

# FSMA's Proposed Produce Rule - 29 Important Numbers

**>0** The number of potentially harmful human pathogens living on produce farms.

**0** The number of food-borne pathogens that know, or care, that a produce farm is large or small or very small, conventional or organic.

**100%** The share of responsibility a farmer, large or small or very small, conventional or organic, has to grow and sell unadulterated produce to the next person in the U.S. food chain per the FDA Food, Drug and Cosmetic Act (FD&C).

**70+** Years since sweeping reforms of U.S. safety laws.

**48M** Illnesses

The CDC's 2011 estimated total *annual* number of food borne-illness cases in the U.S..

**\$78B** The economic damage to the U.S. economy *each year* from food-borne illness (The Ohio State U, 2011).

**128,000** Hospitalizations

**190,000** The number of produce farms in the U.S. in 2008 according to the USDA Census of Agriculture.

**3,000** Deaths

**100%** The FDA's legal responsibility to write rules and enforce laws that reduce food-borne illness risk to the U.S. public.

**19** The actual number of pages of the requirements under the proposed Produce Rule in the Federal Register (pages 3628-3646, Jan. 16, 2013). Total pages are 143 (pages 3504-3646). The additional 124 pages provide scientific justification and other informative discussion – especially important since this will be a brand new rule.

**79%** Estimated total percentage of farms NOT subject to any provisions of the proposed rule OR exempt under the Tester Amendment or qualified exemptions meaning they would need to comply with minimal proposed requirements.

By contrast, the National Organic Program Final Rule (7 CFR Part 205) in the Dec. 21, 2000 Federal Register is **49 pages** (80548-80596).

FSMA proposed Produce Rule

**0** The number of third-party audits required by the proposed Produce Rule. The FDA does not do audits; they do investigations, as appropriate, in response to outbreaks or positive sample findings.

**0-52** Depending on the complexity of the operation, the range of the number of required weekly water tests, for each water source, during the growing season.

**\$50** The approximate average cost of one lab water test for one pathogen. At the high end, if a farmer had to do 52 tests, \$2,600. Cost spread out over 30,000 lbs of produce: \$0.09/lb. At 100,000 lb that additional cost would be \$0.03/lb.

**\$460M** The estimated total annual cost to industry to implement the proposed Produce Rule on 21% of U.S. farms. Estimate includes the costs of water tests and other practices on 40,211 out of a total 190,000 U.S. produce farms.

The estimated average annual costs to implement the proposed Produce Rule on 21% of U.S. farms. Most likely less on farms who are already implementing GAPs, buyer requirements, and/or third-party audits.

<b>\$4,697</b>	Very Small Farms
<b>\$12,972</b>	Small Farms
<b>\$30,566</b>	Other Farms

**6+2** Years from court ordered compliance date, starting on or before June 30, 2015, when Produce Rule will be enforceable, plus the additional years when rules on water will come into force on 21% of U.S. produce farms.

**4+2**

**2+2**

**Most 1.75M**

The number of people who care about the safety of the food they buy, serve, and eat.

