



**C O R N U C O P I A**  
I N S T I T U T E

**December 15, 2014**

**TO:** Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**RE:** Docket Nos. FDA-2011-N-0921-0973 and FDA-2011-N-0920-1553

To whom it may concern:

The Cornucopia Institute respectfully offers the following comments directed toward the FDA's re-proposed rule for Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (hereinafter, proposed rule for HARPC Rule). The following general and specific comments are directed at both proposed rules given the overlapping nature of the concerns expressed by The Cornucopia Institute and a desire for an integrated food safety approach.

The Cornucopia Institute is a national farm and food policy organization engaged in research and education activities concerning sustainable and organic food and agriculture. With more than 10,000 members, and a core constituency of family-scale farmers, The Cornucopia Institute is believed to have more organic farmer members than any similar organization.

**1. The FDA's Risk Analysis Falsely Attributes All Produce Outbreaks to On-Farm Contamination**

As part of its overall regulatory assessment, undertaken to justify the regulatory breadth of the draft Rules onto the nation's produce farms, the FDA relies upon an assessment of risks posed by food safety outbreaks, an economic analysis of the cost of food safety outbreaks (lost days of work per impacted individual), and epidemiological data from the Centers for Disease Control.

The re-proposed provides no new risk analysis. Hence, The Cornucopia Institute is renewing its assertion that the FDA's risk analysis grossly overstates the food safety impact of on-farm activities. This gross overstatement is then improperly relied upon for justification of the costs to farmers of the draft regulations.

The FDA's Memorandum to the File is relatively straightforward, reporting on 131 produce outbreaks between 1996 and 2010 (those not likely caused by contamination at retail or home settings). These 131 outbreaks caused 14,132 illnesses, 1,360 hospitalizations and 27 deaths over 14 years.<sup>i</sup>

Yet no matter how one assigns responsibility for these outbreaks, it is simply not possible that all 131 outbreaks originated on a farm. Some undoubtedly occurred from failures in fresh-cut processing, some due to lack of proper refrigeration (cold chain custody) in transportation, some due to failure to control pathogenic *Listeria* when there was a proper cold chain, some due to contamination of wash water for cosmetic preparation for market (possibly at the retail level), and some due to failure to monitor sanitation of flume or wash water in handling and processing.

Then the source for these 131 food safety outbreaks, and health consequences assigned to them, must also be filtered to include those with known foreign-sourced outbreaks.

However, the FDA's "Qualitative Assessment of Risk," the agency's "Economic Analysis of the Rule" in Appendix A, and the 475-page "Prologue" to the Rule all dramatically extrapolate the impact of food safety outbreaks to come up with the following annual illness estimates:

"FDA has also estimated the total number of all foodborne illnesses caused by microbial contamination of produce commodities **where the contamination occurred on farm**. Accounting for illnesses associated with outbreaks as well as other illnesses not associated with outbreaks, during 2003-2008, we estimate a total of 2,314,715 illnesses associated with produce raw agricultural commodities (other than sprouts), 753,958 illnesses associated with fresh cut produce, and 82,109 illnesses associated with sprouts." [Emphasis added.]

This is found on page 5 of the Qualitative Assessment of Risk which refers to the Economic Analysis, where part of the methodology begins on page 61 culminating in Tables 16, 17 and 18. The detailed description of their methodology then is found in Appendix A to the Economic Analysis.

The FDA takes 14,000 illnesses over ten years (cited in the Memorandum) or 10,440 over five years (cited in the Economic Analysis covering 2003-2008) and creates an estimate of 2.3 million illnesses per single year, due to "FDA regulated produce." This is absurd. The FDA has no basis to claim these illnesses were "due to contamination on-farm" since, as previously discussed, there exist only a handful of cases over the last 25 years where one can confidently assign a root cause due to practices in growing crops on U.S. farms.

Part of this explosion in the number of annual food safety illnesses derives from estimating the number of people sickened who are never hospitalized or report their problem to officials. Another spike results from estimating unattributed illnesses.<sup>ii</sup>

Even if this were accurate, the agency still assigns all of these estimated 2,314,715 illnesses caused by microbial contamination of produce to have resulted from on-farm practices. This leap is made without a shred of analysis or even discussion. It even includes diseases that have never been identified as on-farm contaminants — such as norovirus — and which make up a major portion of actual and estimated illnesses.

