

Food Safety Theater

The Food and Drug Administration's Proposed Rule for the Implementation of the Food Safety Modernization Act

**A Critical Analysis of the FDA's Proposed Standards
for the Growing, Harvesting, Packing and Holding
of Produce for Human Consumption**



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

A White Paper from The Cornucopia Institute

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The Food Safety Modernization Act – An Overview

In the waning hours of 2010, the U.S. Congress enacted sweeping new food safety legislation. The [Food Safety Modernization Act](#) was quickly signed into law by President Obama in early January 2011.

For years, foods contaminated with infectious pathogens had been sickening thousands of individuals, even killing some American consumers. The final straw that forced Congressional action was the widespread peanut contamination outbreak of 2008-09 traced back to the notorious Georgia-based Peanut Corporation of America (PCA). Their salmonella-tainted products killed nine people while hundreds more fell ill in 46 states, according to the Centers for Disease Control and Prevention (CDC)ⁱ.

Bagged spinach, sprouts, eggs, melons and frozen berries mixed with imported pomegranate seeds are among other foods that have infected American consumers in recent years with bacterial pathogens.

In crafting the Food Safety Modernization Act (FSMA), Congress charged the Food and Drug Administration (FDA) with the task of developing new food safety regulations. The complex set of [proposed rules](#) released by the FDA covers not only agribusiness processors but also, for the first time, produce farmers and their crop management practices.

Farmers have historically been suspicious of the FDA, an agency with little background in the growing of food. Their fears appear to have been well grounded. The agency's draft rules, [currently open for public comment](#), threaten to ensnare what many farm experts consider to be some of the country's best and safest farmers in a maze of overly burdensome mandates, testing and record-keeping requirements while accomplishing little to safeguard public health.

The proposed Rule is grossly misdirected and a potential disaster for responsible, family-scale farmers and their loyal customers. At the same time, the root causation (including industrialized livestock production) of much of the contamination that appears in our food supply remains unaddressed, as the FDA's oversight does not extend to these types of operations. The FDA badly misfires at several points, saddling farmers with management of risk factors beyond their control while missing the opportunity to address systemic food safety problems. The food safety proposal misallocates economic burdens on both private and public resources, while it underutilizes the FDA's actual strengths and capacities.

Farmers growing field crops, like soybeans and corn, are not covered by the Rule. But diverse growers, direct marketing as CSA operators or farmers selling fruits and vegetables at local farmers markets or supplying grocery stores and co-ops, may quite possibly be driven from the land by the economic burden FDA's food safety proposal imposes. And it may well prove an overwhelming barrier to entry for new farmers.

The FDA freely acknowledges that the farm cost of implementing their proposed Rule will drive some producers out of business. Record keeping, testing protocols, and the need for an auditor will cost thousands of dollars. The FDA estimates an approximate annual cost of \$4,700 for very small farms and \$13,000 for medium-sized operations.ⁱⁱ In a very narrow margin business, these costs can amount to a significant percentage of a farm family's net income. And these FDA numbers may be an underestimate.

Organic Eggs

In addition to the FDA's draft regulations aimed at produce farmers, the agency has also issued a [Draft Guidance](#) for the prevention of *Salmonella Enteritidis* in shell eggs for egg producers who provide outdoor access for their flock.

A major 2010 salmonella outbreak in eggs, centered on "factory farms" in Iowaⁱⁱⁱ, shone a spotlight on industrial-scale egg houses, each confining tens of thousands of hens in filthy and dangerous conditions.

Despite scientific evidence tying higher rates of pathogenic contamination to older, massive factory farms with caged production/forced molting systems (banned in organics and now out of favor in conventional agriculture), the FDA is zeroing in on flocks providing outdoor access (many certified organic). The new guidance will make it difficult, expensive and perhaps even impossible to maintain medium-sized poultry flocks outdoors.

This could spell the end for commercial-scale, truly organic eggs where hens live outdoors, free to exhibit their native behaviors, as required by USDA's organic regulations. The FDA appears to have colluded with a willing USDA in determining that an enclosed porch, attached to the poultry house, constitutes acceptable outdoor access. To comply with federal organic law, the FDA must delete the "Indoor Area with Porch" as one of the four housing styles acceptable for organic production.

Rather than placing unnecessary and expensive regulatory burdens on honest, organic producers with outdoor access, the FDA should focus its efforts on addressing the significant risk factors of cages and large flocks. Multiple scientific studies, in addition to data from European countries, conclude that the risk of salmonella contamination is significantly increased when hens are kept in cages.

