I am the vegetable and berry specialist with University of Vermont Extension and coordinator of the USDA’s Northeast Sustainable Agriculture Research and Education program. I have been working with diversified horticulture farms on a wide range of production and marketing issues for over 30 years. I support the goal of reducing food safety risks on such farms but I have serious concerns about the impacts of the draft Produce Rule, as follows.

1. Having four different measures of farm production used to determine the type of food safety compliance required will create confusion and unfairness in the marketplace.

The Tester-Hagen amendment uses $500,000 in ‘all food’ sales as a measure; the exclusion from FSMA uses $25,000 in ‘all produce’ sales; the applicability of FSMA is based on ‘covered produce;’ GAPS has no economic threshold but applies to all produce. I understand that FDA cannot change the language in Tester and that it has no authority over GAPS, but the Produce Rule should be written with these in mind so as to 1) minimize differential treatment of wholesale and retail farms of similar size, 2) avoid inconsistencies in the application of the law to farms selling the same products to the same markets and 3) avoid creating deterrents to the development of local farm-to-institution markets.

Here are some examples of what will happen if the draft rule is implemented.

Let’s say I am a part-time strawberry grower and my farm has annual sales just over $25,000 to a wholesale distributor. I will have to follow the same procedures as a strawberry farm with $25 million in sales, whether it is up the road, or across the country. The difference of course is my net income will be just a few thousand dollars so compliance will be a huge burden on my business whereas it will be a small part of operating costs for a large farm. This will give large farms an unfair economic advantage.

Across the road from me is another strawberry farm, and they sell over $200,000 of wholesale berries to the very same distributor that I sell to, but they don’t have to comply with the entirety of the Produce Rule. That’s because they also have $250,000 in retail sales, so they are largely exempt from FSMA under the Tester-Hagen amendment. That farm, with $450,000 in annual sales, will gain a significant, and unfair, economic advantage over my very small farm.

Up the road, my friend grows and sells just over $25,000 of wholesale potatoes. I’ve convinced her to put in some strawberries to sell to my distributor in order to supplement her farm income. She expects to sell just a few thousand dollars of wholesale berries, but that means she would have to comply with the Produce Rule as written. Even though the potatoes are not covered by the rule, the $25,000 exclusion threshold is based on annual sales of all produce. Needless to say those berries will add a compliance burden for a very small amount of revenue, so they will be ripped out when FSMA goes into effect. This will limit her very small farm’s ability to access a promising new market.
Another nearby small farm had sales of $100,000 in covered produce, mostly retail, with sales of ‘excess’ crops to local schools. As is the case in much of the Northeast, the retail market to qualified end users is becoming saturated in our area, so that farm has taken advantage of USDA and State programs to increase their participation in farm to school programs. Their annual sales to schools have steadily increased and the farmer wants continue to focus on this market but if the sales to schools exceed 50% of the farm’s total food sales they will not be exempt from FSMA under the Tester amendment. The farmer who manages all aspects of this small farm does not have the management capacity to comply with the Produce Rule, and given that net revenue is typically only ~20% of gross sales for this type of farm she cannot hire someone to help. The result will be that she has to limit her farm-to-school sales.

Another much larger farm nearby sells one million dollars annually of sweet corn, pumpkins and winter squash. Much of their produce is sold to a supermarket chain that requires GAPS, even though this farm does not have to comply with FSMA because they do not grow ‘covered produce.’ The farm also retails these crops at a small farm stand, where they advertise that their farm’s food safety certification under GAPS. But when asked, they must explain to customers that they do not actually comply with the federal food safety law.

The scenarios above may be somewhat unusual but they highlight the fact that consumers, buyers and farmers will be confused by the application of the Produce Rule. More egregious, the rule will create an unfair economic barrier to entry, expansion, and survival, for small farms selling primarily to wholesale markets which are not ‘qualified end users’.