In other words, the FDA took a very inaccurate small number and factored it into an enormous estimated number of annual food-borne illnesses (reported, unreported, unidentified, estimated, etc.) so that even a small percentage of a category (associated with FDA outbreaks) generates an alarmingly monstrous number. The FDA even failed to eliminate outbreaks that caused under 2,000 cases per year known to have been foreign-sourced or where contamination had happened after harvest.<sup>iii</sup>

The risk analysis demands further review and analysis to account for the apparent discrepancies and switching contexts. Without such a review, it is impossible to accept the burdensome economic costs of the draft Rules.

## 2. **Cost**

The FDA calculates that the cost of compliance with their proposed rules will be high for farmers, as much as \$12,384 for farms with sales of \$500,000 or less. This regulatory burden, particularly given some of the questionable testing protocols (see below) and the faulty risk analysis (above) is an **unacceptable** imposition of financial hardship on producers with no history of food safety problems, particularly as the FDA acknowledges that the farm cost of implementing their proposed Rule will drive some producers out of business.

## 3. **Manure and Compost**

The Cornucopia Institute supports the FDA's decision to bring the draft rules in alignment with National Organic Program standards governing the use of raw manure as a soil fertility adjunct. The decision to require no waiting period between compost application and crop harvesting is a good one.

As the FDA moves forward with a study committee assessing the research on the safety of manure application (vermicompost, static compost, and most compost teas), Cornucopia requests that representatives of certified organic and sustainable production be included in the process. It is vital that working farmers be part of this study committee.

Some of the issues that the FDA should consider as part of the research process include:

- a. Pathogenic organisms grow poorly in aerobic conditions, while thriving under anaerobic conditions. If the “compost” 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.

- b. 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.
- c. In analyzing static compost, truly static piles need to be distinguished from piles to which material is added on an ongoing basis.<sup>iv</sup>
- d. For vermicompost, research has shown adequate pathogen reduction via passage through the digestive system of vermicompost earthworm species.<sup>v</sup> Additional studies are needed to establish best management practices for dual thermophilic-vermicomposting,<sup>vi</sup> 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.
- e. 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. Supercharged and deadly strains of bacteria, such as E. coli O157:H7, are widely found in feedlot manure<sup>vii,viii</sup> where cattle are fed high concentrations of corn, soybeans and various food processing and industrial byproducts. E. coli O157:H7, as an example, was the bacteria implicated in the extensive food contamination and disease outbreak involving bagged spinach in 2006.<sup>ix</sup>
- f. Drying to control controlling 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.
- g. 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 or 6 months?
- h. 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.
- i. 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 assesses the microbiology in its living, natural state, such as by using live microscopy.
- j. The 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.<sup>x</sup> 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. In other words, 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 control while enhancing plant health through modifications to the rhizosphere, 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.

#### **4. Agricultural Water**

FDA is proposing that agricultural water meet an arbitrary 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. **The FDA, as directed by Congress, must take a science- and risk-based approach to regulation.** The proposed requirement for irrigation water fails to do so.

Furthermore, the proposed adoption as a national standard of the EPA's recreational water standard threatens the farmers, who have no history of food safety issues, with a crippling and costly regulation that may have no scientific meaning.

In the absence of appropriate, relevant scientific risk assessments, The Cornucopia Institute

urges requests that the FDA **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 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 shows some correlation with fecal contamination, yet 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 O157:H7.<sup>xi</sup> 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.<sup>xii</sup> The pathogen *Listeria monocytogenes* was found to have an inverse correlation with E. coli<sup>xiii</sup> and E. coli has been shown to have no predictive value for Salmonella.<sup>xiv</sup>
- **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.<sup>xv</sup>
- 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. 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.<sup>xvi</sup>

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

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 – and this is not good public policy.

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."<sup>xvii</sup>

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

Experts agree that no one knows much about the microbiological status of US 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.<sup>xviii</sup>
- 81 percent of Indiana's assessed surface waters failed to meet the Recreational Water Standard due to *E. coli*<sup>xix</sup>, and 50 percent of Virginia's rivers and streams are impaired, mostly because of *E. coli*.<sup>xx</sup>
- 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.<sup>xxi</sup>

Even waters that are generally clean can be expected to exceed the *E. coli* standard 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. It is telling that FDA issued a "Qualitative Risk Analysis", claiming 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 (see the more detailed discussion above).

The lack of an adequate cost analysis was most painfully obvious with respect to agricultural water. The PRIA's authors, searching for some numbers on which to base their cost analysis, chose to use Clean Water Act statistics, but it is impossible 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 stating which of those waters are used for irrigation and how much irrigation water is drawn from impaired sources, since some water sources are used much more intensively than others. The statistics also exclude data about groundwater. Without this information, even the vaguest cost estimates are little more than guesswork.

