


Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 15, 2014

Re: Produce Standards Rule: FDA-2011-N-0921, and RIN 0910-AG35

Dear FDA:

The undersigned organizations represent farmers, food businesses, and consumers across the United States. We jointly submit these comments on the re-proposed rule for Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereinafter, proposed Produce Rule).

I. Agricultural Water

FDA is proposing that agricultural water meet a microbiological standard that is not backed by science. The proposed rule would require farmers to adopt extensive water testing and record-keeping regimes based on this arbitrary standard.

In the absence of appropriate, relevant scientific risk assessments, the undersigned organizations urge the FDA to not adopt a numeric standard for irrigation water at this time. Instead, the agency should conduct studies to assess the risks involved with irrigation water, as it intends to do with manure, and adopt an appropriate standard (whether numeric or qualitative) based on that research. We further urge the agency to reduce the frequency of the required testing for whatever standard is used, as discussed below.

A. The generic E. coli standard is not science-based.

The EPA recreational water standard, which the FDA proposes to adopt, was developed to identify fecal contamination in order to prevent gastrointestinal illness in swimmers. It was not meant for irrigation management and does not account for the fact that microorganisms die off rapidly in the interval between irrigation and harvest.

The standard relies on using generic E. coli bacteria as an indicator organism that suggests

possible fecal contamination in water. Generic E. coli does show some correlation with fecal contamination, but there is wide consensus that neither generic E. coli nor any other indicator organism is a reliable marker for the presence of foodborne pathogens. There are several key problems with using the recreational water standard:

- **The presence of generic E. coli does not mean that pathogens are present**. Studies of irrigation water and river water have shown no correlation between generic E. coli and pathogens such as Salmonella and E. coli 0157:H7.[1] The generic E. coli count can be significantly higher than the proposed standard without the presence of pathogens.
- **The absence of generic E. coli does not mean that the water is free of foodborne pathogens.** In fact, there can be large numbers of pathogens in water with no E. coli at all.[2] The pathogen Listeria monocytogenes was found to have an inverse correlation with E. coli in one study[3] and E. coli has been shown to have no predictive value for Salmonella.[4]
- **Generic E. coli is not even a reliable indicator of fecal contamination** since it has been shown to live and reproduce in soil and sediments.[5]
- **Increased E. coli counts do not necessarily correspond to increased pathogen risk.** Although the presence of generic E. coli shows some correlation with fecal contamination of water, evidence suggests that pathogens are not more likely to be present when the count is high than when it is low.[6] This undermines the validity of FDA's testing regime that requires farmers to treat or discontinue using the water if the E. coli count exceeds a certain number.

FDA has not disputed these findings nor shown that adopting the E. coli standard will improve public safety. FDA has acknowledged the lack of an adequate indicator organism for foodborne pathogens.

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[1] Benjamin L, Atwill ER, Jay-Russell M, Cooley M, Carychao D, Gorski L, Mandrell RE. 2013. Occurrence of generic E. coli, E. coli O157 and Salmonella spp. in water and sediment from leafy green produce farms and streams on the Central California coast. International Journal of Food Microbiology, 165: 65-76.

[2] Edge TA, El-Shaarawi A, Gannon V, Jokinen C, Kent R, Khan IU, Koning W, Lapen D, Miller J, Neumann N, Phillips R, Robertson W, Schreier H, Scott A , Shtepani I, Topp E, Wilkes G, van Bochove E. 2012. Investigation of an Escherichia coli environmental benchmark for waterborne pathogens in agricultural watersheds in Canada. Journal of Environmental Quality, 41(1): 21-30.

[3] Wilkes G, Edge T, Gannon V, Jokinen C, Lyautey E, Medeiros D, Neumann N, Ruecker N, Topp E, Lapen DR. 2009. Seasonal relationships among indicator bacteria, pathogenic bacteria, Cryptosporidium oocysts, Giardia cysts, and hydrological indices for surface waters within an agricultural landscape. Water Research, 43(8): 220923 (2014).

[4] Wright A, van Bruggen A, Vellidis G, Danyluk M. 2013. Science-based evaluation of regional risks for Salmonella contamination of irrigation water at mixed produce farms in the Suwannee River watershed. CPS Final Report.

