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Department of Agricultural and Consumer Economics, University of Illinois Urbana-Champaign

FDA's New Rule for Preventive Controls for Human Foods

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2011's Food Safety Modernization Act (FSMA) is the most extensive overhaul of the Federal Food, Drug, and Cosmetic Act since it was introduced in 1938.[1] The purpose of FSMA is to shift regulations towards prevention of foodborne outbreaks and away from responding after the fact with crisis management. Recently, a *farmdoc daily* article (October 7, 2015) outlined the FDA's new definition of a "farm." Those who meet the definition of a farm under the new rules, are exempt from registration of a food facility under the Bioterrorism Act, however facilities that do not meet the definition of a farm must register, and are required to establish and implement hazard analysis and risk-based preventative controls for human food under a new final rule published in September, 2015.[2] This rule requires that registered facilities create a written food safety plan, conduct a hazard analysis, establish preventive controls, implement monitoring, verification and corrective actions, and maintain a supply chain program, recall plans, and all necessary associated records.

Similarity to HACCP

If these preventive controls sound familiar, it is because they share many similarities with FDA's risk prevention predecessor, Hazard Analysis and Critical Control Point (HACCP). HACCP's have been mandatory for juice and seafood producers for nearly twenty years after a number of highly publicized foodborne illness outbreaks. Despite recognition that HACCP is the best approach for approving food safety, it remains voluntary for other producers.[3] HACCPs, which include seven principles, identify the risks in food production and then apply preventive control measures.[4] The principles include conducting a hazard and risk assessment, determining the critical control points to manage the hazards, establishing limits and procedures to monition the critical control points, establish corrective actions to be taken when an

[1] Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of "Local Foods,"* 33 HAMLINE J. PUB. L. & POL'Y 128 (2011).
[2] Federal register vol. 80 No. 180 Thursday, September 17, 2015, summary
[3] See 60 FR 65096, Dec. 18, 1995; 66 FR 6138, Jan. 19, 2001; Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L. J. 565 (2003).
[4] Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L. J. 565 (2003).

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issue arises, maintain a recordkeeping system, and establish a verification system to ensure the HACCP system is working correctly.[5] These principles are almost identical to the requirements for FSMA's new hazard analysis and risk-based preventive controls for human food listed above, which essentially makes HACCP's mandatory for all facilities that do not qualify for an exemption. This shifts the reliance on end-product testing and inspection, which are reactive and inefficient, to a preventive method that looks at the safety of the entire process.[6] Notably, the statute mentions that while there are similarities between the new FSMA rule and HACCPs, the two are not identical and terminology has been revised to distinguish the two.[7]

Hazard Analysis and Risk-Based Preventive Control Requirements

Under the new rules, required facilities must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for all types of food manufactured, processed, packed, or held at the facility in order to identify whether there are any hazards that require preventive controls.[8] Facilities must consider hazards to food that occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain.[9] The facilities must reanalyze their safety plan at least once every three years.[10] Additionally, many of the requirements of the new rule must be overseen by a preventive controls qualified individual, who has successfully completed training in the development and application of risk-based preventive controls or has enough job experience to develop and apply a food safety system.[11]

Exemptions

Aside from the farm exemption previously mentioned, several other facilities are exempted from the requirements for hazard analysis and risk-based preventive controls. "Qualified Facilities" are exempted for two different types of businesses; the first, a local food exemption, exempts a facility when the business has less than $500,000 in sales annually and at least half the sales are to consumers within the same state or within 275 miles. The second exemption is for very small businesses, which the statute defines as businesses averaging less than $1,000,000 in sales per year during the three year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale. Small businesses (those with less than 500 full-time employees) and very small businesses (those with less than $1,000,000 in sales per year as described above) conducting low-risk, on farm activities are also exempted. Facilities that are already required to follow HACCP rules, including seafood, juice and law-acid canned food, are also exempted from the new rules. Finally, facilities that only store raw agricultural commodities intended for further distribution or processing are exempted.

For more information on this rule and other forthcoming rules, a series of webinars, fact-sheets, and training resources is available on the FDA's FSMA's website.

References

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[5] Key Facts: The Seven HACCP Principles *available at* http://www.fsis.usda.gov/Oa/background/keyhaccp.htm.
[6] Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L. J. 565 (2003).

[7] Federal register vol. 80 No. 180 Thursday, September 17, 2015, Summary of the Major Provisions of the Rule.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*