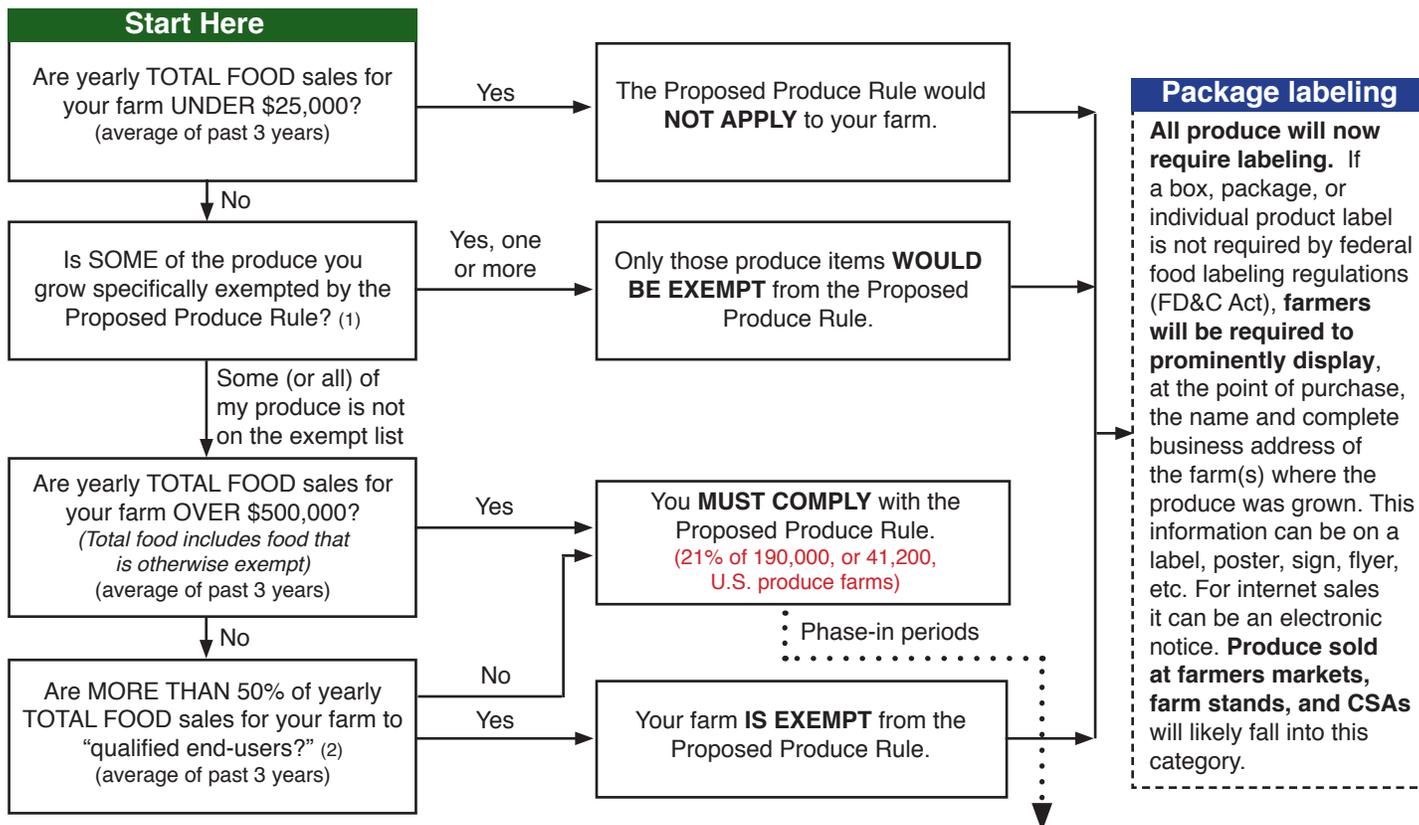
The estimated annual number of food-borne illnesses, 3.6% of 44M illnesses (acute and long-term consequences), that could be prevented by the consistent use of proposed Produce Rule actions on 21% of U.S. farms.

**\$1B** The estimated gross annual dollars (eventually) saved in health care and economic-related costs in the U.S. by implementing the proposed Produce Rule on 21% of U.S. farms. Net savings = \$540M.

# FSMA - Proposed Produce Rule

## Compliance Decision Tree for Growers of Fruits, Vegetables, Nuts, Mushrooms, Herbs, or Sprouts

**ALL U.S. farms that grow food for humans (and animals) must meet minimum federal requirements.** These requirements include those in the FDA Food, Drug and Cosmetic Act (FD&C), which protects consumers (and animals) from contaminated/adulterated food. Note: FDA can withdraw the FSMA Produce Rule exemptions if your farm products are linked to a food contamination outbreak.



### Compliance Phase-in Scope and Timing

The period farmers would have to comply with the proposed Produce Rule will be staggered depending on the size of the farm. The compliance clock would start after the Rule is finalized; probably on or before June 30, 2015 per a federal court ruling. Even then, the emphasis will be on education, rather than enforcement, for the first year of compliance. FDA is proposing the following categories:

**Very Small Businesses** — those having, on a rolling basis, an average yearly value of food sold of no more than \$250,000 during the previous three years. These farms will **have four (4) years from the effective date to comply**. They will have six years to comply with some of the water requirements

**Small Businesses** — those having, on a rolling basis, an average yearly value of food sold of no more than \$500,000 during the previous three years. These farms will **have three (3) years from the effective date to comply**. They will have five years to comply with some of the water requirements.

**Other Businesses (not Small or Very Small)**— they will **have two (2) years from the effective date to comply**. They will have four years to comply with some of the water requirements.

**Attention.** Being “exempt,” or growing Produce “not covered” in the proposed Rule, does not mean being exempt from food safety practices required by buyers or the marketplace. For example, managers of farmers markets may require GAPs (Good Agricultural Practices), a written farm food safety plan, or a third-party audit prior to allowing vendors in their market. This may be true of those buying produce for restaurants or other small markets as well. Visit the Produce Safety Alliance website to find educators in your state who can help you implement GAPs ([www.producesafetyalliance.cornell.edu](http://www.producesafetyalliance.cornell.edu)). **In all cases, producing safe produce is the right thing to do!**

#### Notes

(1) Exempt produce includes produce processed commercially that adequately reduces microorganisms of public health significance (e.g., green beans that will be canned). It also includes produce rarely eaten raw: arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crab apples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugar beet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams.

(2) A qualified end-user is either(a) the consumer of the food; or (b) a restaurant or retail food establishment located in the same state, or if located out of state, no more than 275 miles from the farm.