[5] Litton RM, Ahn JH, Sercu B, Holden PA, Sedlak DL, Grant SB. 2010. Evaluation of chemical, molecular and traditional markers of fecal contamination in an effluent dominated urban stream. Environmental Science and Technology, 44: 7369–7375; Solo-Gabriele HM, Wolfert MA, Desmarais TR, Palmer CJ. 2000. Sources of Escherichia coli in a coastal subtropical environment. Applied and Environmental Microbiology, 66(1): 230–237; Whitman R, Nevers M, Byappanahalli M. 2006. Examination of the watershed-wide distribution of Escherichia coli along Southern Lake Michigan: An integrated approach. Appl. Environ. Microbiol., 72(11): 7301-7310.

[6] Horman, A, Rimhanen-Finne R, Maunula L, von Bonsdorff C, Torvela N, Heikinheimo A, Hanninen M. 2004. Campylobacter spp, Giardia spp., Cryptosporidium spp., Noroviruses, and Indicator Organisms in Surface Water in Southwestern Finland, 2000-2001. Appl. Environ. Mocrobiol. 2004, 70(1):87.

The agency seems to have embraced the recreational water standard because it is the only standard that can be implemented immediately. Expedience is taking the place of good science and measures that might actually protect public health.

According to an issue brief by the Pew Produce Safety Project (which advocates for mandatory enforceable standards for produce), "…a single national standard for irrigation water quality applicable to all commodities, regions, and scales of production seems both unwise and unattainable without creating hardship to the fresh produce sector or allowing sporadic unacceptable levels of risk to consumers. Just as science-based criteria are required for recreational waters, science should be applied to formulate flexible and risk-based criteria for irrigation waters."[7]

B. No one knows how the implementation of this standard would affect American produce farming, but evidence suggests that the impact could be significant.

Experts agree that no one knows much about the microbiological status of U.S. agricultural water. Both the Pew Produce Safety Project and the New York State Irrigation Water Quality Database Project cite a "nationwide knowledge gap regarding the sanitary qualities of irrigation water." Records on water quality are kept by the states, so it is not possible to get an accurate sense of microbiological contamination nationwide. A few statistics suggest that the problem is extensive:

- According to Clean Water Act reporting, 26 percent of America's surface waters are impaired due to pathogens.[8]
- 81 percent of Indiana's assessed surface waters failed to meet the Recreational Water Standard due to E. coli[9], and 50 percent of Virginia's rivers and streams are impaired, mostly because of E. coli.[10]
- According to California's Community Alliance With Family Farmers, managers of irrigation districts report that that surface water flowing into their districts "will frequently fail the proposed standards."
- Onion growers in the Eastern Oregon-Idaho growing region protested the proposed water rules after finding that most of the water in their irrigation systems would not meet the proposed standard.
- Even groundwater is affected. A study of two watersheds in Kentucky's karst Bluegrass region found that springs and wells exceeded bacterial limits 28-87 percent of the time.[11]

Even waters that are generally clean can be expected to exceed the E. coli standard

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[7] Pew Produce Safety Project. Standards for Irrigation and Foliar Contact Water. http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/PSPSummaryWaterpdf.pdf

[8] http://scorecard.goodguide.com/env-releases/water/cwa-us.tcl#cause

[9] https://engineering.purdue.edu/SafeWater/watershed/ecoli.html

[10] http://www.deq.virginia.gov/Portals/0/DEQ/Water/WaterQualityAssessments/IntegratedReport/2012/ir12_Executive_Summary.pdf

[11] Howell JM, Coyne MS, Cornelius P. 1995. Fecal bacteria in the agricultural waters of the Bluegrass Region of Kentucky. J. Environ. Qual., 24: 411-419.

intermittently, during warm weather or when runoff from heavy rains disturbs sediments and carries E. coli into waterways.

C. Without information about the number of water sources failing to meet this standard, it is impossible to perform a cost-benefit analysis.

No rigorous cost-benefit analysis of FSMA has ever been done. Instead, FDA issued a "Qualitative Risk Analysis," on the basis that there was not enough data available for a quantitative risk assessment. FDA points to its Preliminary Regulatory Impact Analysis (PRIA) to indicate that it has complied with Executive Orders 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives. The PRIA, which relied on poor science and deeply flawed analyses, did not even come close to meeting that mandate.