Many of the guidance's recommendations for avoiding contact with wild birds, and other wildlife, are logistically and economically impractical, and risk putting undue burdens on

organic producers who follow the spirit and the letter of the organic law and regulations, which require meaningful outdoor access for all birds.

Netting the entire outdoor runs would be cost-prohibitive and impractical. Noise cannons would presumably scare the hens as well as wild birds, and hens would be discouraged from going outdoors (there is no research presented to suggest otherwise).

The FDA was highly selective in citing scientific studies supporting its conclusion that contact with wild birds should be minimized. The FDA cited only four studies to justify targeting contact with wild birds (of these four studies, one deals with broilers, not layers). And the agency ignored studies from Europe that indicate great success in controlling salmonella without requiring netting, noise cannons or other measures to limit contact with wild birds.

For further in-depth analysis of the relative risks associated with conventional, confinement egg production, and eggs from certified organic farms with access to the outdoors, please refer to a [scientific literature review](#) conducted in 2011 by The Cornucopia Institute or our [comments](#)^{iv} pursuant to the current FDA draft guidance document.

Regulating (or not) Risky Practices in Food Safety

The FDA has demonstrated expertise in identifying or eliminating systemic risk in the past. The agency identified persistent salmonella in ponds used as wash-water sources in whole fresh tomato production in the Southeastern U.S., and mandated stopping such use; and also identified facility and equipment contamination in cantaloupe washing operations during the 2011 Jensen Farms pathogenic Listeria outbreak and investigation.

The proposed FSMA food safety Rule misidentifies sources of risk and subsequently imposes mistargeted controls on produce farmers. Throughout many documents created to support the proposed Rule, post-harvest food safety issues are used to justify oversight of farming practices.

The agency mixes potential hazards that might occur on-farm (from planting to harvest) with post-harvest hazards (washing, packing, etc.), then blends these with hazards that only occur off-farm. The FDA combines risks associated with farming operations and packing operations with hazards that occur at times and points later in the production and distribution chain. Eventually, even retail level contamination of produce is used to justify on-farm regulation through the misrepresentation of epidemiological data and statistics.

The actual record of proven on-farm causation of outbreaks is remarkably thin for such extensive farming practice regulations. Even when one adds in the most probable farm sources of contamination, there are few definitive U.S. cases where such contamination is known to have occurred "from planting to harvest" — perhaps a dozen — as opposed to hundreds related to further processing and distribution, depending on the criteria.^v

One known 2011 farm contamination case occurred in Washington County, Oregon (E. coli O157:H7 on strawberries). This was not included in the FDA's data for analysis. There is ample discussion in the Prologue to the Rule of one other famous pathogenic Listeria case, from Nova Scotia in 1981. Both of these cases could have been quite simply handled without FSMA at all, by saying: "Do not harvest produce that is directly exposed to excrement."

Earthbound Farms, a major U.S. produce grower and distributor, was interviewed by Daniel Cohen in his food safety regulatory analysis^{vi}. Out of a total of 1,000 produce lots rejected for potential contamination, their private system successfully traced back only seven sources of contamination. In just two cases was farm production identified as the source of contamination. One was a farm input (compost) and another was due to an on-farm water system contaminated through a cross-connection.

Careful processing steps can minimize unknown root causes of contamination from being spread to entire production runs. Earthbound Farms, for example, tests water and other inputs for pathogens of public health concern. They consulted with microbiologists in a "test and hold" program where produce is held and tested before entering the plant, and finished product is tested and held before shipping.

Manure, Compost and Sewage Sludge

Exposure to pathogens in fecal material presents one of the biggest risks to produce food safety. The largest animal manure sources of human pathogens are found at CAFOs (concentrated animal feeding operations). These facilities, large-scale feedlots or buildings confining thousands, tens of thousands, or even hundreds of thousands of animals each, are commonly referred to in the popular media as "factory farms."

However CAFOs are not touched by the proposed Rule, despite being a major contributing source — quite possibly the most important source — of increasingly virulent and robust human pathogens entering farms and the farm environment. As noted above, these facilities are not part of FDA's purview in the Rule.