**d. The standard is not consistent with the statute**

The Food Safety Modernization act 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.

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**

An agricultural water standard must also be "based on known safety risks." The FDA has avoided a risk-based approach and is instead trying to mandate a universal metric regardless of actual risk. A risk-based standard backed by research that accounts for regional differences and diverse growing practices will best fulfill the FDA's statutory obligation.

The agency has at least 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 incredibly confusing. The current proposal will inevitably lead to both higher costs and violations for 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.

Setting aside our articulated concerns over the type of standards used for testing, the 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 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 have the capacity 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. The FDA should clarify the facts to be established, such as the allowable distance from the farm that the third-party samples may be taken and still qualify.

**5. Qualified Exemptions under the Tester-Hagan amendment**

The FDA should implement the Tester-Hagan provisions in a manner that respects normal principles of due process and doesn't 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 these other mechanisms be considered, but their existence means that revocation of the exemption is **not** an urgent affair.

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

- Require that the 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 changes:

- Require the 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.

## **6. Definition of a “farm”**

The 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 farms, not facilities.

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.

## **7. How to calculate sales for determining the size of the farm or business**

When Congress passed FSMA, it did not give the FDA authority over all types of food. In addition, the 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.

The Cornucopia Institute supports 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.

The FDA **improperly** bases the size requirements for qualifying for the Tester-Hagan exemption (established by Congress as \$500,000 in annual sales) on all the food sold by the producer — not just the produce subject to the agency’s jurisdiction or regulated under FSMA.

For example, a grass-fed beef producer with a small orchard who sells \$600,000 in beef and \$30,000 in fruit would be subject to all of the new costly FSMA requirements for growing and harvesting \$30,000 worth of produce — even though the FSMA does not regulate beef.

The determination of the Tester-Hagan exemption should be applied only to the sale of produce covered under the food safety rules.

The FDA’s current 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.

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).

The Cornucopia Institute urges 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.

## **8. Domestic Livestock**

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:

- Specify that grazing is not the equivalent of manure application
- Set a *maximum* (not minimum) waiting period of 120 days between grazing and harvest, 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.

## **9. Conservation Measures**

The FDA should explicitly support important conservation measures. Conservation measures support food safety and food security, and it is vital that the agency's rules not discourage them.

The re-proposed Produce Rule fails to promote on-farm conservation practices that help protect our soil, water, and wildlife habitat and places arbitrary restrictions on integrating grazing animals into farm fields. Without explicit support in the rules, conservation practices like planting native plant buffers as bee habitat that are a win-win for conservation and food safety could be discouraged or, worse yet, forcefully removed.

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.

## **10. 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 or 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.
- Require that the records be kept for no more than one year.

The FDA 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.

### **11. CSAs and Direct Marketers**

A “retail food establishment,” which sells the majority of its products directly to individual consumers (not restaurants, retailers, or other businesses), is exempt from registering as a facility with the FDA. Under Tester-Hagan, farmers who sell at farmers markets, distribute through drop points, etc. would still be “retail food establishments” and not facilities subject to the extensive regulations required for food facilities.

Yet the FDA has **failed** to include this definition in the draft regulations — despite clear direction from Congress. The FDA must clearly make this distinction so that CSAs and direct market farmers are not defined as facilities and required to comply with extensive food safety facility regulations.

### **12. Very Small Business**

The Cornucopia Institute supports the definition of “very small business” as a business that grosses \$1 million or less in sales of human food annually. This is an improvement over the previous proposal.

As the FDA has noted, businesses with less than \$1 million in total annual sales of foods produce less than 2% of all food produced in the United States when measured by dollar value. Exempting these businesses from the new HARPC requirements will not affect the vast majority of food sold in this country.

This exemption is important to protect the viability of these very small businesses. The FDA has significantly underestimated the cost of formulating, updating and verifying a HARPC plan. Small facilities do not have the staff capacity or the funds to incur the respective proposed costs of compliance, which will be prohibitive. Businesses will be forced to downsize and to break successful relationships with wholesale buyers in order to qualify for the Tester-Hagan qualified exemption, or face business failure.

By defining “very small business” as those with sales less than \$1 million, the FDA has simplified the application of the qualified exemption in the Preventive Rule without sacrificing food safety. We support this definition, and encourage the agency to further refine the definition to base the threshold on “covered human food,” as discussed next.