The lack of an adequate cost analysis was most obvious with respect to agricultural water. The PRIA's authors, seeking numbers on which to base their cost analysis, chose to use Clean Water Act statistics, but it is not possible to estimate from these statistics how much irrigation water would fail to meet the EPA recreational water standard. The EPA estimates that 15.2 percent of US surface waters fail to meet the standard. But there is no information in the report establishing which of those waters are used for irrigation or how much irrigation water is drawn from impaired sources, since some water sources are used much more intensively than others. The statistics also exclude groundwater. Without this information, the cost estimates are little more than guesswork.

D. The E. coli standard is not consistent with the statute

FSMA requires the FDA to establish "minimum science-based standards for those types of fruits and vegetables….that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks."

Science does not support the use of the E. coli standard to indicate danger to produce crops. In the absence of scientific evidence to justify this standard, the FDA lacks the statutory authority to impose it. If the FDA is to fulfill its statutory mandate of science-based standards, more research is needed to determine what those risks are and how they vary according to region, climate and growing practices.

The regulations must also be "based on known safety risks." With this E. coli standard for irrigation water, the FDA has not taken a risk-based approach, but is instead proposing to mandate a universal metric unrelated to actual risk. In contrast, a risk-based standard backed by research that accounts for regional differences and diverse growing practices would fulfill the FDA's statutory obligation.

Finally, the cost of government regulations must be taken into account. At this time, no adequate estimate of the cost of imposing a single microbial standard exists or can exist, given the state of the current data. What is clear, however, is that the extensive burden this standard would place on farmers is unjustifiable without clear evidence of a public safety benefit.

E. Flexibility is vital, but the rules must also be practical and understandable

The agency has acknowledged the need for flexibility in its re-proposed rule, as well as the fact that pathogens in irrigation water will rapidly die off when applied to produce. However, the algorithm approach that is set out in the re-proposed rule is very confusing. The current proposal will inevitably lead to both higher costs and unintended violations by farmers who simply can't figure out how to reasonably comply.

F. The proposed frequency for testing is too great and too confusing

As with the logarithmic standard, the new proposal for creating a baseline and then reducing the frequency of the testing appears to be an attempt to address a valid problem, but it creates new problems due to its complexity and ambiguity.

FDA should reduce the frequency of testing, requiring no more than 3 samples per growing season. As currently proposed, the testing frequencies are overly burdensome, lack scientific justification, and will impose significant unnecessary costs on farmers.

In the cost-benefit analysis, the FDA has not only underestimated the costs, but has failed to address a key component: who will perform all the lab work? Is there sufficient lab capacity the general public can access to provide for the additional water tests that will be required (from tens of thousands of additional tests annually to millions, potentially)? Although water testing labs are already in place, these new regulations will exponentially increase the number of farmers required to do testing, and it is not clear that the labs will be able to meet the need, or at what cost.

G. Miscellaneous water issues

If FDA uses a generic E. coli standard, the agency should provide farmers with the option to test for pathogens if a water source has exceeded that standard, rather than having to treat or stop using the water, since the presence of generic E. coli does not mean that pathogens are present. We do **not**, however, advocate for requiring pathogen testing on a regular basis because of the exorbitant costs such a requirement would create.

We support the FDA's proposal to allow a farmer to use testing by third parties to monitor his or her water sources. FDA should clarify the facts to be established, such as the distance from the farm that the third party samples may be taken and still qualify.

II. Qualified Exemptions under the Tester-Hagan amendment

FDA should implement the Tester-Hagan provisions in a manner that respects normal principles of due process and does not risk pushing a small-scale producer out of business with a too-hasty or erroneous decision to revoke their exemption and too-short deadlines for compliance.

As the agency has acknowledged, it has other mechanisms to address urgent problems, such as mandatory recall or administrative detention. Not only should those other mechanisms be considered, **but their existence means that revocation of the exemption is <u>not</u> an urgent affair.**

The top three changes required to ensure that the Tester-Hagan amendment is fairly implemented are:

- Require that FDA include a specific statement of the reasons in the notice of revocation, so that the producer can respond to the specific issues of concern.
- Provide appropriate time (at least 90 days) for producers to submit the facts and documentation showing that their exemption should not be withdrawn.
- Provide at least one year for a previously exempt farmer or producer to come into compliance with the FSMA regulations after revocation. Large farms and manufacturers are given two years to come into compliance; requiring small and micro-businesses to comply in just two months would effectively drive them out of business.