Unlike pasture-based livestock production, where animals, principally ruminants, dine on grass, as they genetically evolved to do, supercharged and deadly strains of bacteria, such as E. coli O157:H7, are widely found in feedlot manure^{vii,viii} 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.^{ix}

Pathogens of food safety concern escape from these factory farms, via contaminated ground or surface water and airborne dust particles, polluting large swaths of rural countryside, including nearby fruit and vegetable growers and packing operations. Absent from the FDA's draft Rule (or the other regulatory agencies it collaborated with) are actions aimed at corralling the release of these bacterial contaminants at their source — our nation's giant livestock production facilities. Instead, the responsibility is unjustly

transferred to users of irrigation water (farmers) who will henceforth be required to test for such contaminants.

Organic growers have long practiced under rules and regulations to protect against human pathogens in manures. With few exceptions, federal organic law requires standards for composting of manure prior to its incorporation back into the soil as a key fertility agent.^x The heat generated over time in proper composting cooks most fecal bacteria like *E. coli* and salmonella in manure, then compost curing at cooler temperatures evolves the microbial balance that suppresses remaining pathogens in a well-managed process. Additionally, the direct application in organic production of raw manure is strictly regulated.

Conventional growers, who spread and apply most of the nation's manure inventory, have not been required to follow these same rules and protective practices. The result is that animal manure and composts used in conventional agriculture are often of greater hazard than the same manures, used under more protective rules and regulations, in organic agriculture.

If one wanted to significantly increase food safety with minimal regulatory change and economic burden, a straightforward way to accomplish this would be to mandate that all manure and manure-based compost use must meet or exceed the standards for their use stipulated in the USDA's organic regulations.

Furthermore, there has been no clamor from the farming community for the spreading of municipal sludge — containing human excrement and heavy metals from industrial activities — on produce fields. The use of municipal sludge is wisely banned in organics. But the FDA's proposed food safety Rule would allow sewage sludge to be used in both domestic production and foreign imports of produce.^{xi}

The FDA entirely ignores the Environmental Protection Agency's identified issues of heavy metals in sewage sludge^{xii} — such as copper — and pesticide and pesticide breakdown residues, because the proposed Rule appears to take the position that heavy metals and pesticides are not an issue for produce safety under this Rule.

Unlike some developed nations with greater foresight, the municipal sewage waste streams in the United States are still allowed to be comingled with industrial effluents creating the documented risk of exposure to heavy metals and toxins, in addition to human pathogens.

Sewage sludge of this kind has no place in fresh produce production. Again, the simplest rule would be to ban sewage sludge use in produce, following the Organic Food Production Act's regulations.

Sprouts

Sprouts have proven one of the riskiest categories in terms of food safety. There have been successful tracebacks from sprout outbreaks to seed lots for over 15 years.^{xiii,xiv} The

produce Rule should require that any seeds used for sprout production be grown exclusively for sprout production with a comprehensive post-harvest testing regime. This is the single most useful regulation that could be implemented for sprout production. But the FDA does not propose this.

Repurposing seeds for sprouts that were produced for agronomic use, grown without human food safety in mind, is a needless danger. Sprouting these in a known high risk production system seems like reckless conduct. Perhaps this failure to regulate one of the greatest known hazards in food safety is another example of reckless conduct (in this case by the FDA itself).

Since the beginning of commercial sprouting, that industry has commonly used seeds developed and sold for rangelands and forage production — not for human food use. Merely by virtue of its use for sprouting, a planting seed lot somehow becomes transformed into a human food. In the early days of this industry, even issues of chemical seed treatment were ignored, such as fungicides and other seed protectants, leading to exposure at the consumer level.

Today, most sprout production occurs in highly controlled environments using enclosed facilities, seeds, water and equipment. These artificially sterile environments have long demonstrated the worst food safety performance. But the FDA seems to prefer evolving farms similarly while disregarding the proven food safety value of associated complex microbial ecosystems.^{xv} If sterile environments were a recipe for success, then this type of sprout production should be a roaring success.

Instead, the record is quite the opposite. Current FDA sprout regulations have failed to stem recurrent food safety outbreaks from sprouts, even as increasingly harsh regulatory guidances are imposed.^{xvi}

Some outbreaks, recalls and warnings have been due to facility contamination, separate from seed issues. In general, the current FDA recommendations call for harsh chlorine treatment of seeds prior to sprouting. This is often completely ineffective as pathogen log counts have been documented to increase during sprouting.^{xvii}

Normal sprout production in drums, without access to ecologically beneficial microorganisms, apparently constitutes an ideal system for spreading contamination. Whether tray grown sprouts in soil would actually prove safer or just more costly is an open question justifying further research.