**Recommendation.** The Produce Rule should specify that all commercial produce farms must have food safety plans, but farms that are exempt or excluded from the Federal law will be covered by simpler, scale-appropriate rules developed at the State level. The annual sales threshold for exclusion from FSMA compliance should be raised to $250,000 (of all produce) for farms with primarily wholesale markets (a level comparable to the Tester-Hagen exemption for farms with no more than $500,000 in sales of all food). Thus, small farms with any mix of retail or wholesale markets will be more equally regulated. This will also allow all farms to provide their markets with a reasonable, scale-appropriate, level of food safety assurance, while at the same time reducing risk. The Pesticide Applicator program of EPA is an example of state-level oversight (i.e. cooperative federalism) of an issue that affects most farms and is regulated by Federal law.

Engaging all farms in scale-appropriate food safety regulation is important because once FSMA has been in effect for a period of time, both wholesale and retail customers (and their attorneys and insurance agents) will want assurance that food safety practices are being followed on all the farms they buy from, regardless of their size, location, or crops. I have every confidence that Cooperative Extension and state Agencies of Agriculture can develop small-scale food safety certification systems that fit the farms they work with, following the general principles of the FSMA produce rule and GAPS. In fact, Vermont, Massachusetts and Rhode Island all have or are developing local, practical, programs to help their farmers remain competitive in the marketplace while also reducing food safety risks. Such a diversity of state programs following common principles will enhance our knowledge of how best to manage food safety risks on the farm across the nation’s disparate environmental conditions and production systems.
2. Randomly testing surface water is not likely to improve food safety; the Produce Rule should instead require practices that promote microbial die-off before sale of crops. The science is lacking to establish generic E. coli standards for use of agricultural water from a flowing body of water. Sampling of such waters for recreational safety purposes has repeatedly shown a wide variation over time and place in the level of generic E. coli. Rainfall, the presence of livestock and wildlife, and localized sewage issues all have an influence on the results. Since testing is far from instantaneous, the lab results do not reflect the actual levels in agricultural water at the time of application. In my own experience with hundreds of such samples, it takes over one week to get results back from a lab under the best of circumstances.

Testing for generic E. coli repeatedly, perhaps months before application of surface water to a crop, will waste time and money, harming farm profitability for no good reason. Further, it will create a false sense of security when test results taken long before application to the crop do not reflect actual risk. This approach is similar to saying that if cloudy weather is a food safety risk, farmers should measure the cloud cover 20 times over two years to establish their baseline risk. The resulting calculation is not likely to reflect the actual risk of cloudiness, nor whether it will be cloudy at harvest.

My own on-farm research over the past several years has found elevated levels of generic E. coli in leafy greens wash water in many instances when neither overhead irrigation nor un-composted manure (or any manure in some cases) was applied to the fields where crops were grown. This suggests that wildlife or other factors is the source of contamination.

Recommendation: Instead of an expensive, complicated and unsubstantiated approach to surface water testing, the Produce Rule should focus on use of practices that are known to promote microbial die off before a crop is sold and consumed. These include: waiting to harvest after applying agricultural water, and washing of produce. Once research quantifies the die-off rate during storage of produce this should be included as an accepted practice. Given the draft Produce Rule’s generic E. coli die-off rate of 0.5 log/day there is no practical reason for testing surface water when harvest occurs weeks or months after the last time water contacts the crop.

Using the 0.5 log reduction in generic E. coli and assuming a worst-case scenario of 20,000 CFU/ml in the surface water to be applied to a crop, waiting 6 days after application of the agricultural water would allow for a 3-log reduction, leaving an estimated 20 CFU/ml of generic E.coli. Thus, growers should be able to ‘opt out’ of surface water testing if they allow 6 days to elapse between application of surface water and crop harvest.