We also urge the agency to make the following additional changes:

- Require FDA to have probable cause before initiating an investigation of an exempt farmer or food facility, and to present clear and convincing evidence for revoking the exemption.
- Calculate the date of compliance from the date of the receipt of the order, rather than the issuance of the order, as the agency is now proposing to for the HARPC rule
- Guarantee a hearing so that producers can present their case in person before having their exemption revoked.
- Provide the standard post-decision procedural protections, such as motion for reconsideration and a motion for stay.
- Specify that the reinstatement of the exemption would occur within a reasonable period of time.

III. <u>Definition of a "farm"</u>

FDA should not classify "farms" as "facilities," and impose additional regulations on them, unless there is a specific risk-based reason to do so. A farmer-operated business that engages in farming activities (growing, harvesting, packing, and/or holding raw agricultural commodities) should be consistently classified as a farm, not a facility.

We recommend the following changes in the proposed rule:

- FDA should remove the phrase "in one general physical location" from the farm definition, to reflect the fact that farms may include operations and structures in different locations or on different parcels of land; these aspects do not increase the risk of foodborne illness.
- FDA should remove the phrase "under one ownership" to reflect the fact that farmers may join together in food hubs and cooperatives to market their products without increasing the risk of foodborne illness. For purposes of the definition of a farm, a multi-

ownership operation should be included so long as all of the partial owners are themselves farmers.

- Farmer should be defined as a person who actively participates in the management or daily operations of a farm.

IV. How to calculate sales for determining the size of the farm or business

When Congress passed FSMA, it did not give FDA authority over all types of food. In addition, FDA has recognized that some of the types of food within its jurisdiction should not be covered by the new rules.

These limitations on the scope of the FSMA rules should be reflected in the calculations of sales in determining whether and to what extent a farm is covered by this rule.

We support the change from the first proposed rule, to calculate thresholds for some exemptions based on "produce" rather than all food.

However, we urge the agency to apply this change to the qualified exemption under the Tester-Hagan provision as well, so that the exemptions are consistent and more easily understood. This change is vital for small-scale diversified farms that will otherwise be unfairly regulated based on their sales of foods that FDA does not regulate. Under the FDA's current proposal, sales of meat and grains will all be counted toward the $500,000 gross sales limit. Therefore, for example, a grass-fed beef producer with a small orchard who sells $600,000 in beef and $30,000 of fruit will be subject to all of the new FSMA requirements for growing and harvesting produce, even though the FDA and FSMA do not regulate beef.

This interpretation does not fulfill the intent of the Tester-Hagan provision to protect small-scale, direct-marketing producers of fruits, vegetables, and processed foods from the extensive new federal regulations. Instead, it effectively forces grain and livestock farmers to avoid any diversification, harming farmers financially and discouraging environmentally responsible land use. From a food safety standpoint, it does not make sense to treat the small-scale production of produce the same as large-scale production, simply because the same person is producing other types of food as well.

Sales of food not covered by FSMA should not be considered when calculating a farms qualification for a Tester-Hagan exemption.

The statute's use of the term "food" does not prevent the agency from adopting this proposal, since it is reasonable to assume that Congress intended the term to reflect the scope of the statute (i.e. to not include foods such as meat that are not within the scope of FDA's jurisdiction). We urge the FDA to use its discretion under the law to revise the proposed regulations so that the gross sales test is measured by the sales of food subject to regulations under FSMA.

V. Manure and Compost:

We fully support FDA's decision to require no waiting period between compost application and crop harvesting. We also support FDA's decision to refrain from establishing a waiting period for the application of manure until further research is done.