Another research is use of a kill step during sprout growth instead of relying entirely on seed treatment. Pathogens on developing sprouts are more exposed than the disease causing organisms are while protected by seed coats and other imperfections in seeds. This would need to be a treatment that tender seedlings (sprouts) can survive but pathogens cannot.

Fresh-Cut Produce

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 another high risk product category. Fresh-cut and bagged products should require uniquely specific regulation from farm to fork — something not acknowledged or addressed by the FDA in their proposed Rule.

The extent and severity of many outbreaks are often known to be caused by post-farming practices in these processing facilities.^{xviii,xix,xx} Processing conditions can contaminate an entire production batch, particularly a problem for fresh-cut produce, where:

- unlike 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 should have developed special rules related to produce that is grown for this relatively new fresh-cut market. They fail to connect the dots on fresh-cut, instead applying expensive and extensive regulations on all produce farmers regardless of scale, locale and type of commodities grown or whether they are involved in this high risk industry.

Fresh-cut increasingly looks like food service that overlaps in food safety implications with centrally processed fresh products (like salsas, fruit salads, or finished salads) that can be used as they are intended to be used as delivered. 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.

Food safety issues associated with multi-ingredient products are increasing, as are outbreaks linked to foreign sources of some ingredients.^{xxi} A notable case, earlier this year, was the hepatitis A outbreak attributed to Townsend Farms' antioxidant frozen berry blend, where the source of contamination, as reported by the FDA, was imported pomegranate seeds from Turkey.^{xxii}

A more reasoned approach by the FDA would recognize that a unique processing industry, lacking a kill step, needs the production of its raw ingredients to become a specific farming category. Wise regulation would 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 more appropriately designed for large growers producing for a hazardous processing category. ^{xxiii, xxiv}

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

Irrigation Water

This proposed Rule requires farmers to test irrigation water for generic, common forms of *E. coli*,^{xxv} an organism that is ubiquitous in the environment and not necessarily hazardous to human health. The Rule establishes an acceptable level above which use of the water for irrigation is prohibited.

However there is little correlation between generic *E. coli* and the presence of more dangerous pathogens, such as the virulent O157:H7 strain of *E. coli* and salmonella. This makes the generic *E. coli* standard a completely inappropriate indicator on which to base national policy.

For this irrigation water testing protocol, the FDA draws from California's experience with the Leafy Greens Marketing Agreement^{xxvi,xxvii}, put in place by the industry following the *E. coli* spinach contamination of 2006, adopted first in California and then later also implemented in Arizona.

In California, the LGMA private initiative tried to address issues primarily experienced by processors, handlers and industrial-scale farms in the Salinas Valley — a national center of the higher risk fresh-cut produce business.

It is a marketing agreement among processors and handlers, not a farmer-run program or even a program to specify safety in processing facilities. In fact, farmers — including large scale growers — are mandated what to do if they want to sell their crops to participating fresh-cut marketers.

An EPA standard for recreational swimming^{xxviii}, using generic *E. coli* as an indicator of possible human pathogen contamination, was chosen by the LGMA, and farmers were told to henceforth test for this. Unfortunately, water can pass this metric for generic *E. coli* and still host dangerous levels of pathogens like salmonella and *E. coli* O157:H7. Conversely, water can fail this metric for generic *E. coli* while zero salmonella or O157:H7 and other outbreak-associated human pathogens are present.^{xxix} This metric and the pathogens of concern for produce contamination are not correlated.

Adopted as a national standard in the proposed FDA Rule, this generic *E. coli* metric for irrigation water, and perhaps other metrics, will not be appropriate for food safety enhancement across the U.S. Instead, these seem to be embraced to placate consumer

concern, in effect staging: Food Security Theater.

For example, an onion grower in the Lower Snake River Watershed of Oregon and Idaho, or a Southeast onion producer from Georgia and neighboring states, will likely be hard pressed to accept being forced out of production because of irrigation water standards developed for high-risk areas producing quite different crop types that supply a higher risk food category (fresh-cut). We offer this example as some onion producers have stated that their irrigation water sources will never meet such proposed standards. Adding poignancy, there has never been a human health outbreak resulting from any form of contamination in bulb onions (unlike fresh green onions).