For some situations, in light of the proposed die-off rate, surface water testing is especially unnecessary. Take strawberries for example. Many growers use overhead irrigation from surface water to protect the crop from frost when it flowers in early spring, and there are typically a few green berries present at this time. Once the danger of frost is past they switch to drip irrigation to avoid wetting the fruit and foliage which encourages disease. These growers could also use well water for their spray solutions. But because there were a few green berries present during overhead irrigation for frost, the draft Produce Rule would require that surface water testing regime must be followed, even though it will be weeks or months until the crop is harvested.
There is no practical reason or scientific basis for testing surface water when harvest occurs more than a week after the last time agricultural water contacts the crop, OR if the crop is to be thoroughly washed or treated with a wash water sanitizer labeled for that use.

Recommendation: Research should be initiated to develop on-site tests of surface water so that a relatively instantaneous measure of generic E. coli can be obtained immediately prior to the application of the water to crops. Until such tests are commercially available at an affordable cost, the Produce Rule should instead focus on practices that reduce risk by promoting microbial die-off. (If surface water testing is required it should be limited to three times per year to be consistent with GAPS, but there is no scientific basis for this.)

Given the FDA’s suggested die-off rate after application of agricultural water, and my own on-farm research over the past three years shows that each rinse of leafy greens yields about a one-log die off of generic E.coli, I suggest requiring either a 6-day wait after overhead irrigation OR cleaning of the crop after harvest. The latter could be either a triple rinse, some specific time exposure to a flowing rinse, or use of an approved sanitizer in the wash water. The latter is well-known to be highly effective and should be specifically listed as an acceptable practice in place of water testing.

3. **Not regulating raw manure at all is risky and confusing.** Although it makes sense to delay creation of an aggressive new regulation for raw manure management until there is sufficient scientific evidence, it makes no sense to not require any wait between application of raw manure and harvest. Buyers will not tolerate the idea that raw manure may have been recently applied to crops, and farmers will be confused by a rule that requires testing of water for generic E.coli yet allows a farmer to spread raw manure at any time.

Recommendation. Manure is known to pose a risk to food safety, and pathogens it may contain are known to die off over time after field application. So while more research is needed to optimize manure management recommendations, in the meantime it makes sense to implement the preventative standard that is already widely accepted by growers and buyers. That is the 90 to 120-day waiting period, depending on whether the crop is on the ground or not. This would be consistent with the NOP organic standards as well as GAPS, creating a consistent standard for farmers to follow.

4. **Creating regulatory hurdles based on the location of a farm activity or the ownership structure of businesses engaged in farm activities will harm the economic viability of local food systems.** The proposed rule triggers stricter standards for farmers that conduct certain farm activities off-the-farm, or for farmers that work together through food hubs or other joint ventures. Sorting, mixing, removing stems and husks, washing, packaging and stickering or labeling are all considered farm activities under the Produce Rule, but not if they do not take place “in one general location” or if they are done in a location that is jointly-controlled by multiple farms. These situations would trigger the Preventative Controls rule because the farms would now be ‘facilities’ and require more intense food safety procedures, creating unfair application of food safety regulations to farms with off-site activities and to farms that work together to conduct certain farm activities.
Recommendation. The physical location of a farm’s activities should not determine whether it is a farm or a facility. Remove the term “in one general location.” Farmers working together in joint business ventures to conduct farm activities should not be considered facilities. Rather, the extent of processing (such as chopping, dicing, and peeling) should be the threshold for being classified as a facility rather than a farm, as that is a reasonable justification for additional food safety oversight.

5. Inconsistent definitions will make implementation of FSMA unnecessarily challenging. Because many small farms in the Northeast engage in value-added processing they will fall under both the Produce Rule and the Preventive Controls Rule. The definitions of ‘small’ and ‘very small’ should be the same in the both rules to avoid confusion. The time allowed for farms and food processors to come into compliance after notification of intent to withdraw a qualified exemption should be the same under both rules (120 days for both farms and processors, not 60 days for farms and 120 days for processors.)

6. Lack of clarity about the exemption for charitable food donations may exacerbate hunger. The Produce Rule should clearly and unequivocally state that produce donated to, and handled by, charitable organizations with the intent to provide food for people in need is exempt from all requirements of FSMA.