The manner in which the research is conducted will determine its value in addressing food safety concerns. Below are a few factors that we urge FDA to consider as the agency moves forward with the research on the safety of manure applications (which, under FDA's current definitions, would also include applications of vermicompost, static compost, and most compost teas):

1) Pathogenic organisms grow poorly in aerobic conditions, while thriving under anaerobic conditions. If the material being analyzed is anaerobic, the results from those tests should not be assumed applicable to aerobic conditions. This distinction between aerobic and anaerobic conditions is vital, regardless of whether the compost is being made using a "hot" method, vermicomposting, or static methods.
2) Similarly, moisture content significantly affects the growth of pathogenic organisms. Vermicomposts above 70 percent moisture and other composts above 50 percent moisture levels should be analyzed separately from dryer composts.
3) In analyzing static compost, truly static piles need to be distinguished from piles to which material is added on an ongoing basis.[12]
4) For vermicompost, research has shown adequate-to-substantial pathogen reduction via passage through the digestive system of vermicompost earthworm species.[13] Additional studies would assist in establishing best management practices for dual thermophilic-vermicomposting,[14] on-farm vermicomposting, and commercial vermicompost systems that meet pathogen reduction and produce a quality biological soil amendment with synergistic properties that enhance soil and plant health.
5) The source of the manure can significantly affect the pathogen load. Manure from animals kept in confined feeding operations must be assessed separately from manure from animals on pasture.

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[12] *See*, *e.g.*, Hoitink, H. A. J., and C. M. Changa. "Production and utilization guidelines for disease suppressive composts." XXVI International Horticultural Congress: Managing Soil-Borne Pathogens: A Sound Rhizosphere to Improve Productivity in 635 (2002); Wang, Ping, et al. "Agronomic and soil responses to compost and manure amendments under different tillage systems." Soil science 171.6 (2006): 456-467.Changa, C. M., et al. "Assessment of the reliability of a commercial maturity test kit for composted manures." Compost science & utilization 11.2 (2003): 125-143;

[13] *See*Edwards, C. (1999). The Soil Biology Primer. Chapter 7. Earthworms. The Soil Food Web. NRCS Soil Quality Institute, USDA; Bruce RE, PN Kane, CE Edwards, L Trytek, B Gunadi, AL Stermer, JR Mobley. 2001. The effectiveness of vermiculture in human pathogen reduction for USEPA biosolids atabilization. Compost Science & Utilization, 9(1): 38-49; Arumugam, GK et al. 2004. Municipal Solid Waste Management through Anaecic Earthworm, Lampito Mauritti and their Role in Microbial Modification.
Department of Environmental Technology - Central Leather Research Institute, Chennai-India, *available at* http://www.eco-web.com/cgi-local/sfc?a=/editorial/index.html&b=/editorial/040831.html

[14] *See, e.g.,* P.M. Ndegwa, PM, and SA Thompson. 2001. Integrating composting and vermicomposting in the treatment and bioconversion of biosolids. Bioresource Technology, 76: 107-112,
Available at
http://sites.bsyse.wsu.edu/ndegwa/main/publications/downloads/Publication%20list/Article%2044.pdf

6) Drying to control pathogen growth and spread should be assessed. This should include not only active heat applications, but also methods such as spreading manure and allowing it to dry naturally.
7) Similarly, the effect of aging on pathogen levels should be assessed. How do pathogen levels change if manure is left in a static pile for 3 months, 6 months, or a year?
8) In assessing organisms in compost tea, it is important to recognize that water treated with chlorine or chloramines will kill beneficial organisms as well as pathogens. Thus, the use of treated water in compost teas destroys many of the benefits of their uses.
9) The methodology for assessing the microbial activity in manure or compost should **not** use plate counts, since plate counts will encourage pathogenic bacterial growth at a faster rate than natural conditions in the field. Moreover, the methodology should consider not only bacteria, but all microorganisms, including fungi, protozoa, and nematodes. The studies should use a method that assess the microbiology in its living, natural state, such as by using live microscopy.
10) The analysis must consider sources and rates of bacteria in the general environment. Food is not grown under sterile conditions, and bacteria, both beneficial and pathogenic, occur in the environment even absent any application of biological soil amendments.[15] It is important not to restrict the application of beneficial amendments in a futile attempt to impose a sterile growing environment.

In reviewing the results of research on these issues, it is vital that regulatory requirements based on research on one set of conditions should not necessarily be applied to other conditions, even if similar terminology is often used. For example, just because the term "static compost" is used to describe a compost that has ongoing additions made to it, research done on that type of composting operation should not be used to justify regulatory restrictions on "static composts" that have a clear ending point for the addition of new materials.

