

Is USDA Organic Not Safe Enough for FDA?

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On November 22, 2013, the U.S. Food and Drug Administration (FDA) closed a long public comment period on two proposed rules implementing key provisions of the Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011. FSMA was enacted in order to enable FDA to better protect the public health of Americans by strengthening the food safety system. One of FSMA's primary goals allows FDA to focus more effort on preventing food safety problems rather than relying primarily on regulatory actions after challenging food safety issues occur.

One of the proposed rules, entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule," better known as the "Produce Rule,"¹ has many organic farmers exasperated because as part of its overhaul of food safety regulations, FDA wants to limit the use of animal manure.

According to FDA, as a key element of its new preventive approach, it was mandated under FSMA to establish science-based, minimum standards for the safe growing, harvesting, packing, and holding of produce on farms to minimize contamination that could cause serious adverse health consequences or death. Highly productive farming depends on fertilizer, but the organic farmers who have rejected industrial sources of nutrients—severely limiting the use of animal manure by requiring a full nine months from when farmers spread raw manure on a field until the next harvest of any crops from that field (Produce Rule)—is too much. To many, this rule is tantamount to eliminating a vital ingredient in organic growing in the name of being better safe than sorry.

Granted, the public health stakes are high from an FDA perspective: About 48 million people (one in six Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention (CDC). In fact, FDA has compiled from CDC data information regarding produce-associated outbreaks that occurred between 1996 and 2010 where contamination is likely to have happened early in the production chain—during growing, harvesting, manufacturing, processing, packing, holding, or transportation. By FDA's accounting, this "data set demonstrates that from 1996 to 2010, approximately 131 produce-related reported outbreaks occurred, resulting in 14,350 outbreak-related illnesses, 1,382 hospitalizations and 34 deaths." According to FDA's website describing its FSMA food produce standards, "these outbreaks were associated with approximately 20 different fresh produce commodities. This is a significant public health burden that is largely preventable."²

By contrast, the small organic farmers directly impacted by the Produce Rule are not pleased, claiming among other things that the Produce Rule directly conflicts with established federal organic standards regarding the use of manure and compost. Some comments even aver that by adopting the Produce Rule, FDA is making it effectively impossible for farmers to use manure and even creating barriers to the use of compost (that is supposedly safer because the heat created by compost kills disease-causing microbes). Others point to the fact that FDA science may not conform to existing standards for the use of manure and compost with USDA Agricultural Marketing Service's National Organic Program (NOP) regulations³ that call for the interval between application of untreated manure and harvest to be four months, not the nine months proposed by FDA.

Are the USDA organic regulations considered "not safe enough" for FDA? Is there a law of unintended consequences at work here? Yes, it happens every day inside the federal government. Stay tuned when the price of carrots and kale soar out of control.

¹Reference #1 to the Federal Register Notice: "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Correction," published on March 20, 2013.

²<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm304045.htm>

³<http://www.ams.usda.gov/AMSV1.0/nop>, 7 CFR Part 250, see Organic Foods Production Act (1990)