



Food Safety Modernization Act and the Produce Safety Rule Questions and Answers

This document is intended to provide responses to various questions posed regarding the the federal Food Safety Modernization Act (FSMA or the Act) and the Produce Safety Rule (PSR). The PSR is one of seven food safety-related rules that the Act directed FDA to enact that sets science-based standards for the growing, harvesting, holding, packing and storing of fruits and vegetables for human food.

There are many questions and concerns regarding the Produce Safety Rule and in many cases inaccurate information within the realm of public discourse. This Q&A will be a living document that provides factual answers to concerns and questions raised by farmers or other impacted stakeholders regarding the PSR, or FSMA in general. Responses will constantly be added to new questions as they come up in print or discussion with the Department of Environmental Management, Department of Health, or University of Rhode Island.

Q1. Most farmers have heard about the “Qualified Exemption” or QE that is referenced in the Produce Safety Rule. Without specifically restating the QE, there are those who believe that the FDA will, over the years, take the exemption away or lower the \$500,000 threshold in an effort to include all farmers under the PSR. Is this true?

Answer. No, this is not true. The QE is delineated in the Food Safety Modernization Act that was passed by Congress. FDA **cannot** change it in their PSR. As matter of fact, the law states that the \$500,000 will increase every year, adjusted for with inflation from 2011 baseline – the year the Act was signed into law. What does this mean? In 2011 the value was \$500,000; in 2017 the value is \$551,340. However, the PSR does allow FDA to revoke the Qualified Exemption if the produce grower’s farm is directly linked to a foodborne illness outbreak or if FDA or state regulators determine that there is an imminent public food safety health hazard. Please remember that inspection of QE farms will be limited to presence or absence of signs/labels and financial documentation.

Q2. How many RI farms can be considered farms that may be impacted by the PSR?

Answer. According to the 2012 USDA census, RI has 1243 farms. However, only about 25% or approximately 300 grow produce for human consumption. According to the census 238 RI farms grow vegetables, melons, potatoes, sweet potatoes and 136 farms grow fruit, tree nuts and berries. While this number may not be exact, it is important to reference only those farms growing produce for human food when talking about the Produce Safety Rule.

Q3. Is there a Federal Good Agriculture Practices Act that requires enforcement?

Answer. No. There is no GAP Act at the federal or state level. GAP is a voluntary, third party, on-farm food safety audit program. There is no “enforcement”. There are state GAP programs, the Harmonized GAP program and the USDA GAP/GHP program (GHP – Good Handling Practices). Both Harmonized and USDA GAP/GHP programs are used nationally. While the USDA audits their own extensive program, the Harmonized GAP Program can have auditors from different sources, including USDA but not solely USDA.

Voluntary GAP audit programs are carried out by state agencies, USDA, and private auditing firms. Audit standards can also include those tailored to specific commodities (tomatoes, greens, mushrooms). The buyer can determine which audit a farmer must use. In RI, we have the RI GAP program that is jointly administered by a partnership between the URI Cooperative Extension Food Safety Education Program and RIDEM/Division of Agriculture. The RI GAP program has been successfully implemented for close to 15 years and has been specifically targeted to small farmers.

Q4. Does FSMA or PSR have any impact on nutritional labeling requirements?

Answer. No. The Nutritional Labeling and Education Act (NLEA) governs labeling. Produce – as raw agricultural commodities – has no nutritional labeling requirements. Labeling requirements lie outside of FSMA and any of the rules. The PSR does include “labeling” requirements for “labels”, or point of purchase placards identifying the farm name and address for those farms that meet the Qualified Exemption. Produce destined for commercial processing must be accompanied by a “label” and documentation indicating that it has not been treated to destroy pathogens.

Q5. Does FDA approve ingredient or nutritional labels?

Answer. No. The FDA does not approve labels. If you need help, RIDOH/Division of Food Protection can help. There are minimum requirements for labels per the NLEA and the state of RI – for example ingredient list, allergen statement (if necessary), address - however, there are exemptions regarding nutritional labeling which most small processors, if not all, would meet. It is easy to meet the exemptions – there are many!!

Q6. How does maple syrup fit into FSMA and PSR?

Answer. A product like maple syrup would need a label indicating facility, ingredient(s) and net weight – requirements of NLEA and the state. Any food safety requirements for maple syrup fall under the Preventive Controls Rule for Human Food (CFR 117). If there are any questions regarding maple syrup, contact Diane Hirsh, University of Connecticut at diane.hirsch@UConn.edu.

Q7. Has the USDA historically regulated all production issues?

Answer. No. FDA has had regulatory authority for most food, except meat and poultry which has been regulated – production and process – by the USDA. FDA has always had authority over produce regarding safety issues. As a matter of fact, contrary to what most people believe, FDA has regulatory authority over eggs in the shell while USDA has regulatory authority over eggs when out of the shell. USDA only governs quality issues of eggs through its grading program (e.g. Grade A) – not safety.

Q8. Does the PSR mandate buffer zones around houses?

Answer. No. There is nothing in the PSR that addresses buffer zones around houses and growing of produce. There may be some confusion new rules that RIDEM are enforcing regarding pesticides.

Q9. Does the PSR require that farmers have to keep records regarding animals in the field? What are the expectations and what records are required?