The studies need to recognize that sustainable farmers employ a wide variety of beneficial "biological soil amendments" and biologically-based farming practices to promote healthy soils and healthy plants, which is achieved, in part, via the principle of microbial density and diversity. These amendments and practices include: compost teas (ACT), liquid compost extracts (LCE), steeped compost watery extracts (CWE), DIY on-farm biofermentations (fermented plant juices, biofertilizers derived from methane digestates, and related beneficial indigenous microbial fermentations), bokashi, ecosystem composts, biodynamic preparations, and commercial microbial inoculants; as well as strategies that aim for Bio-Augmentation (adding biology through sources such as listed above) and Bio-Stimulation (microbial foods: molasses, humic acid, fish hydrolysate, seaweed, milk, sea minerals).

These practices enrich the complexity of soil organisms that perform a wide variety of soil functions and ecosystem services. More tangibly, these practices – either directly or indirectly – build soil organic matter and improve soil tilth, water infiltration, nutrient cycling, and biological

[15] *See*, e.g., Guzman, J. A., G. A. Fox and J. B. Payne, 2010. Surface runoff transport of Escherichia coli after poultry litter application on pastureland. Trans. ASABE.; Metcalf, J.H., at al. 2014. Bacterial content in runoff from simulated rainfall applied to plots amended with poultry litter. International Journal of Poultry Science. 13(3):133-137.

control while enhancing plant health through modifications to the rhizsosphere, phyllosphere, and endosphere.

Consequently, these practices reduce reliance on commercial fertilizers and pesticides, thereby reducing the chemical pollution of fresh produce and waterways that endanger our nation's health. Therefore, these practices are vital to the long-term economic and ecological viability of sustainable farms and can increase the nutritional value of the foods produced. They have also been used traditionally without evidence of foodborne illnesses resulting. In the absence of data showing that a specific method significantly increases the risk of foodborne illness, these practices should not be restricted. Studies showing that a specific practice increases the risk of foodborne illness cannot be generalized to other practices on this list.

Moreover, FDA should provide for an advisory board that includes representatives of all types of agricultural production, including conventional, certified organic, and sustainable production. It is vital that working farmers be included in the process. Specifically, the advisory board should include:

- Farmers conducting on-farm composting and compost tea operations
- Livestock producers, including producers from 100 percent grassfed operations
- Conventional, certified organic, and sustainable producer farmers
- Animal scientists
- Soil scientists with expertise in ecosystem services
- Individuals with experience in pre-harvest food safety
- Individuals with expertise in assessing systemic risk in the food system
- Individuals with expertise in food-related studies in the social sciences, such as anthropology or sociology
- Regional representation, to address the variations in issues faced in different parts of the country and varying ecosystem conditions

VI. Domestic Livestock

As was raised in our original comments in 2013, the proposed regulations for domestic livestock are ambiguous and could easily lead to alleged violations simply because the field inspector disagrees with the farmer's view of what is "reasonable." Specifically, the proposed rule requires that farmers wait an "adequate" time in between grazing livestock in a field and harvesting the crop from that field, but what does that mean?

We urge the FDA to clarify these requirements as follows:

1) Specify that grazing is not the equivalent of manure application
2) Set a *maximum* (not minimum) waiting period of 120 days between grazing and harvestm, and specify that it may be shorter if steps are taken to prevent or detect contamination of the crop, including the use of hand harvesting.

VII. Conservation Measures

FDA should explicitly support important conservation measures. Conservation measures enhance both food safety and food security, and it is vital that the agency's rules not discourage them. Specific support should be stated for:

- Planting native and flowering plants along field perimeters (buffers and borders) and within crops fields (bio-islands and intercrops) for the purpose of bee and pollinator habitat and beneficial/predatory insect refugia; and
- Employing extensive use of cover crops.

VIII. Records and Recordkeeping Requirements

In response to FDA's request for comments as to whether to require farms that sell and/or purchase produce to other farms to keep certain records, we make no recommendation as to whether such records should be required. If the FDA decides to require such recordkeeping, we urge the agency to limit the recordkeeping requirements as follows:

- Accept records kept in the ordinary course of business that reflect the immediate buyer and/or seller, such as an invoice.
- Accept paper records, whether typed of handwritten. A requirement that records be kept electronically would be unnecessary, impose undue expense, and discriminate against farmers who have no or limited access to computer technology.
- Not require that the records be kept for more than one year.

