



FDA Revises Definition of “Farm”

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The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011, is perhaps the most far reaching reform of the food safety system since the enactment of the 1938 Federal Food, Drug, and Cosmetic Act. Recent data from the Centers for Disease Control and Prevention estimate that 48 million (1 in 6) Americans suffer from a foodborne illness each year. Moreover, 128,000 are hospitalized and 3,000 people die from this largely preventable public health issue. ^[1] In an effort to minimize foodborne illnesses, the FSMA directs the FDA to implement comprehensive, prevention-based controls throughout the food supply chain—a new legislative mandate that expands FDA jurisdiction beyond its traditional post-farm gate areas of responsibility. In September 2015, the agency released its final *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls* for both [Human](#) and [Animal](#) Food. Embedded within these new regulations is a revised definition of what constitutes a “farm”—an important definition for not only compliance with the Preventative Control rules, but also facility registration requirements under the [2002 Bioterrorism Act](#).

Most commercial grain and livestock operations will qualify under the FDA’s expanded “farm” definition, and thus remain exempted from both the Bioterrorism Act facility registration requirement and the new Preventative Control rules. Under the new rules, non-exempt registered food facilities must maintain a written food safety plan, conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility, institute specific preventative controls for the mitigation of the identified hazards, monitor and verify the effectiveness of the control measures, and maintain records documenting these activities.

Regulatory Definition of a Farm

The revised regulations distinguish between Primary Production Farms and a Secondary Activity Farm. Title 21, Section 1.227 of the Code of Federal Regulations (21 C.F.R. § 1.227) defines a Primary Production Farm as “an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, harvesting of crops, raising of animals

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(including seafood), or any combination of these activities.” These operations may also pack or hold raw agricultural commodities, as well as in *very* limited and *specific* instances, pack, hold or manufacture processed food. A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting, packing, and/or holding raw agricultural commodities, provided that the majority owner of the operation is the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm. This seemingly complex addition to the definition of a farm, enables farmers in some packing operations that were formerly considered “off-farm” to benefit from inclusion in the farm definition and thus gain exemption from some of the FSMA rules. ^[2]

The FDA’s new risk-based rules for animal food also implicate the expanded definition of a farm. For example, a beef cattle operation that also operates a feed mill would be considered a single farming operation and thus not subject to the preventative controls rule for animal food so long as the feed mill is managed by the same company as the cattle operation, is in the same general location, and produces feed that is fed only to animals on the primary cattle operation or another farm under the same management. In sum, fully vertically integrated farming operations with feed mills (i.e., the mill, animals, and land are under common ownership) would most likely qualify under the definition of a farm, and are therefore outside the scope of the preventative control rules. ^[3] However, the FDA has signaled that future rules may require feed mills integrated in these operations to implement current good manufacturing practices established by the new preventative controls rules. ^[4]

It is important to note that although many grain and livestock operations will qualify as “farms,” and are thus exempt from the preventative control and registration rules, a separate and forthcoming *Produce Safety Rule* will implement on-farm standards for the growing, harvesting, packing and holding of produce intended for human consumption. A summary of the proposed (but not yet final) rule is available on the FDA’s [website](#).

Finally, the FDA has pledged to work closely with USDA and the farming community to provide outreach and guidance documents to assist in understanding these and other forthcoming rules under the FSMA. A series of webinars, fact-sheets, and training resources is available on the FDA’s Food Safety Modernization Act’s [website](#).

Notes

[1] FDA, Background on the FDA Food Safety Modernization Act (FSMA), available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm239907.htm>.

[2] FDA, Final Rule on Preventative Controls for Human Food, available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

[3] FDA, Final Rule on Preventive Controls for Animal Food, available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>

[4] Id.