Regulatory Scale

The FDA freely acknowledges that the farm cost of implementing their proposed Rule will drive some producers out of business. Record keeping, testing protocols, and the need for an auditor will cost thousands of dollars. The FDA estimates an approximate annual cost of \$4,700 for very small farms and \$13,000 for medium-sized operations.^{xxx}

When crafting the FSMA, Congress, responding to pressure from family farm advocates, exempted local farmers doing less than \$500,000 worth of business per annum with the "Tester Amendment" (authored by Senator Jon Tester of Montana, the Senate's only certified organic farmer). The FDA, however, still exercises great power over food safety on any farm under their proposal. If a small owner-managed farm, delivering directly to consumers or local stores, does anything the FDA doesn't like, the agency can, without any due process, almost immediately force small farms to comply with the same expensive testing and record-keeping that larger operations must maintain.^{xxxi}

"In practical terms," explains Judith McGeary, a member of The Cornucopia Institute's policy advisory panel and Executive Director of the Farm and Ranch Freedom Alliance, "the FDA will be able to target small farms one-by-one and put them out of business, with little to no recourse for the farmers."

This is a tremendous regulatory hammer that the FDA will hold over the heads of all family-scale growers whom Congress actually intended to exempt from the most burdensome aspects of this rulemaking.

Just a few thousand farms, primarily in California and Mexico, produce over 80% of our nation's fresh produce supply.^{xxxii,xxxiii} These large-scale producers have a differentially significant impact on national produce safety. But this doesn't necessarily mean that one should regulate based on farm size.

However, most of the largest farms also produce for the fresh-cut market, and special regulation for the growing of this inherently more dangerous processing use would include them. This regulatory approach would be scale-neutral, as appropriate, since even the smallest producer growing for fresh-cut should have to meet stricter rules.

The USDA has developed a free tool available to all farmers to assist them with improving food safety practices. Available at www.onfarmfoodsafety.org, the tool has been successfully used by farmers for good agricultural practices standards (GAP) for their production.

Another issue is that of employment. A number of well-established organic specialty and truck farms provide permanent employment at a rate of from one job per acre to one per ten acres. In contrast, many field crops growers provide fewer than one job per 600 acres.^{xxxiv} Regulating poorly for produce safety will not only harm farms inversely to farm size. It will have an even greater negative impact on farm employment and rural economic health, particularly as people determine whether or not it is economically viable to even enter farming.

Environmental Health Versus the Goal of Farm Sterility

"Only an idiot would not be concerned with food safety," says Tom Willey, a successful long-time organic farmer operating a 75-acre CSA in California with approximately 800 subscribers. Farming since 1980, his mid-sized, diverse produce farm would be fully covered by the proposed Rule (not qualifying for the small farm exemption).

Such new regulations will have less impact on the Willey farm because he already takes many of the safety and documentation steps based on his status as a Certified Organic grower subject to the comprehensive federal organic regulations. He also stopped producing salad mixes years ago because of their inherent food safety risks and, for the same reasons, does not bag any produce.

The Willey farm already does pathogen testing. Willey uses drip irrigation from a pathogen-tested well and uses a different pathogen-tested well for produce wash water. The farm's out-sourced organic compost is already tested for O157:H7 and salmonella as well as for indicator organisms. His operation already has a comprehensive employee food safety program. And they already enforce their own farm-specific good management practices plan.

Yet Willey opposes most of the FDA's proposed Rule.^{xxxv} He views the role of complex microbial communities and biological diversity as essential to — not opposed to — food safety. Willey is especially concerned with and knowledgeable about soil microbiological complexity and the plant microbe interactions in soil ecology. The cornerstone of his fertility program is rigorously tested composts from both dairy cows and urban green materials.

Willey opposes any "sterility" approach to food safety on farms, something that the draft FDA Rule promotes. He compares the FDA's sterility mindset with that agency's spotty record with managing safety in sprout production — the enclosed production method most resembling a sterile, controlled environment.

Plants, he observes, deliberately exude nutrients and other materials into the soil through their roots to encourage favorable rhizosphere partners and favorable soil ecology. Sprouting seeds attempt to do the same thing, but in the absence of any soil rhizosphere ecology to interact with in closed container [drum] production, nature can go dangerously awry.

In the absence of appropriate soil micro-organisms, any present human pathogens may benefit from these nutrients to survive or even thrive (without competition) under the favorable sprouting environment. Gnotobiology [organisms produced in sterility without their associated microbial ecology] creates a dangerous vacuum. Human pathogens, if present, can readily move in to fill that vacuum.

Will Daniels, food safety officer of Earthbound Farms, a national scale produce producer-shipper, shares similar concerns regarding making the farm environments more sterile.^{xxxvi} According to Daniels, the dominant food safety attitudes favoring on-farm sterile environments, including landscape surrounding farms actually potentiates greater pathogen danger.