### **13. The FDA Must Address High-Risk Product Category of Fresh-Cut and Bagged Produce**

The Cornucopia Institute offers one final observation and suggestion for action. The manufacture and distribution of fresh-cut and bagged produce (including premixed salad

greens), for sale in supermarkets and for food service industry use, is a **unique high-risk product category that demands singular attention and an integrated food safety approach**.

Fresh-cut and bagged products require specific regulation from farm to fork. Given the FDA's limited resources, regulatory attention should be focused on the highest risk categories.

The extent and severity of many outbreaks are often caused by post-farming practices in these fresh-cut processing facilities.<sup>xxii,xxiii,xxiv</sup> Processing conditions can contaminate an entire production batch. This is particularly a problem for fresh-cut produce, where:

- unlike for many other processed foods, there is no kill step;
- damaging plant tissue, a major risk, is part of the actual preparation for market;
- packaging can facilitate the increase of pathogens in a contained environment;
- distant transportation plus intended shelf life means time from processing / shipping to consumption may extend beyond two weeks.

The FDA must develop special rules governing produce that is grown for the relatively new and expanding fresh-cut market. Given the scale of today's fresh-cut industry, one single food safety contamination incident, incurred by a large-scale agribusiness concern engaged in national commerce, can sicken many people across a wide swath of the nation.

Further complicating the fresh-cut sector are regionalized centers of production. For example, California's Salinas Valley (dubbed "the nation's salad bowl") is a West Coast production hub that leads to centralized processing of these crops that are then distributed across the country. Food safety outbreaks here can impact the entire United States.

The FDA must recognize that a unique processing industry, lacking a kill step, needs the production of its raw ingredients to become a specific farming category. This regulatory approach would connect the dots, and tie an exclusive category of fresh-cut growers together with specific rules for fresh-cut processors/shippers.

If the FDA took this course of action, the separate regulation of growers and fresh-cut processors would free over 90% of farmers in the United States that produce unprocessed fruits and vegetables from onerous regulations that are more appropriately designed for large growers producing for a hazardous processing category.<sup>xxv, xxvi</sup>

Any farmer seeking to enter such a high-hazard market will understand that it comes with greater regulatory costs that should command increased compensation.

Just a few thousand farms, primarily in California and Mexico, produce over 80% of our nation's fresh produce supply.<sup>xxvii,xxviii</sup> These large-scale producers have a differentially significant impact on national produce safety. Most of the largest farms also produce for the fresh-cut market. An interconnected regulatory approach would address this higher risk category. This is a scale-neutral approach, and appropriate, since even the smallest

producer growing for fresh-cut should have to meet stricter rules.

Failing to take an integrated approach in the fresh-cut sector wrongly assigns risk, and once again applies an expensive and extensive package of regulations on all produce farmers regardless of their scale, locale and type of commodities grown or whether they are involved in the high-risk fresh-cut industry.

On Behalf of The Cornucopia Institute,



Will Fantle, Codirector

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<sup>i</sup> (Proposed Rule, Reference #36. D'lima, C. and Vierk, K. Subject: Produce Related Outbreaks and Illnesses. To: Memorandum to File). Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. Second list of references. Analysis of Economic Impact Regulatory Impact Analysis Reference List 1-97.

<sup>ii</sup> Appendix A (starts p. 364). Reference #265 FDA. Analysis to Examine Impacts of Produce Safety Rule. PR. Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. First list of references.

<sup>iii</sup> See, e.g., "norovirus" Table 138 Appendix A (previous citation, op cit.) p. 371. Compare with: Hall, A. J., Eisenbart, V. G., Etingüe, A. L., Gould, L. H., Lopman, B. A., Parashar, U. D. "Epidemiology of foodborne norovirus outbreaks, United States, 2001–2008." *Emerging Infectious Diseases Journal* [Internet]. 2012 Oct [September 09, 2013]. <http://dx.doi.org/10.3201/eid1810.120833>

<sup>iv</sup> 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;

<sup>v</sup> 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>

<sup>vi</sup> 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.bsye.wsu.edu/ndegwa/main/publications/downloads/Publication%20list/Article%2044.pdf>

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<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3123879/>
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- <sup>ix</sup> CDC. "Multistate Outbreak of Shiga Toxin-producing *Escherichia coli* O157:H7 Infections Linked to Organic Spinach and Spring Mix Blend (Final Update)"  
<http://www.cdc.gov/ecoli/2012/O157H7-11-12/>
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