We also re-iterate the previous comment we offered in 2013 with respect to any requirements for record-keeping by farms exempt under the qualified (Tester-Hagan) exemption. The FDA specifically sought comments on the issue of whether farmers should have to comply with record keeping requirements in order to prove that they qualify under the Tester-Hagan exemption. The provisions governing farms in the Tester-Hagan exemption make no mention whatsoever of submitting documentation to FDA. *See* FSMA Sec. 419(f). In contrast, FSMA specifically requires that a "qualified facility" – a facility that qualifies for the Tester-Hagan exemption – submit documentation to the FDA to demonstrate specific things. *See* FSMA Sec. 418(l)(2).

The difference in the statutory language between the two sections is significant. Congress expressed its intention to required facilities falling within the Tester-Hagan exemption to submit documentation. By omitting such a requirement for farms falling within the Tester-Hagan exemption, Congress implicitly expressed its intention that such farms should **not** have to comply with such requirements. *See Sosa v. Alvarez–Machain*, 542 U.S. 692, 711, n. 9, 124 S.Ct. 2739, 159 L.Ed.2d 718 (2004) ("When the legislature uses certain language in one part of the statute and different language in another, the court assumes different meanings were intended.").

Thus, the agency should not require a farm exempted under the Tester-Hagan amendment to comply with the new record-keeping requirements of the proposed rules, nor develop and maintain any documents outside the farm's regular course of business.

IX. Re-urge Previous Comments

We re-urge the comments submitted by our organizations on November 22, 2013. In particular, there are significant flaws with the agency's assessment of both the benefits and the costs of the proposed rule, which have not been addressed in the revised proposed rule. The original comments are copied below; while the precise numbers have changed, the difference is small and does not affect the substance of the critique.

A. The FDA significantly overestimates the benefits of the proposed rule

FDA estimated that the benefits from the produce safety rule would be over $1 billion. *See* Regulatory Impact Analysis (RIA) at p.52. However, to reach this figure, FDA made several unjustified leaps of logic.

First, the FDA significantly overestimated the number of foodborne illnesses attributed to produce. The FDA relies heavily on a single study by Scallan et al, which looked at the number of foodborne illnesses that are reported and developed a multiplier to try to account for the illnesses that are not reported.

The FDA took Scallan's multiplier and applied it to the number of foodborne illneses from identified causes in raw agricultural commodities other than sprouts. The FDA then ***also*** used the multiplier on the number of foodborne illnesses from *unidentified* causes in raw agricultural commodities. *See* RIA at p.62. Yet FDA acknowledges that Scallan's own estimates of the number of foodborne illnesses from unidentified causes was significantly lower. *See* RIA at p.63. In other words, the FDA chose to use one study to estimate the number of illnesses and, without any justification, expand on its results to significantly increase its estimates.

This single, unjustified step has significant consequences. Using Scallan's methodology in a consistent manner leads to an estimated 996,390 illnesses from raw agricultural products, less than one third the FDA's estimate. *See* RIA at p.63.

It is important to recognize how speculative all of these multipliers are in the first place. In the time period examined by FDA, there were only 4,293 illnesses actually reported from raw agricultural commodities other than sprouts. *See* RIA at p.59. FDA's series of assumptions led to an estimate of 2,314,715 illnesses from such products; ion other words, FDA estimated that there were more than five hundred times as many unreported illnesses as there are reported. Even using Scallan's estimates would still lead to the conclusion that there are over two hundred times as many unreported illnesses as there are reported.

Second, the FDA's estimate that the proposed rule would prevent about 65 percent of these illnesses from happening (p.51) was based on a shaky survey. The effectiveness of the proposed rule was based on interviews with "industry experts", based solely on the leafy green and tomato industries and based on practices used more than three years ago. *See* RIA at p.75. Particularly since tomatoes and leafy

greens have been linked to by far the greatest number of outbreaks (p.60), even if the industry experts' responses were accurate, it would be difficult to justify extrapolating those results to all produce.