One aspect of the FDA proposed regulations would be an attempt to exclude wildlife from farming operations by eradicating certain aspects of the natural ecosystem (vegetation).

Daniels argues that what really happens when eliminating habitat surrounding farms is that animals are then more prone to enter production fields. Protecting riparian areas along rivers and creeks and streams instead provides a more comfortable habitat for animals, rather than encouraging them to venture into farm fields as when such buffers are removed.

Balanced healthy ecosystems promote food safety rather than impede it. When you consider fish, ducks and plants to be hazards in an irrigation pond and instead turn it into a lined, sterile-looking container, you've now created a vacuum and a petri dish for human pathogens.

Following the E. coli spinach contamination in 2006 and the creation of California's LGMA, Jo Ann Baumgartner of the Wild Farm Alliance observed growers being forced by their buyers to choose between selling their crops and following misguided food safety recommendations targeted at removing wildlife. Some of the wildlife habitat destruction was "blatant," according to Baumgartner.

"FDA," Baumgartner says, "must give clear direction in the Rule." The agency's comments on wildlife and conservation are buried in the Rule's preamble, and not apparent in the proposed regulations.^{xxxvii}

Food Safety Risk on the Farm

In order to justify such massive intrusion 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.

One of the FDA's analyses, the 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. ^{xxxviii}

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.

Yet 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.

They take 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 turn this into 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.^{xxxix}

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. They make this leap without a shred of analysis or even discussion. They include diseases that have never been identified as on-farm contaminants — such as norovirus — 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.^{x1}

Perhaps the FDA needed to overestimate large numbers of on-farm illnesses to justify the economic costs of their regulation, as required by federal law.

In general, each of the FDA's supporting documents parses carefully, or carelessly, to create an implication that food service data and analysis being discussed is actually farming data. These documents must be read with lawyerly attention to detail and context because these contexts keep switching.

Conclusion

If you were to base this proposed Rule on the actual text of the law (FSMA), as passed by Congress, and documented evidence on the record, one would leave all farming operations, from planting to harvest, alone. A wiser and more honest FDA would start with processors of fresh produce, move on to handlers and then finally to handling operations that occur on-farm (looking at processing regardless of which entity does it and whether such occurs in a factory-like facility or on a farm that does its own processing/direct marketing).

And, as noted, CAFOs are not touched by the proposed Rule, despite being a major contributing source — quite possibly the most important source — of increasingly virulent and robust human pathogens entering farms and the farm environment. Regardless of whose regulatory purview it is, either FDA or USDA, the failure to coordinate a regulatory approach aimed at minimizing the threat to food safety that CAFOs present is a fundamental error.

Farmers are made to pay the price for others' failures and for systemic failure in our complex food system. The Rule implies all food safety outbreaks are the consequence of individual actions on a farm. There certainly are known hazards on farms. Systemic hazards need addressing in appropriate rules, and so do repeated outbreaks from the same crop-regional combinations.

This Rule most certainly helps exonerate food processors while it shifts the burden of safety back onto farms. Clear evidence or research supporting this burden is missing.

Doing nothing about farming operations from planting through harvest would achieve more than the proposed Rule, meaning that it would do less harm. The Rule in its current form does much harm — and that harm is to the nation’s small- and medium-scale farmers creating access to authentic organic food and local food, that is correctly perceived as safer by a growing legion of American consumers.

ⁱ <http://www.cdc.gov/salmonella/typhimurium/update.html>

ⁱⁱ FDA. “Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption,” p. 317

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm334171.htm>

ⁱⁱⁱ <http://www.cdc.gov/salmonella/enteritidis/>

^{iv} The Cornucopia Institute. “Comment to the FDA on Draft Guidance for the Prevention of Salmonella Enteritidis in Shell Eggs.” 9/23/2013. http://www.cornucopia.org/FoodSafety/FDA_SalmonellaComments.pdf

^v D’lima, C. and Vierk, K. “Memo to File: Produce Related Outbreaks and Illnesses,” 12/13/2011, Reference #36 in FDA, “Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.”

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm334171.htm>

^{vi} Cohen, D. B. “Comment on ‘Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption’; Proposed Rule Document issued by the Food and Drug Administration (FDA)”. September 2013.

http://www.cornucopia.org/FoodSafety/COHEN_FSMA_COMMENT.pdf

^{vii} Ferens, W. A. and Hovde, C. J. “Escherichia coli O157:H7: Animal reservoir and sources of human infection.” *Foodborne Pathogens and Disease*, 2011, 8.4: 465-487.

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