

Getting Good Guidance – How Growers Can Effectively Comment on the Produce Safety Rule Draft Guidance

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After what seems like years of saying “it’s coming,” on farm inspections under the Produce Safety Regulation are actually here. The U.S. Food & Drug Administration (FDA) – or state agencies in states where FDA has entered cooperative agreements with the state agency (like Colorado)—will begin inspecting farms that grow more than \$500,000 in produce annually during the January 2019 growing season.

Coinciding with the commencement of inspections, FDA released Oct. 22, 2018 its long-anticipated draft guidance on implementation of the Produce Safety Rule. Find a link to the draft guidance [here](#). Guidance documents are not law, but they are very helpful in understanding how the agency expects to implement and enforce a rule when certain sections of regulations may be open to multiple interpretations. FDA also accepts comments on this draft guidance document until April 22, 2019.

Why, you may ask, should I review this draft guidance and consider submitting comments? My answer: FDA simply doesn’t know what it doesn’t know. You, however, know your farm better than anyone. If you are 100 percent clear on exactly how every aspect of the Produce Safety Rule applies to your operation, that is fantastic. I am happy for you. However, if you are like many of us – there are places in the rule where you are still unsure how it will apply to your operation— the goal of the guidance is to clarify those places in the rule. If you still don’t know the answer after reviewing the draft guidance, join the club. Also, do yourself and your industry a favor and *tell the agency that*.

So, what does it take to write an effective comment to the FDA? Well, first you have to read the guidance. I know it’s long; 141 pages to be exact. However, you have probably been to a PSA training by now, sat down with your records and have at least some sense of what parts of the rule are giving you fits. Maybe it’s harvesting, packing and holding, or maybe it’s sanitation, or maybe it’s records. Pull out your PSA manual and write down the list of things you still have questions about. Then, go to draft guidance table of contents, find the section that looks like it should address your question and read it. Ask yourself, does this answer my question about what to do here? If it does, great! Get it done. However, if you read it and you see how that works for that farm or that instance, but it doesn’t work for you, ask yourself why. Then write it down, and send it to the agency on your farm letterhead by going [here](#) and clicking the “comment now” button. The reality is, good comments are just as simple as that. They are specific and grounded in real problems with the rule experienced by real people. They simply need to tee up the issue so the agency has a better opportunity to address it.

So, why take the time before 11:59 ET on April 22, 2019? Guidance documents are frequently the place where the rubber meets the road in implementing a regulation. It’s unfortunate, but in my experience, sometimes an inspector shows up and offers a stricter interpretation of a regulation than you are prepared for despite your diligent efforts. When that happens, nothing is more effective than quoting the words of the agency back to it in getting the agency to guide the agency in a certain direction.

Right now, produce safety inspections are brand new, and it is hard to know what you don't know, and we can't help that. However, you can do something about the questions you already have. If you don't read that guidance and provide your comment, that example that looks like your farm, simply won't be there to draw on years down the road when you are face-to-face with an inspector. The reality is we are in this for the long haul, and ultimately what is in this guidance will matter years from now. So, PLEASE, spend an afternoon to go through it before April of this year.