The combination of unjustified assumptions about the number of illnesses that occur and about the number of illnesses that would be prevented means that FDA's estimate of the benefits of the rule are unjustified and likely overstated by a significant amount.

We therefore urge the FDA to re-analyze the alleged benefits of the rule.

B. The costs of the proposed rule would be crippling to many farms

In contrast to the speculative and overstated benefits from the proposed rule, FDA's estimates of the costs are extremely conservative.

According to FDA's own analysis, the **annual** costs of compliance would be:

- $4,697 for very small farms (average annual food sales under $250,000)
- $12, 972 for small farms (average annual food sales under $500,000)
- $30,566 for large farms (average annual food sales over $500,000)

The actual costs are likely to be much greater, particularly with respect to farmers' ability to source biological soil amendments that meet FDA's standards and the costs associated with water testing.

The FDA disguises the first-year costs of the regulations by annualizing them over 7 years for depreciation. *See* RIA at p.8. This ignores the issue of whether the farmer has the money to comply in the first year to begin with, as well as the fact that many small farmers do not have sufficient income to make depreciation cycles relevant.

The FDA severely underestimates the costs of the rule by assuming that small and very small farms (under $500,000 per year) only operate for 3 months per year, and only harvest, pack, or hold produce for 45 days out of the year; the agency estimates that large farms (over $500,000 per year) operate only 6 months per year and harvest, pack, or hold produce only 90 days. *See* RIA at p.10 & 163. While that may be true for monoculture farms that grow only one or two crops per year, it is **absolutely false** for diversified farms. For example, in Texas, many diversified produce farms operate for at least 9 months each year, with some growing produce year-round, with harvesting, packing, or holding activities occurring multiple days every single week.

With respect to the costs of the new limitations on the use of manure, compost teas, and composts, the FDA assumes that the cost is nothing more than switching to purchasing treated compost, since that is the "minimum cost alternative." *See* RIA at p.189. Yet what if the treated compost that is available in the area is of poor quality? What if the farmer uses compost teas for foliar applications, which is impossible to do

with compost? The costs that are imposed by these new requirements are far more complex and far-reaching than is reflected by FDA's analysis.

In estimating the costs of the 9-month rule, FDA uses the rental value per acre of the property, estimating that it is $359 for a full year. *See* RIA at p.185. But small farms raising produce make far more than that per acre. Indeed, consider the implications of FDA's numbers: if an acre is only worth $359 in production per year, it would take almost 700 acres to produce a gross income of only $250,000, which is FDA's cut-off for very small farms. This is absurd. Obviously, use of the acreage is far more valuable than just $359 per year – and thus the costs of leaving such acreage unused for 9 months of the year is orders of magnitude greater than FDA's estimate.

In fact, these numbers contradict FDA's own estimates. The FDA assumes that "the midpoint of the acreage" for 112.5 acres for very small farms. *See* RIA at p.203. Even that is a gross overestimate of the likely acreage of such farms, and it still would mean an average production of over $2,000 per acre.

With respect to the provisions for agricultural water, the FDA's cost estimates appear to be based on wishful thinking. The agency states that "there are currently no EPA-approved water treatments that are available to consumers." *See* RIA at p.152. In other words, it would be impossible for farmers to treat their irrigation water currently in a way that complies with the regulations. The FDA is simply assuming that there will be safe treatment options developed and approved by EPA before the rules go into effect. If not, the FDA acknowledges that farmers who rely on water that does not meet the standards will have to stop irrigating or buy water from public water supplies, although the agency's cost estimates do not address the high cost of these outcomes. *See* RIA at p.153. Remember that the water might fail the standards even if it contains **no** pathogens.

FDA's over-estimate of the benefits and under-estimate of the costs of the proposed rules means that the costs of the rule will **exceed** any benefits. Moreover, there will be indirect costs, in the form of discouraging new farmers, as well as favoring chemical methods of agriculture over sustainable methods. The costs attributable to these effects need to be addressed before FDA moves forward with regulations under FSMA.

We therefore urge the FDA to re-analyze the alleged costs of the rule.

Conclusion

We urge the agency to make the changes discussed above, as well as the additional changes urged in our earlier comments submitted on November 22, 2013.

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