food tracing system. The Bill also imposes annual registration fees of \$1,000 on all facilities processing food. These new stipulations may cause consequences for your current business practices if passed by Congress.

Todd Millar can be reached directly at tmillar@shrr.com or 231.486.4512.

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With offices in some of the agricultural hotspots of Michigan, and an attorney team that includes an agricultural economist, biologist, and small farm owner, Smith Haughey is uniquely qualified to help agribusinesses thrive. We offer clients a comprehensive, one-stop solution for all their legal needs.

Our clients rely on us for knowledgeable, proactive counsel on ever-changing regulatory matters, including environmental, labor and employment, product labeling, product recalls, food liability issues, land use, water and mineral rights, and interstate transportation.

The agribusiness team consists of lawyers who help clients with general business issues such as financing, corporate entity formation, lease and contract preparation, estate and tax planning, workers' compensation, government relations, e-commerce, insurance coverage, and litigation. We are well equipped to assist every level of agribusiness operation, from small farmers who are facing more sophisticated legal issues than ever before, to corporations that wrestle with the complexities of international distribution.

Our agribusiness attorneys are also called upon to help family farms and vineyards launch agri-tourism (or value-added agriculture) operations. Whether a farmer wants to offer a corn maze in the fall or a vineyard owner seeks a liquor license for an on-site tasting room, we have the experience and insight to smooth the way.

We are also pleased to assist farmers and other landowners with another emerging business issue: the granting of their wind and solar rights to third parties. Our Renewable Energy Team has provided invaluable counsel to land owners venturing into this arena.

We are an accessible, efficient, economical legal resource for the agricultural community.

Jon VanderPloeg serves as Chair of Smith Haughey's Agribusiness Industry Team. To learn more about how the team can help you and your business, please contact Jon at 616.458.1365 or jvanderploeg@shrr.com.

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**SMITH HAUGHEY RICE & ROEGGE'S
AGRIBUSINESS INDUSTRY TEAM**



Jon Vander Ploeg, Chair
616.458.1365
jvanderploeg@shrr.com



George F. Bearup
231.486.4510
gbearup@shrr.com



Joseph E. Belsito
616.458.2490
jbelsito@shrr.com



Andrew J. Blodgett
231.486.4537
ablodgett@shrr.com



Ellen A. Fred
231.486.4558
efred@shrr.com



Patrick F. Geary
616.458.5358
pgeary@shrr.com



Scott D. Harvey
231.486.4545
sharvey@shrr.com



Jane C. Hofmeyer
616.458.5388
jhofmeyer@shrr.com



Todd W. Millar
231.486.4512
tmillar@shrr.com



Robert W. Parker
231.486.4504
rparker@shrr.com



Anthony J. Quarto
616.458.1336
aquarto@shrr.com



Jeffrey R. Wonacott
231.486.4509
jwonacott@shrr.com