Answer. No. Farmers are **not** required to keep records regarding animals in field or even the assessments made by farmers concerning potential animal feces. The law requires that if a farmer sees animal intrusion in the fields of **high risk produce** (e.g. tomatoes, cucumbers, lettuce) that the farmer assess the area to make sure that the animal(s) have not left contamination behind. If they have, the law does require that action be taken not to harvest that particular area. A good example of why this is required can be seen in the outbreak on a small Oregon strawberry farm, Jaquith, in 2011. There were 15 illnesses (there was probably more) and one death documented in this outbreak due to E coli 0157:H7. The cause – deer in the field.

However, no records are required. In fact, the PSR actually requires fewer records than most GAP programs! The records that are required by the Produce Safety rule are those for water, biological soil amendments, training, cleaning/sanitizing and produce destined for commercial processing. Yes, those records must be kept for 2 years. This is no different than any other food safety rule that **both** the FDA and USDA implement for all other products and processes. We **recommend** that additional records are kept to protect the farmer and the farm – but they are not required and regulatory agencies have no access. There is a requirement for 3 year record

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retention as proof that the farmer meets the Qualified Exemption criteria since it is a 3 year rolling average for documentation.

Q10. Are there fines associated with non-compliance? If a farmer misses something or makes a mistake, will the FDA or state regulatory agency fine the farm?

Answer. No. There have been quotes in local papers of \$2500 - \$18,500 depending on the violation. There are **no fines** associated with deficiencies that an inspection may find on the farm as long as the problems are fixed. Issues associated with an imminent public health hazard must be dealt with quickly and all other violations of the rule must be corrected in a timely manner. The only time fines are implemented by FDA is if there is negligence. No other food safety rule, FDA or USDA, implements fines if a problem is found as long as it is corrected. If there is information that we do not know about we would appreciate that you contact Lori Pivarnik, 401-874-2972 or lpivarnik@uri.edu and let her know.

Q11. Does a farmer have to turn away a customer at a pick your own operation if they are sneezing?

Answer. No, but it is a bit more complicated. A sneeze may not be a sign of illness. However, a farmer should not want an ill person in the pick your own field if the visitor is ill. This would be in the same way a farmer should not want an ill worker to be picking his/her produce for sale. The Produce Safety Rule requires that a farmer make visitors aware of their food safety policies and procedures. What does that mean? Perhaps a sign requesting visitors wash their hands prior to entering the field or letting them know that if they are sick they should not be picking the produce at that time. The rule states that farmers need to take all reasonable steps to ensure that visitors are aware and comply. Do the best you can!! The rule also requires that toilet and handwashing facilities be accessible to visitors. Customers do appreciate when a farm shows that they are interested in the safety of their produce and simple signs are effective – nothing fancy!

Q12. What happens if generic E. coli levels in surface water are higher than allowed by the rule? Does this mean that farmers cannot harvest for 3 days? Will my buyer wait?

Answer. No – it depends. The rule allows for die-off from 1-4 days depending on how far above the *E. coli* limit of 126 CFU/ml. So, it may be only a one day waiting period – not 3 days.

Processors or wholesalers that buy produce have either implemented or will be implementing requirements under another of the 7 rules – Preventive Controls for Human Food. Part of the requirements for that rule is supplier controls – this would include the produce you are selling. These process facilities will insist that there is compliance with the Produce Safety Rule when needed – they will have to.

FYI – the water requirements under the rule are currently under review. Stay tuned. While it is recommended that farmers who know they have to comply continue to do some testing – surface

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and ground waters - we are not necessarily recommending that farmers do the water profile requirements until we know how FDA finally implements this requirement. We recommend that farmers continue to implement preventive strategies to keep the water safe as agricultural water. As a reminder, there is a water testing requirement for all GAP programs including RI GAP.

Q13. Is the Produce Safety Rule 600 pages?

Answer. No. The produce safety rule is not 600 pages. There is often confusion between what the actual rule is and what is in the preamble. In the preamble, the FDA is required to document all comments made by trade associations, state agencies, scientists, educators, farmers etc. and FDA responses. It serves as good information regarding what the FDA was “thinking” and can be used to help a farmer understand what and why they have to do certain activities. For example, while manure application times are still being studied by the FDA, responses in the preamble indicate that the FDA is willing to accept the National Organic Program’s 90/120 day waiting period for compost and raw manure application. This is not in the actual rule but is useful to a farmer. The actual rule – CFR part 112 – is about 85 pages – depending on how it is printed. There are parts of the rule – such as introduction, definitions, removal of exemption, appeals etc. – that you will not be using.

Q 14. What is the cost to attend the PSR/RI GAP training?

Answer. While there is FDA money to subsidize the required training, the costs to farmers will be only be \$35.00 for those who want or need a certificate for compliance. There is no cost to those who do not want the certificate. This compares to \$190 for seafood, and over \$300 for meat/poultry and Preventive Controls for Human Food trainings. However, if the grant money goes away, the cost to farmers will be about \$120 (\$85 without certificate) which covers the curriculum book, certificate, printing, flash drive, and food.

Questions – contact Lori Pivarnik, URI Cooperative Extension, Food Safety Education Program.
Tel: 401-874-2972; E-mail: urifoodsafety@etal.uri.edu

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